FICHA DE DATOS DE SEGURIDAD
(de acuerdo con el Reglamento (UE) 2015/830)

365A2Q-NITRATO DE COBRE 3-H Q.P.

Versión 1 **Fecha de emisión: 6/10/2010**
Versión 20 (sustituye a la versión 19) **Fecha de revisión: 21/09/2021** **Fecha de impresión: 21/09/2021**

SECCIÓN 1: IDENTIFICACIÓN DE LA SUSTANCIA O LA MEZCLA Y DE LA SOCIEDAD O LA EMPRESA.

1.1 Identificador del producto.

Nombre del producto:	NITRATO DE COBRE 3-H Q.P.
Código del producto:	365A2Q
Nombre químico:	Nitrato de cobre (II) hidratado
N. CAS:	10031-43-3
N. registro:	01-2119969290-34-XXX

1.2 Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados.

Genérico industrial

Usos desaconsejados:
Usos distintos a los aconsejados.

1.3 Datos del proveedor de la ficha de datos de seguridad.

Empresa:	**Barcelonesa de Drogas y Productos Químicos, S.A.**
Dirección:	Crom, 14 - P.I. FAMADES
Población:	08940 - Cornellà del Llobregat
Provincia:	Barcelona
Teléfono:	93 377 02 08
Fax:	93 377 42 49
E-mail:	barcelonesa@barcelonesa.com
Web:	www.grupbarcelonesa.com

1.4 Teléfono de emergencia: 704 10 00 87 (Disponible 24h)

SECCIÓN 2: IDENTIFICACIÓN DE LOS PELIGROS.

2.1 Clasificación de la sustancia o de la mezcla.
Según el Reglamento (EU) No 1272/2008:
- Ox. Sol. 2 : Puede agravar un incendio; comburente.
- Skin Corr. 1B : Provoca quemaduras graves en la piel y lesiones oculares graves.
- Eye Dam. 1 : Provoca lesiones oculares graves.
- Aquatic Acute 1 : Muy tóxico para los organismos acuáticos.
- Aquatic Chronic 2 : Tóxico para los organismos acuáticos, con efectos nocivos duraderos.

2.2 Elementos de la etiqueta.
Etiquetado conforme al Reglamento (EU) No 1272/2008:
Pictogramas:

Palabra de advertencia:
Peligro
Frases H:

H272	Puede agravar un incendio; comburente.
H314	Provoca quemaduras graves en la piel y lesiones oculares graves.
H318	Provoca lesiones oculares graves.
H400	Muy tóxico para los organismos acuáticos.
H411	Tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Frases P:

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P210 Mantener alejado del calor, de superficies calientes, de chispas, de llamas abiertas y de cualquier otra fuente de ignición. No fumar.
P260 No respirar el polvo/el humo/el gas/la niebla/los vapores/el aerosol.
P273 Evitar su liberación al medio ambiente.
P280 Llevar guantes/ropa de protección/equipo de protección para los ojos/la cara/los oídos/...
P301+P330+P331 EN CASO DE INGESTIÓN: Enjuagar la boca. NO provocar el vómito.
P303+P361+P353 EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitar inmediatamente toda la ropa contaminada. Enjuagar la piel con agua [o ducharse].
P304+P340 EN CASO DE INHALACIÓN: Transportar a la persona al aire libre y mantenerla en una posición que le facilite la respiración.
P305+P351+P338 EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado.
P310 Llamar inmediatamente a un CENTRO DE TOXICOLOGÍA/médico.
P501 Eliminar el contenido/el recipiente de conformidad con la normativa local, regional, nacional o internacional.

Contiene:
Nitrato de cobre (II) hidratado

2.3 Otros peligros.
En condiciones de uso normal y en su forma original, el producto no tiene ningún otro efecto negativo para la salud y el medio ambiente.

SECCIÓN 3: COMPOSICIÓN/INFORMACIÓN SOBRE LOS COMPONENTES.

3.1 Sustancias.

Nombre químico:	Nitrato de cobre (II) hidratado
N. CAS:	10031-43-3
N. registro:	01-2119969290-34-XXX

3.2 Mezclas.
No Aplicable.

SECCIÓN 4: PRIMEROS AUXILIOS.

4.1 Descripción de los primeros auxilios.
En los casos de duda, o cuando persistan los síntomas de malestar, solicitar atención médica. No administrar nunca nada por vía oral a personas que se encuentren inconscientes.

Inhalación.
Situar al accidentado al aire libre, mantenerle caliente y en reposo, si la respiración es irregular o se detiene, practicar respiración artificial.

Contacto con los ojos.
Lavar abundantemente los ojos con agua limpia y fresca durante, por lo menos, 10 minutos, tirando hacia arriba de los párpados y buscar asistencia médica. No permita que la persona se frote el ojo afectado.

Contacto con la piel.
Quitar la ropa contaminada. Lavar la piel vigorosamente con agua y jabón o un limpiador de piel adecuado. NUNCA utilizar disolventes o diluyentes. Es recomendable para las personas que dispensan los primeros auxilios el uso de equipos de protección individual (ver sección 8).

Ingestión.
Si accidentalmente se ha ingerido, buscar inmediatamente atención médica. Mantenerle en reposo. NUNCA provocar el vómito.

4.2 Principales síntomas y efectos, agudos y retardados.
Producto Corrosivo, el contacto con los ojos o con la piel puede producir quemaduras, la ingestión o la inhalación puede producir daños internos, en el caso de producirse se requiere asistencia médica inmediata.
El contacto con los ojos puede producir daños irreversibles.

4.3 Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente.

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Solicite ayuda médica de inmediato. No administrar nunca nada por vía oral a personas que se encuentren inconscientes. No inducir el vómito. Si la persona vomita, despeje las vías respiratorias. Cubra la zona afectada con un apósito estéril seco. Proteja la zona afectada de presión o fricción.

SECCIÓN 5: MEDIDAS DE LUCHA CONTRA INCENDIOS.

5.1 Medios de extinción.
Medios de extinción apropiados:
Polvo extintor o CO2. En caso de incendios más graves también espuma resistente al alcohol y agua pulverizada.

Medios de extinción no apropiados:
No usar para la extinción chorro directo de agua. En presencia de tensión eléctrica no es aceptable utilizar agua o espuma como medio de extinción.

5.2 Peligros específicos derivados de la sustancia o la mezcla.
Riesgos especiales.
El fuego puede producir un espeso humo negro. Como consecuencia de la descomposición térmica, pueden formarse productos peligrosos: monóxido de carbono, dióxido de carbono. La exposición a los productos de combustión o descomposición puede ser perjudicial para la salud.

5.3 Recomendaciones para el personal de lucha contra incendios.
Refrigerar con agua los tanques, cisternas o recipientes próximos a la fuente de calor o fuego. Tener en cuenta la dirección del viento. Evitar que los productos utilizados en la lucha contra incendio pasen a desagües, alcantarillas o cursos de agua. Los restos de producto y medios de extinción pueden contaminar el medio ambiente acuático.

Equipo de protección contra incendios.
Según la magnitud del incendio, puede ser necesario el uso de trajes de protección contra el calor, equipo respiratorio autónomo, guantes, gafas protectoras o máscaras faciales y botas.

SECCIÓN 6: MEDIDAS EN CASO DE VERTIDO ACCIDENTAL.

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia.
Para control de exposición y medidas de protección individual, ver sección 8.

6.2 Precauciones relativas al medio ambiente.
Producto peligroso para el medio ambiente, en caso de producirse grandes vertidos o si el producto contamina lagos, ríos o alcantarillas, informar a las autoridades competentes, según la legislación local. Evitar la contaminación de desagües, aguas superficiales o subterráneas, así como del suelo.

6.3 Métodos y material de contención y de limpieza.
Contener y recoger el vertido con material absorbente inerte (tierra, arena, vermiculita, tierra de diatomeas...) y limpiar la zona inmediatamente con un descontaminante adecuado.
Depositar los residuos en envases cerrados y adecuados para su eliminación, de conformidad con las normativas locales y nacionales (ver sección 13).

6.4 Referencia a otras secciones.
Para control de exposición y medidas de protección individual, ver sección 8.
Para la eliminación de los residuos, seguir las recomendaciones de la sección 13.

SECCIÓN 7: MANIPULACIÓN Y ALMACENAMIENTO.

7.1 Precauciones para una manipulación segura.
Para la protección personal, ver sección 8.
En la zona de aplicación debe estar prohibido fumar, comer y beber.
Cumplir con la legislación sobre seguridad e higiene en el trabajo.
No emplear nunca presión para vaciar los envases, no son recipientes resistentes a la presión. Conservar el producto en envases de un material idéntico al original.

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7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades.
Almacenar según la legislación local. Observar las indicaciones de la etiqueta. Almacenar los envases entre 5 y 25 °C, en un lugar seco y bien ventilado, lejos de fuentes de calor y de la luz solar directa. Mantener lejos de puntos de ignición. Mantener lejos de agentes oxidantes y de materiales fuertemente ácidos o alcalinos. No fumar. Evitar la entrada a personas no autorizadas. Una vez abiertos los envases, han de volverse a cerrar cuidadosamente y colocarlos verticalmente para evitar derrames.
El producto no se encuentra afectado por la Directiva 2012/18/UE (SEVESO III).

7.3 Usos específicos finales.
No disponible.

SECCIÓN 8: CONTROLES DE EXPOSICIÓN/PROTECCIÓN INDIVIDUAL.

8.1 Parámetros de control.

El producto NO contiene sustancias con Valores Límite Ambientales de Exposición Profesional.El producto NO contiene sustancias con Valores Límite Biológicos.
8.2 Controles de la exposición.

Medidas de orden técnico:
Proveer una ventilación adecuada, lo cual puede conseguirse mediante una buena extracción-ventilación local y un buen sistema general de extracción.

Concentración:	**100 %**				
Usos:	**Genérico industrial**				
Protección respiratoria:					
EPI:	Máscara filtrante para la protección contra gases y partículas				
Características:	Marcado «CE» Categoría III. La máscara debe tener amplio campo de visión y forma anatómica para ofrecer estanqueidad y hermeticidad.				
Normas CEN:	EN 136, EN 140, EN 405				
Mantenimiento:	No se debe almacenar en lugares expuestos a temperaturas elevadas y ambientes húmedos antes de su utilización. Se debe controlar especialmente el estado de las válvulas de inhalación y exhalación del adaptador facial.				
Observaciones:	Se deberán leer atentamente las instrucciones del fabricante al respecto del uso y mantenimiento del equipo. Se acoplarán al equipo los filtros necesarios en función de las características específicas del riesgo (Partículas y aerosoles: P1-P2-P3, Gases y vapores: A-B-E-K-AX) cambiándose según aconseje el fabricante.				
Tipo de filtro necesario:	A2				
Protección de las manos:					
EPI:	Guantes de protección contra productos químicos				
Características:	Marcado «CE» Categoría III.				
Normas CEN:	EN 374-1, En 374-2, EN 374-3, EN 420				
Mantenimiento:	Se guardarán en un lugar seco, alejados de posibles fuentes de calor, y se evitará la exposición a los rayos solares en la medida de lo posible. No se realizarán sobre los guantes modificaciones que puedan alterar su resistencia ni se aplicarán pinturas, disolventes o adhesivos.				
Observaciones:	Los guantes deben ser de la talla correcta, y ajustarse a la mano sin quedar demasiado holgados ni demasiado apretados. Se deberán utilizar siempre con las manos limpias y secas.				
Material:	PVC (Cloruro de polivinilo)	Tiempo de penetración (min.):	> 480	Espesor del material (mm):	0,35
Protección de los ojos:					
EPI:	Gafas de protección con montura integral				
Características:	Marcado «CE» Categoría II. Protector de ojos de montura integral para la protección contra salpicaduras de líquidos, polvo, humos, nieblas y vapores.				
Normas CEN:	EN 165, EN 166, EN 167, EN 168				
Mantenimiento:	La visibilidad a través de los oculares debe ser óptima para lo cual estos elementos se deben limpiar a diario, los protectores deben desinfectarse periódicamente siguiendo las instrucciones del fabricante.				
Observaciones:	Indicadores de deterioro pueden ser: coloración amarilla de los oculares, arañazos superficiales en los oculares, rasgaduras, etc.				
Protección de la piel:					
EPI:	Ropa de protección contra productos químicos				

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Características:	Marcado «CE» Categoría III. La ropa debe tener un buen ajuste. Se debe fijar el nivel de protección en función un parámetro de ensayo denominado "Tiempo de paso" (BT. Breakthrough Time) el cual indica el tiempo que el producto químico tarda en atravesar el material.
Normas CEN:	EN 464,EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034
Mantenimiento:	Se deben seguir las instrucciones de lavado y conservación proporcionadas por el fabricante para garantiza una protección invariable.
Observaciones:	El diseño de la ropa de protección debería facilitar su posicionamiento correcto y su permanencia sin desplazamiento, durante el período de uso previsto, teniendo el cuenta los factores ambientales, junto con los movimientos y posturas que el usuario pueda adoptar durante su actividad.
EPI:	Calzado de trabajo
Características:	Marcado «CE» Categoría II.
Normas CEN:	EN ISO 13287, EN 20347
Mantenimiento:	Estos artículos se adaptan a la forma del pie del primer usuario. Por este motivo, al igual que por cuestiones de higiene, debe evitarse su reutilización por otra persona.
Observaciones:	El calzado de trabajo para uso profesional es el que incorpora elementos de protección destinados a proteger al usuario de las lesiones que pudieran provocar los accidentes, se debe revisar los trabajor para los cuales es apto este calzado.

SECCIÓN 9: PROPIEDADES FÍSICAS Y QUÍMICAS.

9.1 Información sobre propiedades físicas y químicas básicas.
Aspecto:Polvo cristalino azul
Color: Azul
Olor:Agrio
Umbral olfativo:N.D./N.A.
pH:N.D./N.A.
Punto de Fusión:114 ºC
Punto/intervalo de ebullición: N.D./N.A.
Punto de inflamación: N.D./N.A.
Tasa de evaporación: N.D./N.A.
Inflamabilidad (sólido, gas): No muy inflamable
Límite inferior de explosión: N.D./N.A.
Límite superior de explosión: N.D./N.A.
Presión de vapor: N.D./N.A.
Densidad de vapor:2.6 x 10-9 @ 25°C.
Densidad relativa:2,39 g/cm3 @ 20°C
Solubilidad:N.D./N.A.
Liposolubilidad: N.D./N.A.
Hidrosolubilidad: Soluble. 1450 g/L @ 25 °C
Coeficiente de reparto (n-octanol/agua): N.D./N.A.
Temperatura de autoinflamación: N.D./N.A.
Temperatura de descomposición: N.D./N.A.
Viscosidad: N.D./N.A.
Propiedades explosivas: N.D./N.A.
Propiedades comburentes: N.D./N.A.
N.D./N.A.= No Disponible/No Aplicable debido a la naturaleza del producto.

9.2 Otros datos.
Punto de gota: N.D./N.A.
Centelleo: N.D./N.A.
Viscosidad cinemática: N.D./N.A.
% Sólidos: N.D./N.A.
N.D./N.A.= No Disponible/No Aplicable debido a la naturaleza del producto.

SECCIÓN 10: ESTABILIDAD Y REACTIVIDAD.

10.1 Reactividad.
Si se cumplen las condiciones de almacenamiento, no produce reacciones peligrosas.

10.2 Estabilidad química.

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Estable bajo las condiciones de manipulación y almacenamiento recomendadas (ver epígrafe 7).

10.3 Posibilidad de reacciones peligrosas.
Puede agravar un incendio; comburente.

10.4 Condiciones que deben evitarse.
Evitar las siguientes condiciones:
- Contacto con materiales incompatibles.

10.5 Materiales incompatibles.
Evitar los siguientes materiales:
- Materias inflamables.
- Materias explosivas.
- Materias tóxicas.
- Materias corrosivas.

10.6 Productos de descomposición peligrosos.
Dependiendo de las condiciones de uso, pueden generarse los siguientes productos:
- Oxígeno.
- Vapores o gases comburentes.

SECCIÓN 11: INFORMACIÓN TOXICOLÓGICA.

11.1 Información sobre los efectos toxicológicos.
No existen datos disponibles ensayados del producto.
Las salpicaduras en los ojos pueden causar irritación y daños reversibles.

a) toxicidad aguda;
Datos no concluyentes para la clasificación.

b) corrosión o irritación cutáneas;
Producto clasificado:
Corrosivo cutáneo, Categoría 1B: Provoca quemaduras graves en la piel y lesiones oculares graves.

c) lesiones oculares graves o irritación ocular;
Producto clasificado:
Lesión ocular grave, Categoría 1: Provoca lesiones oculares graves.

d) sensibilización respiratoria o cutánea;
Datos no concluyentes para la clasificación.

e) mutagenicidad en células germinales;
Datos no concluyentes para la clasificación.

f) carcinogenicidad;
Datos no concluyentes para la clasificación.

g) toxicidad para la reproducción;
Datos no concluyentes para la clasificación.

h) toxicidad específica en determinados órganos (STOT) - exposición única;
Datos no concluyentes para la clasificación.

i) toxicidad específica en determinados órganos (STOT) - exposición repetida;
Datos no concluyentes para la clasificación.

j) peligro por aspiración;
Datos no concluyentes para la clasificación.

SECCIÓN 12: INFORMACIÓN ECOLÓGICA.

12.1 Toxicidad.

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No se dispone de información relativa a la Ecotoxicidad.

12.2 Persistencia y degradabilidad.

No se dispone de información relativa a la biodegradabilidad.
No se dispone de información relativa a la degradabilidad.
No existe información disponible sobre la persistencia y degradabilidad del producto.

12.3 Potencial de Bioacumulación.
No se dispone de información relativa a la Bioacumulación.

12.4 Movilidad en el suelo.
No existe información disponible sobre la movilidad en el suelo.
No se debe permitir que el producto pase a las alcantarillas o a cursos de agua.
Evitar la penetración en el terreno.

12.5 Resultados de la valoración PBT y mPmB.
No existe información disponible sobre la valoración PBT y mPmB del producto.

12.6 Otros efectos adversos.
No existe información disponible sobre otros efectos adversos para el medio ambiente.

SECCIÓN 13: CONSIDERACIONES RELATIVAS A LA ELIMINACIÓN.

13.1 Métodos para el tratamiento de residuos.
No se permite su vertido en alcantarillas o cursos de agua. Los residuos y envases vacíos deben manipularse y eliminarse de acuerdo con las legislaciones local/nacional vigentes.
Seguir las disposiciones de la Directiva 2008/98/CE respecto a la gestión de residuos.

SECCIÓN 14: INFORMACIÓN RELATIVA AL TRANSPORTE.

Transportar siguiendo las normas ADR/TPC para el transporte por carretera, las RID por ferrocarril, las IMDG por mar y las ICAO/IATA para transporte aéreo.
Tierra: Transporte por carretera: ADR, Transporte por ferrocarril: RID.
Documentación de transporte: Carta de porte e Instrucciones escritas.
Mar: Transporte por barco: IMDG.
Documentación de transporte: Conocimiento de embarque.
Aire: Transporte en avión: IATA/ICAO.
Documento de transporte: Conocimiento aéreo.

14.1 Número ONU.

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Nº UN: UN1477

14.2 Designación oficial de transporte de las Naciones Unidas.
Descripción:
ADR: UN 1477, NITRATOS INORGÁNICOS, N.E.P., 5.1, GE III, (E)
IMDG: UN 1477, NITRATOS INORGÁNICOS, N.E.P., 5.1, GE/E III, CONTAMINANTE DEL MAR
ICAO/IATA: UN 1477, NITRATOS INORGÁNICOS, N.E.P., 5.1, GE III

14.3 Clase(s) de peligro para el transporte.
Clase(s): 5.1

14.4 Grupo de embalaje.
Grupo de embalaje: III

14.5 Peligros para el medio ambiente.
Contaminante marino: Si

Peligroso para el medio ambiente

14.6 Precauciones particulares para los usuarios.
Etiquetas: 5.1

Número de peligro: 50
ADR cantidad limitada: 5 kg
IMDG cantidad limitada: 5 kg
ICAO cantidad limitada: 10 kg

Disposiciones relativas al transporte a granel en ADR:
VC1 Está autorizado el transporte a granel en vehículos entoldados, en contenedores entoldados o en contenedores para granel entoldados.
VC2 Está autorizado el transporte a granel en vehículos cubiertos, en contenedores cerrados o en contenedores para granel cerrados.
AP6 Cuando el vehículo o el contenedor sea de madera o esté construido en otro material combustible, deben estar provistos de un revestimiento impermeable e incombustible o de un enlucido de silicato de sosa u otro producto similar. El toldo deberá ser igualmente impermeable e incombustible.
AP7 El transporte a granel no debe ser efectuado nada más que en cargamento completo.
Transporte por barco, FEm - Fichas de emergencia (F – Incendio, S – Derrames): F-A,S-Q
Actuar según el punto 6.

14.7 Transporte a granel con arreglo al anexo II del Convenio MARPOL y del Código IBC.
El producto no está afectado por el transporte a granel en buques.

SECCIÓN 15: INFORMACIÓN REGLAMENTARIA.

15.1 Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla.
El producto no está afectado por el Reglamento (CE) nº 1005/2009 del Parlamento Europeo y del Consejo, de 16 de septiembre de 2009, sobre las sustancias que agotan la capa de ozono.

El producto no se encuentra afectado por la Directiva 2012/18/UE (SEVESO III).
El producto no está afectado por el Reglamento (UE) No 528/2012 relativo a la comercialización y el uso de los biocidas.

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El producto no se encuentra afectado por el procedimiento establecido en el Reglamento (UE) No 649/2012, relativo a la exportación e importación de productos químicos peligrosos.

15.2 Evaluación de la seguridad química.
No se ha llevado a cabo una evaluación de la seguridad química del producto.
Se dispone de Escenario de Exposición del producto.

SECCIÓN 16: OTRA INFORMACIÓN.

Códigos de clasificación:

Acute Tox. 4 : Toxicidad oral aguda, Categoría 4
Aquatic Acute 1 : Toxicidad aguda para el medio ambiente acuático, Categoría 1
Aquatic Chronic 2 : Efectos crónicos para el medio ambiente acuático, Categoría 2
Eye Dam. 1 : Lesión ocular grave, Categoría 1
Eye Irrit. 2 : Irritación ocular, Categoría 2
Ox. Sol. 2 : Sólido comburente, Categoría 2
Skin Corr. 1B : Corrosivo cutáneo, Categoría 1B
Skin Irrit. 2 : Irritante cutáneo, Categoría 2

Modificaciones respecto a la versión anterior:

- Cambios en la información del proveedor (SECCIÓN 1.3).
- Cambio en la clasificación de peligrosidad (SECCIÓN 2.1).
- Eliminación de consejos de prudencia/indicaciones de peligro/pictogramas/palabra de advertencia (SECCIÓN 2.2).
- Añadidos consejos de prudencia/indicaciones de peligro/pictogramas/palabra de advertencia (SECCIÓN 2.2).
- Modificaciones en los primeros auxilios (SECCIÓN 4.1).
- Modificación de los síntomas (SECCIÓN 4.2).
- Modificación de las medidas de atención médica (SECCIÓN 4.3).
- Modificaciones en las precauciones de manipulación y almacenamiento (SECCIÓN 7.1).
- Modificaciones en las precauciones de manipulación y almacenamiento (SECCIÓN 7.2).
- Modificación en los valores de las propiedades físico-químicas (SECCIÓN 9).
- Modificación de la información de las condiciones estabilidad y reactividad (SECCIÓN 10.2).
- Modificación de la información de las condiciones estabilidad y reactividad (SECCIÓN 10.3).
- Modificación de la información de las condiciones estabilidad y reactividad (SECCIÓN 10.4).
- Modificación de la información de las condiciones estabilidad y reactividad (SECCIÓN 10.5).
- Modificación de la información de las condiciones estabilidad y reactividad (SECCIÓN 10.6).
- Cambio en la clasificación de peligrosidad (SECCIÓN 11.1).

Clasificación y procedimiento utilizado para determinar la clasificación de las mezclas con arreglo al Reglamento (CE) nº 1272/2008 [CLP]:

Peligros físicos	Conforme a datos obtenidos de los ensayos
Peligros para la salud	Método de cálculo
Peligros para el medio ambiente	Método de cálculo

Se aconseja realizar formación básica con respecto a seguridad e higiene laboral para realizar una correcta manipulación del producto.

Se dispone de Escenario de Exposición del producto.

Abreviaturas y acrónimos utilizados:
ADR: Acuerdo europeo sobre el transporte internacional de mercancías peligrosas por carretera.
CEN: Comité Europeo de Normalización.

-Continúa en la página siguiente.-

EPI: Equipo de protección personal.
IATA: Asociación Internacional de Transporte Aéreo.
ICAO: Organización de Aviación Civil Internacional.
IMDG: Código Marítimo Internacional de Mercancías Peligrosas.
RID: Regulación concerniente al transporte internacional de mercancías peligrosas por ferrocarril.

Principales referencias bibliográficas y fuentes de datos:
http://eur-lex.europa.eu/homepage.html
http://echa.europa.eu/
Reglamento (UE) 2015/830.
Reglamento (CE) No 1907/2006.
Reglamento (EU) No 1272/2008.

La información facilitada en esta ficha de Datos de Seguridad ha sido redactada de acuerdo con el REGLAMENTO (UE) 2015/830 DE LA COMISIÓN de 28 de mayo de 2015 por el que se modifica el Reglamento (CE) no 1907/2006 del Parlamento Europeo y del Consejo, relativo al registro, la evaluación, la autorización y la restricción de las sustancias y mezclas químicas (REACH), por el que se crea la Agencia Europea de Sustancias y Preparados Químicos, se modifica la Directiva 1999/45/CE y se derogan el Reglamento (CEE) nº 793/93 del Consejo y el Reglamento (CE) nº 1488/94 de la Comisión así como la Directiva 76/769/CEE del Consejo y las Directivas 91/155/CEE, 93/67/CEE, 93/105/CE y 2000/21/CE de la Comisión.

La información de esta Ficha de Datos de Seguridad del Producto está basada en los conocimientos actuales y en las leyes vigentes de la CE y nacionales, en cuanto que las condiciones de trabajo de los usuarios están fuera de nuestro conocimiento y control. El producto no debe utilizarse para fines distintos a aquellos que se especifican, sin tener primero una instrucción por escrito, de su manejo. Es siempre responsabilidad del usuario tomar las medidas oportunas con el fin de cumplir con las exigencias establecidas en las legislaciones.

-Fin de la ficha de datos de seguridad.-

CHEMICAL SAFETY REPORT

Substance Name: Copper dinitrate

EC Number: 221-838-5

CAS Number: 3251-23-8

Registrant's identity: Joint Chemical Safety Report

Update: **June 2019 (amended text shown in red)**

CONTENTS

TABLES

FIGURES

PART A

1 SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures are described in the Exposure Scenarios presented in Section 9 of part B of the joint CSR.

2 DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

I declare that the risk management measures referred to in section 1 are implemented.

3 DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

I declare that the risk management measures referred to in section 1 are communicated to my customers, when they are relevant for their uses.

Introductory Note to the Copper Voluntary Risk Assessment

In response to a request from the European Commission to "start preparing the initial assessments for substances on the EU working list as these were considered as Community priorities in the context of the industry voluntary initiatives for high production volume chemicals" the copper industry committed to undertake a Voluntary Risk Assessment (VRA) for copper and the copper compounds on the EU working list: Cu, CuO, Cu_2O, $CuSO_4$ and $Cu_2Cl(OH)_3$. This initiative was endorsed by the EU CAs in 2001. A comprehensive VRA dossier was compiled by the European Copper Institute (ECI) in co-operation with expert consultants from the University of Birmingham/ICON for human health toxicity, from BR. Stern and Associates for human health deficiency, and from Euras/Ecolas for the environment. It is based on the principles of Regulation 793/93, 1488/94 and the detailed methodology laid down in the revised Technical Guidance Document on Risk Assessment for New and Existing Substances. Methodological experiences gained through other metal Risk Assessments, e.g. the incorporation of bioavailability for zinc, were incorporated as appropriate. Additional up to date scientific information was integrated into the assessment where scientifically relevant (i.e. the use of bioavailability models for water, sediment and soil, plus information on copper as an essential nutrient). A broad cross section of the European copper industry has been fully involved in the process and has submitted a significant amount of proprietary data.

To ensure the transparency and quality of the dossier, the initial draft RA reports have been refined by incorporating inputs from the Review Country (Italy – Istituto Superiori di Sanità) and independent peer review panels.

For several of the substances under consideration, targeted risk assessments were required under the Biocidal Product Directive (98/8/EC). These dossiers, which have been/will be provided to the competent authorities (France) by the respective end user industry groups, contain confidential information not available to ECI. However, ECI has worked closely with both of these groups in incorporating relevant information to ensure consistency to the extent possible.

Under the Voluntary risk assessment, a single dossier covers the assessments for copper metal and the copper compounds, with substance specific aspects provided where relevant. For the base data compilation, extensive literature searches were performed for each substance. Data gaps were filled with analogous data, where relevant, or by additional testing where possible. Where the information was either unnecessary for the copper risk assessment, or impossible to obtain, waiving for testing and/or justification to support derogation is discussed. Some remaining data gaps were identified and will be tackled as a follow-up to this report.

Since the initial submission of the dossier in 2005, comments have been received from several Member States. The current 2008 version reflects comments made by the Member States in writing and during the TCNES meetings. To ensure the transparency and quality of the dossier, the current version and the responses to Member States comments have been refined in close co-operation with the Review Country (Italy – Istituto Superiori di Sanità).

The human health and environmental sections of the report have been agreed by TCNES (see TCNES opinions) and sent to SCHER for final review. The SCHER agreed with the conclusions drawn and made some additional recommendations for further follow-up.

All reports and assessments related to the copper Voluntary Risk assessment are available from: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp.

Introductory Note to the Core Copper Dossier

The hazards database presented in this Chemical Safety Report is based on the core copper dossier contained in the copper REACH submission, accessed by means of a Letter of Access from the European Copper Institute.

PART B

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

The substance **copper dinitrate** is a mono constituent substance (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

Table 1: Substance identity

EC number:	221-838-5
EC name:	copper dinitrate
CAS number (EC inventory):	3251-23-8
CAS number (Trihydrate form):	10031-43-3
CAS name:	Nitric acid, copper(2+) salt
IUPAC name:	copper(II) nitrate
Molecular formula:	Cu.2HNO3
Molecular weight range:	187.5558

Structural formula:

1.2 Composition of the substance

The EC Number for copper dinitrate also covers hydrated forms of the compound.

Name: Copper dinitrate

Description: Sameness was agreed by the SIEF to be ≥ 271 g/kg (as Cu), ≥ 80% w/w copper dinitrate. Impurities should be present at levels that do not affect the classification of the substance.

Degree of purity: ≥ 80.0 % (w/w)

Table 2: Constituents

Constituent	Typical concentration	Concentration range	Remarks
Copper dinitrate EC no.: 221-838-5 CAS no.: 3251-23-8	≥ 80% w/w	≥ 80% w/w	

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Total impurities	See remarks	See remarks	Individual impurities are present at levels that do not affect the classification of the substance.

Table 4: Additives

Constituent	Function	Typical concentration	Concentration range	Remarks
				No additives are present in this substance.

Name: Copper dinitrate hemi(pentahydrate)

Description: Sameness was agreed by the SIEF to be ≥ 219 g/kg (as Cu), ≥ 80% w/w copper dinitrate hemi(pentahydrate). Impurities should be present at levels that do not affect the classification of the substance.

Degree of purity: ≥ 80.0 % (w/w)

Table 5: Constituents

Constituent	Typical concentration	Concentration range	Remarks
copper dinitrate EC no.: 221-838-5 CAS no.: 19004-19-4		≥ 80.0 % (w/w)	

Table 6: Impurities

Impurity	Typical concentration	Concentration range	Remarks
Total unspecified impurities		≥ 20.0 % (w/w)	Individual impurities are present at concentrations that do not affect the classification of the substance.

Table 7: Additives

Constituent	Function	Typical concentration	Concentration range	Remarks
				No additives are present in this substance.

Name: Copper dinitrate trihydrate

Description: Sameness was agreed by the SIEF to be ≥ 210 g/kg (as Cu), ≥ 80% w/w copper dinitrate trihydrate. Impurities should be present at levels that do not affect the classification of the substance.

Degree of purity: ≥ 80.0 % (w/w)

Table 8: Constituents

Constituent	Typical concentration	Concentration range	Remarks
copper dinitrate EC no.: 221-838-5 CAS no.: 10031-43-3		≥ 80.0 % (w/w)	

Table 9: Impurities

Impurity	Typical concentration	Concentration range	Remarks
Total unspecified impurities		≥ 20.0 % (w/w)	Individual impurities are present at concentrations that do not affect the classification and labelling of the substance.

Table 10: Additives

Constituent	Function	Typical concentration	Concentration range	Remarks
				No additives are present in this substance.

1.3 Physicochemical properties

Table 11: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20 °C and 101.3 kPa	Solid.	Form: Crystalline. Colour: Blue with a Munsell colour value of 2.5PB 5/10. Odour: Odourless.
Melting/freezing point	255 °C.	
Boiling point	Not applicable.	No boiling point before decomposition. Decomposed from approx. 266 °C.
Relative density	2.39 at 20.0 ± 0.5 °C.	
Vapour pressure	2.6×10^{-9} at 25°C.	Estimated using a computer-based method.
Surface tension	73.2 mN/m at 20.2 ± 0.5 °C.	The material is not surface active.
Water solubility	145 g/100 mL at 25 °C.	
Partition coefficient n-octanol/water (log value)	Not applicable.	The octanol:water partition coefficient, Pow, is defined as the ratio of the equilibrium concentrations of a dissolved substance in each of the phases in a two phase system consisting of octanol and water. It is usually expressed on a log scale. It is a key parameter in studies of the environmental fate of organic substances, indicating the potential for bioaccumulation and soil absorption. However, the mechanisms of absorption of Cu^{2+} into organic matter and living cells are understood to be different from those traditionally attributed to carbon-based substances and the parameter therefore has little relevance to ionic copper. The parameter is therefore not considered to be relevant to copper dinitrate.
Flash point	Not applicable.	The study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids.
Flammability	Not highly flammable.	Failed to ignite in the preliminary screening test. Based on experience in use, copper dinitrate is not pyrophoric (EU Method A.13) and is not flammable in contact with water (EU Method A.12).
Explosive properties	Not explosive.	

Property	Value	Remarks
Self-ignition temperature	No self-ignition temperature below the melting temperature.	
Oxidising properties	Oxidising solid (Category 2).	The test substance has oxidizing properties when tested according to UN-MTC Procedure O.3. Substance/cellulose mixtures (1:1 and 4:1) were found to exhibit a mean burning rate greater than that of a 1:1 mixture of calcium peroxide and cellulose and less than that of a 3:1 mixture of calcium peroxide and cellulose.
Granulometry	(Fern and Carse, 2015) Particle size distribution analysis, both the volume- (standard reporting of particle size distribution data) and number-based (pertinent to the nanomaterial definition), was undertaken on a bulk sample of copper dinitrate. Analysis was undertaken on the 'as is' powders in the bulk dry state using laser diffraction using a Malvern Mastersizer 3000 in accordance with ISO 13320:2009. The following results were obtained: The mean of the volume-rated distributions were as follows: D(v, 0.1) 66.47 µm; D(v, 0.5) 227.33 µm; D(v, 0.9) 511.67 µm. The mean of the number- rated distributions were as follows: D(n, 0.1) 4.86 µm; D(n, 0.5) 6.56 µm; D(n, 0.9) 16.20 µm.	To account for the possibility that materials with a smaller particle size may be produced for certain specialist uses, the Exposure Scenarios developed under REACH are based on the worst-case assumption that 100% of any material becoming airborne is respirable.
Stability in organic solvents and identity of relevant degradation products	Not applicable.	As stated in the REACH regulations, the study does not need to be conducted if the substance is inorganic.
Dissociation constant	Not applicable.	The dissociation constant in water was not determined as the test item, being an inorganic salt, would be ionized in solution

Property	Value	Remarks
		within the environmentally relevant pH range and therefore the test is not applicable.
Viscosity	Not applicable.	Not applicable to solids.
Auto flammability	No self-ignition temperature below the melting temperature.	

Data waiving

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: study scientifically unjustified

Justification: The octanol: water partition coefficient, Pow, is defined as the ratio of the equilibrium concentrations of a dissolved substance in each of the phases in a two phase system consisting of octanol and water. It is usually expressed on a log scale. It is a key parameter in studies of the environmental fate of organic substances, indicating the potential for bioaccumulation and soil absorption. However, the mechanisms of absorption of Cu^{2+} into organic matter and living cells are understood to be different from those traditionally attributed to carbon-based substances and the parameter therefore has little relevance to ionic copper. The parameter is therefore not considered to be relevant to copper dinitrate.

Information requirement: Flash point

Reason: study scientifically unjustified

Justification: The study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids.

Information requirement: Flammability

Reason: study scientifically unjustified

Justification: Based on experience in use, copper dinitrate is not pyrophoric (EU Method A.13) and is not flammable in contact with water (EU Method A.12).

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: study scientifically unjustified

Justification: As stated in the REACH regulations, the study does not need to be conducted if the substance is inorganic.

Information requirement: Dissociation constant

Reason: study scientifically unjustified

Justification: The dissociation constant in water was not determined as the test item, being an inorganic salt, would be ionized in solution within the environmentally relevant pH range and therefore the test is not applicable.

Information requirement: Viscosity

Reason: study technically not feasible

Justification: Not applicable to solids.

2 MANUFACTURE AND USES

Tonnage band 100 – 1000 tonnes/year. Detailed information on quantities (in tonnes/year) is provided in IUCLID Section 3.2 (Estimated Quantities).

Generic Emission Scenarios related to manufacture and use of copper dinitrate are listed in Section 9.1, Overview on exposure scenarios and coverage of copper dinitrate life cycle Table 73.

2.1 Manufacture

Table 12: Manufacture

Identifiers	Use descriptors	Other information
#1: Reaction of cupric oxide (CuO) [or other copper compound] and nitric acid	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Remarks: A spERC for production of metal compounds is also available.
#2: Dissolution of copper in nitric acid.	**Variation 1:** **Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):**	Remarks: A spERC for production of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 26: Handling of solid inorganic substances at ambient temperature **Variation 2:** **Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	

Table 13: Manufacturing process related to the specified manufacture(s)

Related manufacture(s)	Description of manufacturing process
M-1: Reaction of cupric oxide	This is an aqueous process in which black CuO is added to nitric acid and

Related manufacture(s)	Description of manufacturing process
(CuO) [or other copper compound] and nitric acid	water and the resulting exothermic reaction is controlled to keep the process below 80 °C. No filtration is applied as the product is sold as a liquid.
M-2: Dissolution of copper in nitric acid.	**Variation 1:** Copper dinitrate is made by dissolving copper in nitric acid, followed by filtration and drying. **Variation 2:** Copper dinitrate intermediate is made by dissolving copper metal cathodes or shot in nitric acid in a dissolution tank.

No information available on production of articles covered by the specified use(s)

2.2 Identified uses

Table 14: Formulation

Identifiers	Use descriptors	Other information
#1: Generic formulation	**Environmental release category (ERC):** ERC 2: Formulation of preparations ERC 3: Formulation in materials **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category formulated:** PC 2: Adsorbents PC 3: Air care products PC 9a: Coatings and paints, thinners, paint removers	Substance supplied to that use: As such In a mixture Remarks: This scenario covers formulation of preparations and/or materials during the following identified uses: Absorbents; Catalyst manufacture; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Laboratory chemicals/reagents, quality control; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. A spERC for the formulation of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PC 9b: Fillers, putties, plasters, modelling clay PC 12: Fertilisers PC 14: Metal surface treatment products, including galvanic and electroplating products PC 15: Non-metal-surface treatment products PC 18: Ink and toners PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 21: Laboratory chemicals PC 23: Leather tanning, dye, finishing, impregnation and care products PC 24: Lubricants, greases, release products PC 31: Polishes and wax blends PC 32: Polymer preparations and compounds PC 39: Cosmetics, personal care products PC 0: Other: Colouring agents, pigments **Technical function of the substance:** Agents adsorbing and absorbing gases or liquids Process regulators, other than polymerisation or vulcanisation processes Process regulators, used in vulcanisation or polymerisation processes Colouring agents, pigments Colouring agents, dyes Plating agents and metal surface treating agents Fertilisers Intermediates Laboratory chemicals Lubricants and lubricant additives Processing aid, not otherwise listed Other: Non-metal surface treatment Other: Catalysts	
#2: Formulation as an intermediate	**Environmental release category (ERC):**	Substance supplied to that use:

Identifiers	Use descriptors	Other information
under SCC	ERC 2: Formulation of preparations **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities **Product Category used:** PC19: Intermediates **Technical function of the substance:** Intermediates	In a mixture Remarks: This identified use covers formulation of preparations and/or materials during the following identified uses: Process intermediate for manufacture of other copper compounds e.g. catalysts;

Table 15: Uses at industrial sites

Identifiers	Use descriptors	Other information
#3: Absorbents	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids ERC 6c: Industrial use of monomers for manufacture of thermoplastics **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting **Product Category used:** PC 2: Adsorbents PC 3: Air care products PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents **Sector of end use:** SU3: Industrial uses. SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Agents adsorbing and absorbing gases or liquids	
#4: Catalyst manufacture	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Catalyst manufacture may be a continuous process containing integrated production and formulation steps. Consequently, ERC 1 and ERC 2 are therefore considered for this use. A spERC for formulation of metal compounds has also

Identifiers	Use descriptors	Other information
	opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation **Product Category used:** PC 2: Adsorbents PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents **Sector of end use:** SU 3: Industrial uses. SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Intermediates Process regulators, other than polymerisation or vulcanisation processes Process regulators, used in vulcanisation or polymerisation processes Other: Catalysts	been utilised. A spERC for the manufacture of catalysts is available.
#5: Catalyst use	**Environmental release category (ERC):** ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids **Process category (PROC):**	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting **Product Category used:** PC 2: Adsorbents PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 32: Polymer preparations and compounds **Sector of end use:** SU 3: Industrial uses. SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Intermediates Process regulators, other than polymerisation or vulcanisation processes Process regulators, used in vulcanisation or polymerisation processes Other: Catalysts	Remarks: A spERC for the use of metal compounds is also available.
#6: Ceramics	**Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for	Substance supplied to that use: As such In a mixture

Identifiers	Use descriptors	Other information
	formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 3: Industrial uses. SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 19: Building and construction work **Technical function of the substance:** Colouring agents, pigments	Subsequent service life relevant for that use: yes Link to the subsequent service life: A-1: Ceramics Remarks: A spERC for the use of metal compounds is also available.
#7: Coatings, Inks	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 19: Hand-mixing with intimate contact and only PPE available. **Product Category used:** PC 9a: Coatings and paints, thinners, paint removers PC 18: Ink and toners **Sector of end use:** SU 3: Industrial uses. SU 7: Printing and reproduction of recorded media SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Colouring agents, dyes Colouring agents, pigments	
#8: Cosmetics	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Technical function of the substance is not known. A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent **Product Category used:** PC 39: Cosmetics, personal care products **Sector of end use:** SU 3: Industrial uses. SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 0: Other: Cosmetics	
#9: Electroplating and galvanic	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-2: Electroplating and galvanic Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 15: Use as laboratory reagent PROC 25: Other hot work operations with metals **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products **Sector of end use:** SU 3: Industrial uses. SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 14: Manufacture of basic metals, including alloys SU 16: Manufacture of computer, electronic and optical products, electrical equipment **Technical function of the substance:** Plating agents and metal surface treating agents	
#10: Fertiliser	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 13: Treatment of articles by dipping and pouring PROC 26: Handling of solid inorganic substances at ambient temperature PROC 7: Industrial spraying	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	Product Category used: PC 12: Fertilisers **Sector of end use:** SU 3: Industrial uses. SU 1: Agriculture, forestry and fishing SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Fertilisers	
#11: Glass	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 3: Industrial uses.	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-3: Glass Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement **Technical function of the substance:** Colouring agents, pigments	
#12: Laboratory chemicals/reagent, quality control	**Environmental release category (ERC):** ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 15: Use as laboratory reagent **Product Category used:** PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 21: Laboratory chemicals **Sector of end use:** SU 3: Industrial uses: SU 24: Scientific research and development **Technical function of the substance:** Laboratory chemicals	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.
#13: Leather and textile dyes	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-4: Leather and textiles Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation **Product Category used:** PC 23: Leather tanning, dye, finishing, impregnation and care products PC 24: Lubricants, greases, release products **Sector of end use:** SU 3: Industrial uses SU 5: Manufacture of textiles, leather, fur **Technical function of the substance:** Colouring agents, dyes	
#14: Lubricants and greases, release products	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 7: Industrial use of substances in closed systems **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	PROC 13: Treatment of articles by dipping and pouring PROC 17: Lubrication at high energy conditions and in partly open process **Product Category used:** PC 24: Lubricants, greases, release products **Sector of end use:** SU 3: Industrial uses SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Lubricants and lubricant additives	
#15: Non-metal surface treatment	**Process category (PROC):** PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 13: Treatment of articles by dipping and pouring **Product Category used:** PC 15: Non-metal-surface treatment products **Sector of end use:** SU 3: Industrial uses SU 15: Manufacture of fabricated metal products, except machinery and equipment **Technical function of the substance:** Non-metal surface treatment	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-5: Non-metal surface treatment Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
#16: Polishes and waxes	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities **Product Category used:** PC 31: Polishes and wax blends **Sector of end use:** SU 3: Industrial uses SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Technological function of the substance is not known. A spERC for the use of metal compounds is also available.
#17: Process intermediate for manufacture of other copper compounds e.g. catalysts	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 21: Low energy manipulation of substances bound in materials and/or articles **Product Category used:** PC 19: Intermediate **Sector of end use:** SU 3: Industrial uses SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Intermediates Other: Catalysts	
#18: Processing aids	**Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	(charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting **Product Category used:** PC 2: Adsorbents PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents **Sector of end use:** SU 3: Industrial uses SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals **Technical function of the substance:** Processing aid, not otherwise listed	
#19: Putties, fillers, construction chemicals	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
	containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 19: Hand-mixing with intimate contact and only PPE available. **Product Category used:** PC 9b: Fillers, putties, plasters, modelling clay **Sector of end use:** SU 3: Industrial uses SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 19: Building and construction work **Technical function of the substance:** Colouring agents, pigments	
#20: Pyrotechnics	**Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 3: Industrial uses SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Colouring agents, pigments	Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.
#21: Raw material for production of other compounds and fine chemicals	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another	Substance supplied to that use: As such In a mixture

Identifiers	Use descriptors	Other information
	substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature **Product Category used:** PC 19: Intermediate **Sector of end use:** SU 3: Industrial uses SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Intermediates	Subsequent service life relevant for that use: no Remarks: A spERC for the use of metal compounds is also available.

Identifiers	Use descriptors	Other information
#22: Use as an intermediate under SCC	**Environmental release category (ERC):** ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) **Product Category used:** PC19: Intermediates **Sector of Use:** SU 3: Industrial uses SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance:** Intermediates	Substance supplied to that use: In a mixture Subsequent service life relevant for that use: no Remark: This identified use covers use as a process intermediate for manufacture of other copper compounds e.g. catalysts

Table 16: Uses by professional workers

Identifiers	Use descriptors	Other information
#6: Ceramics	**Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-1: Ceramics

Identifiers	Use descriptors	Other information
	(charging/discharging) from/to vessels/large containers at dedicated facilities PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 19: Building and construction work SU 22: Professional uses **Technical function of the substance:** Colouring agents, pigments	Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#7: Coatings/Inks	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 11: Non industrial spraying **Product Category used:** PC 9a: Coatings and paints, thinners, paint removers PC 18: Ink and toners **Sector of end use:** SU 7: Printing and reproduction of recorded media SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 22: Professional uses **Technical function of the substance:** Colouring agents, dyes Colouring agents, pigments	
#8: Cosmetics	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Technical function of the substance is not known.

Identifiers	Use descriptors	Other information
	(charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent **Product Category used:** PC 39: Cosmetics, personal care products **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 0: Other: Cosmetics SU 22: Professional uses	
#9: Electroplating and galvanic	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring ~~PROC 15: Use as laboratory reagent~~	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-2: Electroplating and galvanic Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.

Identifiers	Use descriptors	Other information
	PROC 25: Other hot work operations with metals PROC 11: Non industrial spraying **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 14: Manufacture of basic metals, including alloys SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 22: Professional uses **Technical function of the substance:** Plating agents and metal surface treating agents	
#10: Fertiliser	**Environmental release category (ERC):** ERC 8b: Wide dispersive indoor use of reactive substances in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8e: Wide dispersive outdoor use of reactive substances in open systems ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC 9b: Wide dispersive outdoor use of substances in closed systems **Process category (PROC):** PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 12: Fertilisers **Sector of end use:** SU 1: Agriculture, forestry and fishing SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 22: Professional uses **Technical function of the substance:** Fertilisers	
#11: Glass	**Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature.	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Link to the subsequent service life: A-3: Glass Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.

Identifiers	Use descriptors	Other information
	Industrial setting PROC 11: Non industrial spraying **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 22: Professional uses **Technical function of the substance:** Colouring agents, pigments	
#14: Lubricants and greases, release products	**Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 9a: Wide dispersive indoor use of substances in closed systems ERC 9b: Wide dispersive outdoor use of substances in closed systems **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 17: Lubrication at high energy conditions and in partly open process **Product Category used:** PC 24: Lubricants, greases, release products **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 22: Professional uses **Technical function of the substance:** Lubricants and lubricant additives	
#16: Polishes and waxes	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8e: Wide dispersive outdoor use of reactive substances in open systems **Process category (PROC):** PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities **Product Category used:** PC 31: Polishes and wax blends **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Technical function of the substance is not available.

Identifiers	Use descriptors	Other information
	re-packaging (excluding alloys) SU 22: Professional uses	
#19: Putties, fillers, construction chemicals	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 11: Non industrial spraying **Product Category used:** PC 9b: Fillers, putties, plasters, modelling clay **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 19: Building and construction work SU 22: Professional uses **Technical function of the substance:**	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no

Identifiers	Use descriptors	Other information
	Colouring agents, pigments	
#20: Pyrotechnics	**Process category (PROC):** PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) **Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 22: Professional uses **Technical function of the substance:** Colouring agents, pigments	Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: no Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.

Table 17: Consumer uses

Identifiers	Use descriptors	Other information
#6: Ceramics	**Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Colouring agents, pigments	Substance supplied to that use: As such In a mixture Link to the subsequent service life: A-1: Ceramics Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#7: Coatings/Inks	**Product Category used:** PC 9a: Coatings and paints, thinners, paint removers	Substance supplied to that use: As such

Identifiers	Use descriptors	Other information
	PC 18: Ink and toners **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Colouring agents, dyes Colouring agents, pigments	In a mixture Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#8: Cosmetics	**Product Category used:** PC 39: Cosmetics, personal care products **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Cosmetics	Substance supplied to that use: As such In a mixture Remarks: Technical function of the substance not known. Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#9: Electroplating and galvanic	**Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Plating agents and metal surface treating agents	Substance supplied to that use: As such In a mixture Link to the subsequent service life: A-2: Electroplating and galvanic Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#10: Fertiliser	**Product Category used:** PC 12: Fertilisers **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:**	Substance supplied to that use: As such In a mixture Remarks: Emissions to the environment occur as a result of a wide

Identifiers	Use descriptors	Other information
	Fertilisers	dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#11: Glass	**Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Colouring agents, pigments	Substance supplied to that use: As such In a mixture Link to the subsequent service life: A-3: Glass Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#13: Leather and textile dyes	**Product Category used:** PC 23: Leather tanning, dye, finishing, impregnation and care products PC 24: Lubricants, greases, release products **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Colouring agents, dyes	Substance supplied to that use: As such In a mixture Link to the subsequent service life: A-4: Leather and textiles Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#14: Lubricants and greases, release products	**Product Category used:** PC 24: Lubricants, greases, release products **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Lubricants and lubricant additives	Substance supplied to that use: As such In a mixture Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.

Identifiers	Use descriptors	Other information
#15: Non-metal surface treatment	**Product Category used:** PC 15: Non-metal-surface treatment products **Sector of end use:** SU 21: Consumer uses **Technical function of the substance:** Non-metal surface treatments	Substance supplied to that use: As such In a mixture Link to the subsequent service life: A-5: Non-metal surface treatment Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#16: Polishes and waxes	**Product Category used:** PC 31: Polishes and wax blends **Sector of end use:** SU 21: Consumer uses	Substance supplied to that use: As such In a mixture Remarks: Technical function of the substance not known. Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#19: Putties, fillers and construction chemicals	**Product Category used:** PC 9b: Fillers, putties, plasters, modelling clay **Sector of end use:** SU 21: Consumer uses **Technical function of the substance** Colouring agents, pigments	Substance supplied to that use: As such In a mixture Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.
#20: Pyrotechnics	**Product Category used:** PC 0: Other: Colouring agents, pigments **Sector of end use:**	Substance supplied to that use: As such In a mixture

Identifiers	Use descriptors	Other information
	SU 21: Consumer uses **Technical function of the substance** Colouring agents, pigments	Remarks: Emissions to the environment occur as a result of a wide dispersive use pattern. Refer to CSR Sections 9 and 10 for further information on emissions.

Table 18: Article service life

Identifiers	Use descriptors	Other information
#1: Ceramics	**Article category related to subsequent service life (AC):** AC 4: Stone, plaster, cement, glass and ceramic articles **Technical function of the substance during formulation:** Colouring agents, pigments	Remarks: There is no intended release of copper dinitrate
#2: Electroplating and galvanic	**Article category related to subsequent service life (AC):** AC 2: Machinery, mechanical appliances, electrical/electronic articles **Technical function of the substance during formulation:** Plating agents and metal surface treating agents	Remarks: There is no intended release of copper dinitrate
#3: Glass	**Article category related to subsequent service life (AC):** AC 4: Stone, plaster, cement, glass and ceramic articles **Technical function of the substance during formulation:** Colouring agents, pigments	Remarks: There is no intended release of copper dinitrate
#4: Leather and textiles	**Article category related to subsequent service life (AC):** AC 6: Leather articles AC 5: Fabrics, textiles and apparel **Technical function of the substance during formulation:**	Remarks: There is no intended release of copper dinitrate.

Identifiers	Use descriptors	Other information
	Colouring agents, dyes	
#5: Non-metal surface treatment	**Article category related to subsequent service life (AC):** AC 01: Other (not intended to be released): Various articles **Technical function of the substance during formulation:** Non-metal surface treatment	Remarks: There is no intended release of copper dinitrate.

Copper dinitrate is used in several product types that fall under the control of separate regulations, e.g. as a food and feed additive; in pharmaceuticals; in biocidal products and in plant protection products. As these uses fall outside the scope of REACH they are not considered any further in this assessment.

Copper dinitrate is also used as an ingredient of cosmetic products. As consumer use of cosmetics is outside the scope of REACH, this use has been excluded from this assessment.

2.3 Uses advised against

There are no uses advised against.

3 CLASSIFICATION AND LABELLING[1]

3.1 Classification and labelling according to CLP / GHS

The following classification and labelling is applicable to the anhydrous and hydrated forms of copper dinitrate.

Name: Copper dinitrate (self-classification)

Implementation: EU

State/form of the substance: powder

Remarks: Classification and labelling for copper dinitrate has been proposed on the basis of available information.

Classification

The substance is classified as follows:

[1] The template will be updated once the Regulation on Classification, Labelling and Packaging of substances and mixtures (implementing the GHS) will be adopted.

Table 19: Classification and labelling according to CLP / GHS for physicochemical properties

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:	Oxid. solid 2	H272: May intensify fire; oxidiser.	conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non-) classification can be found in the CSR section indicated

Table 20: Classification and labelling according to CLP / GHS for health hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Skin corrosion / irritation:	Skin Corr. 1B	H314: Causes severe skin burns and eye damage.		5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitisation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non-) classification can be found in the CSR section indicated

Table 21: Classification and labelling according to CLP / GHS for environmental hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life.		7.5
Hazards to the aquatic environment (long-term):	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.		7.5
M-Factor acute: 10				
M-Factor chronic: 1				
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.5

*) Justification for (non-) classification can be found in the CSR section indicated

Labelling

Signal word: Danger

Hazard pictogram:

GHS04: oxidising

GHS05: corrosion

GHS09: environment

Hazard statements:

H272: May intensify fire; oxidiser.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

H411: Toxic to aquatic life with long lasting effects.

Precautionary statements:

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P221: Take any precaution to avoid mixing with combustibles...

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER or doctor/physician.

P391: Collect spillage.

P501: Dispose of contents/container to ...

4 ENVIRONMENTAL FATE PROPERTIES

General summary of the information on environmental fate and pathways

Copper is a natural element and transition metal with more than one oxidation state. Copper in its metallic form (Cu°) is not available. Copper needs to be transformed to its ionic forms to become available for uptake by living organisms

Stability and Biodegradation

The classic standard testing protocols on hydrolysis, photo-transformation, are not applicable to copper and copper compounds.

> *This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex): 'Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i.e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification.' For a discussion on this please see Section 7.6.*

Relevant fate aspects for copper in the environment have been included in the section 'additional **information on fate and pathways**' and are summarized below.

As outlined in the CLP guidance (2009), the understanding of the transformation of copper into more or less bioavailable species is relevant to the environmental hazard assessments and this is described below.

- Transformation of Cu-ions released in the environment - Copper speciation

Once released to the environment, copper ions have more than one oxidation state and copper is thus characterized as transition metal. The principal ionic forms are cuprous (Cu(I), Cu^{+}) and cupric (Cu(II), Cu^{2+}). The trivalent form (Cu(III), Cu^{3+}) occurs but is relatively unimportant in physical and biological systems. Cu^{+} is unstable in aqueous media and soluble Cu^{1+}compounds readily transforms into soluble Cu^{2+}ions, compounds and/or insoluble Cu^{2+}ions, compounds (e.g. copper sulphides) that precipitate. This transformation of Cu^{+} to Cu^{2+} is a result of a redox reaction initiated through atmospheric water vapour as well as in aqueous solution. However, monovalent copper cations are only susceptible to such transformation when they are not chemically bound in insoluble compounds or stabilised in complexed forms.

The transformation of Cu(I) to Cu (II) can be described by:

(1) $2\ Cu_2O + 2H_2O = 4Cu^{+} + 4OH^{-}$

and

(2) $4Cu^{+} + O_2 + 4H^{+} = 4Cu^{2+} + 2H_2O$

Both sub-reactions are summarised as:

$2Cu_2O(s) + O_2(g) + 4H^+ = 4Cu^{2+} + 4OH^-$

Among the copper species released/transformed, Cu (II) is thus the most environmental relevant species. It is further recognised that Cu (II) ions - commonly named free cupric ions- are the most active copper species and that total Cu or Cu(II) concentrations are usually not directly related to ecological effects since exposure of biota may be limited by processes that render Cu unavailable for uptake (ICPS, 1998). Assessing the species of Cu (II) therefore has ecotoxicological relevance. After being released into the environment, the Cu(II) ions typically bind to inorganic and organic ligands contained within water, soil, and sediments. In water Cu(II) binds to dissolved organic matter (e. g. humic or fulvic acids). The Cu(II) ion forms stable complexes with $-NH_2$, -SH, and, to a lesser extent, -OH groups in these organic acids. Cu(II) will also bind with varying affinities to inorganic and organic components in sediments and soils. For example, Cu(II) binds strongly to hydrous manganese and iron oxides in clay and to humic acids, but much less strongly to aluminosilicates in sand. In all environmental compartments (water, sediment, soil), the binding affinities of Cu(II) with inorganic and organic matter is dependent on pH, the oxidation-reduction potential in the local environment, and the presence of competing metal ions and inorganic anions.

Some key papers on copper speciation in freshwater, marine waters, sediments and soils are provided in the section '*additional information on environmental fate*'

- Copper attenuation, removal from water column, geochemical cycling- Quantitative assessment

As described above, after the release of Cu(II) in the environment, further transformations occur thereby changing the potential for toxicity, induced by the free cupric ions. The concentrations of 'active' cupric ions, that remains available for uptake by biota depends on different processes: precipitation, dissolution, adsorption, desorption, complexation and competition for biological adsorption sites (ligands). These processes are critical for the fate of copper in the environment. This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex):

> *'Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i.e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification. '*

The use of laboratory mesocosm and/or field tests for evaluating removal of soluble metal species through precipitation/partitioning processes over a range of environmentally relevant conditions are described in the CLP guidance (2009) and for copper, such laboratory/mesocosm and/or field tests have therefore been assessed.

-*In the water compartment*, removal of soluble copper species through precipitation/partitioning processes over a range of environmentally relevant conditions, was assessed in Rader *et al.,* 20120 and described in the section '*additional information on environmnetal fate and pathways*'.

The assessment relies on modeling simulations, based on the Tableau Input Coupled Kinetics Equilibrium Transport (TICKET) model (Farley *et al.,* 2008). The numerical engine of the model is a screening level model used to assess the fate and effects of chemicals through simultaneous consideration of chemical partitioning, transport, reactivity, and bioavailability (MacKay TICKET-UWM). The software includes metal-specific binding to inorganic ligands, DOC and POC (using information from metal speciation models such as WHAM) and average-annual cycling of organic matter and sulfide production in the lake.

The model was applied to a standard lake environment (EUSES characteristics), complemented with a sensitivity analysis on model parameters such as pH. The validity of the model outcome (removal rate) was assessed from mesocosm and field data. The main conclusions are formulated as follows:

- For a standard lake environment consisting of the EUSES model lake parameters and the Kd derived in the copper RA (Log Kd: 4.48), copper removal from the water column satisfies the criterion of rapid removal of 70% dissolved copper removal in 28 days;
- For a standard lake environment consisting of the EUSES model lake parameters but with pH varying between 6 and 8 (Kd estimated form the model), copper removal from the water column satisfies the criterion of rapid removal of 70% dissolved copper removal in 28 days;
- For an experimental freshwater mesocosm study, carried out with a range of copper loadings (Schaefers *et al.,* 2003), the measured data demonstrate a half life of 4 days and thus satisfy the criterion of rapid removal of copper (i.e. greater than 70% in 28 days);
- For the whole-lake spike addition studies (LakeCourtilleand Saint Germain les Belles Reservoir), TICKET-UWM results, in concert with the measured data, indicate rapid removal of copper (i.e. greater than 70% in 28 days) for both lake systems;
- Hypothetical TICKET-UWM simulations modeling the removal of copper in the MELIMEX limno-corrals following termination of copper loading demonstrate copper removal that does not meet the rapid removal benchmark because of a low settling velocity, low distribution coefficient, and low suspended solids concentration.

Considering that the MILIMEX system is the only scenario that could not demonstrate 'rapid removal' it is critical to assess the environmental relevance of the MILIMEX system. The MILIMEX System was characterised by a setting velocity that is 10 times lower then the one in the EUSES system (0.2 versus 2.5 m/d) and a suspended solid concentration that is almost 3 times lower then the EUSES system (5.9 vesrus 16 mg/L). It is therefore concluded that the MILIMEX study was carried out under extreme conditions.

From Rader *et al.,* 2010, it can therefore be concluded that under 'environmental relevant'conditions, copper-ions are rapidly removed from the water-column.

This information is relevant to the environmental classification.

-*<u>In the sediment compartment</u>,* copper binds to the sediment organic carbon (particulate and dissolved) and to the anareobic sulphides, resulting in the formation of CuS. CuS has a very low stability constants/solubility limit (LogK=-41 (Di Toro *et al.,*1990) – see section *adsorption/desorption*) and therefore the 'insoluble' CuS keeps copper in the anaerobic sediment layers, limiting the potential for remobilization of Cu-ions into the water column.

To examine the potential for remobilization of copper from sediments, a series of 1-year simulations were performed, using the TICKET-UWM. These focused on re-suspension, diffusion, and burial to/from the sediment layer, their net effect on copper concentrations in the water column and changes in speciation in the sediment. Simulations were made with an oxic sediment layer as well as with an anoxic sediment layer (with varying concentrations of Acid Volatile Sulfides (AVS)) and varying re-suspension rates (up to 10 times the default EUSES model lake value).

In simulated sediments with AVS present in excess of copper, essentially all copper in sediment was present as copper sulfide because the affinity of copper for sulfides is much larger than the affinity for Organic Carbon. CuS has a very low solubility product constant (Kps) and therefore, full copper sulfide precipitation was generally demonstrated in all cases where AVS >1 µmol (reasonable worst case AVS concentration in European surface waters) and at environmentally relevant copper concentrations (< 0.1mg/L). As a result of this strong binding, the sediment log Kd greatly exceeded the water column log Kd and the net diffusive flux of copper was directed into the sediment. For anoxic sediments devoid of AVS and for oxic sediments, the net diffusive flux was small and directed out of the sediment. However, for all cases considered, the pseudo steady-state total and dissolved copper concentrations were at least 8 times lower than the concentration corresponding to conditions of 70% removal from the water column (see conditions detailed above).

Simpson *et al.,* (1998) and Sundelin and Erikson (2001) (see section *adsorption/desorption)* provide field evidence on the stability of the CuS binding :

- Simpson *et al.,* (1998) investigated the oxidation rates of model metal sulfide phases to provide mechanistic information for interpreting the observations on natural sediments. CuS phases were kinetically stable over periods of several hours.
- Sundelin and Erikson (2001) provide further evidence that, after long term oxygenation of sediment cores (3 to 7 months) Cu remains comparatively unavailable.

Last but not least, the assessment of 2 field experiments with intermittent copper dosing (LakeCourtille and the Saint Germain les Belles Reservoir lakes, yearly dosed with copper), assessed in Rader *et al.,* 2010, provides further support for the absence of re-mobilization. Since both waterbodies are shallow, polymictic lakes, wind-driven resuspension is expected to play a role in copper dynamics in the water column. Neverteless, even if long-term resuspension does in fact occur, for both waterbodies, > 70% removal in less then 28 days was observed. The information therefore validates the results from the model simulations and absence of remobilization from the water column (Rader *et al.,* 2010).

-*In soils,* decreases in copper solubility and in copper bio-availability are observed following copper spiking in the laboratory and from long-term field copper exposure experiments. Short term attenuation and long term ageing of copper, spiked in soluble forms to soils was demonstrated from laboratory and field experiments (Ma *et al.,* 2006a and 2006b) and reported in the section '*adsorption/desorption'*.

The soil environmental factors governing short term attenuation and ageing rates are soil pH, organic matter content, incubation time and temperature with soil pH being the key factor for ageing of Cu added to soils. From a range of laboratory and field experiments an ageing factor of 2 was derived as a reasonable worst case when considering field exposure data. This information is relevant to the soil PNEC derivation.

Transport and distribution

Relevant partitioning coefficients are available from literature.

-Aquatic compartment

Partition coefficient in freshwater suspended matter Kp_{susp}= 30,246 l/kg (log Kp (pm/w) = 4.48) (50th percentile)

Partition coefficient in freshwater sediment Kpsed = 24,409 l/kg (log Kp(sed/w) = 4.39) (50th percentile)

Partition coefficient in estuarine suspended matter Kp_{susp}= 56,234 l/kg (log Kp (pm/w) = 4.75) (50th percentile)

Partition coefficient in marine suspended matter Kp_{susp}= 131,826 l/kg (log Kp (pm/w) = 5.12) (50th percentile)

-Terrestrial compartment

Partitioning coefficient Kd value soil: 2120 L/kg (log Kp (pm/w) = 3.33) (50th percentile)

Bioaccumulation

Because copper is an essential nutrient, all living organisms have well developed mechanisms for regulating copper intake, copper elimination and internal copper binding. The information in the accumulation section demonstrates that copper is well regulated in all living organisms and that highest BCF/ BAF values are noted when copper concentrations in water, sediments and soils are low and for organisms/ life stages with high nutritional needs. The BCF/ BAF values therefore have no ecotoxicological meaning. It should be mentioned that the non-applicability of BCFs for metal and especially for essential metals was already recognized in the regulatory framework of aquatic hazard classification (OECD, 2001).

Importantly, the literature review demonstrates that copper is not biomagnified in aquatic or terrestrial ecosystems.

The section further includes critical data related to (1) the accumulation of copper on critical target tissues (e.g. gills in aquatic organisms); (2) the influence of environmental parameters (e.g. Organic Carbon, pH, Cationic Exchange Capacity) as well as food intake on the accumulation of copper. This information is relevant to the understanding of the accumulation as well as the mechanism of actions, described in the section *ecotoxicological information*

Information relevant to assessing copper toxicity from dietary exposure - of relevance to secondary poisoning assessments is included in the section '*ecotoxicological information*'.

More detailed summaries on respectively aquatic and terrestrial bioaccumulation are available from the aquatic and terrestrial bioaccumulation summary sections.

The summary record "ecotoxicological information" further provides an overall summary of the rational for the absence of bio-accumulation and no-concern for secondary poisoning (see also section 7.5.2 – secondary poisoning).

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

Data waiving

Information requirement: Hydrolysis

Reason: study scientifically unjustified

Justification: Hydrolysis not an applicable endpoint for the inorganic substance copper

Related copper relevant information is provided in "**additional information on environmental fate and pathways**"

4.1.1.2 Phototransformation in air

Data waiving

Information requirement: Phototransformation in air

Reason: study scientifically unjustified

Justification: phototransformation is not an applicable endpoint for the inorganic substance copper

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

4.1.2.1.1 Screening tests

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: study scientifically unjustified

Justification: Biodegradation as used for organic substances does not apply to inorganic substances such as copper.

This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex): “Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i. e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification. "

For more information: see summary “environmental fate and pathways" and "**additional information on environmental fate**".

4.1.2.1.2 Simulation tests (water and sediments)

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: study scientifically unjustified

Justification: Biodegradation as used for organic substances does not apply to inorganic substances such as copper.

This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex): “Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i. e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification.

For more information: see summary "environmental fate and pathways" and "**additional information on environmental fate**".

4.1.2.2 Biodegradation in soil

Data waiving

Information requirement: Soil simulation testing

Reason: study scientifically unjustified

Justification: Biodegradation as used for organic substances does not apply to inorganic substances such as copper.

This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex): “Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i. e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification.

For more information: see summary “environmental fate and pathways" and "**additional information on environmental fate**".

4.1.3 Summary and discussion of degradation

4.1.3.1 Stability, Abiotic degradation

Copper is not degraded in classic terms, therefore information on hydrolysis and photo-transformation are not relevant.

Copper needs to be transformed to become bio-available. Transformation/dissolution of copper and subsequent copper attenuation in water, soils and sediments and removal of copper from the water column are relevant fate properties. Records are described in ‘*additional information on environmental fate and behaviour*’.

4.1.3.2 Biodegradation

Biodegradation as used for organic substances does not apply to inorganic substances such as copper but attenuation of the toxicity is observed for copper.

Metals are not degraded in classic terms. This was recognized in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging of substances and mixtures (metal annex): “Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i. e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification. "

The information on “changes in copper speciation, removal from the water-column and the potential of copper remobilization from sediments” are considered as equivalent to “bio-degradation of organic substances”. Relevant records (e.g. Rader *et al.,* 2013) are available from “additional information on environmental fate and behaviour”. The information is summarized in the summary record “environmental fate and behaviour”.

4.2 Environmental distribution

Relevant partitioning coefficients are available from literature.

- For the aquatic compartment, the summaries from Heijerick and Van Sprang (2005 and 2008) have been agreed under the copper RAR (2008) and are used the risk characterization.

- For the terrestrial compartments, in the RA report, preference has been given to the Sauvé *et al.,* dataset as it covers the widest range of soil conditions relevant for the risk assessment and these have been used for the risk characterization under the copper RAR (2008).

Information on short term and long term attenuation of copper in soils as a function of soil chemistry was assessed by Ma *et al.,* 2006a & 2006b. The soil and environmental factors governing short term attenuation and ageing rates are soil pH, organic matter content, incubation time and temperature with soil pH being the key factor for ageing of Cu added to soils.

From the field experiments and a mechanistic understanding of the decrease in bioavailable copper as a function of time following exposures, an ageing factor of 2 was derived as a reasonable worst case when considering field exposure data. This information is relevant to the soil PNEC derivation.

4.2.1 Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 22: Overview of studies on adsorption/desorption

Method	Results	Remarks	Reference
Study type: adsorption (soil) batch equilibrium method Measurements of amount of copper concentrations extracted from the soil and from the pore water to determine the partitioning coefficient	Adsorption coefficient: Kd: 25 — 135 at 20 °C (forest soils A, H, I, K, M, N: having low pH, Om, clay, Fe oxides, Al oxides and CEC) Kd: 92 — 4318 at 20 °C (Soils from river banks and meadows, containing more OM, clay, Fe oxides and Al oxides (B, C, D, E, F, G, J, L, O, P, Q, R, S, T))	2 (reliable with restrictions) weight of evidence experimental result **Test material (field): environmental copper concentrations**	Janssen, R.P.T. *et al.,* (1997)
Study type: adsorption (sediment) Assessing the absence binding strength of Cu to sulphides as a measure of its solubility and critical to the assessment of the removal of Cu back from sediment into the water from the CuS stability constant - In accordance to Guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures 21 July 2009, Annex IV	Adsorption coefficient: Log Ksp: -40.94	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphide**	Di Toro DM, Mahony JH Hansen D J, Scott K J, Hicks M B, Mayr S M and (1990)
Study type: adsorption (suspended particular matter - brackish water)	Adsorption coefficient: Log Kd: 4.76 (Forth Estuary - from Owens *et al.,* 1997)	2 (reliable with restrictions) weight of evidence	Heijerick D. & P. Van Sprang (2008)

Method	Results	Remarks	Reference
review Measurements of dissolved and Suspended Particulate Matter (SPM) copper concentrations to determine the partitioning coefficient	Log Kd: 4.65 (Tay Estuary - from Owens *et al.*, 1997) Log Kd: 4.67 (Rhine - from Golimoski *et al.*, 1990 (in:Turner *et al.*, 1992)) Log Kd: 5.01 (Waal - from Golimoski *et al.*, 1990 (in:Owens *et al.*, 1992)) Log Kd: 5.53 (Maas - from Golimoski *et al.*, 1990 (in:Owens *et al.*, 1992)) Log Kd: 4.1 (Weser - from Turner *et al.*, 1992 (in: Owens *et al.*, 1997)) Log Kd: 4.61 (Seine - from Chiffoleau *et al.*, 1994 (in: Owens *et al.*, 1997)) Log Kd: 4.88 (Mersey - from Comber *et al.*, 1995 (in: Owens *et al.*, 1997)) Log Kd: 3.85 (Humber - from Comber *et al.*, 1995 (in: Owens *et al.*, 1997)) Log Kd: 5.22 (Baltic sea - from Pohl and Hennings, 1999) Other adsorption coefficients: Log Kd: 4.74 (Scheldt - from Nolting *et al.*, 1999; Paucot and Wollast, 1997; Monteny *et al.*, 1993; Valtenta *et al.*, 1986) Log Kd: 4.5 (Rhone - from Regnier *et al.*, 1990) Log Kd: 4.6 (Lena - from Martin *et al.*, 1993) Log Kd: 4.74 (North sea estuaries - from Balls, 1989 (in: Nolting *et al.*, 1999)) Log Kd: 6.16 (Conwy estuary - from Zhou *et al.*, 2003) Log Kd: 4.55 (San Francisco Bay - from Sanudo-Wilhelmy *et al.*, 1996) Log Kd: 4.8 (Six estuaries in Texas, USA - from Benoit *et al.*, 1994)	review **Test material (field): environmental copper concentrations**	
Study type: adsorption (suspended particular matter - salt water) review Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 5.62 (Atlantic Ocean - from Helmers, 1996) Log Kd: 5.11 (Australian Ocean - from Munksgaard and Parry, 2001) Log Kd: 4.6 (Rhone - from Regnier *et al.*, 1990) Log Kd: 5 (Lena - Martin *et al.*, 1993) Log Kd: 5.6 (San Francisco Bay, Golden Gate - from Sanudo-Wilhelmy *et al.*, 1996)	2 (reliable with restrictions) weight of evidence review **Test material (field): environmental copper concentrations**	Heijerick D. & P. Van Sprang (2008)

Method	Results	Remarks	Reference
	Log Kd: 4.78 (North Sea - from Tappin *et al.,* 1995 and McManus and Prandle, 1996)		
Study type: adsorption (suspended particular matter - fresh water) review This study discusses the different publications that report reliable KD-values and, where possible, provides information on the parameters that most likely affect copper binding to suspended and sediment particles.	Adsorption coefficient: Log Kd: 4.17 (Dintel - from Koelmans and Radovanovic, 1998) Log Kd: 4.4 (Lake Hollandsch Diep - from Koelmans and Radovanovic, 1998) Log Kd: 3.87 (Lake Volkerak - from Koelmans and Radovanovic, 1998) Log Kd: 3.85 (Lake Zoom - from Koelmans and Radovanovic, 1998) Log Kd: 4.4 (River Trent - from Tipping *et al.,* 1998) Log Kd: 3.92 — 5 (River Calder (n=19) - from Lofts and Tipping, 2000) Log Kd: 3.36 — 5.46 (River Nidd (n=16) - from Lofts and Tipping, 2000) Log Kd: 4.91 — 5.15 (River Swale (n=2) - from Lofts and Tipping, 2000) Log Kd: 3.79 — 5.1 (River Trent (n=29) - from Lofts and Tipping, 2000) Log Kd: 4.31 (River Rhône - from Elbaz-Poulichet *et al.,* 1996) Other adsorption coefficients: Log Kd: 4.5 (River Ebro - from Guieu *et al.,* 1991; in Elbaz-Poulichet *et al.,* 1996) Log Kd: 4.11 — 4.91 (River Rhine - from Golimowski *et al.,* 1990) Log Kd: 3.7 — 5.3 (River Waal - from Golimowski *et al.,* 1990) Log Kd: 4.7 — 5.79 (River Meuse - from Golimowski *et al.,* 1990) Log Kd: 4.55 (Po River (Italy) - from Pettine *et al.,* 1994) Log Kd: 4.38 (Czech Lakes (n=119) - from Vesely *et al.,* 2001) Log Kd: 4.54 (River Conwy - from Zhou *et al.,* 2003)	2 (reliable with restrictions) weight of evidence review **Test material (field): environmental copper concentrations**	Heijerick D. & P. Van Sprang (2005)
Study type: adsorption (sediment - fresh water) review This study discusses the different publications that report reliable	Adsorption coefficient: Log Kd: 4.67 (Mersey River (UK) - from Turner *et al.,* 2002 (between surface water and sediment compartment)	2 (reliable with restrictions) weight of evidence review **Test material**	Heijerick D. & P. Van Sprang (2005)

Method	Results	Remarks	Reference
KD-values and, where possible, provides information on the parameters that most likely affect copper binding to suspended and sediment particles.	Log Kd: 4.51 — 4.65 (River Rhine (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.56 (River Waal (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.75 (River Maas (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.74 (Haringvliet (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.7 (Ketelmeer (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.68 (Ijsselmeer (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.6 (Nieuwe Merwede (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.67 (Nieuwe Waterweg (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Log Kd: 4.67 (Oude Maas (NL) - from Van Der Kooij *et al.,* 1991 (between surface water and sediment compartment)) Other adsorption coefficients: Log Kd: 4.38 (Background concentrations (50Psed/50Pwater)- own data) Log Kd: 4.4 (Ambient concentrations (50Psed/50Pwater) - own data) Log Kd: 3.92 (Background concentrations (10Psed/90Pwater)- own data) Log Kd: 4.98 (Ambient concentrations (10Psed/90Pwater) - own data) Log Kd: 4.95 (Background concentrations (90Psed/10Pwater)- own data) Log Kd: 5.04 (Ambient concentrations (90Psed/10Pwater) - own data)	**(field): environmental copper concentrations**	
Study type: adsorption (soil) data compiled of 70 different	Adsorption coefficient: Median and mean Log Kd: 3.3 —	2 (reliable with restrictions)	Sauvé S., W. Hendershot, H.E.

Method	Results	Remarks	Reference
studies Soil-liquid partitioning coefficients (Kd) for many elements but especially for the metals cadmium, copper, lead, nickel, and zinc were compiled from over 70 studies of various origins collected from the literature.	3.68	weight of evidence critical review **Test material (field): environmental copper concentrations**	Allen (2000)
Study type: adsorption (sediment) field measurements Determination of the partition coefficient of copper through measurements of copper in the solid phase and in the pore water.	Adsorption coefficient: Log Kd: 2.68 (Mean Log Kd (method: aqua regia destruction)) Log Kd: 2.84 (Mean Log Kd (method: HNO3 destruction))	2 (reliable with restrictions) weight of evidence experimental result **Test material (field): environmental copper concentrations**	De Groot A.C., W.J.G.M. Peijnenburg, M.A.G.T. van den Hoop, R. Ritsema (1998)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 5.2 — 6.3	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Paucot H. & R. Wollast (1997)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.2 — 4.9	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Sanudo-Wilhelmy S.A., I. Rivera-Duarte and A.R. Flegal (1996)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.78 (Forth estuary) Log Kd: 4.64 (Tay estuary)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Owens R.E., P.W. Balls and N.B. Price (1997)
Study type: adsorption (suspended particular matter - salt water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.78	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Tappin A.D., G.E. Millward, P.J. Statham, J.D. Burton and A.. Morris (1995)
Study type: adsorption (suspended particular matter -	Adsorption coefficient: Log Kd: 4.5 — 5.9	2 (reliable with restrictions)	Eckard Helmers (1996)

Method	Results	Remarks	Reference
salt water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient		supporting study experimental result **Test material (field): environmental copper concentrations**	
Study type: adsorption (suspended particular matter - salt water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 5.11 — 5.92	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	McManus J.P. & D. Prandle (1996)
Study type: adsorption (suspended particular matter - salt water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 3.7 — 5.4 (coastal and estuarine surface waters from Australia)	2 (reliable with restrictions) supporting study estimated by calculation **Test material (field): environmental copper concentrations**	Munksgaard N.C. & D.L Parry (2001)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient.	Adsorption coefficient: Log Kd: 4.54 — 6.46	2 (reliable with restrictions) supporting study experimental result **Test material (field): suspended particular matter**	Zhou J.L., Y.P. Liu, P.. Abrahams (2003)
Study type: adsorption (suspended particular matter - fresh to saltwater) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.8 (salinity 5 g/L) Log Kd: 4.7 (salinity 10 g/L) Log Kd: 4.5 — 4.8 (salinity 15 g/L) Log Kd: 4.5 (salinity 20 g/L) Log Kd: 4.8 — 4.9 (salinity 25 g/L) Log Kd: 4.5 (salinity 30 g/L (marine))	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Nolting R.F., W. Helder, H.J.W. de Baar, L.J.A. Gerringa (1999)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 5.14 (salinity 0-2 ppt) Log Kd: 4.74 (salinity 10-15 ppt) Log Kd: 4.36 (salinity 25-35 ppt (marine))	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Monteny F., M. Elskens and W. Baeyens (1993)
Study type: adsorption (suspended particular matter - brackish water)	Adsorption coefficient: Log Kd: 5.49 (median value (depth 0-240 m) 1992)	2 (reliable with restrictions) supporting study	Pohl C. & U. Hennings (1999)

Method	Results	Remarks	Reference
Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Log Kd: 5.47 (median value (depth 0-240 m) 1993) Log Kd: 5.23 (median value (depth 0-240 m) 1994) Log Kd: 5.31 (median value (depth 0-240 m) 1995) Log Kd: 5.2 (median value (depth 0-240 m) 1996)	experimental result **Test material (field): environmental copper concentrations**	
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 3 — 5.1 (range in Log Kd for the 6 estuaries)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Benoit G., S.D. Oktay-Marshall, A. Cantu, E.M. Hood, C.H. Coleman (1994)
Study type: adsorption (suspended particular matter - brackish water) Field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: log Kd: 4.4 — 5.3 (Range log Kd Eastern and Western Scheldt) log Kd: 6.1 (Ocean water)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Valenta P., E.K. Duursma, A.G.A. Merks, H. Rutzel and H.W. Nurnberg (1986)
Study type: adsorption (sediment) calculated from published data	Adsorption coefficient: Log Kd: 4.66 (Calculated medium value for Dutch river sediments)	2 (reliable with restrictions) supporting study estimated by calculation **Test material (field): Kd measurements from other studies**	Van Der Kooij L.A., D. Van De Meent, C.J. Van Leeuwen, W.A. Bruggeman (1991)
Study type: adsorption (suspended particular matter) estimated using modelling The dissolved and particulate metal speciation in the surface water of the Humber system (UK) was estimated, using the Windermere Humic Aqueous Model (WHAM) (Tipping, 1994) for the dissolved phase and a simple adsorption model for the particulate phase.	Adsorption coefficient: Log Kd: 3.3 — 3.7 (underestimation (real Log Kd of River Trent is 4.4))	2 (reliable with restrictions) supporting study estimated by calculation **Test material (field): environmental copper concentrations**	Tipping E., S. Lofts and A.J. Lawlor (1998)
Study type: adsorption (suspended particular matter) field measurements A 4-year study (1987-1991) of the River Rhône and its estuary was undertaken by Elbaz-Poulichet *et al.,* (1996) in the framework of the EROS-2000 project of the EU, in order to	Adsorption coefficient: Log Kd: 4.31 (River Rhône) Log Kd: 4.5 (Ebro river (spain))	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Elbaz-Poulichet F., J-M. Garnier, D.M. Guan, J-M. Martin and A.J. Thomas (1996)

Method	Results	Remarks	Reference
reassess dissolved and particulate concentrations of different metals, including copper			
Study type: adsorption (suspended particular matter) field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.18 — 4.95 (Rhine 1978) Log Kd: 4.11 — 4.91 (Rhine 1984) Log Kd: 4.11 — 5.3 (Waal 1978) Log Kd: 3.7 — 4.84 (Waal 1984) Log Kd: 4.78 — 5.79 (Meuse 1978) Log Kd: 4.7 — 5 (Meuse 1984)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Golimowski J., A.G.A. Merks, P. Valenta (1990)
Study type: adsorption (sediment) modelling Development of a conceptual Kdmodel (SWAMP, Sediment Water Algorithm for Metal Partitioning) that expressed Kd values for suspended solids as a function of aqueous and solid phase characteristics	Adsorption coefficient: Kd: 7110 — 25200 Log Kd: 3.85 — 4.4	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Koelmans A.A. and H. Radovanovic (1998)
Study type: adsorption (suspended particular matter) field measurements estimated using modelling	Adsorption coefficient: Log Kd: 3.92 — 5 (Calder) Log Kd: 3.36 — 5.46 (Nidd) Log Kd: 4.91 — 5.15 (Swale) Log Kd: 3.79 — 5.1 (Trent)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Lofts S. & E. Tipping (2000)
Study type: adsorption (suspended particular matter) field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: log Kd: 4.6 (low salinity) Log Kd: 5 (marine)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Martin J.M., D.M. Guan, F. Elbaz-Poulichet, A.J. Thomas, V.V. Gordeev (1993)
Study type: adsorption (suspended particular matter) field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Kd (average): 40000 Log Kd (average): 4.6 Kd (median): 35200 Log Kd (median): 5.5	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Pettine M., M. Camusso, W. Martinotti, R. Marchetti, R. Passino, G (1994)
Study type: adsorption (suspended particular matter) field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd: 4.5	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental**	Regnier P., M. Hoenig, L. Chou, R. Wollast (1990)

Method	Results	Remarks	Reference
		copper concentrations	
Study type: adsorption (suspended particular matter) field measurements Trace metals in the dissolved phase, and in operationally defined available and total particulate associations were determined, along an axial transect of the Weser estuary.	Adsorption coefficient: Log Kd: 4.15 (Weser estuary)	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Turner A., G.E. Millward, B. Schuchardt, M. Schirmer and A. Prange (1992)
Study type: adsorption (suspended particular matter) field measurements Partition data for trace metals (Cd, Cr, Cu, Hg, Ni, Pb, Zn) from a number of independent studies, conducted in a highly contaminated, organic-rich estuary (Mersey, UK), were examined	Adsorption coefficient: Log Kd (sediment-water): 4.66	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Turner A., M. Martino and S.M. Le Roux (2002)
Study type: adsorption (suspended particular matter) field measurements Measurements of dissolved and SPM copper concentrations to determine the partitioning coefficient	Adsorption coefficient: Log Kd (median): 4.43	2 (reliable with restrictions) supporting study experimental result **Test material (field): environmental copper concentrations**	Vesely J., V. Majer, J. Kucera, V. Havranek (2001)
Study type: adsorption (soil) field measurements Measurement of labile (isotopically exchangeable) pools of metals (Evalues) in soil to assess the size of metal pools potentially available to soil organisms, from both a micronutrient deficiency and metal toxicity viewpoint.	Adsorption coefficient: : (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): environmental copper concentrations**	Ma, Y B *et al.,* (2006)
Study type: adsorption (soil) field measurements Isotopic dilution techniques are used to investigate the short- term (30d) natural attenuation of Cu added to 19 European soils at two effective concentrations shown to inhibit plant (tomato) growth by 10 and 90 %. The lability of Cu added to soils is assessed at different pHs and different incubations temperature.	Adsorption coefficient: : (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Ma,Y B *et al.,* (2006)

4.2.2 Additional information on environmental fate

The IUCLID section includes critical references related to the binding of copper to freshwater and marine DOC, to soils as well as to sediment sulphides. The IUCLID section further includes the study that assessed the removal of cupric ions from the water column, of relevance to classification and labelling.

4.3 Bioaccumulation

The review assessed the literature related to bioconcentration, bioaccumulation and biomagnification of copper

The section further includes critical data related to (1) the accumulation of copper on critical target tissues (e.g. gills in aquatic organisms); (2) the influence of environmental parameters (e.g. Organic Carbon, pH, Cationic Exchange Capacity) as well as food intake on the accumulation of copper. This information is relevant to the understanding of the accumulation as well as the mechanism of actions, described in the section '*ecotoxicological information'*

Information relevant to assessing copper toxicity from dietary exposure - of relevance to a secondary poisoning assessment is included in the section '*ecotoxicological information*'.

4.3.1 Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 23: Overview of studies on aquatic bioaccumulation

Method	Results	Remarks	Reference
Pimephales promelas aqueous (freshwater) Acclimated adult fathead minnows were exposed to waterborne copper. Experiments were run in the presence or absence of dissolved organic carbon of different origin. Fish were killed at the end of the 2-3-h exposures, and the Cu analysed.	copper accumulation in gill: (kinetic) (Measured copper concentrations in gills correlate to free copper ion concentration, not total copper concentration in test water)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper compound**	Playle, R.C. *et al.,* (1993a)
Pimephales promelas aqueous (freshwater). Adult fathead minnows (Pimephales promelas) were exposed to copper for 2 to 3 h in synthetic soft water solutions at pH 6.2 containing either naturally-occurring, freeze-dried dissolved organic carbon (DOC) or synthetic ligands such as EDTA. After exposures, gills were assayed for bound Cu or Cd.	copper concentration in gills: (copper levels in gills decreased with increasing DOC)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper compound**	Playle, R.C. *et al.,* (1993b)
Oncorhynchus mykiss aqueous (freshwater) flow-through	: (These results demonstrate that elevated dietary NaCl modulates Na+ and Cl⁻ homeostasis and	2 (reliable with restrictions) weight of evidence	Kamunde, C.N. *et al.,* (2005)

Method	Results	Remarks	Reference
The influence of dietary sodium on the accumulation and effects of waterborne copper to Juvenile rainbow trout (Oncorhynchus mykiss) was assessed.	reduces whole body and tissue Cu accumulation and toxicity of waterborne Cu.)	experimental result **Test material (Common name): soluble copper**	
Oncorhynchus mykiss aqueous (freshwater) Total uptake duration: 30 d Fish were exposed to 2 copper concentrations and a control. Effects of chronic copper exposure on a suite of indicators were examined: acute toxicity, acclimation, growth, sprint performance, whole-body electrolytes, tissue residues, and gill copper binding characteristics.	Cu accumulation at gill: (the data are used to measure the Cu-Gill binding stability constant. Diet and acclimation reduce copper toxicity)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Taylor, L.N. *et al.,* (2000)
Callinectes sapidus, Gobiosoma bosci, Palaemonetes pugio; Epibiota: Balanus eburneus, Conopeum sp., Bugula turita, Enteromorpha intestinalis aqueous (freshwater) field study Total uptake duration: 12 wk The uptake of metals leached from chromated copper arsenate (CCA)-treated wood, across the trophic chain, were measured in caged organisms exposed to treated and untreated wood panels for 3 months. Biomagnification was assessed.	BMF: < 1 (No accumulation in fish, some accumulation in amphipods)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Chromated copper arsenate**	Weis, P. and Weis, J.S. (1999)
35 invertebrate taxa aqueous (freshwater) field study Evaluation of trophic chain transfer of metals in insects (35 species) from a stream food web influenced by acid main drainage with copper levels up to 100 µg Cu/L.	BMF: < 1	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Quinn, M.R. *et al.,* (2003)
Lepomis macrochirus aqueous (freshwater) flow-through Total uptake duration: 88 wk This was a non-regulatory study designed to determine accumulation of copper in the bluegill sunfish, Lepomis macrochirus during a 22 month exposure period.	: (accumulation in tissues) (The liver, kidney and gills of fish exposed to 162 µg Cu/l contained significantly higher levels of copper compared to the controls. Gills from fish exposed to 77 and 40 µg Cu/l also contained significant levels of copper.)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Benoit, D.A. (1975)
many species aqueous (freshwater) The theoretical and experimental	BCF: (whole body ww) (steady state) (BCF are varying: regressions of BCF as a function	2 (reliable with restrictions) weight of evidence	McGeer, J.C. *et al.,* (2003)

Method	Results	Remarks	Reference
basis for the use of BCF/BAF in the hazard assessment of metals was assessed using experimental data from literature.	of copper concentrations in water are provided)	modelling **Test material (Common name): soluble copper**	
Cyprinus carpio aqueous (freshwater) semi-static Total uptake duration: 3 wk Accumulation experiments were carried out with a cyprinid, Cyprinus carpio, during 3 weeks at three different water hardness (50, 100, 300 mg/L as CaCO3). Bioaccumulation, gill depuration and adaptation was assessed.	: (See summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Peres, I. and Pihan, J.C. (1991)
Oncorhynchus mykiss aqueous (freshwater) flow-through Total uptake duration: 30 d Juvenile rainbow trout were exposed to Cu (as CuSO4) and DOC as humic acid (HA, as sodium salt) for one month in synthetic soft water to give treatments with varying combinations of free ionic and HA complexed Cu. The influence of dissolved organic carbon (DOC) on the bioavailability of waterborne Cu to rainbow trout (Oncorhynchus mykiss) was examined.	: (See summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper sulphate**	McGeer, J.C. *et al.,* (2002)
Daphnia magna aqueous (freshwater) semi-static Total uptake duration: 7 d The accumulation of copper in Daphnia magna with and without humic acid. Cu2+ was tested. At the end of the study period the test organisms were acid digested and analysed for copper by flameless acid digestion.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Winner, R.W. (1984)
Chironomus anthracinus and Stictochironomus histrio aqueous (freshwater) semi-static Both the field and laboratory experiments were carried to determine the accumulation of copper at different life stages	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Timmermans, K. R. & Walker, P.A. (1989)
Nassarius reticulates aqueous (freshwater) semi-static The Accumulation and Sub	: (see summary)	2 (reliable with restrictions) supporting study experimental result	Kaland, T. Andersen, T. & Hylland, K. (1993)

Method	Results	Remarks	Reference
cellular Distribution of copper in the Marine Gastropod Nassarius reticulatus was assessed		**Test material (Common name): soluble copper**	
Dreissena polymorpha aqueous (freshwater) Total uptake duration: 27 d Total depuration duration: 14 d The study investigated the accumulation of copper in the freshwater mussel Dreissena polymorpha. Exposure to Cu2+, delivered as copper sulphate, was carried out over a 27-day period followed by a 14-day post-exposure period, both with and without added algae as a food source. At the end of the study period soft tissues were analysed.	: (BCF not constant - with regulation at 9 µg Cu/L)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Mersch, J., Morhain, E. & Mouvet, C. (1993)
15 algal species aqueous (freshwater) static Total uptake duration: 20 — 30 d Fifteen species of phytoplankton were exposed to 34 µg Cu/l for 20-30 days (until a suitable cell density was reached). At the end of the exposure period, the algae were harvested, ashed in atomic oxygen and analysed spectrographically for copper.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Riley, J. & Roth, I. (1971)
marine organisms aqueous (saltwater) field study With a simple kinetic model requiring measurements of metal assimilation efficiency (AE), metal efflux rate and ingestion activity of the relevant animals, the transfer (and potential biomagnification) of metals along diverse marine food chains is predicted. In this paper, food chain transfer in different marine food chains (planktonic and benthic) is reviewed, and any potential biomagnification of metals is predicted using the simple kinetic equation.	BMF: < 1 (Decreases in metal concentrations across food chain related to high effluxes in copepods and low assimilation efficiencies in fish)	2 (reliable with restrictions) weight of evidence review article **Test material (Common name): soluble copper**	Wang, W.X. (2002)
Elminius modestus (Thoracica, crustacean), Echinogammarus pirloti (Amphipod, crustacean), Palaemon elegans (Decapod crustacean) aqueous (saltwater) The paper is a review on the ability of invertebrates to regulate	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Rainbow, P.S. & White, S. L. (1989)

Method	Results	Remarks	Reference
internal metal- including Cu- concentrations in a wide variety of aquatic organisms, including marine species.			
Carcinus maenas (crustacean) aqueous (saltwater) Total uptake duration: 21 d Copper Tissue concentrations of crabs, exposed to a range of copper concentrations for 21 days were assessed.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Rainbow, P.S. (1985)
Semibalanus balanoides (crustacean) aqueous (saltwater) Total uptake duration: 27 d Accumulation in Natural populations' barnacles from Southend-on-Sea and exposed to additional copper for 27 days was assessed .	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Rainbow, P.S., Scott, A.G., Wiggins, E.S. & Jackson, R.W. (1980)
Crangon crangon aqueous (saltwater) The aim of the study was to establish the relations between the bioaccumulation and toxicity of copper in the crustacean Crangon crangon. Test organisms were exposed to a range of copper concentrations over a 96-hour period. The number of mortalities was recorded and the LD50 determined.. Dead animals were removed every day and at the end of the study surviving organisms were sacrificed and prepared for analysis of body copper content.	: 0.02 — 20 mg Cu/L (No accumulation up to 200µg Cu/L. BCF related to body size)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Amiard, J.C., Amiard-Triquet, C. & Metayer, C. (1985)
Phyllodoce maculate aqueous (saltwater) semi-static Total uptake duration: 21 d The accumulation of copper in the polychaete Phyllodoce maculata was assessed. Test species, collected from the field, were exposed to 0, 10, 20, 30, 40, 50, 60, 70, 80, 100, 120, 150, 200, 500 or 1000 µg Cu/l (delivered as copper sulphate) over an exposure period of 14 days. The test solutions were renewed every 2-3 days.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	McLusky, D.S. & Phillips, C.N.K. (1975)
Crassostrea virginica aqueous (saltwater) Total uptake duration: 20 wk The accumulation of copper in	: (see summary)	2 (reliable with restrictions) supporting study experimental result	Shuster, C. N. & Pringle, B. H. (1969)

Method	Results	Remarks	Reference
oysters exposed to either 25 or 50 µg Cu/l(delivered as copper nitrate) for a total of 20 weeks in flow through conditions was assessed. At regular intervals throughout the study and test termination samples of oysters for taken for growth determination and copper accumulation (atomic absorption spectrometry).		**Test material (Common name): copper nitrate**	
American Eastern Oyster, Crassostrea virginica, Northern Quahaug, Mercenaria mercenaria and the soft shell clam Mya arenaria aqueous (saltwater) flow-through Total uptake duration: 20 wk The bioaccumulation of copper in three shellfish species; the American oyster Crassostrea virginica, the Northern Quahaug, Mercenaria mercenaria and the soft shell clam, Mya arenaria was assessed. The shellfish were exposed to various copper concentrations for an exposure period of 20 weeks. At the end of the exposure period the soft parts were removed and the contents acid digested and analysed for copper.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Shuster, C.N and Pringle, B.H. (1969)
Ostrea edulis aqueous (saltwater) field study The mechanism of copper immobilisation in 'green sick' (oysters naturally exposed to high levels of copper have a green pigmentation in their flesh) and normal oysters was assessed.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	George, S.G., Pirie, B.J.S., Cheyne, A.R., Coombs, T.L. & Grant, P.T. (1978)
Oncorhynchus mykiss sediment Total uptake duration: 67 d Juvenile rainbow trout (Oncorhynchus mykiss) were fed live diets of Lumbriculus *variegatus* cultured in natural metal-contaminated sediments, uncontaminated reference sediment, or an uncontaminated culture medium. Individual growth as well as the nutritional quality and caloric value of each trout's consumed diet were determined.	: (See summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Hansen J.A., J. Lipton, P.G. Welsh, D. Cacela, B. MacConnell (2004)

Method	Results	Remarks	Reference
Oncorhynchus mykiss feed (freshwater) flow-through Total uptake duration: 28 d Juvenile rainbow trout (Oncorhynchus mykiss) were exposed to copper in the diet for 28 days, with a background waterborne Cu concentration of 3 µg·L–1. Copper tissue levels and effects from copper exposure were assessed.	Concentration accumulated compared to controls: 2 — 4 Increase in tissue concentrations with increased dietary exposures (whole body ww.) (Time of plateau: 14)(steady state) (Increase in Dietary Cu pre-exposure decreased the uptake of waterborne Cu across the gills, providing the first evidence of homeostatic interaction between the two routes of uptake.)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Kamunde, C.N. *et al.,* (2001)
11 seals, 22 porpoises, 8 dolphins and 1 Minke whale feed (saltwater) field study Samples of liver from forty-two marine mammals of six species found on the coast of Wales and the Irish Sea in 1989-91 have been analysed for a range of trace metals (including copper). The animals sampled comprised eleven seals, twenty-two porpoises, eight dolphins and one Minke whale.	: (Field study : Elevated concentrations of Cu were found in a neonatal porpoise and a common dolphin foetus, relative to those found in their mothers)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Law, R.J. *et al.,* (1992)
Monodonta mutabilis (Philippi), Cerithium vulgatum (Bruguibre), and Murex trunculus (Linnaeus) as prey tissue, and hermit crabs Clibanarius erythropus (Latreille) feed (saltwater) The availability of copper, naturally incorporated in snails and administered to the crabs was assessed. The authors used digestive glands from three species of marine snail, Monodonta mutabilis (Philippi), Cerithium vulgatum (Bruguibre), and Murex trunculus (Linnaeus) as prey tissue, and hermit crabs Clibanarius erythropus (Latreille) as predators; the digestive glands and faecal pellets from all animals were analysed by atomic absorption spectroscopy and x-ray microanalysis.	Cu uptake by gut: (Copper detoxified by the snails are unavailable to the crabs and they pass straight through the gut and appear in the faecal pellets)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Nott, J.A. and Nicolaidou, A. (1994)
aqueous and sediment (freshwater) field study Type of sediment: natural sediment Metals were measured in sediments, biofilm, benthic macroinvertebrates, and fish from	BMF: < 1 (steady state) (smaller invertebrates had higher Cu concentrations then larger invertebrates)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Farag, A.M. *et al.,* (1998)

Method	Results	Remarks	Reference
the Coeur d'Alene (CDA) River to characterize the pathway of metals transfer between these components.			
several species water or water and food (freshwater) laboratory and field data Experimental data from literature are used to assess the variability and relevance BCF, BAF and BSAF values. The BCF is the tissue concentration at steady-state divided by the exposure concentration in water in an exposure system that explicitly excludes significant dietary exposure. The BAF is an equivalent measure for an exposure that considers both waterborne and dietary exposure pathways. Hence, BCFs are typically derived in the laboratory while most BAFs are derived from field data. The biota-sediment accumulation factors (BSAF) are derived using sediment rather than water concentrations to characterize exposure.	BCF and BAF: 20 — ca. 300000 dimensionless (whole body ww.) (steady state) (BAFs vary with Cu concentrations in the water) BSAF: ca. 0.02 — ca. 30 dimensionless (whole body ww.) (steady state) (BCF varies with copper concentration in sediments)	2 (reliable with restrictions) weight of evidence experimental and estimated result **Test material (Common name): Environmental copper species**	Adams, W.J. *et al.,* (2003)
many species fish, birds, mammals water and food (saltwater) field study The available experimental data wherein age or developmental stage of marine vertebrate organisms were major variables in assessing trace metal levels; documented trends; and discussed the significance of these trends in terms of biotic and physiochemical modifiers, monitoring programs and physiological senescence	tissue accumulation: (field copper concentrations in fish, seabirds and seals as function of body length)	2 (reliable with restrictions) weight of evidence Review **Test material (Common name): soluble copper**	Eisler, R. (1984)
Crustacea water and/or food The paper is a review paper relevant to the metal accumulation and homeostasis in invertebrates	Internal detoxification: (Summary on invertebrate internal detoxification mechanisms)	2 (reliable with restrictions) weight of evidence Review **Test material (Common name): soluble copper compounds**	Rainbow, P.S. (2002)
carnivores, omnivores, detrivores, planktivores, herbivores, autotrophs and zooplankton	BMF: < 1 (whole body dw) (steady state) (copper accumulated due to the essential nature of this trace metal for	2 (reliable with restrictions) weight of evidence experimental result	Barwick, M. and Maher, W. (2003)

Method	Results	Remarks	Reference
(freshwater) field study Total depuration duration: 48 h The bio transfer of metals was measured in a contaminated seagrass ecosystem, to determine if biomagnification of these trace metals is occurring and if they reach concentrations that pose a threat to the resident organisms or human consumers.	many species of molluscs and crustaceans)	**Test material (Common name): soluble copper**	
16 species of waterfowl (freshwater) field study The concentrations of metals n the liver and eggs of 16 species of waterfowl found dead in the Park after a spill from a mine were determined.	: (See summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Hernández, L.M. *et al.,* (1999)
Hyalella azteca (freshwater) semi-static Total uptake duration: 10 wk This was a non-regulatory study designed to determine the bioconcentration of copper in the amphipod Hyalella azteca	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Borgmann, U., Norwood, W. P. & Clarke, C. (1993)
Asellus meridianus (freshwater) The uptake of copper from three populations of the isopod Asellus meridianus, collected from two locations in the UK was determined.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Brown, B.E. (1977)
64 tropical, subtropical, subantarctic and antarctic seabird taxa (saltwater) field study Concentrations of the copper were determined in a range of tissues of seabird collected in the field.	accumulation in seabird tissues: (liver copper levels are higher in young then in adults)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Lock, J.W. *et al.,* (1992)
Cherax destructor The bioaccumulation of copper through a simple food chain was assessed. The copper was first absorbed by the floating aquatic macrophyte *Lemna* minor to an average concentration of 74 µg/g, before being fed to C. destructor.	: (See summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Allinson G., L.J.B. Laurenson, G. Pistone, F. Stagnitti and P.L. Jones (2000)
Dreissena polymorpha The accumulation of copper in the zebra mussel Dreissena polymorpha was investigated over an exposure period of 9-	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material**	Kraak, M.H.S., Lavy, D, Peeters, W.J.M & Davids, C. (1992)

Method	Results	Remarks	Reference
11weeks. The mussels were exposed to Cu^{2+} (delivered as copper chloride) in two experiments at 4 dose concentrations and one control		**(Common name): copper chloride**	
Platichthys flesus Total uptake duration: 37 — 42 d Copper accumulation in the gills, liver, kidney and plasma of seawater-adapted and freshwater-adapted Platichthys flesus exposed to elevated ambient concentrations of copper was assessed .	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper nitrate**	Stagg, R.M. and Shuttleworth, T.J. (1982)
Ictalurus nebulosus The accumulation of copper in brown bullheads (Ictalurus nebulosus) exposed to mean concentrations of 3.4, 6.5, 10, 16, 27 and 53 µg Cu/l for 20 months were investigated. At the end of the exposure period tissue and blood samples were collected and analysed for copper by atomic absorption spectrometry.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Brungs, W.A., Leonard, E.N. & McKim, J.M. (1973)
Corbicula fluminea The accumulation of copper in the clam (Corbicula fluminea) in artificial stream systems during a 28-day exposure period was determined	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Graney, R.L., Cherry, D.S. & Cairns, J. (1983)
Neanthes arenaceodentata (Polychaete) The accumulation strategy of the laboratory bred adult male Neanthes arenaceodentata to Cu2+under flow through conditions (with and without sand) for an exposure period of 28 days was assessed. Test organisms were exposed to a range of Cu concentrations of and were fed Enteromorpha sp. The study was conducted at 17°C with salinity of 31 g/l.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Pesch, C. & Morgan, D. (1978)
Eudistylia vancouveri The accumulation strategy of the wild caught polychaete, Eudistylia vancouveri to Cu^{2+} (delivered as copper chloride) under flow through conditions for an exposure period 5 days , 5 weeks and 29 days were assessed. Test organisms were exposed to concentrations of 1, 3	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Young, J.S, Buschbom, R.L., Gurtisen, J.M. & Joyce, S.P. (1979)

Method	Results	Remarks	Reference
and 6 µg Cu/l.			
aquatic organisms This is a review of the use of bioconcentration factors for hazard classification of metals and metal compounds	: (see summary)	2 (reliable with restrictions) supporting study review **Test material (Common name): copper compound**	Brix, K.V. and DeForest, D.K. (2000)

4.3.2 Terrestrial bioaccumulation

The results of terrestrial bioaccumulation studies are summarised in the following table:

Table 24: Overview of studies on terrestrial bioaccumulation

Method	Results	Remarks	Reference
Lactuca sativa cv. Milanesa, Lycopersicum esculentum cv. Red Cloud, Allium cepa cv. Sonic A one-year greenhouse experiment was conducted to study the transfer of copper from contaminated agricultural soils to edible and non-edible structures of lettuce, tomato, and onion plants.	: (Copper concentrations in the plants increased with soil Cu content but to a much lesser extend)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper salt not reported**	Ginocchio, R. *et al.,* (2002)
Lactuca sativa Plant growth assays were performed in the greenhouse using field-collected, non-spiked soils. The soils were characterized using several chemical extraction reagents, as well as electrochemical speciation of the soil solution free metal species. The effectiveness of these evaluations to predict plant concentrations were assessed	: (BCF values decreased with increasing soil copper content)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper salt not reported**	Tambasco, G. *et al.,* (2000)
different species of worms, slugs, isopods, diplopods, chilopods and spiders The uptake of copper, used in copper fungicides, in different species of worms, slugs, isopods, diplopods, chilopods and spiders in regard to their different trophic levels.	: (No relation between trophic level and copper concentrations)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper containing fungicides**	Wittassek, R. (1986)
Eisenia andrei OECD guideline 207: Earthworm acute toxicity tests	: (BCF decreased with increasing soil Cu content)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name):**	Janssen R.P.T. *et al.,* (1997)

Method	Results	Remarks	Reference
		Soil copper	
different trophic levels of a grassland ecosystem food chain transfer of Cu in contaminated grassland around a refinery.	: (steady state) (BMF<1 - animal/diet ratio decreased with increasing soil Cu content)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soil copper**	Hunter, B.A. and M.S. Johnson (1982)
pasture herbage Assessment of metal contamination of soils, attributable to mineralisation and mining activity, and the composition of washed pasture herbage.	: (Relative accumulation (concentration of Cu in herbage/concentration of Cu in soil) decreased rapidly at higher soil concentration)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soil copper**	Abrahams, P.W. and Thornton, I (1994)
Eisenia Andrei Exposure of the earthworm Eisenia andrei to an increasing range of soil copper concentrations in the laboratory and assessing a threshold range for the neutral-red assay (a biomarker) at soil copper concentrations between 40 and 80 mg Cu/kg.	BCF: 0.3 — 1 dimensionless (whole body dw) (BCF thus decreased with increasing copper concentrations in soils)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Svendsen, C. and Weeks, J.M. (1997)
Arthropoda and Lumbricidae In this literature study, accumulation data of metals in terrestrial invertebrates were collected and compared (Arthropoda and Lumbricidae). Based on total soil concentrations and body concentrations, regression equations were calculated for each metal (Cd, Cu, Pb and Zn) and each taxonomic group.	: (BAF decreased with increasing soil concentration)	2 (reliable with restrictions) weight of evidence literature study **Test material (Common name): soluble copper**	Heikens, A. *et al.,* (2001)
Lumbricus sp. A literature search was performed for studies that reported chemical concentrations in co-located earthworm and soil samples. To ensure relevancy to field situations, only field studies in which resident earthworms were collected were considered.	: (Tissue levels between 2 & 60 mg Cu /kg at field data Cu concentrations between 3 and >1000ppm)	2 (reliable with restrictions) weight of evidence modelling **Test material (Common name): soil copper species**	Sample, B. E. *et al.,* (1999)
trophic level study The pattern of biomagnification of Cu in the terrestrial invertebrates' food web was explored. Based on 37 biomagnification factors representing herbivores, carnivores and detrivores, the slope of the linear regression was less than one suggesting	: (BMF<1)	2 (reliable with restrictions) weight of evidence modelling/calculatio n **Test material (Common name): soil copper**	Laskowski, R. (1991)

Method	Results	Remarks	Reference
regulation of Cu concentration.			
Lycopersicon esculentum, Allium cepa A field experiment to study the transfer of copper from contaminated soils to edible parts of tomato and onion plants	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soil copper**	Badilla-Ohlbaum, R. *et al.,* (2001)
Pieris canidia Caterpillars of the common white butterfly (Pieris canidia) were fed with the waste-grown vegetables and the level of metals and body weight of the organisms was assessed.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soil copper**	Wong, M H and Cheung Y H (1986)
Helix aspersa (snail) The transfer of Cd, Cu, Ni, Pb and Zn was evaluated in a soil-plant (lettuce, Lactuca sativa) - invertebrate (snail, Helix aspersa) food chain during a microcosm experiment. Two agricultural soils, polluted and unpolluted, were studied.	: (see summary)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soil copper**	Scheifler R., A. de Vaufleury, M. Coeurdassier, N. Crini and PM Badot (2006)
different crops A review on metal deficiencies and toxicities, including uptake/elimination	: (see summary)	2 (reliable with restrictions) supporting study review **Test material (Common name): soil copper**	Chaney, R. and Giordano, P. (1977)

4.3.3 Summary and discussion of bioaccumulation

4.3.3.1 Aquatic bioaccumulation

4.3.3.1.1 <u>Bioconcentration factors (BCF) and bioaccumulation factors (BAF)</u>

There is a considerable amount of copper accumulation data available, that could potentially be used to calculate bioconcentration factors (BCF) and bioaccumulation factors (BAF) and assesses the corresponding potential risks in aquatic food chains. However due to the homeostatic regulation of copper (and other metals), the BCF/BAF are not independent of exposure concentration (Review papers of Adams *et al.,* 2003; Mc Geer *et al.,* 2003; supported by many papers from many authors (see IUCLID supportive record-summaries). Increase/decreased copper intake/eliminations, lead to BCFs, BAFs that are inversely related to exposure concentration (i.e. decreasing BCF/BAFs with increasing exposure concentration (water and diet). Particular to copper, this inverse relationship was clearly demonstrated for BCFs, BAFs and biota-sediment accumulation factors (BSAFs). The observed inverse relationship has been explained by homeostatic regulations of internal tissue concentrations: at low metal concentrations organisms are actively accumulating metals in order to meet their metabolic requirements while at high ambient metal concentration, organisms are able to excrete excess metals or limit uptake.

A more mechanistic understanding of copper regulations of accumulations as well as internal copper binding mechanisms and sequestrations are provided by e.g. Borgmann, 1993 and Rainbow (1980, 1985, and 1989).

Additionally, different BCFs for different species, life stages and seasons have been observed, depending on the organism's metabolic need (in e.g. Cu-enzymes). Resulting different copper levels are found in tissues from different strains, species, life stages and species. Moreover, aquatic invertebrates such as gastropods, crustacea and bivalves, relying on phaetocyanin as respiratory pigment have typically higher copper levels (and thus higher BCFs) than invertebrates relying on haemoglobin as respiratory pigment (e.g. Timmermans, 1989; Amiard *et al.,* 1985).

Field data further show that copper concentrations in tissues of marine mammals and coastal seabirds, regardless of species, except brain, tend to decrease with increasing age (Eisler 1984, Lock *et al.,* 1992). Neonatal marine mammals have higher copper levels compared to the mothers (Law *et al.,* 1992).

As a result, use of a simple ratio C_{biota}/C_{water} or $C_{biota}/C_{sediments}$ as an overall approach for estimating copper bioconcentration factors or copper body burdens is not appropriate. Useful to mention that the non-applicability of BCFs for metal and especially for essential metals was already recognized in the regulatory framework of aquatic hazard classification (OECD, 2001).

The section further includes critical data related to the accumulation of copper to the critical target tissue for copper (e.g. gills in aquatic organisms) and on the influence of dissolved organic matter, calcium and sodium on the accumulation of copper.

- Benoit, 1975, Perez, 1991 and Kaland 1993, described the importance of copper target accumulation to the gills

- Playle, 1993a demonstrated that copper concentrations in the target organ (gills) correlates to the free copper concentration, not to the total copper concentration in the test water. The study provides a mechanistic understanding of the biotic ligand model by determining the Metal- Gill stability constant and thereby predicting metal accumulation on gills and therefore toxicity to fish.

- McGeer *et al.,* 2002, demonstrated that the addition of dissolved organic matter (administered as humic acids) decreased Cu accumulation in gills and liver.

- Playle 2003b provides a mechanistic understanding of the protective effect of dissolved organic matter for copper toxicity to fish because: copper levels in gills decreased with increasing DOC. Lake of origin or molecular size fraction of DOC did not influence Cu binding to gills, while DO concentration did.

The section further includes some critical data of relevance to secondary poisoning

- Kamunde *et al.,* 2005 demonstrated interaction between Cu uptake from water and diet: from detailed copper uptake experiments, they demonstrated that elevated dietary NaCl modulates Na^+ and Cl^- homeostasis and reduces accumulation and toxicity of waterborne Cu.

- Taylor (2000) provided evidence on the interaction between water and food for the homeostasis of copper: The data suggest that the availability of food prevents growth inhibition and initial ion (Na) losses that usually result from waterborne Cu exposure. The data further demonstrate copper acclimation: a 2 fold increase in LC50 after pre-exposure of the fish to copper.

- Kamunde, 2001 observed that dietary copper pre-exposure decreased the uptake of Cu across the gills providing further evidence of homeostatic interaction between the two routes of uptake. Rainbow trout regulated dietary Cu at the level of the gut by increasing clearance to other tissues, at the liver by increasing biliary Cu excretion, and at the gill by reducing waterborne Cu uptake in response to dietary exposure. The modest morphological changes in the intestinal tract suggested high cell and organelle turnover and local regulation of Cu. In spite of possible increased energy demand for regulation and tissue repair, there was no significant growth inhibitory effect following dietary exposure.

- Hansen *et al.,* (2004), performed a metal exposure study on growth performance in rainbow trout fed a live diet pre-exposed to metal contaminated sediments. The study indicates the absence of copper toxicity at high dietary copper levels.

- Allinson (2002) investigates the bioaccumulation of copper through a simple food chain (*Lemna minor – C. destructor*) and observed regulation of copper by the crayfish, *C. destructor*, with the gills being the main site for absorption and depuration of copper to and from the water column. *C. destructor* does not appear to be sensitive to dietary copper.

- Nott, 1994 showed that copper, detoxified by the snails are unavailable to the crabs and they pass straight through the gut and appear in the faecal pellets.

Additional information of relevance to the absence of secondary poisoning is available from a well designed study from De Schamphelaere *et al.,* 2004, clearly relating copper toxicity to waterborne and not dietary exposure route (see the section '*ecotoxicological information*')

Importantly, the copper mesocosm study from Roussel (2007) reported in the section 'additional ecotoxicological information' demonstrated a low sensitivity of the predating fish and did not show a concern from secondary poisoning. Also the freshwater pond mesocosm (Schaefers *et al.,* 2002) and the marine pond mesocosm (Foekema *et al.,* 2010) (both reported in the section 'additional ecotoxicological information') did not show a concern from secondary poisoning.

Last but not least secondary poisoning of birds and mammals via fish or mussels was investigated for metals, including copper, by RIVM (Smit *et al.,* 2000) (also in section additional ecotoxicological information) who concluded that for copper it was not necessary to integrate secondary poisoning aspects into the copper aquatic quality criteria

4.3.3.1.2 Biomagnification factors (BMF)

The absence of copper biomagnification, with consistent BMFs<1, was shown from several papers:

- Barwick and Maher (2003), compared trace metal levels in a contaminated seagrass ecosystem in Lake Macquire, the largest estuary in New South Wales (Australia). The structure of the estuarine food web was studied in details and all organisms (algae, invertebrates, fish) were categorised as autotrophs, herbivores, planktivores, detrivores, omnivores and carnivores. The results of the analysis showed the absence of copper biomagnification in this estuarine systems. Copper concentrations ranged between 0.27 µg Cu/g dw (Omnivore: *Monacanthus* and 88 µg Cu/g dw (Herbivore: *Bembicum auratum* (gastropod with haemocyanin)). The higher levels (e.*g. B. auratum*) were associated with species with active accumulation of copper into the respiratory pigment haemocyanin.

- Farag *et al.,* 1998, studied copper concentration in benthic invertebrates that represent various functional groups and sizes from de Coeur d'Alene river, Idaho, influenced by mining activities. The copper concentrations noted across the trophic chain, demonstrated the absence of biomagnification from the sediment to herbivores, omnivores, detrivores and carnivores

- Weis & Weis (1999) demonstrated the absence of trophic transfer of metals in consumers associated with chromated copper arsenate treated wood panels.

- Wang (2002) noted the bio diminution of metals in the classical marine planktonic food chain (phytoplankton to copepods to fish) and explained the phenomenon as the result of the effective efflux of metals by copepods and the low assimilation of metals by marine fish.

- Quinn *et al.,* 2003, evaluated trophic chain transfer of metals in insects (35 species) from a stream food web influenced by acid main drainage with copper levels up to 100 µg Cu/L. They demonstrated that metal concentrations were higher in water and insects closer to the mining sites and taxa richness increased with distance away from the site. The relation between the trophic positions, determined from ^{15}N radio isotope determination, indicated that trophic chain had no effect on copper levels in the insects.

<u>The following information is taken into account for any hazard / risk / bioaccumulation assessment:</u>

There is a considerable amount of copper accumulation data available. The data have been reviewed by two authors in view of assessing the relation between the Cu BCF/BAF values and the copper concentrations in the water and sediment. Additionally some researchers have assessed the influence of water chemistry (dissolved organic matter), and the physiology of the organisms (species, age, seasons...) on the observed BCF/BAF values.

The information demonstrates that copper is well regulated in all living organisms and that BCF and BAF values have no meaning for a hazard assessment.

The data also demonstrate that waterborne exposure is most the critical exposure route and that copper is not biomagnified in aquatic ecosystems.

4.3.3.2 Terrestrial bioaccumulation

4.3.3.2.1 <u>Terrestrial BCF and BAF</u>

As for the aquatic environment, homeostatic regulation of copper (and other metals) is also relevant to soil organisms.

Inverse relationship between copper soil BCF(concentrations in plants/ concentrations in soils) and copper concentrations in the soils were observed by

- Abrahams and Thornton, 1994 for pasture herbage

- Ginocchio *et al.,* (2002) for lettuce, tomato and onions and by Tambasco *et al.,* (2000) for lettuce (*Lactuca sativa*)

Inverse relationship between copper soil BAF (concentrations in invertebrates/ concentrations in soils) and copper concentrations in the soils were observed by

- Janssen *et al.,* 1997 for *Eisenia Andrei*

- Heikens *et al.,* (2001) for different invertebrate species, collected in the field data

- Svendsen and Weeks (1997) for *Lumbricus sp.*

- Sample *et al.,* (1999), who developed a database of Cu concentrations in soil and earthworm tissue.

- Wong and Cheung, 1986 demonstrated that Caterpillars of the white butterfly (*Pieris conidia*) ingesting large amounts of plant leaf material, do not concentrate metals. Lower Cu contents are found in the organism than in the plant material (BCF of 0.1 to 0.3).

The section further includes some supporting data of relevance to secondary poisoning

- Chaney *et al.,* 1983 introduced the term 'Soil-Plant Barrier' for describing the mechanisms behind reduced plant uptake. A 'Soil-Plant Barrier' protects the food chain from toxicity of a microelement when one or more of abiotic or biotic processes limit maximum levels of that element in edible plant tissues to levels safe for animals: 1) insolubility of the element in soil prevents uptake; 2) immobility of an element in fibrous roots prevents translocation to edible plant tissues; or 3) phytotoxicity of the element occurs at concentrations of the element in edible plant tissues below that injurious to animals.

- Smit *et al.,* (2000) assessed the secondary poisoning for copper and calculated an average BAF of 0.09 for earthworms based on an extensive Dutch database (170 data points) – they concluded that for copper it was not necessary to integrate secondary poisoning aspects into the copper aquatic quality criteria.

4.3.3.2.2 Biomagnification factor (BMF)

Lakowski (1991) explored the pattern of biomagnification of Cu in the terrestrial invertebrates' food web. Based on 37 biomagnification factors representing herbivores, carnivores and detrivores, the slope of the linear regression was less than one suggesting regulation of Cu concentration.

Hunter and Johnson (1982) examined the food chain transfer of Cu and Cd in contaminated grassland around a refinery. Metal movement between producers, herbivores and carnivore trophic levels was examined with an emphasis on the small mammal components of the food web. Animal: diet ratios decreased with increasing soil concentrations and were all smaller than 0.2. This illustrates the degree of homeostatic regulation exercised by mammalian systems over body tissue retention of ingested Cu.

On the basis of a literature review, Heikens *et al.,* (2001) compared Cu accumulation between different invertebrate species. Metal body concentrations were highest in Isopoda and lowest in Coleoptera. Differences in metal accumulation between taxonomic groups were ascribed to differences in metal kinetics, regulation mechanism and the exposure route. Terrestrial

Isopoda are detrivores who live on litter and feed on organic matter. On the other hand Coleoptera are either herbivores or carnivores and have less intensive contact with litter.

Wittassek (1987) came to a similar conclusion when studying the uptake of Cu in vineyard soil organisms adapted to 60 years of continuous use of Cu sulphate fungicides. Slugs, Isopods and Diplopods (detrivores) showed the highest accumulation of Cu. Chilopoda and spiders, as predators, had high Cu concentrations only when their prey concentrations were high (they did not bioaccumulate).

<u>The following information is taken into account for any hazard / risk / bioaccumulation assessment:</u>

There is a considerable amount of copper accumulation data available. The data demonstrate an inverse relation between the copper bioaccumulation from soil and the copper concentrations in the soil. The information demonstrates that copper is well regulated in all living organisms and that the BCF and BAF values have no meaning for a hazard assessment. The data also demonstrate that copper is not biomagnified in the terrestrial ecosystems and that there is no issue for secondary poisoning of copper.

4.4 Secondary poisoning

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5.3 ‘Calculation of PNECoral (secondary poisoning)’.

Justification for no PNEC oral derivation: as agreed by the Competent Authorities for Biocides and Existing Substance Regulations.

Justification for PNEC oral derivation: as agreed by the Competent Authorities for Biocides and Existing Substance Regulations.

5 HUMAN HEALTH HAZARD ASSESSMENT

This chapter of the Chemical Safety Report discusses and summarises all the pivotal studies on the human health hazard assessment on copper and copper compounds. There are many studies in the public domain dealing with the repeat and chronic toxicity of copper compounds to several animal species. However, these studies did not meet the higher quality criteria (1 or 2) under REACH criterion selection and will therefore not be used in the risk assessment and will not be described in this document. However, the Voluntary Risk Assessment Report on Copper, Copper II sulphate pentahydrate, copper (I) oxide, copper (II) oxide and Dicopper chloride trihydroxide (VRAR, 2008) provides a full review of these studies and the discussion on the unsuitability/unacceptability of these studies.

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1 Introduction

The toxicokinetics of essential elements such as copper are regulated to a large degree by homeostatic mechanisms. Homeostasis can be described as the maintenance of a constant internal environment in response to changes in internal and external environments. Homeostatic maintenance requires the tightly coordinated control of copper uptake, distribution and efflux in cells and the organism as a whole. Copper plays a major role in the regulation mechanisms that control its cellular homeostasis. As a result of the presence of a homeostatic mechanism for copper, rat and human metabolism of copper are very similar and are therefore discussed together in the following sections.

The ability of the body to control the uptake and excretion of copper makes this an important factor in considering the exposure and effects and this is discussed in more detail in this Section.

5.1.2 Essentiality

Copper is an essential metal present in human body tissues and fluids at concentrations of parts per million or parts per billion. In common with other trace metals, copper has a number of physiological roles that may be classified as regulatory, structural and protective. In the regulatory role they are an essential part of metalloenzymes, acting either as electron donors or acceptors at the active site, or by shaping the enzyme to the configuration necessary for its activity. The structural functions of trace metals may be in, for example, membrane integrity or bone structure, and the protective function may involve antioxidant defence or the immune system (Ralph & Mc Ardle, 2001).

Copper is involved in the reactions and functions of many enzymes, including angiogenesis, neurohormone release, oxygen transport and regulation of genetic expression. Copper is an allosteric component of several enzymes that have oxidation and reduction activity, functioning as an electron transfer intermediate in redox reactions.

5.1.3 Homeostasis

All mammals have metabolic mechanisms that maintain homeostasis (a balance between metabolic requirements and prevention against toxic accumulation). Because of this regulation of body copper, indices of copper status remain stable except under extreme exposure conditions. This stability was demonstrated in a study in which human volunteers received a diet containing total copper in the range 0.8 to 7.5 mg/d. Under these conditions, there were no significant changes in commonly used indices of copper status, including plasma copper, ceruloplasmin, erythrocyte superoxide dismutase and urinary copper (Turnlund *et al.,* 1990; Scott & Turnlund, 1994).

Toxicity/deficiency is likely to occur only when homeostatic control is overwhelmed as a result of excessive high/low exposure and/or if basic cellular defence or repair mechanisms are impaired. The relationship between copper intake and the potential for toxicity or deficiency to occur is graphically represented below (adapted from Ralph & McArdle, 2001).

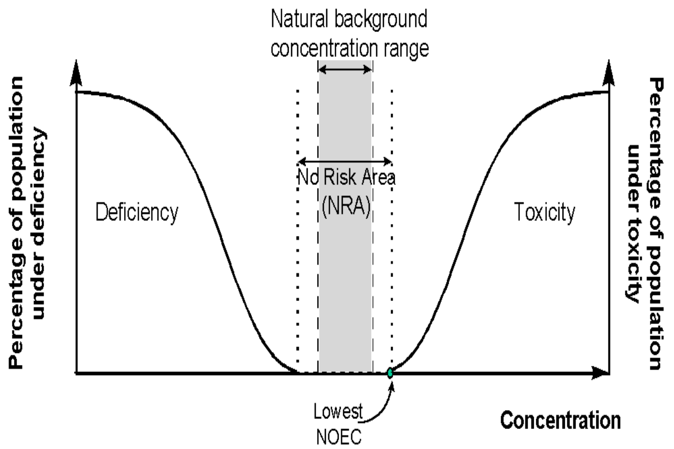

Figure 1: The relationship between copper intake and the potential for toxicity or deficiency

It is important to consider this graph when evaluating the metabolism and toxicity of copper in animal and human epidemiology studies, where the effects observed may be due to copper deficiency in the diet, rather than direct copper toxicity. This is particularly important when considering sensitive endpoints.

5.1.4 Adsorption

5.1.4.1 Oral

A large quantity of oral absorption data are available for animals, specifically rats, and humans. Pooled true absorption data from available rat studies are presented in **Table 25**. These data enable an estimation of true absorption at the relatively high copper intakes used in toxicity studies.

Table 25: Summary of animal studies reporting absorption data for dietary copper

Reference	Animal model	Identity of copper	Dietary Cu			Duration of treatment/ measurement	Analytical method	Absorption of Cu (% of intake)		Other information
			mg/kg feed	µg/d	mg/kg bw/d			Apparent	True	
Van den Berg *et al.*, (1994)	Wistar rat (male)	$CuSO_4$ + ^{64}Cu acetate (i.p. or oral)	5.2 1.1	(a) 74 (0-14 d) (b) 88 (21-35 d) (c) 80 (42-56 d) 15 17 16	0.30 0.35 0.32 0.06 0.07 0.06	Up to 56 d (treatment) 4 d (whole-body ^{64}Cu) 14 d (faeces collection)	Whole-body counting of ^{64}Cu AAS analysis of feed/faecal Cu	32 ± 2 31± 2 22 ± 3 46 ± 4 48 ± 3 53 ± 3	55 ± 5 56 ± 13 52 ± 10 (a) 72 ± 6 (b) 66 ± 3 (c) 58 ± 7	Cu $T_{1/2}$: 5.6 ± 0.4 (i.p.) 18.8 ± 1.1 (i.p.)
Johnson (1988)	Long-Evans rat (male)	NR + ^{67}Cu (i.m.)	6.15 [b] 0.42 [b]	113 7.6	0.45 0.03	4 wk (treatment) 3- (faeces collection)	Radioactivity (liver/kidney & faeces) + isotope dilution AAS analysis of tissue/ faecal Cu	NR	39 ± 7 32 ± 10	Balance: 20 ± 7 µg/d 0.6 ± 0.5 µg/d
Van den Berg & Benyen (1992)	Wistar rat (male)	NR+ ^{64}Cu acetate (i.p. or oral)	5.0 1.0	74 12	0.30 0.05	Up to 26 d (treatment) 2x3 d (faeces collection)	Whole-body counting of ^{64}Cu AAS analysis of feed/faecal Cu	42 70	62 ± 2 NR	Cu $T_{1/2}$: 4.7 ± 0.3 (oral) 5.2 ± 0.4 (i.p.)
Wolf *et al.*, (1998)	Sprague Dawley rat (male)	NR	6.35	89	0.36	(treatment) 8d (faeces collection)	ICP spectrometry (feed/faecal Cu)	29.7 ± 1.2	NR	Cu balance: 23 ± 1 µg/d
Rimbach *et al.*, (1995)	Wistar rat (male)	$CuSO_4$	7.6	80	0.32	(treatment) (faeces collection)	ICP spectrometry (feed/faecal Cu)	33.6 ± 3.4	NR	
Yu *et al.*, (1994)	Wistar rat (male)	$CuSO_4$	8.1	170	0.68	6 wk (treatment) (faeces collection)	AAS analysis of faecal Cu	75 ± 3	NR	
Johnson & Murphy	Sprague Dawley	$CuSO_4$	5.74	78.2	0.31	5 d (faeces collection)	AAS analysis of feed/faecal Cu	22	NR	

Reference	Animal model	Identity of copper	Dietary Cu			Duration of treatment/ measurement	Analytical method	Absorption of Cu (% of intake)		Other information
			mg/kg feed	µg/d	mg/kg bw/d			Apparent	True	
(1988)	rat (male)		0.42	5.6	0.02			27		
Johnson & Hove (1986)	Sprague Dawley rat (male)	$CuSO_4$	8.6 [c] 0.85 [c]	115 11.6	0.46 0.046	(faeces collection)	AAS analysis of feed/faecal Cu	4 59	NR	
Johnson & Flagg (1986)	Sprague Dawley rat (male)	$CuSO_4$	10 [c] 0.94 [c]	130 12	0.52 0.048	21 d (treatment) (faeces collection)	AAS analysis of feed/faecal Cu	14 58	NR	
Johnson & Gratzek (1986)	Sprague Dawley rat (male)	$CuSO_4$	8.3 [c] 0.7 [c]	133 10.5	0.53 0.04	24 d (treatment) (faeces collection)	AAS (tissue and faecal Cu)	14 ± 4 45 ± 3	NR	
Johnson and Lee (1988)	Sprague Dawley rat (male)		0.4 1.7 3.5 5.4 10.6 21.1	7 33 63 92 180 403		(faeces collection)	AAS analysis of feed/faecal Cu		46 40 41 30 23 22	
Himmelstein (2003) [d]	Sprague Dawley rat (male)	Copper (I) oxide Copper oxychloride Copper sulphate Copper hydroxide	20 mg/kg BW (single oral dose – by gavage)			Measurement of Cu in tissues and excreta for 24h after dosing	ICP AES	10.7 – 12.9% of intake (absorption calculated as sum of Cu in whole blood, liver, carcass, bile and urine)		Cu levels in tissues and excreta similar for all substances.
Himmelstein (2003) [d]	Sprague Dawley rat (male)	Copper hydroxide	20 mg/kg BW (single oral dose)			Measurement of Cu in whole blood, plasma and liver for 48h after dosing	ICP AES			Apparent half-life 10 h

Values reported are mean values ± (if specified) standard deviation
NR – not reported

True absorption was determined as there is a large quantity of data available on the absorption of copper in animals and humans, predominantly relating to oral exposure. In these studies, quantitative data on the absorption of copper have been based on faecal monitoring, as faecal excretion is the main excretory route for copper. In several of these studies, the amount absorbed has been determined as the difference between oral intake and faecal excretion. This absorption value represents a measure of *apparent absorption* only, as faecal copper does not distinguish between unabsorbed copper and endogenous copper losses. Endogenous copper losses may occur from (1) biliary excretion of systemically-absorbed copper that mixes with the endogenous pool and is subsequently excreted, and (2) the fraction absorbed by intestinal mucosa and subsequently eliminated into the GI tract as cells are sloughed off (i.e. without systemic absorption). *Apparent absorption* thus represents a somewhat crude measure of copper absorption. In order to measure *true absorption*, which provides a more accurate measure of copper absorption following oral exposure, the percentage of copper intake recovered in the faeces must be corrected for endogenous copper losses.

(Source: Van den Berg *et al*, 1994; Johnson 1988; Van den Berg & Benyen 1992; Johnson & Lee 1988)

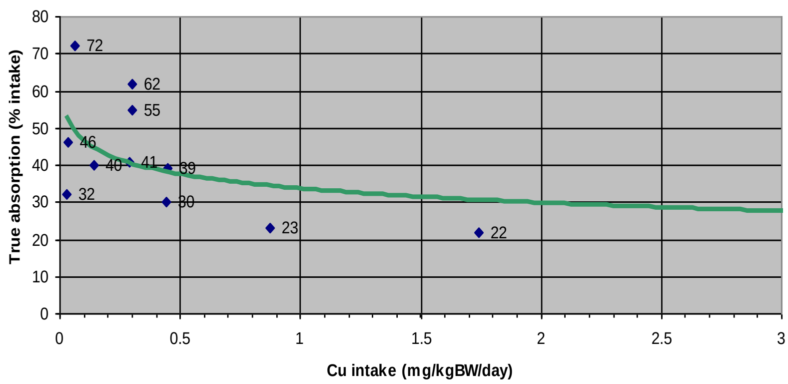

Figure 2: Oral absorption of copper – pooled animal data

Based on these absorption data, an absorption factor of 25% is taken to be the best estimate of true absorption in rats at the high copper intakes which are applicable to the repeated dose toxicity NOAEL. Application of the 25% absorption factor to the NOAEL of 16.3 mg Cu/kg bw/day results in an internal NOAEL of 4.075 mg Cu/kg bw/day. This internal NOAEL for repeated dose toxicity is used to calculate DNEL values. The 25% oral absorption factor was agreed at the Technical Meeting (TM03) in 2008.

The most reliable human data currently available on copper absorption following oral exposure come from volunteer studies by Turnlund *et al.,* (1989; 1998; 2005) and Harvey *et al.,* (2003; 2005). Based on the available true absorption data, oral absorption rates in humans have been derived as shown in **Figure 3**.

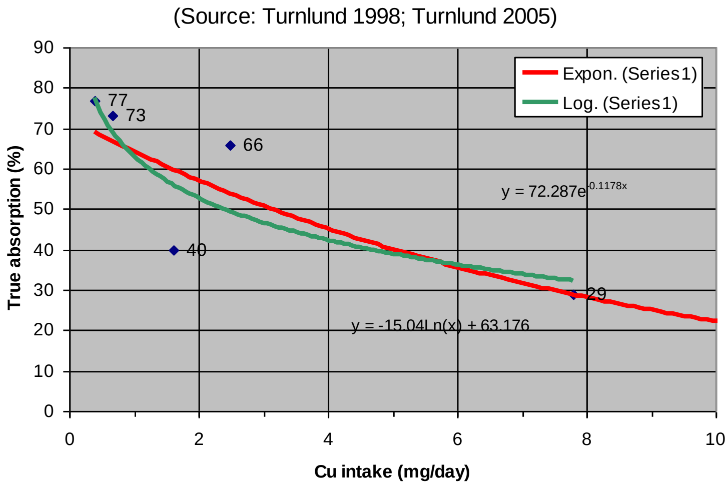

Figure 3: Oral absorption of copper – human data

Oral absorption data for humans and rats presented in **Figure 2** and **Figure 3**.

The available data have been fitted to two functions giving a continuous distribution with mostly similar results:

Equation 1: oral absorption% = -15.0 ln(x) + 63.2

Equation 2: oral absorption% =72.9 $e^{-0.1167x}$

x= copper intake (mg/day)

For a given dose in the GIT, absorption in humans is calculated based on the mean result for these two functions. In humans, this method of calculation is applied to the sum of the oral intake and copper arising from inhalation exposure and subsequently translocated to the GIT. The minimum oral absorption is set to 20%.

Oral absorption data for humans and rats presented in Figure 1 and Figure 2 show qualitative and quantitative similarities between the two species. In both species, absorption of copper over the range of intakes studied is inversely related to copper intake, illustrating the important role of absorption in copper homeostasis. In both species, true absorption of copper from diets containing what are considered as adequate levels of copper (1-10 mg/day in humans; 0.3-0.6 mg/kg bw/day in animals) is in the 30-60% range. The above oral absorption data, and corresponding functions, are based on copper sulphate. Assuming that orally-administered copper will occur in the GIT, at least in part, in the ionic form and therefore be available for absorption, and in view of the solubility of copper sulphate, it is considered appropriate to adopt a conservative approach and to use the oral absorption data for copper sulphate for other less soluble copper species.

5.1.4.2 Dermal absorption and penetration

Quantitative dermal absorption data for humans are available from two unpublished *in vitro* studies (Roper, 2003; Cage, 2003) and two published studies by Pirot *et al.,* (1996a; 1996b). Whilst the studies of Roper (2003) and Cage (2003) have several shortcomings, currently they represent the best available data on the subject.

An unpublished report of an *in vitro* percutaneous absorption study has been made available[2] (Roper 2003 – *unpublished study*). The study was based on OECD guidelines (No. 428), although it did not appear to measure copper content of all the compartments of the test system (i.e. tape strips, skin washings, cell washings). Consequently, mass balance data could not be determined. Receptor fluid was only collected as single sample over a 24-hour period, so the absorption profile could not be determined. It is noted, however, that determining the absorption profile would be difficult given the levels of copper present. Each substance was moistened with water (1:1 w/w), stirred for one hour with a magnetic stirrer and aliquots checked for homogeneity before applying to samples of human breast tissue. Application rates were 5.4 mg/cm^2 (copper (I) oxide) and 3.34 mg/cm^2 (copper oxychloride). Ten samples of skin were tested with each preparation. Following exposure for 6 hours, the skin surface was washed and washings retained for analysis. Receptor fluid was collected as a single sample during the 6-hour exposure period plus a further 18 hours. The underside of the skin was then rinsed. Copper content of receptor fluid + washings from underside of skin were used to calculate dermal absorption. The mean absorbed dose was reported to be 55.56 ng/cm^2 ± 398 (copper oxide) and 82.98 ± 316 ng/cm^2 (copper oxychloride), representing 0.001% (± 0.01) and 0.002% (± 0.01) of the applied dose, respectively. Skin samples were stored at ~-20˚C and then tape stripped to remove the stratum corneum. Stripped dermis was analysed for copper using ICPMS. Copper in tape strips or surface washings were not determined. Dermal delivery was determined as the sum of copper in receptor fluid and stripped dermis; mean values were 3074 ng/cm^2 ± 2261 and 2601 ng/cm^2 ± 1870, respectively (reported as 0.06% ± 0.04 and 0.08% ± 0.06 of the applied dose, respectively). In conclusion, this *in vitro* study reported dermal absorption rates near zero and dermal delivery rates of <0.1% for both copper (I) and copper oxychloride. However, this study has several limitations. Firstly, the lack of mass balance data which means that the applied dose of copper is not fully accounted for. In addition, large standard deviations were evident in the absorption and delivery data. Whilst these wide ranging values are likely to be due to the low levels of copper being measured in the receptor fluid and dermis, they raise uncertainties regarding using the mean values to derive measures of copper absorption/dermal delivery for risk characterisation.

In vitro dermal penetration of four copper substances (copper (I) oxide, copper sulphate, copper powder and copper thiocyanate was investigated in human skin samples in another unpublished study (Cage 2003[3] – *unpublished*). The test was reported to be conducted according to OECD guidelines (No. 428), but only involved measurement of copper in the receptor fluid. Copper retained in the dermis was not determined, nor was copper in other fractions of the skin or skin washings. Consequently, data on copper remaining in the skin after exposure was not available for this study, nor were mass balance data which could account for all the applied copper. Each substance was applied as an aqueous slurry to samples of abdominal or back skin. Slurry samples were prepared to ensure homogeneity of the sample, involving whirl mixing, magnetic stirring and/or ultrasonication. Three different exposure/sampling regimes were employed for each substance: (1) 6-hr exposure, experiment terminated at 6 hr; (2) 6-hr exposure, substance removed by swabbing, experiment terminated at 24 hr; (3) 24-hr exposure, no swabbing, experiment terminated at 24 hr. (2) and (3) are in accordance with OECD test guideline, and (2) is the most relevant for occupational exposure

2 Provided by the EU Copper Task Force to the European Copper Institute under a specific secrecy agreement.

3 Provided by the EU Antifouling Copper Task Force under a specific secrecy agreement.

scenarios. Consequently, results from (2) are presented here. Four or five samples were used for each substance and each sampling regime. Application rates were 1.05 mg/cm^2 (copper (I) oxide), 0.974 mg/cm^2 (copper powder) and 0.942 mg/cm^2 (copper sulphate). Copper content of receptor fluid was analysed by atomic absorption spectrophotometry. The amount of copper absorbed (i.e. copper measured in receptor fluid) was: 1564.6 ng ± 221 (copper (I) oxide); 352.9[4] ng ± 53 (copper powder); 1216.5[5] ng ± 835 (copper sulphate). These values represented 0.157%, 0.038% and 0.136% of the applied dose, respectively. Values expressed as ng/cm^2 were: 1646, 372 and 1277, respectively. In conclusion, this study reported dermal absorption rates of <0.2% for copper (I) oxide and copper sulphate, and <0.1% for copper powder. As with the study by Roper (2003), this study was limited by the absence of mass balance data and the occurrence of fairly large standard deviations. A further limitation was the lack of data concerning copper retained in the skin.

With a view to deriving a dermal absorption factor which can be taken forward to *'Risk Characterisation'*, results from Roper (2003) and Cage (2003) are summarised in **Table 26**. It is notable that absorption values reported in the Roper study are lower than those reported by Cage. For example, values for copper (I) oxide are 0.001% and 0.157%, respectively. These differences may be based on methodological differences, such as sample preparation, dose applied and/or analytical technique employed. Variation between the two studies in terms of methodology and absorption values reported, together with the deficiencies in each of the studies as previously outlined, present significant challenges in terms of deriving a reliable dermal absorption factor for copper. Nevertheless, these two studies appear to present the best dermal absorption data for copper currently available.

Based on these two studies, a dermal absorption factor of 0.3% is proposed for insoluble copper substances. This value is derived from the highest value for copper measured in receptor fluid (0.157% for copper (I) oxide reported by Cage), plus a value for copper retained in the skin (mean of 0.07% and 0.05% reported by Roper). This results in a dermal absorption value of 0.217% ± 0.06 and as a conservative approach this is rounded up to 0.3%.

Copper remaining in the skin is included in the calculation as suggested in the OECD methodology (Test Guideline 428). In the absence of data to indicate whether copper retained in the skin will become bioavailable or not, the inclusion of copper retained in the skin can be considered as a worst case approach.

In the two reviewed studies, the copper compounds were applied in an aqueous medium (slurry). There is uncertainty about the applicability of these absorption data to exposures of dry copper compounds as encountered in occupational exposure scenarios. However, in view of the limitations of the studies on which this dermal absorption factor is based (absence of mass balance data and large standard deviations), the value of 0.3% is considered to represent the best estimate based on data currently available.

Given the available studies provide no consistent evidence that dermal absorption is greater for soluble than for insoluble copper substances, a dermal absorption factor of 0.3% is also proposed.

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4 In 2/5 samples, copper levels were below the limit of quantification.

5 In 1/4 samples, copper levels were below the limit of quantification.

Table 26: Summary of *in vitro* dermal absorption from Roper (2003) and cage (2003)

Reference	Substance	Analytical method	Applied dose (mg Cu/cm^2)	Absorption		Dermal delivery	
				% of applied dose	ng/cm^2	% of applied dose	ng/cm^2
Roper (2003)	Copper (I) oxide	ICPMS	5.4	0.001 ± 0.01	55.56 ± 397.7	0.06 ± 0.04	3074.1 ± 2261.6
Cage (2003)	Copper (I) oxide	AAS	1.05	0.157 ± 0.026	1647	ND	ND
Roper (2003)	Copper oxychloride	ICPMS	3.34	0.002 ± 0.01	82.98 ± 316.07	0.08 ± 0.06	2601.4 ± 1870.2
Cage (2003)	Copper powder	AAS	0.974	0.038 ± 0.006	372	ND	ND
Cage (2003)	Copper sulphate	AAS	0.942	0.136 ± 0.108	1277	ND	ND

The following dermal absorption studies by Pirot *et al.,* (1996a; 1996b) were conducted using topical formulations (emulsions or ointments), which are designed to enhance dermal penetration of copper and other constituents.

The permeability of human skin to solutions of copper salts was measured using female skin from breast tissue in a diffusion cell with saline receptor fluid (Pirot *et al.,* 1996a). Experiments were conducted with $CuSO_4$ and $CuCl_2$ at a concentration of 5% in either white petrolatum or carboxymethylene. The distribution of copper in fresh epidermis (stripped of stratum corneum), dermis and receptor fluid varied widely between the preparations. Little penetration past the epidermis occurred (10-20% of epidermis level) for the $CuSO_4$ preparations, while the corresponding value for $CuCl_2$ preparations was 40-60%. The total absorbed through the fresh epidermis into the dermis and receptor fluid after 72 hours was 30.3-43.1 $\mu g/cm^2$ for $CuCl_2$ preparations and 5.1-7.8 $\mu g/cm^2$ for $CuSO_4$ preparations. $CuCl_2$ in petrolatum produced much the highest levels of permeation at 22.1 $\mu g/cm^2$ after 72 hours, considerably in excess of the other preparations ($p<0.001$). Therefore, penetration of these preparations showed some dependence on both compound and vehicle.

In a further study by the same authors, the absorption of copper 2-pyrrolodine 5-carboxylate (CuPC) and $CuSO_4$ from oil/water emulsions and ointments of unspecified composition was investigated (Pirot *et al.,* 1996b). This study employed a similar methodology to that described above except that abdominal skin was used and data on absorption into the receptor fluid were not presented. Oil/water emulsions contained 0.10% copper as CuPC or 0.09-0.13% copper as $CuSO_4$. The ointments contained 0.09% and 0.05% copper as $CuSO_4$. After 72 hours, skin absorption of copper from CuPC and $CuSO_4$ emulsions was 2.12% and 0.66–2.59% of the dose, respectively. In a second set of experiments, absorption of copper from the CuPC emulsion was compared to absorption of $CuSO_4$ from the ointments to test the significance of the vehicle. Absorption of CuPC was higher than in the first set of experiments (5.04% after 72 hours). Absorption of copper from the ointments ranged from 3.77-3.40% of the dose.

The copper compounds and the vehicle used in these two studies are not relevant to exposure scenarios.

Conclusion

With regard to dermal absorption of copper, two *in vitro* studies using human skin provide the best data currently available (Roper 2003; Cage 2003). Based on these two studies, a dermal absorption factor of 0.3% is derived for insoluble and soluble copper substances in solution or suspension and is used in risk characterisation.

For dry exposure scenarios, a 10-fold lower dermal absorption value is proposed (0.03%), consistent with the approach used in the Zinc Risk Assessment.

5.1.4.3 Inhalation

In absence of relevant inhalation absorption data, the inhalation absorption will be calculated using the Multiple Path Model of Particle Deposition (MPPD) and the particle size distribution data of the copper and copper compounds.

Based on the particle size distribution data, the MPPD model (v1.0) (Asgharian & Freijer, 1999) is then used to predict fractional deposition behaviour in the human respiratory tract for workers. For these calculations, the following model assumptions were used in assessing conditions reflective of workplace conditions:

Table 27: MPPD model parameters using the Respicon particle size data

Airway morphometry	Human Yeh Schum symmetric model
Particle density	1 g/cm³
Particle diameter	MMAD = 4 µm (respirable) 10 µm (tracheobronchial) 50 µm (extrathoracic, nominal)
Inhalability adjustment	Off
GSD	2
Exposure conditions	Constant
Aerosol concentration	1000 µg/m³
Breathing mode	Oronasal normal augmenter
Shift breathing volume	10 m³/8 h*
Breathing frequency	18 breaths/min
Tidal volume	1150 ml

*: occup. breathing volume defined by ICRP as 9.6 m³/8-hour shift, composed of 7 h light exercise, plus 1 h heavy exercise

From the predicted fractional deposition, inhalation absorption factors were calculated based on the following basic assumptions: copper deposited in the alveolar region was assumed to be 100% absorbed (conservative default). Copper deposited in the upper respiratory tracts (ET and TB fractions) was assumed to be translocated to the gut. Here it is assumed to be subject to intake-dependent absorption along with dietary copper.

5.1.5 Distribution

On entering interstitial fluid and blood plasma, absorbed copper initially becomes bound to two proteins; albumin and transcuprein. Most of the copper bound to albumin and transcuprein is rapidly transported via portal blood to the liver. Once in the liver, copper is incorporated into ceruloplasmin, which is subsequently released into the systemic circulation for delivery to other tissues (Lee *et al.,* 1993; Scott & Turnlund, 1994).

5.1.6 Excretion

Quantitative data on excretion were reported in the bioequivalence study by Himmelstein (2003 – *unpublished*[6]). The fate of excess copper was examined in bile-cannulated male Sprague Dawley rats (five per group) following oral administration of a single dose of copper (nominal dose 20 mg Cu/kg BW; actual dose 22-24 mg Cu/kg BW). The substances investigated were copper (I) oxide, copper sulphate, copper oxychloride, copper hydroxide, tribasic copper sulphate and Bordeaux mixture. Copper levels in excreta during the 24-h period after dosing were as follows: bile 1.54-2.48% of dose; urine 0.20-0.39% of dose; faeces 64-76% of dose (although it is noted that faecal copper will also comprise some absorbed copper). Values were found to be similar for all six substances tested. The results showed faecal excretion to be the main route of elimination for orally-administered copper, with urinary excretion as a relatively minor route. In the second part of this study, which was conducted using a single oral dose of copper hydroxide (20 mg Cu/kg bw) as a representative copper compound, the apparent half-life of orally-administered copper was determined in male rats as.

5.1.7 Comparative biology

In mammalian toxicity, it is also considered that the most toxic form of any copper salt is the Cu^{2+} ion. This can be shown through the comparison of the most soluble (e.g. copper sulphate, copper nitrate) and relatively insoluble copper salts, where the solubility, bioavailability and hence toxicity of these salts can vary – with copper sulphate representing the worst-case scenario. When the acute oral toxicity of soluble copper salts (WHO, 2002) are compared with copper (I) oxide, copper thiocyanate or copper powder, the data indicate that copper sulphate is equivalent or more toxic and thus more bioavailable, as a higher level of Cu^{2+} will become available in mammalian gastro-intestinal fluids. As all suitable short- to long-term available animal copper toxicity studies are derived from oral administration, the use of copper sulphate data would represent a worst case scenario for the determination of the effect of relatively insoluble copper compounds in mammalian toxicity. In addition, the use of copper sulphate data would minimise the number of animal studies.

A bioequivalence study by Himmelstein (2003 – *unpublished*[7]) provides relevant information on copper absorption in animals. In this study, absorption, distribution and excretion of several copper substances were investigated in male Sprague Dawley rats following oral administration. In the first part of the study, the fate of excess copper was examined in bile-cannulated animals (five animals per group) following oral administration of a single dose of copper (nominal dose 20 mg Cu/kg BW; actual dose 22-24 mg Cu/kg BW). Copper was administered by gavage in a slurry of ground diet. The copper substances investigated were copper (I) oxide, copper sulphate and copper oxychloride, copper hydroxide, tribasic copper sulphate and Bordeaux mixture. Copper levels were determined in bile, faeces and urine during the 24-h post-dosing period, and in whole blood, plasma, liver, GIT and stomach at study termination (24h after dosing). Copper levels in tissue and excreta were found to be fairly similar for all substances investigated. Mean copper levels for all six substances, when expressed as a percentage of intake, were: whole blood 0.24-0.32%; liver 3.01-3.90%; carcass 5.2-6.88%; bile 1.54-2.48%; urine 0.20-0.39%; faeces 64-76%. Absorption for all six

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6 Provided by the EU Copper Task Force to the European Copper Institute under a specific secrecy agreement.

7 *Provided by the EU Copper Task Force to the European Copper Institute under a specific secrecy agreement.*

substances tested was calculated as ranging from 10.69 to 12.91% of intake; again, fairly similar for all substances investigated. [In contrast to studies previously reported in this section, absorption in this study was determined by adding values for whole blood, liver, carcass, bile and urine. There appears to have been no distinction between recently administered copper or existing body stores of copper. Further, measurements were only made during the 24-h period after dosing and the study involved administration of a single dose. Consequently, these absorption values are not compared with absorption values reported in other previously cited studies.] In conclusion, the results of part one of this study indicate that absorption, distribution and excretion of a single, orally-administered dose of 20 mg Cu/kg BW (nominal dose) in male rats, when expressed as a percentage of intake, was similar for each of the six copper substances tested.

Based on the findings of part one, the second part of the study was conducted using copper hydroxide as the representative copper compound. Whole blood, plasma and liver samples were analysed for copper content in male rats at different time-points up to 48h after receiving an orally-administered dose of copper hydroxide at 20 mg Cu/kg BW. Five treated rats and five control rats were used for each time-point. Plasma copper levels remained fairly stable during 48h post-dosing for treated and control animals (0.737 -1.110 µg/g in treated rats; 0.883-1.140 µg/g in controls). Liver copper levels increased rapidly after dosing, peaking at 12 h, and returning to control levels by 48h. The apparent half-life of copper in this study was determined as.

In addition to the study by Himmelstein (2003), several other studies have investigated comparative bioavailability of copper substances, albeit focussing on agricultural animals.

For the oral exposure route, in a series of bioavailability studies, conducted by several authors the bioavailability of copper sulphate to other relatively insoluble copper salts including copper oxide, cuprous oxide and copper carbonate was compared. In all cases, copper sulphate was shown to be more or equally bioavailable in relation to the other three copper salts (see **Table 28**). Although the species tested are not usual species used in regulatory guidelines, the results are consistent when evaluating a number of studies and appear to be reproducible. In addition, the studies have measured copper levels in the most important organ and body fluid in determining copper adsorption from the gastro-intestinal tract, namely the liver and bile. Therefore, although these studies will not be used in the risk assessment for determining the toxicokinetics of copper they are suitable for examining the concept of comparative bioavailability of copper salts.

Table 28: Relative bioavailability of supplemental copper sources

Source of copper	Species			References (and applicable species)
	Poultry	Swine	Cattle	
Copper sulphate	100	100	100	Aoyagi and Baker, 1993 (poultry) Baker *et al.*, 1991 (poultry) Buescher *et al.*, 1961 (swine) Cromwell *et al.*, 1989 (swine) Kegley and Spears, 1994 (cattle)
Copper oxide	0 (3)	30 (4)	15 (2)	
Cuprous oxide	95.2(2)			Aoyagi and Baker, 1993 (poultry) Baker *et al.*, 1991 (poultry)
Basic copper carbonate	115 (1)	60 (1)		Allen *et al.*, 1961 (swine) Aoyagi and Baker, 1993 (poultry)
Copper carbonate		95 (1)		Buescher *et al.*, 1961 (swine)

Average numbers rounded to the nearest '5' and expressed relative to response obtained with copper sulphate. Number of studies or samples involved indicated within parenthesis.

The low bioavailability of copper in copper oxide, relative to that of copper in the sulphate salt, was also demonstrated in the rat following administration at adequate dietary levels (Rojas *et al.,* 1996).

The comparative bioavailability between the copper salts can also be observed by the dermal route when evaluating the *in vitro* dermal penetration study of Cage, 2003. Comparison of the amount of copper absorbed through human skin following the application of each test material formulation is best assessed using the most occupationally relevant sampling regime (swab at 6 hours, receptor fluid collected at 24 hours post application).

The results may be summarised as follows:

Product name	% applied dose	Ratio
Cuprous oxide composite	0.157	1.15
Cuprous thiocyanate	0.126	0.92
Copper powder	0.038	0.28
Cupric sulphate	0.136	1.00

When comparing the dermal penetration potential between the soluble copper salt (copper sulphate) and the three relatively insoluble copper compounds it can be observed that the dermal penetration capacity of copper (I) oxide and copper thiocyanate is comparable to copper sulphate whereas the dermal capacity of copper powder is significantly lower. This indicates that it is possible to read-across toxicity data on copper sulphate as a worst case in comparison to copper (I) oxide, copper thiocyanate and copper powder. In addition, it will be possible to calculate the route-to-route exposure from available oral toxicity studies on copper sulphate and using dermal penetration studies on insoluble copper compounds. Therefore an equivalent but realistic determination of dermal toxicity may be derived from available sub-chronic oral exposure studies on copper sulphate, permissible systemic copper levels and *in vitro* dermal penetration studies on copper sulphate and insoluble copper compounds (NTP, 1993; Cage, 2003).

Several studies assessed the relative release/dissolution of metal ions from metal bearing materials (minerals, soils, substances) in simulated biological fluids. The resulting value is termed **bioaccessibility or biosolubility** and is defined as the fraction of a substance that is soluble under physiological conditions and therefore 'potentially available' for absorption into systemic circulation. The simulated biological fluids represent exposure- relevant exposure routes (e.g. dissolution in sweat is used to estimate bioavailability after dermal exposure, dissolution in gastric fluid is used to estimate bioavailability after oral exposure,). The concept of bioaccessibility has been applied to human exposures to metals and minerals in soils, consumer products, and to the evaluation of metal substances directly (e.g. Oomen *et al.,* 2002; Van de Wiele *et al.,* 2007; Oswer 2007, Brock and Stopford, 2003; Stopford *et al.,* 2003). Bioaccessibility has already been used in regulatory frameworks: e.g. the EU Nickel Directive, which identifies a nickel release in artificial sweat (EN 1811), the ASTM D5517, identifies metal oral accessibility for Art materials, EN71 identifies metal oral accessibility for toys.

Rodriguez *et al.,* 2010 assessed the relative release/dissolution of copper ions from copper materials and copper compounds in biological fluids simulated oral exposure. The *in vitro* test used by Rodriguez *et al.,* 2010, follows the ASTM D 5517 – 07 protocol, using HCl 0.07N (pH 1.5) as a gastric mimetic fluid. The results from this test a conservative measure of bio-accessibility because only solubility in the gastric fluid (pH 1.5) is assessed and the homeostatic mechanisms at the level of the intestine and liver are ignored. The copper compounds tested, include: copper wires (representing massive copper materials), copper powder (130 µm median diameter), biocidal and non-biocidal coated copper flakes (ca 8.5 µm), cupric oxide and cuprous chloride. Loading rates between 100 mg/L and 2 g/L were assessed. The results are expressed as % mass recovered at the end of the bio-elution test and compared with the results obtained from soluble copper sulphate. The influence of surface area on bioaccessibility, of relevance to copper in powder and massive forms, was also evaluated.

All copper present in CuSO4 was solubilised (99.95%). Cuprous chloride showed a copper solubility between 76.5 and 93.5% under different loading conditions; cupric oxide showed a copper solubility range of 68.4 and 83.7% for 200 mg/L and 2 g/L sample loading, respectively. Biocidal and non-biocidal coated copper flake samples showed similar copper solubility, 41.6 and 44.0%, respectively at 2 g/L loading, and higher solubility at 200 mg/L loading, 71.5 and 60.1%, respectively. The results for copper in granulate form (D50 of 135 µm; 4800 mm2/L) showed a coefficient of variation between the replicas of 66% at sample loading of 2 g/L, with 7% copper release, on the other hand, at 200 mg/L loading 1.1% copper solubility was found with a lower coefficient of variation between vessels. The high variability at the higher loading rate is possibly related to abrasion of the particles. The 'massive' copper materials, tested as wires at different mass loadings (59 to 478 mg/L) and surface loadings (67 – 516 mm2/L) consistently showed a solubility of 0.1%. The results are summarized in **Table 29**.

Table 29: Relative bio-solubility/bioaccessibility of copper and copper compounds, assessed from the recovery of copper after a bio-elution tests in gastric fluids (pH 1.5) in accordance to ASTM D 5517-07

Material tested	Composition	Bio-elution recovery (as % of Cu content)
Cu massive	>99.9% Cu	0.096-0.105
Cu powder	99.7% Cu, 0.3% Cu2O	1.1-(7.3*)
Cu flake - biocidal product	93.7% Cu, 2.6% Cu2O, 3.9% LOI**	42-71
Cu flake - non-biocidal product	96.3% Cu, 1% Cu2O, 2.8% LOI**	44-60
CuO	79.89% Cu	68-84
CuCl	63.78% Cu	67-94
CuSO4	25.45% Cu	100

* The results at the higher loading rate show unacceptable high variability (CV of 66%), possibly related to abrasion of the particles during the test - the results of this test are therefore not considered as reliable.; ** Loss if ignition, as a measure of the organic content

The results show a highest solubility of CuSO4 and CuCl. The lowest solubility was noted for the copper wires. Comparison of the results for CuO from the in vitro gastric biosolubility tests (**Table 29**) with in vivo bioavailability studies (**Table 28**) clearly demonstrate the conservative nature of the gastric biosolubility tests.

For the copper massive and copper powder materials, the results are also expressed as surface loading. For the massive materials, the linear regression observed between the dissolved copper concentration (µg Cu/L) and the surface loading (mm2/L) **Figure 4** allows the calculation of an average surface -specific release rate of 0.9 µg/mm2. Considering that the surface –specific release rate of the powders was somewhat lower than of the massives (0.9 versus 0.5 µg/mm2) but also more variable, it is considered that the surface –specific release rate of the massive material (0.9 µg/mm2) also applies to the powders.

Table 30: Bioaccessibility of copper as a function of the particle surface area as obtained from bio-elution tests in gastric fluids (pH 1.5) in accordance to ASTM D 5517-07

Material tested	Surface loading (mm2/L)	Bio-elution recovery (µg Cu/l)	Surface –specific release (µg/mm2)
Cu massive (wire)	67	62	0.92
Cu massive (wire)	168	144	0.86
Cu massive (wire)	516	460	0.89
Cu powder	4800	2208	0.5*

* the results from the lower loading rates are more reliable and these were therefore retained (see footnote in)

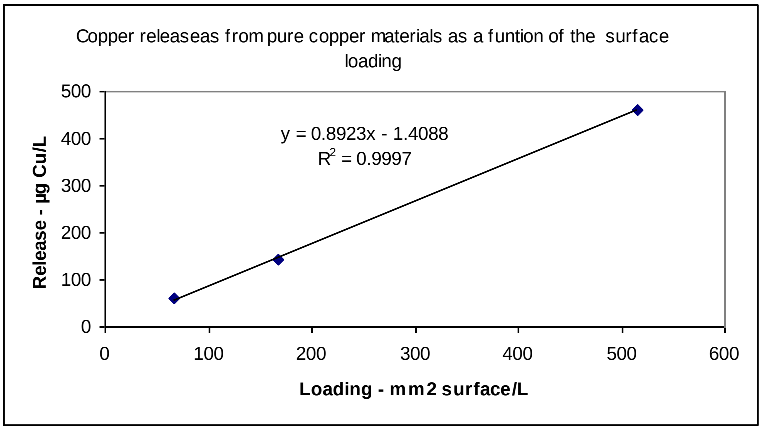

Figure 4: Release o of copper from wires with different amounts of surface exposed to the gastric mimetic fluid

Copper release from the blank and copper wires of 67.3, 167.8 and 516.1 mm^2/L surface loading, equivalent to the surface of spheres of 0.13, 0.4 and 1 mm in diameter, respectively, tested at concentrations of 100 mg/L.

In conclusion, the study from Rodriguez *et al.,* 2010 demonstrated large variability in the gastric bio-accessibility of copper bearing materials. The recorded copper bio-accessibility, relative to copper sulphate, were as follows: copper coated flakes: 42-71%; copper powder: 1.1%; copper massive forms: 0.1%.

5.1.8 Summary and discussion of toxicokinetics

Copper is an essential metal present in human body tissues and fluids at concentrations of parts per million or parts per billion. In common with other trace metals, copper has a number of physiological roles that may be classified as regulatory, structural and protective. In the regulatory role they are an essential part of metalloenzymes, acting either as electron donors or acceptors at the active site, or by shaping the enzyme to the configuration necessary for its activity.

From the toxicokinetics studies, a value of 25% oral absorption was chosen for risk assessment purposes. This figure was derived from evaluating the true absorption from studies on the rat.

Copper compounds have been shown to permeate intact skin minimally (0.3%) when resuspended in saline. A dermal absorption factor of 0.03% is proposed for dry exposure scenarios.

Comparative bioavailability, solubility and toxicity studies have shown that relatively insoluble copper and sparingly soluble copper oxide are less bioavailable than the more soluble copper salts, e.g. copper sulphate pentahydrate and cuprous oxide. Therefore in order to reduce the number of animal testing all long- term studies have been conducted on soluble copper salts.

For the acute hazard assessment, the available toxicological information on copper-sulphate, copper oxide and copper are used in combination with the toxicokinetics to allow for read-across where necessary.

5.2 Acute toxicity

5.2.1 Non-human information

5.2.1.1 Acute toxicity: oral

Data waiving

Information requirement: Acute toxicity after oral administration

Reason: study scientifically unjustified

Justification: According to criteria set out in Annex VIII of the REACH Regulation, an acute oral toxicity study should not be conducted if the substance is classified as corrosive to the skin.

5.2.1.2 Acute toxicity: inhalation

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: study scientifically unjustified

Justification: According to criteria set out in Annex VIII of the REACH Regulation, an acute inhalation toxicity study should not be conducted if the substance is classified as corrosive to the skin.

5.2.1.3 Acute toxicity: dermal

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: study scientifically unjustified

Justification: According to criteria set out in Annex VIII of the REACH Regulation, an acute dermal toxicity study should not be conducted if the substance is classified as corrosive to the skin.

5.2.1.4 Acute toxicity: other routes

There are no applicable data available on other routes of toxicity.

5.2.2 Human information

There are no applicable data available on acute toxicity to humans.

5.2.3 Summary and discussion of acute toxicity

Acute Oral Toxicity:

According to criteria set out in Annex VIII of the REACH Regulation, an acute oral toxicity study should not be conducted if the substance is classified as corrosive to the skin. Accordingly, Copper dinitrate is not classified on the basis of acute oral toxicity.

Acute Inhalation Toxicity:

According to criteria set out in Annex VIII of the REACH Regulation, an acute inhalation toxicity study should not be conducted if the substance is classified as corrosive to the skin. Accordingly, Copper dinitrate is not classified on the basis of acute inhalation toxicity.

Acute Dermal Toxicity:

According to criteria set out in Annex VIII of the REACH Regulation, an acute dermal toxicity study should not be conducted if the substance is classified as corrosive to the skin. Accordingly, Copper dinitrate is not classified on the basis of acute dermal toxicity.

Specific target organ toxicity – single exposure (STOT SE):

There was no evidence of any specific toxic effects on a target organ or tissue following single exposures to the test substance.

Conclusion:

No classification as STOT-SE under regulation (EC) 1272/2008 is proposed. No classification or SCLs are considered necessary.

5.3 Irritation

5.3.1 Skin

5.3.1.1 Non-human information

Copper dinitrate is corrosive in contact with skin. See section 5.4.1.

5.3.1.2 Human information

There are no applicable data available in humans.

5.3.2 Eye

5.3.2.1 Non-human information

Data waiving

Information requirement: Eye irritation

Reason: study scientifically unjustified

Justification: According to criteria set out in Annex VIII of the REACH Regulation, an in vivo eye irritation study should not be conducted if the substance is classified as corrosive to the skin and provided the registrant classifies the substance as an eye irritant. The risk of severe damage to eyes is considered to be implicit.

5.3.2.2 Human information

There are no applicable data available in humans.

5.3.3 Respiratory tract

5.3.3.1 Non-human information

There are no applicable data available on irritation in the respiratory tract.

5.3.3.2 Human information

There are no applicable data available on irritation in the human respiratory tract.

5.3.4 Summary and discussion of irritation

Copper dinitrate is corrosive in contact with skin. The risk of severe damage to eyes is therefore considered to be implicit. On this basis, it is concluded that the following classification applies:

- According to Directive 67/548/EEC: Corrosive (C). R34, Causes burns.
- According to CLP/GHS: Category 1B Corrosive, H314, Causes severe skin burns and eye damage.

5.4 Corrosivity

5.4.1 Non-human information

The results of studies on skin and eye irritation related to corrosivity are summarised in the following table:

Table 31: Studies on skin and eye irritation related to corrosivity

Method	Results	Remarks	Reference
Tissue studied: skin in vitro study OECD Guideline 431 (In Vitro Skin Corrosion: Human Skin Model Test)	Category 1B (corrosive) Relative mean viability: (reconstructed human epidermis model) (Time point: 240 minute exposure period) (The relative mean viability of the test item treated tissues was 18.2% after a 240	1 (reliable without restriction) key study experimental result **Test material**	Warren, N. (2013)

Method	Results	Remarks	Reference
	minute exposure period.) Relative mean viability: (reconstructed human epidermis model) (Time point: 60 minute exposure period) (The relative mean viability of the test item treated tissues was 19.9% after a 60 minute exposure period.) Relative mean viability: (reconstructed human epidermis model) (Time point: 3 minute exposure period) (The relative mean viability of the test item treated tissues was 53.4% after a 3 minute exposure period.)	**(Common name): Copper(II) nitrate hydrate** Form: crystalline	

5.4.2 Human information

There are no applicable data available in humans.

5.4.3 Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation.

5.5 Sensitisation

5.5.1 Skin

5.5.1.1 Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 32: Studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test Induction: intradermal and epicutaneous Challenge: epicutaneous, occlusive	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 2.5% 1st reading: 0 out of 10 (test group); 48 h after chall.; dose: 2.5% 1st reading: 0 out of 10 (test group); 72 h	1 (reliable without restriction) key study experimental result **Test material (Common**	Richeux, F. (2013)

Method	Results	Remarks	Reference
Vehicle: water OECD Guideline 406 (Skin Sensitisation) EU Method B.6 (Skin Sensitisation)	after chall.; dose: 2.5% 1st reading: 0 out of 5 (negative control); 24 h after chall.; dose: 2.5% 1st reading: 0 out of 5 (negative control); 48 h after chall.; dose: 2.5% 1st reading: 0 out of 5 (negative control); 72 h after chall.; dose: 2.5% 1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 1.25% 1st reading: 0 out of 10 (test group); 48 h after chall.; dose: 1.25% 1st reading: 0 out of 10 (test group); 72 h after chall.; dose: 1.25% 1st reading: 0 out of 5 (negative control); 24 h after chall.; dose: 1.25% 1st reading: 0 out of 5 (negative control); 48 h after chall.; dose: 1.25% 1st reading: 0 out of 5 (negative control); 72 h after chall.; dose: 1.25%	**name): Copper(II) nitrate hydrate** Form: crystalline	

5.5.1.2 Human information

There are no applicable data available in humans.

5.5.2 Respiratory system

5.5.2.1 Non-human information

There are no applicable data available on the respiratory sensitisation potential.

5.5.2.2 Human information

There are no applicable data available in humans.

5.5.3 Summary and discussion of sensitisation

A GLP-compliant guinea-pig maximisation test was conducted in accordance with internationally accepted guidelines (Richeux, 2013). No cutaneous reaction attributable to sensitisation (erythema or oedema) was recorded in animals from the treated or control groups after the challenge phase with the test item at 2.5% or 1.25%. On this basis, it is concluded that Copper dinitrate is not a sensitiser.

With regard to sensitisation by inhalation, in the absence of relevant human or animal data, there is no basis for classification of copper substances covered by this Risk Assessment for respiratory sensitisation. This conclusion of the risk assessment is provisionally taken over to the CSR.

These classification criteria are applicable to anhydrous and hydrated forms of the compound.

5.6 Repeated dose toxicity

In order to minimise animal testing, all further studies have utilised available studies on copper sulphate and this strategy has been presented in the Read Across Assessment Report presented in Section 13 of the IUCLID file and summarised in Section 5.1.7. As stated in Section 5.1.7, extensive studies have shown that copper and copper compounds are considered equally or less bioavailable to a number of animal species when compared to copper sulphate, therefore the use of copper sulphate studies in determining the DNEL's is justified on scientific grounds.

There are many studies in the public domain dealing with the repeat and chronic toxicity of copper compounds to several animal species. However, these studies did not meet the higher quality criteria (1 or 2) under the REACH quality criterion selection and will therefore not be used in the risk assessment and will not be described in this document. However, the VRAR, 2008 provides a full review of these studies and the discussion on the unsuitability/unacceptability of these studies for risk assessment. The studies summarised below have been identified as the pivotal studies in this Section.

5.6.1 Non-human information

5.6.1.1 Repeated dose toxicity: oral

Table 33: Overview of experimental studies on repeated dose toxicity

Method	Results	Remarks	Reference
at (F344/N) male/female subchronic (oral: feed) 0, 500, 1000, 2000, 4000 or 8000 ppm in the feed (providing estimated intakes of 0, 33, 66, 132, 264 or 528 mg substance/kg bw/day and 0, 8, 17, 34, 67 or 138 mg Cu/kg bw/day) Exposure: 92 days (7 days per week) equivalent or similar to EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents) (. Method developed by the US NTP specifically for the purposes of this study.)	NOAEL: 1000 ppm (male/female) LOAEL: 2000 ppm (male/female)	1 (reliable without restriction) key study experimental result **Test material (common name):** **Cu^{2+} as copper sulphate pentahydrate**	Hébert, C.D. (1993)
mouse (B6C3F1) male/female subchronic (oral: feed) 0, 1000, 2000, 4000, 8000 or 16000 ppm in the feed (providing estimated intakes of 0, 44, 97, 187, 398 and 815 mg Cu/kg bw/day in males and 0, 52, 126, 267, 536 and 1058 mg Cu/kg bw/day in females). (nominal in diet) Exposure: 92 days (7 days per week) equivalent or similar to EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents) (. Method developed by the US NTP specifically for the purposes of this study.)	NOAEL: 1000 ppm (male/female) LOAEL: 2000 ppm (male/female)	1 (reliable without restriction) key study experimental result **Test material (common name):** **Cu^{2+} as copper sulphate pentahydrate**	Hébert, C.D. (1993)

In summary, repeated administration of CuSO4 in the feed for 13 weeks produced effects in the forestomach, liver and kidney in rats (Hébert *et al.,* 1993; Hébert 1993). Effects also occurred in the haematopoietic system, although these were considered to be transient changes secondary to alterations in iron metabolism that were within the range of homeostatic control. The treatment had no effect on a number of reproductive parameters. Forestomach lesions consisted of hyperplasia of the squamous mucosa of the limiting ridge at the junction of the forestomach and glandular stomach. Hepatic changes consisted of histopathological changes (chronic active inflammation) plus significant alterations in several clinical chemistry parameters. Hepatic changes appeared most pronounced in males. Renal toxicity consisted of histopathological changes (increase in cytoplasmic droplets), together with significant alterations in some urinary parameters. Kidney changes were most marked in males. The NOAEL for effects in the forestomach, liver and kidney was 1000 mg CuSO4/kg diet [255 mg Cu/kg diet; 16.3 and 17.3 mg Cu/kg bw/day added to feed in males and females, respectively].

The liver is the critical organ for copper. Minimal to moderate effects (forestomach, liver, kidney) were observed at 509 mg/kg [129 mg CuSO4/kg bw/day; 32 mg Cu/kg bw/day, respectively]. The incidence and severity of the effects were dose-dependent. Inflammation of the liver occurred in male and female animals at 1018 mg/kg [260 mg CuSO4/kg bw/day; 67 mg Cu/kg bw/day, respectively] and above. The results of this study therefore demonstrate minimal to moderate effects at >100 mg CuSO4/ kg bw/day and severe effects of CuSO4 in the kidney and liver > 200 mg CuSO4/ kg bw/day. The bio-accessibility of Cu from copper in massive and powders from as well as from copper coated flakes is below the one of CuSO4 and therefore the data do not warrant a classification of copper for Specific Target Organ Toxicity (STOT). No classification is therefore proposed.

The NTP study summarised above is considered to be the pivotal study for Cu^{2+} presented as copper sulphate pentahydrate and results in an NOAEL of 16.7 mg Cu $^{2+}$/kg/bw/day in the rat. This study will be used in the subsequent calculation of an oral and systemic DNEL.

A chronic study (>= 1 year) is not considered appropriate, as no serious or severe toxicity effects of particular concern were observed in the 90-day study for which the available evidence is adequate for toxicological evaluation and risk characterisation.

5.6.1.2 Repeated dose toxicity: inhalation

The results of studies on repeated dose toxicity after inhalation exposure are summarised in the following table:

Table 34: Studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Sprague-Dawley) male/female subacute (inhalation) (whole body) 0.2, 0.4, 0.8, 2.0 mg/m3 (nominal conc.) 0.21, 0.41, 0.8, 2.0 mg/m3 (analytical conc.) Vehicle: air (Filtered air. Mean temperature and mean relative humidity between 20 °C to 26 °C and 30% to 70%, respectively.) Exposure: 28 days, 6 hours per day.	NOAEL: >= 2 mg/m³ air (male/female) based on: test mat. (The highest dose level tested and based on the lack of findings in the lung weight ratio.) LOEL: 0.2 mg/m³ air (male/female) based on: test mat. (Non-adverse effects were seen at this dose.)	1 (reliable without restriction) key study experimental result Test material: Cu^{2+} as cuprous oxide	Kirkpatrick, D. (2010)

Method	Results	Remarks	Reference
(5 days per week.) OECD Guideline 412 (Repeated Dose Inhalation Toxicity: 28/14-Day)			

A 28 days repeated dose inhalation study on Cu2O was carried out according to OECD Guideline 412, with the addition of a 13 week recovery period and evaluation of adaptation to the test substance (intermediate time points at 0, 1 and 2 weeks). Further additional study endpoints were measurements of copper levels in lung tissue, lung lavage fluid, liver, brain, as well as wet/dry lung weight ratio and clinical chemistry and cytology of bronchoalveolar lavage fluid of all animals. The additional study endpoints were designed to aid in the interpretation of any test substance effects.

The overarching findings of this study were the exposure level-dependent appearance of macrophages in the lung, an increase in neutrophil number in BALF as well as in blood, and an increase in LDH and protein levels in the BALF. An increase in inflammation scores (neutrophil-dominated inflammation) was observed in the lung (the highest score being “mild”), and there was a decrease in the wet/dry lung weight ratio (highest exposure level only). Some nasal findings were reported for the high and medium-high exposures in the males.

The outcome of the study is further summarized as follows:

Macrophages and Neutrophils

The role of macrophages in the lung is to engulf and eliminate foreign bodies such as aerosol particles. It is possible to interpret their appearance in the BALF upon exposure to cuprous oxide particles as a normal part of lung clearance. Macrophages in turn summon neutrophils. Neutrophils are highly motile and attracted by various factors, including the presence of macrophages, and have a number of mechanisms to defend the host, such as phagocytosis, release of granule proteins, or "respiratory burst".

An increase in neutrophil numbers (blood or BALF), in the absence of an immunotoxic endpoint or evidence of injury to lung epithelium, is not necessarily adverse. Neutrophil effects were seen at all exposure levels, and based on the current study endpoints, it cannot be determined whether or not these effects are adverse (See neutrophil evaluation below (by Gary R. Burleson, Ph.D.). It is therefore concluded that the NOAEL based on neutrophil effects is above 2 mg cuprous oxide/m^3),

LDH and Protein in BALF

There was an exposure-dependent increase in LDH11 and total protein levels in the BALF. LDH increased 11-fold in both males and females at the highest exposure compared to control, and 6-fold in both sexes at the medium-high exposure (0.8 mg cuprous oxide/m3) compared to control. The increase in total protein was slightly lower, with 7-fold (males) and 8.5-fold (females) at the highest exposure, and 5-fold for both sexes at the medium high exposure. Neither LDH nor total protein levels increased with duration of exposure from 1 to 4 weeks (satellite group), and both parameters returned to control levels after the recovery period.

LDH- and protein increases in BALF can be a consequence of damage and leakage of the lung epithelium, however, in this study no indication of epithelial damage or irritation was observed microscopically in the lung parenchyma. LDH and protein can also be released by macrophages upon activation, or by neutrophils.

There is a wealth of studies demonstrating that macrophages can release significant amounts of LDH and protein when challenged. It has been shown that non-cytotoxic doses of metals (including copper) can stimulate release of LDH and protein from macrophages in the oral cavity (Wataha, Hanks, and Sun 1995). Increases of 4.5-fold in LDH release from macrophages were observed in chromium exposed macrophages in vitro (Vandana et al. 2006). A doubling of LDH release from alveolar macrophages during a moderate iron challenge (40 μM iron in medium) versus control medium (3 μM iron) has been observed (Wesselius et al. 1999). For copper, 5-fold increases in LDH release from rabbit alveolar macrophages have been observed after 24 hours of exposure (0.1 μM copper in control medium, versus 1000 μM in copper exposed cells) (Labedzka et al. 1989).

In WIL 708003, the increase in LDH and protein observed in the BALF could be a result of macrophages engulfing large amounts of copper or a large number of particles during the process of clearance, especially in the absence of epithelial damage. This is supported by the fact that the number of macrophages in the lung (histiocytosis) increases linearly with exposure, in parallel to the increase in LDH and protein. BALF LDH and -protein levels and lung histiocytosis are the only measured study endpoints that exhibit a linear exposure-response across the exposure concentrations.

Based on the data, it is reasonable to correlate LDH and protein levels with number of macrophages, rather than with tissue damage in the lung (not observed at any dose; no dose response).

Lung Weights

In WIL-708003, the lung weights (both wet and dry) increased as a function of exposure concentration. There was no increase in the wet/dry ratio, indicating that there was no edema at any exposure level. There was a significant decrease in the wet/dry ratio at the highest exposure level only, suggesting an increase in dry components within the lung at the highest exposure level. Since there were no histopathological findings in the lung, the occurrence of increased collagen staining as an indication of fibrosis was studied with several approaches, see below.

Masson Trichrome Staining for Collagen

The WIL study pathologist defined a very slight increase in collagen in the high dose animals (2 mg/m^3) as not toxicologically relevant, as there was minimal and occasionally mild staining also in the control groups. The staining severity scores between treatment and control, as well as after recovery did not differ significantly from each other, and did not allow a conclusion.

The histopathology slides underwent a re-examination for a qualitative histopathological peer-review by German pathologists (Or. Ernst and Or. Rittinghausen, Fraunhofer Institute and Or. Böttner, Histovia). The findings were "very slight" (Fraunhofer) and "mild to moderate" (Histovia) increases in collagen in the high dose animals (2 mg/m^3), with full reversal of the findings after the recovery period. Of the 4 reports (WIL, 2x Fraunhofer, Histovia), only the Histovia report concluded that these findings were statistically significant.

Further discussions with the WIL study director and study pathologist resulted in the conclusion that all doses should be re-assessed by a quantitative computer-based analysis for increases in collagen as a dose-response.

Morphometric Analysis of Lung Fibrosis

Computerized morphometric analyses of lung samples were conducted to more objectively quantitate lung fibrosis. Mean collagen area percentages were higher for the 0.8 mg/m3 group males (↑33.8%) and for the 2.0 mg/m3 group males and females (↑23.9% and ↑16%, respectively). These differences were not statistically significant, and did not increase with dose. For the 0.2 and 0.4 mg/m3 group males, the mean collagen area percentages were slightly higher (↑10.1 %-12.5%; not statistically significant). Mean collagen area percentages for the 0.2, 0.4, and 0.8 mg/m3 group females were not remarkably altered by test substance exposure, yet lung dry weights were higher for the 0.4 and 0.8 mg/m3 group females. Since collagen staining and lung dry weight do not appear to be correlated, it was proposed that macrophages and/or neutrophils cells may contribute to the dry lung weight measurements.

Following the 13-week recovery period, the mean collagen area percentage for the 2.0 mg/m^3 group females remained slightly higher (↑11.2%; 30% mean collagen area percentage in control females, and 33% in test article treated females). This difference was not statistically significant and was reduced from the higher primary necropsy value. For the 2.0 mg/m3 group males at the recovery evaluation, the mean collagen area percentage was negligibly different (↑1.9%) from the control group mean. However, the control group mean was higher than previously seen at the primary necropsy, with control animals displaying 38.7% mean collagen area percentage in lung and test article treated animals (high dose) displaying 39.5%. This increase in collagen staining in control animals after the recovery period is an unexplained finding.

This is perhaps reflective of the staining seen in the control groups in original examination (Masson Trichrome), and, overall, the morphometric analysis shows that there is no dose-response in collagen staining, as well as some unexplained staining in control animals.

Taking together the outcome of the pathology reports and the computerized analysis, there is no significant effect on collagen content of the lung.

Neutrophil evaluation and conclusions of the 28-day inhalation toxicity study (Kirkpatrick, 2010)

At 0.2 mg/m^3, higher blood neutrophil counts were observed following 4 weeks of exposure to cuprous oxide. Inhalation exposure also resulted in a higher proportion of neutrophils in the BALF of rats on study days 5, 12, and 19 (2.0 mq/m3) and at study week 3 (0.2 mg/m^3 or higher).

Most test substance-related effects at 2.0 mg/m^3 appeared to show a peak in the effect prior to completion of 4 weeks of exposure and therefore, the results were consistent with a possible plateau.

The immune system consists of three (3) arms: (1) the innate immunity arm, (2) the cell-mediated immunity arm, and (3) the humoral-mediated immunity arm. Neutrophils are an important component of innate immunity. In immunotoxicity testing, there may be three areas of concern related to neutrophils: (1) decreased neutrophil numbers leading to increased susceptibility to encapsulated bacteria resulting in bacterial pneumonia, (2) decreased neutrophil function leading to increased susceptibility to encapsulated bacteria resulting in bacterial pneumonia, and (3) increased neutrophil numbers/function which may result in persistent, chronic inflammation. In this study, no indication of persistent, chronic inflammation was found (based on plateau for most effects during the exposure period and full recovery of all effects indicative of inflammation after 13-weeks post-exposure). The pattern of responses in the lung and lung-draining lymph nodes in this study following cuprous oxide exposure is typical for inhalation exposure to aerosol particles. Inhalation exposure with cuprous oxide markedly affected neutrophil numbers at all exposure levels in this study (0.2, 004, 0.8, and 2.0 mq/m^3). However, the effects were reversible and there were no observed test substance-related effects on hematology parameters, BALF parameters, or lung histopathology following the 13-week recovery period. The No-Observed-Adverse-Effect-Level (NOAEL) for the neutrophil effects is therefore considered> 2.0 mg/m^3.

It is therefore concluded that the overall NOAEL for this study is >2 mg/m^3.

Neutrophils and copper - additional considerations

When interpreting studies of essential trace elements, it needs to be remembered that these elements also play a role in many biological functions, have tight homeostatic control, and are closely linked to physiology with effects caused by excess exposure as well as deficiency.

Copper deficiency has many effects, including hematological and immune deficiencies. A decrease in white cells is a well-established and sensitive marker of a beginning copper deficiency (see e.g., (Oanzeisen *et al*. 2007)). Accordingly, in many human copper exposure studies, increases in copper dependent endpoints can be observed (e.g., an increase or restoration in activity of S001).

There is currently little direct evidence for copper causing an increase in neutrophil numbers in a copper replete individual, but there are individual reports indicating that copper supplementation does increase white cell activity and counts. A recent study from non-copper deficient cows reports an increase in the in vitro phagocytic activity of neutrophils upon copper supplementation (20 ppm/cow/day) (Oang *et al*. 2012). Similarly, exposure of freshwater fish Channa punctatus to copper sulphate (0.36 mg/L) caused an increase in blood white cell count, while all other hematological parameters were decrease (e.g. red cells, hemoglobin) (Singh *et al*. 2008).

When interpreting the increase of neutrophils in BALF and blood of the study WIL 708003, the strong relationship of these cells with copper needs to kept in mind.

Proposal for a classification

The 4-weeks study in rat, performed with standard guideline is considered the most relevant.

In the 4-weeks study by inhalation in rat, no serious adverse effects were observed at the maximum tested concentration (2 mg/m^3). Therefore, no STOT-RE classification is warranted.

Deriving a DNEL - inhalation

To determine an inhalation DNEL for copper, the results of the above 28-day study in the rat was used to calculate a Human Equivalent Concentration using the Multiple Path Particle Dosimetry (MPPD) model and incorporated available exposure monitoring data from the copper industry based in Germany (EBRC, 2012). In this report, the recalculation of a NOAEL of 2 mg/m^3 from a 28 d - inhalation (rat) toxicity study with cuprous oxide to a human equivalent concentration (HEC) for “copper” is described.

Since the particle size of any copper particle determines its deposition in the respiratory tract, this HEC calculation intrinsically reflects all inter-species variations of physiological and morphological relevance, as well as any other differences between the exposure conditions prevailing for the laboratory animals and those characteristic of workplace exposures.

Of particular relevance for the latter is the consideration of actual workplace-specific particle-size distributions. These were determined in a comprehensive survey of the entire German copper industry, reflecting all foreseeable workplaces with a potential for exposure to fine or ultra-fine copper aerosols.

This aspect is associated with the reasonable anticipation that local effects in the lungs are driven by alveolar deposition of copper particles, which in turn is obviously closely related to the particle size.

When comparing “hot” and “cold” industrial processes, the potential for the generation of ultrafine airborne particles has been shown to be somewhat higher for hot metallurgical processes that than for cold processes, such as mechanical (downstream) processing of copper metal as well as copper powder handling.

For the sake of transparency, the relative influence of various input parameters was analysed with the aid of a Monte Carlo simulation, demonstrating that the major driving factors are the differences in breathing patterns between rats and humans. The particular strength of this analysis is that it allows selecting a percentile cut-off value for each workplace-specific HEC distribution, which intrinsically reflects the variability of all relevant input parameters and avoids the need for an intra-species sensitivity factor.

Using the above NOAEC (rat) as a point of departure, corresponding conservative HEC values of 1.5 mg/m3 and 3.6 mg/m^3 were derived for hot and cold processes, which can be considered as worst-case values that cover the entire range of processes in the copper industry.

These values are also very close to the existing OEL for copper of 1 mg/m^3 and as this value is currently used by many Member States as a legislative limit for copper, it is proposed that this value is retained for the purposes of the REACH risk assessments and used as an inhalation local DNEL for copper. The equivalent respirable OEL (fume) is 0.1 mg/m^3.

5.6.1.3 Repeated dose toxicity: dermal

This study is usually required when the dermal route of exposure is significant and the compound is known to be toxic by the dermal route and can penetrate through intact skin. The need to conduct this study with copper or copper compounds must therefore be considered not necessary as although the dermal route of exposure is the most significant route there is no evidence to indicate that copper or copper compounds can cause toxicity or indeed pass through intact skin at significant levels. Acute dermal toxicity studies showed no toxic effects up to and including the highest dose tested. Therefore an accurate and realistic determination of dermal toxicity can be derived from available sub-chronic oral exposure studies, permissible systemic copper levels and in vitro dermal penetration studies on copper and copper compounds.

5.6.1.4 Repeated dose toxicity: other routes

These studies are not required under REACH regulation data requirements.

5.6.2 Human information

This Section of the Chemical Safety Report discusses and summarises all the available pivotal human health. The VRAR, 2008 provides a full review of all available studies of lower quality and the discussion on the unsuitability/unacceptability of these studies.

Cohort studies in children

The effect of copper supplementation in the drinking water at the then provisional WHO guideline level of 2 mg/L was investigated in formula-fed and breast-fed infants from 3 to 12 months old in Chile (Olivares *et al.,* 1998). Formula-fed infants were weaned from 3 months, while the breast-fed group started solids at six months following an interim period on modified formula milk where necessary. Infants from each feeding modality were randomly assigned to copper-supplemented (Cu+) and control groups. Drinking water was prepared from $CuSO_4$ solution or a placebo and mixed with tap water by the mothers. The Cu+ groups consumed prepared water containing the WHO guideline level of 31.48 µmol Cu/litre (2 mg/litre), while the non-supplemented (control) groups consumed water containing <1.57 µmol Cu/litre (<0.1 mg/litre). This value is based on the authors' estimate of the typical copper content of Santiago drinking water. Mothers of breast-fed infants consumed the same water as their children. Copper content of water used in the study was monitored weekly on a random basis. Water consumption was recorded on a weekly basis; the amount of water used in infant feed was largely based on information provided by the mothers. Estimated total copper consumption (excluding breast milk at 4-6 months) is shown in **Table 35** is noted that estimated copper intake in the control group ranged from 0.8 to 1.6 mg/day, comparable to adult intakes.

Table 35: Estimated copper intake by infants with and without copper supplementation of drinking water

Age	Formula-fed infants (mg/day)		Breast-fed infants (mg/day)	
(months)	Cu+ group n=39	controls n=24	Cu+ group n=11	controls n=15
4-6	2.3 (± 0.8)	0.8 (± 0.5)	0.1 (± 0.2)	0.1 (± 0.2)
6-9	2.5 (± 0.7)	1.2 (± 0.7)	1.5 (± 1.1)	0.8 (± 0.7)
9-12	2.4 (± 0.8)	1.2 (± 0.7)	2.0 (± 1.1)	1.6 (± 1.3)

Blood samples were taken at 6, 9 and 12 months of age and analysed for a range of biochemical parameters. Weekly reporting of gastrointestinal, respiratory and other disorders was conducted during the study. With regard to biochemical parameters measured, serum copper and ceruloplasmin, erythrocyte CuZnSOD and erythrocyte metallothionein were not significantly altered as a function of copper intake or feeding regime. Indicators of liver function (serum bilirubin, glutamic oxaloacetic transaminase (SGOT), glutamic pyruvic transaminase (SGPT) and γ-glutamyl transferase) were also unaffected. Pooled Cu+ groups had increased ceruloplasmin activity at 9 months (p=0.022). This trend was also observed for Cu+ versus control groups of breast fed infants (p=0.003), but was absent at 12 months suggesting either an adaptive mechanism or maturing homeostatic response. With regard to growth rates and morbidity, there were no differences between the groups which were related to copper intake. Episodes of diarrhoea were significantly less frequent in breast-fed infants compared to formula-fed infants, although this was based a single episode. It was noted that 30% of the total starting population was lost during the study mainly due to 'protocol transgression'. Participant dropout from the Cu+ groups (30/80) exceeded that from the control groups (9/48), raising the possibility that infants in the Cu+ groups were preferentially withdrawn for reasons that are unclear. As the authors of the study noted, this may result in under-reporting of symptoms. Nonetheless, the only observed effect in Cu+ children relative to controls was an increase in ceruloplasmin at 9 months, with no change in either serum or blood copper. In conclusion, this study failed to demonstrate any adverse effects in infants who had consumed water with a copper content of 2 mg/litre during the first 12 months of life. Based on this repeat-dosing study, a NOAEL of 2 mg Cu/litre drinking water can be identified for adverse effects in infants, including liver toxicity and GIT effects. Copper in drinking water at concentrations above 2 mg/L were not investigated in this study.

The association between copper content of tap water and the risk of early childhood liver disease was investigated in two cross-sectional epidemiological studies in Germany (Zietz *et al.,* 2003a; 2003b). Both studies involved infants from household with copper plumbing. In the first study, based in Berlin, the study population comprised infants of up to 18 months (Zietz *et al.,* 2003a). 2944 households were involved in the study. Mean copper levels in two different types of composite samples collected from the households were 0.44 ± 0.42 mg/litre and 0.56 ± 0.49 mg/l, respectively (90th percentile values were 0.96 and 1.20 mg/litre, respectively). Infants from households where copper levels were ≥0.8 mg/litre and where infants received ≥200 ml tap water per day for the previous 6 weeks underwent a physical examination (n=541). 183 of these infants additionally underwent blood serum analysis for indicators of liver malfunction (GOT, GPT, GGT and bilirubin), plus serum copper and ceruloplasmin. Among the infants examined, no confirmed cases of liver malfunction could be identified. Further, no significant correlation could be demonstrated between the serum parameters (GOT, GPT, GGT, total bilirubin, serum copper or ceruloplasmin) and estimated daily and total copper intakes of the infants. In conclusion, this epidemiological study demonstrated no evidence of liver disease among infants living in households where copper levels in drinking water were ≥0.8 mg/litre, with maximum values of ~4 mg/litre reported in the wider study.

A fairly similar investigation was conducted in Lower Saxony by the same group (Zietz *et al.,* 2003b). This study involved a smaller population of infants who were aged up to 12 months. Initially copper levels were determined in stagnant water samples (n=1619) and random daytime samples (n=1660) collected from households. Mean copper levels were 0.18 ± 0.33 mg/litre and 0.11 ± 0.22 mg/litre, respectively. Maximum copper levels were 6.4 and 3.0 mg/litre, respectively. Two different types of composite water samples were subsequently collected from 153 of these households (selected on basis of copper levels being ≥0.5 mg/litre in stagnant or random samples). Mean copper levels in the two types of composite samples were 0.55 mg/litre and 0.59 mg/litre, respectively. Fourteen infants from households with ≥0.8 mg/litre and who had received >200 ml water/day underwent paediatric examination; 11 of these additionally underwent blood serum analysis. Among these infants, no evidence of liver malfunction was detected and none were affected by corresponding symptoms of nausea or vomiting. In conclusion, this investigation failed to demonstrate any signs of liver disease among infants living in households where copper levels in water were ≥0.8 mg/litre, with maximum levels of ~6 mg/litre reported in the wider study.

Effects of repeated exposure to copper gluconate were investigated in a poorly reported study by Pratt *et al.,* (1985). In the double-blind study, three men and four women received 10 mg

Cu/day in the form of capsules containing copper gluconate. Seven other subjects received placebo capsules. Samples (blood, urine and hair) were collected at the beginning of the study, and after 6 and 12 weeks of treatment. Samples were analysed for Cu levels and haematological and biochemical parameters. Among the subjects receiving copper supplementation, there was reported to be no significant change during the 12-week treatment period in Cu levels (hair, serum or urine), haematological parameters (haematocrit or mean corpuscular volume) or biochemical parameters (serum cholesterol, triglyceride, alkaline phosphatase, GGT, LDH or SGOT). The incidence of nausea, diarrhoea and heartburn was reported to be similar in copper-treated subjects and placebo controls. A NOAEL of 10 mg Cu/day administered as a supplement is indicated from the results of this study for acute and chronic effects in adults. This was a briefly reported study, presenting few details of the methodology and reporting few results data to support the conclusions. Nevertheless, the study provides an indication of the absence of health effects (acute and chronic) associated with repeated oral intake of 10 mg Cu/day as a supplement in adults. It is noted that the NOAEL of 10 mg Cu/day from this study has been used as the basis of the Scientific Committee on Food's Tolerable Upper Intake Level for copper (http://europa.eu.int/comm/food/fs/sc/scf/index_en.html). In contrast to this approach, the authors of this Risk Assessment consider data from the Pratt *et al.,* (1985) study to be less robust than animal data from the repeated dose toxicity study by Hébert *et al.,* (1993). Consequently, data from the Hébert *et al.,* (1993) study are used to derive an NOAEL for repeated dose toxicity which is taken forward to *'Risk Characterisation'*; results from the Pratt *et al.,* (1985) study are taken forward as supporting data only.

5.6.3 Summary and discussion of repeated dose toxicity

The pivotal repeat dose study was a 90-day study by the oral route with copper sulphate pentahydrate. In rats and mice, ingestion of copper sulphate pentahydrate produced forestomach lesions that could be to the irritant effects of the compound. The NOAEL for this effect was 16.7 mg Cu/kg bw/day in rats and 97 and 126 mg Cu/kg bw/day in male and female mice respectively. In rats inflammation of the liver was observed. The NOAEL's for liver and kidney damage were 16.7 mg Cu/kg bw/day in rats. This is the pivotal study and the NOAEL of 16.7 mg Cu/kg bw/day will be used in the risk characterisation.

5.7 Specific target organ toxicity – repeated exposure (STOT RE):

5.7.1 Repeated dose toxicity, oral:

The liver is the critical organ for copper. The high quality repeated dose study in rats (Hebert (1993) - rat) is retained for assessing classification according to regulation (EC) 1272/2008 as specific target organ toxicant (STOT-RE) –, oral. Classification criteria are not met since no severe adverse effects were observed at the guidance value, oral for a Category 1 classification of 10 mg/kg bw/day and at the guidance value for a Category 2 classification of 100 mg/kg bw/day. No classification required.

5.7.2 Repeated dose toxicity, inhalation:

In the 4-weeks study by inhalation in rat (Kirkpatrick 2010), no serious adverse effects were observed at the maximum tested concentration (2 mg/m3). Therefore, no STOT-RE classification is warranted.

5.7.3 Conclusions:

No classification as STOT-RE under regulation (EC) 1272/2008 is proposed. No classification or SCLs are considered necessary.

5.8 Mutagenicity

5.8.1 Non-human information

5.8.1.1 In vitro data

Table 36: Overview of experimental studies on genotoxicity

Method	Results	Remarks	Reference
Bacterial reverse mutation assay (e.g. Ames test) (gene mutation) Salmonella typhimurium Strains TA98, TA100, TA1535, TA1537, TA102 (met. act.: with and without) Doses: 1.6, 8, 40, 200, 1000 µg/plate and 50, 100, 200, 400, 800 µg/plate in mutation experiments 1 and 2, respectively. OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Evaluation of results: negative Test results: negative for Salmonella typhimurium Strains TA98, TA100, TA1535, TA1537, TA102 (all strains/cell types tested); met. act.: with and without; cytotoxicity: yes (See additional information on results.)	1 (reliable without restriction) key study experimental result **Test material (common name): Cu^{2+} as copper sulphate pentahydrate**	Ballantyne, M. (1994)

The existence of two negative *in vivo* studies (summarised below) negates the need for *in vitro* mammalian cell assays.

Under normal physiological conditions, the concentration of free copper is extremely low *in vivo* and the majority of the copper is bound to ceruplasmin and albumin (See Section 5.1). In addition, cells contain high concentrations of potent antioxidants (e.g. glutathione). Therefore, the biological relevance of any *in vitro* observations would be uncertain where high concentration of the free ion would be available in cell culture growth medium.

From reviews of public domain data (WHO, 1998; VRAR, 2008), the overwhelming weight of evidence indicates that copper sulphate is negative *in vitro* in bacterial cell reverse mutation assays, and in several other bacterial cell assays up to and including cytotoxic doses (1000-~3000 µg/plate). Similar negative findings have also been reported for copper chloride. Results from *in vitro* mammalian cell tests show that copper sulphate is genotoxic only at high, cytotoxic concentrations (up to 250 mg/l).

Therefore it was considered more appropriate to review the genotoxic potential of copper and copper compounds using *in vivo* studies.

5.8.1.2 In vivo data

Table 37: Overview of experimental studies on in vivo genotoxicity

Method	Results	Remarks	Reference
unscheduled DNA synthesis (DNA damage and/or repair) rat (Wistar) male oral: gavage	Evaluation of results: negative Test results: Genotoxicity: negative (male); toxicity: not examined	1 (reliable without restriction) key study experimental result	Ward, P.J. (1994)

Method	Results	Remarks	Reference
632.5 or 2000 mg/kg (actual ingested) equivalent or similar to OECD Guideline 486 (Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo)		**Test material (common name): Cu^{2+} as copper sulphate pentahydrate**	
micronucleus assay mouse (CD-1) male/female oral: gavage 447 mg/kg EU Method B.12 (Mutagenicity - In Vivo Mammalian Erythrocyte Micronucleus Test) (Cited as Directive 2000/32/EC, B.12)	Evaluation of results: negative Test results: Genotoxicity: negative (male/female)	1 (reliable without restriction) key study experimental result **Test material (common name): Cu^{2+} as copper sulphate pentahydrate**	Riley, S.E. (1994)

There are additional equivocal *in vivo* genotoxicity studies in the public domain. However these studies do not adhere fully to OECD guidelines, have unreliable routes of administration (i.v) and are not conducted to GLP. When toxicity studies are conducted with either i.p. and i.v. routes of administration, they bypass the normal uptake and distribution mechanism that is specifically designed to protect the animal from the toxic/reactive Cu^{2+} ion. This invalidates these studies from regulatory decision-making procedures where the normal production and use of the chemical would not result in direct i.v. or i.p. exposure.

Therefore, these studies have been given lower quality criteria than those summarised above and should not be used for either risk assessment purposes or to classify copper compounds. However, the VRAR, 2008 provides a full review of these studies and the discussion on the unsuitability/unacceptability of these studies.

From the results above, copper sulphate pentahydrate, copper and other copper compounds are not considered genotoxic.

5.8.2 Human information

There are no high quality human data available on the genotoxic potential of copper and copper compounds in humans.

5.8.3 Summary and discussion of mutagenicity

There was no evidence of mutagenic activity in *Salmonella typhimurium* strains in the presence or absence of the metabolic activation system when tested with copper sulphate pentahydrate. In vivo studies conducted with copper sulphate pentahydrate did not induce micronuclei in the polychromatic erythrocytes of the bone marrow of mice treated with 447 mg/kg (x2). Copper sulphate pentahydrate did not induce DNA damage according to rat hepatocyte UDS assay.

Consideration of the weight of evidence from *in vitro* and *in vivo* tests, with greatest emphasis being placed on those *in vivo* tests which had the highest study rating, leads to the conclusion that copper and copper compounds are not genotoxic.

5.9 Carcinogenicity

5.9.1 Non-human information

5.9.1.1 Carcinogenicity: oral

All available studies on the carcinogenicity of copper are public domain studies and therefore, taken in isolation are of limited value to ascertain the carcinogenic potential copper compounds. This is due to the fact that these studies are limited due to shorter exposure periods (<2 years) and group sizes being small. However, when the 3 studies summarised below are assessed on an overall balanced approach, the information from these studies does give useful information as to the carcinogenic potential of copper compounds.

Table 38: Overview of experimental studies on carcinogenicity

Route	Species Strain Sex no/group	dose levels frequency of application	Tumours	Reference
Oral, diet 9 months	Rat, Sprague-Dawley, male 50 or 58 animals/group	1 ppm, 800 ppm (0.05, 40 mgCu/kg/bw/day)	Liver necrosis and transitional nodules in the liver (3/32) and transitional nodules in the liver (1/32) were observed at 40 mgCu/kg/bw/day whereas one kidney tumour (1/42) was observed in the low copper group (not thought significant). Decreased body weight gain and increased mortality were found in the high copper group. Exposure to known carcinogens increased the incidence of liver necrosis and transitional nodules and each induced a similar incidence of liver tumours in rats fed excess copper or copper-deficient diets. In the DMN group, 17/30 rats on the copper-deficient diet and kidney tumours compared to 0/29 given excess copper. The incidence of AAF-induced extrahepatic neoplasms was apparently reduced by the excess copper diet. (5/30 vs 11/27).	Carlton *et al.,* 1973. Dietary copper and the induction of neoplasms in the rat by acetylaminofluorene and dimethylnitrosamine. Fd. Cosmet. Toxicol. Vol 11, 827-840.
Oral drinking water 46 weeks	Mouse C57BL/6J, female 10-12 animals/group	198 mg/l (app. 10 mgCu/kg/bw/day)	The incidences of ovarian tumours after 46 weeks were 0/10, 0/12, 11/11 and 6/11 in the untreated controls, copper treated mice, DMBA-treated mice and DMBA-copper-treated mice respectively. This suggests that copper sulphate may possibly inhibit DMBA-induced tumour development. CuSO4 had no effect on the incidence of DMBA-induced adenomas of the lung, lymphomas and breast tumours.	Burki & Okita, 1969. Effects of oral copper sulfate on 7, 12 dimethyl benz(a)anthracene carcinogenesis in mice. Br. J. Cancer Sep. 23(3): 591-596

Route	Species Strain Sex no/group	dose levels frequency of application	Tumours	Reference
Oral diet, 30-44 weeks	Rat, Sprague-Dawley, male and female, 23-26 animals/ group	0, 530 or 1600 ppm Cu (approx. 0, 27 or 80 mg Cu/kg bw./day in males and 0, 40 or 120 mg Cu/kg bw./day in females).	The growth of rats receiving 1600 ppm Cu as $CuSO_4$ was adversely affected, although organ weights were apparently unaffected (other than increased stomach weight in females). Well-defined abnormalities evident in the 1600 ppm treatment group included 'bronzed' kidneys, 'bronzed' or yellowish livers, hypertrophied ridges between cardiac and peptic portions of the stomach and blood in the intestinal tract. Histological examination revealed varying degrees of testicular degeneration in rats from both the 530 ppm and the 1600 ppm groups and effects on the liver were seen in both males and females. There were no reports of evidence of neoplasms in **any treatment group.**	Harrison *et al.,* 1954. The safety and fate of potassium sodium copper chlorophyllin and other copper compounds. Journal of the American Pharmaceutical Association, 43**(12):** 722-737.

All available studies on the carcinogenicity of copper are public domain studies and therefore, taken in isolation are of limited value to ascertain the carcinogenic potential copper compounds and are given a Quality Criteria of 3 individually. This is due to the fact that these studies are limited due to shorter exposure periods (<2 years) and group sizes being small. However, when the 3 available studies are assessed on an overall balanced approach, they give useful information as to the carcinogenic potential of copper compounds.

These results indicate that copper sulphate and other copper salts do not appear to have carcinogenic potential even at very high dose levels of up to 120 mg Cu/kg/bw/day (Harrison *et al.,* 1954). The data in Carlton *et al.,* 1973 are especially useful since positive control groups were added in this study and showed an induction of neoplasms in the rat, indicating that the exposure period (although not two years) was long enough for neoplasms to appear if you have a positive carcinogen. In addition, this study indicates that excess copper may have a protective effect on known carcinogens.

These animal carcinogenicity studies have been conducted with copper compounds. Short duration, small sample sizes and limited histopathologic examination limit the findings of the studies. Nevertheless, the findings of these studies do not raise concerns with respect to carcinogenic activity.

Chronic toxicity investigations in these studies, and in particular, in Harrison *et al.,* 1954, indicate that, as in the pivotal 90-day rat study of Hebert, 1993, the target organs for copper are the liver and kidney. In addition, the longer duration studies indicate that the adverse effects do not appear to become more severe over longer exposure periods (up to one year). This is probably due to the homeostatic control mechanisms present in animals which would regulate the uptake and excretion of copper on a daily basis. As adverse effects are only observed at relatively high levels of copper outside the normal daily intake of copper for humans (up to 10 mg/day), new chronic studies extending over a 2 year time period are not expected to add further insight into the mechanisms of chronic toxicity and carcinogenicity of copper in humans.

In addition, the available genotoxicity studies support the indication that copper compounds have no carcinogenic potential. The studies include Ames assays in Salmonella typhimurium on copper II sulphate pentahydrate; a micronucleus study on copper II sulphate pentahydrate and an unscheduled DNA synthesis ex vivo study in rat liver on copper II sulphate.

The Ames tests indicated that copper sulphate had no mutagenic activity (Ward, 1994). No evidence of an increase in the incidence of micronuclei was detected in the mouse micronucleus study when mice were orally administered two doses of 447 mg/kg copper sulphate, 24 h apart (Riley, 1994). There was also no evidence of unscheduled DNA synthesis in the rat liver (Ballantyre, 1994).

These studies are consistent and show a lack of in vitro mutagenic activity or in vivo clastogenic potential associated with soluble copper compounds. The results of these studies do not highlight a concern regarding the genotoxic potential of copper compounds.

Available data on the genotoxicity and carcinogenicity of copper and its compounds have been considered against EU classification criteria. The available data for copper and copper compounds do not meet the criteria requiring classification for carcinogenicity.

5.9.1.2 Carcinogenicity: inhalation

There are no high quality inhalation data available. However, there is sufficient data available to indicate that copper and copper compounds do not meet the criteria requiring classification for carcinogenicity.

5.9.1.3 Carcinogenicity: dermal

There are no high quality dermal data available. However, there is sufficient data available to indicate that copper and copper compounds do not meet the criteria requiring classification for carcinogenicity.

5.9.1.4 Carcinogenicity: other routes

This is not a data requirement under the REACH regulations.

5.9.2 Human information

This is not a data requirement under REACH regulations.

5.9.3 Summary and discussion of carcinogenicity

Although the available animal and human data on the carcinogenicity of copper and its compounds are deficient in several respects, the findings do not raise concerns with respect to carcinogenic activity. Consequently, further tests investigating this end-point are not recommended.

The studies on carcinogenicity also give information on the chronic effects of copper on rats and mice. The studies, although limited, indicate that at the doses tested, the pivotal endpoint was a reduction in weight gain at the highest dose rates tested. These results indicate that the NOAEL values derived from the sub-chronic effects observed in the NTP study, 1993 could be regarded as worst case for the risk assessment of copper and copper compounds.

5.10 Toxicity for reproduction

There are several studies in the public domain that investigate the reproductive toxicity potential of copper and copper compounds. In many of these studies, positive or equivocal findings have been reported. However, on investigation, it has been shown that these positive findings have been the result of inappropriate routes of administration. These are namely intra peritoneal (i.p.) and intravenous (i.v.) routes. Neither of these routes of administration is representative of exposure of copper and copper compounds through normal production and use. When toxicity studies are conducted with either i.p. and i.v. routes of administration, they bypass the normal uptake and distribution mechanism that is specifically designed to protect the animal from the toxic/reactive Cu^{2+} ion. This invalidates these studies from regulatory decision-making procedures where the normal production and use of the chemical would not result in direct i.v. or i.p. exposure.

For these reasons, these studies have been summarised in the VRAR, 2008 for completeness but will not be used for classification and labelling purposes or risk assessment.

5.10.1 Effects on fertility

5.10.1.1 Non-human information

Available public domain studies on the fertility of copper, taken in isolation are of limited value to ascertain the reprotoxic potential copper compounds over multi-generations. These studies have been given lower quality criteria than those summarised above and should not be used for either risk assessment purposes or to classify copper compounds. However, the VRAR, 2008 provides a full review of these studies and the discussion on the unsuitability/unacceptability of these studies.

Table 39: Overview of experimental studies on fertility

Method	Results	Remarks	Reference
rat (Crl:CD®(SD)IGS BR) male/female two-generation study oral: feed 0, 100, 500, 1000, 1500 ppm (nominal in diet) Exposure: Duration of exposure before mating: At least 70 days for both P1 and F1 animals. See Other information - Table 5. EPA OPPTS 870.3800 (Reproduction and Fertility Effects) OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)	LOAEL (P): > 1500 ppm (male) based on: test mat. (No reproductive toxicity was seen at any concentration.) LOAEL (P): 1500 ppm (female) based on: test mat. (Decreased spleen weight in P1 adult females. No reproductive toxicity was seen at any concentration.) LOAEL (F1): 1500 ppm (male) based on: test mat. (Decreased spleen weight in F1 male weanlings. No reproductive toxicity was seen at any concentration.) LOAEL (F1): 1500 ppm (female) based on: test mat. (Decreased spleen weight in F1 female weanlings. No reproductive toxicity was seen at any concentration.) LOAEL (F2): 1500 ppm (male) based on: test mat. (Decreased spleen weight in F2 male weanlings.) LOAEL (F2): 1500 ppm (female) based on: test mat. (Decreased spleen weight in F2 female weanlings.) NOAEL (P): 1500 ppm (male) based on: test mat. (Equivalent to 23.6 mg Cu/kg bw/day for P1 males during premating.) NOAEL (P): 1000 ppm (female) based on: test mat. (No reproductive toxicity was seen at any concentration. Equivalent to 19.1, 17.0 and 33.8 mg Cu/kg bw/day for P1 females during premating, gestation and the first 2 weeks of lactation, respectively.) NOAEL (F1): 1000 ppm (male) based on: test mat. (No reproductive toxicity was seen at any concentration. Effects were seen in F1 weanlings. Equivalent to 23.5 mg Cu/kg bw/day for adults at 1000 ppm.) NOAEL (F1): 1000 ppm (female) based on: test mat. (No reproductive toxicity was seen at any concentration. Effects were seen in F1 weanlings. 1000 ppm is equivalent to 26.7, 17.1 and 35.2 mg Cu/kg bw/day for F1 females during premating, gestation and the first 2 weeks of lactation, respectively.) NOAEL (F2): 1000 ppm (male) based on: test mat. (No reproductive toxicity was seen at any concentration. Effects were seen in F2 weanlings.) NOAEL (F2): 1000 ppm (female) based on: test mat. (No reproductive toxicity was seen at any concentration. Effects were seen in F2 weanlings.)	1 (reliable without restriction) key study experimental result **Test material (common name): Cu^{2+}** **as copper sulphate pentahydrate**	Mylchreest E. (2005)

The results of Mylchreest, 2005 indicate that under the conditions of this study, the no-observed-adverse-effect level (NOAEL) for reproductive toxicity was 1500 ppm, the highest concentration tested. The NOAEL for P1 and F1 rats and F1 and F2 offspring during lactation was 1000 ppm, based on reduced spleen weight in P1 adult females, and F1 and F2 male and female weanlings at 1500 ppm however the transient reduced spleen weights are not considered a reproductive endpoint as it did not affect growth or fertility.

In compliance with the 'Definition of reproductive toxicity', OECD document ENV/JM/MONO(2001)6 the spleen effect cannot be considered a reproductive effect as this must include:

Adverse effects on sexual function and fertility in adult males and females

Developmental toxicity in the offspring

For a compound to be considered to be a reproductive toxin 'data for animal studies ideally should provide clear evidence of specific reproductive toxicity in the absence of other, systemic, toxic effects'. Therefore as the results of this study do not indicate specific reproductive toxicity at the highest dose level tested, it is proposed that copper sulphate and, after read-across, copper and copper compounds, are not classified as toxic to reproduction.

5.10.1.2 Human information

This is not a data requirement under the REACH regulations.

5.10.2 Developmental toxicity

5.10.2.1 Non-human information

Table 40: Overview of experimental studies on developmental toxicity

Method	Results	Remarks	Reference
rabbit (New Zealand White) oral: gavage 6, 9, or 18 mg Cu/kg bw/day (analytical conc.) Exposure: Duration of exposure: Day 7–28 of gestation. OECD Guideline 414 (Prenatal Developmental Toxicity Study) EPA OPPTS 870.3700 (Prenatal Developmental Toxicity Study) MAFF guideline 59 NohSan Np. 4200 (1985) EU Method B.31 (Prenatal Developmental Toxicity Study)	Maternal toxicity reported at 9 mg/kg bw/d (inappetance and initial weight loss) and 18 mg/kg bw/d (deaths, weight loss). Effects on foetus (increased incidence of some common skeletal variants and 9 and 18 mg/kg d. NOAEL maternal toxicity 6 mg/kg bw/day NOAEL teratogenicity 6 mg/kg bw/day Results discussed in more detail below.	1 (reliable without restriction) key study experimental result Test material (Common name): Copper hydroxide	Munley, S.M. (2003a)

In the developmental toxicity study (Munley 2003), groups of 22 female NZW rabbits were treated orally by gavage on days 7 to 28 of pregnancy with copper hydroxide (0, 6, 9 or 18 mg Cu/kg/bw/day). A preliminary range-finding test, conducted in non-pregnant rabbits, indicated there were no marked differences between several copper compounds (including copper hydroxide, copper (I) oxide and copper oxychloride) in terms of maternal toxicity. In the main study, maternal toxicity was evident at 9 and 18 mg Cu/kg/bw/day. Initial weight loss and reduced food intake occurred at 9 and 18 mg/kg bw/day, followed by partial recovery during the middle/late pregnancy. At the end of the study, bodyweight gain in these two groups was 31% and 72% lower than controls and total food consumption 17% and 30% lower than controls, respectively. Three deaths and two abortions occurred at 18 mg/kg bw/day which appeared to be related to treatment; necropsy of decedents and one aborted animal showed haemorrhagic and/or ulcerative changes in the stomach lining. No deaths occurred at 9 or 6 mg/kg/bw/day. At 9 mg/kg/bw/day, there were no abortions. At 6 mg/kg/bw/day, there was a single abortion on day 27. This abortion was not considered to be treatment-related in view of the absence of abortions at the higher dose level and earlier occurrence of abortions at 18 mg/kg/bw/day. At 6 mg/kg/bw/day, and bodyweight gain and food intake were only marginally lower than controls. There was no difference between treatment groups and controls in the number of pregnant females, or the number of females showing total resorption or with live offspring. There was no difference between treatment and control groups in the number of corpora lutea, implantations, embryonic deaths, live young or percentage of males in litter. At 18 mg/kg/bw/day, mean foetal weight was slightly lower than in controls (9% less). Four malformed foetuses occurred in the study: one with fused ribs (control group); one with ectopic kidney (6 mg/kg/bw/day); two with hemivertebra (18 mg/kg/bw/day). These malformations were all considered to be unrelated to treatment. With regard to fetal skeletal abnormalities, retarded ossification of pelvis and skull showed a slightly increased incidence at 18 mg/kg/bw/day and occurrence of extra ribs was increased at 9 and 18 mg/kg/bw/day compared to controls. It was noted that the occurrence of extra ribs was a common finding in all treatment groups, including the control group (64%, 67%, 80% and 87% incidence at 0, 6, 9 and 18 mg/kg/bw/d, respectively). With regard to fetal visceral abnormalities, none were recorded for any treatment or control group. In conclusion, this study demonstrated maternal toxicity (initial weight loss and reduced food intake) and effects on the fetus (increased incidence of a common skeletal abnormality) following oral exposure of rabbits to copper hydroxide at 9 mg Cu/kg/bw/day and above during pregnancy. There were no indications of fetal abnormalities associated with treatment at up to maternally toxic levels. The NOAEL for maternal toxicity and developmental effects in rabbits in this study was 6 mg Cu/kg/bw/day. Effects on the fetus were considered to be secondary to maternal toxicity and consequently not a specific effect of copper on reproduction.

Maternal toxicity, reported in this study at 9 mg/kg/bw/day, was represented by initial weight loss. These effects are considered to be local effects on the stomach in rabbits which result from gavage administration of copper hydroxide. Consequently, it is considered inappropriate to use data on maternal toxicity from this study as the basis of a repeat-dose NOAEL for copper.

With the addition of the multi generation study to the existing toxicology data base it is considered that sufficient information is now available to adequately evaluate the developmental toxicity potential of copper. The Mychreest, 2005 study (summarised above) is particularly relevant as the rat is considered the best animal model for evaluating the potential hazard effects on human populations.

The 2 generation oral reproduction study, performed in accordance with OECD test guideline 416, provides information on the effects of repeated exposure to the substance during all phases of the reproductive cycle including gestation. In particular, the study provides information on the reproductive parameters, and on development, growth and survival of offspring.

The NOAEL for reproductive toxicity was 1500 ppm, the highest concentration tested. The NOAEL for P1 and F1 rats and F1 and F2 offspring during lactation was 1000 ppm, based on reduced spleen weight in P1 adult females, and F1 and F2 male and female weanlings at 1500 ppm. However the transient reduced spleen weights were not considered a reproductive endpoint as it did not affect growth and fertility.

In compliance with the 'Definition of reproductive toxicity', OECD document ENV/JM/MONO(2001)6 the spleen effect cannot be considered a reproductive effect as this must include:

- Adverse effects on sexual function and fertility in adult males and females
- Developmental toxicity in the offspring

For a compound to be considered to be a reproductive toxin 'data for animal studies ideally should provide clear evidence of specific reproductive toxicity in the absence of other, systemic, toxic effects'

The dietary concentration of 1000 ppm was equivalent to mean daily intakes of copper of 15.2-23.5 mg/kg body weight/day for male rats during premating and 17.0-35.2 mg/kg body weight/day for female rats during premating, gestation and the first 2 weeks of lactation.

Although the principal aim of this study was to investigate reproduction toxicity it also provides important information on the developmental toxicity potential of the test substance. Notably, investigation of F1 and F2 litters showed no test substance related effects on the following parameters:

- pups survival, sex ratio, and survival indices during the lactation period, body weights and clinical observations during lactation,
- macroscopic examination of pups that died during the lactation period, of weanlings with external abnormalities or clinical signs and of randomly selected weanlings,
- microscopic observations of any gross findings and of liver and brain from randomly selected high-dose and control weanlings.

It is therefore considered that all major manifestations of developmental toxicity (including mortality, structural abnormality, altered growth and functional deficiency) are adequately investigated in this study.

The results of the multigeneration study should also be interpreted in conjunction with the rest of the toxicology data base for copper. The following findings are considered relevant when evaluating the reproductive and developmental toxicity potential of the test substance:

- Subchronic and chronic studies show no adverse effects on reproductive organs or endocrine functions,
- Copper salts show no indication of genotoxicity,

It is also important to consider that copper is an essential element and many countries recommend an increased dietary intake of copper during pregnancy. This increased recommendation is because a foetus requires copper levels up to 10 times adult levels. The copper is absorbed across the placenta and is required for healthy growth and development, especially in blood maturation, bone development, heart development and function, brain development and function and the function of 20 key enzymes (Ralph & McArdle, 2001).

The existing toxicology data package therefore supports the conclusion that copper has no reproductive or developmental toxicity potential.

5.10.2.2 Human information

This is not a data requirement under the REACH regulations.

5.10.3 Summary and discussion of reproductive toxicity

The two-generation study in the rat indicates that that under the conditions of this study, the no-observed-adverse-effect level (NOAEL) for reproductive toxicity was 1500 ppm, the highest concentration tested. The NOAEL for P1 and F1 rats and F1 and F2 offspring during lactation was 1000 ppm, based on reduced spleen weight in P1 adult females, and F1 and F2 male and female weanlings at 1500 ppm however the transient reduced spleen weights are not considered a reproductive endpoint as it did not affect growth or fertility.

In compliance with the ‘Definition of reproductive toxicity’, OECD document ENV/JM/MONO(2001)6 the spleen effect cannot be considered a reproductive effect as this must include:

- Adverse effects on sexual function and fertility in adult males and females
- Developmental toxicity in the offspring

For a compound to be considered to be a reproductive toxin ‘data for animal studies ideally should provide clear evidence of specific reproductive toxicity in the absence of other, systemic, toxic effects’. Therefore as the results of this study do not indicate specific reproductive toxicity at the highest dose level tested, it is proposed that copper sulphate and, after read across, copper (copper coated flakes, and copper in powder and massive forms) are not classified as reproductive compounds.

In addition, the existing data base is now sufficient to adequately evaluate the developmental toxicity of copper with particular reference to the newly available two-generation study in the rat.

It is therefore considered inappropriate to consider copper and copper compounds as potential teratogenic compounds due to the complex role of copper in regulating normal foetus development in humans at levels considered higher than would be expected to occur through the normal production and use of any copper compound.

5.11 Other effects

5.11.1 Non-human information

5.11.1.1 Neurotoxicity

Neurotoxicity is not a data requirement under the REACH regulations.

5.11.1.2 Immunotoxicity

Immunotoxicity is not a data requirement under the REACH regulations.

5.11.1.3 Specific investigations: other studies

This is not a data requirement under the REACH regulations.

5.12 Derivation of DNEL(s) /DMELs[8]

5.12.1 Overview of typical dose descriptors for all endpoints

In order to set acceptable DNEL values it is imperative that the determination takes into account the class of compound under review.

It is impossible to investigate the exposure to copper and copper compounds without considering that copper is an essential metal present in human body tissues and fluids at concentrations of parts per million or parts per billion. It is also under tight homeostatic mechanisms that, as discussed in Section 5.1, can control excess copper exposure by changing the rate of systemic uptake or excretion via the bile in humans. Therefore, in assessing the human health effects of copper the essentiality and homeostatic mechanisms have to be taken into account.

In addition, for copper there are both animal studies and human volunteer studies available to determine an appropriate DNEL. For the purposes of this risk assessment, the values used in the human health risk assessment will be determined using both the animal and human data. It will be seen that the outcome of this evaluation is very similar.

[8] The heading has been slightly modified compared to the format given in Annex I of the REACH Regulation (section 7) to clarify the content of the section.

Table 41: Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment

Endpoint		Quantitative dose descriptor (appropriate unit) or qualitative assessment		Associated relevant effect	Remarks on study
		Local	Systemic		
Acute toxicity	oral				
	dermal				
	inhalation				
Irritation/Corrosivity	skin		NA		
	eye		NA		
	resp. tract		NA		
Sensitisation	skin		NA		
	resp. tract		NA		
Repeated dose toxicity sub-acute/ sub-chronic/ chronic	oral	**NA**	**NOAEL 16.7 mg/kg bw/day**		**This is the pivotal study used in the risk assessment**
	dermal	**NA**	**NA**		
	inhalation	**NA**	Discriminating concentration: 2 mg/m^3 air.		
Mutagenicity	in vitro	**NA**	**Negative**		
	in vivo	**NA**	**Negative**		
Carcinogenicity	oral	**NA**	**Negative**		**No study available- endpoint conclusion determined using genotoxicity/ADME and repeat dose studies**
	dermal	**NA**	**NA**		
	inhalation	**NA**	**NA**		
Reproductive toxicity fertility impairment	oral	NA	**Reproductive NOAEL 1500 ppm**		
	dermal	NA	**NA**		
	inhalation	NA	**NA**		
Reproductive toxicity developmental tox	oral	NA	**NOAEL maternal & teratogenicity 6 mg/kg bw/day**		
	dermal	NA	**NA**		
	inhalation	NA	**NA**		

5.12.2 Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-qualitative descriptor for critical health effects

Table 42: DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	Exposure based waiving				Not required as not necessary to conduct risk assessment.
Acute - systemic effects	Inhalation	Exposure based waiving				Not required as not necessary to conduct risk assessment.
Acute - local effects	Dermal	Exposure based waiving				Not required as not necessary to conduct risk assessment.
Acute - local effects	Inhalation	Exposure based waiving				Not required as not necessary to conduct risk assessment.
Long-term - systemic effects	Dermal (external)	DNEL (Derived No Effect Level) for dry copper compounds	137 mg/kg bw/day		repeated dose toxicity	From internal long term systemic DNEL (0.041 mg/kg bw/d derived from 90 days oral repeat dose rat NOAEL (16.7 mg/kg bw/d; oral absorption factor 25% , AF100)) and dermal adsorption factor (0.03%)
Long-term - systemic effects	Dermal (external)	DNEL (Derived No Effect Level) for slurries or copper compounds in solution	13.7g/kg bw/day		repeated dose toxicity	From internal long term systemic DNEL (0.041 mg/kg bw/d derived from 90 days oral repeat dose rat NOAEL (16.7 mg/kg bw/d; oral absorption factor 25% , AF100)) and dermal adsorption factor (0.3%)
Long-term - local effects	oral	Exposure based waiving				No local skin effects are observed and absorption is very low
Long-term - local effects	Inhalation	DNEL (Derived No Effect Level) for inhalable dust.	1 mg Cu/m^3			1 mg Cu/m^3 based on existing national OEL values. Only transient non-adverse effects were observed in a 28 day repeated dose rat inhalation study (1-2 µm, Cu_2O).
*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and the appropriate						

"Assessment factor". It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Table 43: DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - local effects	Dermal					Not required for the risk assessment of copper compounds to the general population as the long term systemic effects (oral) was used in all cases.
Long-term - systemic effects	Dermal (external)					Not required for the risk assessment of copper compounds to the general population as the long term systemic effects (oral) was used in all cases.
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	0.041 mg/kg bw/day	NOAEL: 16.00 mg/kg bw/day (based on AF of 100)	repeated dose toxicity	An internal long term systemic DNEL (0.041 mg/kg bw/d was derived from the 90 days oral repeat dose rat NOAEL (16.7 mg/kg bw/d; oral absorption factor 25%, AF100)) 0.041 mg/kg bw/day was carried forward to the risk characterisation and used for workers and general population
Long-term - systemic effects	Dermal					Not required for the risk assessment of copper compounds to the general population as the long term systemic effects (oral) was used in all cases.
Long-term - systemic effects	Inhalation					Not required for the risk assessment of copper compounds to the general population as the long term systemic effects (oral) was used in all cases.

Long-term - local effects	Dermal					There are no concerns from dermal exposure (LD50>2000mg/kg body weight). The oral absorption of copper ranges between 0.3 and 0.03%. An internal DNEL for workers and the general population was derived from oral exposure. The internal copper dose, derived from dermal exposure and absorption, is combined with the other exposure routes and compared to this internal DNEL.
Long term - local effects	Inhalation					Not required for the risk assessment of copper compounds to the general population as the long term systemic effects (oral) was used in all cases.

*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and the appropriate "Assessment factor". It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Discussion

Long-term systemic DNEL for workers and general population:

This document describes the derivation of a long term DNEL for copper and copper compounds based on homeostatic mechanisms involved in the oral absorption and bioavailability of copper in both rats and humans, available mammalian toxicity data and the understanding that copper is an essential metal.

In deriving a long term DNEL for a substance, there are several factors that have to be taken into account in determining the global assessment factor to be used in the risk characterization. The default values are set as:

Interspecies variation: This is based on the allometric scale as discussed in the Technical Guidance Document and the RIP-8 for human health under REACH and an additional interspecies factor to take into account other differences/similarities between species.

The default values for interspecies variability are as follows:

Allometric scaling based on rat studies	4
Other interspecies differences	2.5
Overall total	10

Intraspecies variation: In the TGD and RIP-8 for REACH the default value for intraspecies variation is 10. This can be reduced when for instance, the risk characterization only considers a sub-population e.g. workers.

Sub-chronic to chronic factor. If no reliable chronic studies are available, then a default value of 2 is used to determine a long term DNEL from sub-chronic NOAELs (e.g. 90 day studies).

It is proposed that the assessment factors used in setting the long-term systemic DNEL for copper should be based on the following assessment factors:

Table 44: **Overview of proposed assessment factors**

	Default Values	Proposed Assessment Factor for copper
Interspecies variation: Allometric scaling – rat Other interspecies variability	 4 2.5	 4 1.25
Intraspecies variation	10	10
Subchronic-chronic factor	2	2
Proposed assessment factor for long term AEL	200	100

It can be seen from the Table, that the only Assessment Factor to change from the default values is Interspecies variability – other observations. It was considered scientifically invalid to change the other factors, especially workers to general population based on the lack of reliable scientific evidence. Therefore this DNEL is acceptable for workers and general population.

The justification for the reduction from 2.5 to 1.25 was based on the similarities observed between rat and human toxicokinetic mechanism for uptake of copper following oral administration. It was not considered relevant to define factors for dermal and inhalation uptake as the pivotal mammalian toxicity studies (90 day rat dietary study) was based solely on the oral route of administration.

The long-term DNEL is therefore calculated using the following studies/criteria:

Pivotal study 90-day oral repeat dose toxicity study in the rat	16.7 mg/kg bw/d
Oral absorption factor	25%
Assessment factor	100
Long-term systemic DNEL	0.041 mg/kg bw/d

Short-term systemic DNEL:

A short-term systemic DNEL can also be calculated from above by taking into account that the 90-day study is an appropriate term of exposure and removing the need for an assessment factor of 2 (sub-chronic-chronic factor). This would result in a short-term systemic DNEL of 0.082 mg/kg bw/d.

External Inhalation DNEL:

The NOAEL from a repeated dose inhalation study is >2 mg/m^3. Using this value as a point of departure, corresponding conservative HEC values of 1.5 mg/m3 and 3.6 mg/m^3 were derived for hot and cold processes, which can be considered as worst-case values that cover the entire range of processes in the copper industry.

These values are also very close to the existing OEL for copper dust of 1 mg/m^3 and as this value is currently used by many Member States as a legislative limit, it is proposed that this value is retained for the purposes of the REACH risk assessments and used as an inhalation local DNEL for copper. The corresponding OEL for copper fume is 0.1 mg/m^3.

The external inhalation DNEL (short-term and long-term) is therefore:

1 mg/m^3 for copper dust.

0.1 mg/m^3 for copper fume.

External Dermal DNEL:

For screening purposes in the human health risk assessment, an external dermal DNEL (short-term and long-term) can be calculated using the proposed systemic DNELs (outlined above) and the dermal penetration factors proposed in Section 5.1.4.2 of 0.03% for dry copper and copper compounds and 0.3% for copper and copper compounds in solution/suspension.

The external long-term DNEL for dermal exposure has been set at 136.67 mg Cu/kg bw/d for dry copper and copper compounds.

The external long-term DNEL for dermal exposure has been set at 13.67 mg Cu/kg bw/d for copper and copper compounds in a slurry/solution.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

The following criteria apply to both anhydrous and hydrated forms of the compound.

6.1 Explosivity

The available information on explosivity is summarised in the following table:

Table 45: Information on explosivity

Method	Results	Remarks	Reference
EU Method A.14 (Explosive properties)	Evaluation of results: non explosive Study results: Explosive under influence of flame: no Remarks: BAM friction test: Negative. BAM hammer fall test: Negative. Koenen steel tube test, 6 mm orifice plate: Negative. Koenen steel tube test, 2 mm orifice plate: Negative. Refer to attached Tables 1 - 3 for full results.	2 (reliable with restrictions) key study experimental result **Test material (Common name): Copper(II) nitrate hydrate** Form: crystalline	Tremain S.P. (2013)

<u>Classification according to GHS</u>

Name: copper dinitrate

State/form of the substance: powder

Reason for no classification: conclusive but not sufficient for classification

6.2 Flammability

<u>Flammability</u>

The available information on flammability is summarised in the following table:

Table 46: Information on flammability

Method	Results	Remarks	Reference
EU Method A.10 (Flammability (Solids))	Evaluation of results: not highly flammable. Study results: Ignition on contact with air: no Remarks: The pile failed to ignite during the 2 minutes that the Bunsen flame was applied. The result of the preliminary screening test obviated the need to perform the main test.	2 (reliable with restrictions) key study experimental result **Test material (Common name): Copper(II) nitrate hydrate** Form: crystalline	Tremain, S.P. (2013)

Data waiving: see CSR section 1.3 Physicochemical properties.

<u>Flash point</u>

Data waiving: see CSR section 1.3 Physicochemical properties.

<u>Classification according to GHS</u>

Name: copper dinitrate

State/form of the substance: powder

Reason for no classification (Flammable gases): conclusive but not sufficient for classification

Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): conclusive but not sufficient for classification

6.3 Oxidising potential

The available information on the oxidising potential is summarised in the following table:

Table 47: Information on oxidising potential

Method	Results	Remarks	Reference
Contact with: fibrous cellulose UN-MTC Procedure O.3 'Gravimetric test for oxidizing solids'.	Evaluation of results: oxidising mean burning rate (mixture 1:1 substance : cellulose): 0.47 g/s mean burning rate (mixture 4:1 substance : cellulose): 1.01 g/s mean burning rate of reference mixture: 1.23 g/s (Mixture 3:1 (calcium peroxide : cellulose)) mean burning rate of reference mixture: 0.44 g/s (Mixture 1:1 (calcium peroxide : cellulose)) mean burning rate of reference mixture: 0.22 g/s (Mixture 1:2 (calcium peroxide : cellulose)) Remarks: Detailed results: Mixture 1:1 (substance : cellulose) Mixture 4:1 (substance : cellulose) The substance/cellulose mixtures (1:1 and 4:1) exhibit a mean burning rate greater than the mean burning rate of a 1:1 mixture of calcium peroxide and cellulose and less than the mean burning rate of a 3:1 mixture of calcium peroxide and cellulose.	1 (reliable without restriction) key study experimental result Form: crystalline Test material (Common name): Copper(II) nitrate 2.5 hydrate	Keldenich, H.-P. (2015)
Contact with: powdered cellulose EU Method A.17 (Oxidising Properties (Solids))	Evaluation of results: no oxidising properties maximum burning rate of reference mixture: 1.471 mm/s (Barium nitrate:Cellulose Ratio = 60:10. The pile burned with a yellow flame with some sparks, produced grey smoke and left grey/black charred remains.) maximum burning rate of test mixture: 1.439 mm/s (Test item:Cellulose Ratio = 70:30. The pile burned with a green/yellow flame which self-extinguished within the initial 30 mm and smouldered along the 200 mm, producing copious grey smoke and left black charred remains.) maximum burning rate of test mixture: 1.123 mm/s (Test item:Cellulose Ratio = 10:90. The pile burned with a yellow flame	2 (reliable with restrictions) disregarded study experimental result Form: crystalline Test material (Common name): Copper(II) nitrate hydrate	Tremain, S.P. (2013)

	with green tinges and some sparks, produced grey smoke and left black charred remains.) maximum burning rate of test mixture: 1.026 mm/s (Test item:Cellulose Ratio = 20:80. The pile burned with a yellow/green flame with some sparks, roduced grey smoke and left black chrred remains.) Remarks: Preliminary Test: The cone burned with a green/yellow flame for 121 seconds, leaving black charred remains.		

Classification according to GHS

Name: copper dinitrate

State/form of the substance: powder

Classification (Oxidising solids): Oxid. Solid 2 (Hazard statement: H272: May intensify fire; oxidiser.)

Reason for no classification (Oxidising gases): conclusive but not sufficient for classification

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

Approach and data-selection for the environmental hazard assessment

In accordance to the copper RA, **the environmental hazard assessment is based on tests carried out with soluble copper species.**

- Studies reporting quantitative dose responses of Cu^{2+} ions, delivered from soluble copper compounds to aquatic and terrestrial organisms are used for the assessment.

- Bioavailability of the Cu^{2+} ions in both laboratory tests and in the environment may be affected by abiotic factors, (such as pH, alkalinity, hardness and DOC for the water compartment) and therefore copper bioavailability is considered for the interpretation of the copper effects data.

Approach for Environmental classification

The high quality short term effects records retained for the hazard classification of copper, discussed by the competent authorities for EU classification and Labelling have been included in the IUCLID data-base.

For the **acute and chronic classification of copper**, information on acute (short term EC50 values) and chronic (long term NOEC/EC10 values) effects of soluble copper compounds to freshwater organisms (fish, invertebrates, algae and aquatic plants) are included in the IUCLID. Considering the large amount of information available, only high quality data derived from standard testing protocols and species were retained. Further considering the data-richness of the copper database, data summaries were carried out: when 4 or more acceptable L(E) C_{50} /NOEC values are available for the same species, the geometric mean of the toxicity values was used as representative toxicity value for that species instead of the lowest value for the species.

Considering the crucial importance of pH of the test media on the copper solubility and ecotoxicity, for the acute and chronic toxicity endpoints, 3 pH categories were distinguished within the acute and chronic ecotoxicity database: pH 5.5-6.5, >6.5-7.5 and >7.5-8.5. The lowest species-specific acute L(E) $C_{50}$and chronic NOEC values at the three pH levels and across pHs were selected as final environmental classification reference values.

For classification purposes, these are to be translated to the respective soluble copper compounds using a molecular weight translation. They are translated to the classification of sparingly soluble copper compounds, copper powders and copper massives using the results of the transformation/dissolutions.

Approach for PNEC derivation

All high quality and ecological relevant chronic data (NOECs and EC10s) (also from non-standard protocols) were retained for the PNEC derivation. This resulted in a large amount of reliable and relevant environmental effects data of soluble copper compounds for a broad range of relevant species, covering key ecological compartments (freshwater, marine waters, freshwater sediments, terrestrial, sewage treatment plants).

The assessment on the environmental hazards recognizes that copper is a natural element and essential nutrient and therefore important additional information of relevance to the PNEC derivations for the freshwater and marine compartments are retained.

- Effects **due to copper deficiency** in addition to the **effects due to copper excess are reported.**

- Information from scientific studies designed to elucidate **the mechanism of action of Cu-ions are reported.**

- Toxicity from **waterborne and dietary exposure** routes are evaluated

- **Single species as well as multi-species laboratory or field test set-ups are assessed.**

- Considering that both the added and the background copper concentrations may contribute to the observed effects, this risk assessment implements the **total risk approach**. Information on **background variability**(in culture media and natural European environments (water, sediments, soils)) and its influence on a number of biological/ecological processes (e. g. optimal concentration ranges, acclimation/adaptation, field community responses) is nevertheless crucial for the derivation of ecological relevant PNEC values and are therefore considered in the chemical safety report.

Derivation of reference values for environmental classification

Acute freshwater reference values for classification

After data selection, as discussed above, 451 high quality acute data points were retained. For the algae 66 individual data points were selected for 3 standard species (*Pseudokirchneriella subcapitata*, *Chamydomonas reinhardtii* and *Chlorella vulgaris*). For the invertebrates 123 individual data points were selected for 2 standard species *(Ceriodaphnia dubia* and *Daphnia magna*) and for the fish 262 individual data points were selected for 5 standard species (*Oncorhynchus mykiss, Pimephales promelas, Lepomis macrochirus, Brachydanio rerio* and *Cyprinus carpio*).

Chronic reference values for classification

After data selection, 90 high quality chronic data points were retained. For the algae/aquatic plants, 33 individual data points were selected for 4 standard species (*Raphidocelis subcapitata, Chlorella vulgaris, Chlamydomonas reinhardti and Lemna minor*). For the invertebrates 23 individual data points were selected for 3 standard species *(Ceriodaphnia dubia, Daphnia magna*). For the fish, 34 individual data points were selected for 3 standard species (*Oncorhynchus mykiss, Pimephales promelas* and *Salvelinus fontanilis*).

The lowest species-specific acute L(E) $C_{50}$and chronic NOEC values at the three pH levels and across pHs were selected as final environmental classification reference values. The derived values acute and chronic reference values are provided in the **Table 48**

Table 48: Acute and chronic reference values for soluble copper ions

pH range	Acute reference L(E) C50 (µg Cu/l)	Chronic reference NOEC (µg Cu/l)
pH 5.5-6.5	**25**	**20**

pH range	Acute reference L(E) C50 (µg Cu/l)	Chronic reference NOEC (µg Cu/l)
pH >6.5-7.5	**35**	**7.4**
pH >7.5-8.5	**29.8**	**11.4**
Across pHs	**34.4**	**14.9**

The details of the assessment is attached to the IUCLID

Ecotoxicological data of relevance to the of aquatic PNEC derivation

The high quality long term effects records used for the PNEC derivation of copper under the Existing Substances Regulation (TCNES) and Biocidal Products regulations (Technical meetings) have been included in the IUCLID data-base. Tests that were considered as not-reliable for the PNEC derivations have NOT been included in the IUCLID records but have been summarized in the copper RA report (2008).

Freshwater effects: The freshwater effect records include 139 high quality single-species chronic NOEC/L(E) C10 values from 27 different aquatic species, representing different trophic levels (fish, invertebrates, algae, aquatic plants).

These NOECS are carried forward for the freshwater PNEC derivation in a WOE approach. These NOECS are also carried forward as a weight of evidence for the freshwater sediment PNEC derivation using the equilibrium partitioning approach.

The copper threshold values derived for three high quality mesocosm studies, representing lentic and lotic systems and including a wide variety of potentially sensitive species (algae, invertebrates and higher plants) are used as additional WOE for the PNEC derivations of the freshwater and the sediment compartment. *The records are included in section 6.6. (additional ecotoxicological information).*

Considering the importance of understanding the mechanism of action (target tissues, diet-borne versus waterborne exposures, influence of acclimation) for defining the uncertainty around the PNEC, relevant supportive papers that are critical to the understanding of the mechanism of action are included in the database.

Considering the importance of bio-availability for reducing the intra-species variability, the data- base includes supportive information related to the development/validation of the copper bio-availability models (so called Biotic Ligand Models) and the physico-chemistry needed for the normalization the individual NOEC values.

Considering the essential functions of copper, the data-base further includes reliable supporting papers on copper deficiency.

More details are provided in the sections chronic toxicity to fish, invertebrates, algae, aquatic plants and additional ecotoxicological information.

Marine effects: The freshwater effect records include 56 high quality single-species chronic NOEC/L(E) C10 values from 24 different aquatic species, representing different trophic levels (fish, invertebrates, algae, aquatic plants).

These NOEC/L(E) C10 values are carried forward for the marine PNEC derivation in a WOE approach. These NOECS are also carried forward for the marine sediment PNEC derivation using the equilibrium partitioning approach.

In response to the recommendation from TCNES and SCHER, a marine mesocosm has been carried out and these results are included in the IUCLID records. The copper threshold value derived for from this high quality marine mesocosm study, was used for as additional WOE for the PNEC derivation. *The record is included in section 6.6. (additional ecotoxicological information).*

Considering the importance of understanding the mechanism of action for defining the uncertainty around the PNEC, supportive papers that are critical to the understanding of the mechanism of action are included in the database.

- Considering the importance of bio-availability for reducing the intra-species variability, the data- base includes supportive information related to the development/validation of the marine organic carbon normalization, key to copper bio-availability in marine systems. The OC normalization model is used for normalizing the NOEC/L(E) C10 values and deriving the marine PNEC.

More details are provided in the sections chronic toxicity to fish, invertebrates, algae, aquatic plants and *additional ecotoxicological information*.

Effects for Sewage Treatment plants: Data on the toxicity tests performed with aquatic bacteria and protozoa, reported as L(E) $C_{50}$and NOEC values are available. The exposure time among reports varied from short term batch exposures to continuous exposures. The effects endpoints on micro-organisms covered are: heterotrophic respiration inhibition, nitrification inhibition and effects on ciliated protozoa.

More details are provided in the section micro-organisms.

Effects for freshwater sediment organisms: The freshwater sediment effect records include 62 high quality single-species chronic NOEC/L(E) C10 values from 6 different sediment-dwelling organisms that are carried forward for the sediment PNEC derivation in a WOE approach..

The data base includes additional information in support of the incorporation of bioavailability in the PNEC derivations

More details are provided in the section sediment effects.

7.1.1 Toxicity data

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

The results are summarised in the following table:

Table 49: Overview of short-term effects on fish

Method	Results	Remarks	Reference
Pimephales promelas freshwater flow-through measurements were conducted by standard EPA methods	LC50 (96 h): 193 µg/L element (meas. (not specified)) LC50 (96 h): 229.9 µg/L element (meas. (not specified)) LC50 (96 h): 230 µg/L element (meas. (not specified)) LC50 (96 h): 256.2 µg/L element (meas. (not specified)) LC50 (96 h): 38.4 µg/L element (meas. (not specified))	2 (reliable with restrictions) key study read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)
Lepomis macrochirus freshwater flow-through methods according to American Public Health Association, 1965	LC50 (96 h): 1100 µg/L element (meas. (geom. mean))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Benoit DA (1975)
Pimephales promelas freshwater static acute toxicity test of copper on fathead minnows	LC50 (96 h): 210 µg/L element (meas. (not specified)) LC50 (96 h): 390 µg/L element (meas. (not specified)) LC50 (96 h): 360 µg/L element (meas. (not specified)) LC50 (96 h): 410 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Birge WJ, Benson WH and Black JA (1983)
Brachydanio rerio (new name: Danio rerio) freshwater semi-static ISO TC147/SC5/WG3 (secretariat 6)	LC50 (96 h): 35 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): copper sulfate (See endpoint summary for justification of read-across)**	Bresch (1982)

Method	Results	Remarks	Reference
Pimephales promelas freshwater static analyses was performed according to the American Public Health Association (1971)	LC50 (96 h): 600 µg/L dissolved (meas. (initial)) LC50 (96 h): 690 µg/L dissolved (meas. (initial)) LC50 (96 h): 750 µg/L dissolved (meas. (initial)) LC50 (96 h): 830 µg/L dissolved (meas. (initial)) LC50 (96 h): 930 µg/L dissolved (meas. (initial)) LC50 (96 h): 980 µg/L dissolved (meas. (initial)) LC50 (96 h): 820 µg/L dissolved (meas. (initial)) LC50 (96 h): 630 µg/L dissolved (meas. (initial)) LC50 (96 h): 750 µg/L dissolved (meas. (initial)) LC50 (96 h): 770 µg/L dissolved (meas. (initial)) LC50 (96 h): 730 µg/L dissolved (meas. (initial)) LC50 (96 h): 860 µg/L dissolved (meas. (initial)) LC50 (96 h): 840 µg/L dissolved (meas. (initial)) LC50 (96 h): 870 µg/L dissolved (meas. (initial))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-99-8 (See endpoint summary for justification of read-across)**	Brungs WA, Geckler JR and Gast M (1976)
Oncorhynchus mykiss freshwater static renewal short term toxicity of copper on trout was tested	LC50 (96 h): 164 µg/L element (total Cu) (meas. (not specified)) LC50 (96 h): 286 µg/L element (total Cu) (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Buckley JA (1983)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through acute toxicity of copper on fish was tested	LC50 (96 h): 890 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Calamari D and Marchetti R (1973)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through test to toxicity of copper depending on hardness, pH and alkalinity of the water using rainbow trout during 96h procedures of the 'standard methods for the examination of water and	LC50 (96 h): 169 µg/L dissolved (meas. (not specified)) LC50 (96 h): 85.3 µg/L dissolved (meas. (not specified)) LC50 (96 h): 83.3 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name):**	Chakoumakos C, Russo RC and Thurston RV (1979)

Method	Results	Remarks	Reference
wastewater' were used	LC50 (96 h): 103 µg/L dissolved (meas. (not specified)) LC50 (96 h): 274 µg/L dissolved (meas. (not specified)) LC50 (96 h): 128 µg/L dissolved (meas. (not specified)) LC50 (96 h): 221 µg/L dissolved (meas. (not specified)) LC50 (96 h): 165 µg/L dissolved (meas. (not specified)) LC50 (96 h): 197 µg/L dissolved (meas. (not specified)) LC50 (96 h): 514 µg/L dissolved (meas. (not specified)) LC50 (96 h): 243 µg/L dissolved (meas. (not specified))	**Copper(II)chloride (See endpoint summary for justification of read-across)**	
Oncorhynchus mykiss (reported as Salmo gairdneri) freshwater flow-through no guideline was followed for the acute toxicity test of copper on steelhead trout, but principles of the committee on methods for toxicity with aquatic organisms (1975) were followed	LC50 (96 h): 28 µg/L element (meas. (not specified)) LC50 (96 h): 17 µg/L element (meas. (not specified)) LC50 (96 h): 18 µg/L element (meas. (not specified)) LC50 (96 h): 29 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 10125-13-0 (See endpoint summary for justification of read-across)**	Chapman GA (1978)
Oncorhynchus mykiss (reported as Salmo gairdneri) freshwater flow-through acute toxicity tests with copper on salmon no guideline followed, but study base on the principles of the 'committee on methods for toxicity tests with aquatic organisms, 1975'	LC50 (96 h): 57 µg/L element (meas. (geom. mean))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper dichloride (See endpoint summary for justification of read-across)**	Chapman GA and Stevens DG (1978)
Pimephales promelas freshwater static detailed uniform methods proposed by the committee on methods for toxicity tests with aquatic organisms were	LC50 (96 h): 136.5 µg/L element (nominal)	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category	Curtis MW, Copeland TL and Ward CH (1979)

Method	Results	Remarks	Reference
followed		approach) **Test material (EC name): Cupric acetate (See endpoint summary for justification of read-across)**	
Pimephales promelas freshwater static acute toxicity test on fathead minnow and copper	LC50 (96 h): 390 µg/L test mat. (nominal)	2 (reliable with restrictions) weight of evidence experimental result **Test material (IUPAC name): copper di(acetate)**	Curtis MW and Ward CH (1981)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through methods were based on principles from the American Public Health Association (1980)	LC50 (96 h): 4.2 µg/L element (meas. (not specified)) LC50 (96 h): 2.8 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material: Cu Sulphate (See endpoint summary for justification of read-across)**	Cusimano RF, Brakke DF and Chapman GA (1986)
Pimephales promelas freshwater static test investigates the acute toxicity of copper on fathead minnow larvae	LC50 (96 h): 79.7 µg/L element (meas. (not specified)) LC50 (96 h): 71.2 µg/L element (meas. (not specified)) LC50 (96 h): 663 µg/L element (meas. (not specified)) LC50 (96 h): 20.5 µg/L element (meas. (not specified)) LC50 (96 h): 12.4 µg/L element (meas. (not specified)) LC50 (96 h): 17.2 µg/L element (meas. (not specified)) LC50 (96 h): 20.3 µg/L element (meas. (not specified)) LC50 (96 h): 21.6 µg/L element (meas. (not specified)) LC50 (96 h): 23.2 µg/L element (meas. (not specified)) LC50 (96 h): 26.7 µg/L element (meas. (not specified)) LC50 (96 h): 26.7 µg/L element (meas. (not specified)) LC50 (96 h): 28 µg/L	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	element (meas. (not specified)) LC50 (96 h): 35 µg/L element (meas. (not specified)) LC50 (96 h): 42.1 µg/L element (meas. (not specified)) LC50 (96 h): 42.6 µg/L element (meas. (not specified)) LC50 (96 h): 62.3 µg/L element (meas. (not specified)) LC50 (96 h): 62.5 µg/L element (meas. (not specified)) LC50 (96 h): 68.6 µg/L element (meas. (not specified)) LC50 (96 h): 70.1 µg/L element (meas. (not specified)) LC50 (96 h): 77.5 µg/L element (meas. (not specified))		
Pimephales promelas freshwater static test investigates the acute toxicity of copper on fathead minnow larvae	LC50 (96 h): 78.9 µg/L element (meas. (not specified)) LC50 (96 h): 81.6 µg/L element (meas. (not specified)) LC50 (96 h): 83.9 µg/L element (meas. (not specified)) LC50 (96 h): 84.3 µg/L element (meas. (not specified)) LC50 (96 h): 94 µg/L element (meas. (not specified)) LC50 (96 h): 96.7 µg/L element (meas. (not specified)) LC50 (96 h): 97.9 µg/L element (meas. (not specified)) LC50 (96 h): 99.6 µg/L element (meas. (not specified)) LC50 (96 h): 101.5 µg/L element (meas. (not specified)) LC50 (96 h): 103.8 µg/L element (meas. (not specified)) LC50 (96 h): 110.9 µg/L element (meas. (not	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	specified)) LC50 (96 h): 111.8 µg/L element (meas. (not specified)) LC50 (96 h): 113.4 µg/L element (meas. (not specified)) LC50 (96 h): 114.6 µg/L element (meas. (not specified)) LC50 (96 h): 117.4 µg/L element (meas. (not specified)) LC50 (96 h): 122.9 µg/L element (meas. (not specified)) LC50 (96 h): 123.3 µg/L element (meas. (not specified)) LC50 (96 h): 125.4 µg/L element (meas. (not specified)) LC50 (96 h): 125.7 µg/L element (meas. (not specified)) LC50 (96 h): 126.6 µg/L element (meas. (not specified))		
Pimephales promelas freshwater static test investigates the acute toxicity of copper on fathead minnow larvae	LC50 (96 h): 127.1 µg/L element (meas. (not specified)) LC50 (96 h): 129.9 µg/L element (meas. (not specified)) LC50 (96 h): 131.1 µg/L element (meas. (not specified)) LC50 (96 h): 132.8 µg/L element (meas. (not specified)) LC50 (96 h): 137.2 µg/L element (meas. (not specified)) LC50 (96 h): 143 µg/L element (meas. (not specified)) LC50 (96 h): 148.7 µg/L element (meas. (not specified)) LC50 (96 h): 150.3 µg/L element (meas. (not specified)) LC50 (96 h): 151 µg/L element (meas. (not specified)) LC50 (96 h): 152 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	LC50 (96 h): 155.7 µg/L element (meas. (not specified)) LC50 (96 h): 158.1 µg/L element (meas. (not specified)) LC50 (96 h): 160.3 µg/L element (meas. (not specified)) LC50 (96 h): 166.7 µg/L element (meas. (not specified)) LC50 (96 h): 167.3 µg/L element (meas. (not specified)) LC50 (96 h): 167.4 µg/L element (meas. (not specified)) LC50 (96 h): 167.4 µg/L element (meas. (not specified)) LC50 (96 h): 168.4 µg/L element (meas. (not specified)) LC50 (96 h): 172.4 µg/L element (meas. (not specified)) LC50 (96 h): 172.6 µg/L element (meas. (not specified))		
Pimephales promelas freshwater static test investigates the acute toxicity of copper on fathead minnow larvae	LC50 (96 h): 172.8 µg/L element (meas. (not specified)) LC50 (96 h): 175.4 µg/L element (meas. (not specified)) LC50 (96 h): 176.9 µg/L element (meas. (not specified)) LC50 (96 h): 181 µg/L element (meas. (not specified)) LC50 (96 h): 182.4 µg/L element (meas. (not specified)) LC50 (96 h): 183 µg/L element (meas. (not specified)) LC50 (96 h): 183 µg/L element (meas. (not specified)) LC50 (96 h): 183 µg/L element (meas. (not specified)) LC50 (96 h): 189.1 µg/L element (meas. (not specified)) LC50 (96 h): 190.6 µg/L	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	element (meas. (not specified)) LC50 (96 h): 190.8 µg/L element (meas. (not specified)) LC50 (96 h): 191.7 µg/L element (meas. (not specified)) LC50 (96 h): 199.8 µg/L element (meas. (not specified)) LC50 (96 h): 223.7 µg/L element (meas. (not specified)) LC50 (96 h): 226.8 µg/L element (meas. (not specified)) LC50 (96 h): 242.6 µg/L element (meas. (not specified)) LC50 (96 h): 253.5 µg/L element (meas. (not specified)) LC50 (96 h): 262.3 µg/L element (meas. (not specified)) LC50 (96 h): 268.4 µg/L element (meas. (not specified)) LC50 (96 h): 271.4 µg/L element (meas. (not specified))		
Pimephales promelas freshwater static test investigates the acute toxicity of copper on fathead minnow larvae	LC50 (96 h): 283.3 µg/L element (meas. (not specified)) LC50 (96 h): 289.1 µg/L element (meas. (not specified)) LC50 (96 h): 289.1 µg/L element (meas. (not specified)) LC50 (96 h): 292.3 µg/L element (meas. (not specified)) LC50 (96 h): 370.3 µg/L element (meas. (not specified)) LC50 (96 h): 405.1 µg/L element (meas. (not specified)) LC50 (96 h): 496 µg/L element (meas. (not specified)) LC50 (96 h): 521 µg/L element (meas. (not specified)) LC50 (96 h): 644.9 µg/L element (meas. (not	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	specified)) LC50 (96 h): 646.8 µg/L element (meas. (not specified)) LC50 (96 h): 653.8 µg/L element (meas. (not specified)) LC50 (96 h): 758.1 µg/L element (meas. (not specified)) LC50 (96 h): 940.4 µg/L element (meas. (not specified)) LC50 (96 h): 953 µg/L element (meas. (not specified)) LC50 (96 h): 892.1 µg/L element (meas. (not specified)) LC50 (96 h): 905.4 µg/L element (meas. (not specified)) LC50 (96 h): 996.3 µg/L element (meas. (not specified)) LC50 (96 h): 698 µg/L element (meas. (not specified)) LC50 (96 h): 752.9 µg/L element (meas. (not specified))		
Pimephales promelas freshwater flow-through measurements were conducted by standard EPA methods	LC50 (96 h): 12.4 µg/L element (meas. (not specified)) LC50 (96 h): 4.4 µg/L element (meas. (not specified)) LC50 (96 h): 21 µg/L element (meas. (not specified)) LC50 (96 h): 19.7 µg/L element (meas. (not specified)) LC50 (96 h): 18.2 µg/L element (meas. (not specified)) LC50 (96 h): 5.9 µg/L element (meas. (not specified)) LC50 (96 h): 26.9 µg/L element (meas. (not specified)) LC50 (96 h): 36.9 µg/L element (meas. (not specified)) LC50 (96 h): 41.1 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Erickson RJ, Benoit DA and Mattson VR (1996)

Method	Results	Remarks	Reference
	LC50 (96 h): 44.7 µg/L element (meas. (not specified)) LC50 (96 h): 46.3 µg/L element (meas. (not specified)) LC50 (96 h): 52.7 µg/L element (meas. (not specified)) LC50 (96 h): 58.5 µg/L element (meas. (not specified)) LC50 (96 h): 70.5 µg/L element (meas. (not specified)) LC50 (96 h): 70.8 µg/L element (meas. (not specified)) LC50 (96 h): 75.8 µg/L element (meas. (not specified)) LC50 (96 h): 77 µg/L element (meas. (not specified)) LC50 (96 h): 92.9 µg/L element (meas. (not specified)) LC50 (96 h): 112 µg/L element (meas. (not specified)) LC50 (96 h): 122.9 µg/L element (meas. (not specified))		
Brachydanio rerio (new name: Danio rerio) freshwater flow-through acute toxicity of copper sulfate was tested on rainbow trout, zebra fish and other fish	LC50 (96 h): 149 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Fogels A and Sprague JB (1977a)
Oncorhynchus mykiss (reported as Salmo gairdneri) freshwater flow-through acute toxicity of copper sulfate was tested on rainbow trout, zebra fish and other fish	LC50 (96 h): 102 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): copper sulfate**	Fogels A and Sprague JB (1977b)

Method	Results	Remarks	Reference
		pentahydrate (See endpoint summary for justification of read-across)	
Pimephales promelas freshwater static acute toxicity of copper on stream fish was tested; test conducted according to routine bioassay methods recommended by the American Public Health Association (1965)	LC50 (96 h): 750 µg/L dissolved (meas. (initial)) LC50 (96 h): 750 µg/L dissolved (meas. (initial)) LC50 (96 h): 660 µg/L dissolved (meas. (initial)) LC50 (96 h): 950 µg/L dissolved (meas. (initial)) LC50 (96 h): > 800 µg/L dissolved (meas. (initial)) LC50 (96 h): 1060 µg/L dissolved (meas. (initial)) LC50 (96 h): 820 µg/L dissolved (meas. (initial)) LC50 (96 h): 940 µg/L dissolved (meas. (initial)) LC50 (96 h): 810 µg/L dissolved (meas. (initial)) LC50 (96 h): 970 µg/L dissolved (meas. (initial)) LC50 (96 h): > 800 µg/L dissolved (meas. (initial)) LC50 (96 h): 780 µg/L dissolved (meas. (initial)) LC50 (96 h): 640 µg/L dissolved (meas. (initial)) LC50 (96 h): > 610 µg/L dissolved (meas. (initial)) LC50 (96 h): > 810 µg/L dissolved (meas. (initial)) LC50 (96 h): > 780 µg/L dissolved (meas. (initial)) LC50 (96 h): 490 µg/L dissolved (meas. (initial)) LC50 (96 h): 1090 µg/L dissolved (meas. (initial)) LC50 (96 h): 920 µg/L dissolved (meas. (initial)) LC50 (96 h): < 640 µg/L dissolved (meas. (initial))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Geckler JR, Honring WB, Neiheisel TM, Pickering QH and Robinson EL (1976a)
Pimephales promelas freshwater static acute toxicity of copper on stream fish was tested test conducted according to routine bioassay methods recommended by the American Public Health Association (1965)	LC50 (96 h): 750 µg/L dissolved (meas. (initial)) LC50 (96 h): 600 µg/L dissolved (meas. (initial)) LC50 (96 h): 680 µg/L dissolved (meas. (initial)) LC50 (96 h): 920 µg/L dissolved (meas. (initial)) LC50 (96 h): 690 µg/L dissolved (meas. (initial)) LC50 (96 h): 820 µg/L dissolved (meas. (initial)) LC50 (96 h): 580 µg/L	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of**	Geckler JR, Honring WB, Neiheisel TM, Pickering QH and Robinson EL (1976b)

Method	Results	Remarks	Reference
	dissolved (meas. (initial)) LC50 (96 h): 760 µg/L dissolved (meas. (initial)) LC50 (96 h): <= 560 µg/L dissolved (meas. (initial)) LC50 (96 h): 650 µg/L dissolved (meas. (initial)) LC50 (96 h): > 830 µg/L dissolved (meas. (initial)) LC50 (96 h): 830 µg/L dissolved (meas. (initial)) LC50 (96 h): 1400 µg/L dissolved (meas. (initial)) LC50 (96 h): 960 µg/L dissolved (meas. (initial)) LC50 (96 h): 820 µg/L dissolved (meas. (initial))	**read-across)**	
Pimephales promelas freshwater flow-through acute toxicity of copper on stream fish was tested test conducted according to routine bioassay methods recommended by the American Public Health Association (1965)	LC50 (96 h): 465 µg/L dissolved (meas. (not specified)) LC50 (96 h): 1000 µg/L dissolved (meas. (not specified)) LC50 (96 h): 645 µg/L dissolved (meas. (not specified)) LC50 (96 h): 540 µg/L dissolved (meas. (not specified)) LC50 (96 h): 865 µg/L dissolved (meas. (not specified)) LC50 (96 h): 650 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Geckler JR, Honring WB, Neiheisel TM, Pickering QH and Robinson EL (1976b)
Lepomis macrochirus freshwater flow-through Copper was added to the stream for 33 months to maintain a concentration that was expected to adversely affect some species of fish and not others. Methods from the American Public Health Association (1965) were used	LC50 (96 h): 4250 µg/L dissolved (meas. (not specified)) LC50 (96 h): 4300 µg/L dissolved (meas. (not specified)) LC50 (96 h): 9150 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Geckler JR, Horning WG, Neiheisel TM, Pickering QH and Robinson EL (1976)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through bioassay was conducted according to standard methods, 1971	LC50 (96 h): 253 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC**	Hale JG (1977)

Method	Results	Remarks	Reference
		name): copper dinitrate (See endpoint summary for justification of read-across)	
Oncorhynchus mykiss freshwater flow-through test are performed according to OECD approved tests	LC50 (96 h): 28.9 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 22.4 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 40 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 70 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 82.2 µg/L dissolved (meas. (geom. mean)) LC50 (96 h): 31.9 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 81.1 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 47.4 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 298 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 30 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 309 µg/L dissolved (meas. (arithm. mean)) LC50 (96 h): 516 µg/L dissolved (meas. (arithm. mean))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-98-7 (See endpoint summary for justification of read-across)**	Howarth RS and Sprague JB (1978)
Oncorhynchus mykiss freshwater flow-through this study investigates the acute toxicity of copper an rainbow trout and the effect of Co/Cu mixtures.	LC50 (96 h): 18 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): Copper(I) chloride hexahydrate (See endpoint summary for justification of read-across)**	Marr JCA, Hansen JA, Meyer JS, Cacela D, Podrabsky T, Lipton J and (1998)
Oncorhynchus mykiss freshwater	LC50 (96 h): 9.5 µg/L element (meas. (not	2 (reliable with restrictions)	Marr JCA, Lipton J, Cacela D,

Method	Results	Remarks	Reference
flow-through acute toxicity of copper was tested in rainbow trout in simulated environment	specified)) LC50 (96 h): 10.5 µg/L element (meas. (not specified)) LC50 (96 h): 12.5 µg/L element (meas. (not specified)) LC50 (96 h): 16.5 µg/L element (meas. (not specified)) LC50 (96 h): 21.5 µg/L element (meas. (not specified))	weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): copper dichloride hexahydrate (See endpoint summary for justification of read-across)**	Hansen JA, Meyer JS and Bergman HL (1999)
Pimephales promelas freshwater static + flow through see MOUNT and STEPHAN, 1967 for full details of the system	LC50 (96 h): 430 µg/L element (meas. (not specified)) LC50 (96 h): 470 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	Mount DI (1968)
Pimephales promelas freshwater static + flow through toxicity to copper was tested on Pimepales promelas by exposing young and/or their parents to copper American Health Association rules were followed	LC50 (96 h): 84 µg/L element (nominal) LC50 (96 h): 75 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-98-7 (See endpoint summary for justification of read-across)**	Mount DI and Stephan CE (1969)
Oncorhynchus mykiss freshwater flow-through procedures in Standard Methods for Examination of Water and Waste Water (APHA 1980) are followed. loading factors of flow through within recommended limits of toxicity tests	LC50 (96 h): 94 µg/L element (meas. (not specified)) LC50 (96 h): > 89 µg/L element (meas. (not specified)) LC50 (96 h): 93 µg/L element (meas. (not specified)) LC50 (96 h): 68 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Mudge JE, Northstrom TE, Jeane GS, Davis W and Hickam JL (1993)
Pimephales promelas freshwater static acute toxicity of copper in diverse media was tested in Pimepales promelas	LC50 (96 h): 232 µg/L dissolved (meas. (not specified)) LC50 (96 h): 363 µg/L dissolved (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category	Nelson H, Benoit D, Erickson R, Mattson V and Lindberg J (1985)

Method	Results	Remarks	Reference
	LC50 (96 h): > 449 µg/L dissolved (meas. (not specified)) LC50 (96 h): 427 µg/L dissolved (meas. (not specified)) LC50 (96 h): 52 µg/L dissolved (meas. (not specified)) LC50 (96 h): 171 µg/L dissolved (meas. (not specified))	approach) **Test material (IUPAC name): copper sulfate (See endpoint summary for justification of read-across)**	
Pimephales promelas freshwater flow-through Procedures used were those described by the American Public Health Association, 1965	LC50 (96 h): 460 µg/L element (meas. (not specified)) LC50 (96 h): 490 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-99-8 (See endpoint summary for justification of read-across)**	Pickering Q, Brugs W and Gast M (1977)
Cyprinus carpio freshwater acute 96h toxicity tests were conducted on Cyprinus carpio. The bioassays were conducted as described by APHA	LC50 (96 h): 810 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Rehwoldt R, Bida G and Nerrie B (1971)
Cyprinus carpio freshwater acute 96h toxicity tests were conducted on Cyprinus carpio	LC50 (96 h): 800 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Rehwoldt R, Menapace LW, Nerrie B and Alessandrello D (1972)
Pimephales promelas freshwater This study investigates the acute toxicity of copper sulfate to fathead minnows	LC50 (96 h): 450 µg/L element (meas. (not specified)) LC50 (96 h): 297 µg/L element (meas. (not specified)) LC50 (96 h): 311 µg/L element (meas. (not specified)) LC50 (96 h): 513 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): copper sulphate pentahydrate (See endpoint summary for justification of read-across)**	Ruchards Vl and Beitinger TL (1995)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through Copper exposure 6d following	LC50 (96 h): 80 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of	Seim WK, Curtis LR, Glenn W and Chapman GA (1984)

Method	Results	Remarks	Reference
fertilization. At week 7 postfertilization, subsamples of 100 alvins were transferred from incubation chambers to aquaria and exposure continued.		substances (category approach) **Test material (Common name): copper chloride (See endpoint summary for justification of read-across)**	
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater flow-through acute toxicity to fish was investigated for copper sulfate	LC50 (96 h): 200 µg/L element (meas. (not specified)) LC50 (96 h): 190 µg/L element (meas. (not specified)) LC50 (96 h): 210 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence experimental result **Test material (IUPAC name): copper sulfate**	Spear P (1977)
Pimephales promelas freshwater flow-through - procedures followed those described by the American Society for Testing and Materials (ASTM, 1980) - renewal tests were done according to the method of Mount and Norberg, 1984 - criteria concentrations for copper were adjusted for water hardness according to guideline of Stephan, Mount, Hansen, Gentile, Chapman and Brungs (1983)	LC50 (96 h): 96 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material: (IUPAC name): cupric nitrate**	Spehar RL and Fiandt JT (1986)
Pimephales promelas freshwater static acute toxicity of metals was tested for 4 different species	LC50 (96 h): 15 µg/L element (meas. (not specified)) LC50 (96 h): 44 µg/L element (meas. (not specified)) LC50 (96 h): > 200 µg/L element (meas. (not specified))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): Copper (II) nitrate trihydrate (See endpoint summary for justification of read-across)**	Schubauer-Berigan MK, Dierkes JR, Monson PD and Ankley GT (1993a)
Lepomis macrochirus freshwater flow-through methods described by the American public health association were used (1976)	LC50 (96 h): 1000 µg/L element (meas. (geom. mean))	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 10125-13-0 (See endpoint summary for**	Thompson KW, Hendricks AC and Cairns J Jr. (1980)

Method	Results	Remarks	Reference
		justification of read-across)	
Lepomis macrochirus freshwater static acute toxicity test of copper salts on bluegills	LC50 (96 h): 770 µg/L element (colorimetric method) (estimated)	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-98-7 (See endpoint summary for justification of read-across)**	Trama FB (1954a)
Lepomis macrochirus freshwater static acute toxicity test of copper salts on bluegills	LC50 (96 h): 710 µg/L element (nominal)	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7447-39-4 (See endpoint summary for justification of read-across)**	Trama FB (1954b)
Pimephales promelas A copper version of the Biotic Ligand Model is described and assessed.		2 (reliable with restrictions) supporting study modelling **Test material (Common name): Soluble copper**	Santore, R.C. *et al.*, (2001)
freshwater animals Assessment of the mechanism of action of Cu in fish and invertebrates.		2 (reliable with restrictions) supporting study review **Test material (Common name): soluble copper**	Grosell M., C. Nielsen, A. Bianchini (2002)

7.1.1.1.2 Long-term toxicity to fish

The results are summarised in the following table:

Table 50: Overview of long-term effects on fish

Method	Results	Remarks	Reference
Pimephales promelas freshwater flow-through equivalent or similar to OECD	NOEC (270 d): 66 µg/L dissolved (meas. (arithm. mean)) based on: number of eggs/spawn	2 (reliable with restrictions) weight of evidence experimental result	Brungs, W.A. *et al.*, (1976)

Method	Results	Remarks	Reference
Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)		**Test material (Common name): Copper sulphate**	
Perca fluviatilis freshwater adult fish: (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (30 d): 188 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Collvin, L. (1984)
Perca fluviatilis freshwater adult fish: (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (30 d): 39 µg/L dissolved (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Collvin, L. (1985)
Pimephales notatus freshwater flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (30 d): 44.1 µg/L based on: growth rate NOEC (60 d): 71.8 µg/L based on: growth rate NOEC (60 d): 71.8 µg/L based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Horning, W.B. & Neiheisel, T.W. (1979)
Oncorhynchus mykiss freshwater juvenile fish: growth flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (60 d): 2.2 µg/L (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Marr, J.C.A. *et al.,* (1996)
Salvelinus fontinalis freshwater life cycle: reproduction, (sub)lethal effects flow-through Determine the effect of copper on Salvelinus fontinalis yearlings following 244 days exposure, using a flow through test system.	NOEC (244 d): 17.4 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (244 d): 17.4 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (244 d): 17.4 µg/L dissolved (meas. (arithm. mean)) based on: number of eggs/spawn NOEC (189 d): 9.5 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (189 d): 9.5 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	McKim, J.M. & Benoit, D.A. (1971)
Pimephales promelas freshwater life cycle: reproduction, (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (330 d): 33 µg/L based on: growth rate NOEC (330 d): 33 µg/L based on: mortality NOEC (330 d): 14.5 µg/L based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Mount, D.I. (1968)
Pimephales promelas	NOEC (327 d): 10.6 µg/L	2 (reliable with	Mount, D.I.

Method	Results	Remarks	Reference
freshwater early-life stage: reproduction, (sub)lethal effects flow-through OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	based on: growth rate NOEC (327 d): 10.6 µg/L based on: mortality NOEC (327 d): 10.6 µg/L based on: reproduction	restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	& Stephan, C.E. (1969)
Oncorhynchus kisutch, Oncorhynchus mykiss freshwater early-life stage: reproduction, (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (61 d): 22 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (61 d): 24 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (61 d): 45 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (61 d): 24 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (60 d): 21 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (60 d): 18 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (61 d): 28 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (61 d): 28 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Mudge, J.E. *et al.,* (1993)
Pimephales promelas freshwater life cycle: reproduction, (sub)lethal effects flow-through OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (187 d): 69.5 µg/L total Cu (meas. (arithm. mean)) based on: growth rate NOEC (187 d): 25.5 µg/L Total Cu (meas. (arithm. mean)) based on: mean number of eggs per female NOEC (97 d): 23 µg/L Total Cu (meas. (arithm. mean)) based on: mean number of eggs per female NOEC (7 d): 22.5 µg/L Total Cu (meas. (arithm. mean)) based on: mean number of eggs per female	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Pickering, Q. *et al.,* (1977)
Salvelinus fontinalis and Ictalurus punctatus freshwater life cycle: reproduction, (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (60 d): 13 µg/L based on: growth rate NOEC (60 d): 13 µg/L based on: mortality NOEC (30 d): 7 µg/L based on: growth rate NOEC (30 d): 21 µg/L based on: mortality NOEC (60 d): 13 µg/L based on: mortality NOEC (60 d): 7 µg/L based on:	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Sauter, S. *et al.,* (1976)

Method	Results	Remarks	Reference
	reproduction (% eggs hatched) NOEC (30 d): 49 µg/L based on: reproduction (% eggs hatched)		
Pimephales promelas freshwater embryo and sac-fry stage: (sub)lethal effects flow-through equivalent or similar to OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	NOEC (28 d): 61 µg/L mean total copper (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Scudder, B. *et al.,* (1988)
Oncorhynchus mykiss freshwater juvenile fish: growth flow-through equivalent or similar to OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	NOEC (78 d): 16 µg/L (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Seim, W.K. *et al.,* (1984)
Neomacheilus barbatulus, Stone Loach freshwater adult fish: (sub)lethal effects flow-through equivalent or similar to OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)	NOEC (64 d): 120 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Solbé, J.F. de L.G. & Cooper, V.A. (1976)
Pimephales promelas freshwater adult fish: (sub)lethal effects flow-through OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	NOEC (32 d): 4.8 µg/L (meas. (arithm. mean)) based on: growth rate NOEC (32 d): 4.8 µg/L (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Spehar, R.L. & Fiandt, J.T. (1985)
Salvenus fontinalis, Oncorhynchus mykiss, Catostomus commersoni and Esox lucius freshwater embryo and sac-fry stage: (sub)lethal effects flow-through Toxicity of copper on fish larvae, juveniles and embryos of brook trout, rainbow trout, brown trout, lake trout, northern pike, white sucker, herring and smallmouth bass was tested in a 35-60 day exposure experiment.	NOEC (45 d): 11.4 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (45 d): 11.4 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (40 d): 12.9 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (40 d): 12.9 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (35 d): 34.9 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (35 d): 34.9 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (60 d): 22.3 µg/L dissolved (meas. (arithm. mean)) based on: growth rate NOEC (60 d): 22.3 µg/L	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	McKim J.M., J.G. Eaton and G.W. Holcombe (1978)

Method	Results	Remarks	Reference
	dissolved (meas. (arithm. mean)) based on: mortality		
test species not applicable freshwater Develop a chronic fish BLM, using chronic toxicity data from literature.	Fish BLM parameters applicable to fish :	2 (reliable with restrictions) supporting study Modelling **Test material (Common name): soluble copper**	De Schamphelaere, K.A.C. and Janssen C.R. (2004)
Atherinops affinis saltwater life cycle: reproduction, (sub)lethal effects static Three tests are reported, designed to determine effects of copper on fertilisation, embryos and larvae. The fertilization test consisted of exposing sperm to the toxicant, mixing eggs and sperm, and then measuring percentage fertilization. Three embryo experiments were conducted to assess developmental toxicity. The larval test was a 96 -h static toxicity test that measured lethality.	NOEC (12 d): 123 µg/L dissolved (meas. (not specified)) based on: embryo abnormalities NOEC (12 d): 123 µg/L dissolved (meas. (arithm. mean)) based on: hatchability NOEC (12 d): 63 µg/L dissolved (meas. (arithm. mean)) based on: young abnormalities NOEC (12 d): 115 µg/L dissolved (meas. (arithm. mean)) based on: embryo abnormalities NOEC (12 d): 115 µg/L dissolved (meas. (arithm. mean)) based on: hatchability NOEC (12 d): 68 µg/L dissolved (meas. (arithm. mean)) based on: young abnormalities NOEC (12 d): 55 µg/L dissolved (meas. (arithm. mean)) based on: embryo abnormalities NOEC (12 d): 55 µg/L dissolved (meas. (arithm. mean)) based on: young abnormalities NOEC (12 d): 55 µg/L dissolved (meas. (arithm. mean)) based on: young abnormalities	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Anderson, B.S., Middaugh, D.P., Hunt, J.W., and Turpen, S.L. (1991)
Cyprinodon variegatus saltwater juvenile fish: growth flow-through OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	NOEC (7 d): 109 µg/L dissolved (meas. (arithm. mean)) based on: number hatched NOEC (32 d): 109 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (32 d): 57.8 µg/L dissolved (meas. (arithm. mean)) based on: embryo development (weight) NOEC (32 d): 57.8 µg/L dissolved (meas. (arithm. mean)) based on: embryo	1 (reliable without restriction) weight of evidence experimental result **Test material (CAS number): 10125-13-0**	Hurd, K.S. (2006a)

Method	Results	Remarks	Reference
	development (length)		
several fish species This paper explores whether the chronic effects of Cu exposure can be explained by the effects of Cu on neuro-endocrine functions in fish.	toxicity to target tissues is broadly the same from chronic sub-lethal exposure as from acute exposures :	2 (reliable with restrictions) supporting study Review **Test material (Common name): soluble copper**	Handy, R.D. (2003)
Salmo gairdneri (new name: Oncorhynchus mykiss) Growth rate of Rainbow trout (Salmo gairdneri) with varying, copper, pH and hardness combinations was assessed during three 10-days periods	Regression analysis indicated that only Cu^{2+} and CuOH+ could be significantly correlated with growth rate. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Waiwood, K.G. & Beamish, F.W.H. (1978a)
Salmo gairdneri (new name: Oncorhynchus mykiss) Critical swimming velocities of Salmo gairdneri were determined in different combinations of copper, pH and hardness. Measurements were made after exposure for 0,5, 5, 10, and 30 days.	pH and hardness influenced copper toxicity :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Waiwood, K.G. & Beamish, F.W.H. (1978b)
Pimephales promelas Pimephales promelas larvae toxicity tests were conducted using different Natural organic matter isolates?	despite significant differences due to NOM source on copper toxicity, DOC and HA concentrations were the most effective parameters in explaining variability in LC50 values :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Ryan, A.C. *et al.,* (2004)
Pimephales promelas The effects of various water chemistry parameters on the toxicity of copper to larval fathead minnows were investigated.	A variety of copper species might be contributing to toxicity and it is evident that toxicity is also affected by water chemistry in ways not related to copper speciation :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper sulphate**	Erikson, R.J. *et al.,* (1996)
Fundulus heteroclitus Cu toxicity across the full salinity range was determined for the early life stages of Killifish, Fundulus heteroclitus.	fish are more sensitive in freshwater followed by marine waters and least sensitive in estuarine waters.. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper sulphate**	Grosell, M. *et al.,* (2007)

Discussion

NOECS for freshwater fish:

High quality chronic NOEC/(L(E) C10 values are available for 10 species*: Ictalurus punctatus, Oncorhynchus kisutch, Oncorhynchus mykiss, Salvelinus fontinalis,* Pimephales promelas, Pimephales notatus, Perca fluviatilis, Noemacheilus barbatulus, Catostomus commersoni; Esox lucius. Individual high quality NOEC/(L(E) C10 values from different studies range between 2.2 µg/l Cu for the rainbow trout *Oncorhynchus mykiss*(endpoint growth) to 188 µg/l Cu for the perch *Perca fluviatilis* (endpoint mortality). The NOECs are used to derive high quality 'species geometric mean' NOEC values for the most sensitive endpoint for each of the 10 species of fish. These species-specific NOEC/EC10s range from 11.6 µg Cu/L (*Oncorhynchus mykiss,; growth*) to 56.2 µg Cu/L (*Pimephales notatus, growth*). These values are carried forward to the PNEC derivation.

Important intra-species variability in NOEC: L(E) C10 values are observed due to differences in the physico-chemistry of the test waters. The effects data from 2 fish species (*Pimephales promelas* (Erickson *et al.,* 1996)) and *Oncorhynchus mykis (*Waiwood and Beamish, 1979) were used to develop a chronic fish Biotic Ligand Model (De Schamphelaere and Janssen, 2004), useful to the normalization of the NOECS and thus the reduction of the intra-species variability.

Several papers address the mechanism of action of copper after acute and/or chronic exposures: Santore et al.(2001), Handy (2003), Grosell et al.(2002) and Grosell 2007. Interestingly Grosell *et al.,* (2002) provides a mechanistic understanding of the observed higher sensitivity in smaller organisms.

Within the ecotoxicity data base, a decreased growth of *O. mykiss* below 7.8 µg Cu/l and above 16 µg Cu/l indicating an optimal concentration range for copper between 8 & 16 µg Cu /L. Below 7.8 µg Cu/L, a copper deficiency was observed (Seim *et al.,* 1984).

NOECS for Marine fish:

13 high quality chronic single-species NOEC: L(E) C10 values are available for 2 species of marine fish. Individual NOEC: L(E) C10 values range between 55 and 123 µg Cu/L (Both values for Atherinops affinis, reproduction (hatchling growth parameters)). The retained species-specific NOECs are 55 µg Cu/L for topsmelt Atherinops affinis and 57.8 µg Cu/L for sheepshead minnow Cyprinodon variegates. The database contains some records, supportive to the understanding of the mechanism of action on copper. Grosell (2007) provides a mechanistic understanding of the observed lesser sensitivity in estuarine environments compared to freshwater or marine environments.

<u>The following information is taken into account for long-term fish toxicity for the derivation of PNEC:</u>

High quality chronic single-species NOEC/(L(E) C10 values are available for 10 freshwater fish species. A chronic fish Biotic Ligand Model was developed for 2 fish species. These NOECS and the chronic fish Biotic ligand models (BLM) are carried forward to the risk characterisation.

High quality chronic single-species NOEC/(L(E) C10 values are available for 2 marine fish species. These NOECS are carried forward to the risk characterisation.

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 51: Overview of short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Ceriodaphnia dubia freshwater semi-static standard procedures for ceriodaphnia (method 1002.0 USEPA, 1985b) was followed	LC50 (48 h): 14 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 52 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 56 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 28 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 76 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 84 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 31 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 91 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 93 µg/L element (meas. (geom. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Belanger SC and Cherry DS (1990)
Daphnia magna freshwater static - Procedures outlines by the American Public Health Association were used - This study investigates the acute and chronic effects of copper and other metals on Daphnia magna	LC50 (48 h): 9.8 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 60 µg/L element (meas. (geom. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (CAS number): 7447-39-4**	Biesinger KA and Christensen GM (1972)
Daphnia magna freshwater static 48h test on Daphnia and guppies to copper toxicity	LC50 (48 h): 31.8 µg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Brognmann U and Ralph KM (1983)
Daphnia magna freshwater static - Test were conducted on Daphnia magna to compare their sensitivity to chemicals and to evaluate the effect of temperature - Toxicity procedures are based on recommendations in Standard Methods (APHA, 1974) and modified as appropriate	LC50 (48 h): 7 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 10 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 40 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 70 µg/L element (meas. (not	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 7758-99-8 (See endpoint summary for justification of read-across)**	Cairns J Jr, Buikema AL Jr, Heath AG and Parker BC (1978)

Method	Results	Remarks	Reference
	specified)) based on: mortality LC50 (48 h): 90 µg/L element (meas. (not specified)) based on: mortality		
Ceriodaphnia dubia freshwater static renewal test were conducted with reconstituted hard water as recommended by the US EPA (1989)	LC50 (48 h): 8.5 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 8.5 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 10.8 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 10.8 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 39.6 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 39 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 46.9 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 46.3 µg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulfate pentahydrate (See endpoint summary for justification of read-across)**	Cerda B and Olive JH (1993)
Daphnia magna freshwater static acute and chronic toxicity test on daphnia magna to copper	LC50 (48 h): 26 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 30 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 38 µg/L element (meas. (geom. mean)) based on: mortality LC50 (48 h): 69 µg/L element (meas. (geom. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 10125-13-0 (See endpoint summary for justification of read-across)**	Chapman GA, Ota S and Resht F (1980)
Daphnia magna freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 792 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 686 µg/L dissolved (meas. (arithm. mean)) based on: mobility	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	De schamphelaere KAC, Heijerick DG and Janssen CR (2002)

Method	Results	Remarks	Reference
	EC50 (48 h): 648 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 332 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 295 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 40.9 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 529 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 37.9 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 33.8 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 366 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 276 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 399 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 188 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 257 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 281 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 484 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 175 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 119 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 35.2 µg/L dissolved (meas. (arithm. mean)) based on: mobility		
Daphnia magna freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 100 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 200 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 106 µg/L	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	De Schamphelaere KAC, Heijerick DG and Janssen CR (2002a)

Method	Results	Remarks	Reference
	dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 276 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 292 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 92.6 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 210 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 152 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 526 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 826 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 388 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 157 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 136 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 229 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 244 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 100 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 1213 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 421 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 300 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 289 µg/L dissolved (meas. (arithm. mean)) based on: mobility		
Daphnia magna freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 117 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 109 µg/L dissolved (meas. (arithm.	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC**	De Schamphelaere KAC, Heijerick DG and Janssen CR (2002b)

Method	Results	Remarks	Reference
	mean)) based on: mobility EC50 (48 h): 465 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 798 µg/L dissolved (meas. (arithm. mean)) based on: mobility EC50 (48 h): 380 µg/L dissolved (meas. (arithm. mean)) based on: mobility	**name): copper**	
Daphnia magna freshwater static acute 48h toxicity study of copper on D magna	LC50 (48 h): 20 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 22 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 23 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 25 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 26 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 27 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 27 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 28 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 28 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 32 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 33 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 34 µg/L dissolved (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Lazorchak JM (1987)

Method	Results	Remarks	Reference
	LC50 (48 h): 36 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 37 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 39 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 42 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 43 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 44 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 46 µg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 52 µg/L dissolved (meas. (not specified)) based on: mortality		
Daphnia magna freshwater static renewal - study was conducted with daphnia magna to determine the effect of derived copper 48-h LC50 - standardized methods were used (exception: test solutions were prepared in 4 L amounts 18 to 24h before use)	LC50 (48 h): 31 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 38 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 35 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 58 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 37 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 51 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 39 µg/L element (meas. (not	2 (reliable with restrictions) weight of evidence experimental result **Test material (EC name): copper**	Lazorchak JM and Waller WT (1993)

Method	Results	Remarks	Reference
	specified)) based on: mortality LC50 (48 h): 50 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 52 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 31 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 30 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 46 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 63 µg/L element (meas. (not specified)) based on: mortality		
Daphnia magna freshwater static No standard guideline was followed but the test procedure for the toxicity tests and the culture technique followed that of the USEPA (1975).	LC50 (48 h): 26 µg/L element (measured average) (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (IUPAC name): copper oxide**	Lewis MA (1983)
Ceriodaphnia dubia freshwater static acute toxicity test were performed an C dubia in diverse pH and different metals	LC50 (48 h): 9.5 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 28 µg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 200 µg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (EC name): Copper (II) nitrate trihydrate (See endpoint summary for justification of read-across)**	Schubauer-Berigan MK, Dierkes JR, Monson PD and Ankley GT (1993b)
Ceriodaphnia dubia freshwater static - procedures followed those described by the American Society for Testing and Materials (ASTM, 1980) - criteria concentrations for copper were adjusted for water hardness according to guideline of Stephan, Mount, Hansen, Gentile, Chapman and	LC50 (48 h): 66 µg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (CAS number): 10031-43-3 (See endpoint**	Spehar RL and Fiant JT (1986)

Method	Results	Remarks	Reference
Brungs (1983)		**summary for justification of read-across)**	
Daphnia magna Assessment of the relation between the concentration of dissolved natural organic matter and free Cu2+in surface waters, and the biological effect (48 h–median effective concentration [EC50] Daphnia magna, mobility).	These observations consistently show that the presence of organic matter decreases the bioavailability, uptake, and ecotoxicity of copper in the aquatic environment :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper chloride**	Kramer, K.J.M. *et al.,* (2004)
Daphnia magna The extent to which Ca2+, Mg2+, Na+, K+ ions and pH independently mitigate acute copper toxicity for the cladoceran Daphnia magna was examined	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	De Schamphelaere, K.A.C. & Janssen, C.R. (2002)
Daphnia magna OECD Guideline 211 (Daphnia magna Reproduction Test)	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	De Schamphelaere, K.A.C *et al.,* (2002)

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 52: Overview of long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Campeloma decisum (snail) freshwater flow-through The effect of copper on the growth and mortality on Campeloma decisum following a 42 days exposure was investigated. Copper sulphate delivered the Cu^{2+} ion in a flow-through test system.	NOEC (42 d): 8 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Arthur, J.W. & Leonard, E.N. (1970)
Ceriodaphnia sp. freshwater semi-static equivalent or similar to OECD guideline 202	NOEC (7 d): 6.3 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (7 d): 24.1 µg/L dissolved (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Belanger, S.E. *et al.,* (1989)
Ceriodaphnia sp. freshwater static	NOEC (7 d): 10 µg/L dissolved (meas. (arithm. mean)) based on:	2 (reliable with restrictions) weight of evidence	Belanger, S.E. & Cherry, D.S. (1990)

Method	Results	Remarks	Reference
USEPA method 1002.0	reproduction NOEC (7 d): 20 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (7 d): 20 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (7 d): 20 µg/L dissolved (meas. (arithm. mean)) based on: reproduction	experimental result **Test material (Common name): soluble copper**	
Ceriodaphnia sp. freshwater equivalent or similar to OECD guideline 202	NOEC (7 d): 10 µg/L based on: reproduction NOEC (7 d): 20 µg/L based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Cerda, B and Olive, J.H. (1993)
Hyalella azteca freshwater static The effect of copper on the mortality of Hyalella azteca following a 10 days exposure was investigated	NOEC (10 d): 50 µg/L based on: mortality NOEC (10 d): 50 µg/L based on: mortality NOEC (10 d): 82 µg/L based on: mortality NOEC (10 d): 82 µg/L based on: mortality NOEC (10 d): 30 µg/L based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Deaver, E. & Rodgers, J.H. (1996)
Paratanytarus parthenogeneticus freshwater static The effect of copper on the growth and reproduction of Paratanytarsus parthenogeneticus larvae following a 16 day exposure period was examined.	NOEC (16 d): 40 µg/L based on: growth NOEC (16 d): 40 µg/L based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Hatakeyama, S. & Yasuno, M. (1981)
Gammarus pulex freshwater flow-through The population response of Gammarus pulex, following 100 days of copper exposure, was examined	NOEC (100 d): 11 µg/L dissolved based on: Population response	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Maund, S.J. *et al.,* (1992)
Clistoronia magnifica freshwater flow-through The effect of copper on the life cycle of the first and second generation of Clistoronia magnifica following a 240 days exposure was investigated.	NOEC (240 d): 8.3 µg/L based on: life cycle NOEC (240 d): 13.8 µg/L based on: life cycle	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Nebeker, A.v. *et al.,* (1984)
Juga plicifera freshwater flow-through Method: other: see freetext	NOEC (30 d): 6 µg/L dissolved (meas. (not specified)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material**	Nebeker, A. V., A. Stinchfield, C. Savonen and G. A. Chapman (1986)

Method	Results	Remarks	Reference
		(Common name): Copper chloride	
other aquatic crustacea: Hyalella azteca freshwater semi-static Neonates were exposed for a 35-day period to a range of copper concentrations, nominally 18µg/L, 40µg/L, 70µg/L and 260µg/L. The reproductive status of the population was assessed by recording recruitment, the number of precopulatory pairs and number of gravid females. At the end of the experiment, the body lengths of individuals were measured using image analysis	NOEC (35 d): 32 µg/L based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper compound**	Othman, M.S. and Pascoe, D. (2002)
Chironomus riparius freshwater semi-static The effect of copper on the growth of Chironomus riparius eggs following 10 days exposure was assessed.	NOEC (10 d): 16.9 µg/L based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Taylor, E.J. *et al.,* (1991)
Daphnia magna freshwater flow-through and semistatic The effect of copper on the growth (carapace length), mortality and population growth (intrinsic rate of natural increase) of Daphnia magna neonates was determined, following 21 days exposure.	NOEC (21 d): 12.6 µg/L dissolved (meas. (not specified)) based on: growth NOEC (21 d): 36.8 µg/L dissolved (meas. (not specified)) based on: mortality NOEC (21 d): 36.8 µg/L dissolved (meas. (not specified)) based on: population growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	van Leeuwen, C.J. *et al.,* (1988)
Daphnia magna freshwater semi-static OECD Guideline 211 (Daphnia magna Reproduction Test) (N°202 for Daphnia magna)	NOEC (21 d): 28 µg/L based on: reproduction NOEC (21 d): 21.5 µg/L based on: reproduction NOEC (21 d): 71.4 µg/L based on: reproduction NOEC (21 d): 68.8 µg/L based on: reproduction NOEC (21 d): 106 µg/L based on: reproduction NOEC (21 d): 181 µg/L based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Heijerick D., Bossuyt B. and Janssen C. (2001)
Ceriodaphnia sp. freshwater semi-static The effect of copper on the mortality and reproduction of Ceriodaphnia dubia neonates after 7 days exposure was assessed.	NOEC (7 d): 19 µg/L based on: mortality NOEC (7 d): 10 µg/L based on: reproduction NOEC (7 d): 4 µg/L based on: mortality NOEC (7 d): 4 µg/L based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Jop, K.M. *et al.,* (1995)

Method	Results	Remarks	Reference
Ceriodaphnia sp. freshwater renewal and static equivalent or similar to OECD Guideline 211 (Daphnia magna Reproduction Test) (Guideline 202)	NOEC (7 d): 122 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (7 d): 31.6 µg/L dissolved (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper dinitrate**	Spehar, R.L. & Fiandt, J.T. (1985)
Daphnia pulex freshwater renewal This study evaluated the effects of water hardness and humic acid (HA) on the acute and chronic toxicity of copper to Daphnia pulex and on its accumulation by *D. magna*.	NOEC (42 d): 4 µg/L dissolved based on: mortality NOEC (42 d): 20 µg/L dissolved based on: mortality NOEC (42 d): 30 µg/L dissolved based on: mortality NOEC (42 d): 5 µg/L dissolved based on: mortality NOEC (42 d): 20 µg/L dissolved based on: mortality NOEC (42 d): 40 µg/L dissolved based on: mortality NOEC (42 d): 10 µg/L dissolved based on: mortality NOEC (42 d): 15 µg/L dissolved based on: mortality NOEC (42 d): 20 µg/L dissolved based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Winner, R.W. (1985)
Brachionus calyciflorus (freshwater rotifer) freshwater static test protocol 8420 of the APHA	NOEC (2 d): 8.2 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (2 d): 31.2 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (2 d): 47.8 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (2 d): 103 µg/L dissolved (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	De Schamphelaere, K.A.C. *et al.,* (2006)
other aquatic mollusc: Dreissena polymorpha freshwater semi-static This work assessed the potentialities of the zebra mussel Dreissena polymorpha and the aquatic moss	NOEC (27 d): 21 µg/L dissolved (meas. (arithm. mean)) based on: filtration rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Mersch, J., E. Morhain and C. Mouvet (1993)

Method	Results	Remarks	Reference
Rhynchostegium riparioides as indicators of freshwater heavy metal contamination. Simultaneous copper exposure of the two species was performed in the same experimental system developed to fulfil the food requirements of the mussels. The filtration rates of the mussel were used for the assessment of the effects from copper exposure.			
other aquatic mollusc: Villosa iris freshwater flow-through The sensitivity of glochidial stages of unionid mussels was evaluated in a series of exposures to aqueous copper.	NOEC (30 d): 19.1 µg/L dissolved (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Jacobson, P.J., R.J. Neves, D.S. Cherry and J.L. Farris (1997)
other aquatic mollusc: Dreissena polymorpha freshwater semi-static To evaluate the ecological consequences of long-term contaminations, the effects of mixtures of heavy metals on the filtration rate and survival of the freshwater mussel Dreissena polymorpha were studied during chronic exposure.	NOEC (63 d): 13 µg/L dissolved (meas. (arithm. mean)) based on: filtration rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Kraak, M.H.S., H. Schoon, W.H.M. Peeters and N.M. Van Straalen (1994)
Penaeus mergulensis and Penaeus monodon (prawns) saltwater flow-through The effects of dissolved copper on the growth and survival of juveniles of 2 prawn species was investigated during a 2 week exposure experiment.	NOEC (14 d): 33 µg/L dissolved (meas. (arithm. mean)) based on: growth NOEC (14 d): 145 µg/L dissolved (meas. (arithm. mean)) based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper $^{2+}$ in the form of a soluble copper compound**	Ahsanullah, M., & Ying, W. (1995)
other aquatic mollusc: Mytilus edulis saltwater flow-through equivalent or similar to adapted from ASTM (1993)	NOEC (48 h): 6.2 µg/L Total dissolved + labile Cu (meas. (arithm. mean)) based on: Embryo development	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper (II) chloride dihydrate**	Brooks, S. (2006a)
other aquatic mollusc: Crassostreas gigas saltwater flow-through Equivalent or similar to Environmental Agency, 2001. Ecotoxicity test methods for effluent and receiving water assessment – comprehensive guidance.	NOEC (24 h): 10.89 µg/L Total + Labile Cu (meas. (arithm. mean)) based on: Embryo development NOEC (24 h): 10.42 µg/L Total + Labile Cu (meas. (arithm. mean)) based on: Embryo development NOEC (24 h): 12.83 µg/L Total + Labile Cu (meas. (arithm. mean)) based on:	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper (II) chloride dihydrate**	Brooks, S. (2006b)

Method	Results	Remarks	Reference
	Embryo development NOEC (24 h): 19.53 µg/L Total + Labile Cu (meas. (arithm. mean)) based on: Embryo development NOEC (24 h): 28.19 µg/L Total + Labile Cu (meas. (arithm. mean)) based on: Embryo development NOEC (24 h): 47.13 µg/L Total + Labile Cu (meas. (arithm. mean)) based on: Embryo development		
other aquatic crustacea: Eurytemora affinis (estuarine copepod) saltwater semi-static The effect of dissolved and complexed copper on mortality, fecundity and maturation of an estuarine copepod was investigated in an 8 day experiment.	NOEC (8 d): 51.1 µg/L dissolved (meas. (arithm. mean)) based on: most sensitive of Mortality, fecundity and maturation	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride dehydrate**	Hall, L.W. Jr, Anderson, R.D., Kilian, J.V. (1997)
Sea urchin (Paracentrotus lividus) saltwater static Three groups of experiments were performed to study the effect of speciation on Cu toxicity in sea urchin larvae (toxicity of FAs, combinations of Cu+FA and Cu-FA complexes were tested).	NOEC (48 h): 16.5 µg/L total Cu (meas. (arithm. mean)) based on: development	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Lorenzo, J.I., Nieto, O., Beiras, R. (2006)
other aquatic worm: Neanthes arenaceodentata (polychaete) saltwater flow-through Groups of Neanthes arenaceodentata were fed different diets for four weeks and were then exposed to copper in seawater to determine if nutritional history would affect copper toxicity. Two experiments were conducted in which mortality was the endpoint.	NOEC (28 d): 13.5 µg/L (meas. (arithm. mean)) based on: growth NOEC (28 d): 12.1 µg/L (meas. (arithm. mean)) based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Pesch C. E., Schauer, P.S., Balboni, M.A. (1986)
other aquatic mollusc: saltwater daily renewal of solutions Three experiments were performed to determine the effect of copper on growth of mussels in a controlled, flow through system.	NOEC (10 d): 6 µg/L (meas. (arithm. mean)) based on: Growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper (II) chloride**	Redpath, K. J. (1985)
other aquatic mollusc: Protothaca staminea (Clam) saltwater flow-through Clams were exposed for 30 days to a range of copper concentrations.	NOEC (30 d): 18 µg/L ionic or weakly complexed chemical species (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name):**	Roesijadi, G. (1980)

Method	Results	Remarks	Reference
Tissues of surviving clams were analysed for copper concentrations and copper-binding proteins.		**Copper sulfate**	
Pandalus danae saltwater flow-through Mortality of larval coon-stripe shrimp, Pandalus danae, was related to labile copper and the copper complexing capacity of sea water, as measured by differential pulse Anodic Stripping Voltammeter (ASV)	NOEC (46 d): 9.9 µg/L (meas. (arithm. mean)) based on: development NOEC (46 d): 9.9 µg/L (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Young, J.S., Gurtisen, J.M., Apts, C.W., Crecelius, E.A. (1979)
other aquatic crustacea: Tisbe furcata saltwater semi-static Cohorts of the epiphytic marine copepod Tisbe furcata were chronically exposed to copper in life- table experiments to test whether ecologically relevant impacts can occur at sub lethal concentrations. Data on fecundity, longevity, and rate of development were used to calculate the intrinsic rate of natural increase.	NOEC (100 d): 19.1 µg/L dissolved (meas. (arithm. mean)) based on: Survival and reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Bechmann, R.K. (1994)
Placopecten magellanicus (scallop) saltwater flow-through Sea scallops in early gametogenesis were exposed to sub lethal levels of Cu and Cd in a flowing seawater system to determine the effect on gamete production and maturation.	NOEC (8 wk): 10 µg/L dissolved (meas. (arithm. mean)) based on: gonad development	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Gould, E. *et al.,* (1988)
Mercenaria mercenaria (hard clam) saltwater static U.S. EPA Methods 3005, 3010 and 3020	NOEC (288 h): 7 µg/L based on: development	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper nitrate**	LaBreche, T.M.C. *et al.,* (2002)
other aquatic crustacea: Tisbe battagliai saltwater semi-static equivalent or similar to draft OECD Guideline: Harpacticoid Copepod Development and Reproduction test.	NOEC (21 d): 18 µg/L dissolved (meas. (arithm. mean)) based on: mortality NOEC (21 d): 18 µg/L dissolved (meas. (arithm. mean)) based on: reproduction NOEC (21 d): 18 µg/L dissolved (meas. (arithm. mean)) based on: development	1 (reliable without restriction) weight of evidence experimental result **Test material (Common name): Copper chloride**	Williams, T.D. & Hayfield, A.J. (2006)
other aquatic crustacea: Artemia franciscana saltwater static Three experiments were conducted to test the effect of copper on the	NOEC (48 h): 6.6 µg/L dissolved (meas. (arithm. mean)) based on: hatching success	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name):**	Brix, K.V. *et al.,* (2006)

Method	Results	Remarks	Reference
hatching success of brine shrimp cysts: 1) effects of pre-treatment of cysts with antibiotics on brine shrimp sensitivity to metals; 2) effect of ionic composition of the artificial test media on sensitivity; 3) effects of site-specific water quality on metal bioavailability and toxicity)		**Copper chloride**	
Paracetrotus lividus saltwater static ASTM E1563-98	NOEC (48 h): 8.8 µg/L dissolved (meas. (arithm. mean)) based on: development	1 (reliable without restriction) weight of evidence experimental result **Test material (Common name): copper chloride dihydrate**	Hurd, K.S. (2006b)
Acropora tenuis (coral) saltwater static The effect of copper on the settlement success of planula larvae of the reef-building coral Acropora tenuis was investigated.	NOEC (48 h): 17.3 µg/L total Cu (meas. (arithm. mean)) based on: larval settlement	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Reichelt-Brushett A.J. & Harrison P.L. (2000)
Goniastrea aspera (coral) saltwater static A new sub-lethal toxicity test was developed to measure the effect of copper on the motility of coral larvae.	NOEC (72 h): 14.2 µg/L total Cu (meas. (arithm. mean)) based on: motility	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Reichelt-Brushett A.J. & Harrison P.L. (2004)
Lobophytum compactum (coral) saltwater static Two experiments were conducted to determine the effect of copper on fertilization success during the mass coral spawning in 2004 on the Great Barrier Reef (GBR).	NOEC (5 h): 36 µg/L total Cu (meas. (arithm. mean)) based on: fertilisation success	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Reichelt-Brushett A.J.& Michalek-Wagner K (2005)
other aquatic mollusc: one bivalve (M. galloprovincialis) and two echinoderms (S. purpuratus and D. excentricus) saltwater static EPA/600/R-95/136 (short-term methods for estimating the chronic toxicity of effluents and receiving waters to west coast marine and estuarine organisms)	NOEC (48 h): 5.9 µg/L total and dissolved Cu (meas. (arithm. mean)) based on: development NOEC (48 h): 7.5 µg/L total and dissolved Cu (meas. (arithm. mean)) based on: development NOEC (48 h): 9.2 µg/L total and dissolved Cu (meas. (arithm. mean)) based on: development NOEC (48 h): 9.7 µg/L total and dissolved Cu (meas. (arithm. mean)) based on: development	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Rosen G., I. Rivera-Duarte, L. Kear-Padilla and D.B. Chadwick (2005)
other aquatic mollusc: M. edulis and M. galloprovincialis	EC50 (48 h): 3.56 — 5.13 µg/L dissolved (meas.	2 (reliable with restrictions)	Arnold W. Ray, J. S. Cotsifas, D. S.

Method	Results	Remarks	Reference
saltwater static EPA/600/R-95/136 ASTM Standard E724-98	(arithm. mean)) based on: larval development EC50 (48 h): 6.91 — 12.2 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 11.5 — 20.2 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 21.7 — 30.6 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 3.52 — 4.66 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 8.03 — 9.9 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 14 — 17.5 µg/L dissolved (meas. (arithm. mean)) based on: larval development EC50 (48 h): 21.6 — 25.2 µg/L dissolved (meas. (arithm. mean)) based on: larval development	weight of evidence experimental result **Test material (Common name): soluble copper**	Smith, S. Le Page and K.M. Gruenthal (2008)
C. virginica, D. excentricus, S. purpuratus, M. galloprovincialis saltwater static EPA guideline for M. galloprovincialis ASTM guideline for C. virginica	EC50 (48 h): 6.28 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - M. galloprov - L DOC EC50 (48 h): 14.4 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - M. galloprov - IL DOC EC50 (48 h): 28.2 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - M. galloprov - IH DOC EC50 (48 h): 34.8 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - M. galloprov - H DOC EC50 (48 h): 11.2 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - C. virgin. - L DOC EC50 (48 h): 22.4 µg/L dissolved (meas. (arithm. mean)) based on: embryo	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Arnold W. Ray; J.S. Cotsifas, R.S. Ogle, S.G.S. De Palma, D.S. Smith (2010)

Method	Results	Remarks	Reference
	development - C. virgin. - IL DOC EC50 (48 h): 30.7 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - C. virgin. - IH DOC EC50 (48 h): 40.7 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - C. virgin. - H DOC EC50 (48 h): 18.9 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - D. excentr. - L DOC EC50 (48 h): 36.4 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - D. excentr. - IL DOC EC50 (48 h): 46.2 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - D. excentr. - IH DOC EC50 (48 h): > 75.8 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - D. excentr. - H DOC EC50 (72 h): 14.8 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - S. purp.. - L DOC EC50 (72 h): 24.3 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - S. purp.. - IL DOC EC50 (72 h): 30.2 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - S. purp.. - IH DOC EC50 (72 h): 46.4 µg/L dissolved (meas. (arithm. mean)) based on: embryo development - S. purp.. - H DOC		
E. affinis saltwater static The influence of salinity (2.5, 5, 15 and 25 ppt) at dissolved organic carbon (DOC) concentrations of 1.3 -3.3 mg/L	LC50 (96 h): 76.2 µg/L dissolved (nominal) based on: mortality (- 2 mg/L DOC) LC50 (96 h): 108 µg/L dissolved (nominal) based	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name):**	Hall L.W., R.D. Anderson, B.L. Lewis, W.R. Arnold (2008)

Method	Results	Remarks	Reference
and DOC concentrations of 2, 4, 6 and 8 mg/L at a fixed salinity of 10 ppt on the acute toxicity (96 -h LC50s) of copper to the sensitive estuarine copepod, Eurytemora affinis was determined.	on: mortality (- 4 mg/L DOC) LC50 (96 h): 111 µg/L dissolved (nominal) based on: mortality (- 6 mg/L DOC) LC50 (96 h): 166 µg/L dissolved (nominal) based on: mortality (- 8 mg/L DOC) LC50 (96 h): 71 µg/L dissolved (nominal) based on: mortality (- 2.5 ppt salinity) LC50 (96 h): 104 µg/L dissolved (nominal) based on: mortality (- 5 ppt) LC50 (96 h): 67.6 µg/L dissolved (nominal) based on: mortality (- 15 ppt) LC50 (96 h): 58.1 µg/L dissolved (nominal) based on: mortality (- 25 ppt)	**Copper chloride**	
other aquatic crustacea: Hyalella azteca The effect of major ions (Ca, Mg, Na, and K) and pH on Cu toxicity (LC50) to Hyalella azteca was determined in 1 week exposures.	Improvement of the acute BLM needed - separate coefficients are needed to account for the effects of Ca and Na at low and high pH values (6.5-8.4), :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Borgmann U (2005)
Daphnia magna Development of a toxicity model (Biotic Ligand Model) predicting the long-term effects of copper on the reproduction of the cladoceran Daphnia magna that is based on previously reported toxicity tests in 35 exposure media with different water chemistries.	With the model, 79% of the toxicity threshold values were predicted within a factor of two :	2 (reliable with restrictions) supporting study estimated by calculation and experimental result **Test material (Common name): copper sulphate**	De Schamphelaere, K.A. and Janssen, C.R. (2004)
Daphnia magna A multigeneration acclimation experiment was performed with Daphnia magna exposed to different concentrations of copper to assess possible changes in tolerance and to establish the optimal concentration range (OCEE) of this species.	after three generation of acclimation, the optimal concentration ranges (from energy reserves and number of offspring) remained constant between 1 and 35 µg Cu/L :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Bossuyt B.T. and Janssen C.R. (2004a)
Daphnia magna equivalent or similar to OECD Guideline 211 (Daphnia magna Reproduction Test) (including dietary exposure)	Dietary copper exposure did not affect the predictive capacity of the chronic D. magna BLM :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper Chloride**	De Schamphelaere, K.A.C. & Janssen, C.R. (2004)
Lampilis siliquoidea Adapted from ASTM E2455-06,	By linear regression, BLM predictions explained 95%	2 (reliable with restrictions)	Kunz, J.L. *et al.*, (2006)

Method	Results	Remarks	Reference
ASTM E729-96. The acute toxicity of copper in water-only exposures to juvenile freshwater mussels at various levels of water hardness or concentrations of dissolved organic carbon (DOC) was assessed	of the variability in the observed EC50 that varied by a factor of about 40 :	supporting study experimental result **Test material (Common name): soluble copper**	
Hyridella depressa The extended free ion activity model (FIAM) was developed by integrating concepts from the original FIAM into biological receptor theory, to obtain a conceptual model that more precisely quantifies the interaction of chemical species at biological receptor sites.	Valve movement behaviour, measured using an automated data acquisition system, was shown to be a quantifiable and rapid, real-time endpoint for assessing the toxic effects of Cd and Cu exposures. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper chloride**	Markich, S.J. *et al.,* (2003)

Discussion

Freshwater invertebrate NOECS

High quality chronic NOEC/(L(E) C10 values are available for 13 species: 1 rotifer species (*Brachionus calyciflorus*); 3 insect species (*Clistoronia magnifica; Chironomus riparius; Paratanytarsus parthenogeneticus*), 4 mollusc species (*Juga plicifera, Campeloma decisum; Villosa iris; Dreissenia polymorpha*), 5 crustacean species (*Ceriodaphnia dubia; Daphnia magna; Daphnia pulex; Hyalella azteca; Gammarus pulex*).

Individual NOEC/(L(E) C10 values range between 4 µg Cu/L (*Cerodaphnia dubia*) to 188 µg Cu/L (*Daphnia magna reproduction*).

The NOECs are used to derive 'species geo-metric mean' NOEC values for each endpoint and the most sensitive endpoint for each of the 13 species of invertebrates retained as 'species-mean' NOEC values. These 'species mean' NOEC values range from 6.0 µg/l Cu for the snail *Juga plicifera* (mortality; 1 test value) to 50.3 µg/l Cu amphipod *Hyalella azteca* (mortality) and are carried forward for the PNEC derivation. 20 NOECs are available for standard species, with internationally agreed protocols. For these species, the 'species mean' NOECS are derived (*C. dubia* (13.1 µg Cu /L), *D. magna* (12.6 µg Cu/L) and 14.5 (*D. pulex*)) and these are used for Classification and Labelling purposes.

Large intra-species variability is observed in NOEC: L(E) C10 values. Effects data from *Daphnia magna* were used to develop a chronic invertebrate BLM (De Schamphelaere *et al.,* 2004). The capacity of the BLM for predicting of copper toxicity to other invertebrate species was demonstrated from copper toxicity studies with *Brachionus calyciflorus (*De Schamphelaere 2006*), Lampilis siliquoide (*Kunz *et al.,* 2006*), Hyridella depressa (*Marckish *et al.,* 2003*) and Hyalella azteca (*Borgman *et al.,*2006*).*

The database contains a paper demonstrating that dietary copper exposure does not affect the capacity of the biotic ligand model to predict toxicity to D. magna

Research related to copper acclimation and deficiency (Bossuyt *et al.,* 2004) demonstrated that after three generation of acclimation, the optimal concentration ranges (from energy reserves and number of offspring) remained constant between 1and35 µg Cu/L. Below1 µg

Cu/L (a concentration often used as background copper concentration in the ecotoxicity media), copper deficiency was clearly observed.

Marine invertebrate NOECs

32 high quality NOEC: L(E) C10 were retained. for 18 different individual species belonging to different taxonomic groups:6 mollusc species (*Mytilus edulis; Prototheca staminea; Crassostrea gigas, Mercenaria mercenaria, Mytilus galloprovincialis, Placopecten magellanicus),* 1 annelid species (*Neanthes arenaceodentata)* 3 decapod (crustacean) species (*Pandalus danae; Penaeus mergulensis*; *Penaeus monodon),* 3 copepod (crustacean) species*(Eurytemora affinis; Tisbe battagliai, Tisbe furcata*), 1 arthropod (crustacean) species (*Artemia franciscana*) 1 echinoderm species (*Paracentrotus lividus),* 3 cnidaria species*(Acropora tenuis, Goniastrea aspera, Lobophytum compactum)*

Reliable species- NOEC: L(E) C10 values (µg Cu/l) are calculated for the most sensitive endpoints for 18 species. The species- specific NOEC values range from 5.9 µg Cu/L for bivalve *Mytilus galloprovincialis*to 145 µgCu/L for the crustacea *Penaeus monodon* and carried forward for the marine PNEC derivation.

The observed NOEC: L(E) C10 values are influenced by the dissolved organic carbon content of the test media. A relation between the observed NOEC and organic carbon content was established for *Mytilus edulis*. Its applicability to other invertebrate species was demonstrated for *Crassostreas gigas and Paracentrotus lividus, Dendraster exentricus and Strogolocentrus purpuratus*, *Mytilus galloprovincialis* (Arnold *et al.,* 2008 and 2010, Hall 2010 and Brooks 2006)

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

High quality chronic single-species NOEC/(L(E) C10 values are available for 13 freshwater invertebrate species. A chronic Biotic Ligand Model was developed for D. magna and validated for 4 additional species. The NOECs and the chronic invertebrates biotic ligand models (BLM) are carried forward to the risk characterisation.

High quality chronic single-species NOEC/(L(E) C10 values are available for 18 marine invertebrate species. The observed effects are related to the organic carbon content of the test waters. The NOECS and organic carbon relationships are carried forward to the risk characterisation.

7.1.1.3 Algae and aquatic plants

The results are summarised in the following table:

Table 53: Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
Pseudokirchneriella subcapitata, Chlorella vulgaris, Chlamydomonas reinhardtii, Scenedesmus quadricauda (algae) freshwater	EC10 (72 h): 108 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 407 µg/L	2 (reliable with restrictions) weight of evidence experimental result and modelling	De Schamphelaere, K.C. and Janssen, C.R. (2006)

Method	Results	Remarks	Reference
static equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test)	dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 56 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 36 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 173 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 99 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 85 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 162 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 283 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 188 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 510 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 31 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 188 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 404 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 159 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 84 µg/L dissolved (meas. (arithm. mean)) based on: growth	**Test material (Common name): Copper sulphate**	

Method	Results	Remarks	Reference
	rate EC10 (72 h): 132 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 178 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 108 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC10 (72 h): 96 µg/L dissolved (meas. (arithm. mean)) based on: growth rate		
Chlamydomonas reinhardtii (algae) freshwater flow-through equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test)	NOEC (10 d): 22 µg/L based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Schäfer, H. *et al.,* (1994)
other algae: Raphidocelis subcapitata (algae) freshwater static equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test)	NOEC (72 h): 15.7 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 17.9 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 19.3 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 23.1 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 35.4 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 49 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 52.9 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 56.4 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 61.8 µg/L	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Heijerick D., Bossuyt B. and Janssen C. (2001)

Method	Results	Remarks	Reference
	dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 65.5 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 94.7 µg/L dissolved (meas. (not specified)) based on: biomass NOEC (72 h): 164 µg/L dissolved (meas. (not specified)) based on: biomass		
Pseudokirchneriella subcapitata (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	NOEC (72 h): 63.9 µg/L dissolved (meas. (arithm. mean)) based on: cell number (-Bihain 1) NOEC (72 h): 110.6 µg/L dissolved (meas. (arithm. mean)) based on: cell number (-Bihain 2) NOEC (72 h): 57.5 µg/L dissolved (meas. (arithm. mean)) based on: cell number (-Bihain 6) NOEC (72 h): 59.1 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Bihain 7) NOEC (72 h): 111.2 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 1) NOEC (72 h): 112.8 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 2) NOEC (72 h): 49.4 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 3) NOEC (72 h): 19.4 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 4) NOEC (72 h): 174 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 5) NOEC (72 h): 53.7 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 6) NOEC (72 h): 67.7 µg/L dissolved (meas. (arithm. mean)) based on: cell	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	De Schamphelaere K.A.C., F.M. Vasconcelos, D.G. Heijerick, F.M.G. (2003)

Method	Results	Remarks	Reference
	number (- Ossenkolk 7) NOEC (72 h): 170.8 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ossenkolk 9) NOEC (72 h): 40.8 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 1) NOEC (72 h): 89.2 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 2) NOEC (72 h): 97.2 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 5) NOEC (72 h): 60.2 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 7) NOEC (72 h): 37.6 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 8) NOEC (72 h): 91.3 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 9) NOEC (72 h): 53.3 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 10) NOEC (72 h): 54.6 µg/L dissolved (meas. (arithm. mean)) based on: cell number (- Ankeveen 11)		
Raphidocelis subcapitata (new name: Pseudokirchneriella subcapitata) (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 152 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 84 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 194 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 32 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 52.7 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 65.4 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 33.9 µg/L dissolved (meas. (initial)) based on: biomass	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper sulphate pentahydrate (See endpoint summary for justification of read-across)**	Heijerick D., Bossuyt B., De Schamphelaere K., Indeherberg M., Min-Gazzini (2005)

Method	Results	Remarks	Reference
	EC50 (72 h): 113 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 163 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 36.9 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 245 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 97.4 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 108 µg/L dissolved (meas. (initial)) based on: biomass EC50 (72 h): 16.5 µg/L dissolved (meas. (initial)) based on: biomass		
Chlamydomonas reinhardtii (algae) freshwater flow-through OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (96 h): 0.047 mg/L dissolved (meas. (not specified)) based on: growth EC50 (7 d): 0.032 mg/L dissolved (meas. (not specified)) based on: growth EC50 (10 d): 0.032 mg/L dissolved (meas. (not specified)) based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (IUPAC name): copper sulfate pentahydrate**	Schäfer H, Hettler H, Fritsche U, Pitzen G, Röderer G and Wenzel A (1994)
Chlorella vulgaris (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 333 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 773 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 99 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 506 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 296 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 254 µg/L dissolved (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper chloride (See endpoint summary for justification of read-across)**	De Schamphelaere K. and Janssen C. (2006)

Method	Results	Remarks	Reference
	EC50 (72 h): 60 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 200 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 446 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 440 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 987 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 111 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 380 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 602 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 238 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 364 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 208 µg/L dissolved (meas. (arithm. mean)) based on: growth rate		
Chlamydomonas reinhardtii (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 380 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 315 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 146 µg/L dissolved (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper chloride (See endpoint summary for justification of read-across)**	De Schamphelaere K. and Janssen C. (2006)

Method	Results	Remarks	Reference
Pseudokirchneriella subcapitata (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 230 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 824 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 93 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 35 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 268 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 156 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 190 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 219 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 462 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 199 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 811 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 92 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 35 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 346 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 178 µg/L dissolved (meas. (arithm.	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper chloride (See endpoint summary for justification of read-across)**	De Schamphelaere K, Vasconcelos F., Heijerick D., Tack F., Delbeke (2003)

Method	Results	Remarks	Reference
	mean)) based on: growth rate EC50 (72 h): 281 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 161 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 685 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 122 µg/L dissolved (meas. (arithm. mean)) based on: growth rate		
Pseudokirchneriella subcapitata (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 368 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 51 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 30 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 151 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 99 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 105 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 55 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 174 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 205 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 59 µg/L dissolved (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence read-across based on grouping of substances (category approach) **Test material (IUPAC name): copper chloride (See endpoint summary for justification of read-across)**	De Schamphelaere K, Vasconcelos F., Heijerick D., Tack F., Delbeke (2003)

Method	Results	Remarks	Reference
	EC50 (72 h): 209 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 756 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 193 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 102 µg/L dissolved (meas. (arithm. mean)) based on: growth rate EC50 (72 h): 100 µg/L dissolved (meas. (arithm. mean)) based on: growth rate		
other aquatic plant: giant kelp Macrocystis pyrifera (algae) saltwater static Tests were conducted to determine the effect of copper on germination, germ-tube growth and sporophyte production in different populations of giant kelp.	NOEC (19 d): 10.2 µg/L dissolved (meas. (arithm. mean)) based on: sporophyte growth NOEC (19 d): 10.2 µg/L dissolved (meas. (arithm. mean)) based on: germ-tube growth NOEC (19 d): 50.1 µg/L dissolved (meas. (arithm. mean)) based on: germination	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Anderson, B.S., Hunt, J.W., Turpen, S.L., Coulon, A.R., Martin, M. (1990)
other algae: Marine macroalgae Fucus vesiculosis (algae) saltwater flow-through The study investigates the effects of different levels of dissolved organic carbon (DOC) on copper speciation and its bioavailability and subsequent toxicity to the germling life stages of the macroalgae, Fucus vesiculosis, following a 14 d exposure.	NOEC (14 d): 11 µg/L dissolved and labile (meas. (arithm. mean)) based on: growth rate NOEC (14 d): 14 µg/L dissolved and labile (meas. (arithm. mean)) based on: growth rate NOEC (14 d): 18.5 µg/L dissolved and labile (meas. (arithm. mean)) based on: growth rate NOEC (14 d): 32 µg/L dissolved and labile (meas. (arithm. mean)) based on: growth rate NOEC (14 d): 46 µg/L dissolved and labile (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Brooks, S. (2006c)
Phaeodactylum tricornutum (algae) saltwater static equivalent or similar to OECD Guideline 201 (Alga, Growth	EC10 (72 h): 2.9 µg/L dissolved (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material**	Simpson, S. *et al.*, (2003)

Method	Results	Remarks	Reference
Inhibition Test)		**(Common name): Copper sulphate**	
Phaeodactylum tricornutum (algae) saltwater static ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with *Skeletonema* costatum and Phaeodactylum tricornutum)	NOEC (72 h): 5.7 µg/L dissolved (meas. (geom. mean)) based on: growth rate	1 (reliable without restriction) weight of evidence experimental result **Test material (CAS name): 10125-13-0**	Smyth, D.V., Kent, S. (2006)
Skeletonema costatum (algae) saltwater static ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum)	NOEC (72 h): 7.54 µg/L dissolved (meas. (geom. mean)) based on: growth rate	1 (reliable without restriction) weight of evidence experimental result **Test material (CAS number): 10125-13-0**	Smyth, D.V. (2006)
Pseudokirchneriella subcapitata (algae) The effect of long-term copper acclimation of the freshwater green algae Pseudokirchneriella subcapitata to copper was investigated using different physiological and toxicological endpoints.	Based on the algal biomass, the growth rate, the pigment diversity and the autotrophic index, an optimal concentration range was observed between 1 and 35µg Cu/L. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Bossuyt B.T. and Janssen C.R. (2004b)
Lemna minor (aquatic plants) freshwater static The effect of copper on the growth rate of Lemna minor (doubled fronded colonies) following an exposure period of 7 days was determined	NOEC (7 d): 30 µg/L labile/free (nominal) based on: growth rate	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Teisseire, H. *et al.,* (1998)

Discussion

Effects on algae / cyanobacteria

Freshwater algae NOECS

High quality chronic NOEC/(L(E) C10 values are available for 3 species: *Chlamydomonas reinhardti, Chlorella vulgaris and Pseudokirchernella subcapitata.*

The NOECs were used to calculate high quality ‘species geometric mean’ NOEC values for each endpoint and the most sensitive endpoint for each of the algae species was retained as ‘species-mean’ NOEC. The ‘species mean’ NOEC value range from 43 µg/l Cu for *Pseudokirchernella subcapitata* (endpoint growth; n=4) to 138 µg/l Cu for *Chlorella vulgaris* (endpoint growth; n=17). These values are used for the PNEC derivation.

Large intra-species variability is observed. The effects data-set from *Pseudokirchernella subcapitata* was used for the development of an algae BLM (De Schamphelaere *et al.,* 2003) The capacity of the BLM for predicting copper toxicity to other algae species was demonstrated from copper toxicity studies with *Chlamydomonas reinhardti* and *Chlorella vulgaris* (De Schamplelaere and Janssen, 2006).

Research related to copper acclimation and deficiency (Bossuyt *et al.,* 2004) demonstrated that, based on the algal biomass, the growth rate, the pigment diversity and the autotrophic index, an optimal concentration range was observed between 1 and 35µg Cu/L. Deficiency was observed at lower levels, toxicity was observed at higher levels.

Marine algae NOECS

High quality chronic NOEC values are available for 4 species: 2 diatoms (*Phaeodactylum tricornutum* and *Skeletonema costatum*) and 2 macroalgae (*Macrocystis pyrifera* and *Fucus vesiculosis*). Individual NOEC values range between 2.9 µg Cu/L (*Phaeodactylum tricornutum*, growth) to 50 µg Cu/L*(Macrocystis Pyrifera*, germination).

High quality 'species mean' NOEC values are derived for the most sensitive endpoint for each of the 4 species of marine algae. The 'species mean' NOEC value range from 2.9 µg/l Cu for the *Phaeodactylum tricornutum* to 11 µg/l for *Fucus vesiculosis*. Large intra-species variability are observed due differences in DOC. A relation between the observed NOEC and organic carbon content was established for *Fucus vesuculosis*.

<u>The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:</u>

High quality single-species EC50 values and NOEC/(L(E) C10 values are available for 3 freshwater algae species. A chronic Biotic Ligand Model was developed for S. Subcapitata and validated for 3 additional species. The NOECs and the chronic algae biotic ligand models (BLM) are carried forward to the risk characterisation.

High quality chronic single-species NOEC/(L(E) C10 values are available for 4marine algae species. The observed effects are related to the organic carbon content of the test waters. The NOECS and organic carbon relationships are carried forward to the risk characterisation.

<u>Effects on aquatic plants other than algae</u>

One high quality NOEC is available for higher plants.

Toxicity data from terrestrial plants (Barley root elongation) demonstrated that the algae model can be used for normalization of the Lemna NOEC values.

<u>The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:</u>

High quality chronic NOEC values are available for Lemna minor (growth) with a NOEC value of 30 µg Cu/L µg Cu/L

7.1.1.4 Sediment organisms

The results are summarised in the following table:

Table 54: Overview of long-term effects on sediment organisms

Method	Results	Remarks	Reference
Tubifex tubifex, Hyallela azteca, Chironomus riparius, Lumbriculus	NOEC (28 d): 138.5 mg/kg sediment dw element (Cu)	2 (reliable with restrictions)	De Schamphelaere,

Method	Results	Remarks	Reference
variegatus, Gammarus pulex freshwater long-term toxicity (laboratory study) semi-static OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	(meas. (arithm. mean)) based on: survival NOEC (28 d): 78.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 78.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 580.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 580.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 580.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 54 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 18.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 18.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 95.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 56.1 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 32.2 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 98.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 53 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 53.2 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate	weight of evidence experimental result **Test material (Common name): Copper chloride**	K.A.C. *et al.*, (2005)

Method	Results	Remarks	Reference
	NOEC (28 d): 337.6 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) NOEC (28 d): 538.6 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 171 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 141 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 21.8 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate		
Hyalella azteca; Chironomus riparius; Hexagenia spp.; Tubifex tubifex freshwater long-term toxicity (laboratory study) static The relative sensitivity of four benthic invertebrates (Hyalella azteca, Chironomus riparius, Hexagenia spp., and Tubifex tubifex) was determined for Cd, Cu, and Ni in water-only and in spiked-sediment exposures.	NOEC (28 d): 59.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 66.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 155.1 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 59.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 66.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 52.3 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (21 d): 39.2 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): 33.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): 44.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): 23.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean))	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	Milani, D., Reynoldson, T.B., Borgmann, U. & Kolasa, J. (2003)

Method	Results	Remarks	Reference
	based on: growth rate NOEC (21 d): 29.2 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (21 d): 44.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 237.8 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 246.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 270.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 127.8 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 129 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 270.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction		
Tubifex tubifex freshwater long-term toxicity (laboratory study) static ASTM E1383-94 (Sediment Toxicity Test (Media: Sediment-freshwater))	NOEC (28 d): 67.25 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 67.25 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 231.7 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 385.8 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 62.64 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): 101.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): 69.1 mg/kg	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper sulphate**	Vecchi, M. *et al.,* (1999)

Method	Results	Remarks	Reference
	sediment dw element (Cu) (meas. (arithm. mean)) based on: mortality		
Tubifex tubifex, Hyallela azteca, Chironomus riparius, Lumbriculus variegatus, Gammarus pulex freshwater long-term toxicity (laboratory study) semi-static OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	NOEC (28 d): 140 mg/kg sediment dw element (meas. (arithm. mean)) based on: survival NOEC (28 d): 49.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 59.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 59.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: emergence rate NOEC (28 d): 292 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 292 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: emergence rate NOEC (28 d): 505.9 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 177.1 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 75.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 54.2 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 54.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 85.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (28 d): 55.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (28 d): 80.5 mg/kg sediment dw element (Cu) (meas. (arithm. mean))	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): Copper chloride**	De Schamphelaere, K.A.C. *et al.*, (2005)

Method	Results	Remarks	Reference
	based on: biomass NOEC (28 d): 91.8 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: biomass NOEC (35 d): 94.7 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (35 d): 94.7 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate NOEC (35 d): 97.4 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: survival NOEC (35 d): 30.6 mg/kg sediment dw element (Cu) (meas. (arithm. mean)) based on: growth rate		
Synedra ulna, Oscillatoria sp. The effect of copper additions (Cu ranging from 0 to 30 µM) on the photosynthesis of three different microalgae biofilms was studied to identify the factors that cause sensitivity differences between benthic and pelagic algae	The physical structure of the biofilm (package of cells and thickness), and not the species composition, was the main factor regulating the sensitivity of the biofilm to Cu toxicity during short-term exposures. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Barranguet C. *et al.,* (2000)
a variety of benthic organisms freshwater long-term toxicity (field study) static To assess the influence of variations in field sediments (acid-volatile sulfides (AVS) and simultaneously extracted metals (SEM) on benthic toxicity , sediments spiked with metals were deployed for four months and recolonization by benthic organisms investigated.	Biological exposure took place in near-surface sediments, where AVS exceeded SEM. Lack of biological response was related to vertical distributions of AVS and SEM. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Boothman, W.S. *et al.,* (2001)
Tubifex tubifex long-term toxicity (extended laboratory study) static Comparison of the results of a 28d reproductive bioassay with T. tubifex with a 6 month cohort experiment with the same species	the 28-day reproductive bioassay does provide information that is relevant in assessing long-term toxic effects at the population level. :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Pasteris, A. *et al.,* (2003)
Tubifex tubifex, Hyallela azteca, Chironomus riparius, Lumbriculus variegatus, Gammarus pulex OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	LC50 (28 d): 59 — 194 mg/kg sediment dw (meas. (arithm. mean))	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Roman, Y.E., K.A.C. De Schamphelaere, L.T.H. Nguyen and C.R. Janssen (2007)

Discussion

Freshwater sediment NOECS

The high quality records retained for the PNEC derivation of copper under the Existing Substances Regulation (TCNES) and Biocidal Products regulations (Technical meetings) have been included in the IUCLID data-base. Tests that were considered as not-reliable for the PNEC derivations have NOT been included in the IUCLID records but have been summarized in the copper RA report (2008).

106 high quality chronic NOEC/(L(E) C10 values are available for 6 different sediment-dwelling organisms. the amphipods *Hyalella azteca* and *Gammarus pulex*, the oligochaetes *Tubifex tubifex* and *Lumbriculus variegatus*, the insect *Chironomus riparius* and the insect *Hexagenia*.

The Individual NOEC values range between 18.3 mg/kg dry weight and >3,158 mg/kg (min-max value). Large intra-species variability are observed due to variations in organic carbon (OC) content and acid volatile sulphide (AVS) content of the sediments (De Schamphelaere *et al.,*2005). Normalization of the NOECs/(L(E) C10 for OC was demonstrated. Normalization of the effects data for AVS was not possible and therefore only NOEC/(L(E) C10 values generated under conditions that represent 'aerobic' conditions (Low AVS) were considered as adequate for the PNEC derivation. Effects data from studies with AVS concentration lower than the 10th percentile of the AVS concentration (i.e. 0.77 mmol/kg dry weight) were thus retained. Using this exclusion rule, the original dataset containing 106 NOEC values was reduced to a trimmed data set of 62 NOEC values for copper.

The data base includes additional information in support of the importance if AVS binding in the field (Boothman *et al.,* 2001) and demonstrating the lesser sensitivity of algae in the biofilm compared to free living algae(Barranguet *et al.,* 2000) and the applicability of long term benthic studies to the life cycle (Pasteris *et al.,* 2003).

The records related to effects observed in freshwater mesocosm studies (multi-species, covering water and sediment) are included in section 6.6. (additional ecotoxicological information). Copper threshold values from three high quality mesocosm studies, representing lotic and lentic systems are available.

Sediment PNEC derivation

For the freshwater PNEC derivation, a weight of evidence approach is applied, using the information from the different environmental compartments: (1) using the freshwater PNEC in an equilibrium partitioning approach; (2) using the high quality freshwater sediment NOECS and (3) comparison with soil NOECS

For the estuarine and marine PNEC derivations, the equilibrium partitioning approach is used

Summaries on the sediment PNEC derivations are provides as attachments

The following information is taken into account for sediment toxicity for the derivation of PNEC:

The freshwater sediment effect records include 62 high quality single-species chronic NOEC/L(E) C10 values from 6 different sediment- dwelling species of relevance to setting the freshwater aerobic sediment PNEC in a WOE approach.

Considering the importance of bio-availability for reducing the intra-species variability, the data- base includes supportive information related to the development/validation of the sediment organic carbon normalization. The NOECS and OC normalization model are used for the aerobic sediment PNEC derivation. Information in support of the protective effect of sediment sulphides is useful to the risk characterization.

7.1.1.5 Other aquatic organisms

The results are summarised in the following table:

Table 55: Overview of short-term effects on other aquatic organisms

Method	Results	Remarks	Reference
Xenopus laevis freshwater flow-through An evaluation of the effects of low-level copper and pentachlorophenol exposure on various early life stages of the South African clawed frog, Xenopus laevis, was performed.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Fort, D.J. and Stover, E.L. (1996)
Xenopus laevis freshwater The effect of copper (Cu) deficiency on the reproduction and development in Xenopus laevis was evaluated, culminating in the development of a defined concentration-response relationship. At the same time, information on adverse effects of increased Cu levels was generated.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Fort, D.J. *et al.,* (2000)
Xenopus laevis freshwater Sets of adult male and female Xenopus laevis were administered a copper-deficient (-Cu) diet under low-copper culture conditions, or a copper-supplemented (+Cu) diet under ambient copper culture conditions, for 120 d in order to assess the effects on reproduction, early embryogenesis, or limb development in the progeny.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	Fort, D.J. at al. (2000)
Rana tigrina freshwater Five freshwater species (amongst which	see summary :	2 (reliable with restrictions) supporting study	Khangarot, B.S. *et al.,* (1981)

Method	Results	Remarks	Reference
tadpole larva of R. Tigrina)		experimental result **Test material (Common name): copper sulphate**	
Rana hexadactyla freshwater The effects of the chelating agent ADTA-Na salt on the acute toxicities of Cu and Zn on the tadpoles of the frog Rana hexadactyla was investigated in available natural soft water.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Khangarot, B.S. and Bhakin, M.K. (1981)
Rana ridibunda freshwater Some effects of Cu on the liver, the impact of Cu on two biomarkers of exposure, lipid peroxidation and glutathione (GSH) were examined. Therefore, the levels of malondialdehyde (MDA; lipid peroxidation product), GSH and Cu concentration in the liver of Rana ridibunda were measured.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Papadimitriou, E. and Loumbourdis, N.S. (2002)
Rana pipiens freshwater Embryo-larval bioassays were conducted	see summary :	2 (reliable with restrictions) supporting study experimental result and review **Test material (Common name): copper sulphate**	Birge, W.J. and Black, J.A. (1979)
Rana sphenocephala Southern leopard frog (Rana sphenocephala) tadpoles were exposed to five chemicals (4 -nonylphenol, carbaryl, copper, pentachlorophenol, permethrin). LC50s were determined and compared with published values for organisms more commonly used in toxicological testing.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Bridges, C.M. *et al.,* (2002)
Rana pipiens The primary focus of this study was to determine if exposure to sub lethal concentrations of copper would cause behavioural changes that may leave Rana	see summary :	2 (reliable with restrictions) supporting study experimental result	Redick, M.S. and La Point, T.W. (2004)

Method	Results	Remarks	Reference
pipiens tadpoles more susceptible to secondary stressors. Secondarily, recovery times after sub lethal exposures with regard to length of tadpole were determined.		**Test material (Common name): soluble copper**	

Discussion

Almost all tests gathered from literature on the effect of copper towards amphibians were performed on early life stages, in laboratory water (with low DOC concentration), with 4 days exposure times and according to standard guidelines. The results clearly show that amphibians (data were found for *Xenopus laevis, Rana pipiens, Rana ridibunda, Rana hexadactyla, Rana Sphenocephala* and *Rana tigrina*) are not sensitive towards copper. Indeed LC50 and NOEC/(L(E) C10 values respectively between 39 and 1,250 µg/l and between 40 and 100,000 µg/l were found.

Most of the studies report however EC50 values and test concentrations were not measured and therefore the data-reliability is low. These data were therefore not retained for the PNEC calculations

Fort *et al.,* 2000 determined optimal copper concentration ranges for the early life stages of the amphibia *X. Laevis*: 1 to 10 µg Cu/L. Copper deficiency was observed at copper concentrations < 1 µg Cu/L.

The following information is taken into account for any hazard / risk assessment:

A range of studies are available that relate to copper toxicity towards amphibians. Only nominal NOECs/EC50 values are available and these were therefore not used for the PNEC derivation.

7.1.1.6 Overview of freshwater and marine mesocosm studies

The detailes of the studies are provided in section ‘additional ecotoxicological information’

Information from high three quality mesocosm studies, mimicking lotic and lentic systems are available

Freshwater mesocosms

Schaefers *et al.*, 2003

The effects of a permanent copper sulphate ($CuSO_4$) exposure to a lentic aquatic system were observed for a period of 110 days simulating early summer to autumn in indoor semi-realistic microcosms including phyto- and zooplankton, macrophytes, and benthic invertebrates. Sixty different taxonomic groups were assessed. Nominal concentrations of 5, 10, 20, 40, 80, and 160 µg total copper/l were maintained by three treatments weekly. The measured concentrations were 9, 14, 19.4, 33, 64, respectively 122 µg/l total copper). Up to nominal/measured concentrations of 20 µg/l, more the 90% of total copper was dissolved. The systems are characterised by an average DOC of 4.4 mg/L, a pH of 9 and a hardness of

47 mg CaCO3/L. Because the complexation capacity was around 30 µg/l, concentrations of the free Cu^{2+} were very low.

With respect to water qualities and bioavailable exposure comparable to that of the microcosms tested the NOEAC (No Observed Ecologically Acceptable Concentration) and LOEAEC (Lowest Observed Ecologically Adverse Effects Concentration) for this study were set to 20 µg/l and 40 µg Cu/L total dissolved copper. At the NOEAC, some significant effects occurred. However, all these effects were slight and mainly temporary effects without permanent impact on ecosystem quality, neither in structure nor in function (standing crop).

Hedtke, 1984

Among the mesocosm studies, the lowest NOEC of 4.0 µg/l (total copper)/ 3.6 µg/l (dissolved copper) is given by Hedke (1984) for *primary producers*. The lowest NOEC values for benthic macro-invertebrates were respectively 9.3 µg/l (total copper) and 8.8 µg/l (dissolved copper). The study was conducted in laboratory microcosms with a 5 cm layer of natural pond sediment (depth of the water body = 15 cm). The systems were exposed over 32 weeks exposure under flow-through conditions to nominal concentrations of 0, 10, 30, 90, 270 and 810 µg Cu/l ($CuSO_4$). The corresponding mean concentrations in the water were 1.4 (control), 4.0. 9.3, 30, 90, 420 µg/l total Cu. Concentration of dissolved copper were close to the total concentrations with values of 1.4 (control), 3.6, 8.8, 25, 70, and 360 µg/l Cu respectively. The water was characterised by an alkalinity of 180 mg/l, a hardness of ±200 mg/l , a pH of 8.9 . The average DOC level was calculated as 1.8 mg/L.

At the end of the study, 32 weeks after the starting exposition, gross primary production was significantly lower at 9.3 µg/l total Cu, respectively 8.8 µg/l dissolved Cu (reduction around 22 % compared to control, significant according Dunnett's t-test, α=0.05). The macroalgae *Vaucheria* showed significantly lower abundances at 8.8 µg dissolved Cu/l after 32 weeks (reduction around 71 % compared to controls). On the first of the two observations, after 16 weeks, no effects were found at 8.8 µg dissolved Cu/l. Based on observed abundances of different taxonomic groups (including cladoceran zooplankton groups), the authors further concluded that macro-invertebrate abundance, microbial population activities and periphyton growth were less sensitive than primary producers or zooplankton species. 25 µg dissolved Cu/l was the lowest concentration for which effects were observed (eg reduced survival of snails *Viviparus)*.

In summary, Hedke (1984) states that substantial structural effects were observed only at 25 µg dissolved Cu/l . Considering all the results, a NOEAC of 3.6 µg Cu/L and a LOAEC of 8.8 µg Cu/L can be derived.

Roussel, 2005

Roussel (2005) aimed to evaluate the effects of copper on the structure and function of freshwater ecosystems. To achieve this goal, the use of experimental streams allowed to realize an ecologically realistic study while controlling many parameters (contaminant exposure, water and sediment quality, antecedent of biotic and abiotic material, etc.). During 18 months, environmentally realistic concentrations of copper (0, 5, 25 and 75 µg/L) were applied on 12 outdoor mesocosms of 20 m long (using tapwater). Each river system distinguished two regions with distinct depth profiles and sediments type. The mesocosm is characterised by large variation in physico-chemical characteristics (eg 0.6 to 6.8 mg DOC/L). Mean measured abiotic factors in the mesocosms were a pH of 7.6, Ca concentration of 119 mg/l and a DOC level of 1.8 mg/l. Community structure of phytoplankton, periphyton, macrophytes, zooplankton, macroinvertebrates, emerging insects, aquatic hyphomycètes and population dynamics of three-spined sticklebacks was monitored. The taxonomic groups assessed, include 39 genus of phytoplankton, 50 genus of periphyton, 13 taxa of macrophytes, 21 zooplankton taxa and 38 taxa of macroinvertebrates. Copper effects on the ecosystem functioning was studied through (1) the leaf decomposition process and (2) the build up of a food web model followed by qualitative loop analyses. Results showed, in the 75 µg/L treatment, a decreased abundance of macrophytes, zooplankton, macroinvertebrates and an increased abundance of periphyton, emerging insects and fish. Taxa richness was lowered in all communities in the 75 µg/L treatment. The Principal Response Curve analyses, showed that copper at 25 and 75 µg/L altered community structure of all communities. Functioning of the leaf decomposition was altered at 75 µg/L. Aquatic hyphomycetes showed functional redundancy in their ability to degrade leaf litter. Copper direct toxic effects propagated within the trophic levels lead to indirect positive or negative effects. To help disentangling all these effects a food web model based on functional groups was build and qualitatively analyzed with loop analyses. Factors other than trophic interactions probably played an important role in structuring the ecosystem (tolerance, seasonal benefit, habitat availability, external invasion, access to more resources such as light or nutrient etc.). In conclusion, this study highlighted the interest of studying both ecosystem structure and function to identify a range of responses as symptoms of ecosystem dysfunctions. Considering all those results, a NOEAEC ecosystem was set at 4 µg/l (as dissolved), with a LOAEC of 20 µg Cu/L.

<u>Marine mesocosm studies</u>

Foekema, 2010

An outdoor marine mesocosm study was performed to investigate the effects of continuous exposure to a series of actively maintained concentrations of dissolved copper. The mesocosm consisted of circular glass-fibre tanks with a volume of 4.6 m^3. (height 180 cm, diameter 180 cm). For this study 18 of these mesocosms were provided with a ca. 20 cm layer of natural sediment below a layer of natural seawater of approx. 140 cm, containing a natural plankton community. Various macro invertebrate species were added to each mesocosm in known numbers. Before the start of the copper application the mesocosms were given 33 days to establish. During this period the systems were hydrologically connected to a central tank. During this period the water was circulated continuously to ensure a comparable development in all mesocosms. Just before the start of the copper application the mesocosms were disconnected and thus became static. Water circulation within each mesocosm was created by continuous aeration at about 10 cm above the sediment in the centre of the tank. During the following 5 days concentrations of dissolved copper in the water column were gradually build up by adding dissolved $CuSO_4$ using small pumps, until a concentration series ranging from 1 (untreated controls) to 31 µg Cu/L dissolved copper (as confirmed by chemical analysis) was created. Based on chemical analyses of mesocosm water samples collected three times per week these levels were maintained at these levels during the next 80 days by adding dissolved $CuSO_4$, where necessary. All treatments (5) and the untreated controls were run in triplicate, thus totalling 18 mesocosm systems.

In the two highest treatments, 16 and 31 µg Cu/L respectively, clear adverse direct effects were observed on zooplankton, bivalves and sponges and, to a lesser extent, on the periphyton (sessile algae) development and the shell growth of gastropods. The phytoplankton concentration and related primary production increased as a response to the reduced grazing pressure.

During the course of the study the DOC levels in the water column of the 16 and 31 µg/Cu L level mesocosms doubled from the initial 3 mg Cu/L to almost 7 mg Cu/L, probably as a result of enrichment of the water due to decaying tissues of dead organisms and algal growth.

No effects were detected in the two lowest treatments (2.9 and 5.7 µg Cu/L respectively).

In the intermediate treatment (9.9 µg Cu/L) some effects on periphyton development and the zooplankton community were observed, but these were of short term character. However, the reproduction success of the bivalve cockle (*Cerastoderma edule*) was strongly negatively affected. This adverse ecological effect formed the most sensitive endpoint of this study. Therefore the $NOEC_{mesocosm}$ and the $NOEAEC_{mesocosm}$ for this study are equal: 5.7 µg Cu/L. The LOEC is 9.9 µg Cu/L.

The two highest treatment levels caused clear direct and indirect effects on various endpoints, while no indication of effect of the treatment was seen at the lowest two test concentrations. The most sensitive endpoint was the reduction of the reproduction success of the bivalve cockle (*Cerastoderma edule).* This ecologically adverse effect was significant in treatments of 9.9 µg Cu/L and higher. Since in the next lower treatment, 5.7 µg Cu/L, no effects (including short term effects) were observed, the No Observed Ecological Adverse Effect Concentration (NOEAEC) that can be derived from this study is similar to the NOEC.

Considering that the copper RA is based on a PNEC, derived after organic carbon normalization, the quality of the DOC was assessed (Smith *et al.,* 2010). The main conclusions from the DOC

characterisation were that based on these analyses the water from the mesocosms looked very similar to water from pristine natural environments with low anthropogenic or terrestrial inputs.

The following information is taken into account for any hazard / risk assessment:

The results from the mesocosms are carried forward to the risk characterisation

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

See Annexes 1 – 10.

7.1.2.1 PNEC water

Table 56: PNEC aquatic

	Value	**Assessment factor**	**Remarks/Justification**
PNEC aqua – freshwater (µg/l)	7.8	1	Extrapolation method: statistical extrapolation as agreed by the Competent Authorities for Biocides and Existing Substance Regulations
PNEC aqua - marine water (µg/l)	5.2	1	Extrapolation method: assessment factor in accordance to the discussions with the Competent Authorities for Biocides and Existing Substance Regulations.
PNEC aqua – intermittent releases (mg/l)	-	-	Not applicable

A. PNEC freshwater : 7.8 µg dissolved Cu/L (Reasonable Worst Case PNEC)

See Annexes 1 – 2.

A1. Approach

The copper freshwater effects database contains a large number of high quality chronic NOEC/L(E)C10 values. In accordance with the TGD & REACH guidance, the use of the statistical extrapolation method, using all NOEC/L(E)C10 values is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC/L(E)C10 value.

Considering the information copper effects to surface water organisms, three phenomena determine the ecotoxicity:

The toxicity response is species-specific and related to water-borne exposure

The toxicity response is highly dependent on water type, and

The toxicity response is dependent on background levels and thus acclimation of the organisms.

A11. Accounting for species –specific differences : The copper aquatic effects database contains a large number of high quality chronic NOEC values. In accordance with the TGD & REACH guidance, the use of the statistical extrapolation method, using all NOEC values is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC value.

A12. Accounting for dependence on the water type : Cu bioavailability and toxicity to aquatic organisms is influenced by abiotic parameters such as pH, hardness, and dissolved organic carbon (DOC) . This resulted in considerable variability in observed NOECS within one species and thus raised the need to use a bioavailability normalization process for the PNEC derivation. Biotic Ligand Models were developed in order to provide a mechanistic basis for understanding and predicting bioavailability through integration of chemical parameters (e. g. pH, hardness, DOC) and biological parameters (receptor sites on organism, mode of action).

The BLM models developed/validated for 10 species, representing the three basic trophic levels (algae, invertebrates and fish) are:

(1) a unified chronic model was developed for the algae (*P. subcapitata, Chlamydomonas reinhardtii and Chlorella vulgaris*). The applicability of the model for predicting higher plant ecotoxicity (hydrocultures of Barley) was demonstrated

(2) a chronic BLM was developed for invertebrates (*Daphnia magna*) The capacity of the BLM for predicting copper toxicity to other invertebrate demonstrated from copper toxicity studies with *Brachionus calyciflorus, Lampilis siliquoidea, Hyridella depressa and Hyalella azteca*

(3) a unified chronic model was developed from the copper ecotoxicity data for 2 fish species (*Pimephales promelas and Oncorhynchus mykiss*).

The Boundaries of the BLM applicability is provided in the table below and en compasses the $10/90^{th}$ percentiles of the physico-chemistry of European surface waters

Endpoint	Species	Range Phys-chem			
		pH	H	DOC	Other boundaries
DEVELOPED/VALIDATED					
Algae growth	P. subcapitata	5.5-8.7	10-500	0-20	Al < 332 mg/L and Fe < 307 mg/L
Invertebrate reproduction	D. magna	5.5-8.5	10-500	0-20	Al < 332 mg/L and Fe < 307 mg/L
Fish growth	O. mykiss/P. promelas	6-8.6	12-360	0-18	

The BLMs developed for chronic fish (*P. promelas and O. mykiss*), invertebrates (*D. magna*) and algae (*P. subcapitata*) were used for normalizing all retained chronic NOEC values of respectively fish, invertebrates and algae/plant species. Briefly, the bioavailability normalization process normalizes the ecotoxicity data to sets of standard physicochemical conditions for important abiotic factors (i.e., pH, hardness, and dissolved organic carbon (DOC)). This approach allows for the comparison of intrinsic toxicity among organisms on an equal basis.

Normalization were carried out towards seven EU scenario's, selected to include a range of typical cases of bioavailability and to encompass the 10th/90thpercentile of the DOC, pH and hardness for surface waters. The normalization of the NOECs with the BLMs allowed to obtain small intra-species variability and resulted in robust and meaningful species-specific NOEC values.

A13. Accounting for acclimation : only NOECS for organisms acclimated to low copper levels in the test media were used for the PNEC derivation.

A2. Derivation of the HC5-50

The NOEC values and related physico-chemical characteristics of the test waters are summarized in Annexes 1 -3.

A Species Sensitivity Distributions was constructed using the non-normalized species-mean NOEC values for the most sensitive endpoints and resulted in a log normal HC5-50 of 6.1 µg Cu/L.

With due considerations of bio-availability, Species Sensitivity Distributions were constructed using the normalised NOEC data and a range of physico-chemical conditions, applicable to European surface waters. The resulting EU scenario specific HC5-50 range between 7.8 to 27.2 µg Cu/L when using the log normal distributions (see table below).

Water Type	Name	Country	pH	Hardness (mg CaCO3/L)	DOC (mg/L)	Na (mg/L)	Alkalinity (mgCaCO3/L)	HC5-50 (µg Cu/L)
Small (ditches with flow rate of ± 1,000 m³/d)	Generic	The Netherlands	6.9	350.1 (Ca: 88.2; Mg: 31.6 mg/l)	12	59.8	265	27.5
Medium (rivers with flow rate of ± 200,000 m³/d)	River Otter	United Kingdom	8.1	165 (Ca: 46.9; Mg: 11.6 mg/l)	3.2	14.2	116	7.8
Medium (rivers with flow rate of ± 200,000 m³/d)	River Teme	United Kingdom	7.6	159 (Ca: 49.9; Mg: 8.4 mg/l)	8	12.9	118	21.9
Large (rivers with flow rate of ± 1,000,000 m³/d)	River Rhine/	The Netherlands	7.8	217 (Ca: 68.9; Mg: 10.9 mg/l)	2.8	36.8	119	8.2
Mediterranean river	River Ebro	Spain	8.2	273 (Ca: 72.9; Mg: 22.1 mg/l)	3.7	5.3	35.8	10.6
Oligotrophic systems	Lake Monate	Italy	7.7	48.3 (Ca: 13.6; Mg: 3.5 mg/l)	2.5	2.3	50.6	10.6
Acidic system	Generic	Sweden	6.7	27.8 (Ca: 8.7; Mg: 1.5 mg/l)	3.8	7.7	13.6	11.1

The most sensitive eco-region HC5-50 (7.8 µg Cu/L) is considered as EU-wide Reasonable Worst Case (RWC) PNEC value and used in absence of site-specific physico-chemistry data.

To further evaluate the validity of this RWC HC5-50 (7.8 µg Cu/L), a comparison between the HC5 derived for the most sensitive eco-region, the 10^{th}-90^{th} percentile of the bioavailability parameters and non-normalized HC5 values was made and demonstrated that the HC5 values are almost identical (ranging between 7.5 and 7.9 µg/l)

To further evaluate the geographic representativeness of the RWC HC5-50, the distribution of the BLM-calculated HC5-50 across Europe was further assessed. Sites characterized by having site-specific information on physico-chemistry (DOC, Hardness, pH…) as well as copper concentrations reported are available for Belgium, Germany, UK, Sweden, Spain, Austria, the Netherlands and France and allowed to calculated HC5-50 for a wide range of sites.

- The data allowed estimating site-specific HC5-50 (using aggregated (averages) physico-chemical characteristics) for a range of sites in different EU countries. For regions with georeferenced data, the aggregated PNECs were used to map HC5-50 in the different EU countries, through Krigging techniques
- The HC5-50 maps allows calculating an EU wide RWC P HC5-50 of 10.5 µg Cu/L (median of the 10^{th} percentile HC5-50 for the different EU regions), further demonstrating the validity of the RWC value (7.8 µg Cu/L).

A3. Uncertainty analysis and Derivation of the PNEC

The copper aquatic effects database contains a large number of high quality chronic NOEC values (139 chronic NOECs for 27 species). The use of statistical extrapolation, using all NOECs in the ecotoxicity database is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC. Considering that, both the added and the background copper concentrations may contribute to the observed effects, this risk assessment implements the total risk approach.

Uncertainty considerations are needed to define the additional assessment factor (AF) on the HC5-50 of the SSD, with an AF between 1 and 5, to be judged on a case by case basis. The uncertainty analysis, the mesocosms, the information on copper background levels and the information on copper's essentiality and homeostasis are therefore used to derive the final PNEC from the single species studies.

A summary and evaluation of the ecotoxicity database and derived HC5-50 values therefore is provided below.

A31. Data quality

The overall quality of the database and the end-points covered, e.g., if all the data are generated from 'true' chronic studies (e.g., covering all sensitive life stages; real chronic exposure time)

- The Cu-database covered only ecological relevant endpoints. The selected endpoints were all very relevant for potential effects at population level: mortality, growth and reproduction,
- The NOEC data were extracted from tests performed in a variety of natural/artificial freshwaters, covering a considerable part of the wide range of the freshwater characteristics that are normally found in European freshwaters. Ranges of background concentrations, pH, DOC and hardness used in the ecotoxicological tests varied respectively between 0.45-7.0 µg/l Cu, between 5.5-9.0, between 0.1- 20.4 mg/l DOC and hardness between 7.9-486 mg/l $CaCO_3$. Therefore the Cu-data properly reflect the variability in physico-chemical conditions encountered in European surface waters.
- Covering of sensitive life stages and 'chronic' exposure times are also achieved for all trophic levels in the Cu database. For algae, exposure times up to 10 days are found covering therefore different generation times (most exposure times are 3 days). Sensitive life stages of invertebrates are included in the database: e.g. newly born daphnids (<24 hrs old) exposed for 42 days, insect larvae exposed to Cu for 240 days. For fish very sensitive life stages are also included in the database: e.g. fry of fathead minnow exposed to Cu for 330 days, yearlings from brook trout exposed to Cu for 244 days.
- Comparison of the incipient NOEC values with the median exposure time for invertebrates and fish from the ecotoxicity database revealed that the latter values (21 days for the invertebrates and 60 days for the fish) equals or exceeds the incipient NOEC for the invertebrates (11 days) and fish (between 30 and 60 days). Therefore the compilation of chronic data from organisms exposed for a longer duration to copper would not lead to higher sensitivity of the organisms. The database seems to reflect therefore true chronic exposure.
- Based on the analysis of the maintenance of the copper concentrations during testing of copper to organisms exposed in different systems (static, renewal and flow-through), it could be concluded that the copper level is maintained through the duration of the toxicity tests. Therefore, the selected NOEC values are reliable.

From the evaluation of the NOEC data quality and quantity it can be concluded that the Cu-database is of high quality, covers complete life stages and has built-in factors providing additional degrees of protection. Two important built-in conservative factors are :

1. Copper is homeostatically regulated. Acclimation to changes in copper concentrations in the aquatic environment have however not been accounted for in this RA. Further, it is worthwhile noting that 60% of the laboratory test waters had copper background levels below the range of copper background levels as reported by Zuurdeeg *et al.,* (1992) for European lowlands. This leads to further protection and conservatism as organisms acclimated to low copper levels in culture waters were demonstrated to be 1-3 times more sensitive.
2. It has been demonstrated that overestimation of toxicity values often occur for tests performed in flow through systems, characterized by separate inflow of test substance and test medium, because the Cu-DOC complexes in such systems have not yet been fully formed (Ma *et al.,* 1999). In comparison to natural surface waters, the laboratory flow-through test set-up will indeed have higher free cupric ion activity, which leads to lower NOECs (µg dissolved copper/L). In this effects data-set, 43% of the retained single species NOECs were derived from flow through systems: 100% of the fish tests, 16% of the invertebrate tests and 3% of the algae tests were carried out in flow-through system. The difference in sensitivity due to the non-equilibrated Cu-DOC in laboratory systems versus natural surface waters therefore leads to a build-in conservative factor that has not been accounted for in this risk assessment.

Conclusion: From the evaluation of the data quality it can be concluded that the Cu-database is of high quality, covers full life stages and has built-in conservative factors.

A32. The mechanism of action and taxonomic groups covered

- From the extracted data, it seems that the Cu-database does largely fulfil the requirement of 10-15 different NOEC values. Indeed, 139 individual NOEC values resulting in 27 different species NOEC values (fish, invertebrates and algae) were compiled from the database.
- In addition, the taxonomic group requirements are well fulfilled in this database. Species from the 9 different taxonomic groups are found in the Cu-database. Chronic NOEC values are available for 3 unicellular algal species (*Raphidocelis subcapitata*; *Chlamydomonas reinhardtii; Chlorella vulgaris*), 1 higher plant (*Lemna minor*), 1 rotifer species (*Brachionus calyciflorus*); 3 insect species (*Clistoronia magnifica*; *Chironomus riparius; Paratanytarsus parthenogeneticus*), 4 mollusc species (*Juga plicifera*, *Campeloma decisum; Villosa iris; Dreissenia polymorpha*), 5 crustacean species (*Ceriodaphnia dubia; Daphnia magna; Daphnia pulex; Hyalella azteca; Gammarus* pulex) and 10 fish species (*Pimephales notatus; Pimephales promelas; Oncorhynchus mykiss; Oncorhynchus kisutch; Ictalurus punctatus; Perca fluviatilis; Salvelinus fontanilis; Noemacheilus barbatulus; Catostomus commersoni; Esox lucius*). The database includes all the 8 taxonomic groups (families) mentioned in the taxonomic list that has been taken as a starting point.
- In addition, NOEC data from amphibian early life stages were assessed and demonstrated that these organisms are less sensitive to copper than some of the organisms included in the retained database and their inclusion in the analysis will therefore not influence the PNEC.
- In addition to the species covered in the single species studies, a large range of additional taxonomic groups have been evaluated in the mesocosm studies (see section 5).
- Information further shows similar modes of actions across species:
    - The cellular mechanism of copper toxicity/deficiency as well as the cellular mechanisms of copper homeostasis have been largely preserved through

evolution. The key indicator of copper toxicity is disturbance of the sodium homeostasis. The key target tissue for copper toxicity is therefore the water/organism interfaces with cell wall and gill-like surfaces acting as target biotic ligands in all species investigated. This results in relative small observed overall inter-species variability (max/min ratio of 23 for 27 species) and small acute to chronic ratios (typical a factor of 1 to 3).

- The observed differences in copper toxicity among species were further shown to be related to the organisms body size (Grosel *et al.,* 2007). The copper database includes taxonomic groups/endpoints with small sizes (e.g. crustaceans and rotifers, larval stages of insects and molluscs), indicating that sensitive organisms are covered in the database.
- Additional, it is useful to mention that the information on the mechanism of action, the homeostatic regulatory mechanisms, the observed small acute EC50 to chronic NOEC ratio's, the comparison of the effects data obtained from exposures through respectively water and food and the information on copper accumulations across trophic chains do not indicate towards concern from secondary poisoning nor trophic chain transfer.

Minimum taxonomic groups requirements for the extrapolation method

Taxonomic groups		**Cu-database**
1)	Fish (usually tested species like salmons, bluegill, channel catfish, etc.)	OK (e.g. O. mykiss)
2)	A second family in the phylum Chordata (fish, amphibian, etc.)	OK (e.g. N. barbatulus)
3)	A crustacean (e.g. cladoceran, copepod, ostracoda, isopod, amphipod, crayfish etc.)	OK (e.g. D. magna)
4)	An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.)	OK (e.g. C. magnifica)
5)	A family in a phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.)	OK (e.g. C. decisum)
6)	A family in any order of insect or any phylum not already represented	OK (e.g. C. riparius)
7)	Algae	OK (e.g. R. subcapitata)
8)	Higher plants	OK (e.g. L. minor)

Conclusion: Based on the taxonomic groups requirements, the small inter-species variability and the mode of action, it can be concluded that the effects database covers key taxonomic groups and endpoints.

A33. Treatment of multiple data for one species

The TGD and REACH guidance specifies to make a pre-selection of the data in relation to realistic environmental parameters in Europe (hardness, pH, DOC…). Multiple values from the same species should be investigated on a case by case basis, looking for reasons for differences.

Detailed investigation of the ecotox database covers realistic environmental conditions in Europe. The original database showed large variations among multiple values from the same species. A sensitivity analysis was performed to understand the relative importance of bioavailability versus acclimation/adaptation of the organisms to a range of copper concentrations. The results clearly showed that bioavailability was the most important factor explaining the large intra-species variability.

The copper risk assessment is therefore based on a 'total risk' approach, with the incorporation of bioavailability.

Chronic copper bioavailability models (Biotic Ligand Models) were therefore developed and validated for a 3 taxonomic groups (4 species) and their read across was validated for 7 additional species. Key elements responding to the read across criteria are :

- The similarity of the chronic Cu-BLM parameters across fish species (*Oncorhynchus* and *Pimephales*).
- The demonstration that the chronic algae Cu-model, developed for *Pseudokirchernella* is also valid for two other algae taxonomic groups (*Chlorella* and *Chlamydomonas*).
- Spot checking's, demonstrating the read across of the chronic *D. magna* Cu-BLM parameters towards three other taxonomic groups : amphipods (*Hyalella azteca*), rotifers (*Brachydanio rerio*) and molluscs (*Hyridella depressa* and *Lampsilis siliquoidea)*.
- The demonstration of the comparability between the chronic algae Cu model and the terrestrial plant models and the applicability of the algae model to predict effects in higher plants (egg Barley root elongation).
- Additional laboratory and field validations of the acute copper BLMs for a wide range of cladocerans and *Hyalella*
- The sensitivity analysis related to the read-across of the D. magna BLM towards insect
- The uncertainty analysis whereby it is demonstrated that full read across, using the chronic BLM parameters developed for each trophic level will reduce the uncertainty in the copper NOEC values usually down to a factor of 2, while limited read-across for copper will not allow such reduction in uncertainty.
- The mechanistic understanding of the copper toxicity

The research data therefore justify the full BLM read across for copper: all algae and higher plant NOECs can be normalized with the chronic algae Cu-BLM, all fish NOECs can be normalized with the chronic fish Cu-BLM and all invertebrates can be normalized with the chronic *D. magna* Cu-BLM.

The full BLM read across allows to maintain the large database (no need for pre-selection) and to normalize all NOEC values to a series of realistic environmental conditions in Europe (the 7 EU scenario's, agreed under the multi-metal TCNES discussions). For each of these scenarios, the intra-species variability after normalization is drastically reduced and allows for the derivation of meaningful species–specific geometric mean NOEC values for each endpoint and species. For each species, the lowest endpoint-specific geometric mean value was used as input into the SSDs. The BLM normalized HC5 was thus calculated for each of the typical EU scenario's and allowed to derive HC5-50 values ranging between 7.8 and 22.1 µg Cu/L (best fitting distributions) and to similar values (between 7.8 and 22.7 µg Cu/L) when using the log normal distributions.

The sensitivity analysis with regards to variations in DOC and pH as well the applications of the full versus more limited BLMs have demonstrated the robustness of the derived HC5-50 values.

Conclusion: the copper RAR complies with the TGD/REACH criteria related to multiple species inputs. The validity of the BLMs and applicability of the BLM to other species have been demonstrated. The BLM applications allow the reduction of the uncertainty related to bioavailability and allowed for setting a robust HC5-50 while maintaining the data-richness.

A35. Statistical uncertainties around the 5th percentile estimate

- The statistical uncertainty related to the derivation of species mean values has been drastically reduced by BLM normalisation of the NOEC values.
- The probability distribution of the Cu dataset used for the calculations of the 5th percentile values has been checked with the Anderson-Darling goodness-of-fit test. This goodness-of-fit test highlights differences between the tail of the distribution (lower tail is the region of interest) and the input data. Based on this analysis, a best fit of the data was achieved with the log-normal or beta distribution function depending on the eco-region considered.
- The difference between the HC5 and its lower 50 % confidence limit (HC5-50), calculated for the different EU scenario's varies on average by a factor of 1.07 with the best fitting approach and by a factor of 1.02 with the log normal distributions.
- The relatively small difference between the one-sided 95% left (HC5-5) and the 50% confidence limit (the factor varied between 1.1 and 1.8 for the different eco-regions with an average of 1.3 for the best fitting distributions; the factor varies between 1.5 and 1.8 with an average of 1.6 for the log normal distributions) together with the goodness-of-fit statistics reported showed that the statistical uncertainties around the 5th % are minimized.
- HC5-50 versus HC5-5 values was also determined from individual NOECs instead of the species mean NOEC values (log-normal distribution). The individual NOEC-HC5-50 values are similar to the HC5-50 values derived from species mean NOECS. A consistent HC5-50/HC5-5 ratio of 1.2 is observed across all scenarios for the log-normal distribution, based on all 139 individual NOEC values.

In agreement with the TGD/REACH guidance, the normalized HC5-50 values for the seven EU scenarios were used as a basis for the PNEC setting

Conclusion: The conventional approach using the log-normal and beta distribution function results in the 'best fitting' SSD, depending on the eco-region are considered. Based on the statistical uncertainty analysis, it can be concluded that the HC5-50 is a statistical robust determination.

A36. Evaluation of NOEC values below the HC5-50

Comparison of normalized HC5-50 values for the different EU scenario's with the species-specific normalized copper NOEC values for these scenario's, shows that only one and for some scenario's two out of the 27 species-specific NOEC values (*Brachionus calyciflorus* and in some cases *J. plicifera)* falls under the HC5-50. It is important to keep in mind that as the chronic data set increase in size (N) the probability of having a value below the HC5-50 increases equivalently. Therefore, consideration of NOEC values below the HC_5-50 should not be considered in the application of an additional assessment factor in isolation without taking the total number of data points into account. Further, it is useful to mention that the difference between the NOEC for the most sensitive species, *Brachionus calyciflorus,* and the HC5-50 is very small : the NOEC is on average a factor of 1.3 (best fit SSD) and 1.4 (log normal SSD) below the HC5-50. Finally, it is useful to mention that 38% of the individual *Brachionus calyciflorus* NOECs are actually above the HC5-50 values, further illustrating that we are dealing with very small remaining uncertainties, within the variability of the ecotoxicity testing methods.

Additionally, we point out that the BLM, derived for *Daphnia magna* was validated for many invertebrates, including *Brachionus calyciflorus,* providing evidence on similar modes of actions between *Daphnia magna* and the most sensitive species, *Brachionus calyciflorus.*

Conclusions: Only one or two out of the 27 species-specific NOECs falls under the HC5-50 value. The observed similarity in mechanism of action among invertebrates, including the most sensitive species, *Brachionus calyciflorus,* as well as the large ecotox database and small difference between the NOEC for *Brachionus calyciflorus* and the SSD-HC5-50 does demonstrate the applicability of statistical extrapolation to the copper database

A4. Summary of the derived HC5-50 and conservative elements built into the HC5-50

From the above summary, it is concluded that the copper aquatic effects database complies with the TGD/REACH guidance and contains a large number of high quality chronic NOEC values (139 chronic NOECs for 27 species), covering sensitive life stages and taxonomic groups. The Biotic ligand models have been validated and applied to the toxicity database. The uncertainty and sensitivity analysis of the data and data treatment clearly demonstrate the robustness of the derived copper HC5-50 values and do not indicate for an additional need of an AF on the HC5-50 values.

Some key conservative elements have been incorporated in the HC5-50 settings proposed in the RAR:

- The 50th % confidence limit is used for the PNEC derivation
- Overestimation of toxicity values often occur for tests performed in flow through systems because the Cu-DOC complexes have not yet been formed in the tests media.
- No acclimation of the organisms (no limit was set to the copper in the test media). The influence of background values was tested and demonstrated that acclimation may decrease the sensitivity up to a factor of 3.

Some key further uncertainties to be further addressed below are

- Is the HC5-50 protective towards deficiency and toxicity, especially as acclimation was not accounted for
- Can the HC5-50 protect sensitive waters
- Is the HC5-50 protective to field systems

A5. Comparison of the HC-50 with background levels

Considering that copper is a natural element, essential for all life forms, it is important to compare the proposed PNEC for the EU scenario considered with the copper background levels, the optimal concentration ranges and the essentiality levels.

The total dissolved HC5-50 values, derived for EU typical scenario's (7.8 to 22.1 µgCu/L with the best fitting distribution and 7.8 to 27.2 µg Cu/L with the log normal distribution) are above the average country-specific copper background range reported. (0.3 and 2 µg Cu/L). The HC5-50 values derived for the EU typical scenario's are however just above the range of natural background levels reported for Europe by Zuurdeeg *et al.,* 1992 (between 0.8 – 5 µg Cu/L) and within the ambient levels reported in pristine areas in Europe by FOREGS (range between 0.1 and 14 µg Cu/L).

BLM calculations of 635 pristine sites, identified by FOREGS, demonstrated that the BLM can also protect very sensitive waters, outside the 10/90th percentile of EU surface waters. The analysis of the FOREGS data further showed that the application of an AF 2 on BLM calculated HC5-50 values lead to the identification of inappropriate risks in 11% of the pristine areas within low background levels (median 1 µg Cu/L).

Conclusion: The proposed HC5-50 values may thus already be below background levels in some EU waters. This therefore cautions to the use of an unnecessary AF on the derived HC5-50 values.

A6. Comparison of the HC-50 with levels on essentiality and homeostasis

Different studies have quantified levels of homeostasis in invertebrates, fish and amphibian. Levels below 1 µg Cu/L were leading to copper deficiency.

Bossuyt *et al.,* 2004 performed acclimation experiments with D. magna and showed that after three generation of acclimation, the optimal concentration ranges (from energy reserves and number of offspring's) remained constant between 1 and 35 µg Cu/L. Below 1 µg Cu/L (a concentration often used as background copper concentration in the ecotoxicity media), copper deficiency was clearly observed. BLM calculations carried out in the water used for the acclimation experiments allows to calculate an HC5-50 of 7.8 µg Cu/L, being right at the centre of optimal concentration range.

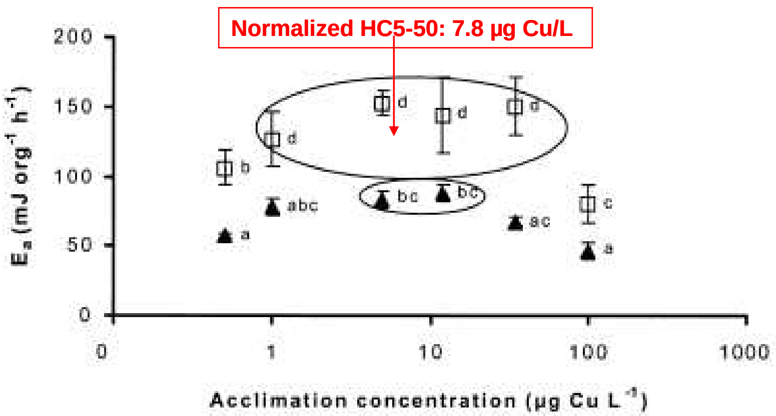

Figure 5: Energy reserves (Ea) of first (triangles) and 4th to 15th (squares) generation D. magna acclimated to different copper concentrations.
Error bars represent standard deviations. Mean levels for same letter are not significantly different at p<00.5. Ovals represent the optimal concentration range. From Bossuyt *et al.,* 2004

Additionally, the total dissolved HC5-50 values of the most sensitive eco-regions are close to reported decreased fish growth at < 8 µg Cu/l (Seim *et al.,*1984).

Fort *et al.,* 2000 determined optimal copper concentration ranges for the early life stages of the amphibia *X. Laevis* : 1 to 10 µg Cu/L.

Conclusion: *The* HC5-50 is protective towards toxicity and essentiality and the information on essentiality and homeostasis cautions to the use of an unnecessary AF on the derived HC5-50 values.

A7. Validation of the HC5-50 derivation for sensitive environments

The protective nature of the BLM can be further evaluated from BLM calculations using the physico-chemistry of a Dutch standard water. The predicted HC5-50 values for the Dutch standard media scenario's is actually 1 µg Cu/L, being below the average natural background in Europe and at the deficiency edge of the copper optimal concentration range (Figure **5**). This Dutch standard waters scenario is clearly outside the scope of the RA but illustrates that the BLM can protect very sensitive waters.

The evaluation of the applicability of the single species HC5-50 values to lotic and lentic multi-species ecosystems were evaluated from mesocosm data. Species-specific NOECs and threshold values, protective of ecosystem structure and functions are obtained from three distinct high quality mesocosm studies, representing lentic and lotic system. The taxonomic groups assessed in these mesocosm studies include more than 39 genus of phytoplankton, 50 genus of periphyton, 13 taxa of macrophytes, 21 zooplankton taxa and 38 taxa of macroinvertebrates. The mesocosm studies include direct and indirect effects to a large variety of taxonomic group and integrate effects from uptake from water as well as from food. Detailed comparison between to the BLM predicted single species NOECs and HC5-50 values, at the physicochemistry of the mesocosm, and the observed mesocosm NOEAECs[9] / LOEAEC [10] and HC5-50 values, calculated from the geometric mean NOECs for the species assessed in the mesocosm study, clearly demonstrate that BLM derived HC5-50 values can adequately predict the mesocosm sensitivity within a factor of 2. The BLM calculated HC5-50 resulted in predicted/observed ratio's ranging between 0.5 (Schaefers, 2003), 0.9 (Hedtke, 1984) and 1.3 (Roussel, 2005) with an average ratio of 0.9. The difference between the Schaefers (2003) and the other two studies can be explained by the fact that no pre-equilibration between the copper dose and the test media was applied in Hedtke (1984) or Roussel (2005). The application of the pre-equilibration factor determined from Ma *et al.,* 1999 and the Roussel mesocosm hydrodynamics indeed further demonstrate that the BLM derived HC5-50 is protective for the Roussel mesocosm system, evaluating pooled samples across the river system

Figure 6). It can therefore be concluded that the single species HC5-50 can adequately protect natural ecosystems.

[9] NOEAEC : No Observed Ecological Adverse Effects Concentrations

[10] LOEAEC : Lowest Observed Ecological Adverse Effects Concentrations

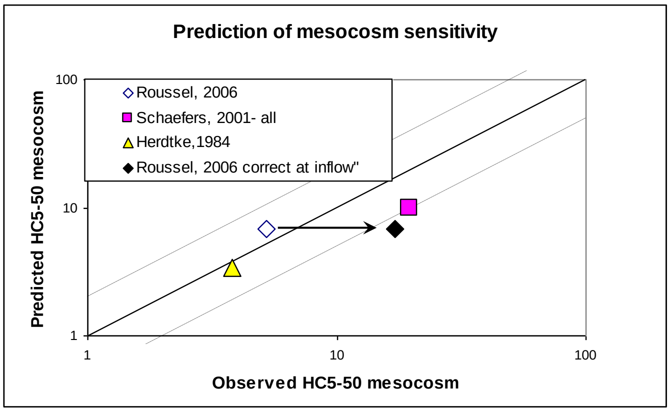

Figure 6: BLM predicted HC5-50 value NOECs versus observed mesocosm HC5-50 values. Predicted mesocosm HC5-50 values were calculated from the single species NOEC database (section 2) and BLM normalization of these single species NOECs towards the physico-chemistry of the mesocosms. The observed HC5-50 values are calculated from the observed species-specific NOECs for the mesocosm species. For the Roussel, 2005 study, a range between the original HC5-50 and the HC5-50 corrected for non-equilibration at the inflow is provided.

Conclusion: The BLM scenario calculations thus further confirm that the derived HC5-50 values are protective to sensitive multi-species ecosystems. The data therefore demonstrate that there is no need for an AF on the derived HC5-50 values. The HC5-50 values are therefore proposed as PNECs.

A RWC PNEC of 7.8 µg Cu/L is carried forward to the risk characterization

B. PNEC Marine: 5.2 µg dissolved Cu/L (Reasonable Worst Case PNEC)

B1. Approach

The differences in physiology between freshwater and marine organisms, and the related differences in ecotoxic behaviour led to the derivation of a separate PNEC for freshwater and marine environments.

The copper marine effects database contains a large number of high quality chronic NOEC values. In accordance with the TGD & REACH guidance, the use of the statistical extrapolation method, using all NOEC values is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC value.

Considering the information copper effects to marine water organisms, three phenomena determine the ecotoxicity:

The toxicity response is species-specific and related to water-borne exposure

The toxicity response is highly dependent on the characteristics of the marine water, and

The toxicity response is dependent on background levels and thus acclimation of the organisms.

B11. Accounting for species –specific differences : The copper marine effects database contains a large number of high quality chronic values (56 chronic NOECs/EC10s for 24 species). In accordance with the approach followed for the freshwater compartment, the use of statistical extrapolation is used for the marine PNEC derivation.

B12. *Accounting for the characteristics of the marine water :* As for the freshwater system, Cu -availability and toxicity to marine organisms is influenced by the strong binding of copper to the dissolved organic carbon (DOC). This resulted in considerable variability in observed NOECS within one species and thus raised the need to use an availability normalization process for the PNEC derivation.

A relation between the EC50s or NOEC/EC10 values and the DOC levels were assessed for 6 species: *Fucus vesiculosus*-zoospore growth (Chromophycota, 'bladderwrack'), *Crassostreas gigas* - embryo development (Mollusca, 'Pacific oyster'), embryo life stages (48 hour tests) of *Mytilus galloprovincialis (*Mollusca, 'Mediterranean mussel'), Mortality of *Dendraster excentricus* (Echinodermata, 'Sand Dollar') and *Strongylocentrotus purpuratus* (Echinodermata, 'Purple Sea Urchin'). Since the six data sets are statistically equivalent, it is appropriate to combine them for derivation of an overall descriptor of the protective effects of DOC. This equation was used to translate all NOEC data to a standard DOC levels of 2 mg DOC/L for coastal waters and of 0.2 mg DOC/L for open sea.

Briefly, the availability normalization process normalizes the ecotoxicity data to a standard dissolved organic carbon (DOC)). This approach allows for the comparison of intrinsic toxicity among organisms on an equal basis.

B13 Accounting for acclimation: copper deficiency is a well known phenomenon in open ocean. This was described in the copper RA but not used for the marine PNEC derivation

B2. Derivation of the HC5-50

A Species Sensitivity Distributions was constructed using the non-normalized NOECs and resulted in an HC5-50 of 4.6 µg Cu/L . A best fit distribution was used because the fitting was rejected when the log-normal distribution was used.

An organic carbon normalization was carried out and the HC5-50 was derived at a DOC level, representative to coastal and open ocean area's (2 and 0.2 mg/l). From the high quality data, HC5-50 values of respectively 5.2 and 1.3 µg Cu/l (best fitting distribution), were thus derived. The log normal distribution showed only marginal acceptance in the goodness of fit tests and therefore best fitting distributions were retained.

The copper RA (2008) also includes additional evaluations of Q2 and Q3 NOECs and the additional assessment of EC50s from single species and multi-species marine studies, adding weight to the validity of the HC5-50 value derived from the best fitting distribution on the high quality NOECs. Considering the available weight of evidence, the HC5-50 of 5.2 µg Cu/L was used as a basis for the PNEC derivation for coastal zone area's

B3. Uncertainty assessment

The high quality Cu-database contains 56 individual NOEC (EC10) values resulting in 24 different species NOEC values (fish, invertebrates and algae).

The copper RA includes a sensitivity analysis whereby also lower quality data were used for the derivation of the HC5-50; a summary is hereby included. Details are provided in the copper RAR 2008

Uncertainty considerations are needed to define the additional assessment factor on the HC5-50 of the SSD, with an AF between 1 and 5, to be judged on a case by case basis. The uncertainty analysis, the mesocosms, the information on copper background levels and the information on copper's essentiality and homeostasis are therefore used to derive the final PNEC from the single species studies.

B31. Data quality

The overall quality of the database and the end-points covered, e.g., if all the data are generated from 'true' chronic studies (e.g., covering all sensitive life stages; real chronic exposure time)

- The marine Cu-database covers only ecological relevant endpoints. The selected endpoints are all very relevant for potential effects at population level: mortality, reproduction, hatching, growth, spawning frequency, and abnormalities.
- 'Chronic' exposure times or relevant exposure periods for sensitive life-stages were achieved for all trophic levels in the high quality Cu database. The exposure times for macro-algae were between 14 to 19 days. For the invertebrates, exposure times from 24 hours (embryo exposure) to >42 days (mortality, development), and for fish, exposure times of up to 32 days in an embryo-larval early life stage test were reported.
- Sensitive life stages are covered in the high quality database. All fish experiments were performed with eggs, embryo or embryo-larval stages. Chronic tests with crustaceans/molluscs were initiated with larvae or juveniles, while most of the tests with echinoderms were performed with young organisms (e.g. larvae). From the chronic tests using polychaetes, larvae were used for initiating the tests with *Neanthes arenaceodentata*. All tests using macro-algae were initiated with very young life stages, i.e. zoospores.
- The analysis of the copper concentrations during the ecotoxicity tests, showed that, for the retained studies, the copper exposure levels were maintained through the duration of the toxicity tests. Therefore, the selected NOEC values are reliable.

From the evaluation of the NOEC/EC10 data quality and quantity it can be concluded that the marine Cu-database is of high quality and covers complete or sensitive life stages. Two important built-in conservative factors are :

> * Copper is homeostatically regulated. Acclimation to changes in copper concentrations in the marine environment have however not been accounted for in this RA. Some of the test organisms have been retained form open ocean - copper deficient- systems and their susceptibility to increased copper exposures is thus expected to be higher than the ones observed in organisms acclimated to coastal systems.
>
> * It has been demonstrated for the freshwater compartment that overestimation of toxicity values often occur for non-equilibrated test systems due to a lesser Cu-DOC complexation. Such equilibration is of equal importance in marine as in freshwater systems. Some of the single-species tests were carried out with pre-equilibrated test media but a large proportion of the single species NOECs were established without including a pre-equilibration period to allow for copper-DOC binding to occur prior to exposure of the organisms to the test media. In such test systems, the organisms have likely been exposed to a higher fraction of free cupric ions/dissolved copper then naturally occurring in marine systems and therefore lower NOECs are expected.

Conclusion: From the evaluation of the data quality it can be concluded that the Cu-database is of high quality, covers full life stages and has built-in conservative factors.

B32. The mechanism of action and taxonomic groups covered

From the extracted data, it seems that the Cu-database does considerably exceed the requirement of 10-15 different NOEC values, set for the freshwater environment.

Species covered

- High quality chronic NOEC values (Q1 NOECs) are available for 2 unicellular algal species (*Phaeodactylum tricornutum*; *Skeletonema costatum*), 2 macroalgal species (*Macrocystis pyrifera; Fucus vesiculosus*), 6 mollusc species (*Mytilus edulis; Prototheca staminea; Crassostrea gigas, Mercenaria mercenaria, Mytilus galloprovincialis, Placopecten magellanicus)*, 1 annelid species (*Neanthes arenaceodentata)* 3 decapod (crustacean) species (*Pandalus danae; Penaeus mergulensis*; *Penaeus monodon),* 3 copepod (crustacean) species *(Eurytemora affinis; Tisbe battagliai, Tisbe furcata*), 1 arthropod (crustacean) species (*Artemia franciscana*) 1 echinoderm species (*Paracentrotus lividus),* 3 cnidaria species *(Acropora tenuis, Goniastrea aspera, Lobophytum compactum)* and 2 fish species (*Cyprinodon variegatus; Atherinopsis affinis*).
- Supportive information from Q2 and Q3 data are described in the copper RAR (2008)

Taxonomic groups covered

The copper NOECs cover a wide range of marine taxonomic groups. Data from the following taxa are included in the high quality data set that is the basis for the high quality species sensitivity distribution;

- *Vertebrata (fish)*
- *Arthropoda - Crustacea*
- *Mollusca*
- *Echinodermata*
- *Annelida*
- *Cnidaria*
- *Micro-algae*
- *Macro-algae*

It has to be noted that the high quality database contains only chronic NOECs for 2 fish species. However, the derived chronic endpoints, combined with information on acute toxicity indicate that fish are less

Information on copper's mode of action, having a similar basis (iono-regulation) as observed for freshwater organisms, provides final confidence in the taxonomic groups covered:

- o Grosell *et al.,* 2007 recently demonstrated indeed that the sensitivity of fish across a full salinity gradient is related to osmoregulatory disturbance (similar to what is observed for freshwater organisms). The authors demonstrated further that not the absolute ionic concentrations but the sodium gradient from the blood plasma to the water, influences the copper sensitivity across the salinity gradient The latter mechanism explained the observed higher copper sensitivity of *Fundulus heteroclitus* in freshwater, followed by seawater and waters of intermediate salinity.
- o The key indicator of copper toxicity is thus, as for freshwater, the disturbance of the sodium homeostasis. The key target tissue for copper toxicity is therefore the water/organism interface with cell wall and gill-like surfaces acting as target

ligands in all species investigated. This results in relative small observed overall inter-species variability in marine NOECs (max/min ratio of 34 (after normalization for DOC) for 24 species).

- For freshwater, the observed differences in copper toxicity among species was further shown to be related to the organisms body size (Grosell *et al.,* 2007). The copper database includes taxonomic groups/endpoints with small sizes (egg crustaceans, larval stages of molluscs and fish), indicating that sensitive organisms and life stages are covered in the marine database.

Conclusion: Based on the taxonomic groups covered, the mode of action and the small inter-species variability, it can be concluded that the effects database is protective for key taxonomic groups and endpoints of the marine ecosystem.

B33. Treatment of multiple data for one species

The freshwater effects part of the TGD/REACH specifies to make a pre-selection of the data in relation to realistic environmental parameters in Europe (hardness, pH, DOC…). Multiple values from the same species should be investigated on a case by case basis, looking for reasons for differences.

Detailed investigation of the ecotoxicity database covers realistic environmental conditions of marine waters. The original database showed large variations among multiple values from the same species. The results clearly showed that copper-DOC binding and the related copper availability was the most important factor explaining the large intra-species variability.

The assessment is therefore based on a 'total risk' approach, with the incorporation of a DOC normalization. Chronic as well as acute copper effects were indeed shown to be related to the DOC levels in the test media. Copper effects -DOC relationships were established and compared for a range of marine organisms: *Mytilus edulis* (Mollusca, bivalve, mussel), *Fucus vesiculosus* (Chromophycota, 'bladderwrack'), *Crassostreas gigas* (Mollusca, 'Pacific oyster'), *Mytilus galloprovincialis (*Mollusca, 'Mediterranean mussel'), *Dendraster excentricus* (Echinodermata, 'Sand Dollar'), *Strongylocentrotus purpuratus* (Echinodermata, 'Purple Sea Urchin').

The data demonstrate that there is no statistical difference between the observed copper effects-DOC relationships among taxonomic groups and thus allows to perform a DOC normalization, applicable to all taxonomic groups. The application of the DOC normalization to all taxonomic groups investigated, allows to predict all observed NOEC/EC10 values (derived under varying DOC levels) within a factor of 2. All species-specific copper NOECs/EC10s were therefore normalized to a range of DOC values: 0.2-2 mg C/L, as agreed in the EU MAMPEC model and confirmed by a literature search on DOC levels in European coastal and open sea waters.

Conclusion: the marine copper effects assessment complies with the TGD//REACH principles related to multiple species inputs. The validity of the DOC normalization across species was demonstrated. The DOC normalization allows to reduce the uncertainty related to copper availability in marine waters. The Normalized NOEC/EC10 values are the basis for a robust species sensitivity distribution and HC5-50 derivation, while maintaining the full data richness.

B34. Statistical uncertainties around the 5th percentile estimate

Parametric statistical analysis is undertaken using the BestFit software (Palisade Inc.) and the ETX model. The different parametric curve fittings are ranked by statistical tests of fitness. The data were also assessed with the semi-parametric kernel density estimation.

Based on the parametric tests, HC5-50 values, derived from the Q1 data-set, coastal zone (2 mg DOC/L) scenario range between of 4.4 µg Cu/L (log normal) to 5.2 µg Cu/L(Best-fit). The Log Normal analysis demonstrates only a marginal pass for the Anderson-Darling statistic (failed at 0.1; pass at 0.05), and a fail for the Cramer von Mises and Kolmogorov-Smirnov analysis test. The HC5-50 value derived from the semi-parametric Kernel Density Estimation was 4.8 µg Cu/L.

To evaluate the robustness of the HC5-50 values derived, several sensitivity analysis was performed : (1) using only NOECs/EC10s from 'truly filtered' systems; (2) inclusion of the Q2 and Q3 NOECs/EC10s; (3) considering varying DOC quality. The HC5-50 values obtained from non-rejected parametric distributions range between 4.3 and 6.0 µg Cu/L with a median value of 5.1 µg Cu/L (at 2mg DOC/L)

Conclusion: Based on the statistical uncertainty and sensitivity analysis, it can be concluded that an HC5-50 value of 5.2 µg Cu/L is a robust, statistically sound HC5-50 determination, applicable to coastal waters. The sensitivity analysis shows that the uncertainty around this value is very low.

B35. Evaluation of NOEC values below the HC5-50

The lowest species-specific NOEC (4.4µg Cu/L for *Phaeodactylum*) is only a factor of 1.2 below the HC5-50 value (5.2 µg Cu/l), derived with the best fitting. The same NOEC is also slightly below (factor 1.1) the HC5-50 of 4.8 µg Cu/L, obtained from the Flexible Kernel Density Estimation. Having one NOEC below the HC5-50 is thus merely a statistical phenomenon related to the large number of species in the database (24 species). Comparing the HC5-50 values with the species-specific NOECs obtained from the Q1+Q2+Q3 dataset shows that the species (geometric) mean NOEC values for the most sensitive endpoints have increased: for *Phaeodactylum* 4.4 µg l^{-1} (Q1 only) to 13.4 µg l^{-1} (all data). The Q3 dataset (64 species-mean NOECs) returns another species with species mean NOEC at or below the HC5-50 (*Spisula solidissima*, with a NOEC of 5 µg Cu/L). Having one NOEC below the HC5-50 is thus again merely a statistical phenomenon related to the large number of species in the database (64 species).

The comparison between the Q1 & Q2 & Q3 datasets therefore adds robustness to the Q1 HC5-50 values.

Conclusion*:* Only one of the 24 species-specific Q1 NOECs falls under the Q1 HC5-50 value. Similarly, only one of the 64 species-specific Q1, Q2, and Q3 NOECs falls under the Q1 HC5-50 value. The difference between the NOECs below the Q1 HC5-50 value is always less than a factor of 1.2, demonstrating the applicability of statistical extrapolation to the marine copper database as well as the robustness of the derived HC5-50.

B4. Summary of the derived HC5-50 and conservative elements built into the HC5-50

From the above summary, it is concluded that the copper marine effects database contains a large number of high quality chronic NOEC values (56 chronic NOECs for 24 species), covering sensitive life stages and taxonomic groups. The organic carbon normalization was validated for 6 species and applied to the whole toxicity database. The uncertainty and sensitivity analysis of the data and data treatment clearly demonstrate the robustness of the derived copper HC5-50 values and do not indicate for an additional need of an AF on the HC5-50 values.

Some key conservative elements have been incorporated in the HC5-50 settings proposed:

- The 50th % confidence limit is used for the PNEC derivation
- Overestimation of toxicity values often occur for tests performed in non-equilibrated systems because the Cu-DOC complexes have not yet been formed in the tests media.
- No acclimation of the organisms.

Some key further uncertainties to be further addressed below are

- Comparison of the HC5-50 with background levels
- Is the HC5-50 protective to field systems

B5. Comparison of the HC5-50 with background levels

Nutrient deficiency, including copper deficiency is documented in open ocean scenarios. For the OSPAR regions, dissolved background copper levels, estimated from off shore samples, range between 0.050 and 0.360 µg/L (OSPAR,2001). The HC5-50 derived for the open ocean MAMPEC program (0.2 mg/l) is 1.3 µg Cu/L and thus slightly above the background levels of an open ocean system.

Copper levels in the controls of the retained Q1 ecotoxicity tests were < 4.3 µg Cu/l with a median value of 2.4 µg Cu/L. The Q1 HC5-50 values derived from best fitting distributions (1.3 to 5.2 µg Cu/l) is thus around the copper levels in control test media, further demonstrating that the use of assessment factors needs to be done with caution.

Conclusion: The proposed HC5-50 values are close to copper concentrations in control media and above reported copper background concentrations in open oceans. This therefore gives confidence to the proposed HC5-50 values but cautions to the use of an unnecessary AF on the derived HC5-50 values.

B6. Validation of the HC5-50 derivation for mesocosm/field studies

As a follow-up on the copper RA, a marine mesocosm study (Foekema *et al.,* 2010) has been carried out. Ecosystem NOEC and LOEC values of respectively 5.7 and 9.9 µg dissolved Cu/L were derived.

For the NOEC and LOEC doses, the DOC in the mesocosm ranged between 2.74 and 4.82 mg/L with an average of 3.53 mg DOC/L.

To account for the copper 'availability', the single-species NOECs were normalized to the low, median and high DOC levels observed in the mesocosm study, using the organic carbon normaliser. The OC normalized NOECs were integrated into the RIVM SSD tool and HC5-50 values of 5.96, 7.7 and 10.5 µg dissolved Cu/L were calculated. These organic carbon normalized single species HC5-50 values are consistent with the NOEC and LOECs derived from the mesocosm system (5.7 and 9.9 µg Cu/L).

To further assess the quality the DOC, an Early Life Stage CuSO4 Mytilus ecotoxicity test (one of the most sensitive endpoints of the SSD) was carried out in the control mesocosm water (Smith *et al.,* 2010). Relative large variability's in observed effects are observed, possibly due to the long delay between the collection of the mesocosm water and the Mytilus test. The average NOECs, LOECs and EC10 were calculated as respectively 4.6, 7.2 and 8.7 µg Cu/L. The most robust average EC10 value (8.7 µg Cu/L) fits between the NOEC and LOEC values derived from the mesocosm study. **Figure 7** compares the different threshold values derived above and clearly demonstrates that the Organic Carbon normalized single species HC5-50 is protective to the structure and function of multi-species systems. The

Figure 7 also indicates the RWC HC5-50 of 5.2 µg Cu/L, carried forward to the risk characterisation

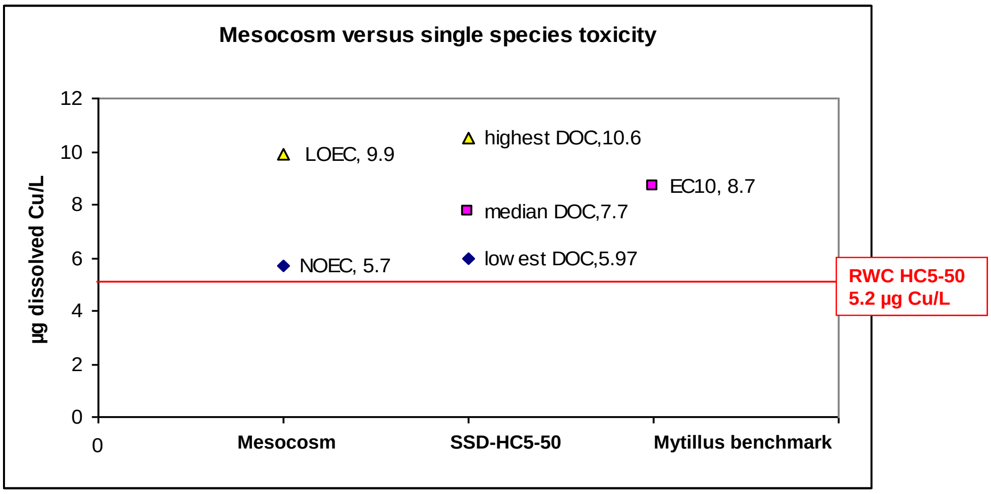

Figure 7: **Comparison between threshold values** obtained from the (1) the marine mesocosm study (mesocosm); (2) the single species HC5-50 obtained from the species sensitivity distribution of the single species NOECs, normalized to the range DOC applicable to the mesocosm study (at 5.7 and 9.9 µg/L doses) and (3) the EC10 value for a Mytilus Tests carried out in the mescosm control water. The red line is the RWC HC5-50 carried forward to the risk characterization.

Conclusion: The mesocosm study confirms the HC5-50 obtained from the single-species study. The data therefore confirm that the DOC- normalized single species HC5-50 is protective to the ecosystem structure and function.

B7. Final summary and conclusion

Thorough consideration of

- the large amount of high quality single species chronic NOEC values for a wide variety of taxonomic groups
- the knowledge on the mechanism of action of copper
- the robustness of the DOC normalization
- the small statistical uncertainty around the HC5-50
- the overestimation of copper toxicity in laboratory non-equilibrated compared to natural systems due to limited Cu-DOC binding
- the use of the total risk approach
- the marine natural open ocean background levels and copper levels observed in control media
- the essentiality of copper and the homeostatic capacity of aquatic organisms

it is concluded that the OC normalized HC5-50 values for marine scenarios are robust and ecologically relevant and are proposed as PNECs for marine waters.

In the copper RAR (2008), in absence of a high quality mesocosm, an assessment factor 2 has been applied on the HC5-50 and a marine PNEC of 2.6 µg Cu/L was derived and carried forward to the risk characterization under the ESR.

TC NES agreed that, considering the large amount of information available, this assessment factor could in future be reduced if the HC5-50 could be validated with reliable, representative and comprehensive mesocosm data. This statement was endorsed by SCHER

As recommended by TCNES and SCHER, the data from the mesocosm confirm the single species PNEC and thus allow to remove the AF2 on the HC5-50.

Conclusion: The HC5-50, derived from the best fitting distribution (5.2 µg Cu/L) was retained for the PNEC setting. TCNES agreed that, considering the large amount of information available, this assessment factor could in the future be reduced if the HC5-50 could be validated with reliable, representative and comprehensive mesocosm data.

The newly generated mesocosm data are now able to confirm the single species HC5-50 values and therefore, an AF=1 will be used for the CSR and a PNEC of 5.2 µg Cu/L carried forward to the risk characterisation.[11]

7.1.2.2 PNEC sediment

Table 57: PNEC sediment

	Value	Assessment factor	Remarks/Justification
PNEC sediment [freshwater] (mg/kg dw)	87	1	
PNEC sediment [marine] (mg/kg dw)	676	1	Extrapolation method: partition coefficient in accordance to the discussions with the Competent Authorities for Existing Substance Regulations.

<u>PNEC freshwater sediment : 87 mg/kg dry weight (Reasonable Worst Case PNEC)</u>

See Annex 7

C1. Approach

The sediment PNEC has been derived, from a total risk approach, using the weight of evidence from different sources and tiers of information : (1) pelagic ecotoxicity data in combination with Kd values derived through different approaches, (2) benthic sediment ecotoxicity data with total sediment exposures, (3) soil ecotoxicity data and soil bioavailability models and (4) mesocosm/field studies.

1.Using the EqP approach, $HC5\text{-}50_{sediment\ (EP)}$ values were derived for seven EU scenarios, representative for the physico-chemical characteristics of EU surface waters (the EU scenario's defined in the aquatic effects section). The scenario-specific $HC5\text{-}50_{sediment\ (EP)}$ values were thus calculated from the scenario-specific aquatic HC5-50 values (see summary

[11] Considering that the absence of high quality marine mesocosm/field data, an AF = 2 was applied for the copper RAR and a PNEC of 2.6 µg Cu/L was carried forward to the risk characterization. TCNES and SCHER agreed that, considering the large amount of information available that this assessment factor could be reduced to 1 if the HC5-50 can be validated with mesocosm data.

'setting of PNEC-aquatic for copper') and the application of respectively, the EU median Kd $_{suspended\ solids}$, the EU median Kd $_{sediment}$ and the scenario-specific Kd values as calculated from WHAM VI (Kd $_{WHAM}$). These approaches resulted in the HC5-50 $_{sediment\ (EP\ SS)}$, HC5-50$_{sediment\ (EP\ Sed)}$ and HC5-50$_{sediment\ (EP\ WHAM)}$. Considering the relevance of organic carbon binding, all values were normalized for their organic carbon content. For each approach, the EU scenario with the lowest HC5-50s was selected as the reasonable worst case HC5-50$_{sediment\ (EP)}$ values. The respective HC5-50 and the 5th and 95th confidence limits are:

HC5-50$_{sediment\ (EP\ WHAM)}$: 1,833 (1,642-2,007) mg Cu/kg OC ;

HC5-50$_{sediment\ (EP\ SS)}$: 2,358 (1,331-3,539) mg Cu/kg OC;

HC5-50$_{sediment\ (EP\ Sed)}$: 3,808 (2,148-5,712) mg Cu/kg OC).

(2) Evaluation of the benthic sediment ecotoxicity data (106 NOECs from 6 species) revealed the importance of organic carbon and the Acid Volatile Sulphide pool to control the chronic toxicity of Cu towards sediment-dwelling organisms. The derivation of the freshwater HC5-50$_{sediment\ (benthic\ SSD)}$ has therefore been based on the organic carbon normalized dataset, using only low AVS sediments. The retained database includes 6 species-specific data points representing 62 NOEC values. The HC5-50$_{sediment\ (benthic\ SSD)}$ and their 5th/95th confidence limits), using the best fitting and log normal fittings are respectively **2,021 (1,963-2,110)** and **1,741 (1,112-2,071) mg Cu/kg OC**.

(3) Considering sediments as 'wet soils' allows for a comparison between the HC5-50 values, derived from sediment NOECs with OC normalization and the HC5-50 values derived from soil NOEC data (251 NOECs, covering 19 species of plants/invertebrates and 9 microbial endpoints) and soil bioavailability models (pH, OC and CEC normalizations). **The comparison was carried out for a range of representative sediment scenario's and shows that the HC5-50s estimated from respectively sediment and soil data are highly correlated and not significantly different**. The HC5-50 values derived from the sediment NOECs/OC normalization were on average between a factor 0.7 to 0.8 below HC5-50 values derived from soil NOECs and soil bioavailability models (OC, pH, CEC based).

(4) Sediment threshold values and benthic NOECs are available from the 4 mesocosm studies and one field cohort study. The mesocosm data include multi-exposure routes and multi-species interactions and account for benthic structures as well as functions (including sediment decomposition). The studies cover ecotoxicological relevant endpoints for wide ranges of taxonomic groups, important for the benthic structure as well as the benthic functions: *Cyclopoida, Ostracoda, Chironomidae, Tubificidae, Nematoda, Crustacaea, Gastropoda, Insecta, Oligochaet*a macroalgae, perifyton, microbial functions (particulate organic carbon production, leaf decomposition, fungi richness). The lowest mesocosm organic carbon normalized NOEC is 4,285 mg Cu/kg OC. An organic carbon based HC5-50$_{sediment\ (mesocosm\ SSD)}$ (5th and 95th Confidence limits) was calculated as **3,007 (2,204-3,743) mg Cu/kg OC**. The mesocosm data include multi-exposure routes and multi-species interactions and account for benthic structures as well as functions (including sediment decomposition).

From this analysis it is concluded that the HC5-50$_{\textbf{sediment (benthic SSD)}}$ obtained from the sediment ecotoxicity data through best fitting distributions (**2,021 mg Cu/kg OC**) or log normal distributions (**1,741 mg Cu/kg OC**) are similar or lower than the HC5-50 $_{sediment\ (EP\ SS)}$, HC5-50$_{sediment\ (EP\ Sed)}$,, HC5-50$_{sediment\ (EP\ WHAM)}$ and HC5-50$_{sediment\ (mesocosm\ SSD)}$ and will therefore protect benthic organisms from copper exposures under oxic conditions. Using the TGD/REACH default OC value of 5%, HC5-50$_{\textbf{sediment (benthic SSD)}}$ from respectively best fitting distributions and log normal distributions of **101 mg Cu/kg dry** weight and **87 mg Cu/kg dry weight** are retained**.** These values are therefore proposed as PNEC $_{sediment.}$

Considering that higher HC5-50 values are derived through the equilibrium partition approach in natural sediments as well as in mesocosm/field exposures, additional binding of copper to acid volatile sulfides need to be considered for the risk characterisation.

C2. The single species NOECs, HC5-50 derivation and uncertainty analysis

The use of statistical extrapolation is preferred for HC5-50 derivation rather than the use of an assessment factor on the lowest NOEC. In accordance with the Workshop recommendation the 50% confidence level of the 5th percentile value, using the best fitting distribution function would result in a HC5-50$_{sediment\ (benthic\ SSD)}$ of ,2021 mg Cu/kg OC. The conventional log normal distribution results in a HC5-50 $_{sediment\ (benthic\ SSD)}$ of 1,741 mg Cu/kg OC.

A summary and evaluation of the ecotoxicity database and derived HC5-50 values is provided below.

C21. Data quality

The overall quality of the database and the end-points covered, e.g., if all the data are generated from 'true' chronic studies (e.g., covering all sensitive life stages; real chronic exposure time)

- Benthic NOECS
    - The Cu-database covered only ecological relevant endpoints. The selected benthic endpoints were all very relevant for potential effects at population level: mortality, growth and reproduction.
    - The NOEC data were extracted from tests performed in a variety of natural/artificial freshwater sediment, covering a considerable part of the wide range of the sediment characteristics (AVS, OC) that are normally found in European freshwater sediments.
    - Covering of sensitive life stages and 'chronic' exposure times are achieved for all sediment- dwelling organisms covered in the Cu database. All tests were performed in agreement with international agreed standard procedures (e.g. ASTM) and comprise chronic exposure times for the different organisms between 28 and 42 days. The age of the test organisms used for toxicity testing was dependent on the type of test used: i.e. the reproduction tests with oligochaetes were initiated with adult organisms while the toxicity tests with the amphipods and insect were started with respectively juveniles and larvae.
- aquatic NOECs (used for the equilibrium partitioning approach)
    - see aquatic summary
- terrestrial NOECs (used for comparison with the sensitivity of benthic species)
    - see terrestrial summary

Conclusion: From the evaluation of the data quality it can be concluded that the Cu-database is of high quality and covers full life stages.

C22. The mechanism of action and taxonomic groups covered

- High quality chronic NOEC values (62 NOEC values in total) are available for 6 different sediment-dwelling invertebrates, belonging to 3 different families (i.e. oligochaetes, crustaceans and insects) with different feeding habits and ecological niches: *Tubifex tubifex, Hyalella azteca, Chironomus riparius, Lumbriculus variegatus, Gammarus pulex, Hexagenia sp..* The organic carbon based geometric mean NOEC values of the benthic species vary by a factor 3.

- Seven benthic species were incorporated in the aquatic SSD and thus evaluated under the equilibrium partitioning approach, described above. The chronic aquatic SSD thus adds chronic NOECs for 4 additional benthic species *: Juga plicifera, Campelona decisum, Dreissena polymorpha, Villosa iris.*
- Comparing the HC5-50s from the tier 1 and tier 2 further show:

  - no significant differences between the RWC HC5-50$_{\textbf{sediment (EP, WHAM)}}$, HC5-50$_{\textbf{sediment (EP,SS)}}$ and HC5-50$_{\textbf{sediment (benthic SSD)}}$.

  - that the RWC HC5-50$_{\textbf{sediment (benthic SSD)}}$ is a factor 1.9 (best fit) to 2.2 (log normal) lower (not significant at the 0.05 level , but significant at the 0.1 level) than the HC5-50$_{\textbf{sediment (EP-Sed)}}$,

- In the RAR (2008) additional acute effects data were reported for 13 additional benthic species : *Cherax destructor, Parataya Australiensis, Macrobrachium, Velusunio angasi, Carbiculina australis, Tanytarsus dissimilis, Pteronarcys californica, Ephemerella grandis, Pomacea paludosa, Unionidae mussels, Lampsilis stralinea claibornensis, Procambarus clarkia, Lithoglyphus virens.* None of these data conflicts with the HC5-50 values aquatic, confirming that benthic species have similar sensitivity to pelagic species.
- Results further showed that pelagic phytoplanktonic algae are more sensitive than single species benthic cultures, the latter being less sensitive than perifyton due to a reduced bioavailability in the biofilm related to a dense mucous matrix (organic matter, silt particles).
- The mesocosm studies include the following taxonomic groups and functions***:*** *Cyclopoida, Ostracoda, Chironomidae, Tubificidae, Nematoda, Crustacaea, Gastropoda, Insecta, Oligochaet*a macroalgae, perifyton, microbial functions (particulate organic carbon production, leaf decomposition, fungi richness).

- Information further shows similar modes of actions across species:
  - The cellular mechanism of copper toxicity/deficiency as well as the cellular mechanisms of copper homeostasis has been largely preserved through evolution. The similarity in organic carbon based HC5-50 values, calculated from the benthic NOECs, aquatic NOECS (equilibrium partitioning) and soil NOECs/bioavailability models further indicate similar mechanisms of actions across compartments and demonstrate that benthic organisms are not more sensitive than soil nor aquatic organisms.

  - Additional, it is useful to mention that the information on the mechanism of action, the homeostatic regulatory mechanisms, the comparison of the effects data obtained from exposures through respectively water and food and the information on copper accumulations across trophic chains do not indicate towards concern from secondary poisoning nor trophic chain transfer.

Conclusion: Based on the taxonomic groups assessed and the small difference in organic carbon based HC5-50 values derived from respectively the aquatic NOECS (EP approach), the benthic NOECs and soil NOECs, it can be concluded that the effects database will be protective to key taxonomic groups and endpoints.

C23. Treatment of multiple data for one species

The TG/REACH guidance specifies to make a pre-selection of the data in relation to realistic environmental parameters in Europe (hardness, pH, DOC…). Multiple values from the same species should be investigated on a case by case basis, looking for reasons for differences.

Detailed investigation of the ecotox database covers realistic environmental conditions in Europe. The original data set showed large variations in benthic NOEC values, related to differences in Acid Volatile Sulphide (AVS) pools and Organic Carbon (OC) content of the sediments used for the ecotoxicity tests. The derivation of the freshwater $HC5\text{-}50_{\text{sediment (benthic SSD)}}$ for copper has therefore been based on the organic carbon normalized dataset, using only low AVS sediments.

The organic carbon normalization, clearly reduces the NOEC variability for the tests conducted in test media with different organic carbon content: *T. tubifex*, *H. azteca*, *C. riparius* - all endpoints.

The lowest organic carbon based species geometric mean NOECs were retained for the final PNEC derivation.

Conclusion: the copper RAR complies with the TGD/REACH criteria related to multiple species inputs. The Organic Carbon normalization is compliant with TGD/REACH guidelines and its validity was demonstrated for several species. The OC applications allow to reduce the uncertainty related to metal availability and allowed for setting a robust HC5-50.

C24. Statistical uncertainties around the 5th percentile estimate

The probability distribution of the Cu dataset used for the calculations of the 5th percentile values have been checked with the Anderson-Darling goodness-of-fit test. This goodness-of-fit test highlights differences between the tail of the distribution (lower tail is the region of interest) and the input data. Based on this analysis, the best fit of the log-transformed data were achieved with the Beta distribution.

The relatively small difference between the one-sided 95% left (HC5-5) and the 50% confidence limit, respectively 1,963 and 2,021 mg Cu/kg (different by a factor 1.03), together with the goodness-of-fit statistic reflect the good performance of this distribution for the Cu-dataset. The statistical uncertainty analysis for the conventional log normal distribution showed a difference between the one-sided 95% left and the 50% confidence limit of respectively 1112 and 1741 mg Cu/kg OC (different by a factor 1.6).

Conclusion: Based on the statistical uncertainty analysis, it can be concluded that the beta distributions has the highest statistical certainty. The HC5-50s from both distributions are statistical robust determinations.

C25. Evaluation of NOEC values below the HC5-50

One species geometric NOEC value is a factor 1.02 below the $HC5\text{-}50_{\text{sediment (benthic SSD)}}$ derived from the best fitting approach. No species mean NOEC values are below the $HC5\text{-}50_{\text{sediment (benthic SSD)}}$ derived from the log normal fitting.

Conclusions: The HC5-50 values are similar (maximum ratio 1.02) or below all species geometric mean benthic NOECS.

C3. Summary of the derived HC5-50 and conservative elements built into the HC5-50

The benthic high quality database includes 61 NOECs for 6 species, representative for different ecological niches and feeding habits. This weight of evidence approach demonstrated that the benthic

HC5-50 values (best fit and log normal) are similar to or somewhat below the HC5-50 values derived form aquatic NOECs (EP approach) as well as soil HC5-50s.
Some key conservative elements have been incorporated in the HC5-50 settings proposed in the RAR:

- The 50th % confidence limit is used for the PNEC derivation
- The effects analysis indicated a higher binding affinity of copper in natural sediments compared to the ones used for the benthic ecotoxicity tests. Indeed for the ecotoxicity tests, only artificial media and sediments from 2 natural sites, characterised by low clay content (respectively 3.8 and 9% clay) and low AVS content were retained for the analysis. Furthermore, the Kd values observed in the semi static test systems are lower than what is observed in the field.
- No acclimation of the organisms (no limit was set to the copper in the test media).

Some key further uncertainties to be further addressed below are

- Is the HC5-50 protective towards deficiency and toxicity, especially as acclimation was not accounted for
- Can the HC5-50 protect sensitive waters
- Is the HC5-50 protective to field systems

C4. Comparison of the HC-50 with background levels

Considering that copper is a natural element, essential for all life forms, it is important to compare the proposed PNEC with the background levels in Europe. Copper background levels were reported for different EU member states and varied between 1.7 and 59 mg/kg dry weight. The country-specific median background values ranged between 16 and 32 mg Cu/kg dry weight. The 10^{th}-90^{th} percentiles of the ambient copper levels, reported for pristine areas in Europe by Foregs range between 4 and 44 mg Cu/kg dry weight. These values are below the proposed PNEC value but caution to the use of an unnecessary AF on the HC5-50

Conclusion: The proposed HC5-50 values are therefore above most background levels in EU sediments. The information further cautions to the use of an unnecessary AF on the derived HC5-50 values.

C5. Comparison of the HC-50 with levels on essentiality and homeostasis

No data are available on the copper deficiency of sediment dwelling organisms. Considering however that the HC5-50 $_{sediment\ benthic\ SSD}$ are similar to the HC5-50 $_{sediment\ EP}$, as for the aquatic compartment, caution is needed with the use of unnecessary AF s on the HC5-50.

Conclusion: *The* HC5-50 needs to be protective towards toxicity and essentiality and the information on essentiality and homeostasis obtained from the aquatic compartment cautions to the use of an unnecessary AF on the derived HC5-50 values.

C6. Validation of the HC5-50 derivation for sensitive environments

Sediment threshold values and benthic NOECs are available from the 4 mesocosm studies and one field cohort study. The studies include uptake from water, suspended solids as well as sediments and cover ecotoxicological relevant endpoints for a wide ranges of taxonomic groups important for the benthic structure as well as the benthic functions : *Cyclopoida, Ostracoda, Chironomidae, Tubificidae, Nematoda, Crustacaea, Gastropoda, Insecta, Oligochaet*a macroalgae, perifyton, microbial functions (particulate organic carbon production, leaf decomposition, fungi richness). The lowest mesocosm organic carbon normalized NOEC (4285 mg Cu/kg OC) is a factor 2.1 (best fit) to 2.5 (log normal) above the HC5-50$_{\mathbf{sediment\ (benthic\ SSD)}}$. An organic carbon based HC5-50$_{sediment\ (mesocosm\ SSD)}$ (5^{th} and 95^{th}

Confidence limits) was calculated as 3,007 (2,204-3,743) mg Cu/kg OC. The mesocosm HC5-50 is a factor 1.5 to 1.7 above the derived HC5-50$_{\textbf{sediment (benthic SSD)}}$ (not significant at 0.05 level but significant differences at the 0.01 level). The mesocosm data therefore clearly demonstrate that the HC5-50$_{\text{sediment}}$ values, derived through equilibrium partitioning and single species sediment toxicity testing are protective for a wide range of benthic organisms, tested in a variety of conditions. The mesocosm validations include multi-exposure routes and multi-species interactions and account for benthic structures as well as functions.

Conclusion: The derived **HC5-50**$_{\text{sediment (benthic SSD)}}$ values are therefore protective to multi-species ecosystems. The data therefore demonstrate that there is no need for an AF on the derived HC5-50 values. The **HC5-50**$_{\text{sediment (benthic SSD)}}$ values are therefore proposed as PNECs.

C7. Final summary and conclusion

Thorough consideration of

- the large amount of high quality single species and multi-species chronic NOEC values for a wide variety of taxonomic groups
- the knowledge on the mechanism of action of copper
- the robustness of the OC normalization
- the small statistical uncertainty around the HC5-50
- the validation of the OC predicted HC5-50 values for mesocosms threshold values, protective to the structure and functioning of the ecosystems and representing lotic and lentic systems of varying sensitivity
- the use of the total risk approach
- the EU natural background levels
- the essentiality of copper and the homeostatic capacity of living organisms
- the assessment factors used in other RAs,

it is concluded that the OC derived HC5-50 values are robust and ecological relevant. The HC5-50 values do include sufficient build-in conservative factors and were shown to be protective to multi-species systems. The analysis therefore suggests that there is no need for an AF on the derived HC5-50. The comparison between the HC5-50 and background levels and optimal concentration ranges further cautions towards the use of unnecessary assessment factors. Comparison of the copper database with other databases for which an AF was used shows that, for copper, the AF of 2 is not applicable. Rather an AF of 1 is proposed. The available effects analysis therefore allows the derivation of a sediment PNEC equal to the OC calculated **HC5-50**$_{\text{sediment (benthic SSD)}}$ values.

The HC5-50$_{\textbf{sediment (benthic SSD)}}$ from the log normal distribution (87 mg Cu/kg dry weight – at TGD/REACH **default OC content of 5%, AF=1) is carried forward as PNEC to the risk characterization.**

Considering that only low AVS sediments were used for the PNEC setting, an AVS correction is applied at the exposure side in the risk characterization.

D. PNEC marine and estuarine sediment : 676 and 288 mg/kg dry weight (Reasonable Worst Case PNEC)

D1. Approach

The sediment PNEC has been derived, from a total risk approach, using the marine pelagic ecotoxicity data in combination with Kd values derived for respectively marine and estuarine sediments.

D2. PNEC derivation

Respective marine and estuarine K_D-value of 131826 and 56234 L/kg were derived from the literature review. These values are converted to the dimensionless form (m^3/m^3) according to:

$$K_{susp\text{-}water} marine = Fraction_{water} + Fraction_{solid} \times \frac{K_D}{1000} \times RHO_{solid} = 32957 \text{ m}^3/\text{m} \quad \text{(Eq. 3)}$$

$$K_{susp\text{-}water} estuarine = Fraction_{water} + Fraction_{solid} \times \frac{K_D}{1000} \times RHO_{solid} = 14059 \text{ m}^3/\text{m}^3 \quad \text{(Eq. 3)}$$

with $Fraction_{water}$=0.9; $Fraction_{solid}$=0.1; RHO_{solid}= 2500; $K_{susp\text{-}water}$ expressed as m^3/m^3 and K_D expressed as L/kg

The $PNEC_{sediment}$ for the marine and estuarine environments are calculated using Equations 1 and 2 and are presented in the tables below. A value of 1150 is used for $RHO_{susp.solid}$.

Table 58: Derivation of a marine $PNEC_{sediment}$ with the equilibrium partitioning method, using the physicochemical properties of suspended solid

Scenario	$PNEC_{aquatic}$ (µg Cu/L)	PNEC marine sediment (mg Cu/kg wet wt)	PNEC marien sediment (mg Cu/kg dry wt) Conv. factor: 0.22
DOC: 2 mg/L ; Pearson V-fit	5.2	148	676

These values do not include a correction for the sediment OC.

Table 59: Derivation of an estuarine $PNEC_{sediment}$ with the equilibrium partitioning method, using the physicochemical properties of suspended solid

Scenario	$PNEC_{aquatic}$ (µg Cu/L)	PNEC estuarine sediment (mg Cu/kg wet wt)	PNEC estuarine sediment (mg Cu/kg dry wt) Conv. factor: 0.22
DOC: 2 mg/L ; Pearson V-fit	5.2	64	288

These values do not include a correction for the sediment OC.

The partitioning method thus resulted in a PNEC of 288 mg/kg dwt (estuarine environment) and 676 mg/kg dwt (marine environment) (suspended solids method). These PNECs are used for the risk characterization.

According to the EU TGD/REACH an assessment factor of 10 should be applied to the PNEC for substances that sorbs strongly to sediment to take exposure via ingestion into account. However, in the case of copper, no additional assessment factor needs to be applied to the derived PNEC for the following reasons : .

- the freshwater effects chapter demonstrated that the dietary uptake of copper does not contribute to the toxicity
- the mechanism of action in marine fish pointed to the importance of osmoregulatory disturbance to be key in the toxicity profile
- the fact that for the most sensitive invertebrates (eg bivalves) short term exposures to early life stages provided the most sensitive NOECs shows that water exposure is key to the marine effects assessment

As no information on AVS was available for the marine sites, used for the local and regional PEC derivations, this correction was not carried out.

7.2 Terrestrial compartment

7.2.1 Toxicity data

The high quality records retained for the PNEC derivation of copper under the Existing Substances Regulation (TCNES) and Biocidal Products regulations (Technical meetings) have been included in the IUCLID data-base. Tests that were considered as not-reliable for the PNEC derivations have NOT been included in the IUCLID records but have been summarized in the copper RA report.

The terrestrial effects records include 252 good quality single-species **chronic NOEC/EC10 values representing different trophic groups (micro-organisms, plants, invertebrates)** These NOECS are carried forward for the terrestrial PNEC derivation in a WOE approach.

Additionally information on 8 single species studies in field contaminated soils and 5 multi-species studies (freshly spiked and field contaminated) were used for as additional WOE for the PNEC derivations of the freshwater and the sediment compartment.

Considering the importance of bio-availability for reducing the intra-species variability, the data- base includes supportive information related to the development/validation of the terrestrial copper bio-availability regression models. The bio-availability regression models are used for normalizing the NOECS and deriving the terrestrial PNEC.

Considering the importance of differences in toxicity of copper to terrestrial organisms between lab spiked soils and field contaminated soils, the records information from freshly spiked soils and aged soils

NOECS for Invertebrates:

The invertebrate (including arthropods) effect records include 108 NOEC//(L(E) C10 values; hard and soft bodied organisms with different exposure routes and feeding strategies belonging to 10 different species and 6 different families (i. e. the *Eisenia andrei*, *Eisenia fetida*, *Lumbricus rubellus* belonging to the family of the Lumbricidae; *Cognettia sphagnetorum*to the family of the Enchytraedae; *Isotoma viridis*, *Folsomia candida*, *Folsomia fimetaria* to the family of the Isotomidae; *Hypoaspis aculeifer*to the family of the Laelapidae, *Platynothrus peltifer* to the family of the Camisiidae , *Plectus acuminatus* to the family of the Plectidae).

Individual high quality NOEC/(L(E) C10 values from different studies range from 8.4 mg/kg for *Eisenia andrei* coco on production to 1,460 mg/kg for *Folsomia candida* reproduction.

Remarkably low NOEC values are found in some tests that used Eisenia species (*E. fetida and E. andrei*). The lowest value is found for *E. Andrei* reproduction (8.4 mg total Cu/kg) in a natural soil (a German standard soil often used in toxicity tests, LUFA 2.2). This value is below the limit for essentiality. Van Gestel *et al.,* 1989 actually warn against use of cocoon production as reliable endpoint for Eisena Feitida

Important intra-species variability in NOEC: L(E) C10 values are observed due to differences in the physico-chemistry of the soils. For invertebrates, 2 models were developed the *E. fetida* model, representing soft-bodied species and the *F. candida* model representing hard-bodied species. These models were used for the normalization of the invertebrate NOEC data and the derivation of the PNEC

Records are available on the influence of soil ageing/leaching on the plant toxicity, especially those on reported by Ma *et al.,* 2006 and Ma *et al.,* 2006 b – see section adsorption/desorption are also of relevance to the terrestrial PNEC

This information was used for the PNEC derivation relevant to monitoring data.

NOECs for plants

The plant effect records include 67 high quality single-species chronic NOEC/EC10 values covering monocotyle and dicotyle plants including agricultural and wild species belonging to 9 different species and 5 different families: (*Polygonum convolvulus*– family of the Polyonaceae; *Lycopersicon esculentum*– family of the Solanaceae; *Hordeum vulgare*, *Avena sativa*, *Pao annua*– family of the Poaceae; *Senecio vulgaris*, *Andryala integrifolia*, *Hypochoeris radicata*– family of the Asteraceae; *Lolium perenne*– family of the Gramineae). The retained NOECS are carried forward for the terrestrial PNEC derivation in a WOE approach

Individual high quality NOEC/(L(E) C10 values from different studies range between ranging from 18 mg/kg for *Hordeum vulgare*to 698 mg/kg for *Lycopersicon esculentum*.

Important intra-species variability in NOEC: L(E) C10 values are observed due to differences in the physico-chemistry of the soils. For plants, 2 models were developed (Rooney *et al.,* 2004 and 2006): *L. esculentum* model (endpoint yield) and *H. vulgare* root elongation model. These models were used for the normalization of the plant NOEC data and the derivation of the PNEC

Additional records available on the influence of soil chemistry, soil ageing and soil leaching on the plant toxicity (Ginochio *et al.,* 2006; Zhao *et al.,* 2006).

Strandberg *et al.,* 2006 further showed that plant community composition was significantly correlated with soil copper concentration and community composition at soil copper concentrations above 200 mg/kg differed significantly from community composition at lower copper levels.

The studies on soil attenuation, reported by Ma *et al.,* 2006 and Ma *et al.,* 2006 b – see section adsorption/desorption are also of relevance to the terrestrial plant PNEC

This information was used for the PNEC derivation relevant to monitoring data

NOECS for Microbial processes:

The effect records related to microbial processes include 77 NOEC/EC10 values; 9 different endpoints representing the C- and N-cycle and measurement of microbial biomass are available (i. e. maize induced respiration, substrate induced respiration, litter decomposition, glutamic acid decomposition, N-mineralisation, denitrification, nitrification, ammonification, biomass C, biomass N).

Individual high quality NOEC/(L(E) C10 values from different studies range from 30 mg/kg (glucose respiration)) to 2,402 mg/kg (maize respiration).

Important intra-species variability in NOEC: L(E) C10 values are observed due to differences in the physico-chemistry of the soils. For microbial processes, 3 bio-availability models were developed: the nitrification process model, the maize respiration model (using a natural substrate) and the substrate induced respiration model (Smolder and Oorts 2004 and Oorts, 2006a). These models were used for the normalization of the NOEC data for microbial processes and the derivation of the PNEC

Records are available on the influence of soil ageing/leaching on the plant toxicity (eg Chander and Brooks, 1993; Oorts 2006b). This information was used for the PNEC derivation relevant to monitoring data.

Toxicity to birds

One study reports an LD50 or Cu2O to Bobwhite qual. Cu2O was suspended in Tylose and administered through gavage. The administration route does not allow for the natural attenuation as reported in the environmental fate and behaviour section and the ecological relevance is therefore questioned.

7.2.1.1 Toxicity to soil macro organisms

The results are summarised in the following table:

Table 60: Overview of effects on soil macro-organisms

Method	Results	Remarks	Reference
other soil dwelling worm: Cognettia sphagnetorum (annelids) long-term toxicity (laboratory study) Substrate: LUFA 2.2 soil with peat and inoculated with either algae (Pleurococcus spp) or fungus (Mortierella isabellina) The effect of copper and food sources on the growth and fragmentation of the enchytraeid Cognettia sphagnetorum was investigated	NOEC (35 d): 63 mg/kg soil dw (meas. (arithm. mean)) based on: growth and fragmentation NOEC (63 d): 441 mg/kg soil dw (meas. (arithm. mean)) based on: growth and fragmentation NOEC (42 d): 312 mg/kg soil dw (meas. (arithm. mean)) based on: growth and fragmentation NOEC (70 d): 455 mg/kg soil dw (meas. (arithm. mean)) based on: growth and fragmentation	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Augustsson, A. K., & Rundgren, S. (1998)
Aporrectodea tuberculata, microorganisms long-term toxicity (laboratory study)	NOEC (40 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: growth (;	2 (reliable with restrictions) weight of evidence	Bogomolov, D.M., Chen, S.K., Parmalee, R.W,

Method	Results	Remarks	Reference
Substrate: multi-species microcosm In this study, copper contamination was assessed in a small laboratory soil microcosm. Microcosm soils were treated with copper sulphate at concentrations of 0 to 800 mg Cu/kg. 5, 10, 20 and 40 days after soil treatment the following organism level measurements were taken: microbial biomass N, substrate induced respiration (SIR) and soil urease ??? activity; total nematode numbers; earthworm mortality, growth and body accumulation of copper.	A. tuberculata) NOEC (40 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: substrate induced respiration NOEC (40 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: litter decomposition NOEC (40 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance; Nematoda (total nematode numbers) NOEC (40 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance; N-mineralisation	experimental result **Test material (Common name): copper sulphate**	Subler, S. & Edwards, C.A. (1996)
Plectus acuminatus (nematods) long-term toxicity (laboratory study) Substrate: artificial soil The effect of copper on the production of adults, juveniles and the adult:juvenile ratio in Plectus acuminatus in artificial OECD soil was determined over a 21 day exposure period. Copper chloride delivered Cu^{2+} at dose concentrations of 0 to 1000 mg/kg dry weight.	NOEC (21 d): 32 mg/kg soil dw (meas. (arithm. mean)) based on: juvenile production (added NOEC)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Kammenga, J.E., Van Koert, P.H.G., Riksen, J.A.G., Korthals, G.W. (1996)
Zea mays, Solanum tuberosum, Nematoda long-term toxicity (field study) Substrate: multi-species microcosm The long term effect of Cu was investigated in field conditions on the invertebrates (nematodes: total abundance and trophic level abundance) and higher plants Zea mays (maize yield) and Solanum tuberosum (potato yield). The soil type used originates from the Gelderse valley (the Netherlands).	NOEC (3650 d): 48.2 mg/kg soil dw based on: yield (based on shoot) - Zea mays (a) NOEC (3650 d): 42.3 mg/kg soil dw based on: yield (based on shoot) - zea mays (b) NOEC (3650 d): 75.1 mg/kg soil dw based on: yield (based on shoot) - zea mays (c) NOEC (3650 d): 99.6 mg/kg soil dw based on: yield (based on shoot) - zea mays (d) NOEC (3650 d): 72.2 mg/kg soil dw based on: yield (based on tubers) - S. tuberosum(a) NOEC (3650 d): 71.8 mg/kg soil dw based on: yield (based on shoot) - S. tuberosum(b) NOEC (3650 d): 105.3 mg/kg soil dw based on: yield (based on shoot) - S.	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Korthals, G.W., Alexiev, A.D., Lexmond, T.M., Kammenga, J.E. & Bongers, T. (1996)

Method	Results	Remarks	Reference
	tuberosum(c) NOEC (3650 d): 99.6 mg/kg soil dw based on: trophic level abundance - nematoda (omnivores) (d)		
Nematoda short-term toxicity (laboratory study) Substrate: multi-species microcosm In a freshly spiked soil, the effects of copper on soil nematodes from different feeding and life-history strategy groups were investigated. The soil used was a sandy soil.	NOEC (14 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance NOEC (14 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: maturity index NOEC (14 d): < 100 mg/kg soil dw (meas. (arithm. mean)) based on: maturity index	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Korthals, G.W., van de Ende, A., van Megen, H., Lexmond, T.M., Kammenga (1996)
other soil dwelling microorganisms: Hypoaspis aculeifer long-term toxicity (laboratory study) Substrate: LUFA 2.2 soil The effect of copper on the mortality and reproduction of the predatory mite Hypoaspis aculeifer was determined after 21 days of exposure.	NOEC (21 d): 174 mg/kg soil dw (meas. (arithm. mean)) based on: mortality and reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Krogh, P.H. & Axelsen, J.A. (1998)
other soil dwelling worm: Eisenia andrei and Eisenia fetida long-term toxicity (laboratory study) Substrate: Two types of soil were used, an artificial OECD soil and LUFA 2.2 soil OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	NOEC (28 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on cocoon production) - E. andrei, OECD soil NOEC (28 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on juvenile production) - E. andrei, OECD soil NOEC (28 d): 3.2 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on cocoon production) - E. andrei, LUFA 2.2 NOEC (28 d): 10 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on cocoon production) - E. fetida, OECD soil NOEC (28 d): 32 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on juvenile production) - E. fetida, OECD soil NOEC (28 d): 32 mg/kg soil dw (meas. (arithm.	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Kula, H. & Larink, O. (1997)

Method	Results	Remarks	Reference
	mean)) based on: reproduction (based on juvenile production) - E. fetida, LUFA 2.2		
Zea mays long-term toxicity (field study) Substrate: aged field soil In this study the maize plant Zea mays was grown in a field experiment under various copper concentrations and pH levels over an exposure period of 145 days. The soil was a loamy sand in the Netherlands.	NOEC (145 d): 34 mg/kg soil dw (meas. (arithm. mean)) based on: yield (based on shoot) NOEC (145 d): 34 mg/kg soil dw (meas. (arithm. mean)) based on: yield (based on shoot) NOEC (145 d): 64.6 mg/kg soil dw (meas. (arithm. mean)) based on: yield (based on shoot)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Lexmond, T. M. (1980)
Lumbricus rubellus (annelids) long-term toxicity (laboratory study) Substrate: sandy loam soil The study examined the effect of various copper concentrations (0, 20, 150, 1000 and 3000 mg/kg) on the earthworm Lumbricus rubellus in sandy loam soil (pH 7.3, organic matter 8, clay 17%) over a 12 week exposure period.	NOEC (84 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Ma, W.-C. (1982)
Lumbricus rubellus long-term toxicity (laboratory study) Substrate: the test was performed in loam sand and in a calcareous sandy loam soil The effect of copper to the mortality, growth, reproduction and leaf litter breakdown of adult Lumbricus rubellus following 6 weeks exposure. Copper was added at concentrations of 13 (unamended soil), 63, 136 and 373 mg Cu/kg.	NOEC (42 d): 40 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (loamy sand) NOEC (42 d): 40 mg/kg soil dw (meas. (arithm. mean)) based on: litter breakdown (loamy sand) NOEC (42 d): 117 mg/kg soil dw (meas. (arithm. mean)) based on: growth (loamy sand) NOEC (42 d): 117 mg/kg soil dw (meas. (arithm. mean)) based on: mortality (loamy sand) NOEC (42 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: litter breakdown (calcareous sandy loam) NOEC (42 d): 123 mg/kg soil dw (meas. (arithm. mean)) based on: mortality (calcareous sandy loam)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Ma, W.-C. (1984)
Microarthropoda and Nematoda short-term toxicity (laboratory study) Substrate: multi-species microcosm The effect of copper on the population abundance of nematodes and micro-arthropods from a forest soil (pH 3.8,	NOEC (7 d): 229.1 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance - microarthropoda NOEC (7 d): 90.3 mg/kg	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name):**	Parmelee, R. W., Wentsel, R.S., Phillips, C.T., Simini, M. & Checkai, R.T. (1993)

Method	Results	Remarks	Reference
organic matter 5.9%, clay 11%, sand 33%, silt 56%) was determined after an exposure period of 7 days. Copper sulphate delivered the Cu^{2+} in deionised water at nominal concentrations of 0, 100, 200, 400 and 600 µg/g (mean measured concentrations 9.6, 72, 185, 399 and 566 mg/kg).	soil dw (meas. (arithm. mean)) based on: total abundance - nematoda NOEC (7 d): 464.4 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance - nematoda (fungivores) NOEC (7 d): 464.4 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance - nematoda (herbivores) NOEC (7 d): 464.4 mg/kg soil dw (meas. (arithm. mean)) based on: total abundance -nematodes (hatchlings)	**copper sulphate**	
Folsomia candida, I. viridis long-term toxicity (review) Substrate: artificial soil described by Wiles and Krogh (1998)	NOEC (21 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: growth (F. candida) - LUFA 2.2 NOEC (21 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (F. candida) - LUFA 2.2 NOEC (56 d): 800 mg/kg soil dw (meas. (arithm. mean)) based on: growth (F. candida) - OECD soil NOEC (56 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (F. candida) - OECD soil NOEC (56 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: growth (I.viridis) - LUFA 2.2 NOEC (56 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: growth (I. viridis) - OECD soil	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Rundgren S. & Van Gestel, C.A.M. (1998)
Eisenia fetida (annelids) long-term toxicity (laboratory study) Substrate: sandy clay soil Eisenia fetida was exposed in the laboratory to a range of elevated soil copper concentrations under two different contamination histories and effects on survival, reproduction and cocoon wet weights were determined.	NOEC (21 d): 700 mg/kg soil dw (meas. (arithm. mean)) based on: growth NOEC (21 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction NOEC (21 d): 196 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (- aged soil)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Scott-Fordsmand, J.J., Weeks, J.M & Hopkins, S.P. (2000)
Eisenia fetida long-term toxicity (laboratory study)	NOEC (56 d): 200 mg/kg soil dw (meas. (arithm.	2 (reliable with restrictions)	Spurgeon, D.J., Hopkin, S.P. &

Method	Results	Remarks	Reference
Substrate: artificial soil OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	mean)) based on: mortality NOEC (56 d): 10 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on cocoon production)	weight of evidence experimental result **Test material (Common name): copper nitrate**	Jones, D.T. (1994)
Eisenia fetida long-term toxicity (laboratory study) Substrate: artificial soil equivalent or similar to OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	NOEC (21 d): 29 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (based on cocoon production) NOEC (21 d): 725 mg/kg soil dw (meas. (arithm. mean)) based on: growth NOEC (21 d): 293 mg/kg soil dw (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Spurgeon, D.J. & Hopkin, S.P. (1995)
Lumbricus rubellus (annelids) long-term toxicity (laboratory study) Substrate: clay loam soil Juvenile worms were exposed to copper. Survival, growth, and development of worms over the exposure period was first monitored after 28 days, with sampling repeated after 56, 77, 98, 119, 140, 168, 196, 231; 266, and 294 days.	NOEC (294 d): 139.6 mg/kg soil dw (meas. (arithm. mean)) based on: growth (added)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Spurgeon, D., Svendsen, C., Kille, P., Morgan, A., Weeks, J. (2004)
Lumbricus rubellus (annelids) long-term toxicity (semi-field study) Substrate: forest soil (no further details given) The effect of copper on the mortality and growth of Lumbricus rubellus was determined over an exposure period of 110 days. Copper was added at concentrations of 3 (control), 20, 40, 80, 160 and 320 mg Cu/kg.	NOEC (110 d): 73 mg/kg soil dw based on: growth (added) NOEC (110 d): 150 mg/kg soil dw based on: mortality (added)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Svendsen, C. & Weeks, J. M. (1997)
Eisenia sp. long-term toxicity (laboratory study) Substrate: artificial soil The effect of copper on the weight and sexual development of Eisenia andrei was assessed during 84 days exposure experiment.	NOEC (84 d): 56 mg/kg soil dw (meas. (arithm. mean)) based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	van Dis, W.A., Van Gestel, C.A.M., & Sparenburg, P.M. (1988)
other soil dwelling worm: Eisenia andrei long-term toxicity Substrate: artificial soil The effects of various copper concentrations (10-100 mg/kg) on the growth and sexual development of E. andrei were assessed.	NOEC (84 d): 56 mg/kg soil dw (meas. (arithm. mean)) based on: growth and sexual reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	van Gestel, C.A.M., van Dis, W.A., Dirven-van Breeman, E.M., Sparenburg (1991)
Platynothrus peltifer (mites) long-term toxicity (laboratory study) Substrate: LUFA 2.2 soil The effect of copper on the juvenile	NOEC (70 d): 63 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (at 12°C	2 (reliable with restrictions) weight of evidence experimental result	Van Gestel, C.A.M. & Doornekamp, A. (1998)

Method	Results	Remarks	Reference
production of Platynothrus peltifer at three different temperatures, 12°C, 16°C and 18-20°C over an exposure period of 70 days.	(added)) NOEC (70 d): 63 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (at 16°C (added)) NOEC (70 d): 63 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction (at 18-20°C (added))	**Test material (Common name): copper chloride**	
Eisenia andrei long-term toxicity (laboratory study) Substrate: artificial soil Effects of copper chloride on the reproduction of the earthworm Eisenia andrei in an artificial soil substrate are assessed. After a one week pre-conditioning period, worms were exposed for three weeks to treated soil, followed by a recovery period of three weeks in untreated soil.	NOEC (28 d): 120 mg/kg soil dw (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	van Gestel, C.A.M. *et al.,* (1989)
Dendrobaena rubida long-term toxicity (laboratory study) Substrate: natural soil Survival of adult Dendrobaena rubida, cocoon production, cocoon viability, and growth of juveniles were examined in laboratory experiments when the worms were reared in acidified and metal polluted soils.	NOEC (90 d): 100 mg/kg soil dw element based on: reproduction (No bioavailability correction possible as CEC is not given or can not be derived. The data were therefore not used for the bio-availability based PNEC derivation)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper nitrate**	Bengtsson, G. *et al.,* (1986)
Octolasium cyaneum (Lumbricidae) long-term toxicity (laboratory study) Substrate: natural soil Copper sulfate toxicity in Octolasium cyaneum (Lumbricidae) was studied using different soil types.	NOEC (30 d): 100 — 1200 mg/kg soil dw element based on: mortality (No bioavailability correction possible as CEC is not given or can not be derived)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Jäggy, A. and Streit, B. (1982)
Aporrectodea caliginosa long-term toxicity (laboratory study) Substrate: natural soil The effects of mixtures of three heavy metals, cadmium, copper and zinc, on the growth of earthworms were assessed.	NOEC (6 wk): 25 mg/kg soil dw element (meas. (arithm. mean)) based on: growth (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Khalil M.A. *et al.,* (1996)
Aporrectodea caliginosa long-term toxicity (laboratory study) Substrate: natural soil Earthworms were exposed to several copper concentrations in a natural soil. Mortality and cocoon production were measured over 56 days	NOEC (56 d): 70 mg/kg soil dw element (meas. (arithm. mean)) based on: reproduction (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Khalil, M.A. *et al.,* (1996)
Allolobophora caliginosa long-term toxicity (laboratory study) The effects of various pesticides on	NOEC (14 d): 50 mg/kg soil dw element (meas. (initial)) based on: cocoon	2 (reliable with restrictions) supporting study	Martin, N.A. (1986)

Method	Results	Remarks	Reference
survival and cocoon production of earthworms were assessed. Juvenile (4-week-old) earthworms reared in a laboratory were kept individually for 7 days in soil treated with several concentrations of pesticides. Mortality and weight change were recorded.	production (No bioavailability correction possible as CEC is not given or can not be derived.) NOEC (14 d): 500 mg/kg soil dw element (meas. (initial)) based on: mortality (No bioavailability correction possible as CEC is not given or can not be derived.)	experimental result **Test material (Common name): copper sulphate**	
Eisenia fetida (laboratory study) The experimental design was set out to describe chronic earthworm toxicity using test systems designed to define acute toxicity.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): soluble copper**	van Gestel, C.A.M., Van Dis, W.A., Breemen, E.M. & Sparenburg, P.M. (1989)
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) equivalent or similar to ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: rate of population increase	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Herbert, I.N., Svendsen, C., Hankard, P.K. & Spurgeon, D.J. (2004)
Folsomia fimeteria and F. candida long-term toxicity (laboratory study) The experimental design was set out to compare copper accumulation in collembolans for different exposure routes (water, spiked soil, and field soil) and to assess the effect on reproduction of collembolan species	EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction (F. fimeteria)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Pedersen, M.B., van Gestel, C.A.M., Elmegaard, N. (2000)
Folsomia fimetaria (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) The effect of aging of copper contaminated soils (between 1 day and 12 weeks) on the reproduction of collembolan species was investigated.	EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction EC10 (21 d): EC10 element (Cu) (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Pedersen, M.B. & Van Gestel, C.A.M. (2001)
Folsomia candida long-term toxicity (laboratory study) This was a non-regulatory study designed to examine the effect of copper on the growth and reproduction of Folsomia candida.	NOEC (56 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (56 d): NOEC element (Cu) (meas. (arithm. mean)) based on:	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Rundgren S. & Van Gestel, C.A.M. (1998)

Method	Results	Remarks	Reference
	reproduction		
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants) (draft recommendation for the Folsomia candida standard test (Riepert, 1993)) equivalent or similar to OECD test Guideline 207 (OECD, 1984)	NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Sandifer, R.D. & Hopkin, S. P. (1996)
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) OECD standard earthworm test, Guideline 207 (OECD 1984) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (28 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (42 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction NOEC (42 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Sandifer, R.D & Hopkin, S.P. (1997)
Folsomia sp. (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) This was a non-regulatory study designed to examine the effect of copper on the survival and reproductive success of the springtail Folsomia candida.	NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Scott-Fordsmand, J.J., Krogh P.H. & Weeks, J.M. (1997)
Folsomia sp. (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) This was a non-regulatory study designed to examine the effect of copper on the survival and reproductive success of the springtail Folsomia candida.	NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Scott-Fordsmand, J.J., Krogh, P.H & Weeks, J.M. (2000)

Method	Results	Remarks	Reference
	NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: mortality NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: growth NOEC (21 d): NOEC element (Cu) (meas. (arithm. mean)) based on: reproduction		
Folsomia candida and Eisenia fetida long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants) ISO 11268-2	NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, sandy loam Nottingham) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Houthalen) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Rhydtalog) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, sandy clay, Souli) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Montpellier) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, clay, Aluminusa) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (sandy clay loam, Woburn) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, silt loam, Ter Munck) NOEC (28 d): NOEC	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Criel, P., De Schamphelaere, K.A.C. & Janssen, C.R. (2005)

Method	Results	Remarks	Reference
	(meas. (not specified)) based on: reproduction (- F. candida, silty clay loam, Vault de lugny) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, silty clay loam, Rots) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, Clay, Souli) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, silt loam, Marknesse) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loam, Barcelona) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, clay, Brécy) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loam, Guadalajara) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, sandy clay, Hygum) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Wageningen A) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Wageningen D) EC10 (28 d): EC10 (meas. (not specified)) based on: reproduction (- F. candida, Sandy clay loam, Zegveld) EC10 (28 d): EC10 (meas. (not specified)) based on: reproduction (- F. candida, loamy sand, Kovlinge)		
Folsomia candida and Eisenia fetida long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants) ISO 11268-2	NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, Sand, Woburn cake)	2 (reliable with restrictions) weight of evidence experimental result **Test material**	Criel, P., De Schamphelaere, K.A.C. & Janssen, C.R. (2005)

Method	Results	Remarks	Reference
	NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, loamy sand, Gudow) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, sandy loam, Nottingham) NOEC (28 d): NOEC (meas. (arithm. mean)) based on: reproduction (- E. fetida, sandy clay loam, Zegveld) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, loamy sand, Kovlinge) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, sandy clay, Souli) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, sandy loam, Kovlinge) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, loamy sand, Montpellier) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, sandy clay loam, Woburn) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, silt loam, Ter Munck) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, silty clay loam, Vault de lugny) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, silty clay loam, Rots) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, Clay, Souli) NOEC (28 d): NOEC	**(Common name): copper chloride**	

Method	Results	Remarks	Reference
	(meas. (not specified)) based on: reproduction (- E. fetida, silt loam, Marknesse) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, clay, Brécy) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, sandy clay, Hygum) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. fetida, OECD soil) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- E. andrei, Lufa 2.2 soiol)		
Folsomia candida and Eisenia fetida long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants) ISO 11268-2	NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, Sandy clay, Hygum. Equilibration period > 70y) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (- F. candida, Wageningen A, >20y) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (F. candida, Wageningen D. >20y) NOEC (28 d): NOEC (meas. (not specified)) based on: reproduction (F. candida, Sand Woburn cake. >8 y)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Criel, P., De Schamphelaere, K.A.C. & Janssen, C.R. (2005)
microarthropods (several groups) long-term toxicity (field study) The effect of copper contamination, soil characteristics and plant cover data on the abundance and distribution of populations of soil microarthropods was studied in the field and compared to the outcome of single species laboratory tests in the same soil type.	EC10 : EC10 (meas. (arithm. mean)) based on: reproduction (Folsomia fimetaria (toxicity test of spiked control soil))	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Pedersen M.B., J.A. Axelsen, B. Strandberg, J. Jensen and M.J. Attrill (1999)

7.2.1.2 Toxicity to terrestrial plants

The results are summarised in the following table:

Table 61: Overview of effects on terrestrial plants

Method	Results	Remarks	Reference
other terrestrial plant: Hordeum vulgare (Monocotyledonae (monocots)) short-term toxicity (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: artificial and natural soil (sandy forest soil) OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test)	*Hordeum vulgare*: added NOEC (14 d): 304.8 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: shoot growth *Hordeum vulgare*: added NOEC (14 d): 20.2 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root growth *Hordeum vulgare*: added NOEC (14 d): 111.8 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: seedling emergence	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Ali, N.A. *et al.*, (2004)
Senecio vulgaris, Poa annua, Andryala integrifolia, Hypocharis radicata long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil This was a non-regulatory study designed to determine the effect of elevated soil Cu on development of five ruderal plant species.	*Senecio vulgaris*: LC0 (105 d): 67 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: survival *Senecio vulgaris*: EC10 (105 d): 28 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: number of plants that set seed *Senecio vulgaris*: EC10 (105 d): 181 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: mean number of seeds per plant that set seed *Poa annua*: LC10 (210 d): 379 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: survival *Poa annua*: EC10 (210 d): 42 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: number of plants that set seed *Poa annua*: EC10 (210 d): 158 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: mean number of seeds per plant that set seed *Andryala integrifolia*: LC10 (175 d): 76 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: survival *Andryala integrifolia*: EC10 (175 d): 78 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: mean number of seeds per	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Brun, L.A., Le Corff, J. & Maillet, J. (2003)

Method	Results	Remarks	Reference
	plant that set seed *Hypochoeris radicata*: LC10 (196 d): 192 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: survival *Hypochoeris radicata*: EC10 (196 d): 192 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: number of plants that set seed *Hypochoeris radicata*: EC10 (196 d): 181 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: mean number of seeds per plant that set seed		
Avena sativa (Monocotyledonae (monocots)) long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil This was a non-regulatory study designed to determine the effects of copper on an oat species (Avena sativa).	*Avena sativa*: added NOEC (150 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: growth (; yield (based on grain)) *Avena sativa*: added NOEC (150 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: growth (; yield (based on grain)) *Avena sativa*: added NOEC (150 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: growth (; yield (based on grain)) *Avena sativa*: added NOEC (150 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: growth (; yield (based on grain)) *Avena sativa*: added NOEC (150 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: growth (; yield (based on grain))	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper acetate**	De Haan, S., Rethfeld, H. & van Driel, W. (1985)
Lolium perenne (Monocotyledonae (monocots)) long-term toxicity (laboratory study) seed germination/root elongation toxicity test Substrate: natural soil The uptake of copper by the ryegrass Lolium perenne was investigated in a loamy soil (pH 7.5, organic carbon	*Lolium perenne*: added NOEC (102 d): 95.3 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: shoot yield *Lolium perenne*: added NOEC (102 d): 95.3 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on:	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Jarvis, S.C. (1978)

Method	Results	Remarks	Reference
1.8%, clay 12.8%) spiked with copper concentrations ranging from 0 to 953.0 µg/g dry soil.	root yield		
other terrestrial plant: Polygonum convolvulus (Black Bindweed) (now referred to as Fallopia convolvulus). (Dicotyledonae (dicots)) long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil This was a non-regulatory study designed to determine the effects of Cu^{2+} on black bindweed, a terrestrial plant.	*Polygonum convolvulus*: Added NOEC (34 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: Yield (based on total plant) *Polygonum convolvulus*: Added NOEC (34 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: reproductive dry matter *Polygonum convolvulus*: Added NOEC (105 d): 125 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: Mortality *Polygonum convolvulus*: added NOEC (105 d): 200 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: seed biomass	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Kjær, C. & Elmegaard. N. (1996)
other terrestrial plant: Fallopia convolvulus (Black blindweed). (Dicotyledonae (dicots)) long-term toxicity (laboratory study) seed germination/root elongation toxicity test Substrate: natural soil This was a non-regulatory study designed to determine the effects of copper sulphate on black bindweed, a terrestrial plant.	*Fallopia convolvulus*: added NOEC (35 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: yield (based on shoot) *Fallopia convolvulus*: added NOEC (35 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: yield (based on root)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Pedersen, M.B., Kjær, C. Elmegaard, N. (2000)
Lycopersicon esculentum (Dicotyledonae (dicots)) long-term toxicity (laboratory study) early seedling growth toxicity test Substrate: natural soil This was a non-regulatory study designed to determine the Cu levels of soil and plant tissue, which are associated with reduced growth, and to determine the influence of soil acidity on Cu uptake and growth response of tomatoes to soil Cu.	*Lycopersicon esculentum*: added NOEC (42 d): 175 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot weight) (experiment 1, limed) *Lycopersicon esculentum*: added NOEC (42 d): 350 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot weight) (exp 2, unlimed) *Lycopersicon esculentum*: added NOEC (42 d): 350 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot weight) (exp 2, limed)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper (II) hydroxide**	Rhoads, F.M. (1989)
other terrestrial plant: Raphanus sativus in aged field soil	*Raphanus sativus*: NOEC : 338 mg/kg soil dw (meas.	2 (reliable with restrictions)	Belanger, A., Levesque, M.P. &

Method	Results	Remarks	Reference
(Dicotyledonae (dicots)) long-term toxicity (field study) vegetative vigour test Substrate: natural soil This was a non-regulatory study designed to determine the effects of copper sulphate a radish species (Raphanus sativa).	(arithm. mean)) based on: root yield -Mesisol peat soil *Raphanus sativus*: NOEC : 338 mg/kg soil dw (meas. (arithm. mean)) based on: yield (leaves) - Mesisol peat soil	weight of evidence experimental result **Test material (Common name): copper sulphate**	Mathur, S.P. (1987)
other terrestrial plants: Hordeum vulgare; Lycopersium esculentum long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil ISO 11269-1 method for measuring the inhibition of root growth (Hordeum vulgare) ISO 11269-2 method for measuring the inhibition on emergence and growth of higher plants (Lycopersicon esculentum)	*Hordeum vulgare*: added NOEC (4 d): 58 mg/kg soil dw element (Cu) (meas. (not specified)) based on: root length (sandy loam; Nottingham) *Hordeum vulgare*: added NOEC (4 d): 16 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (loamy sand; Houthalen) *Hordeum vulgare*: added NOEC (4 d): 30 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (loamy sand; Rhydtalog) *Hordeum vulgare*: added NOEC (4 d): 80 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (sandy clay loam; Zegveld) *Hordeum vulgare*: added NOEC (4 d): 45 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (loamy sand; Kovlinge I) *Hordeum vulgare*: added NOEC (4 d): 77 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (sandy clay; Souli I) *Hordeum vulgare*: added NOEC (4 d): 37 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (sandy loam Kovlinge II) *Hordeum vulgare*: added NOEC (4 d): 38 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (loamy sand; Montpellier) *Hordeum vulgare*: added NOEC (4 d): 252 mg/kg	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Rooney, C.P. *et al.,* (2004)

Method	Results	Remarks	Reference
	soil dw element (Cu) (meas. (arithm. mean)) based on: root length (Clay; Aluminosa) *Hordeum vulgare*: added NOEC (4 d): 144 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (Sandy clay loam; Woburn) *Hordeum vulgare*: added NOEC (4 d): 55 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (silt loam; Ter Munck) *Hordeum vulgare*: added NOEC (4 d): 154 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (silty clay loam; Vault de Lugny) *Hordeum vulgare*: added NOEC (4 d): 47 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (silty clay loam Rots) *Hordeum vulgare*: added NOEC (4 d): 120 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (Clay; Souli II) *Hordeum vulgare*: added NOEC (4 d): 37 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (silt loam Marknesse) *Hordeum vulgare*: added NOEC (4 d): 77 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (loam; Barcelona) *Hordeum vulgare*: added NOEC (4 d): 44 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (Clay; Brecy) *Hordeum vulgare*: added NOEC (4 d): 114 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length (sandy clay; Hygum) *Hordeum vulgare*: added NOEC (4 d): 44 mg/kg soil		

Method	Results	Remarks	Reference
	dw element (Cu) (meas. (arithm. mean)) based on: root length (Sand, Woburn salt) *Lycopersicon esculentum*: added NOEC (28 d): 19 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (sandy loam; Nottingham) *Lycopersicon esculentum*: added NOEC (28 d): 357 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (loamy sand; rhydtalog) *Lycopersicon esculentum*: added NOEC (28 d): 628 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (sandy clay loam, zegveld) *Lycopersicon esculentum*: added NOEC (28 d): 85 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (loamy sand Kovlinge I) *Lycopersicon esculentum*: added NOEC (28 d): 43 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (sandy clay Souli I) *Lycopersicon esculentum*: added NOEC (28 d): 197 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (sandy loam Kovlinge II) *Lycopersicon esculentum*: added NOEC (28 d): 176 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (clay, aluminosa) *Lycopersicon esculentum*: added NOEC (28 d): 91 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (sandy clay loam, Woburn)		

Method	Results	Remarks	Reference
	Lycopersicon esculentum: added NOEC (28 d): 198 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (silt loam Ter Munck) *Lycopersicon esculentum*: added NOEC (28 d): 311 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (silty clay loam; Vault de Lugny) *Lycopersicon esculentum*: added NOEC (28 d): 660 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (silty clay loam, Rots) *Lycopersicon esculentum*: added NOEC (28 d): 628 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (clay, Souli I) *Lycopersicon esculentum*: added NOEC (28 d): 227 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (silt loam, Marknesse) *Lycopersicon esculentum*: added NOEC (28 d): 315 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (Loam, Barcelona) *Lycopersicon esculentum*: added NOEC (28 d): 100 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (clay, Brecy) *Lycopersicon esculentum*: added NOEC (28 d): 313 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (loam, Guadalajara) *Lycopersicon esculentum*: added NOEC (28 d): 106 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot		

Method	Results	Remarks	Reference
	growth) (Sandy clay; Hygum) *Lycopersicon esculentum*: added NOEC (28 d): 71 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) (Loamy sand, Wageningen D) *Hordeum vulgare*: NOEC (4 d): 42 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length - aged soil (>20y) (loamy sand, Wageningen A) *Hordeum vulgare*: NOEC (4 d): 147 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: root length - aged soil (>20y) (sand, Woburn salt) *Lycopersicon esculentum*: NOEC (28 d): 42 mg/kg soil dw element (Cu) (meas. (arithm. mean)) based on: yield (shoot growth) - aged soil (>20y) (loamy sand, Wageningen A)		
Triticum aestivum long-term toxicity Effect of different levels of copper (0, 5, 10, 20, 40, 80, 160, 320 and 640 mg/kg soil) was studied on `WL 1562` wheat (Triticum aestivum L. emend. Fiori & Paol.) grown on a Fatehpur loamy sand soil under greenhouse conditions.	*Triticum aestivum*: NOEC : 40 mg/kg soil dw element (meas. (initial)) based on: yield (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper compound not reported**	Chhibba, I.M. *et al.,* (1994)
Medicago sativa (Dicotyledonae (dicots)) This study was designed to investigate the effect of copper on alfalfa, grown on 10 different soils.	*Medicago sativa*: NOEC (12 mo): 816 — 1500 mg/kg soil dw element (meas. (arithm. mean)) based on: yield (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Gonzales, S.P. (1991)
Vigna mungo This study was designed to examine the effect of copper on the growth of blackgram.	*Vigna mungo*: NOEC (45 d): 50 mg/kg soil dw element (meas. (initial)) based on: yield stem (No bioavailability correction possible as CEC is not given or can not be derived.) *Vigna mungo*: NOEC (45 d): 100 mg/kg soil dw	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Kalyanaraman, S.B. and Sivagurunathan, P. (1993)

Method	Results	Remarks	Reference
	element (meas. (initial)) based on: yield leaves (No bioavailability correction possible as CEC is not given or can not be derived.)		
Cleopatra mandarin and Swingle citrumelo long-term toxicity (laboratory study) Substrate: natural soil The effects of 5 rates of Cu (0-200 mg/kg) amendment to a Candler fine sand (Typic Quartzipsamment) on root and shoot growth and concentrations of Cu in the respective plant parts of Cleopatra mandarin(CM) and Swingle citrumelo(SC) rootstock seedlings were evaluated at 3 pH levels ranging from pH 5 to 7.	*Cleopatra mandarin*: added NOEC (106 d): 100 — 200 mg/kg soil dw element based on: shoot and root dry weight (No bioavailability correction possible as CEC is not given or can not be derived) *Swingle citrumelo*: added NOEC (106 d): 50 — 100 mg/kg soil dw element based on: root dry weight (No bioavailability correction possible as CEC is not given or can not be derived) *Swingle citrumelo*: added NOEC (106 d): > 200 mg/kg soil dw element based on: shoot dry weight (No bioavailability correction possible as CEC is not given or can not be derived)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Mozaffari, M. *et al.,* (1996)
Avena sativa long-term toxicity (laboratory study) Substrate: natural soil This study was designed to determine P concentration of oat plants as a function of soil-Cu at three lime rates.	*Avena sativa*: NOEC (49 d): 100 mg/kg soil dw element based on: yield (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper dihydroxide**	Rhoads, F.M. *et al.,* (1992)
Avena sativa *Glycine max (G. soja)* long-term toxicity (laboratory study) Substrate: natural soil This study was designed to determine the availability to plants of Ni and Cu added to a soil at various rates and to identify, if possible, the forms present in the soil from which the plants obtained these metals.	*Glycine max (G. soja)*: NOEC (46 d): 1946 mg/kg soil dw element based on: yield (No bioavailability correction possible as CEC is not given or can not be derived.)	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Roth, J.A. *et al.,* (1971)
Hordeum vulgare (Monocotyledonae (monocots)) *Lycopersicon esculentum* (Dicotyledonae (dicots)) ISO 11269-2 method for measuring the inhibition on emergence and growth of higher plants (Lycopersicon esculentum) ISO 11269-1 method for measuring the inhibition of root growth (Hordeum	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Rooney, C.P. *et al.,* (2006)

Method	Results	Remarks	Reference
vulgare)			
Lactuca sativa (Dicotyledonae (dicots)) (laboratory study) Substrate: natural soil This study was designed to determine copper bioavailability and bioaccumulation in agricultural soils spiked with different types of copper-rich mine solid wastes	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Ginocchio R., P. Sanchez, L.M. de la Fuente, I. Camus, E. Bustamante (2006)
Hordeum vulgare (Monocotyledonae (monocots)) *Lycopersicon esculentum* (Dicotyledonae (dicots)) (laboratory study) This study was designed to determine whether the variation in toxicity effect concentrations (tomato and barley) can be explained by the solubility or speciation of Cu in soil solutions or the diffusive gradients in thin films (DGT) measurement.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): CuCl2**	Zhao F-J, C.P. Rooney, H. Zhang and S.P. McGrath (2006)
community level study *Fallopia convolvulus (Black bindweed)* (field study) Substrate: natural soil This study was designed to determine the effect of a copper gradient on a natural plant community structure.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulfate**	Strandberg B., J.A. Axelsen, M.B. Pedersen, J. Jensen and M.J. Attrill (2006)

7.2.1.3 Toxicity to soil micro-organisms

The results are summarised in the following table:

Table 62: Overview of effects on soil micro-organisms

Method	Results	Remarks	Reference
Species/Inoculum: soil dwelling microorganisms This was a non-regulatory study designed to examine the effect of copper on the microbial N-mineralisation and nitrification of a sandy loam soil.	NOEC (21 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: N-mineralisation (added) - pH 5.9 NOEC (21 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: nitrification (added) - pH 5.9 NOEC (21 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: nitrification (added) - pH 7.3	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Quraishi, M.S.I. & Cornfield, A.H. (1973)
Species/Inoculum: soil dwelling microorganisms	NOEC (21 d): 1000 mg/kg soil dw (meas. (arithm.	2 (reliable with restrictions)	Premi, P.R. & Cornfield, A.H.

Method	Results	Remarks	Reference
This was a non-regulatory study designed to examine the effect of copper on the microbial ammonification and nitrification of a sandy loam soil.	mean)) based on: ammonification (aerobic) (added NOEC) NOEC (21 d): 1000 mg/kg soil dw (meas. (arithm. mean)) based on: nitrification (added NOEC)	weight of evidence experimental result **Test material (Common name): copper sulphate**	(1969)
Species/Inoculum: soil dwelling organisms This was a non-regulatory study designed to examine the effect of sludge metals on soil micro-organisms and microbial processes.	NOEC (49 d): 118 mg/kg soil dw (meas. (arithm. mean)) based on: microbial biomass C (added) NOEC (49 d): 468 mg/kg soil dw (meas. (arithm. mean)) based on: microbial biomass N (added) NOEC (49 d): 268 mg/kg soil dw (meas. (arithm. mean)) based on: N-mineralisation (added)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): elemental copper**	Khan, M. and Scullion, J. (2002)
Species/Inoculum: soil dwelling organisms This was a non-regulatory study designed to examine the effect of copper on the decomposition of glutamic acid in four different Dutch soils.	NOEC (540 d): 55 mg/kg soil dw element (meas. (arithm. mean)) based on: glutamic acid decomposition (added) ; silty loam NOEC (540 d): 55 mg/kg soil dw element (meas. (arithm. mean)) based on: glutamic acid decomposition (added) ; clay NOEC (540 d): 400 mg/kg soil dw element (meas. (arithm. mean)) based on: glutamic acid decomposition (added) ; sandy peat	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Haanstra, L. & Doelman, P. (1984)
Species/Inoculum: denitrifying bacteria (Pseudomonas sp.) This was a non-regulatory study designed to examine the effect of copper on the denitrification of soils.	NOEC (21 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: denitrification (added)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Bollag, J-M, Barabasz, W. (1979)
Species/Inoculum: soil dwelling microorganisms This was a non-regulatory study designed to examine the effect of copper on the phosphatase activity, sulphatase activity and substrate induced respiration in three New Zealand soils.	NOEC (7 d): 635 mg/kg soil dw (meas. (arithm. mean)) based on: substrate induced respiration ; loam NOEC (7 d): 635 mg/kg soil dw (meas. (arithm. mean)) based on: substrate induced respiration ; silt loam	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper nitrate**	Speir, T.W., Kettles, H.A., Percival, H.J. & Parshotam, A. (1999)
Species/Inoculum: soil The study was designed to assess bioavailability and toxicity of copper	NOEC (28 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate	2 (reliable with restrictions) weight of evidence	Smolders, E. & Oorts, K (2004)

Method	Results	Remarks	Reference
to soil microorganisms.	formation rate (- sandy loam Nottingham (Cb 17 mg/kg; CEC 6.7 cmol/kg)) NOEC (4 d): 1200 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- sandy clay Loam Zegveld (Cb 70 mg/kg; CEC 35.3 cmol/kg)) NOEC (28 d): 25 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- loamy sand, Kovlinge I (Cb 6 mg/kg; CEC 2.4 cmol/kg)) NOEC (28 d): 25 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- sandy clay; Souli 1; Cb 31 mg/kg; CEC 11.2 cmol/kg) NOEC (14 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- sandy loam Kovlinge II; Cb 8 mg/kg; CEC 4.7 cmol/kg) NOEC (28 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- Clay Aluminosa; Cb 21 mg/kg ; CEC 22.6 cmol/kg) NOEC (4 d): 300 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- sandy clay loam Woburn (Cb 22 mg/kg; CEC 23.4 cmol/kg) NOEC (7 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- silt loam Ter Munck; Cb 22 mg/kg ; CEC 8.9 cmol/kg) NOEC (4 d): 800 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- silty clay loam Vault de Lugny; Cb 21 mg/kg; CEC 26.2 cmol/kg) NOEC (7 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- silty clay loam Rots; Cb 14 mg/kg: CEC 20 cmol/kg)	experimental result **Test material (Common name): copper chloride**	

Method	Results	Remarks	Reference
	NOEC (14 d): 600 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- clay Souli II; Cb 34 mg/kg; CEC 36.3 cmol/kg) NOEC (7 d): 800 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- silt loam Marknesse; Cb 18 mg/kg; CEC 20.1 cmol/kg) NOEC (11 d): 300 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- loam barcelona; Cb 88 mg/kg; CEC 14.3 cmol/kg) NOEC (4 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- Clay Brécy; Cb 31 mg/kg; CEC 23.5 cmol/kg) NOEC (7 d): 52 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- loam Guadalajara, Cb 7 mg/kg; CEC 16.9 cmol/kg) NOEC (14 d): 127 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- Sandy clay Hygum; Cb 21 mg/kg; CEC 6.7) NOEC (18 d): 65 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- Loamy sand Wageningen D; Cb 19 mg/kg; CEC 1.9 cmol/kg) NOEC (14 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- Sand Woburn salt, Cb 13 mg/kg; CEC 8.4 cmol/kg) NOEC (14 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (- sand Woburn cake; Cb 35 mg/kg ; CEC 11.6 cmol/kg)		
Species/Inoculum: soil The study was designed to assess bioavailability and toxicity of copper to soil microorganisms.	NOEC (4 d): 1200 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand,	2 (reliable with restrictions) weight of evidence experimental result	Smolders, E. & Oorts, K (2004)

Method	Results	Remarks	Reference
	Gudow ; Cb 2 mg/kg NOEC (4 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy loam, Nottingham; Cb 17 mg/kg NOEC (4 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand, Houthalen ; Cb 2 mg/kg NOEC (4 d): 600 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - Loamy sand, Rhydtalog ; Cb 14 mg/kg NOEC (4 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy clay loam, Zegveld ; Cb 70 mg/kg NOEC (4 d): 25 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand, Kovlinge I; Cb 6 mg/kg NOEC (4 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy clay, Souli I ; Cb 31 mg/kg NOEC (4 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy loam, Kovlinge II ; Cb 8 mg/kg NOEC (4 d): 25 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand, Montpellier ; Cb 5 mg/kg NOEC (4 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - clay Aluminosa ; Cb 21 mg/kg NOEC (4 d): 300 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy clay loam, Woburn; Cb 22 mg/kg NOEC (4 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - silt loam, Ter Munck; Cb 22 mg/kg	**Test material (Common name): copper chloride**	

Method	Results	Remarks	Reference
	NOEC (4 d): 102 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - silt clay loam, Vault de Lugny; Cb 21 mg/kg NOEC (4 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - silt clay loam, Rots; Cb 14 mg/kg NOEC (4 d): 89 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - clay, Souli II; Cb 34 mg/kg NOEC (4 d): 23 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration -silt loam, Marknesse ; Cb 18 mg/kg NOEC (4 d): 300 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loam, Barcelona; Cb 88 mg/kg NOEC (4 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - clay, Brécy; Cb 31 mg/kg NOEC (4 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loam, Guadalajara; Cb 7 mg/kg NOEC (4 d): 170 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sandy clay, Hygum; Cb 21 mg/kg		
Species/Inoculum: soil The study was designed to assess bioavailability and toxicity of copper to soil microorganisms.	NOEC (4 d): 12 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand, Wageningen A; Cb 19 mg/kg NOEC (4 d): 25 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - loamy sand, Wageningen D; Cb 19 mg/kg NOEC (4 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sand, Woburn salt ; Cb 13 mg/kg	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Smolders, E. & Oorts, K (2004)

Method	Results	Remarks	Reference
	NOEC (4 d): 27 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - sand, Woburn cake; Cb 35 mg/kg NOEC (28 d): 2400 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Gudow; Cb 2 mg/kg NOEC (28 d): 1200 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - sandy loam, Nottingham; Cb 17 mg/kg NOEC (28 d): 1200 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Rhydtalog; Cb 14 mg/kg NOEC (28 d): 300 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - sandy clay, loam Zegveld; Cb 70 mg/kg NOEC (28 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Kovlinge I; Cb 6 mg/kg NOEC (28 d): 200 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - sandy clay, Souli II; Cb 31 mg/kg NOEC (28 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - sandy loam, Kovlinge II; Cb 8 mg/kg NOEC (28 d): 50 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Montpellier; Cb 5 mg/kg NOEC (28 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - Clay, aluminosa; Cb 21 mg/kg NOEC (28 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - Sandy clay loam, Woburn; Cb 22 mg/kg NOEC (28 d): 50 mg/kg soil dw (meas. (arithm.		

Method	Results	Remarks	Reference
	mean)) based on: maize respiration - silt loam, Ter Munck; Cb 22 mg/kg NOEC (28 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - silty clay loam, Vault de Lugny; Cb 21 mg/kg NOEC (28 d): 600 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - clay, Souli II; Cb 34 mg/kg NOEC (28 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - silt loam, Marknesse; Cb 18 mg/kg NOEC (28 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loam Barcelona; Cb 88 mg/kg NOEC (28 d): 51 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Wageningen A; Cb 19 mg/kg		
Species/Inoculum: soil The study was designed to assess bioavailability and toxicity of copper to soil microorganisms.	NOEC (28 d): 83 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - loamy sand, Wageningen D; Cb 19 mg/kg NOEC (28 d): 100 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - sand, Woburn Cake; Cb 35 mg/kg NOEC (14 d): 79 mg/kg soil dw (meas. (arithm. mean)) based on: nitrate formation rate (loamy sand, Wageningen D -- Equilibration period > 20y) NOEC (4 d): 13 mg/kg soil dw (meas. (arithm. mean)) based on: glucose respiration - Loamy sand Wageningen A -- Equilibration period >20 y NOEC (28 d): 147 mg/kg soil dw (meas. (arithm. mean)) based on: maize respiration - Sand, Woburn salt -- Equilibration time >	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Smolders, E. & Oorts, K (2004)

Method	Results	Remarks	Reference
	20y		
Species/Inoculum: soil dwelling microorganisms This study was designed to determine the effect of copper on the respiration of microorganisms in five soils: sand, sandy loam, silty loam, clay and sandy peat collected from various locations in the Netherlands.	NOEC (490 d): 150 mg/kg soil dw (meas. (arithm. mean)) based on: respiration (medium: sand) NOEC (574 d): 400 mg/kg soil dw (meas. (arithm. mean)) based on: respiration (added) (medium: sandy peat)	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Doelman, P. & Haanstra, L. (1984)
Species/Inoculum: soil In several series the influence of soluble salts of Cd, Cr, Zn, Cu, Ni and Hg in various concentrations was tested on the development of bacteria and fungi in cultural studies and in soil model systems. In addition, the changes in microbial biomass, in the activity of oxidoreductases and hydrolases, and in nitrification were measured in five soils.	NOEC : 100 mg/kg soil dw element (nominal) based on: no bio-availability correction possible- no clay content	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Beck, T. (1981)
Species/Inoculum: soil The phospholipid fatty acid (PLFA) pattern was analyzed in forest humus and in an arable soil experimentally polluted with Cd, Cu, Ni, Pb, or Zn at different concentrations.	see summary : 763 mg/kg soil dw element based on: No bioavailability correction possible as clay content and CEC is not given or can not be derived.	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Frostegård, Å. *et al.,* (1993)
Species/Inoculum: soil Relationships between total metals, CaCl2-extractable metals and soil microbial biomass were investigated in a sandy loam soil (Cuckney series) at Gleadthorpe Experimental Husbandry Farm, U.K.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): elemental copper**	Chander, K. and Brookes, P.C. (1993)
Species/Inoculum: soil A comparative study was made using three different microbial assays (nitrification potential, glucose-induced respiration, and C-mineralisation of a plant residue) in 29 soils (for Cu) or 16 (for Ni) with contrasting soil properties.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): Copper chloride**	Oorts K, U. Ghesquiere, K. Swinnen and E. Smolders (2006)
Species/Inoculum: soil A systematic comparison of Cu toxicity thresholds was made between freshly spiked soils and soils in which elevated Cu concentrations have been present for various times.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Oorts K, H. Bronckaers and E. Smolders (2006)

7.2.1.4 Toxicity to other terrestrial organisms

No data.

7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

Table 63: PNEC soil

	Value	Assessment factor	Remarks/Justification
PNEC soil (mg/kg dw)	65	1	in accordance to the Competent Authorities for Biocides and Existing Substance Regulations

Derivation of the PNEC soil

A. Approach

The copper terrestrial effects database contains a large number of high quality chronic NOEC values. In accordance with the TGD & REACH guidance, the use of the statistical extrapolation method, using all NOEC values is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC value.

Considering the bioavailability of copper in soils, three phenomena on the ecotoxicity of copper to soil organisms are apparent:

- The toxicity response is species-specific
- The toxicity response is highly dependent on soil type , and
- The toxicity response is highly dependent on the time: copper toxicity under field conditions is hardly detectable, or only observed at much higher doses than under laboratory conditions

- *Accounting for species –specific differences* : The copper terrestrial effects database contains a large number of high quality chronic NOEC values. In accordance with the TGD & REACH guidance, the use of the statistical extrapolation method, using all NOEC values is therefore preferred for the PNEC derivation rather than the use of the assessment factor method on the lowest NOEC value.

- *Accounting for is dependence on the soil type* : To normalize the data for bio-availability for soil type, a total of 7 regression models were derived to predict toxicity of copper to terrestrial organisms for a wide range of soil types. For plants, the *L. esculentum* model (endpoint yield) was applied only on data for tomato while all other plant data were normalised using the *H. vulgare* root elongation model because this endpoint is the most sensitive for plants. For the invertebrates the *E. fetida* model was used to normalise all soft-bodied species, while the *F. candida* model was used to normalise all hard-bodied species. For the microbial processes, all NOEC values related to the N-cycle were normalised based on the CEC slope of the nitrifying micro-organisms. The maize respiration model was used for normalisation of all microbial processes using a natural substrate. All other microbial processes were normalised using the substrate induced respiration model.

- *Accounting for dependent on time* : Extensive research was done to investigate the differences in toxicity of copper to terrestrial organisms between lab spiked soils and field contaminated soils. This database was used to derive a leaching-ageing factor. A conservative factor was derived based on the 25-percentile of the ecotoxicity database. This factor for Cu was further supported by the mechanistic research on ageing and ionic strength (leaching) effects.

The general approach used for implementing Cu bioavailability in soils is summarized below;

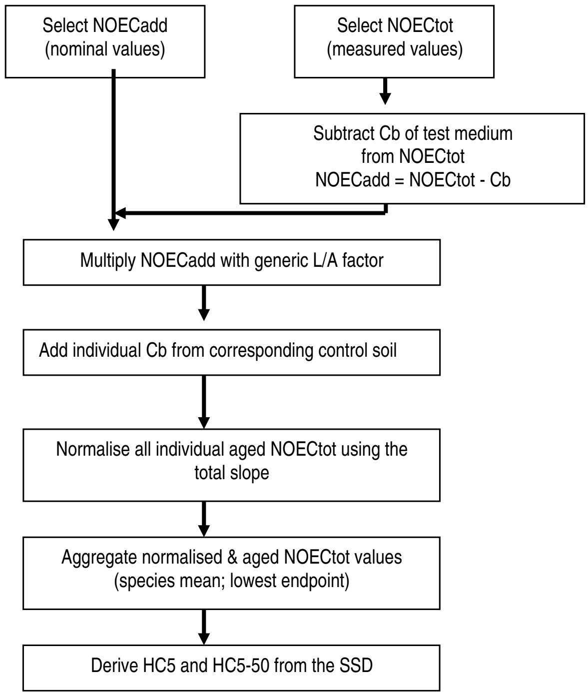

Figure 8: General approach used for the incorporation of Cu -bioavailability in soils

The normalization procedure uses the following steps :

- Select the good quality NOEC data (see Annex)
- Derive the $NOEC_{add}$ values by subtracting the Cu background concentration of the tested control soils from the total NOEC values (measured NOEC) or use the $NOEC_{add}$ values from nominal NOECs.
- Compile the aged $NOEC_{add}$ values by multiplying the individual $NOEC_{add}$ values with the L/A factor.
- Add the Cu background concentration from each individual test[12] in order to calculate the total aged NOEC values.
- Sort the total aged NOEC values of the existing database in 7 different groups (related to the 7 regression functions), i.e. tomato, all other plants, soft-bodied invertebrates, hard-bodied invertebrates, N-cycle related microbial processes, microbial respiration induced by artificial substrate, microbial respiration induced by natural substrate.
- Normalise each total aged NOEC value towards a reference soil using the total slope –this is the slope based on the total ecotoxicity data- of the respective regression function (**Figure 8**). CEC, pH, clay and OM of the tested soils should be known. If CEC is unknown, it is estimated from % clay, % OM and pH[13]. If these soil properties are unknown, these data can not be used for normalisation.

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[12] In case no background concentration is reported a default value of 10.7 mg/kg is used (see chapter 1.2.3). A sensitivity analysis was performed to assess the influence of using different background concentrations on the PNEC setting.

[13] If the CEC was missing from an ecotoxicity test, then it was estimated from % clay, pH and %organic matter using an experimentally derived regression model: CEC=(30+4.4 pH)*clay/100+(-34.66+29.72 pH)*OM/100; the clay is the % clay in the soil (Helling *et al.,*

$$NOEC_{ref} = NOEC\left[\frac{abioticfactor_{ref}}{abioticfactor}\right]^{slope} \qquad (Eq-1)$$

E.g. regression applied for plant data (except tomato)

$$NOEC_{ref} = NOEC\left[\frac{CEC_{ref}}{CEC_{testedsoil}}\right]^{0.69} \qquad (Eq-2)$$

Where multiple data are available for the same species and endpoint, calculate the species mean value for the most sensitive endpoint for each species. Build the SSD from the species geomean NOEC values. Derive the HC_5/ HC_{5-50}

The size of the AF on the HC5-50 can range between 5 and 1 and the exact value will depend on an evaluation of the uncertainties around the derivation of the 5th percentile.

The uncertainty analysis including an analysis of available field studies and mesocosms and a comparison with the background level in soils is therefore used to derive the final PNEC.

B. Uncertainty assessment and final PNEC derivation

B1. Quality and representativeness of the terrestrial database

B11. Quality and relevancy of the input data

*TGD//*REACH*: To be considered are the overall quality of the database and the end-points covered, e.g., if all the data are generated from 'true' chronic studies (e.g., covering all sensitive life stages; real chronic exposure time)*

A summary of the terrestrial toxicity data and the related soil chemistry is provided in Annexes 8 to 10.

The toxicity data on terrestrial organisms are from ecotoxicity tests that study relevant ecotoxicological parameters such as survival, growth, reproduction, root elongation, yield, litter breakdown, abundance. Relevant endpoints for soil micro-organisms focused on functional parameters (such as respiration, nitrification, mineralisation) and microbial growth[14].

Data are either from tests focusing on sensitive life stages (eg. root elongation, reproduction) or from 'chronic exposure' (eg. growth, mortality).

Only data from observations in natural and artificial (OECD) soil media with properties relevant for European soils have been used in this report. The physico-chemical properties of the soils tested represent those encountered in the EU; ranges for pH, OM content and Cu

1964; regression based on CEC measured at various pH values on 60 different soils; CEC refers to the cEC measured at soil pH). The test result was *not* used if either %clay or % OM was missing. The clay content of standard OECD soils were set at 0% (=inert soils). No indirect estimates were made if the pH was missing for a test with soil microbial processes.

14 A number of enzymatic endpoints have been evaluated in an annex to the Cu-VRA.

background are well covered (Table 64) For the CEC content and to some extent also the clay content, the ecotoxicity database is enriched by soils with lower clay content and soils with a lower CEC. In other words, soils expected to be more 'sensitive' to copper are well represented in the effects database.

Table 64: Soil parameters of the selected toxicity studies and European soils (reported as 10th and 90th %)

Parameter		Plants	Invertebrates	Microbial tests
pH	Toxicity studies	4.5-7.5	4.1-7.3	4.3-7.5
	European soils		4.6-6.2	
OM (%)	Toxicity studies	2.0-7.0	1.6-10	1.4-20.4
	European soils		2.7-26.7	
CEC (cmol/kg)	Toxicity studies	4.7-26.2	5.8-26.2	2.4-36.3
	European soils		12.8-46.5	
Clay (%)	Toxicity studies	8.0-46.0	5.1-38	7.0-46.0
	European soils		17.1-29.2	
Cu background concentration (mg/kg)	Toxicity studies	6.2-158	3.2-21.8	6.2-50
	European soils		6.9-45.1	

There is a wealth of data on copper toxicity in the terrestrial environment, contrary to most substances. Literature data were screened for relevancy and filtered for their quality, building on criteria previously agreed upon for other metal risk assessments.

The terrestrial database for copper consists of **252 good quality chronic NOEC/EC10** values.

B12. Diversity and representativeness of the taxonomic groups

TGD: At least 10 reliable NOECs (preferably more than 15) from chronic/long-term studies for different species covering at least 8 different taxonomic groups from 3 trophic levels.

Available and selected data represent 3 trophic levels:

Plants: 67 NOEC/EC10 values; monocotyle and dicotyle plants including agricultural and wild species belonging to 9 different species and 5 different families (*Polygonum convolvulus* – family of the Polyonaceae; *Lycopersicon esculentum* – family of the Solanaceae; *Hordeum vulgare*, *Avena sativa*, *Pao annua* – family of the Poaceae; *Senecio vulgaris*, *Andryala integrifolia*, *Hypochoeris radicata* – family of the Asteraceae; *Lolium perenne* – family of the Gramineae)

Invertebrates: 108 NOEC/EC10 values; hard and soft bodied organisms with different exposure routes and feeding strategies belonging to 10 different species and 6 different families (i.e. the *Eisenia andrei*, *Eisenia fetida*, *Lumbricus rubellus* belonging to the family of the Lumbricidae; *Cognettia sphagnetorum* to the family of the Enchytraedae; *Isotoma viridis*, *Folsomia candida*, *Folsomia fimetaria* to the family of the Isotomidae; *Hypoaspis aculeifer* to the family of the Laelapidae, *Platynothrus peltifer* to the family of the Camisiidae, *Plectus acuminatus* to the family of the Plectidae).

Microbial processes: 77 NOEC/EC10 values; 9 different endpoints representing the C- and N-cycle and measurement of microbial biomass are available (i.e. maize induced respiration, substrate induced respiration, litter decomposition, glutamic acid decomposition, N-mineralisation, denitrification, nitrification, ammonification, biomass C, biomass N).

Conclusion database: 252 good quality chronic NOEC/EC10 values from 3 trophic groups are available; data cover the EU 10P-90P range of the soil properties influencing bioavailability of copper. The available database complies with the TGD/REACH criteria for the application of the statistical extrapolation technique.

B13. How to deal with multiple data for one species? – correction for differences in bioavailability

TGD/REACH*: The most sensitive endpoint should be taken as representative for the species.*

Multiple values for the same endpoint with the same species should be investigated on a case-by-case basis, looking for reasons for differences between the results. For equivalent data on the same end-point and species, the geometric mean should be used as the input value for the calculation.

For several species and functions, multiple data were available for the same endpoints (for some endpoints more than 20 data).

Toxicity data differed widely: up to a factor 24 for plants, up to a factor 48 for invertebrates and to a factor 73 for micro-organisms.

A research project was set-up –build on the Zn-RA Conclusion I project- to understand and explain the differences in toxicity.

Research results showed that differences in toxicity can be attributed to differences in bioavailability, the latter related to differences in soil properties and to differences in ageing and application mode and rate (leaching or ionic strength effect).

-Regression models

A total of 7 regression models were derived to predict toxicity of copper to terrestrial organisms for a wide range of soil types: 2 for plants (1 monocotyle and 1 dicotyle plant); 2 for invertebrates (1 for soft-bodied and 1 for hard-bodied invertebrates); 3 for micro-organisms functions (1 related to the N-cycle and 2 related to the C-cycle).

The parameter explaining best the variability in toxicity for most of the endpoints is the CEC.

The models were applied on the ecotoxicity database as follows:

For plants, the *L. esculentum* model (endpoint yield) was applied only on data for tomato while all other plant data were normalised using the *H. vulgare* root elongation model because this endpoint is the most sensitive for plants. For the invertebrates the *E. fetida* model was used to normalise all soft-bodied species, while the *F. candida* model was used to normalise all hard-bodied species. For the microbial processes, all NOEC values related to the N-cycle were normalised based on the CEC slope of the nitrifying micro-organisms. The maize respiration model was used for normalisation of all microbial processes using a natural substrate. All other microbial processes were normalised using the substrate induced respiration model.

Application of these models on the database significantly lowered the variability in the toxicity data were multiple data are available for the same endpoint. The intra-species and functions variability after normalization was drastically reduced to remaining levels of variability which can be expected between laboratories (inter-lab variability assessed in ringtests) and allowed the derivation of meaningful geometric mean NOEC/EC10 values for each endpoint. For each species, the lowest endpoint-specific geometric mean value was used as input into the SSD.

A sensitivity analysis was made to assess the influence of applying one single model for invertebrates and one single model for plants. For invertebrates, this resulted in a smaller reduction of the variability and less good predictions of the toxicity values. For plants, no differences were found.

An additional benefit of these models is that it allows the derivation of soil or soil type specific SSDs and so PNEC values.

- Leaching-Ageing factor

Extensive research was done to investigate the differences in toxicity of copper to terrestrial organisms between lab spiked soils and field contaminated soils. This research included ecotoxicity tests with single species and microbial functions using freshly spiked, spiked-aged and field contaminated soils in the lab under similar conditions (food availability, abiotic conditions) and mechanistic research to explain the mechanisms behind the reduction in toxicity. On the basis of this research and available literature data an extensive database was collected including 37 paired ecotoxicity data for 7 different soils including several acid sandy soils. This database was used to derive a leaching-ageing factor. No significant influence could be found of soil type or trophic level on the leaching-ageing factor and a conservative factor was derived based on the 25-percentile of the ecotoxicity database (in the Zn-RA, the factor corresponds to the 40-percentile of the ecotoxicity database). This factor for Cu was further supported by the mechanistic research on ageing and ionic strength (leaching) effects.

Conclusion multiple data - correction for differences in bioavailability: For several species multiple data are available for the same endpoint. Large differences in effects of copper can be explained by differences in bioavailability. Models explaining these differences in toxicity are available so that

-the terrestrial ecotoxicity data can be normalised to the same conditions and variability reduced,

-the most sensitive endpoint per species can be identified as input into the TGD/REACH

-soil or soil type specific SSDs and PNEC values can be derived.

B14. Fit to a distribution and statistical uncertainties around the 5th percentile estimate

TGD/REACH*: Different distributions like e.g. log-logistic, log-normal or others may be used (Aldenberg and Jaworska, 2000, Aldenberg and Slob, 1993).*

The Anderson–Darling goodness of fit test can be used in addition to the Kolmogorov-Smirnovtest, as a criterion for the choice of a parametric distribution for comprehensive data sets. Results should be discussed in regards to the graphical representation of the species distribution and the different p values that were obtained with each test. Finally, any choice of a specific distribution function should be clearly explained.

*The TGD/*REACH guidance *proposes the use of the 5th percentile as the intermediate value for the derivation of the PNEC. The 50 % confidence interval associated with this concentration should also be derived.*

Different distributions have been evaluated for different soil types or scenarios. Both statistical (e.g. Kolmogorov-Smirnov, Andersen-Darling tests) and visual (e.g. Q-Q plots) goodness-of-fit techniques were used in order to select the most appropriate distribution function for the compiled chronic data set. The final distribution function was eventually selected on the basis of the Anderson-Darling goodness-of-fit test as this test highlights differences between the tail of the distribution (lower tail is the region of interest) and the input data.

A comparison was made of the uncertainty around the HC5 between the best fitting distribution and the log-normal distribution. The actual model for the best-fitting distribution depends on the soil scenario.

The statistical uncertainty related to the HC5 value is reflected in the small differences between the HC5 and the HC5-50, ranging between a factor 1.0 to 1.3, depending on the soil scenario and fitting distribution.

Table 65: Evaluation of the uncertainty around the HC5 derived for a range of typical EU soil scenarios. Comparison between the HC5 and its 50 % confidence limit for the best-fitting and log-normal distributions.

Soil scenario	HC5 (mg/kgdw) Best-fit - Log-normal fitting	HC5-50 (mg/kgdw) Best-fit - Log-normal fitting
1. Acid sandy soil-Sweden	26 - 26	20 - 25
2. Loamy soil-the Netherlands	104 - 89	90 - 88
3. Peaty soil-the Netherlands	176 - 176	173 - 173
4. Acid sandy soil-Germany	55 - 40	48 - 39
5. Clay soil-Greece	168 -144	142 - 141
6. Loamy soil-Spain	86 - 80	73 - 79

Conclusion statistical uncertainties around the 5th percentile**:** The statistical analysis demonstrates the robustness of the derived HC5 values.

B15. Evaluation of NOEC values below the HC5-50

*TGD/*REACH*: NOEC values below the 5% of the SSD need to be discussed*

A comparison of the normalized HC_{5-50} values with the normalized NOEC values for 6 typical EU soil scenarios, shows that only one out of the 28 NOEC values (*Plectus acuminatus*) falls below the HC_{5-50} derived from the SSD. This is not the case for all soil types but for 5 of the 6 soil types. The NOEC value is a factor 1.0 to 1.4 times below the HC_{5-50}.

Plectus acuminatus : The effect of Cu on reproduction of *Plectus acuminatus* was investigated in one study. The LOEC value for this species is 3-times higher than the NOEC. At the LOEC value 14% effect is found. The LOEC value is for all soil types well above the HC_{5-50}. It should further be noted that no standard test protocol is available for this species, several technical problems occur including recovery of organisms added which render interpretation of the data difficult. This was also noted in this study in which only 54 of the 100 adult control animals were recovered in the control soils.

Conclusion NOEC values below HC5-50: Only 1 single datapoint out of 28 is found below the HC5-50 in 5 out of 6 typical EU soil scenarios. The LOEC value –which is around the EC10- is however well above the HC5-50 in all soil scenarios analysed.

B16. Comparison of the HC-50 with the EU background and essentiality levels

Considering that copper is a natural element, essential for all life forms (from micro-organisms to humans), it is important to compare the derived HC5-50 and eventual PNEC with the copper background levels and the essentiality levels for the EU soil scenario considered.

The HC5-50 values derived for typical EU soil scenario's ranges between 20 to 173 mg Cu/kg, with lower values for acid sandy soils and higher values for clay and peaty soils. These values are generally above the range of the reported average and 90P copper background values for natural (forest) soils (see regional exposure chapter of the Cu-VRA). Reported 90P values by country range between 7.3 and 40.2 mg Cu/kg and average values range between 2.7 and 20.6 mg Cu/kg with lower values for sandy soils and higher values for clay and peaty soils.

Copper is an essential element. Minimum levels of copper in soil to ensure good growth of plants are 5-10 mg/kg in sandy soils and 30 mg/kg in organic soils.

Conclusion HC5-50 versus background and essentiality levels: The proposed HC5-50 values are above the background levels and essentiality levels.

B17. Mesocosm and field studies

TGD/REACH*: It is recommended to compare the field and mesocosm studies, where available, with the 5th percentile and mesocosm/field studies to evaluate the laboratory to field extrapolation.*

The method to derive the PNEC for copper to terrestrial organisms typically relies on the use of single species tested in freshly laboratory spiked soils.

Validation of the proposed PNEC could be carried out by comparing this PNEC value with NOEC values from single-species tests performed in aged field soils and multi-species experiments in lab and field.

For copper, 8 single-species tests performed in aged field soils are available and 5 multi-species tests performed in lab and field.

- Single –species tests in aged field soils

Ecotoxicity tests included a range of endpoints covering micro-organisms, invertebrates and plants.

Soils tested cover a wide range of European soil types: sandy, peaty soil, sandy loam, sandy clay, loamy sand with a CEC ranging between 1.2 cmol/kg and > 100 cmol/kg.

The ecotoxicity values (NOEC/EC10) have been normalized to the 6 EU soil types and species mean values were compared with the HC5-50 of these soil types.

For all soil types, the HC5-50 was lower than the species NOEC/EC10 values indicating the HC5-50 to be protective.

- Multi –species tests in lab and field

Five multi-species studies are available, 3 of which tested freshly spiked soils in the lab, in 2 studies field-contaminated soils, contaminated more than 10 years ago and more than 70 years ago were tested. Ecotoxicity tests included a range of endpoints covering micro-organisms, invertebrates and plants.

The effect of copper was investigated for a set of soils which are expected to be more sensitive to copper (sandy soils, low pH, low CEC ranging between 4.5 and 10 cmol/kg).

For each of these multi-species studies the HC5-50 was derived by normalizing the single-species ecotoxicity database (SSD) to the soil properties of the multispecies tests.

For most endpoints of the multi-species tests NOEC/EC10 values could be derived. NOEC/EC10 values are generally well above the derived HC5-50.

A few unbounded LOEC values were reported in the freshly spiked multi-species studies for omnivore & predator nematodes[15] and for mesostigmatida and oribatida microarthropods. Unbounded LOEC values are a factor 4.5 to 6 above the HC5-50. These taxonomic groups were also investigated in field contaminated aged soils, with similar soil properties. The NOEC values for these taxonomic groups in field contaminated soils are above the HC5-50.

Conclusions mesocosm and field studies: 8 single species studies in field contaminated soils and 5 multi-species studies (freshly spiked and field contaminated) are available. Results indicate the HC5-50 to be protective in the field, including in soils in which copper bioavailability is high.

B2. Derivation of the PNEC – evaluation of the uncertainties

-252 chronic NOEC/EC10 values are available: 67 plant data, 108 invertebrates' data, 77 micro-organisms data

- data cover 3 trophic group, include 19 species from several taxonomic groups and 9 microbial endpoints; data cover the range of EU soils.

  -9 different plant species –including agricultural and wild species, monocotyls and dicotyls- from 5 different families

  -10 different invertebrate species –including hard- en soft-bodied organisms with different feeding strategies- from 6 different families

  -measurement of microbial biomass and 6 different microbial functions representing the C- and N-cycle

[15] It should be noted that testing of nematodes in soils is not without technical difficulties and data need careful interpretation.

-there is no specific group which is significantly more sensitive to copper, giving confidence in the representativeness of the database for the terrestrial ecosystem. This is also confirmed by the additional species tested in field and multi-species studies.

-data cover more than 90% of the range of soil properties influencing bioavailability of copper in soil

- For several species multiple data are available for the same endpoint. Large differences in effects of copper can be explained by differences in bioavailability. Models explaining these differences in toxicity are available so that the terrestrial ecotoxicity data can be normalized to the same conditions and variability reduced.

Bioavailability models are applicable for a wide range of EU soils covering the 10P-90P -and beyond- of soil properties influencing the bioavailability of copper! These models allow the derivation of soil or soil type specific SSDs and PNEC values.

-A conservative leaching-ageing factor is available to correct for differences between lab and field due to leaching-ageing effects. This factor is based on the 25-P of an extensive ecotoxicity dataset (in the Zn-RA this was based on the 40-P).

- HC5-50-values can be derived for a range of EU soil types, using the log-normal and best-fit models. Differences between HC5 and HC5-50 and also between HC5-50 and HC5-95, are small and, depending on the soil scenario, range between a factor 1 to 1.3 and 1.1 to 1.4 respectively.

- Only 1 single datapoint out of 28 is found below the HC5-50 in 5 out of 6 evaluated soil types. The LOEC value (14% effect) is however well above the HC5-50.

-A comparison of the HC5-50 with the background (natural forest soils) and essentiality levels indicates the HC5-50 to be above the background levels and essentiality levels.

- A total of 8 single species studies are available in which the toxicity of Cu to micro-organisms, invertebrates and plants in field contaminated aged soils was investigated for a wide range of European soil types (peaty, sandy, clay).

A total of 5 multi-species studies are available, 3 of which studied the effects of copper in freshly spiked soils and 2 in field contaminated aged soils. Several of the soils are expected to be more sensitive to copper (sandy soils, low pH, low CEC). Invertebrates, plants and micro-organisms were studied.

Single species and multi-species studies indicate the HC5-50 to be protective in the field.

Conclusion evaluation of uncertainties and PNEC derivation: Taking all the above information into account, an AF of 1 is proposed on the HC5-50 for the derivation of the PNEC.

The PNECs derived from the log-normal distributions are carried forward to the risk characterization.

B3. Defining a Reasonable worst case PNEC for European soils

For the copper RA, the Spanish Loamy soil was considered as a reasonable worst case (RWC) PNEC (79 mg Cu/kg dry weight). The RWC value was based on based on mapping of existing soil pH, CEC, organic matter and clay content. SCHER commented that the database was not sufficiently comprehensive and recommended to assess further assess physico-chemistry of European soils.

The GEMAS-project (Geochemical Mapping of Agricultural and Grazing Land Soil project) provides good quality and comparable exposure data of metals and soil properties known to influence the bioavailability (pH, organic matter content, clay content and effective CEC) in agricultural and grazing land soil in Europe. The aim of this project was to produce a harmonized and directly comparable dataset on soil quality and metals in soils at the EU scale. Data from the GEMAS project allow calculating site-specific predicted no effect concentrations (PNEC) for Cu in 4331 soil samples taken from arable and grazing lands across Europe (Reimann, *et al.,* 2009).

Cu PNEC values were calculated for each data-point, using the soil copper bio-availability model described above. The derived Cu PNEC values are summarized in Table 66. The table shows large variations in PNECs with min-max values ranging between 13 and 205 mg Cu/kg dry weight, depending on the soil chemistry. The 10th percentile, median values and 90th percentile PNEC values derived through the different statistical approaches are quite consistent.

To be consistent with the approach for the RWC regional PEC derivation, the PNECs- RWC calculated as the median (50th percentile) of country-specific 10th percentiles are retained and carried forward to the risk characterization.

A RWC 10th percentile of 69.6 mg Cu/kg dry weight is retained for the grazing land

A RWC 10th percentile of 59.5 mg Cu/kg dry weight is retained for the arable land.

The overall soil median RWC PNEC value across the two land-types is 64.6 mg Cu/kg dry weight (Oorts and van Nederkassel, 2010)

Table 66: **Distributions of site-specific Cu PNEC values for arable and grazing land in Europe.**

Country	Number of data	Min.	10th percentile	Median	90th percentile	Max.
		mg Cu/kg dw				
Grazing land						
All data-	2115	17.8	61.4	100.1	150.3	204.8
EU-27 + Norway *	1832	17.8	60.9	97.7	148	203.3
EU-27 + Norway **			69.6	101.1	142.9	
			(48-101)	(67-127)	(107-191)	

Country	Number of data	Min.	10th percentile	Median	90th percentile	Max.
		mg Cu/kg dw				
EU-27 + Norway ***		21.1	68.1	95	130.5	193.1
Arable Land						
All data	2198	13.4	52.3	89.9	131.8	201.4
EU-27 + Norway *	1916	13.4	51.1	87	127.1	201.4
EU-27 + Norway **			59.5	88.7	122.5	
			(36-84)	(64-123)	(93-162)	
EU-27 + Norway ***		14.3	55.9	84.7	116.4	192.1

* percentiles calculated based on all individual data
**percentiles calculated as the median (50th percentile) of country-specific percentiles (5th and 95th percentiles between brackets)
*** percentiles calculated via area-based distribution of interpolated sample data

The detailed derivation of the RWC PNEC for Europe, based on the GEMAS data is attached to the IUCLID summary record on terrestrial effects.

Conclusion PNEC derivation:

A RWC terrestrial PNEC of 65.5 mg Cu/kg dw is derived for Europe and is used in absence of site-specific soil chemistry data

7.3 Atmospheric compartment

Not applicable to copper.

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic micro-organisms

The results are summarised in the following table:

Table 67: Overview of effects on micro-organisms

Method	Results	Remarks	Reference
activated sludge freshwater flow-through equivalent or similar to ISO DIS 9509 (Method for Assessing the Inhibition of Nitrification of Activated Sludge Microorganisms by Chemicals and	NOEC (30 d): 0.23 — 0.45 mg/L dissolved (meas. (arithm. mean)) based on: respiration rate NOEC (30 d): 0.26 — 0.29 mg/L dissolved (meas. (arithm. mean)) based on:	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): soluble copper**	Cha, D.K., Allen, H.E. & Song, J.S. (2004)

Method	Results	Remarks	Reference
Waste Waters)	nitrification rate		
activated sludge freshwater static The aim of this study was to determine the acute toxicity of copper on the protozoan community of activated sludge from a wastewater treatment plant. The acute toxicity was based on the reduction of both cell densities and species richness.	NOEC (24 h): 0.32 — 0.64 mg/L dissolved (meas. (arithm. mean)) based on: survival	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): hydrated copper chloride**	Madoni, P., Davole, D., Gorbi, G. & Vescovi, L. (1996)
Tetrahymena pyriformis freshwater semi-static This study was designed to determine the relative toxicity of 16 environmental pollutants, on marine fibroblasts and on the ciliated protozoa Tetrahymena pyriformis.	NOEC (48 h): 3.6 — 3.8 mg/L dissolved (nominal) based on: growth inhibition	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper chloride**	Sauvant, M.P. (1997)
Tetrahymena pyriformis freshwater static OECD Guideline 201 (1984)	NOEC (48 h): 3.563 mg/L dissolved (nominal) based on: growth inhibition NOEC (96 h): 3.818 mg/L dissolved (nominal) based on: growth inhibition	2 (reliable with restrictions) weight of evidence experimental result **Test material (Common name): copper sulphate**	Schäfer, H. *et al.,* (1994)
sewage, domestic freshwater static The reduction of nitrate was assessed after copper additions to a synthetic medium and in lake water.	EC50 (100 d): 25 µg/L total (meas. (arithm. mean)) based on: nitrate reduction	2 (reliable with restrictions) weight of evidence experimental result **Test material: >>>??? ID not the same as in section 1.1, although 'yes' is indicated in field 'Identity of test material same as for substance defined in section 1 (if not read-across)'<<<**	Waara, K.O. (1992)
activated sludge of a predominantly domestic sewage A rapid and sensitive technique for determining chemical inhibition of water-soluble compounds by using a fed-batch reactor is presented.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Almanza G., Cruz L.E., Diaz-Baez M.C. (1996)
activated sludge of a predominantly domestic sewage OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Fiebig, S. and Noack, U. (2004)
activated sludge	see summary :	2 (reliable with	Dutka, B.J. *et al.,*

Method	Results	Remarks	Reference
Four short term microbiological toxicity screening tests were compared.		restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	(1983)
activated sludge The toxic effect of CuSO4on mixed populations of activated sludge by means of reduction in oxygen uptake (i.e. respiration activity) was studied.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper sulphate**	Miksch, K. and Schürmann, B. (1988)
anaerobic sludge The toxicity of copper on methanogenic activity from anaerobic domestic sludges from a wastewater treatment plant was assessed.	see summary :	2 (reliable with restrictions) supporting study experimental result **Test material (Common name): copper chloride**	Codina, J., Munoz, M.A, Cazorla, F.M., Perez-Garcia, A., Morinigo (1998)

Discussion

NOECS for micro-organisms- STP

Data on the toxicity tests performed with aquatic bacteria and protozoa, reported as L(E) $C_{50}$and NOEC values. The following high quality publications were selected for assessing the toxic effects of copper on bacterial populations: Dutka (1983), Waara (1992), Madoni *et al.,* (1996), Milksch & Schürmann (1988), Almanza *et al.,* (1996), Fiebig & Noack (2004) and the results from the Cha *et al.,* (2003) research project. The date from Sauvant *et al.,* 1997 ; Schäfer *et al.,* 1994, Girling *et al.,* 2000 were used for assessing the effects on protozoan populations

The exposure time among reports varied from short term batch exposures to continuous exposures. The effects endpoints on micro-organisms covered are: heterotrophic respiration inhibition, nitrification inhibition and effects on ciliated protozoa.

The bacterial studies using mixed population tests (e. g. activated sludge) representative for microbial degradation in STP, resulted in NOEC values (reported as total or nominal concentrations) ranging from <0.5-1 and 5.4 mg/l for the heterotrophs and between 3.5 and >20 mg/l for the nitrifiers. The EC_{50}values for the micro-organisms representative for microbial degradation in STP range from 2.1 to 26 mg/l Cu (as total or nominal copper) for the heterotrophs and between 9.9 and 49.1 mg/l for the nitrifiers (as total or nominal copper). Expressed as dissolved copper concentrations, a NOEC range for heterotrophs between 0.23 and 0.45 mg/l was observed. For the nitrifiers, a NOEC range between 0.26 and >0.92 mg/l was observed.

Protozoan tests resulted in NOEC/L(E) C50 values depending on the test species and test-set-up used. The short term tests with *T. pyriformis*, the species recommended by the TGD/REACH(1996, revisions 2003), resulted in NOEC and EC_{50}(growth) values between, respectively, 3.6 - 3.8 mg/l and 8.0-10.2 mg/l nominal copper. These toxicity test results are based on short term experiments (between 2 and 4 days) performed in artificial media. The results obtained from protozoan communities were deemed to be more representative for the functioning of STPs and were therefore retained for the PNEC derivation.

Across endpoints/studies 0.23 mg dissolved Cu/L was considered as the most reliable NOEC

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

High quality effects endpoints on micro-organisms are available for: heterotrophic respiration inhibition, nitrification inhibition and effects on ciliated protozoa from sewage treatment plants. The NOEC/L(E) C10 values from these studies are carried forward for the PNEC derivation in a WOE approach.

Value used for CSA:

EC10/LC10 or NOEC for aquatic micro-organisms: 0.23 mg/L

7.4.2 PNEC for sewage treatment plant

Table 68: PNEC sewage treatment plant

	Value	Assessment factor	Remarks/Justification
PNEC stp (µg/l)	230	1	Extrapolation method: statistical extrapolation as agreed by the Competent Authorities for Biocides and Existing Substance Regulations

Discussion – see above.

7.5 Non compartment specific effects relevant for the food chain (secondary poisoning) 16

7.5.1 Toxicity to birds

The results are summarised in the following table:

[16] The effects via food chain accumulation have to be evaluated (see Annex I of REACH Regulation, section 3.0.2) and it is suggested to report the effect assessment relevant for that purpose under this heading, although it does not exist in the format given in Annex I of REACH Regulation, section 7.

Table 69: Overview of effects on birds

Method	Results	Remarks	Reference
Colinus virginianus acute oral toxicity (gavage) Doses: 1000,1300,1600 and 2000 mg/kg body weight doses adjusted to administer 1 ml/animal The doses were administered as a single dose via gavage with the test substance suspended in Tylose (CMC) with each dose adjusted to the individual body weights of the birds. Birds were weighed predose and on day 14 post dose.	see summary (14 d): ca. 1400 mg/kg bw test mat. based on: mortality	2 (reliable with restrictions) key study experimental result **Test material (EC name): dicopper oxide**	Dickhaus, S. (1988)

This study indicated that birds have a similar sensitivity as rats, extensively studies in the toxicity section.

7.5.2 Calculation of PNECoral (secondary poisoning)

Table 70: PNEC oral

	Value	Assessment factor	Remarks/Justification
No potential for bioaccumulation as agreed by the Competent Authorities for Biocides and Existing Substance Regulations			

Justification for no PNEC oral derivation: as agreed by the Competent Authorities for Biocides and Existing Substance Regulations

Justification for PNEC oral derivation: as agreed by the Competent Authorities for Biocides and Existing Substance Regulations

A more detailed justification for absence of bioaccumulation potential and, hence, secondary poisoning, is summarized below

Essential trace element

Copper is an essential micronutrient, needed for optimal growth and development of micro-organisms, plants, animals and humans. It plays a vital role in the physiology of animals: for foetal growth and early post-natal development, for haemoglobin synthesis, connective tissue maturation especially in the cardiovascular system and in bones, for proper nerve function and bone development, and inflammatory processes. Copper acts as an active cofactor in over 20 enzymes and proteins, notably the respiratory enzymes haemocyanin and cytochrome oxidase and the anti-oxidant superoxide dismutase (WHO, 1998).

Copper deficiency has been observed in intensive cultures of fish, crops and farm animals. The most striking examples of copper deficiency come from farming practices. Insufficient bioavailable copper in soils has been shown to reduce agricultural yields and to produce metabolic copper deficiencies in animals. Copper deficiency was first recognised in Europe in the 1930s and its incidence increased with the intensification of arable farming over the last 50 years. Copper deficiency has also been noted in a wide variety of soils world-wide (IPCS 1998).

Depending on the organism's metabolic need, different copper levels are found in tissues from different strains, species and life stages.

Differences among species and strains: Aquatic invertebrates such as gastropods, some crustacea and bivalves, relying on haemoocyanin as respiratory pigment, have typically higher copper levels than invertebrates relying on haemoglobin as respiratory pigment (e.g. Timmermans et al, 1989).

In higher organisms (vertebrates), homeostatic control of copper supply is achieved mainly by storage in the liver and biliary secretion (Underwood and Suttle, 1999). Copper is bound to proteins such as ceruloplasmin and metallothionenin, functioning as copper storage and mobilised as needed.

Differences within species: Of all factors that affect the physiology of animals, body size exerts the major effect and provides an integrated value of all physiological processes (Marsden and Rainbow, 2004). In aquatic environments, several investigators demonstrated an inverse relation between copper tissue levels and the length or weight of the organisms (e.g. Timmermans et al, 1989).

Different copper needs are of relevance to both agricultural and medical practices:

Copper supplements are provided to piglets and pigs to enhance growth. Considering the high needs during the fast growth stages, copper levels given to piglets are much higher than those given to adult pigs.

The copper concentration in the liver of a mammalian and human foetus is much higher during the last term of pregnancy than in an adult. This is because of the high copper need during this period, as well as during the first months after birth, and because breast milk contains little copper. Consequently, the milk formulae for premature babies contain higher copper levels than those for newborns.

In summary, as an essential element, all organisms will naturally accumulate copper without deleterious effects. Different levels of accumulation in tissue reflect differences in nutritional needs.

Homeostatic control, uptake and depuration of copper ions

The natural copper levels, available for plants, micro-organisms and animals, living in a specific environment, depend on the natural geological and physico-chemical characteristics of the water, sediments and soils. Homeostatic regulation of copper allows organisms, within certain limits, to maintain the physiologically required levels of copper in their various tissues, both at low and high copper intakes.

The molecular mechanism of copper homeostasis is related to 2 key elements: P-type ATPases that can pump copper across biological membranes in either direction or copper chaperones, important for intracellular copper homeostasis (Odermatt et al, 1992). The latter is considered to be universal as the sequences of copper chaperones are highly conserved between species (Wunderli et al. 1999).

Besides these active cellular regulation mechanisms, some groups of organisms have developed additional mechanisms (molecular binding to e.g. metallothioneins and sequestration in granules) to prevent copper excess (Borgmann, 1993 and Rainbow, 1980, 1985, 1989; Marsden and Rainbow, 2004).

Vertebrate dietary copper exposure studies (fish, mammals, birds and humans) demonstrate additional organ-related homeostasis. Intestinal adsorption/biliary excretion of copper is regulated with varying dietary intakes (WHO, 1998).

Due to the homeostatic regulation of copper (and other metals), BCF/BAFs are not independent of exposure concentration (e.g. Mc Geer *et al.,* 2003). Increased/decreased copper intakes/eliminations, lead to BCFs and BAFs that are inversely related to exposure concentration (i. e. decreasing BCF/BAFs with increasing exposure concentration (water and diet). For copper, this inverse relationship was clearly demonstrated for BCFs, BAFs and biota-sediment accumulation factors (BSAFs) (Adams *et al.,* 2003). The observed inverse relationship has been explained by homeostatic regulations of internal tissue concentrations at low metal concentrations, organisms are actively accumulating metals in order to meet their metabolic requirements, while at high ambient metal concentrations, organisms are able to excrete excess metals or limit uptake.

Additionally, different BCFs for different species, life stages and seasons have been observed, depending on the organism’s metabolic need (in e.g. Cu-enzymes). Further complicating the application of BCF and BAF to metals is that many aquatic organisms store metals in detoxified forms, such as in inorganic granules or bound to metallothionein-like proteins. The use of granules is of particular note in the context of BCFs, because high body burdens are often associated with this storage mechanism, but there is a lack of adverse effects.

Using BCF and BAF for essential metals and their compounds to assess ecotoxicity therefore ignores fundamental physicochemical and toxicological properties associated with these substances.

Compared with the diffusional uptake of neutral organics, metal uptake is complex. It includes a diversity of mechanisms, accumulation of both essential and non-essential elements from the natural background, homeostatic control of accumulation, as well as internal detoxification, storage and elimination.

Mechanism of action of copper toxicity/deficiency

Freshwater

From the copper risk assessment, it was clearly concluded that the most sensitive uptake route for acute and chronic copper toxicity is directly from the water with free Cu-ions as most potent Cu-species. The key indicator of copper toxicity is disturbance of the sodium homeostasis (e.g. Paquin *et al.,* 2002; De Schamphelaere and Janssen, 2003; Kamunde *et al.,* 2001 & 2005). The key target tissue for copper toxicity is therefore the water/organism interface, with cell wall and gill-like surfaces acting as target biotic ligands in all species investigated.

The importance of water-borne exposure was confirmed from the freshwater chronic ecotoxicity database, demonstrating:

- The influence of water chemistry on chronic copper toxicities (influence of DOC, pH,... on chronic NOECs)
- The small inter-species variability in observed NOECs (after BLM normalisation) (max/min NOEC ratio of 23 for 27 species),
- Small acute to chronic ratios (typically a factor of 1 to 3)
- Higher sensitivity of smaller compared to larger organisms (Grosel *et al.,* 2007).
- No concern of secondary poisoning from copper mesocosm studies:
- Roussel (2007) reported for a lentic mesocosm study a low sensitivity of the predating fish compared to the invertebrates and algae.
- The freshwater pond mesocosms (Schaefers et al, 2002 and Rousel (2007) and the marine pond mesocosm (Foekema *et al.,* 2010) did not show a concern from copper secondary poisoning.

Marine

Freshwater and marine organisms face very different ion- and osmo-regulatory problems related to living in either a very dilute or concentrated salt environment. These differences in ion- and osmo-regulatory physiology may also lead to differences in metal accumulation and metal toxicity (Prosser, 1991; Wright 1995; Rainbow, 2002). Marine organisms are, as freshwater organisms, also exposed via the gills. But in addition, they take in water via the gut exposing an additional series of epithelial structures to the metals (Wang and Fisher 1998; Glover *et al.,* 2003; Mouneyrac *et al.,* 2003). Both the epithelia of gills and gut are thus important and potentially sensitive targets because they provide a variety of essential physiological functions such as the energy dependent transport of nutrients across the interface and the maintenance of homeostatic balance. Despite these apparent physiological differences, it has been shown that marine fish also suffer from osmo-regulatory disturbances under metal exposure.

The importance of waterborne exposure was confirmed from marine ecotoxicity databases, demonstrating:

- The mitigating effect of DOC on the marine NOECs/EC10s.
- The absence of a higher copper sensitivity with increasing trophic chain level.
- For the bivalve Mytilus edulis, the short term (48 hrs) early life stage NOEC was similar to the 10 days growth inhibition NOEC.

The 83 days marine mesocosm study (Foekema *et al.,* 2010), furthermore showed that the safe level in the mesocosm could be predicted from the single-species SSD and DOC correction, developed for water-only exposure.

<u>The interaction between free copper-ions and “gill-like structures” induce osmo-regulatory stress. Osmo-regulatory disturbance from waterborne exposure is recognised as the primary symptom of copper toxicity to aquatic organisms.</u>

Copper toxicity from dietary versus waterborne exposures

Invertebrates: *A few key studies are available:*

- De Schamphelaere and Janssen (2003) demonstrated the influence of water characteristics on the chronic toxicity of D. magna and showed that, for D. magna, waterborne copper and not dietary copper uptake is responsible for copper toxicity (De Schamphelaere and Janssen, 2004).

Similarly, Allinson (2002) investigated the bioaccumulation of copper through a simple food chain (Lemna minor – C. destructor) and observed regulation of copper by the crayfish, C. destructor, with the gills being the main site for absorption and depuration of copper to and from the water column. C. destructor does not appear to be sensitive to dietary copper.

Fish:

- Kamunde, 2001 observed that dietary copper pre-exposure decreased the uptake of copper across the gills, providing further evidence of homeostatic interaction between the two routes of uptake. Rainbow trout regulated dietary copper at the level of the gut by increasing clearance to other tissues, at the liver by increasing biliary copper excretion, and at the gill by reducing waterborne copper uptake in response to dietary exposure. The modest morphological changes in the intestinal tract suggested high cell and organelle turnover and local regulation of copper. In spite of possible increased energy demand for regulation and tissue repair, there was no significant growth inhibitory effect following dietary exposure.

- Blust *et al.,* 2007, reviewed the literature on copper toxicity after dietary copper exposures of fish and compared waterborne versus diet borne toxicity of copper to fish. After detailed evaluation of the Clearwater *et al.,* 2002 review paper, Blust derived critical diet borne toxicity effects value for Atlantic salmon and Rainbow trout of respectively 15.5 and 44 mg Cu/kg fresh weight/day. Blust et al, 2007 further assessed if the waterborne exposures, PNEC of 7.8 µg Cu//l, as derived in the copper risk assessment, would result in a dietary copper dose or copper food concentration exceeding a critical level. The concentrations in food were calculated from the regressions presented in McGeer et al. (2003) which allow the estimation of the whole body copper concentration, for different types of aquatic organisms, as a function of the copper waterborne concentration. The results of the simulations show that aquatic invertebrates exposed to 8 µg Cu/l waterborne copper reach mean Cu body levels of 53-84 mg Cu/kg dry weight (depending on the diet). The resulting daily uptake by fish at 7.8 µg Cu/L was < 4.20 mg Cu/kg fresh weight/day. These results lead to the conclusion that the copper concentrations in food items and daily dietary copper dose in fish are unlikely to cause negative effects at the threshold waterborne copper concentration of 7.8 µg/l.

Comparison of the dietary copper levels and "normal" background Cu levels in live food items

Cu is a naturally occurring element and is essential to all living organisms. Naturally, a background Cu burden is present in all organisms to fulfil their biochemical requirements. Table 1 presents a summary of a few 'background' Cu concentrations in freshwater biota that may serve as food items for fish.

Table 71: Background Cu burdens of selected freshwater biota that may be considered food items for fish.

Species	Cu_{H2O} (µg/L)	Cu_{food} (mg/kg dry wt)	Reference
Daphnia magna (adults)	1	10.2 - 22.1	Bossuyt et al. (2005a,b) a
Daphnia magna (juveniles)	1	20 - 120	Bossuyt et al. (2005a,b) a
Hyalella azteca	3.5	79	Borgmann et al. (1993)

[a] Fifth or 6th generation daphnids taken from a multi-generation exposure; 1 µg/L was sufficient to avoid deficiency

Bossuyt et al. (2005a, b) reported background body burdens of 40 d old D. magna at 1 µg Cu/L between 10.2 and 22.1 mg Cu · kg-1 dry wt. Juvenile daphnids of up to 2 days old seemed to have higher copper body burdens between 20 and 120 mg Cu · kg-1 dry wt. Borgmann et al. (1993) report a Cu burden in *Hyalella. azteca* of 79 mg Cu · kg-1 dry wt in organisms exposed to control conditions, i.e. 3.5 µg Cu/L.

The background copper burdens (10 - 120 mg Cu/kg dry weight) as determined above, furthermore encompass the simulated Cu body levels of 53 - 84 mg Cu/kg dry weight calculated for aquatic invertebrates exposed to 8 µg Cu/l waterborne copper and therefore provide additional evidence that the Cu concentrations in food items and daily dietary Cu dose in fish are unlikely to cause negative effects at the threshold waterborne Cu concentration of 8 µg/l.

Waterborne Cu is therefore recognised as the critical copper exposure route for invertebrates and fish**.**

Critical papers of relevance to bio-magnification

The absence of copper bio-magnification, with consistent BMFs < 1, was shown from several papers:

- Barwick and Maher (2003), compared trace metal levels in a contaminated seagrass ecosystem in Lake Macquire, the largest estuary in New South Wales (Australia). The structure of the estuarine food web was studied in detail and all organisms (algae, invertebrates, fish) were categorised as autotrophs, herbivores, planktivores, detrivores, omnivores and carnivores. The results of the analysis showed the absence of copper bio-magnification in this estuarine system. Copper concentrations ranged between 0.27 µg Cu/g dw (Omnivore: Monacanthus and 88 µg Cu/g dw (Herbivore: Bembicum auratum (gastropod with haemocyanin)). The higher levels (e.g. *B. auratum*) were associated with species with active accumulation of copper into the respiratory pigment haemocyanin.

- Farag *et al.,* 1998, studied copper concentration in benthic invertebrates that represent various functional groups and sizes from de Coeur d'Alene river, Idaho, influenced by mining activities. The copper concentrations noted across the trophic chain, demonstrated the absence of bio-magnification from the sediment to herbivores, omnivores, detrivores and carnivores.

- Wang (2002) noted the bio-diminution of metals in the classical marine planktonic food chain (phytoplankton to copepods to fish) and explained the phenomenon as the result of the effective efflux of metals by copepods and the low assimilation of metals by marine fish.

- Quinn *et al.,* 2003, evaluated trophic chain transfer of metals in insects (35 species) from a stream food web influenced by acid mine drainage with copper levels up to 100 µg Cu/L. They demonstrated that metal concentrations were higher in water and insects closer to the mining sites and taxa richness increased with distance away from the site. The relation between the trophic positions, determined from ^{15}N radio isotope determination, indicated that the trophic chain had no effect on copper levels in the insects.

Copper is therefore not bio-magnified across the trophic chain**.**

Conclusion

There is a substantial amount of information available on copper.

The data clearly demonstrate that:

- Copper is an essential nutrient for all living organisms.
- Copper ions are homeostatically controlled in all organisms and the control efficiencies increase with trophic chain. As a consequence,
- copper BCF/BAF values decrease with increasing exposure concentrations (water and food).
- vary depending on the nutritional needs (seasonal, life stage, species dependent).
- vary pending on "internal detoxification" mechanisms.
- Copper BMFs values are < 1.
- Copper waterborne exposure (and not diet borne exposure) is the exposure route critical to copper toxicity.

7.6 Conclusion on the environmental classification and labelling

Special guidance is available for the environmental classification of metals and metal compounds. For metals, classification is based on comparing the soluble metal-concentration, measured after Transformation/Dissolution (T/D) with the ecotoxicity reference values of the corresponding metal ion.

When assessing the classification of metals (and metal compounds), whether readily or poorly soluble, recognition has to be given to a number of additional factors. For inorganic compounds and metals, the concept of degradability, as commonly applied to organic substances, clearly has limited or no meaning. Rather, the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally, the log K_{ow} cannot be considered as a measure of the potential to accumulate. Nevertheless, the concept that a substance, or a toxic metabolite/reaction product may not be rapidly lost from the environment and/or may bio-accumulate, are as applicable to metals and metal compounds as they are to organic substances. Accordingly:

- The potential for 'rapid loss from the environment' of copper ions has been evaluated in accordance with the 2009 and revised 2011 CLP guidance[17], by assessing the removal

[17] The discussion on the acceptance of "rapid removal from the water-column" are still ongoing

rates of copper ions through partitioning and their subsequent potential for sediment mineralization/remobilization.

- In the revised 2012 CLP guidance, assessing the bioaccumulation potential is only needed in the absence of chronic data. As chronic toxicity data are available for copper, this assessment was not required for determining the classification of copper and copper compounds.

- To define the acute and chronic ERVs for the soluble copper compounds, all high quality data from tests performed with soluble copper compounds were combined and expressed as soluble Cu^{2+} concentration (µg dissolved Cu/L).

- To determine the acute and chronic classification of metals and sparingly soluble metal compounds, transformation/dissolution tests have been performed, as appropriate, and used for the environmental classification.

7.6.1 Information on fate of copper ions, equivalent to "biodegradation of organic substances"

Removal from the water-column

Considering that the 2012 CLP guidance is not explicit for metals such as copper, information on "rapid removal from the water-column" was assessed following the CLP 2009[18] guidance, which states that: "*Laboratory tests evaluating changes of metal species to less soluble metal species, laboratory/mesocosm studies, and field data and/or supported by relevant models could be useful in evaluating removal of soluble metal species through precipitation/speciation processes over a range of environmentally relevant conditions*".

Therefore, a desk study was performed, aimed at evaluating, from model simulations covering a range of environmentally relevant conditions and from laboratory mesocosm and field tests, the removal of soluble copper species through precipitation/partitioning processes and the potential for remobilization. The details of the assessment are available from Rader, 2010 and 2013. The model simulations are based on "The Tableau Input Coupled Kinetics Equilibrium Transport Unit World Model for Metals in Lakes" (hereafter referred to as TICKET-UWM and available from http://blog.unitworldmodel.net), which was developed to address the complexities of metal speciation and its influence on the fate and effects of metals in the environment. Processes considered by the model include complexation by aqueous inorganic and organic ligands such as dissolved organic carbon (DOC), adsorption to particulate phases such as particulate organic carbon (POC) and iron/manganese oxides and cycling of organic matter and sulfide production in lakes. The model output was validated with information from laboratory mesocosm and field tests.

The main conclusions are summarised as follows:

[18] Not conclusive in 2012 CLP guidance

- For a standard lake environment consisting of the EUSES model lake parameters (pH varied between 6 and 8) and the Kd derived in the copper RA (Log Kd: 4.48), 70% copper removal from the water column is reached in less than 5 days.

- For an experimental freshwater mesocosm study, carried out with a range of copper loadings (Schaefers *et al.,* 2003), the measured data demonstrate a half-life of 4 days and more than 70% of removal was observed after 8 days.

- For whole-lake spike addition studies (Lake Courtille), TICKET-UWM results, in concert with the measured data, indicate 70% removal of dissolved copper within 15 days after copper addition.

- For whole-lake spike addition studies (Saint Germain les Belles Reservoir), TICKET-UWM results, in concert with the measured data, indicate 70% removal of dissolved copper occurred within 1.5 days after copper addition.

- Hypothetical TICKET-UWM simulations modelling the removal of copper in the MELIMEX limno-corrals following termination of copper loading demonstrate copper removal < 70% within 28 days. The MILIMEX System was characterised by a setting velocity that is 10 times lower than that used in the EUSES system (0.2 versus 2.5 m/d) and a suspended solid concentration that is almost 3 times lower than the EUSES system (5.9 versus 16 mg/L). It is therefore concluded that the MILIMEX study was carried out under extreme conditions, not relevant to classification purposes. It is worth noting that no measurements were made following termination of the copper loading and therefore the assessment is based on "simulations".

It can therefore be concluded that under "environmentally relevant "conditions, more than 70% of dissolved copper ions are removed within 28 days.

<u>Absence of remobilization from the sediment compartment</u>

To examine the potential for remobilization of copper from sediments, a series of 1-year simulations were performed, using the TICKET-UWM. These focused on re-suspension, diffusion, and burial to/from the sediment layer, their net effect on copper concentrations in the water column and changes in speciation in the sediment. Simulations were made with an oxic sediment layer as well as with an anoxic sediment layer (with varying concentrations of Acid Volatile Sulfides (AVS)) and varying re-suspension rates (up to 10 times the default EUSES model lake value).

In simulated sediments with AVS present in excess of copper, essentially all sediment copper was present as copper sulfide because the affinity of copper for sulfides is much larger than the affinity for Organic Carbon. CuS has a very low solubility product constant (K_{ps}) and therefore, full copper sulfide precipitation was generally demonstrated: in all cases where AVS $\geq$1 µmol (reasonable worst case AVS concentration in European surface waters) and at environmentally relevant copper concentrations ($\leq$ 0.1 mg/L). As a result of this strong binding, the sediment log *K*D greatly exceeded the water column log *K*D and the net diffusive flux of copper was directed into the sediment. For anoxic sediments devoid of AVS and for oxic sediments, the net diffusive flux was small and directed out of the sediment. However, for all cases considered, the pseudo steady-state total and dissolved copper concentrations were at least 8 times lower than the concentration corresponding to 70% removal.

Research (Simpson *et al.,* 1998; Sundelin and Eriksson, 2001) from field evidence suggests that the potential for copper release from sulfides and other sediment binding phases is limited. This supports the idea that additional metal immobilization capacity afforded by sulfides in sediment is long-lived and indicates that the potential for copper remobilization from sediment is extremely limited.

Last but not least, the assessment of 2 field experiments with intermittent copper dosing (Lake Courtille and the Saint Germain les Belles Reservoir lakes, yearly dosed with copper), assessed in Rader, 2010, provides further support for the absence of re-mobilization. Since both water bodies are shallow, polymictic lakes, wind-driven re-suspension is expected to play a role in copper dynamics in the water column. Nevertheless, even if long-term re-suspension does in fact occur, for both water bodies, > 70% removal in less than 28 days was observed. This information therefore validates the results from the model simulations and absence of remobilization from the water column (Rader, 2010).

It can therefore be concluded that copper sulphide complexes (Cu-S) are stable and remobilisation of Cu-ions to the water-column is not expected or likely.

Copper is therefore considered as rapidly removed, equivalent to "rapid degradation of organic substances".

7.6.2 Derivation of ecotoxicity reference values (ERV) of Copper-ions

The ecotoxicity database and reference values, agreed by the EU classification and labelling group and used for the ANNEX IV entries have been largely retained.

All available ecotoxicity data on soluble copper compounds were compiled and combined and the results (EC_{50}, NOEC/EC_{10} values) were expressed as soluble Cu^{2+}. After a data quality assessment (e.g. dose-response relationship, measured test concentrations) and applying relevance criteria (e.g. standard OECD species, endpoints, test durations and test media (pH between 5.5 and 8.5), high quality acute $L(E)C_{50}$ values and high quality chronic NOEC/EC_{10} values were retained. The detailed assessment is provided as attachment to the IUCLID.

Acute reference values for classification

After data selection, 451 high quality acute data points were retained. For the algae, 66 individual data points were selected for 3 standard species (*Pseudokirchnerella subcapitata, Chamydomonas reinhardtii* and *Chlorella vulgaris*). For the invertebrates, 123 individual data points were selected for 2 standard species (*Ceriodaphnia dubia* and *Daphnia magna*) and for the fish, 262 individual data points were selected for 5 standard species (*Oncorhynchus mykiss*, *Pimephales promelas, Lepomis macrochirus, Brachydanio rerio* and *Cyprinus carpio*).

Chronic reference values for classification

After data selection, 90 high quality chronic data points were retained. For the algae/aquatic plants, 33 individual data points were selected for 4 standard species (*Raphidocelis subcapitata, Chlorella vulgaris, Chlamydomonas reinhardti* and *Lemna minor*). For the invertebrates, 23 individual data points were selected for 2 standard species (*Ceriodaphnia dubia, Daphnia magna*). For the fish, 34 individual data points were selected for 3 standard species (*Oncorhynchus mykiss, Pimephales promelas* and *Salvelinus fontanilis*).

The lowest species-specific acute $L(E)C_{50}$ and chronic NOEC/EC10 values at the three pH levels and across pHs were selected as final environmental classification reference values. Data-summaries were carried out in accordance with the CLP guidance. Geometric mean values were calculated if more than 4 data-points were available for the same species/endpoint.

The acute and chronic ERVs are summarised in the following Table:

Table 72: Summary of the acute and chronic ERVs used for the classification of copper

pH range	Acute ERV L(E)C50 (mg Cu/l)	Chronic ERV NOEC (mg Cu/l)
pH 5.5-6.5	0.025	0.020
pH >6.5-7.5	0.035	0.0074
pH >7.5-8.5	0.0298	0.0114
Across pHs	0.0344	0.0149

7.6.3 Conclusions on environmental classification

For the environmental classification of copper compounds, the reference effects data obtained with soluble copper compounds (Table 72) are compared to the results of the water solubility test (Section 1.3, Physicochemical properties).

The following water solubility value has been obtained for copper dinitrate:

145 g/100 mL at 25 °C.

The water solubility of copper dinitrate is too high to affect the environmental classification applied to soluble copper compounds. It is therefore given the same classification as copper sulphate as a worst case.

Conclusions on Acute classification for the environment:

Copper dinitrate is classified Acute Category 1. An M factor of 10 is applied.

Conclusions on Chronic classification for the environment:

Copper dinitrate is classified Chronic Category 2. An M factor of 1 is applied.

8 PBT AND VPVB ASSESSMENT

8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Copper is a natural, essential element, which is needed for the optimal growth and development of all living organisms, including man. All living organisms have homeostasis mechanisms that actively regulate copper uptake and absorption/excretion from the body; due to this regulation, the bio-accumulation criterion does not apply

Copper is an element, and as such the criterion ‘persistence’ is not relevant for the metal and its inorganic compounds in a way as it is applied to organic substances. The removal of inorganic substances from the water column has been discussed as a surrogate for persistence. The rapid removal of copper from the water column documented that for copper this criterion does not apply

Considering the above, copper is not a PBT or vPvB.

9 EXPOSURE ASSESSMENT

The copper dinitrate environmental and human health exposure section is based on data and reports gathered by the Copper Compound Consortium (CCC) with participation of the following consultants: ECI, RCL and ARCHE. The exposure scenarios presented rely on the data analysis performed by RCL and ARCHE.

This section also uses the information and approaches collated under the framework of the Existing Substance Regulation (ESR) program (Directive 93/67/EEC) for the development of the copper and copper compounds EU Voluntary Risk Assessment (VRA) (2008). This document has also since been accepted under the Biocidal Product Directive (BPD) for the support of existing biocidal products (PT08).

The EU copper VRA contains relevant information with respect to exposure, emissions, Operational Conditions (OCs) and Risk Management Measures (RMMs) from industrial sites located in the EU-15 countries. Since this document was completed, copper compound producers and users have developed new best available technologies, adapted and improved operations and processes, and upgraded their RMMs. In addition, the EU has expanded to 27 Member States. Therefore, for the purposes of the REACH exposure assessment, updated and new information on the producers and Downstream Users (DUs) of copper dinitrate located in the EU-27 countries was gathered in 2008-2009 for the 2010 submissions and 2011 – 2012 for the 2013 submissions by RCL/Copper Compound Consortium via questionnaire. The REACH questionnaire focused on general exposure and contextual information, such as: Production facility details, tonnage of copper compound produced, general description of use, manufacturing processes, RMMs, detailed environmental emission information (*e.g.* emission data, ambient monitoring data, dilution factor and bioavailability parameters) and occupational exposure information (*e.g.* particle size information, efficiency information of exhaust equipment and Personal Protective Equipment (PPE)).

The REACH questionnaire and the copper VRA (2008) were used to develop appropriate Generic Exposure Scenarios (GES). The GES describe typical uses, processes, associated exposures and recommendations on RMMs. GES have been developed for EU copper compound producers and DUs. They contain the necessary information for downstream communication with regards to appropriate conditions for the control of worker exposure and environmental emissions. Secondary poisoning, Waste water Treatment Plant (WWTP) and Sewage Treatment Plant (STP) exposure and risk characterisation assessments have also been developed and presented separately from the GES for copper dinitrate producers and DUs.

The Man via the Environment (MvE) exposure and risk characterisation assessments will be placed separately from the GES. Although these exposure assessments are not communicated in the GES, relevant recommendations based on the results of these assessments can potentially be included in the GES (*e.g.*, for MvE, if a risk is observed for the air compartment in the surrounding of the plant then RMMs should be recommended as part of the iterative process of REACH).

With regards to selection of appropriate data for development of the GES, it is worth noting that:

- When updated information was not available, information was taken from the Cu VRA (2008) or from the published literature.

- When no exposure data were available for an identified use or the available data were considered insufficient (*e.g.* only a low number of data points were available, contextual information was lacking or the data were not considered representative of the sector or use), either data from similar uses and/or exposure situations were used to estimate exposure, if available, or modelling was used to predict exposure.

- A generic sector-wide (copper compounds) approach was followed, based on aggregated site/process information. Summary information on typical exposures, conditions of use and recommended RMMs are described in the GES.

- Measured regional concentrations were used to determine the local concentrations of copper from all activities involving copper dinitrate (see Section 9.6).

For the environment, the exposure assessment was based on total emissions to the various environmental compartments from all operations and processes related to copper dinitrate production or a particular DU. It was not possible to attribute specific emission loads to a distinct activity or process as emissions are treated in a central waste water treatment plant (WWTP) and discharged at a single point source (*e.g.*, waste water emissions). It is worth noting that copper dinitrate production sites may also be involved in the production of other copper substances. As a consequence, the environmental exposure estimates relate to the concentration of copper originating from both the production of copper dinitrate and the other copper substances. This is also the case for some downstream use sectors; for example, a variety of copper-containing raw materials are used in the catalyst sector. Therefore, the overall approach can be considered to be highly protective of the receiving environment.

In contrast to the overall site environmental exposure assessment, occupational exposure information relating to specific processes or operations was gathered. These data were used to build a more detailed assessment of occupational exposures during production and use and to formulate risk management recommendations at the operational/activity level.

All predicted environmental concentrations (PECs) and worker/consumer exposure data are based on copper and no adjustment has been made for the copper compound. This is considered a suitable worst-case strategy for this compound since;

- purities of the substance may differ between manufacturing sources;

- substance impurities may include other copper compounds;

- all available monitoring data have been reported in terms of copper, as distinguishing the copper compound in the environment, or at industrial sites where other copper activities take place is not possible.

This approach allows for individual sites and DU to scale their individual risk assessments according to substance and site specific knowledge; ensuring that their site and use patterns are acceptable when compared to the information presented within this document.

It should be noted that the Predicted Environmental Concentration (PEC) values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). Similarly, the evaluation of worker safety is based on standardised assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of RMMs (e.g. Local Exhaust Ventilation (LEV); Respiratory Protective Equipment (RPE)). These standardised assumptions may not accurately reflect the conditions that prevail within a specific site. As such, the information presented in this document in relation to both environmental and worker exposure should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

The GES tends to represent the broad range of OCs and RMMs for the sectors of consideration and to demonstrate controlled risk. The GES allows flexibility to scale these conditions to the actual conditions of the sites. It is therefore recommended that site managers apply the Scaling Tool (Metals EUSES IT tool, see section 4 of GES) for the environmental conditions. There are opportunities to refine the workers occupational exposure levels by monitoring copper at the workplace.

9.1 Generic scenario development

Representative information was used to generate GES for each sector. Table 73 provides an overview of all the GES presented for copper dinitrate production and DUs. Each GES defines the general conditions under which the risks associated with an identified use(s) of a substance can be controlled. These include OCs, such as whether a particular process is carried out under closed conditions, the duration and frequency of processes and emissions, amount of substances used (tonnage), release factors and dilution capacity and RMMs (*e.g.* waste water and gas treatment, LEV and RPE). Each GES also includes measured exposure data (where available) related to specific RMMs implemented for safe use, or includes recommendations for additional RMMs where a risk is identified, to facilitate control of exposure and thus risk.

When performing the environmental assessment, more particularly for the freshwater aquatic compartment, it was apparent that in many cases a safe use exposure scenario could not be established on the basis of default assumptions, and that safe uses could only be established for small scale operations. For larger operations it was necessary to modify these assumptions and use site-specific information, where available, to establish safe use taking into account the typical dilution factors for the production sector based on the data received from the REACH questionnaires and the copper EU VRA (2008).

The scenarios presented in this document are based on the maximum representative copper tonnage that can be produced and/or used before a risk threshold is triggered for an environmental compartment (*e.g.*, terrestrial, freshwater, marine, air, *etc.*). For the purpose of developing representative GES using pragmatic RMMs, scenarios have been defined using current copper dinitrate production site information and used to determine the maximum tonnages that result in an acceptable risk situation for all the environmental compartments. For small-scale operations, emissions to freshwater sediment is often the limiting factor.

Similarly, if risks were identified for some occupational exposures levels, additional RMMs have been recommended, such as the use of RPE, and these have been taken into account in the risk characterisation. The additional RMMs are recommended based on information provided by the sectors, based on their implemented RMM programs. According to the ECHA guidance for occupational exposure estimation (Chapter R14) the 75th percentile is used as the point estimate for comparison with Derived No Effect Levels (DNELs). For scenarios where the number of measurements is low or surrogate data is used, the 90th percentile is preferred.

The (DNELs) for human health risk characterisation are calculated according to the REACH guidance (Chapter R8). Refer to section 5.11 on DNEL derivation.

Table 73: Overview on exposure scenarios and coverage of copper dinitrate life cycle

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses			Resulting life cycle stage		Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) / Process category (PROC)[2]	Article category (AC)
					Formulation	End use	Consumer use	Service life (for articles)	Waste stage					
GES1	Manufacture as a result of reacting of cupric oxide (CuO) [or other copper compound] and nitric acid in a batch/continuous process	*E-GES-P1.0*	900	X	-	-	-	-	X	-	SU 8, 9, 10	N/A	ERC 1 spERC	-
		E-GES-P2.0	134000											
		E-GES-P1.1	5.75											
		E-GES-P2.1	1725											
		W-GES-P(High)	-										PROC 1 PROC 2 PROC 3 PROC 8b	
		W-GES-P(Med)												
		W-GES-P(Low)												
		W-GES-P(Liquid)												

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Resulting life cycle stage: Service life (for articles)	Resulting life cycle stage: Waste stage	Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
GES2	Manufacture by dissolution of copper in nitric acid in a batch/continuous process	*E-GES-P1.2*	32 [1] 71.25 [2]	X	-	-	-	-	X	-	SU 8, 9, 10	N/A	ERC 1 spERC	-
		E-GES-P2.2	9450 [1] 21000 [2]											
		E-GES-P1.1	5.75											
		E-GES-P2.1	1725											
		W-GES-P(High)	-										Variant 1: PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8b PROC 9 PROC 26 Variant 2: PROC 1 PROC 2 PROC 3 PROC 8a PROC 8b	
		W-GES-P(Med)												
		W-GES-P(Low)												
		W-GES-P(Liquid)												
GES3	Downstream use - Manufacture of catalyst	*E-GES-CM2.1*	40	X	X	-	-	-	X	IU 4	SU 3, 8, 9, 10	PC 2, 19 ,20	spERC only	-
		E-GES-CM3.1	3250											
		E-GES-CM2.2	500											
		E-GES-CM3.2	1100											

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses			Resulting life cycle stage		Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
					Formulation	End use	Consumer use	Service life (for articles)	Waste stage					
		W-GES-CM(High)	-										PROC 1 PROC 2 PROC 3 PROC 4 PROC 8a PROC 8b PROC 9 PROC 14	
		W-GES-CM(Med)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 14	
		W-GES-CM(Low)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 8a PROC 8b PROC 9 PROC 14	
		W-GES-CM(Liquid)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9	

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Resulting life cycle stage: Service life (for articles)	Resulting life cycle stage: Waste stage	Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
GES4	Downstream use - Use phase for catalyst products	*E-GES-CU0*	45000	-	-	X	-	-	X	IU 5	SU 3, 8, 9, 10	PC 2, 19, 20, 32	ERC 6a ERC 6b spERC	-
		E-GES-CU1.1(6a)	10.375											
		E-GES-CU1.1(6b)	4.15											
		E-GES-CU2.1	34.5											
		E-GES-CU1.2(6a)	60* 127.5**											
		E-GES-CU1.2(6b)	23* 52**											
		E-GES-CU2.2	190* 432**											
		W-GES-CU(High)	-										PROC 1 PROC 2 ~~PROC 3~~ PROC 4 PROC 8b ~~PROC 9~~ PROC 22	
		W-GES-CU(Med)												
		W-GES-CU(Low)												
		W-GES-CU(Liquid)												
GES5	Downstream use – Industrial generic formulation of copper dinitrate	*E-GES-DU0*	25000	-	-	X	-	-	X	IU 1-21	SU 3, 8, 9, 10	PC 0, 2, 3, 9a, 9b, 12, 14, 15, 18, 19, 20, 21, 23, 24, 31, 32, 39	ERC 2 ERC 3 spERC	-
		E-GES-DU1.1(2)	ES1 – 10 ES2&3 - 17											
		E-GES-DU1.1(3)	ES1 – 100 ES2&3 - 170											
		E-GES-DU2.1(F)	ES1 – 41 ES2&3 - 67											
		W-GES- DU (High)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b	
		W-GES- DU(Med)												

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Resulting life cycle stage: Service life (for articles)	Resulting life cycle stage: Waste stage	Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) / Process category (PROC)[2]	Article category (AC)
		W-GES- DU(Low)											PROC 9 PROC 14 PROC 19 PROC 21 PROC 26	
		W-GES- DU(Liquid)												
GES6	Downstream use – Industrial generic use of copper dinitrate	*E-GES-DU0 (4-7, 12a)*	25000	-	-	X	-	-	X	IU 5-21	SU 0, 1, 3, 5, 7, 8, 9, 10, 13, 14, 15, 16, 19, 24	PC 0, 2, 3, 9a, 9b, 12, 14, 15, 18, 19, 20, 21, 23, 24, 31, 32, 39	ERC 4 ERC 5 ERC 6a ERC 6b ERC 6d ERC 7 ERC 12a spERC	A-1[3] A-2 A-3 A-4 A-5
		E-GES-DU1.1(4)	ES1 – 0.2 ES2&3 – 0.3											
		E-GES-DU1.1(5)	ES1 – 0.4 ES2&3 – 0.65											
		E-GES-DU1.1(6a)	ES1 – 10 ES2&3 -17											
		E-GES-DU1.1(6b)	ES1 – 4 ES2&3 -6.5											
		E-GES-DU1.1(6d)	ES1 – 4100 ES2&3 – 5000											
		E-GES-DU1.1(7)	ES1 – 4 ES2&3 -6.5											
		E-GES-DU1.1(12a)	ES1 – 8 ES2&3 -13											
		E-GES-DU2.1(U)	ES1 – 35 ES2&3 - 190											
		W-GES- DU (High)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 14 PROC 15 PROC 19	

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Resulting life cycle stage: Service life (for articles)	Resulting life cycle stage: Waste stage	Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
													PROC 22 PROC 23 PROC 24 PROC 25 PROC 26	
		W-GES- DU(Med)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 14 PROC 15 PROC 19 PROC 22 PROC 23 PROC 24 PROC 25 PROC 26	
		W-GES- DU(Low)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 14 PROC 15 PROC 19 PROC 21 PROC 22	

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Resulting life cycle stage: Service life (for articles)	Resulting life cycle stage: Waste stage	Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
													PROC 23 PROC 24 PROC 25 PROC 26	
		W-GES- DU(Liquid)											PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 7 PROC 8a PROC 8b PROC 9 PROC 10 PROC 13 PROC 14 PROC 15 PROC 17 PROC 19 PROC 20	
GES7	Downstream use – Professional generic use of copper dinitrate ***	*PW-GES-DU(High)* *PW-GES- DU(Med)* *PW-GES- DU(Low)*	SEE GES9	-	-	X	-	-	X	IU 6-11, 14, 16, 19, 20	SU 0, 1, 7, 8, 9, 10, 13, 14, 16, 19, 22	PC 0, 9a, 9b, 12, 14, 18, 24, 31, 39	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15 PROC 17	A-1[3] A-2 A-3

ES number	Short title and ES sub-descriptors		Volume (Maximum annual tonnes)[1]	Manufacture	Identified uses			Resulting life cycle stage		Linked to Identified Use (IU)	Sector of Use (SU)	Preparation Category (PC)	Environmental Release Category (ERC) Process category (PROC)[2]	Article category (AC)
					Formulation	End use	Consumer use	Service life (for articles)	Waste stage					
		PW-GES- DU(Liquid)											PROC 19 PROC 20 PROC 21 PROC 22 PROC 25 PROC 26	
GES8	Downstream use – Consumer generic use of copper dinitrate ***	*C-GES-DU*	SEE GES9	-	-	-	X	-	X	IU 6, 7, 9-11, 13-16, 19, 20	-	PC 0, 9a, 9b, 12, 14, 15, 18, 23, 24, 31, 39	N/A	A-1[3] A-2 A-3 A-4 A-5
GES9	Downstream use – wide dispersive used of copper dinitrate [environment only]	*E-GES-WDU*	Downstream wide dispersive use in terms of defining safe threshold limits is not appropriate as all uses of copper should be considered in parallel as the resulting concentrations will be additive. Therefore, as shown by the VRA, measured levels of copper reported in STP effluent is a more appropriate method of addressing the wide dispersive uses from all uses where environmental releases of copper may occur.	-	-	X	X	-	X	IU 6-11, 13-16, 19, 20	SU 21, 22	PC 0, 9a, 9b, 12, 14, 15, 18, 23, 24, 31, 39	N/A	A-1[3] A-2 A-3 A-4 A-5

[1]- Expressed as copper not copper compound
[2]- Not all PROC codes are applicable for all compound forms – further clarification is given within exposure scenario tables
[3]- No intended release
*[Biological WWTP] **[Physico-chemical WWTP] *** - Environmental releases associated with WDU

9.2 Generic exposure scenarios for production of copper dinitrate

9.2.1 Introduction to copper dinitrate production

Estimated and measured (where available) environmental (*i.e.,* in freshwater, marine aquatic, air and terrestrial compartments) and occupational (*i.e.,* process-specific occupational hygiene data from personal/static monitoring) exposure data for copper dinitrate production, are detailed in the following sections and provide full details on the exposure and risk characterisation data used in the GES presented. Detailed information on the environmental tiered approach for site-specific exposure assessment and risk characterization is found in the relevant exposure scenarios. Detailed information on local exposure calculation factors and regional ambient backgrounds can be found in Section **9.6**.

As discussed in section 9.1, since it was not possible to attribute emissions to any specific process/activity, the environmental exposure assessment was conducted for copper dinitrate production sites as a whole. Conversely, the occupational exposure assessment was broken down by process/activity. Therefore, the GES presented in the following sections for each different copper dinitrate production process includes process-specific human exposure information and common production sector environmental assessment elements. In addition, secondary poisoning, WWTP and STP assessments are presented in separate sections for the entire copper compound production sector. The MvE assessments will be placed separately from the GES.

9.2.2 Development of generic exposure assessments for copper compound production

In order to address exposure assessments for the production of copper dinitrate that can be used to inform both current and future practices under REACH, information has been gathered across the copper compound producing industries. This has been done so that common working patterns and practices can be established and used to address the individual copper compounds of concern.

Through the Copper Compound Consortium all known copper compound producers registered as part of the Consortium were contacted. Fifteen copper compound production sites were found to be applicable for REACH registrations submitted in 2013, having sites for the production of one or more of: Bordeaux mixture, copper acetate, copper dichloride, copper dihydroxide, copper dinitrate, copper iodide, copper oxychloride, copper sulphide and dicopper sulphide.

As producers of copper compounds, these sites were all given the opportunity to supply data regarding production methods, process codes and risk mitigation measures so that generic exposure assessments for workers and the environment could be derived. The results are reported as strictly confidential; individual companies are not identified, but are reported in a coded manner in the risk assessment. The total production volume of the individual copper chemicals in the EU is confidential. The same is true for export figures outside the EU. The import volume is unknown. Therefore, it was also decided to provide aggregated production figures only (per substance) and not to reveal specific locations or detailed activity and emission factors of individual companies.

The data presented in this document are a collation of information gathered from the copper industry for the purposes of supporting the 2010 and 2013 REACH registrations. The information presented represent a total of 26 Copper Compound Consortium members located across the EU in; France, Germany, UK, Finland, Netherlands, Belgium, Denmark, Spain, Italy, Poland and Norway.

9.2.2.1 Environmental Generic Exposure Scenario (E-GES)

The E-GES for production will depend on the potential routes of exposure resulting from the activities within each of the identified exposure titles. For each exposure title, the predicted environmental concentrations (PEC) for the relevant compartments have been calculated using EUSES 2.0. These PEC values have then been compared to the relevant predicted no effect concentrations (PNEC) in order to determine the risk characterisation (PEC:PNEC) and define the maximum allowable tonnage (PEC:PNEC must not exceed 1). The maximum safe tonnage of copper compounds (presented as copper) has been predicted for each of the exposure scenarios defined in the following sections.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of RMMs (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the producer to ensure that a compound is produced safely within the context of their site and in full consultation with the relevant local authorities.

According to REACH guidance, the default Environmental Release Code (ERC) for the production step is ERC1 (see assumptions below). This has therefore been used for the Tier 1 assessment for copper compound production. According to the revised (May 2010) *Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation* ERC 1 is covered by the following description;

Manufacture of chemicals
The release factors are based on the information for the manufacture of basic chemicals and chemicals used in synthesis (including monomers and catalysts). Besides basic (organic) chemicals both the production of chemicals in the petrochemical industry and the metal extraction and refining industry are included. Release factors are derived from the general release factors for the production of chemicals provided in EC (2003).

In addition to ERC1, a spERC (specific ERC) for Production [Manufacture] of metal compounds (www.arche-consulting.be/metal-csa-toolbox/sperc v1.1) has been developed. This spERC is considered appropriate for both open and closed systems using both wet and dry processes and is based on information gathered for metal compound manufacture (including copper) within the EU. The spERC has been developed on the basis of the ERC1 assumptions, which have then been refined by the application of RMMs currently in place within EU sites involved in metal compound manufacture, in addition to measured data. For air emission, the spERC value is based on the findings that the RMMs for air are present in >90% of the sites, including:

- Electrostatic precipitation (not common)
- Fabric or bag filters (reported as most common)
- Ceramic filters
- Wet scrubbers (reported as second most common)

- Dry or semi-dry scrubbers

From the available data the maximum 90th percentile reported site-specific release factors to air (after RMM) from the formulation processes investigated was 0.03%

For the releases to waste water the spERC value is based on the RMMs for water present in >60% of the sites including:

- Chemical precipitation
- Sedimentation
- Filtration
- Electrolysis (not common)

The 50th percentile of the reported site-specific removal efficiency for 9 sites was 98% (90.00% – 99.98%). The maximum emission of the 90th percentiles of reported site-specific release factors to waste water was given as 0.5%. This is a worst-case assumption as waste water RMMs were confirmed at >50% site, suggesting that the 90th percentile release factor did not include RMMs. Therefore, an additional on-site removal step via an on-site WWTP may be added to the exposure scenario.

The following assumptions form the basis of the exposure scenario for copper compound production;

Environmental Exposure	ERC	spERC
	1	Metal Compound Production
Life cycle stage (LCS)	Production	Production
Containment	Open/closed	Open/closed
Type of use in LCS	N/A	N/A
Dispersion of emission sources	Industrial	Industrial
Indoor/outdoor	Indoor	Indoor
Release promotion during service life	N/A	N/A
Amount of substance used as input to emission calculation	100% M/I* volume	100% M/I volume
Fraction used by largest customer - main source	1	1
Release times per year	20-300 [TGD default]	240
Default release to air from process [%]	5	0.03
Default release to water from process [%]	6	0.02
Default release to soil from process [%]	0.01**	0.01**
Dilution to be applied for PEC aquatic derivation (freshwater)	10 (20000 m^3/d)	10 (20000 m^3/d)

* - Manufacture/Industrial production volume for EUSES
** - Regional calculations only, no local soil releases assumed (in line with REACH guidance D:R.16 Environmental exposure estimation May 2010)

For industrial production, formulation and use (ERC 1-7) and industrial processing of articles (ERC12); air and water releases are considered for exposure at both the local and the regional scale. Direct releases to soil are however only taken into account at the regional scale. This is due to the fact that industrial soil is not considered a protection target in the framework of chemicals assessment. Also, whilst potential direct on-site exposure of the soil compartment has been identified within the exposure titles, this is considered to be largely due to accidental spillage (outside the scope of this risk assessment) and will result in limited and localised exposure. This is recognised by the REACH guidance and the available ERCs, where releases to soil are limited to outdoor use scenarios only. However, indirect exposure of the wider soil environment (industrial, natural and agricultural) that will occur as a result of emissions to air and waste water (STP sludge disposal) have been considered. Also, where an on on-site WWTP is present it is likely that this will involve physico-chemical treatment processes, but it is also possible that some sites utilise biological treatment processes. In order to protect the microbial populations of these facilities, the default position has therefore been to assume that WWTP are biological in nature. Where this has been shown to limit the predicted 'safe' tonnages of copper used in the production of copper compounds, a second calculation has been introduced to illustrate the situation for sites with physico-chemical WWTP.

The following sections summarise the available site-specific information provided from copper compound manufacturers in the Copper Compound Consortium, which will be used to define the tier 1 (ERC1) and tier 2 (spERC) E-GES for the generic environmental assessment of copper compound production.

9.2.2.1.1 Air

11 out of 27 sites (40.74%) do not make analyses of air emissions on site, 3 sites (11.1%) have stated that they do analyse for on-site air emissions but have not provided the data. Measured copper data have been provided by 14 of the sites (See Table 74 for a summary of data provided) with emission periods given as between 7 and 24 hours a day, 220 to 365 days a year. Six of these sites have confirmed that RMMs are in place for air with various filters described, such as wet scrubbers, Demister, HEPA abatement systems, HEPA, double, gag, ceramic, fabric or bag filters. These data support the spERC for metal compound production produced by ARCHE consultancy, where RMMs for air included fabric and bag filters as the most commonly reported management system. According to the spERC for metal compound production, these air filter systems reduce the air emissions by 90 – 98.99%.

Therefore, according to the data available, a reasonable worst-case (RWC) GES for the air compartment would need to consider local and regional emissions for 365 days, both with and without RMMs.

Table 74: Summary of copper in air as recorded on sites producing copper compounds collated between 2006 and 2013

Site	Range	Median	Mean	Actual	Units	Number of samples
CCCP03	7.4 - 12.1	-	9.7	-	kg/ y	1
CCCP05	-	-	-	97	kg/yr	1
CCCP08	-	-	<2.26	-	mg/Nm^3	7 emissions points
CCCP09	533.818 - 444.127	-	328.99	-	kg/yr	Copper smelter is main source of emissions and represents total from 45 dust emission points
CCCP10	30 – 70	40	-	-	kg/yr	40
CCCP13	-	71	-	-	kg/yr	-
CCCP14	-	0.00826	0.00834	-	mg/m^3	3 x 0.5 h samples, at site of LEV
CCCP15	Main dust stack Reduction dust stack	0.015 0.008	0.017 0.008	-	mg/m^3	3 x 0.5 h samples, at site of LEV
CCCP16	-	<0.1	<0.1	<0.1	mg/l	-
CCCP18	Total dust max < 0.29 resp; Cu max < 0.056				mg/m^3	-
CCCP19	Stack 1: 0.125 - 0.157 Stack 2: 0.029 - 0.194	-	Stack 1: 0.145 Stack 2: 0.111	-	mg/m^3	-
CCCP25	-	-	0.6 - 5	-	kg/yr	-
CCCP27	-	-	<0.001 - 0.057	-	mg/Nm^3	4 per measurement
CCCP30	-	-	0.1 0.43	-	mg/m^3	1

9.2.2.1.2 Water

Of the 27 sites included in this analysis; one site (3.7%) has provided no information with respect to waste water emissions. Of the remaining sites; 13 sites (48.1%) have stated that there are no releases of waste water resulting from the production of copper compounds.

For the remaining 13 sites (48.1%); on-site waste water treatment plants (WWTPs) were reported with removal efficiencies of 92 to > 99.99%; with subsequent direct release to surface waters for 7 sites and via a further off-site municipal sewage treatment plant (STP) for 6 sites. The available data have been summarised in **Table 75** below.

Table 75: Summary of data provided by copper compound production sites operating on-site WWTP facilities

Site	ON-SITE STP (WWTP)	% Cu removal efficiency [essential information]	On-site waste water flow rate [m^3/d]	Mean WWTP effluent concentrations provided [mg Cu/l]	Off-site waste water emission	Flow rate of receiving waters compared to EUSES default for freshwater [factor greater than 20000 m^3/d]
CCCP03	Specific Ion Exchange Resins	> 98% (less than 5 mg/l from a stream of 400 mg/l)	240 (365 days/yr)	Not provided	Direct to surface waters	>20
CCCP05	YES - no details	>>99%	50 (185 days/yr)	0.11	Via STP	>60
CCCP08	100% treated on site	> 99.99%	100 (220 days/yr)	< 0.5	Via STP	>2
CCCP09	YES on-site WWTP (Physical-chemical system)	99.96%	35	N/A	Via STP	>300
CCCP12*	YES on-site WWTP (Physical-chemical system)	99%	534	Not available	Via STP	~ 2
CCCP14	On site WWTP processes [precipitator]	> 99.9%	452	< 0.1 due to all copper activity on site	Via STP	>60
CCCP15	On site WWTP processes [precipitation and adsorption]	> 99.9%	410 (365 days/yr)	N/A	Via STP	>100000
CCCP16	YES on-site WWTP (Physical-chemical system)	>99%	1370	1000 kg/yr permissioned, <100 kg/yr actual	Direct to surface waters	Not given
CCCP17	YES on-site WWTP (Physical-chemical system)	>92%	129 (permissioned)	<0.4 mg Cu/l [0.4 mg/l permissioned limit]	Direct to surface waters	>6

Site	ON-SITE STP (WWTP)	% Cu removal efficiency [essential information]	On-site waste water flow rate [m^3/d]	Mean WWTP effluent concentrations provided [mg Cu/l]	Off-site waste water emission	Flow rate of receiving waters compared to EUSES default for freshwater [factor greater than 20000 m^3/d]
CCCP18	Specialised WWTP	92%	340000 (300 days/yr)	0.038	Direct to surface waters	>6000
CCCP22*	YES on-site WWTP (Physical-chemical system)	92%	445 (365 days/yr) [2010 substances] 25 [2013 substances]	0.011	Direct to surface waters	Not given
CCCP27	YES on-site WWTP (Physical-chemical system)	92%	60	Not provided	Via STP	>5000
CCCP29	YES on-site WWTP (Physical-chemical system)	99%	459	2.3 kg/yr	Via STP	>100

*site information provided for completeness and to inform the exposure scenario development of copper compound production; for production of 2013 substances at these sites, the production processes do not result in waste water emissions.

These data (**Table 75**) show that the on-site WWTP flow rate ranged from 25 to 340000 m^3/d, with maximum Cu effluent levels reported to be < 0.5 mg/l with a definitive maximum value of 0.18 mg/l also given. The information provided also indicates that the majority of sites the receiving surface waters have very high dilution factors compared to the EU default value of 10 (flow rate 18000 m^3/d).

In addition to the on-site treatment of waste, production processes have been developed to maximise the recovery of the copper compounds and minimise the waste released off-site. Such processes reported for the copper compounds under review include; sedimentation, reduction, precipitation, filtration, screening, centrifugation and purification techniques. According to the metal compound production spERC (ARCHE consultancy) such processes are recognised RMMs for emissions via the water phase and can reduce emissions by 90 – 98.99% (98% is the 50^{th} percentile value).

For off-site waste water treatment the copper VRA (2008) used a value of 80% removal based on the available data at that time (see Table 76) to represent a RWC removal of Cu in STP in the EU.

Table 76: Cu input, output data (tonnes Cu/year) and removal rate data (%) for Sewage Treatment Plants in the Netherlands

Year	Total input to STP (tonnes Cu/year)	Total output from STP (tonnes Cu/year)	Removal rate	Reference
1981	132	40	70	CBS, 2004
2000	158	18	88%	CBS, 2004
2001	152	21	86%	CBS, 2004
2002	142	18	87%	CBS, 2004
		Average (2000-2002)	**87%**	

According to the guidance provided by REACH (Appendix R.7.13-2: Environmental risk assessment for metals and metal compounds), more recent data shows that the removal rates have since improved further. Table 77 (reported in Appendix R.7.13-2) shows weighted average metal removal rates calculated as the ratio of total metal input to Dutch Sewage Treatment Plants (STP) versus total metal output of 100 Dutch urban waste water treatment plants. The implementation of new techniques for the removal of phosphates and nitrates in the 90s also resulted in a better removal of metals. Longer residence times and low sludge loads result in an increase in adsorption of metals to activated sludge particles, and higher removal rates are thus observed (CBS, 2007).

Table 77: Example 2-3: Overview of removal rates for metals (%) in municipal Sewage Treatment Plants (STPs) in the Netherlands (CBS, 2007)

Metal	2000	2004	2005
Arsenic (As)	52	54	54
Cadmium (Cd)	54	73	81
Chromium (Cr)	78	83	80
Copper (Cu)	**89**	**92**	**92**
Mercury (Hg)	72	74	77
Lead (Pb)	86	87	86
Nickel (Ni)	53	57	55
Zinc (Zn)	77	81	82

The removal rates used for the environmental exposure assessments of copper compounds have therefore assumed a removal of 92% of copper via sludge for all assessments that include municipal STPs.

From the available data, a RWC GES for the aquatic compartment would need to consider local and regional emissions for 365 days, with

- no off-site aquatic emissions (air only),
- with direct (no STP) surface water emissions following treatment at an on-site WWTP (92% - 99% removal efficiency) [with and without RMMs] or
- with indirect (via STP; 92% removal efficiency) surface water emissions following treatment at an on-site WWTP [with and without RMMs].

9.2.2.1.3 Soil

Direct soil contamination is not expected at these sites. However, indirect exposure of the wider soil environment via air emissions and sewage sludge disposal can be expected. Information provided by the sites using on-site WWTP, suggests that there is no additional soil exposure to be taken into account due to additional sludge spread on land as disposal is via recycling or controlled incineration and landfill (see Table 78). Therefore, according to these data, a RWC GES for the soil compartment would be adequately addressed by the proposed GES scenarios given for the aquatic compartment.

Table 78: Summary of solid waste disposal options by copper compound production sites operating on-site WWTP facilities

Site	Solid waste recovery description
CCCP03	Recycled on-site
CCCP05	Recycled off-site
CCCP08	Solid waste: ~750 tonnes sludge corresponds only to industrial sludges of copper compound production; recycled off-site.
CCCP09	All sludge produced in waste water treatment plant is filtered and reversed on site to the copper smelting furnace. No solid waste is produced.
CCCP12	Site waste ~ 75 tonnes sent off-site
CCCP14	WWTP produce a filter cake, which is processed for metal reclamation.
CCCP15	WWTP produce a filter cake, which is processed for metal reclamation.
CCCP16	Recycled
CCCP17	Recycled via Cu smelter (off-site contractor)
CCCP18	Solid waste part of site WWTP sludge goes to incineration.
CCCP22	Incineration
CCCP27	Yes filtercake from on-site WWTP of 1800 mg/kg per year goes to landfill.
CCCP29	No solid waste generated

9.2.2.1.4 Environmental GES descriptors for production of copper compounds

Using the information provided, the following RWC GES combinations are considered applicable to the environmental exposure assessment of the production of copper compounds which are identified in this assessment by the generic prefix of **E-GES-P.** No soil emissions are given as only regional concentrations resulting from industrial environmental releases are considered relevant according to REACH. Regional soil concentrations for copper are discussed in Section 9.6.4.

Two assessment tiers, each with 3 possible emission scenarios have been used:

Tier 1: Assessment based on Default ERC emissions

E-GES-P1.0

Waste water emissions: None

Air emissions: Default 5%

E-GES-P1.1

Waste water emissions: Default 6% [via on-site WWTP assuming 92% removal efficiency]

Air emissions: Default 5%

E-GES-P1.2

Waste water emissions: Default 6% [via on-site WWTP and off-site STP assuming 92% removal efficiency]

Air emissions: Default 5%

<u>Tier 2: Assessment based on spERC* emissions</u>

** -ARCHE metal compound production*

E-GES-P2.0

Waste water emissions: None

Air emissions: Default 0.03% [Assumes on-site RMMs]

E-GES-P2.1

Waste water emissions: Default 0.02% [Assumes on-site RMMs] [via on-site WWTP assuming 92% removal efficiency]

Air emissions: Default 0.03% [Assumes on-site RMMs]

E-GES-P2.2

Waste water emissions: Default 0.02% [Assumes on-site RMMs] [via on-site WWTP and off-site STP assuming 92% removal efficiency]

Air emissions: Default 0.03% [Assumes on-site RMMs]

Using the above RWC GES approach, the maximum acceptable tonnage (per day/annum) has been predicted for copper for each scenario assuming 365 days of production. Based on site-specific data reviewed in this report, all three environmental exposure scenarios are applicable to the production of copper dinitrate; E-GES-P1.0/2.0, E-GES-P1.1/2.1 and E-GES-P1.2/2.2.

9.2.2.2 Workers Generic Exposure Scenario (W/PW-GES)

In contrast to the environmental assessment, the occupational exposure information used in the GES does not rely on a specific selected tonnage range but rather on occupational exposure monitoring information. This approach was taken since tonnage does not directly influence the outcome of the RMM recommendations.

The relevant REACH guidance (PART D, R.12 & R.14) foresees assessment of occupational exposure on the basis of process categories (PROC). These PROCs may be seen as surrogates for specific process steps/tasks/workplaces. To assess occupational exposure, the guidance foresees a ‘tiered approach’. The initial screening exercise for copper compounds has used the targeted risk assessment (TRA) tool developed by ECETOC (ECETOC, 2009), which is promoted for use in the assessments required under REACH. TRA provides initial exposure estimates on a PROC-specific basis, with exposure values for each PROC selected from a ‘look-up table’ according to the selected/assigned ‘fugacity class’. The initial estimates can be refined by several parameters (such as the frequency and duration of exposure, the presence of local exhaust ventilation (LEV), etc.). Whilst, the applicability of this tool for metal compound assessments as is considered to be limited, it has been used for copper compounds as a worst-case Tier 1 assessment.

In addition to the initial screening using the TRA, a second tool called the ‘Metals EASE’ model (MEASE) is available. This occupational exposure assessment tool, developed for REACH by EBRC on behalf of EUROMETAUX, has also been used to assess all the relevant PROC codes. MEASE has been designed to estimate and assess substance exposure by combining the approaches within the EASE expert system utilised by the TRA tool with those from the health risk assessment guidance for metals (HERAG). Its aim is to provide a 1st tier screening tool for the estimation of occupational inhalation and dermal exposure to metals and inorganic substances. For inhalation exposure, the tool follows the PROC-specific approach of the TRA tool and selects initial exposure estimates from three so-called 'fugacity classes'. In contrast to the TRA tool, the initial exposure estimates in MEASE are based on measured data from the metals industry. RMMs are based on a publication of Fransman *et al.,* (2008) who screened and analysed more than 400 publications for data on the efficiency of RMMs. As a result, MEASE gives users the possibility to choose between several RMMs instead of just having LEV as an implemented RMM. For dermal exposure, MEASE is based on the classification system of the EASE system. The exposure estimates are however supplemented by real measured data for several metals.

The initial screening exercise was carried out to establish what generic conditions, according to the TRA/MEASE, were required for an acceptable level of risk to be established for each of the PROC codes identified for the worker GES for the production of copper compounds. However, it was clear that the MEASE model, being designed for metal and metal compounds, was more applicable. Therefore, for the purpose of assessing the exposure of workers to copper compounds, only the MEASE model outputs have been used and the results for all available PROCs presented in full in Annex 14.

Of the 27 EU copper production sites that have responded to the initial questionnaires for information on the basic activities involved in the production of copper compounds, 25 have provided a list of activities against the PROC codes required for the exposure assessment of workers. These are summarised in **Table 79**, which has been used to define the generic mapping on which the GES assessment has been based (see **Table 80**; full mapping presented in Annex 12).

Table 79: Summary of PROC and common activities included in the production of copper compounds in the EU

PROC code description	ES breakdown	Contributative ES (Short description of process or activity)
PROC1 Use in closed process, no likelihood of exposure. Industrial setting;	Compound manufacture & preparation	Production processes: dissolution, dilution, chemical synthesis: precipitation, sulfiding, heating, oxidating, calcination, filtration, rinsing, screening, forming, drying, compaction
	Fresh product packaging	Weighing operations Filling operations Packing Transfer [storage & transport]
PROC2 Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting;	Compound manufacture & preparation	Production processes: dissolution, dilution, chemical synthesis, pre-leaching with acid, mixing, milling, crystallization, filtration, rinsing, calcination, compaction, screening, forming, separation, drying
	Fresh product packaging	Weighing operations Filling operations Sieving Packing Transfer [storage & transport]
PROC3 Use in closed batch process (synthesis or formulation). Industrial setting;	Compound manufacture & preparation	Production processes: adjustment of pH, concentrations and temperatures of reagents, dissolving, chemical synthesis, distillation, sulfiding, heating, oxidating, precipitation, mixing of reagents in a closed reactor, calcination, impregnation, separation, centrifugation, filtration, washing/rinsing, screening, drying [spray, spin-flash methods], milling, compaction, tabletting, solution recycling**.** Product recovery.
	Fresh product packaging	Weighing operations Filling operations Unloading/transfer [storage (bags) & (bulk) transport]
	Maintenance & Cleaning	Maintenance & Cleaning
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting;	Compound manufacture & preparation	Production processes: production processes, chemical synthesis, lixiviation, oxidating, sedimentation, distillation, filtration, centrifugation, drying, and solution recycling. Product recovery
	Fresh product packaging	Filling operations (transfer to transport containers)
	Maintenance & Cleaning	Maintenance & Cleaning (production)
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial setting;	Compound manufacture & preparation	Production processes: production of process intermediate, mixing of formulants.
	Fresh product packaging	Packaging

PROC code description	ES breakdown	**Contributative ES** (Short description of process or activity)
PROC 8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Fresh product packaging	Filling operations Transfer [storage]
	Maintenance & Cleaning	Maintenance & Cleaning (production)
PROC 8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Compound manufacture	Production processes: production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, dissolution, dilution, drying, forming.
	Fresh product packaging	Filling operations Transfer [storage & transport]
	Maintenance & Cleaning	Maintenance & cleaning (Production)
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting;	Fresh product packaging	Filling operations Transfer [storage & transport]
PROC14 Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting;	Compound manufacture	Forming Operations
PROC22 Potentially closed processing operations (with minerals) at elevated temperature;	Compound manufacture	[Furnace process] Calcining Drying
		Industrial worker elevated
PROC23 Open processing and transfer operations (with minerals) at elevated temperature;	Compound manufacture	Industrial worker elevated temperature
PROC26 Handling of solid inorganic substances at ambient temperature	Maintenance & Cleaning	Maintenance & cleaning (Production)

Table 80: Worker generic exposure scenario for production of copper compounds

ES title	ES breakdown	Contributative ES (Short description of process or activity)	HH Exposure routes: Inhalation	HH Exposure routes: Dermal	HH Exposure routes: Ingestion	HH Exposure Modifier: Duration and frequency (exposure time)	HH Exposure Modifier: Work pattern		HH Exposure Modifier: Outdoor/Indoor Operation	Indoor: GEV	Indoor: LEV*	PPE: Respiratory protection	PPE: Eye protection (goggles)	PPE: Protection of hands (gloves)	Other Technical measures	Use descriptors [worker]: Sector of use (SU)	Use descriptors [worker]: Process Category (PROC)	Use descriptors [worker]: Product category (PC)
Production	Compound manufacture	Production processes/Chemical synthesis	x	x		Up to 8 h	Up to 8 h/d	Up to 220 d a year	Indoor	-/x	-/x	As required				SU 9, 8 (10)	1/2/3/4/5/8a/8b	N/A
		Adjustment of pH, concentrations and temperatures of reagents	x	x					Indoor	-/x	-/x						3	
		Charging of the raw gold slime to the pre-leaching tank.	x	x					Indoor	-/x	-/x						8b	
		Chemical lixiviation	x	x					Indoor	-/x	-/x						4	
		Mixing of formulants, pre-leaching with acid, dissolving, heating,	x	x					Indoor	-/x	-/x						1/2/3/5	
		Sulfiding, oxidating, calcination	x	x					Indoor	-/x	-/x						1/2/3/4	
		Impregnation, crystallization, precipitation (mixing of reagents in a closed reactor), centrifugation, separation, sedimentation, filtration, rinsing	x	x					Indoor	-/x	-/x						1/2/3/4/8b	
		Furnace process - [Industrial worker elevated temperature]: Drying [including spray, spin-flash methods]: Calcination	x	x					Indoor	-/x	-/x						1/2/3/4/8b/22/ 23	
		Forming Operations: milling, compaction, tableting, screening, extrusion, noodling	x	x					Indoor	-/x	-/x						1/2/3/8b/14	
	Fresh product packaging	Filling operations (transfer of product to storage depot transfer to transport containers)	x	x					Indoor	-/x	-/x						1/2/3/4/8a/8b/9	
	Maintenance & cleaning	Maintenance & cleaning (Production)	x	x					Indoor	-/x	-/x						3/8a/8b/26	

*** -/x = with/without LEV**

9.2.2.2.1 Worker GES descriptors for production of copper compounds

For each identified PROC code, the TRA or MEASE (as applicable) assessment tools have been used to establish the acceptable working patterns during the production of copper compounds. In order to include all stages of production the assessment has considered worker exposure as a result of:

1. Sector of Use [SU] 8, 9 & 10 – which result in one assessment according to TRA outputs.

2. Indoor (with LEV as standard) and outdoor activity

3. Compound form: Solid (3 forms; high, medium and low dustiness) and liquid. Defined (according to MEASE guidance) as;

- Solid, high dustiness: fine powders having high potential to become and stay airborne.
- Solid, low dustiness: Granules, pellets, wetted powders, etc. with little potential for dust emissions (dustiness is less than 2.5% according to the Rotating Drum Method (RDM)).
- Solid, medium dustiness: powders and dust consisting of relatively coarse particles with moderate potential to become (and stay) airborne (dustiness is less than 10% (RDM)).
- Liquid (aqueous solution/slurry): typically solid substance (at room temperature) dissolved in water. For most of the existing PROCs, the use of aqueous solutions is assumed to be associated with a very low emission potential (90% reduction of estimate for "low fugacity").

It may also be considered that the dustiness of a compound decreases with increased moisture content, which will reduce the risk of inhalation. However, dermal uptake from 'wet' copper compounds will be greater than from dry compounds, which has been accounted for by the calculation of 2 levels of risk characterisation (Dry and Wet) for all activities considered.

The outcome from the screening assessment (acceptable risk characterisation values) has been presented in full for each PROC code in Annex 14. These show a range of restrictions for workers across the activities assessed from no restriction, to limited periods of activity with and without personal protection for workers.

Using the information provided, the following RWC GES combinations are considered applicable to the worker exposure assessment of the production of copper dinitrate, which are identified by the generic prefix of **W-GES-P.** Four possible emission scenarios have been used for each of the PROC codes:

W-GES-P(High)

MEASE tool: solid high dustiness

W-GES-P(Med)

MEASE tool: solid medium dustiness

W-GES-P(Low)

MEASE tool: solid low dustiness

W-GES-P(Liquid)

MEASE tool: liquid (aqueous solution or slurry)

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solids) or from evaporation of liquid during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters:

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

The outcome from the GES screening assessment (acceptable risk characterisation values) has been presented in full for each PROC code in Annex 14 and 15. These show a range of restrictions for workers across the activities assessed from no restriction, to requiring LEV with personal protection for workers where necessary to achieve an acceptable exposure pattern.

9.2.3 Description of activities and processes covered in the exposure scenario

The Copper Compound Consortium has received information on copper dinitrate production processes carried out at the following four sites: CCCP12, CCCP15, CCCP16 and CCCP27. The following three distinct manufacturing processes have been identified:

1. **Reaction of cupric oxide (CuO) [or other copper compound] and nitric acid**
   Copper dinitrate is manufactured in an aqueous process in which black CuO (or another copper compound) is added to nitric acid and water and the resulting exothermic reaction is controlled to keep the process below 80°C. The product is sold as a liquid & filtration may or may not be required.

The processes that have been identified for this production approach are:

- chemical synthesis, transfer of product to storage tank, transfer to Bulk Transport vehicle (PROC 1 - Use in closed process, no likelihood of exposure. Industrial setting);

- production processes, filling operations (PROC 2 - Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting);

- production processes, filling operations (transfer to transport containers), maintenance & cleaning (Production) (PROC 3 - Use in closed batch process (synthesis or formulation). Industrial setting);

- reaction of raw materials to produce final product, filling operations (transfer to transport containers), maintenance & cleaning (Production) (PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities).

2. Copper dinitrate is manufactured by dissolution of copper in nitric acid

Variant 1: Dissolving copper metal in nitric acid in a batch process.

No technical details were provided for this method.

The process codes identified for the worker exposure assessment of this manufacturing process are:

- chemical synthesis (PROC 1 - Use in closed process, no likelihood of exposure. Industrial setting);
- drying, mixing, filling operations (transfer to transport containers) (PROC 2 - Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting);
- chemical synthesis, precipitating, centrifugation, drying, mixing, filling operations (transfer to transport containers) (PROC 3 - Use in closed batch process (synthesis or formulation). Industrial setting);
- production processes, filling operations (transfer to transport containers) (PROC 4 - Use in batch and other process (synthesis) where opportunity for exposure arises);
- production processes (PROC 5 - Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial setting);
- filling operations (transfer to transport containers) (PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities);
- filling operations (transfer to transport containers) (PROC 9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting);
- maintenance & cleaning (Production) (PROC 26 - Handling of solid inorganic substances at ambient temperature).

Variant 2: Dissolving copper metal cathodes in nitric acid in a continuous process.

Copper nitrate intermediate is made by dissolving copper metal cathodes in nitric acid in a dissolution tank.

The processes that have been identified for this production approach are:

- dissolution, dilution (PROC 1 - Use in closed process, no likelihood of exposure. Industrial setting);
- dissolution, dilution (PROC 2 - Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting);
- dissolution, dilution (PROC 3 - Use in closed batch process (synthesis or formulation). Industrial setting);
- dissolution, dilution (PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities).
- dissolution, dilution (PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities).

The production process is continuous in the case of catalyst production, but for the purpose of this document only the production of copper dinitrate is considered here. Catalyst production and downstream use (DU) will be considered as a separate industry sector in a separate specific DU section following production (see Section 9.3).

9.2.4 Exposure Scenarios

A detailed assessment of the GES and risk characterisation is provided in Annex 12 for copper compound production. Both occupational and environmental scenarios are based on predicted local concentrations.

GES1: Copper dinitrate is manufactured **by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process** in a batch process. From the information provided, two environmental release scenarios are required; in the first process, copper dinitrate is manufactured without any releases to waste water [E-GES-P1.0/2.0], in the second process, waste waters are released to surfaces waters after passing through an on-site treatment plant [E-GES-P1.1/2.1]. For both processes, worker exposure has been addressed for activities covered by PROCs 1, 2, 3 and 8b within four worker exposure scenarios [W-GES-P(High/Med/Low/Liquid)].

1. Title GES - copper dinitrate manufacture as a result of reacting of cupric oxide (CuO) [or other copper compound] and nitric acid in a batch/continuous process	
Life cycle	Manufacture of copper dinitrate
Free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

Systematic title based on use descriptor	**SU:** SU10 - Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU8 - Manufacture of bulk, large scale chemicals (including petroleum products) SU9 - Manufacture of fine chemicals **PC**: Not relevant **ERC:** ERC1 – Manufacture of substances spERC – Production of metal compounds **PROC:** PROC 1 - Use in closed process, no likelihood of exposure. Industrial setting PROC 2 - Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting PROC 3 - Use in closed batch process (synthesis or formulation). Industrial setting PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Processes, tasks, activities covered (environment)	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process in a batch/continuous process
Processes, tasks, activities covered (workers)	PROC 1 - chemical synthesis, transfer of product to storage tank, transfer to Bulk Transport vehicle, PROC 2 - production processes, filling operations PROC 3 - production processes, filling operations (transfer to transport containers), maintenance & cleaning (Production) PROC 8b - reaction of raw materials to produce final product, filling operations (transfer to transport containers), maintenance & cleaning (Production)
2. Operational conditions and risk management measures (RMMs)	
2.1 Control of environmental exposure [E-GES-P1.0]	
Environmental related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Systematic title based on use descriptor (environment)	ERC1 – Manufacture of substances
Processes, tasks, activities covered (environment)	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process in a batch/continuous process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	2.47 tonnes Cu per day
Maximum annual use at a site	900 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	365 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d

Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No releases **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.2 Control of environmental exposure [E-GES-P1.1]	
Environmental related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Systematic title based on use descriptor (environment)	ERC1 – Manufacture of substances
Processes, tasks, activities covered (environment)	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process in a batch process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	0.016 tonnes Cu per day
Maximum annual use at a site	5.75 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	365 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs; 6% emission (adjusted to 0.48 and 0.06% for on-site WWTP with 92% or 99% removal). **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant

Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.3 Control of environmental exposure [E-GES-P2.0]	
Environmental related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Systematic title based on use descriptor (environment)	spERC – Production of metal compounds
Processes, tasks, activities covered (environment)	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process in a batch/continuous process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	367.1 tonnes Cu per day
Maximum annual use at a site	134000 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	365 days per year
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No releases. **Air:** The spERC emission factor of 0.03% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.4 Control of environmental exposure [E-GES-P2.1]	
Environmental related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Systematic title based on use descriptor (environment)	spERC – Production of metal compounds
Processes, tasks, activities covered (environment)	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process in a batch/continuous process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC

Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	4.73 tonnes Cu per day (WWTP - 92% removal efficiency)
Maximum annual use at a site	1725 tonnes Cu per year (WWTP - 92% removal efficiency)
Frequency and duration of use	
Pattern of release to the environment	365 days per year
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
RMMs: Filtration, precipitation, centrifugation etc – see spERC 'Production of Metal Compounds'	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
On-site WWTP with minimum removal efficiency of 92%	
Waste water: The spERC emission factor of 0.02% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment can be either onsite or offsite with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.03% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
RMMs and on-site WWTP with minimum removal efficiency of 92%	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.5 Control of worker exposure contributing to exposure scenario [W-GES-P(High)]	
Workers related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 8b

Processes, tasks, activities covered	Compound manufacture (dissolution, dilution, **chemical synthesis:** precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, **transfer** [storage & transport]) (PROC 1) **Compound manufacture** (**production processes**, dissolution, dilution, pre-leaching with acid, mixing, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, drying, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (**production processes**, adjustment of pH, concentrations and temperatures of reagents, dissolution, dilution, chemical synthesis, distillation, sulfiding, heating, oxidating, precipitation, mixing of reagents in a closed reactor, calcination, impregnation, separation, centrifugation, filtration, washing/rinsing, screening, drying [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), **Maintenance & cleaning** (PROC 3) Compound manufacture (production processes, filtration, washing/rinsing, **reaction of raw materials to produce final product**, charging of the raw gold slime to the pre-leaching tank, calcination, dissolution, dilution, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8b)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (High dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV required (LEV generic, ECETOC reference)
PROC 3	LEV required (LEV generic, ECETOC reference)
PROC 8b	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	

Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 8b	RPE required : Inhalation APF = 4
2.6 Control of worker exposure contributing to exposure scenario [W-GES-P(Med)]	
Workers related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 8b
Processes, tasks, activities covered	Compound manufacture (dissolution, dilution, **chemical synthesis:** precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, **transfer** [storage & transport]) (PROC 1) **Compound manufacture (production processes**, dissolution, dilution, pre-leaching with acid, mixing, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, drying, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (**production processes**, adjustment of pH, concentrations and temperatures of reagents, dissolution, dilution, chemical synthesis, distillation, sulfiding, heating, oxidating, precipitation, mixing of reagents in a closed reactor, calcination, impregnation, separation, centrifugation, filtration, washing/rinsing, screening, drying [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), **Maintenance & cleaning** (PROC 3) Compound manufacture (production processes, filtration, washing/rinsing, **reaction of raw materials to produce final product**, charging of the raw gold slime to the pre-leaching tank, calcination, dissolution, dilution, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8b)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (Medium dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	

Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV required (LEV generic, ECETOC reference)
PROC 8b	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 8b	No RPE required
2.7 Control of worker exposure contributing to exposure scenario [W-GES-P(Low)]	
Workers related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 8b
Processes, tasks, activities covered	Compound manufacture (dissolution, dilution, **chemical synthesis:** precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, **transfer** [storage & transport]) (PROC 1) **Compound manufacture** (**production processes**, dissolution, dilution, pre-leaching with acid, mixing, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, drying, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (**production processes**, adjustment of pH, concentrations and temperatures of reagents, dissolution, dilution, chemical synthesis, distillation, sulfiding, heating, oxidating, precipitation, mixing of reagents in a closed reactor, calcination, impregnation, separation, centrifugation, filtration, washing/rinsing, screening, drying [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing &

	filling, unloading/**transfer** [storage (bags) & (bulk) transport]), **Maintenance & cleaning** (PROC 3) Compound manufacture (production processes, filtration, washing/rinsing, **reaction of raw materials to produce final product**, charging of the raw gold slime to the pre-leaching tank, calcination, dissolution, dilution, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8b)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (Low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV not required
PROC 8b	LEV not required
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 8b	No RPE required
2.8 Control of worker exposure contributing to exposure scenario [W-GES-P(Liquid)]	
Workers related free short title	Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 8b
Processes, tasks, activities covered	Compound manufacture (dissolution, dilution, **chemical synthesis:** precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, **transfer** [storage & transport]) (PROC 1)

	Compound manufacture (**production processes**, dissolution, dilution, pre-leaching with acid, mixing, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, drying, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (**production processes**, adjustment of pH, concentrations and temperatures of reagents, dissolution, dilution, chemical synthesis, distillation, sulfiding, heating, oxidating, precipitation, mixing of reagents in a closed reactor, calcination, impregnation, separation, centrifugation, filtration, washing/rinsing, screening, drying [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), **Maintenance & cleaning** (PROC 3) Compound manufacture (production processes, filtration, washing/rinsing, **reaction of raw materials to produce final product**, charging of the raw gold slime to the pre-leaching tank, calcination, dissolution, dilution, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8b)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV not required
PROC 8b	LEV not required
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	

PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 8b	No RPE required

3. Exposure and risk mitigation

Generic exposure scenarios

Environment

All tables:

* mean of agricultural soil and grassland (180 days)

**including a country-specific regional background;

Freshwater = median value of 2.9 µg dissolved Cu/L
Freshwater sediment = not applicable
Marine = median value of 1.1 µg dissolved Cu/L
Marine sediment = median value 16.1 mg/kg dw
Soil = median value of 24.4 mg/kg dw

E-GES-P1.0: ERC 1: Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

Tier 1: EUSES 2.0 calculations with RWC assumptions

Maximum tonnage 900 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0003	0.0032	0.41
	Sediment	mg/kg dw	87.1	8.79	8.79	0.1
Marine	**Aquatic**	mg/l	0.0056	3.7E-05	0.0011	0.2
	Sediment	mg/kg dw	676	1.12	17.2	0.03
Terrestrial	**Soil**	mg/kg dw	64.6	27.9*	52.3*	0.81*
	Groundwater	mg/l	-	0.013*	-	-

E-GES-P2.0 spERC [Metal compound production]: Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

Tier 2: EUSES 2.0 calculations with spERC assumptions

Maximum tonnage 134000 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0003	0.003	0.41
	Sediment	mg/kg dw	87.1	7.86	7.86	0.09
Marine	**Aquatic**	mg/l	0.0056	3.31E-05	0.0011	0.2
	Sediment	mg/kg dw	676	1.0	17.1	0.03
Terrestrial	**Soil**	mg/kg dw	64.6	24.95*	49.35*	0.76*
	Groundwater	mg/l	-	0.012*	-	-

E-GES-P1.1 ERC 1: Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

Tier 1: EUSES 2.0 calculations with RWC assumptions [E-GES-P1.1]

Maximum tonnage 5.75 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0026	0.0055	0.7
	Sediment	mg/kg dwt	87.1	78.7	78.7	0.9
Marine	**Aquatic**	mg/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg/kg dwt	676	7.87	24.0	0.04
Terrestrial	**Soil**	mg/kg dwt	64.6	0.178*	24.58*	0.4*
	Groundwater	mg/l	-	0.00008*	-	-

E-GES-P2.1 spERC [Metal compound production]: Manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

Tier 2: EUSES 2.0 calculations with spERC assumptions [E-GES-P2.1]

Maximum tonnage 1725 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0026	0.0055	0.7

	Sediment	mg/kg dwt	87.1	78.8	78.8	0.9
Marine	**Aquatic**	mg/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg/kg dwt	676	7.88	23.98	0.04
Terrestrial	**Soil**	mg/kg dwt	64.6	*	24.72*	0.4*
	Groundwater	mg/l	-	*	-	-

Worker exposure : Indoor activities for the manufacture copper dinitrate by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process

GES	**Physical form**		**PROC**	**Duration of activity [hours/day]**	**Worker protection required**			**RCR**
					PPE	**LEV**	**RPE [AFP]**	**Total Exposure**
W-GES-P (High)	Solid [Dustiness]	High	1	> 4 hours	No	No	No	0.023
W-GES-P(Med)		Med		> 4 hours	No	No	No	0.023
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.023
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.126
W-GES-P(High)	Solid [Dustiness]	High	2	> 4 hours	No	Yes	No	0.125
W-GES-P(Med)		Med		> 4 hours	No	No	No	0.525
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.035
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.252
W-GES-P(High)	Solid [Dustiness]	High	3	> 4 hours	No	Yes	No	0.113
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.113
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.113
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.135
W-GES-P(High)	Solid [Dustiness]	High	8b	> 4 hours	No	Yes	Yes [4]	0.338
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.275
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.125
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.261

4. Guidance to evaluate whether a site works inside the boundaries set by the ES

Environment

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

Workers

As for the environment, it should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

GES2: Copper dinitrate is manufactured by **dissolution of copper in nitric acid** in both batch and continuous processes by two variant methods. From the information provided, two environmental release scenarios are required and the GES below assumes that the waste waters are released either; directly to surface waters after on-site treatment (E-GES-P1.1/2.1) or via both on (WWTP) and off-site (STP) treatment facilities (E-GES-P1.2/2.2). Worker exposure will be addressed for activities covered by PROC 1, 2, 3, 4, 5, 8a, 8b, 9 and 26 within 4 worker exposure scenarios (W-GES-P(High/Med/Low/Liquid).

1. Title GES - copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process	
Life cycle	Copper dinitrate manufacture
Free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Systematic title based on use descriptor	**SU:** SU10 - Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU8 - Manufacture of bulk, large scale chemicals (including petroleum products) SU9 - Manufacture of fine chemicals **PC**: Not relevant **ERC:** ERC1 – Manufacture of substances spERC – Production of metal compounds **PROC:** PROC 1 - Use in closed process, no likelihood of exposure. Industrial setting PROC 2 - Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting PROC 3 - Use in closed batch process (synthesis or formulation). Industrial setting PROC 4 - Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting. PROC 5 - Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial setting PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting PROC 26 - Handling of solid inorganic substances at ambient temperature
Processes, tasks, activities covered (environment)	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process
Processes, tasks, activities covered (workers)	PROC 1 - dissolution, dilution, chemical synthesis PROC 2 - dissolution, dilution, drying, mixing, filling operations (transfer to transport containers)

	PROC 3 - dissolution, dilution, chemical synthesis, precipitating, centrifugation, drying, mixing, filling operations (transfer to transport containers) PROC 4 - production processes, filling operations (transfer to transport containers) PROC 5 - production processes PROC 8a - dissolution, dilution PROC 8b - dissolution, dilution, filling operations (transfer to transport containers) PROC 9 - filling operations (transfer to transport containers) PROC 26 - maintenance & cleaning (Production)
2. Operational conditions and risk management measures (RMMs)	
2.1 Control of environmental exposure [E-GES-P1.1]	
Environmental related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Systematic title based on use descriptor (environment)	ERC1 – Manufacture of substances
Processes, tasks, activities covered (environment)	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	0.016 tonnes Cu per day
Maximum annual use at a site	5.75 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	365 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs; 6% emission (adjusted to 0.48 and 0.06% for on-site WWTP with 92% or 99% removal). **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.2 Control of environmental exposure [E-GES-P1.2]	
Environmental related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Systematic title based on use descriptor	ERC1 – Manufacture of substances

(environment)	
Processes, tasks, activities covered (environment)	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	0.09 tonnes Cu per day [Biological WWTP] 0.2 tonnes Cu per day [Physico-chemical WWTP]
Maximum annual use at a site	32 tonnes Cu per year [Biological WWTP] 71.25 tonnes Cu per year [Physico-chemical WWTP]
Frequency and duration of use	
Pattern of release to the environment	365 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs; 6% emission (adjusted to 0.48 and 0.06% for on-site WWTP with 92% or 99% removal). **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	YES
Discharge rate of the Municipal STP	Default 200 m^3 per 10000 capita per day
Incineration of the sludge of the Municipal STP	None - disposal to land assumed
Conditions and measures related to external treatment of waste for disposal	
92% removal of Cu to sludge assumed	
Conditions and measures related to external recovery of waste	
Disposal via land (taken into account in PECs to soil)	
2.3 Control of environmental exposure [E-GES-P2.1]	
Environmental related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Systematic title based on use descriptor (environment)	spERC – Production of metal compounds
Processes, tasks, activities covered (environment)	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	4.73 tonnes Cu per day (WWTP - 92% removal efficiency)
Maximum annual use at a site	1725 tonnes Cu per year (WWTP - 92% removal efficiency)
Frequency and duration of use	

Pattern of release to the environment	365 days per year
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
RMMs: Filtration, precipitation, centrifugation etc – see spERC 'Production of Metal Compounds'	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
On-site WWTP with minimum removal efficiency of 92%	
Waste water: The spERC emission factor of 0.02% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment can be either onsite or offsite with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.03% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
RMMs and on-site WWTP with minimum removal efficiency of 92%	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Not applicable.	
2.4 Control of environmental exposure [E-GES-P2.2]	
Environmental related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Systematic title based on use descriptor (environment)	spERC – Production of metal compounds
Processes, tasks, activities covered (environment)	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid in a continuous/batch process
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum daily use at a site	25.89 tonnes Cu per day [Biological WWTP] 57.5 tonnes Cu per day [Physico-chemical WWTP]
Maximum annual use at a site	9450 tonnes Cu per year [Biological WWTP] 21000 tonnes Cu per year [Physico-chemical WWTP]
Frequency and duration of use	
Pattern of release to the environment	365 days per year
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default) m^3/d
Dilution capacity, marine	100 (default) m^3/d
Other given operational conditions affecting environmental exposure	
Closed-system	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: The spERC emission factor of 0.02% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th	

percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment can be either onsite or offsite with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.03% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No waste from process.	
Conditions and measures related to external recovery of waste	
Disposal via land (taken into account in PECs to soil)	
2.5 Control of worker exposure contributing to exposure scenario [W-GES-P(High)]	
Workers related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 26
Processes, tasks, activities covered	Compound manufacture (**dissolution**, **dilution**, **chemical synthesis**: precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, transfer [storage & transport]) (PROC 1) Compound manufacture (**dissolution**, **dilution**, pre-leaching with acid, **mixing**, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, **drying**, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (production processes, adjustment of pH, concentrations and temperatures of reagents, **dissolution, dilution, chemical synthesis**, distillation, sulfiding, heating, oxidating, **precipitation**, **mixing** of reagents in a closed reactor, calcination, impregnation, separation, **centrifugation**, filtration, washing/rinsing, screening, **drying** [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), Maintenance & cleaning (PROC 3) Compound manufacture (**production processes**, chemical synthesis, lixiviation, oxidating, sedimentation, distillation, filtration, centrifugation, drying, solution recycling), Product recovery, Packaging (**filling operations**, **transfer** [transport containers]), Maintenance & cleaning (PROC 4)

	Compound manufacture (**production processes**, production of process intermediate, mixing of formulants), Packaging (PROC 5) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8a) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (**filling** & **transfer** operations [storage & transport]), Maintenance & cleaning (PROC 8b) Packaging (**filling**, **transfer** [storage & transport]) (PROC 9) **Maintenance & cleaning** (PROC 26)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (High dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV required (LEV generic, ECETOC reference)
PROC 3	LEV required (LEV generic, ECETOC reference)
PROC 4	LEV required (LEV generic, ECETOC reference)
PROC 5	LEV required (LEV generic, ECETOC reference)
PROC 8a	LEV required (LEV generic, ECETOC reference)
PROC 8b	LEV required (LEV generic, ECETOC reference)
PROC 9	LEV required (LEV generic, ECETOC reference)
PROC 26	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)

Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 4	RPE required : Inhalation APF = 4
PROC 5	RPE required : Inhalation APF = 4
PROC 8a	RPE required : Inhalation APF = 10
PROC 8b	RPE required : Inhalation APF = 4
PROC 9	RPE required : Inhalation APF = 4
PROC 26	RPE required : Inhalation APF = 4

2.6 Control of worker exposure contributing to exposure scenario [W-GES-P(Med)]	
Workers related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 26
Processes, tasks, activities covered	Compound manufacture (**dissolution**, **dilution**, **chemical synthesis**: precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, transfer [storage & transport]) (PROC 1) Compound manufacture (**dissolution**, **dilution**, pre-leaching with acid, **mixing**, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, **drying**, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (production processes, adjustment of pH, concentrations and temperatures of reagents, **dissolution, dilution, chemical synthesis**, distillation, sulfiding, heating, oxidating, **precipitation**, **mixing** of reagents in a closed reactor, calcination, impregnation, separation, **centrifugation**, filtration, washing/rinsing, screening, **drying** [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), Maintenance & cleaning (PROC 3) Compound manufacture (**production processes**, chemical synthesis, lixiviation, oxidating, sedimentation, distillation, filtration, centrifugation, drying, solution recycling), Product recovery, Packaging (**filling operations**, **transfer** [transport containers]), Maintenance & cleaning (PROC 4) Compound manufacture (**production processes**, production of process intermediate, mixing of formulants), Packaging (PROC 5)

	Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8a) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (**filling & transfer** operations [storage & transport]), Maintenance & cleaning (PROC 8b) Packaging (**filling**, **transfer** [storage & transport]) (PROC 9) **Maintenance & cleaning** (PROC 26)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (Medium dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV required (LEV generic, ECETOC reference)
PROC 4	LEV required (LEV generic, ECETOC reference)
PROC 5	LEV required (LEV generic, ECETOC reference)
PROC 8a	LEV required (LEV generic, ECETOC reference)
PROC 8b	LEV required (LEV generic, ECETOC reference)
PROC 9	LEV required (LEV generic, ECETOC reference)
PROC 26	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required

PROC 4	No RPE required
PROC 5	No RPE required
PROC 8a	No RPE required
PROC 8b	No RPE required
PROC 9	No RPE required
PROC 26	No RPE required
2.7 Control of worker exposure contributing to exposure scenario [W-GES-P(Low)]	
Workers related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 26
Processes, tasks, activities covered	Compound manufacture (**dissolution**, **dilution**, **chemical synthesis**: precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, transfer [storage & transport]) (PROC 1) Compound manufacture (**dissolution**, **dilution**, pre-leaching with acid, **mixing**, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, **drying**, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (production processes, adjustment of pH, concentrations and temperatures of reagents, **dissolution, dilution, chemical synthesis**, distillation, sulfiding, heating, oxidating, **precipitation**, **mixing** of reagents in a closed reactor, calcination, impregnation, separation, **centrifugation**, filtration, washing/rinsing, screening, **drying** [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), Maintenance & cleaning (PROC 3) Compound manufacture (**production processes**, chemical synthesis, lixiviation, oxidating, sedimentation, distillation, filtration, centrifugation, drying, solution recycling), Product recovery, Packaging (**filling operations**, **transfer** [transport containers]), Maintenance & cleaning (PROC 4) Compound manufacture (**production processes**, production of process intermediate, mixing of formulants), Packaging (PROC 5) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution,**

	dilution, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8a) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (**filling** & **transfer** operations [storage & transport]), Maintenance & cleaning (PROC 8b) Packaging (**filling**, **transfer** [storage & transport]) (PROC 9) **Maintenance & cleaning** (PROC 26)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: Solid (Low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV not required
PROC 4	LEV not required
PROC 5	LEV not required
PROC 8a	LEV not required
PROC 8b	LEV not required
PROC 9	LEV not required
PROC 26	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 4	No RPE required
PROC 5	No RPE required
PROC 8a	No RPE required
PROC 8b	No RPE required

PROC 9	No RPE required
PROC 26	No RPE required
2.8 Control of worker exposure contributing to exposure scenario [W-GES-P(Liquid)]	
Workers related free short title	Copper dinitrate is manufactured by dissolution of copper metal in nitric acid
Use descriptor covered	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8a PROC 8b PROC 9 PROC 26
Processes, tasks, activities covered	Compound manufacture (**dissolution**, **dilution**, **chemical synthesis**: precipitating, sulfiding, heating, oxidating, calcination, impregnation, filtration, washing/rinsing, screening, drying, compaction, forming), Packaging (weighing & fillings, transfer [storage & transport]) (PROC 1) Compound manufacture (**dissolution**, **dilution**, pre-leaching with acid, **mixing**, milling, crystallization, precipitating, calcination, filtration, washing/rinsing, compaction, screening, separation, **drying**, forming), Packaging (weighing, **filling**, sieving, packing, transfer [storage & transport]) (PROC 2) Compound manufacture (production processes, adjustment of pH, concentrations and temperatures of reagents, **dissolution, dilution, chemical synthesis**, distillation, sulfiding, heating, oxidating, **precipitation**, **mixing** of reagents in a closed reactor, calcination, impregnation, separation, **centrifugation**, filtration, washing/rinsing, screening, **drying** [spray, spin-flash methods], milling, compaction, tabletting, solution recycling), Product recovery, Packaging (weighing & **filling**, unloading/**transfer** [storage (bags) & (bulk) transport]), Maintenance & cleaning (PROC 3) Compound manufacture (**production processes**, chemical synthesis, lixiviation, oxidating, sedimentation, distillation, filtration, centrifugation, drying, solution recycling), Product recovery, Packaging (**filling operations**, **transfer** [transport containers]), Maintenance & cleaning (PROC 4) Compound manufacture (**production processes**, production of process intermediate, mixing of formulants), Packaging (PROC 5) Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (filling & transfer operations [storage & transport]), Maintenance & cleaning (PROC 8a)

	Compound manufacture (production processes, filtration, washing/rinsing, reaction of raw materials to produce final product, charging of the raw gold slime to the pre-leaching tank, calcination, **dissolution, dilution**, drying, forming), Packaging (**filling** & **transfer** operations [storage & transport]), Maintenance & cleaning (PROC 8b) Packaging (**filling**, **transfer** [storage & transport]) (PROC 9) **Maintenance & cleaning** (PROC 26)
Assessment Method	Estimation of exposure based on predicted data
Product characteristic	
Specific to manufacture source: liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	LEV not required
PROC 2	LEV not required
PROC 3	LEV not required
PROC 4	LEV not required
PROC 5	LEV not required
PROC 8a	LEV not required
PROC 8b	LEV not required
PROC 9	LEV not required
PROC 26	N/A
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	No RPE required
PROC 2	No RPE required
PROC 3	No RPE required
PROC 4	No RPE required
PROC 5	No RPE required
PROC 8a	No RPE required
PROC 8b	No RPE required
PROC 9	No RPE required
PROC 26	N/A
3. Exposure and risk mitigation	

<u>Generic exposure scenarios</u>
Environment
All tables:
* mean of agricultural soil and grassland (180 days)
**including a country-specific regional background;
Freshwater = median value of 2.9 µg dissolved Cu/L
Freshwater sediment = not applicable
Marine = median value of 1.1 µg dissolved Cu/L
Marine sediment = median value 16.1 mg/kg dw
Soil = median value of 24.4 mg/kg dw

E-GES-P1.1 ERC 1: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid

Tier 1: EUSES 2.0 calculations with RWC assumptions [E-GES-P1.1]

Maximum tonnage 5.75 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0026	0.0055	0.7
	Sediment	mg/kg dwt	87.1	78.7	78.7	0.9
Marine	**Aquatic**	mg/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg/kg dwt	676	7.87	24.0	0.04
Terrestrial	**Soil**	mg/kg dwt	64.6	0.178*	24.58*	0.4*
	Groundwater	mg/l	-	0.00008*	-	-

E-GES-P1.2: ERC 1: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid

Tier 1: EUSES 2.0 calculations with RWC assumptions

Maximum tonnage 32 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0012	0.0041	0.5
	Sediment	mg/kg dw	87.1	35.3	35.3	0.4
Marine	**Aquatic**	mg/l	0.0056	0.00012	0.0012	0.2
	Sediment	mg/kg dw	676	3.54	19.6	0.03
Terrestrial	**Soil**	mg/kg dw	64.6	6.7*	31.1*	0.09*
	Groundwater	mg/l	-	0.0032*	-	-

E-GES-P2.1 spERC [Metal compound production]: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid

Tier 2: EUSES 2.0 calculations with spERC assumptions [E-GES-P2.1]

Maximum tonnage 1725 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0026	0.0055	0.7
	Sediment	mg/kg dwt	87.1	78.8	78.8	0.9
Marine	**Aquatic**	mg/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg/kg dwt	676	7.88	23.98	0.04
Terrestrial	**Soil**	mg/kg dwt	64.6	*	24.72*	0.4*
	Groundwater	mg/l	-	*	-	-

E-GES-P2.2: spERC [Metal compound production]: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid

Tier 2: EUSES 2.0 calculations with spERC assumptions

Maximum tonnage 9450 tonnes per annum, 365 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg/l	0.0078	0.0012	0.004	0.5
	Sediment	mg/kg dw	87.1	35	35	0.4
Marine	**Aquatic**	mg/l	0.0056	0.00012	0.0012	0.2
	Sediment	mg/kg dw	676	3.52	19.62	0.03
Terrestrial	**Soil**	mg/kg dw	64.6	7.38*	31.78*	0.5*
	Groundwater	mg/l	-	0.0035*	-	-

Worker exposure : Indoor activities for copper dinitrate manufacture by dissolution of copper metal in nitric acid

GES	Physical form		PROC	Duration of activity [hours/day]	Worker protection required			RCR
					PPE	LEV	RPE [AFP]	Total Exposure
W-GES-P(High)	Solid [Dustiness]	High	**1**	> 4 hours	No	No	No	0.023
W-GES-P(Med)		Med		> 4 hours	No	No	No	0.023
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.023
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.126
W-GES-P(High)	Solid [Dustiness]	High	**2**	> 4 hours	No	Yes	No	0.125
W-GES-P(Med)		Med		> 4 hours	No	No	No	0.525
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.035
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.252
W-GES-P(High)	Solid [Dustiness]	High	**3**	> 4 hours	No	Yes	No	0.113
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.113
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.113
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.135
W-GES-P(High)	Solid [Dustiness]	High	**4**	> 4 hours	No	Yes	Yes [4]	0.625
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.525
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.525
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.30
W-GES-P(High)	Solid [Dustiness]	High	**5**	> 4 hours	No	Yes	Yes [4]	0.625
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.525
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.525
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.30
W-GES-P(High)	Solid [Dustiness]	High	**8a**	> 4 hours	No	Yes	Yes [10]	0.55
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.52
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.55
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.261
W-GES-P(High)	Solid [Dustiness]	High	**8b**	> 4 hours	No	Yes	Yes [4]	0.338
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.275
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.125
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.261
W-GES-P(High)	Solid [Dustiness]	High	**9**	> 4 hours	No	Yes	Yes [4]	0.525
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.525
W-GES-P(Low)		Low		> 4 hours	No	No	No	0.125
W-GES-P(Liquid)	Liquid			> 4 hours	No	No	No	0.261
W-GES-P(High)	Solid [Dustiness]	High	**26**	> 4 hours	No	Yes	Yes [4]	0.553
W-GES-P(Med)		Med		> 4 hours	No	Yes	No	0.823
W-GES-P(Low)		Low		> 4 hours	No	Yes	No	0.373

4. Guidance to evaluate whether a site works inside the boundaries set by the ES

Environment

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

Workers
As for the environment, it should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.
Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.
Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

9.2.4.1 Waste related measures

See Section 9.4.

9.2.5 Exposure estimation

9.2.5.1 Environmental exposure

9.2.5.1.1 Environmental releases

Releases to the local environment as a result of copper dinitrate are summarised below in **Table 81**. No direct regional releases are presented as measured regional data have been used (see Section 9.6).

Table 81: Summary of the releases* to the environment resulting from the production of copper dinitrate

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
E-GES-P1.0 [GES1]		
Aquatic (without STP)	N/A	Maximum tonnage of 900 tonnes of copper per annum.
Aquatic (after STP)	N/A	
Air (direct + STP)*	123	
Soil (direct releases only)	0	
E-GES-P2.0 [GES1]		
Aquatic (without STP)	N/A	Maximum tonnage of 134000 tonnes of copper per annum.
Aquatic (after STP)	N/A	
Air (direct + STP)*	110	
Soil (direct releases only)	0	
E-GES-P1.1 [GES1&GES2]		
Aquatic (without STP)	0.076	Maximum tonnage of 5.75 tonnes of copper per annum.
Aquatic (after STP)	N/A	
Air (direct + STP)*	0.788	
Soil (direct releases only)	0	
E-GES-P2.1 [GES1&GES2]		

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
Aquatic (without STP)	0.076	Maximum tonnage of 1725 tonnes of copper per annum.
Aquatic (after STP)	N/A	
Air (direct + STP)*	1.42	
Soil (direct releases only)	0	
E-GES-P1.2 [Biological WWTP] **[GES2]**		
Aquatic (without STP)	0.421	Maximum tonnage of 32 tonnes of copper per annum.
Aquatic (after STP)	0.034	
Air (direct + STP)*	4.38	
Soil (direct releases only)	0	
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**		
Aquatic (without STP)	0.937	Maximum tonnage of 71.25 tonnes of copper per annum.
Aquatic (after STP)	0.075	
Air (direct + STP)*	9.76	
Soil (direct releases only)	0	
E-GES-P2.2 [Biological WWTP] **[GES2]**		
Aquatic (without STP)	0.414	Maximum tonnage of 9450 tonnes of copper per annum.
Aquatic (after STP)	0.033	
Air (direct + STP)*	7.77	
Soil (direct releases only)	0	
E-GES-P2.2 [Physico-chemical WWTP] **[GES2]**		
Aquatic (without STP)	0.921	Maximum tonnage of 21000 tonnes of copper per annum.
Aquatic (after STP)	0.074	
Air (direct + STP)*	17.3	
Soil (direct releases only)	0	

* - local direct only, no emissions at STP due to lack of volatilisation.

9.2.5.1.2 Exposure concentration in sewage treatment plants (STP)

Table 82: Predicted Exposure Concentrations (PEC) in sewage resulting from the production of copper dinitrate

Endpoint (units)	Value	Justification
E-GES-P1.0 [GES1]		
Concentration in sewage (PECstp)(in mg Cu/l)	N/A	Maximum tonnage of 900 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	N/A	
E-GES-P2.0 [GES1]		
Concentration in sewage (PECstp)(in mg Cu/l)	N/A	Maximum tonnage of 134000 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	N/A	
E-GES-P1.1 [GES1&GES2]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.0378	Maximum tonnage of 5.75 tonnes of copper per annum.

Endpoint (units)	Value	Justification
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
E-GES-P2.1 [GES1&GES2]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.0373	Maximum tonnage of 1725 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
E-GES-P1.2 [Biological WWTP] **[GES2]**		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.21	Maximum tonnage of 32 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0168	
Concentration in sewage sludge (in mg Cu/kg dw)	490	
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.468	Maximum tonnage of 71.25 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0375	
Concentration in sewage sludge (in mg Cu/kg dw)	1090	
E-GES-P2.2 [Biological WWTP] **[GES2]**		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.207	Maximum tonnage of 9450 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0166	
Concentration in sewage sludge (in mg Cu/kg dw)	482	
E-GES-P2.2[Physico-chemical WWTP] **[GES2]**		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.46	Maximum tonnage of 21000 tonnes of copper per annum.
Concentration in sewage sludge (in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0368	
Concentration in sewage sludge (in mg Cu/kg dw)	1070	

* Not calculated since waste disposal is not to land but are disposed of to landfill or via incineration in accordance with waste regulations.

9.2.5.1.3 Exposure concentration in aquatic pelagic compartment

Table 83: Predicted Exposure Concentrations (PEC) in aquatic compartment resulting from the production of copper dinitrate

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-P1.0 [GES1]			
Freshwater (in mg Cu/l)	N/A	N/A	Maximum tonnage of 900 tonnes of copper per annum.
Marine water (in mg Cu/l)	N/A	N/A	
E-GES-P1.0 [GES1]			
Freshwater (in mg Cu/l)	N/A	N/A	Maximum tonnage of 134000 tonnes of copper per annum.
Marine water (in mg Cu/l)	N/A	N/A	
E-GES-P1.1 [GES1&GES2]			
Freshwater (in mg Cu/l)	0.0026	0.0055	Maximum tonnage of 5.75 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00026	0.00136	
E-GES-P2.1 [GES1&GES2]			
Freshwater (in mg Cu/l)	0.0026	0.0055	Maximum tonnage of 1725 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00026	0.00136	
E-GES-P1.2 [Biological WWTP] **[GES2]**			
Freshwater (in mg Cu/l)	0.0012	0.0041	Maximum tonnage of 32 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00012	0.0012	
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**			
Freshwater (in mg Cu/l)	0.0026	0.0055	Maximum tonnage of 71.25 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00026	0.00136	
E-GES-P2.2 [Biological WWTP] **[GES2]**			
Freshwater (in mg Cu/l)	0.0012	0.0041	Maximum tonnage of 9450 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00012	0.00122	
E-GES-P2.2 [Physico-chemical WWTP] **[GES2]**			
Freshwater (in mg Cu/l)	0.0026	0.0055	Maximum tonnage of 21000 tonnes of copper per annum.
Marine water (in mg Cu/l)	0.00026	0.00136	

9.2.5.1.4 Exposure concentration in sediments

Table 84: Predicted Exposure Concentrations (PEC) in sediments resulting from the production of copper dinitrate

Compartments	Local concentration	PEC sediment (local+regional)	Justification
E-GES-P1.0 [GES1]			

Compartments	Local concentration	PEC sediment (local+regional)	Justification
Freshwater sediments (in mg Cu/kg dw)	N/A	N/A	Maximum tonnage of 900 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	N/A	N/A	
E-GES-P2.0 [GES1]			
Freshwater sediments (in mg Cu/kg dw)	N/A	N/A	Maximum tonnage of 134000 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	N/A	N/A	
E-GES-P1.1 [GES1&GES2]			
Freshwater sediments (in mg Cu/kg dw)	78.7	78.7	Maximum tonnage of 5.75 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.87	24.0	
E-GES-P2.1 [GES1&GES2]			
Freshwater sediments (in mg Cu/kg dw)	78.8	78.8	Maximum tonnage of 1725 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.88	23.98	
E-GES-P1.2 [Biological WWTP] **[GES2]**			
Freshwater sediments (in mg Cu/kg dw)	35.3	35.3	Maximum tonnage of 32 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	3.54	19.6	
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**			
Freshwater sediments (in mg Cu/kg dw)	78.7	78.7	Maximum tonnage of 71.25 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.89	24.0	
E-GES-P2.2 [Biological WWTP] **[GES2]**			
Freshwater sediments (in mg Cu/kg dw)	35	35	Maximum tonnage of 9450 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	3.52	19.62	
E-GES-P2.2 [Physico-chemical WWTP] **[GES2]**			
Freshwater sediments (in mg Cu/kg dw)	77.9	77.9	Maximum tonnage of 21000 tonnes of copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.82	23.92	

9.2.5.1.5 Exposure concentrations in soil and groundwater

Table 85: Predicted Exposure Concentrations (PEC) in soil and groundwater resulting from the production of copper dinitrate

Compartments	Local concentration	PEC soil/groundwater (local+regional)	Justification
E-GES-P1.0 [GES1]			
Soil averaged (mg Cu/kg dw)	27.9	52.3	Maximum tonnage of 900 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0096	-	
E-GES-P2.0 [GES1]			
Soil averaged (mg Cu/kg dw)	24.95	49.35	Maximum tonnage of 134000 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0086	-	
E-GES-P1.1 [GES1&GES2]			
Soil averaged (mg Cu/kg dw)	0.178	24.58	Maximum tonnage of 5.75 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.000062	-	
E-GES-P2.1 [GES1&GES2]			
Soil averaged (mg Cu/kg dw)	0.322	24.72	Maximum tonnage of 1725 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0001	-	
E-GES-P1.2 [Biological WWTP] **[GES2]**			
Soil averaged (mg Cu/kg dw)	6.7	31.1	Maximum tonnage of 32 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0042	-	
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**			
Soil averaged (mg Cu/kg dw)	14.95	39.35	Maximum tonnage of 71.25 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0093		
E-GES-P2.2 [Biological WWTP] **[GES2]**			
Soil averaged (mg Cu/kg dw)	7.38	31.78	Maximum tonnage of 9450 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0044	-	
E-GES-P2.2 [Physico-chemical WWTP] **[GES2]**			
Soil averaged (mg Cu/kg dw)	16.4	40.8	Maximum tonnage of 21000 tonnes of copper per annum.
Groundwater (mg Cu/l)	0.0098	-	

9.2.5.1.6 Atmospheric compartment

Table 86: Predicted Exposure Concentration (PEC) in air resulting from the production of copper dinitrate

Compartments	Local concentration	PEC air (local+regional)	Justification
E-GES-P1.0 [GES1]			
Annual average (mg Cu/m^3)	0.0343	0.0343	Maximum tonnage of 900 tonnes of copper per annum.
E-GES-P2.0 [GES1]			
Annual average (mg Cu/m^3)	0.0306	0.0306	Maximum tonnage of 134000 tonnes of copper per

Compartments	Local concentration	PEC air (local+regional)	Justification
			annum.
E-GES-P1.1 [GES1&GES2]			
Annual average (mg Cu/m^3)	0.0002	0.0002	Maximum tonnage of 5.75 tonnes of copper per annum.
E-GES-P2.1 [GES1&GES2]			
Annual average (mg Cu/m^3)	0.00039	0.00039	Maximum tonnage of 1725 tonnes of copper per annum.
E-GES-P1.2 [Biological WWTP] **[GES2]**			
Annual average (mg Cu/m^3)	0.0012	0.0012	Maximum tonnage of 32 tonnes of copper per annum.
E-GES-P1.2 [Physico-chemical WWTP] **[GES2]**			
Annual average (mg Cu/m^3)	0.0027	0.0027	Maximum tonnage of 71.25 tonnes of copper per annum.
E-GES-P2.2 [Biological WWTP] **[GES2]**			
Annual average (mg Cu/m^3)	0.0022	0.0022	Maximum tonnage of 9450 tonnes of copper per annum.
E-GES-P2.2 [Physico-chemical WWTP] **[GES2]**			
Annual average (mg Cu/m^3)	0.0048	0.0048	Maximum tonnage of 21000 tonnes of copper per annum.

9.2.5.1.7 Exposure concentration relevant for the food chain (Secondary poisoning)

Copper is an essential trace element, well regulated in all living organisms. Difference in copper uptake rates are related to essential needs, varying with the species, size, life stage and seasons. Copper homeostatic mechanisms are applicable across species with specific processes being active depending on the species, life stages. Simple estimations on secondary poisoning are therefore not adequate.

There is overwhelming evidence to show the absence of copper biomagnification across the trophic chain in the aquatic and terrestrial food chains. Differences in sensitivity among species are not related to the level in the trophic chain but to the capability of internal homeostasis and detoxification. Field evidence has further provided evidence on the mechanisms of action of copper in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning.

9.2.5.2 Workers exposure

9.2.5.2.1 Acute/Short term exposure

Not applicable to downstream industrial uses as worst-case assumptions have considered long-term exposure only.

9.2.5.2.2 Long-term exposure

A summary of the predicted long-term exposure values for workers involved in the industrial downstream use of copper compound are presented in Table 87.

Table 87: Summary of long-term exposure concentration to workers involved in the production of copper dinitrate

GES1: Production by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(High)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.313	

GES1: Production by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Med)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.25	

GES1: Production by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Low)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	

GES1: Production by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	

GES1: Production by reacting cupric oxide (CuO) [or other copper compound] and nitric acid as an aqueous process		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Liquid)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(High)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV + RPE (APF 10) required
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.313	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.45	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Med)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Med)		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.72	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Low)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Low)		
Inhalation exposure (in mg Cu/m3)/8h workday	0.27	

GES2: Production by dissolution in nitric acid		
Routes of exposure	**Concentrations**	**Justification**
W-GES-P(Liquid)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/ m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)		PROC 26 NOT APPLICABLE
Inhalation exposure (in mg Cu/m3)/8h workday		

9.2.5.3 Consumer exposure

Not applicable.

9.2.5.4 Indirect exposure of humans via the environment (oral)

See Section 9.4.1.

9.3 Generic exposure scenarios for downstream use of copper dinitrate

All downstream use exposure scenario predictions are based on the standard EUSES 2.0 model for the environment and MEASE for the worker exposure in line with the available guidance for REACH.

9.3.1 Catalyst sector

This section presents an example of how an exposure scenario for a downstream use can be developed in accordance with specific industry information. The following exposure scenario has been developed from information made available through the European Catalyst Manufacturer's Association (ECMA) prior to 2013. Catalyst manufacturers and downstream users that find the following exposure scenario does not represent their specific use mapping, i.e. require different ERC/PROC codes, should use the additional information provided in section 9.3.2.

Copper compounds are commonly used as catalysts in the chemicals industry. The manufacture of catalysts containing copper dinitrate will often include the production of the copper dinitrate as part of the overall process, an activation step or a regeneration step. Information provided by the catalyst manufacturers has been used to inform the generic manufacturing exposure scenarios for copper compounds, ensuring that the production GES was sufficiently inclusive of the industries involved. For this reason, the environmental release information provided by the catalyst industry, which includes the production of copper dinitrate (ERC1 and spERC for metal compound production), has also been included in Section 9.2 above.

The ECMA has provided generic catalyst sector mapping for both the environment and worker exposure that includes the following titles (see Annex 13);

- Manufacture
- Use
- Ex-situ regeneration, and
- Recycling.

In addition to the mapping released in 2010, the ECMA have since published;

1. a spERC (ECMA 1.1a, v2.0, 2012) in conjunction with ARCHE consultancy (http://www.arche-consulting.be/content/documents/Metal-Catalysts-SPERC-V5---27Feb-2012.pdf) and
2. a position paper '*REACH and Catalysts: A position paper by the European Catalyst Manufacturers Association (ECMA).'* (ECMA, Amended May 2012 published via www.cefic.org). This document highlights issues that may have regulatory implications for the downstream user where catalyst use results in production of new chemical substances, in-situ/ex-situ regeneration, and recycling (waste) of the catalyst compounds. *It should be noted that it is the responsibility of the downstream user to ensure that where the use of a catalyst involves recovery of spent catalyst containing* ***copper dinitrate*** *i.e. via regeneration and/or recycling activity, this has been assessed appropriately according to REACH, taking advice from the relevant competent authority where necessary*.

The generic exposure scenario (GES) detailed in the following section has been taken from all of the information available at the time of drafting and is intended to aid the development of site-specific manufacture and DU of catalysts containing copper dinitrate.

9.3.1.1 GES descriptors for catalyst sector

The environmental and worker exposure occurring as a result of the use of copper dinitrate as a catalyst has been considered in 2 parts;

i) **Manufacture** including **regeneration** of catalysts containing copper dinitrate, and

ii) **In-use** phase of catalysts (excluding regeneration activity), which can take place at the site of manufacture or DU sites.

In order to identify each generic exposure scenario (GES) the following descriptor codes have been developed. The Environmental Generic Exposure Scenarios will all have the prefix **E-GES** and the Worker Generic Exposure Scenarios will all have the prefix **W-GES**. Both will then have '**C**' for catalyst with either '**M**' for manufacture or '**U**' for use. In order to define the specific release category or activities investigated within the individual GES title additional sub-categories have been added;

Scenario			Description
E-GES-CM	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data (default dilution in receiving waters)
		3	Tier 3 - spERC/measured data (realistic dilution in receiving waters)
	Waste water treatment	0	No waste water emission
		1	Waste water treated at on-site WWTP*
		2	Waste water treated on-site (WWTP*) and off-site (STP)
E-GES-CU	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data
	Waste water treatment	0	No waste water emission
		1	Waste water emission via an on-site WWTP*
		2	Waste water treated on-site (WWTP*) and off-site (STP)
	Environmental release category (ERC)	(2)	Formulation - Not included into matrix
		(4)	Use - Processing aid
		(6a)	Use - Intermediate
		(6b)	Use - Reactive processing aid
		spERC	As given in text
W-GES-CM/U	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry

** On-site WWTP is assumed to be physico-chemical treatment; therefore, the impact of copper exposure on sewage sludge microorganisms has not been carried out. Should an on-site biological treatment plant be in use, this assessment should be added by the catalyst user.*

The E-GES for catalysts will depend on the potential routes of exposure resulting from the activities within each of the identified exposure titles. Although potential direct on-site exposure of the soil compartment has been identified within the exposure titles, this is considered to be largely due to accidental spillage (outside the scope of this risk assessment) and will result in limited and localised exposure. This is recognised by the REACH guidance and the available environmental release categories (ERC), where releases to soil are limited to outdoor use scenarios only. However, indirect exposure of the wider soil environment (industrial, natural and agricultural) that will occur as a result of emissions to air and waste water (STP sludge disposal) have been considered at the regional level. For each exposure title, the predicted environmental concentrations (PEC) for the relevant compartments have been calculated using EUSES 2.0. These PEC values have then been compared to the relevant predicted no effect concentrations (PNEC) in order to determine the risk characterisation (PEC:PNEC) and define the maximum allowable tonnage (PEC:PNEC must not exceed 1).

The maximum safe tonnages of copper dinitrate (presented as copper, within a catalyst) have been predicted for each of the exposure scenarios outlined below. Although the majority of on-site WWTP involve physico-chemical treatment processes, it is also the case that some sites utilise biological treatment. In order to protect the microbial populations of these facilities, the default position has therefore been to assume that WWTP are biological in nature. As this tends to limit the predicted 'safe' tonnages of copper used in the manufacture of catalysts, a second calculation has been introduced to illustrate the situation for sites with physico-chemical WWTP.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of RMMs (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

The W-GES for catalysts will depend on the level, route (dermal or inhalation) and length of exposure as derived from the mapping data produced by the ECMA. Both the TRA and MEASE calculation tools have been used to determine the acceptability of the exposure patterns undertaken by workers during catalyst manufacture and/or use by calculating the risk characterisation ratio for inhalation, dermal and total exposures (RCR must not exceed 1).

As for the environment, it should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of RMMs (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

9.3.1.2 Generic exposure scenario development – Manufacture of catalysts

Manufacture (including regeneration) has been broken down into the following process steps,

i) RM delivery & handling
ii) Catalyst Manufacture
iii) Fresh Catalyst Packaging
iv) Maintenance & Cleaning
v) Fresh Catalyst Storage
vi) Spent catalyst delivery & handling
vii) Regeneration
viii) Regenerated Catalyst Packaging
ix) Maintenance & Cleaning (regeneration)
x) Regenerated catalyst storage

It is the activities within each of the above steps that determine the emission routes for environmental compartments of concern and worker exposure. Therefore, each process step and expected activities are considered further, according to the mapping information supplied (see Annex 13), with respect to the potential for;

- emissions to air and waste water for the environment and
- dermal and inhalation exposure of workers.

9.3.1.2.1 Environmental Generic Exposure Scenario for Catalyst Manufacture [E-GES-CM]

Processing steps in the manufacture of catalysts may be broken down as follows:

i) Raw Material (RM) delivery & handling includes activities involving both solid and liquid RM;

- Bulk delivery of solid RM (e.g. tank, silo, car)
- Semi-bulk delivery of solid RM (bags, drums...)
- Delivery of liquid RM
- Storage of solid RM
- Storage of liquid RM
- Transfer of RM from delivery containers into hopper or central supply system
- Conveying RM (transport to machine for processing)

All of the activities have the potential for release to the air compartments as particulates/dusts (solid RM) or from evaporation (liquid RMs) during transfer or spills. The main concern for the environmental releases of copper dinitrate will be emissions to air via particulates as the volatility of these compounds is not expected to be of concern. Air filters as RMMs are expected to be fitted to all locations where evaporation or excess particulate releases are likely to occur. Direct releases to waste water are unlikely unless due to spillage/leakage during liquid storage. Such emissions would not be routine and procedures should be in place to recover large spillages/leakages, with small scale spills/leaks inclusive of the cleaning and maintenance activities covered during catalyst manufacture.

ii) Catalyst manufacture may involve many activities, which follow a typical process order as listed;

- Dissolving
- Precipitating
- Filtrating
- Drying
- Mixing
- Forming
- Impregnation continuous/ batch
- Calcination (oxidation at elevated temperatures)
- Sulphiding
- Stripping
- Reduction
- Stabilisation
- Screening (adjusting particle size distribution)

Exposure of the air compartment to particulates of copper dinitrate can be predicted from the point of drying onwards. However, in all cases particulate air filters (RMMs) are assumed to be present as a standard (as shown in the mapping information in Annex 13). The only step in the process of catalyst manufacture where release to waste water occurs is at the filtration step as the filtrate is released. Filtration immediately follows the precipitation step in the manufacture of catalysts; both steps are considered RMMs for the water compartment as this ensures that maximum recovery of the copper dinitrate with minimum loss via the filtrate can be achieved.

iii) Fresh Catalyst Packaging involves filling operations (transfer to transport containers) during which particulate emissions to air can be expected, but air filters as a RMM are assumed as standard. No release to waste water is expected during this process.

iv) Maintenance & Cleaning (manufacturing): Emissions via air and waste water have been assumed. The presence of air RMMs will be dependent on the location of the activity but since air filters are assumed during manufacture processes where particulates are likely to be released [and require cleaning activities to take place], the logical assumption is that air RMMs will be present during the maintenance cleaning step. Waste water treatment is also assumed to be present for this process step where releases to waste water occur.

v) Fresh catalyst storage involves the final product storage prior to use and is considered to be largely contained with some potential releases to air (particulates) but these can be expected to be during the transfer to and from storage and covered within the handling activities.

vi) Spent catalyst delivery & handling includes the following activities: semi-bulk delivery of spent catalyst (IBC, drums), storage of spent catalyst, emptying of containers of spent catalyst and conveying spent catalyst. The main release to be considered is to air, which is managed by the presence of air filters.

vii) Regeneration (in-situ/ex-situ) of spent catalysts is considered a manufacturing step. As a process step it presents the potential for releases to air and uses air filters, where required, for the following activities: drying, calcination (oxidation at elevated temperatures) and screening (adjusting particle size distribution).

viii) Regenerated Catalyst Packaging includes filling operations (transfer to transport containers) and can result in releases of particulates to air, but in all cases air filters are used.

ix) Maintenance & cleaning (regeneration) activities have the potential for releases to air and water, therefore RMMs include air filters and wastewater treatments are used.

x) Regenerated catalyst storage is the final process step, but is unlikely to result in any environmental releases.

The mapping provided by the ECMA suggests that the environmental release codes for these manufacturing activities should be covered within a combination of ERC1 (Production), ERC 2 (Formulation – of preparations), ERC 4 (Use - processing aids in processes and products, not becoming part of articles) , ERC 6a (Use – resulting in manufacture of another substance [use of intermediates]) and ERC 6b (Use – reactive processing aids in batch or continuous processes) which include the following assumptions;

Environmental Exposure	ERC				
	1	2	4	6a	6b
Life cycle stage (LCS)	Production	Formulation	Use	Use	Use
Containment	Open/closed	Open/closed	Open/closed	Open/closed	Open/closed
Type of use in LCS	N/A	Not included into matrix	Processing aid	Intermediate	Reactive processing aid
Dispersion of emission sources	Industrial	Industrial	Industrial	Industrial	Industrial
Indoor/outdoor	Indoor	Indoor	Indoor	Indoor	Indoor
Release promotion during service life	N/A	N/A	N/A	N/A	N/A
Amount of substance used as input to emission calculation	100% M/I volume	100% M/I volume	100% M/I volume	100% M/I volume	100% M/I volume
Fraction used by largest customer - main source	1	1	1	1	1
Release times per year	20-300	20-300	20-300	20-300	20-300
Default release to air from process [%]	5	2.5	100^{+}	5	0.1
Default release to water from process [%]	6	2	100^{+}	2	5
Default release to soil from process [%]	0.01*	0.01*	5*	0.1*	0.025
Dilution to be applied for PEC aquatic derivation (freshwater)	10 (20000 m^3/d)	10 (18000 m^3/d)	10 (18000 m^3/d)	10 (18000 m^3/d)	10 (18000 m^3/d)

$^{+}$ - Depends on volatility and solubility. *- applicable to regional exposure only, and not used for the assessment of copper dinitrate as measured data are available for copper.

None of the standard ERC assumptions include the use of waste water treatment (on- or off-site) or RMMs to reduce emissions via air or waste water. Therefore, using the ERC assumptions alone would overestimate the predicted exposure concentrations (PECs) and unnecessarily restrict the maximum allowable tonnages of copper compounds used within the catalyst sector. However, the available spERC ‘Manufacture of metal-containing catalysts’ (ECMA 1.1a, v2.0) can be used by catalyst manufacturers that are able to comply with the assumptions as described by the spERC.

The available spERC describes the production of metal containing catalysts via processes based on impregnation or precipitation, filtration, drying (optional heating/calcination or reduction) and forming of the final product. The manufacture of metal-containing catalysts has been assumed to include both open and closed systems and both wet and dry processes. The default release factors have been derived from on-site emission data, measured between 2008 and 2010, taken from catalyst manufacturing sites in various EU member states. The release factors have been calculated as realistic worst-case values based on metal-specific 90th percentile site-specific release factors from 19 metal-containing catalysts production sites.

Emissions to air may arise from delivery, handling, drying, forming, impregnation, calcinations, reduction, screening and filling. Direct emissions to air should be mitigated by application of one or more of the following RMMs:

- HEPA filtration (EUPHRACS 06.1520003), Fabric filters (EUPHRACS 06.1520001) and Bag or Ceramic Filters,
- Wet scrubbers (EUPHRACS 06. 1520014 & 1520015) (second most commonly reported)
- Dry or semi-dry scrubbers
- Metallic grids (not common)

One or more of these RMMs (of which HEPA/bag filtration and wet scrubbers were the most common) were reported to be present in > 88% of sites. The RMM efficiency (RE_{sperc}) was reported to be ≥ 99%. From the available data the maximum 90th percentile site-specific release factors reported to air (after RMM) from the manufacture of metal containing catalysts was 0.025%. Particulate material captured from airborne emissions is also sent for recycling.

The important sources of wastewater during catalyst production are filtration, maintenance and cleaning. The spERC assumes that all wastewater is treated in an effluent treatment plant and the resulting filter cake is generally sent for recycling to recover metals. Direct emissions to water are mitigated by application of one or more of the following RMMs:

- Precipitation (EUPHRACS 06.1522000)
- Sedimentation (EUPHRACS 06.1526000)
- Filtration (EUPHRACS 06.622000)
- Distillation
- Ion Exchange (EUPHRACS 06.1524001)

One or more of these RMMs (of which chemical precipitation was the most common) were reported to be present at > 70% of sites. The RMM efficiency varied between 95 - 99.9%, and the 50th percentile of 99% has been adopted as the RE_{sperc}. The maximum emission of the 90th percentiles of reported site-specific release factors to waste water was given as 0.067%.

Emissions to soil were not considered to be relevant to metal containing catalyst manufacture as the activities are undertaken largely indoors.

According to the ECMA catalyst sector mapping information (Annex 13), the process steps included in the catalyst manufacture exposure scenario include RMMs for both air and water and as such the spERC for metal containing catalyst manufacture (Tier 2 assessment) should be applied as the standard E-GES for catalyst manufacture (see below) and not the default values presented for ERC 1, ERC2, ERC4, ERC6a or ERC6b (Tier 1 assessment).

Environmental Exposure	SPERC Manufacture of metal-containing catalysts
Life cycle stage (LCS)	Manufacture of catalysts comprising metal compounds
Containment	Open/closed
Type of use in LCS	Production of powdered or shaped catalysts or catalyst embedded in an organic matrix / Regeneration of previously used catalysts.
Dispersion of emission sources	Industrial
Indoor/outdoor	Indoor
Release promotion during service life	N/A
Amount of substance used as input to emission calculation	100% M/I volume
Fraction used by largest customer - main source	1
Release times per year	280
Default release to air from process [%]	0.025 (after on-site RMMs)
Default release to water from process [%]	0.067 (after on-site RMMs)
Default release to soil from process [%]	0
Dilution to be applied for PEC aquatic derivation (freshwater)	10 (18000 m^3/d)

In addition to the ECMA mapping information presented in Annex 13, copper compound catalyst manufacturers have provided additional site-specific specific confidential information via the Copper Compound Consortium. This information covers 8 sites where catalysts manufacture involves copper compounds across the EU (Germany [3], Netherlands [2], Denmark [1], Italy [1] and UK [1]) and has been used to modify [where considered necessary] the available spERC values to better reflect the Copper Compound Consortium catalyst manufacturing sites. The available information has been considered in parallel with the ECMA metal containing catalyst manufacture spERC to define the input parameters for the generic manufacturing environmental exposure scenario for catalysts containing copper compounds:

1. Wastewater emission value [%]: From the available data, the 90th percentile site-specific emission to waste water effluent (prior to on-site waste water treatment) was calculated as 0.094% and the mean value 0.032% (maximum value 0.18%). The available data are considered to support the use of the revised spERC wastewater release factor of 0.067%, which are applied after on-site RMMs and are based on a larger dataset.

2. Air emission value [%]: RMMs for air are in place at all of the catalyst sites with the following listed; HEPA filter or double filter; baghouse filter with and without wet scrubber; filter >99%; dust filter, bag filter and HEPA abatement systems. Measured data for the air emissions show that the mean emission to air was 0.008% and the 90th percentile was 0.016% based on 6 of the EU catalyst manufacturing sites. However, it was not clear if these emissions are based on measurements taken before or after passing the RMMs for air. The available data from 8 sites involved in copper

compound catalyst manufacture are considered to support the use of the revised spERC release factor of 0.025%, which are applied after on-site RMMs and are based on a larger dataset.

3. Release times per year [manufacturing days]: The data on the number of manufacturing days that result in releases to air (90^{th} percentile = 330 days) and water (90^{th} percentile = 365 days) from the Copper Compound Consortium members supports the 350 days proposed within the ECMA catalyst sector mapping (Annex 13). Therefore, 350 days should remain as a reasonable worse-case (RWC) value, not the 280 days given by the spERC.

4. Wastewater water treatment facilities [WWTP]: The above information on release fractions to water, assumes that all sites manufacturing catalysts that result in emissions to wastewater off-site have already passed through on-site RMMs. On-site RMMs include precipitation, filtration, sedimentation, distillation and ion exchange; which are considered equivalent to an on-site treatment facility [WWTP]. However, where connection to an off-site STP has been identified the 0.067 % release to wastewater is adjusted for 92 % copper removal prior to release into the receiving waters. According to the information provided by the copper compound catalyst manufacturers, 7 (87.5%) of the catalyst manufacturing sites operate with an on-site WWTP, followed by discharge either direct to surface waters (5 sites) or following additional treatment at a municipal STP (2 sites). These support the use of the spERC developed by the ECMA for the assessment of copper compounds used in the manufacture of catalysts.

5. Flow rate of receiving water: According to guidance on risk assessment using EUSES 2.0, the flow rate of the receiving water for a freshwater body results in a dilution factor of 10 for any local emission values. The available data shows that the flow rates of the receiving water bodies associated with the copper compound catalyst manufacturers are all in excess of the default of 18000 m^3/d (dilution factor of 10) with a mean value of 61432750 m^3/d (dilution factor of 30700). However, in order to present a reasonable worst-case scenario, the 10th percentile (extreme worse-case) value of 958100 m^3/d (dilution factor of 480) has been applied to the generic environmental exposure assessment for catalyst manufacture containing copper dinitrate. This can be considered as a Tier 3 refinement to demonstrate the impact of site specific scaling.

In considering all of the available information, no Tier 1 assessment is considered applicable for the manufacturing sites involved in catalyst production using copper compounds i.e. no GES using ERC codes have been defined. Therefore, 2 scenarios (E-GES-CM2.1/2.2) for catalyst manufacture have been defined according to the number of wastewater treatment steps and used to determine the maximum tonnage for catalyst manufacture for a single site as calculated by EUSES using the available spERC for the manufacture of metal-containing catalysts according to both Tier 2 (modified spERC [350 emission days]) and Tier 3 (modified spERC with increased receiving water flow rate);

Environmental Exposure	**Catalyst manufacture (CM)**		**Source**
	E-GES-CM2.1/3.1	**E-GES-CM2.2/3.2**	
Life cycle stage (LCS)	Manufacture of metal-containing catalysts		spERC
Containment	Open/closed		spERC
Type of use in LCS	Production of powdered or shaped catalysts or catalyst embedded in an organic matrix / Regeneration of previously used catalysts.		spERC
Dispersion of emission sources	Industrial		spERC
Indoor/outdoor	Indoor		spERC
Amount of substance used as input to emission calculation	100% M/I volume		ERC default
EUSES input parameters			
Fraction used by largest customer - main source	1		ERC default
Release times per year	350		ECMA/CCC
Wastewater treatment [Efficiency]	Single treatment at; on-site WWTP*	Treatment at both; on-site WWTP* and off-site STP[92%]	CCC
Default release to air from process [%]	0.025	0.025	SPERC**
Default release to water from process [%]	0.067	0.067	
Default release to soil from process [%]	0		
Dilution to be applied for PEC aquatic derivation (freshwater)	Tier 2: 10 (18000 m^3/d) Tier 3: 480 (958100 m^3/d)**		EUSES default Catalysts manufacture site specific data

CCC – Copper Compound Consortium catalyst manufacturing site data (2010)
**- all information provided in 2013 suggests that this is a physico-chemical no sites with an on-site biological STP have been identified*
*** - only freshwater receiving waters considered*

The predicted maximum allowable tonnages for sites undertaking manufacture of copper compound containing catalysts (expressed in terms of copper content) in accordance with the above defined GES are presented in Table 88 below.

Table 88: Maximum allowable tonnage (manufacture) for the catalyst sector using copper dinitrate

EUSES output	E-GES-CM			
	2.1	3.1	2.2	3.2
Maximum allowable manufacturing tonnage (as Cu) per site (tonnes per annum)	40	3250	500	1100
Maximum allowable manufacturing tonnage (as Cu) per site (tonnes Cu per day) [350 days per year]	0.11	9.29	1.43	3.14

The concentration of copper in the post on-site effluent data predicted by EUSES was shown to be significantly higher (mean 0.547 mg Cu l^{-1}, 90th percentile 0.922 mg Cu l^{-1}) than the data provided by Copper Compound Consortium catalyst manufacturing sites (overall mean 0.07 mg Cu l^{-1}, 90th percentile 0.10 mg Cu l^{-1} [where site activity may also include use and manufacture of other copper containing compounds]), which supports the use of the generic scenario as definitely worst-case and protective of the environment.

These data show that catalyst manufacture carried out in accordance with the assumptions presented for either of the 2 scenarios investigated (E-GESCM2.1/3.1 and 2.2/3.2) does not pose an unacceptable risk to the environment within the maximum allowable tonnages given. For sites that do not meet these conditions, scaling of the risk associated with their operation should be carried out using site-specific data in conjunction with the freely available scaling tool: 'Metals EUSES IT tool' (http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool).

The data also show that evaluated sites involved in the manufacture of copper dinitrate as part of the catalyst production process are sufficiently contained and do not pose a risk to the environment. Furthermore, for any catalyst use taking place at these sites, the RMMs currently in place sufficiently restrict releases to the environment.

Catalyst products are also sold to downstream users (DU) and therefore the next phase of use has been considered further in Section 9.3.1.3.

9.3.1.2.2 Worker Generic Exposure Scenario for Catalyst Manufacture [W-GES-CM]

For the purpose of assessing the exposure of workers to copper compounds, only the MEASE model outputs have been used and the results for all available PROCs are presented in full in Annex 14. These outputs have been used to map the exposures for workers involved in the catalyst sector in accordance with the ECMA mapping (see Annex 13), with additional confidential information provided by the members of the Copper Compound Consortium who manufacture catalysts. Acceptable working conditions are defined as those under which the risk characterisation was calculated to be <1.

The information provided by the Copper Compound Consortium was confined to PROC codes and the physical form of the substance or preparation (solid – high, medium and low dustiness; or liquid – aqueous solution or slurry) and the GES for each of the exposure scenario activities have been defined using this information (see Table 89). Dustiness is defined (according to MEASE guidance) as;

- Solid, high dustiness: fine powders having high potential to become and stay airborne.
- Solid, low dustiness: Granules, pellets, wetted powders, etc. with little potential for dust emissions (dustiness is less than 2.5% according to the Rotating Drum Method (RDM)).
-Solid, medium dustiness: powders and dust consisting of relatively coarse particles with moderate potential to become (and stay) airborne (dustiness is less than 10% (RDM)).
-Liquid = aqueous solution/slurry: typically solid substance (at room temperature) dissolved in water. For most of the existing PROCs, the use of aqueous solutions is assumed to be associated with a very low emission potential (90% reduction of estimate for 'low fugacity').

Where different PROC codes have been assigned to catalyst manufacturing activities by the Copper Compound Consortium, compared to those suggested by the ECMA, it is the Consortium information that has been used. This is because the information provided is considered more representative and relevant for the assessment of the catalyst sector supporting this report.

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solid RM) or from evaporation (liquid RMs) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009).
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high.

Table 89: Activities defined by PROC within the catalyst manufacture exposure scenario

Contributative ES (Short description of process or activity)	Description	Physical form (substance)	PROC
RM delivery & handling	Semi-bulk delivery	Solid - low dustiness	PROC 2, PROC 8a and PROC 8b
	Semi-bulk delivery	Solid - high dustiness	PROC 1, PROC 2
	Storage	Solid - low dustiness	PROC 1, PROC 2
	Storage	Solid - high dustiness	PROC 1, PROC 2
	Transfer	Solid - low dustiness	PROC 1, PROC 2 PROC 8a and PROC 8b
	Transfer	Solid - high dustiness	PROC 8a and PROC 8b
	Transfer	Solid - unspecified*	PROC 2, PROC 8a and PROC 8b

Contributative ES (Short description of process or activity)	Description	Physical form (substance)	PROC
	Conveying	Solid - low dustiness	PROC 1, PROC 2
	Conveying	Solid - high dustiness	PROC 1, PROC 2
	Conveying	Solid - unspecified*	PROC 8a and PROC 8b
Catalyst manufacture - process	Dissolving	Solid - low dustiness	PROC 1, PROC 2, PROC 8a and PROC 8b
	Precipitation	Liquid	PROC 1, PROC 2 and PROC 3
	Precipitation	Solid - low dustiness	PROC 1, PROC 2 and PROC 3
	Filtrating	Liquid	PROC 1, PROC 2, PROC 3, PROC 4, PROC 8a and PROC 8b
	Filtrating	Solid - low dustiness	PROC 1, PROC 2, PROC 3, PROC 4, PROC 8a and PROC 8b
	Drying	Solid - low dustiness	PROC 1
	Drying	Solid - medium dustiness	PROC 2, PROC 8b
	Drying	Solid - high dustiness	PROC 1 and PROC 2
	Drying	Solid - unspecified*	PROC 3
	Mixing	Solid - high dustiness	PROC 1
	Mixing	Solid - unspecified*	PROC 2, PROC 3
	Mixing & blending	Solid – unspecified*	PROC 5
	Mixing & blending	Liquid	PROC 5
	Forming	Solid - low dustiness	PROC 1, PROC 2 , PROC 8b and PROC 14
	Forming	Solid - medium dustiness	PROC 14
	Forming	Solid - high dustiness	PROC 14
	Forming	Solid - unspecified*	PROC 14
	Impregnation (continuous)	Solid - low dustiness	PROC 3
	Impregnation (batch)	Liquid	PROC 3
	Impregnation (batch)	Solid - unspecified*	PROC 3
	Calcination	Solid - low dustiness	PROC 2
	Calcination	Solid - high dustiness	PROC 1 and PROC 2
	Calcination	Solid - unspecified*	PROC 1 and PROC 2, PROC 3
	Reduction	Solid - high dustiness	PROC 1
	Sulphiding	Solid - unspecified*	PROC 1
	Stripping	Solid - unspecified*	PROC 1
	Stabilisation	Solid - high dustiness	PROC 1
	Screening	Solid - low dustiness	PROC 2
	Screening	Solid - medium dustiness	PROC 2 and PROC 4
	Screening	Solid - unspecified*	PROC 2
Fresh catalyst packaging	Filling operations	Solid - low dustiness	PROC 8a, PROC 8b and PROC 9
	Filling operations	Solid - medium dustiness	PROC 9
	Filling operations	Solid - high dustiness	PROC 2
	Filling operations	Solid - unspecified*	PROC 8a, PROC 8b and PROC 9
Maintenance & Cleaning (manufacturing)	Maintenance	Solid - low dustiness	PROC 2
	Maintenance	Solid - medium dustiness	PROC 2
	Maintenance	Solid - high dustiness	PROC 2
	Cleaning	Liquid	PROC 9
	Cleaning	Solid - low dustiness	PROC 2
	Cleaning	Solid - medium dustiness	PROC 2 and PROC 4
	Cleaning	Solid - high dustiness	PROC 2
Fresh catalyst storage	Storage	Solid - low dustiness	PROC 1
	Storage	Solid - medium dustiness	PROC 1

Contributative ES (Short description of process or activity)	Description	Physical form (substance)	PROC
Spent catalyst delivery & handling	Semi-bulk delivery	Solid – high, low, medium dustiness and liquid assessed	PROC 2
	Storage		PROC 2
	Transfer		PROC 8b
	Conveying		PROC 8b
Regeneration	Drying		PROC 2, PROC 3 and PROC 4
	Calcination		PROC 2 and PROC 1
	Screening		PROC 2
Regenerated Catalyst Packaging	Filling operations		PROC 9
Maintenance & Cleaning (regeneration)	Maintenance		PROC 2
	Cleaning		PROC 2
Regenerated catalyst storage	Storage		PROC2

* Where the form of the solid is unspecified, it has been assumed that a ‘medium’ dustiness form is present for the exposure assessment of the associated activity.

All initial exposure assessments have assumed no LEV, but where refinement of unacceptable exposure predictions was required, the assessment including LEV was carried out prior to the assessment with RPE of increasing efficiency (see MEASE outputs in Annex 14). Respiratory protective equipment in MEASE is defined by the ‘assigned protection factor’ (APF) as given in BS EN 529:2005.

Refinement of the basic worst-case parameters may be possible at the site specific level. Such information was, however, not available and may be subject to change. Therefore, the following assessments can only be considered as illustrative of the acceptable working practices during the manufacture of catalysts using copper dinitrate. Individual sites may need to carry out a further or modified assessment, including their own specific working practices not explicitly covered within the following assessment. Consideration of the working patterns and worker protection requirements need to be defined at a local level with a reasonable worst-case (RWC) approach taken with regards to assumptions on the expected exposure challenges faced by an individual worker during their normal working day (see 9.3.1.2.1).

i) RM delivery & handling includes activities which may involve both solid and liquid raw materials (RM). However, according to the data provided by the Copper Compound Consortium, only solid raw materials are handled by sites within the Consortium. For the development of a generic assessment for the delivery and handling of raw materials, there are 3 PROC codes associated with the delivery and handling activities (see **Table 90**), which are;

- 1 [Use in closed process, no likelihood of exposure. Industrial setting],
- 2 [Use in closed, continuous process with occasional controlled exposure]
- 8a [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities and
- 8b [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities].

Therefore, the GES will be limited to: **W-GES-CM(High)**, **W-GES-CM(Med)** and **W-GES-CM(Low)** defined by the exposure estimates for PROC 1, PROC 2, PROC 8a and PROC 8b. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 90**).

Table 90: Worker RMM proposals for the raw material delivery and handling activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Semi-bulk delivery	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO
		PROC 8a	NO	NO
		PROC 8b	NO	NO
Storage	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO
		PROC 1	NO	NO
Transfer	W-GES-CM(High)	PROC 2	YES	NO
		PROC 8a	YES	YES [4]
		PROC 8b	YES	YES [4]
	W-GES-CM(Med)	PROC 2	NO	NO
		PROC 8a	YES	NO
		PROC 8b	YES	NO
	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 8a	NO	NO
		PROC 8b	NO	NO
Conveying	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Med)	PROC 8a	YES	NO
		PROC 8b	YES	NO
	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 2	NO	NO

The above data suggest that for the majority of activities no RMM are required, with the exception of activities defined within PROC 8a and PROC 8b where solid compounds of high or medium dustiness are involved. For on-site risk assessments, caution should be applied where activities that do require RMM are identified and due consideration given to the total exposure estimates calculated for the daily activity of individual workers.

ii) Catalyst Manufacture may involve many activities and follow a typical process order as listed in the mapping provided by the ECMA, of which the following are detailed as relevant to the Copper Compound Consortium manufacturing sites;

- Dissolving
- Precipitating
- Filtrating
- Drying
- Mixing
- Forming
- Impregnation continuous/ batch
- Calcination (oxidation at elevated temperatures)
- Sulphiding

- Stripping
- Reduction
- Stabilisation
- Screening (adjusting particle size distribution)

The data provided by the Copper Compound Consortium is considered relevant to the development of a generic assessment for catalyst manufacture, which indicates that there are 8 PROC codes associated with the manufacture processing activities (see **Table 91**), which are;

- 1 [Use in closed process, no likelihood of exposure. Industrial setting],
- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting],
- 3 [Use in closed batch process (synthesis or formulation). Industrial setting],
- 4 [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting],
- 5 [Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)],
- 8a [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities],
- 8b [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] and
- 14 [Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting].

Therefore, all 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**, defined by the exposure estimates for PROCs 1, 2, 3, 4, 5, 8a, 8b and 14. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 91**).

Table 91: Worker RMM proposals for the manufacture process activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Dissolving	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 2	NO	NO
		PROC 8a	NO	NO
		PROC 8b	NO	NO
Precipitation	W-GES-CM(Liquid)	PROC 1	NO	NO
		PROC 2	NO	NO
		PROC 3	NO	NO
	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 2	NO	NO
		PROC 3	NO	NO
Filtrating	W-GES-CM(Liquid)	PROC 2	NO	NO
		PROC 3	NO	NO
		PROC 4	NO	NO
		PROC 8a	NO	NO
		PROC 8b	NO	NO
	W-GES-CM(Low)	PROC 2	NO	NO
		PROC 3	NO	NO
		PROC 4	NO	NO
		PROC 8a	NO	NO
		PROC 8b	NO	NO
Drying	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
		PROC 3	YES	NO
		PROC 8b	YES	NO
	W-GES-CM(Low)	PROC 1	NO	NO
Mixing & blending	W-GES-CM(High)	PROC 1	NO	NO
	W-GES-CM(Med)	PROC 3	YES	NO
		PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 5	NO	NO
	W-GES-CM(Med)	PROC 5	YES	NO
Forming	W-GES-CM(High)	PROC 14	YES	YES [4]
	W-GES-CM(Med)	PROC 14	YES	NO
	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 2	NO	NO
		PROC 8b	NO	NO
		PROC 14	NO	NO
Calcination	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Med)	PROC 1	NO	NO
		PROC 2	NO	NO
		PROC 3	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO
Impregnation (continuous)	W-GES-CM(Low)	PROC 3	NO	NO
Impregnation (batch)	W-GES-CM(Liquid)	PROC 3	NO	NO
	W-GES-CM(High)	PROC 3	YES	NO
Reduction	W-GES-CM(High)	PROC 1	NO	NO

Description	GES	PROC	LEV	RPE [APF]
Sulphiding	W-GES-CM(Med)	PROC 1	NO	NO
Stripping	W-GES-CM(Med)	PROC 1	NO	NO
Stabilisation	W-GES-CM(High)	PROC 1	NO	NO
Screening	W-GES-CM(Med)	PROC 2	NO	NO
		PROC 4	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO

Many of the processing activities within catalyst manufacture do not require extensive RMM, except for some activities where solid compounds of high and medium dustiness are present. According to these estimates, only situations involving PROC 14 activities with material that has high dustiness required personal respiratory protection apparatus. However, the above predictions are only made within the confines of the GES and represent only a portion of a worker's daily activity. Therefore, caution should be applied where activities that do require RMM are highlighted when considering the remainder of a worker's daily activity for an individual's risk assessment.

iii) Fresh Catalyst Packaging is limited to filling operations (transfer to transport containers) during which particulate emissions to air can be expected to be proportional to the dustiness of the physical form of the catalyst. According to the Copper Compound Consortium manufacturing sites, 4 PROC codes are required to define the activities, which are;

- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting],
- 8a [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities],
- 8b [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] and
- 9 [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting].

Also the information presented in **Table 92** suggests that only solid catalyst products are present at this point in the catalyst manufacture GES but that all levels; low, medium and high dustiness require assessment. Therefore, the GES will be limited to: **W-GES-CM(High)**, **W-GES-CM(Med)** and **W-GES-CM(Low)** defined by the exposure estimates for PROC 2, PROC 8a, PROC 8b and PROC 9. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 92**).

Table 92: Worker RMM proposals for the catalyst packing activity within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Filling operations	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 8a	YES	NO
		PROC 8b	YES	NO
		PROC 9	YES	NO
	W-GES-CM(Low)	PROC 8a	NO	NO
		PROC 8b	NO	NO
		PROC 9	NO	NO

The above data suggest that no RMM are required where the activities involve solid copper compounds with a low dustiness. For the activities defined by PROCs 2, 8a and 8b and 9; that are associated with solids of high or medium dustiness, generic LEV is required. As stated previously, the above predictions are made within the confines of the GES and represent only a portion of a worker's daily activity. An individual worker risk assessment would need to consider the impact of any activity requiring RMM alongside all other activities undertaken as part of their routine pattern of work.

iv) Maintenance & Cleaning (manufacturing) according to **Table 93** are limited to 2 PROC codes;

- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] and
- 4 [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting].

Also the physical form of the catalyst product present during this activity is limited to solids with medium and high dustiness. Therefore, the GES for this activity will be limited to **W-GES-CM(High)** and **W-GES-CM(Med)**. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 93**).

Table 93: Worker RMM proposals for the maintenance and cleaning activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Maintenance	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
	W-GES-CM(Low)	PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 2	NO	NO
Cleaning	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
		PROC 4	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 9	NO	NO

The above data suggest that for the majority of activities no RMM are required, except for generic LEV in 2 scenarios. However, caution should be applied where activities that do require RMM are highlighted when considering the remainder of a worker's daily activity for an individual's risk assessment.

v) Fresh catalyst storage involves the final product storage prior to use and is considered to be largely contained with some potential releases to air (particulates) but these will be very limited and only during the transfer to and from storage and covered within the handling activities. For these reasons, the Copper Compound Consortium catalyst manufacturing sites have concluded that this activity is described best by PROC code 1 [Use in closed process, no likelihood of exposure. Industrial setting]. The physical form of the product at this stage in the catalyst manufacture is considered to be a solid of low to medium dustiness only and will be covered by GES **W-GES-CM(Low)** and **W-GES-CM(Med)**. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 94**).

Table 94: Worker RMM proposals for the fresh catalyst storage activity within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Fresh catalyst storage	W-GES-CM(Med)	PROC 1	NO	NO
	W-GES-CM(Low)	PROC 1	NO	NO

The above data suggest that no RMM are required. However, on-site consideration of this activity should be made as part of the individual site risk assessment for specific worker or working patterns.

vi) Spent catalyst delivery & handling includes the following activities: semi-bulk delivery of spent catalyst (IBC, drums), storage of spent catalyst, emptying of containers of spent catalyst and conveying spent catalyst. The main activities may involve both solid and liquid raw materials (RM). For the development of a generic assessment there are 2 PROC codes associated with the delivery and handling of spent catalyst activity (see **Table 90**), which are;

- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] and
- 8b [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities].

All 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**, defined by the exposure estimates for PROC 2 and PROC 8b. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 95**).

Table 95: Worker RMM proposals for the raw material delivery and handling activities of spent catalyst within the manufacture exposure scenario

Description	GES	PROC	LEV	RPE [APF]
Storage & Semi-bulk delivery	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)		NO	NO
	W-GES-CM(Low)		NO	NO
	W-GES-CM(Liquid)		NO	NO
Transfer & Conveying	W-GES-CM(High)	PROC 8b	YES	YES [4]
	W-GES-CM(Med)		YES	NO
	W-GES-CM(Low)		NO	NO
	W-GES-CM(Liquid)		NO	NO

The above data suggest that for the majority of activities no RMM are required, with the exception of activities defined within PROC 8b where solid compounds of high or medium dustiness are involved. For on-site risk assessments, caution should be applied where activities that do require RMM are identified and due consideration given to the total exposure estimates calculated for the daily activity of individual workers.

vii) Regeneration (in situ/ex-situ) as a process step is assumed to follow a typical process order as listed in the mapping provided by the ECMA, of which the following are detailed as relevant to the Copper Compound Consortium manufacturing sites;

- Drying
- Calcination (oxidation at elevated temperatures)
- Screening

The data provided by the Copper Compound Consortium is considered relevant to the development of a generic assessment for catalyst manufacture, which indicates that there are 4 PROC codes associated with the manufacture processing activities (see **Table 91**), which are;

- 1 [Use in closed process, no likelihood of exposure. Industrial setting],
- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting],
- 3 [Use in closed batch process (synthesis or formulation). Industrial setting],
- 4 [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting],

All 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**, defined by the exposure estimates for PROCs 1, 2, 3 and 4. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 96**).

Table 96: Worker RMM proposals for the regeneration process activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Drying	W-GES-CM(High)	PROC 2	YES	NO
		PROC 3	YES	NO
		PROC 4	YES	YES [4]
	W-GES-CM(Med)	PROC 2	NO	NO
		PROC 3	YES	NO
		PROC 4	YES	NO
	W-GES-CM(Low)	PROC 2	NO	NO
		PROC 3	NO	NO
		PROC 4	NO	NO
	W-GES-CM(Liquid)	PROC 2	NO	NO
		PROC 3	NO	NO
		PROC 4	NO	NO
Calcination	W-GES-CM(High)	PROC 1	NO	NO
		PROC 2	YES	NO
	W-GES-CM(Med)	PROC 1	NO	NO
		PROC 2	NO	NO
	W-GES-CM(Low)	PROC 1	NO	NO
		PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 1	NO	NO
		PROC 2	NO	NO
Screening	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
	W-GES-CM(Low)	PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 2	NO	NO

Many of the processing activities within catalyst manufacture do not require extensive RMM, except for some activities where solid compounds of high and medium dustiness are present. According to these estimates, only situations involving PROC 4 activities with material that is high in dustiness required personal respiratory protection (RPE) apparatus. However, the above predictions are only made within the confines of the GES and represent only a portion of a worker's daily activity. Therefore, caution should be applied where activities that do require RMM are highlighted when considering the remainder of a worker's daily activity for an individual's risk assessment.

viii) Regenerated Catalyst Packaging is limited to filling operations (transfer to transport containers) during which particulate emissions to air can be expected to be proportional to the dustiness of the physical form of the catalyst. According to the Copper Compound Consortium manufacturing sites, a single PROC code is required to define the activity, which is;

- 9 [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting].

All 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**, defined by the exposure estimates for PROC 9. According to the MEASE outputs (presented in full in Annex 14) the following safe working practices may be defined within the parameters of this assessment (see **Table 97**).

Table 97: Worker RMM proposals for the regenerated catalyst packing activity within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Filling operations	W-GES-CM(High)	PROC 9	YES	YES [4]
	W-GES-CM(Med)	PROC 9	YES	NO
	W-GES-CM(Low)	PROC 9	NO	NO
	W-GES-CM(Liquid)	PROC 9	NO	NO

The above data suggest that RMMs are only required where the activities involve solid copper compounds with a high and medium dustiness where generic LEV is required. In addition with material that has high dustiness, personal respiratory protection (RPE) apparatus is required. As stated previously, the above predictions are made within the confines of the GES and represent only a portion of a worker's daily activity. An individual worker risk assessment would need to consider the impact of any activity requiring RMM alongside all other activities undertaken as part of their routine pattern of work.

ix) Maintenance & cleaning (regeneration) activities have the potential for releases to air and according to **Table 98** are limited to one PROC code. All 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**;

- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting]

Table 98: Worker RMM proposals for the maintenance and cleaning activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Maintenance & Cleaning	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
	W-GES-CM(Low)	PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 2	NO	NO

Many of the processing activities within catalyst manufacture do not require extensive RMM, except for some activities where solid compounds of high dustiness are present where generic LEV is required. However, the above predictions are only made within the confines of the GES and represent only a portion of a worker's daily activity. Therefore, caution should be applied where activities that do require RMM are highlighted when considering the remainder of a worker's daily activity for an individual's risk assessment.

x) Regenerated catalyst storage is the final process step and these activities have the potential for releases to air, which according to **Table 99** are limited to one PROC code. All 4 available GES will be required: **W-GES-CM(High/Med/Low/Liquid)**;

- 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting]

Table 99: Worker RMM proposals for the maintenance and cleaning activities within catalyst manufacture

Description	GES	PROC	LEV	RPE [APF]
Regenerated catalyst storage	W-GES-CM(High)	PROC 2	YES	NO
	W-GES-CM(Med)	PROC 2	NO	NO
	W-GES-CM(Low)	PROC 2	NO	NO
	W-GES-CM(Liquid)	PROC 2	NO	NO

Many of the processing activities within catalyst manufacture do not require extensive RMM, except for some activities where solid compounds of high dustiness are present where generic LEV is required. However, the above predictions are only made within the confines of the GES and represent only a portion of a worker's daily activity. Therefore, caution should be applied where activities that do require RMM are highlighted when considering the remainder of a worker's daily activity for an individual's risk assessment.

9.3.1.2.3 Exposure scenario for catalyst manufacture

GES3: Use of **copper dinitrate** in catalyst manufacture.

1. Title GES - copper dinitrate use in catalyst manufacture	
Life cycle	Formulation stage of copper dinitrate
Free short title	Catalysts manufacture using copper dinitrate
Systematic title based on use descriptor	SU: SU 03 - Uses of substances as such or in preparations at industrial sites SU 09 – Manufacture of fine chemicals SU 08 - Manufacture of bulk, large scale chemicals (including petroleum products) SU 10 - Formulation [mixing] of preparations and/or re-packaging (excluding alloys) PC: PC 2 [Adsorbents] PC 19 [Intermediate] PC 20 [Processing aids used in the chemical industry] ERC: spERC – Manufacture of metal-containing catalysts (ECMA) [modified by data from copper compound catalyst sector] PROC: PROC 1 [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2 [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 3 [Use in closed batch process (synthesis or formulation). Industrial setting] PROC 4 [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 5 [Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial setting] PROC 8a [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities] PROC 8b [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 9 [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting] PROC 14 [Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting]
Processes, tasks, activities covered (environment)	Catalysts manufacture

Processes, tasks, activities covered (workers)	Processes, tasks and activities include (as appropriate): − Raw material delivery and handling, − Catalyst manufacture: dissolving, precipitating, filtrating, drying, mixing, forming, impregnation, calcination, sulfiding, stripping, regeneration, reduction, stabilisation, coating and screening, loading of reactor (transfer from big bags/drums/containers). − Fresh catalyst packaging: filling operations, cleaning and maintenance and storage of final product.
2. Operational conditions and risk management measures (RMMs)	
2.1 Control of environmental exposure [E-GES-CM2.1/3.1]	
Environmental related free short title	Catalysts manufacture
Systematic title based on use descriptor (environment)	spERC – Manufacture of metal containing catalysts (ECMA 1.1a, v2.0) modified by measured data provided by catalyst manufacturers
Processes, tasks, activities covered (environment)	Catalysts manufacture
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts manufactured	
Maximum daily manufacture at a site	0.11 tonnes Cu per day [Tier 2] E-GES-CM2.1 9.29 tonnes Cu per day [Tier 3] E-GES-CM3.1
Maximum annual manufacture at a site	40 tonnes Cu per year [Tier 2] E-GES-CM2.1 3250 tonnes Cu per year [Tier 3] E-GES-CM3.1
Frequency and duration of catalyst manufacture	
Pattern of release to the environment	350 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d [Tier 2] E-GES-CM2.1 958100 m^3/d [Tier 3] E-GES-CM3.1
Dilution capacity, freshwater	10 (default) [Tier 2] E-GES-CM2.1 480 [Tier 3] E-GES-CM3.1
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
Various; closed-system, open-system, filtration, precipitation etc.,	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: RMMs assumed; 0.067% emission after on-site RMMs [WWTP] no off-site STP. **Air:** RMMs assumed; 0.025% emission. No emissions to soil.	
Organizational measures to prevent/limit release from site	
On-site WWTP	

Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	*Not relevant*
Discharge rate of the Municipal STP	*Not relevant*
Incineration of the sludge of the Municipal STP	*Not relevant*
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled off-site location for metal reclamation or disposal.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.2 Control of environmental exposure [E-GES-CM2.2/3.2]	
Environmental related free short title	Catalysts manufacture
Systematic title based on use descriptor (environment)	spERC – Manufacture of metal containing catalysts (ECMA 1.1a, v2.0) modified by measured data provided by catalyst manufacturers
Processes, tasks, activities covered (environment)	Catalysts manufacture
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts manufactured	
Maximum daily manufacture at a site	1.43 tonnes Cu per day [Tier 2] E-GES-CM2.2 3.14 tonnes Cu per day [Tier 3] E-GES-CM3.2
Maximum annual manufacture at a site	500 tonnes Cu per year [Tier 2] E-GES-CM2.2 1100 tonnes Cu per year [Tier 3] E-GES-CM3.2
Frequency and duration of catalyst manufacture	
Pattern of release to the environment	350 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d [Tier 2] E-GES-CM2.2 958100 m^3/d [Tier 3] E-GES-CM3.2
Dilution capacity, freshwater	10 (default) [Tier 2] E-GES-CM2.2 480 [Tier 3] E-GES-CM3.2
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
Various; closed-system, open-system, filtration, precipitation etc.,	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: RMMs assumed; 0.067% emission to waste water after on-site RMMs [WWTP] with release via off-site municipal STP (92% efficiency assumed). **Air:** RMMs assumed; 0.025% emission. No emissions to soil.	
Organizational measures to prevent/limit release from site	
On-site WWTP with discharge to off-site municipal STP	

Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated and results in restricted tonnage due to risk in soil compartment being triggered when municipal STP is used.
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling. Solids waste from municipal STP disposed of to land or in accordance with local waste regulations.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.3 Control of worker exposure contributing to exposure scenario (W-GES-CM(High))	
Workers related free short title	Catalysts manufacture:
Use descriptor covered	PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 3: [Use in closed batch process (synthesis or formulation). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8a: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 9: [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting] PROC 14: [Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting]
Processes, tasks, activities covered	PROC 1: for activities within; - RM delivery & handling includes activities: • Semi-bulk delivery of solid RM (bags, drums) • Storage of solid RM • Conveying RM (transport to machine for processing) - Catalyst Manufacture: • Drying • Mixing • Calcination (oxidation at elevated temperatures) • Reduction • Stabilisation - Regeneration • Calcination PROC 2: for activities within; - RM delivery & handling includes activities: • Semi-bulk delivery of solid RM (bags,

	drums) • Storage of solid RM • Conveying RM (transport to machine for processing) - Catalyst Manufacture: • Drying • Calcination (oxidation at elevated temperatures) - Fresh Catalyst Packaging: • Filling operations - Maintenance & Cleaning (manufacturing): • Maintenance • Cleaning - Spent catalyst delivery and handling • Semi-bulk delivery • Storage - Regeneration • Drying • Calcination • Screening - Maintenance & Cleaning (regeneration) • Maintenance • Cleaning - Regenerated catalyst storage • Storage PROC 3: for activities within; - Regeneration • Drying PROC 4: for activities within; - Regeneration • Drying PROC 8a: for activities within; - RM delivery & handling includes activities: • Transfer of RM from delivery containers into hopper or central supply system PROC 8b : for activities within; - RM delivery & handling includes activities: • Transfer of RM from delivery containers into hopper or central supply system - Spent catalyst delivery & handling includes activities: • Transfer • Conveying PROC 9: for activities within; - Regenerated catalyst packaging: • Filling operations PROC 14: for activities within; - Catalyst Manufacture: • Forming
Assessment Method	Estimation of exposure based on predicted data using MEASE

Product characteristic	
Specific to manufacture source: Solid (High dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	Local generic LEV not required
PROC 2	Local generic LEV required (LEV generic, ECETOC reference)
PROC 3	Local generic LEV required (LEV generic, ECETOC reference)
PROC 4	Local generic LEV required (LEV generic, ECETOC reference)
PROC 8a	Local generic LEV required (LEV generic, ECETOC reference)
PROC 8b	Local generic LEV required (LEV generic, ECETOC reference)
PROC 9	Local generic LEV required (LEV generic, ECETOC reference)
PROC 14	Local generic LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	Not required
PROC 2	Not required
PROC 3	Not required
PROC 4	RPE (APF 4) required.
PROC 8a	RPE (APF 4) required.
PROC 8b	RPE (APF 4) required.
PROC 9	RPE (APF 4) required.
PROC 14	RPE (APF 4) required.
2.4 Control of worker exposure contributing to exposure scenario [W-GES-CM(Med)]	
Workers related free short title	Catalysts manufacture:
Use descriptor covered	PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 3: [Use in closed batch process (synthesis or formulation). Industrial setting] PROC 4: [Use in batch and other process (synthesis)

	where opportunity for exposure arises. Industrial setting] PROC 5: [Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial setting] PROC 8a: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 9: [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting] PROC 14: [Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting]
Processes, tasks, activities covered	PROC 1: for activities within; - Catalyst Manufacture: • Sulphiding • Stripping • Calcination - Fresh catalyst storage • Storage [fresh catalyst] PROC 2: for activities within; - RM delivery & handling includes activities: • Transfer of RM from delivery containers into hopper or central supply system - Catalyst Manufacture: • Drying • Screening • Mixing & blending • Calcination • Screening - Maintenance & Cleaning (manufacturing): • Maintenance • Cleaning - Spent catalyst delivery and handling • Semi-bulk delivery • Storage - Regeneration • Drying • Calcination • Screening - Maintenance & Cleaning (regeneration): • Maintenance • Cleaning - Regenerated catalyst storage • Storage PROC 3: for activities within; - Catalyst Manufacture: • Drying • Mixing • Calcination (oxidation at elevated temperatures) • Impregnation batch

	• Calcination - Regeneration • Drying <u>PROC 4:</u> for activities within; - Catalyst Manufacture: • Screening - Maintenance & Cleaning (manufacturing): • Cleaning Regeneration • Drying <u>PROC 5</u>: for activities within; - Catalyst Manufacture: • Mixing & blending <u>PROC 8a:</u> for activities within; - RM delivery & handling includes activities: • Transfer of RM from delivery containers into hopper or central supply system • Conveying RM (transport to machine for processing) - Fresh Catalyst Packaging: • Filling operations <u>PROC 8b:</u> for activities within; - RM delivery & handling includes activities: • Transfer of RM from delivery containers into hopper or central supply system • Conveying RM (transport to machine for processing) - Catalyst Manufacture: • Drying - Fresh Catalyst Packaging: • Filling operations - Spent catalyst delivery & handling includes activities: • Transfer • Conveying <u>PROC 9</u>: for activities within; - Fresh Catalyst Packaging: • Filling operations - Regenerated catalyst packaging: • Filling operations <u>PROC 14:</u> for activities within; - Catalyst Manufacture: • Forming
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Solid (Medium dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily.	

> 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	Local generic LEV not required
PROC 2	Local generic LEV not required
PROC 3	Local generic LEV required (LEV generic, ECETOC reference)
PROC 4	Local generic LEV required (LEV generic, ECETOC reference)
PROC 5	Local generic LEV required (LEV generic, ECETOC reference)
PROC 8a	Local generic LEV required (LEV generic, ECETOC reference)
PROC 8b	Local generic LEV required (LEV generic, ECETOC reference)
PROC 9	Local generic LEV required (LEV generic, ECETOC reference)
PROC 14	Local generic LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	Not required
PROC 2	Not required
PROC 3	Not required
PROC 4	Not required
PROC 5	Not required
PROC 8a	Not required
PROC 8b	Not required
PROC 9	Not required
PROC 14	Not required
2.5 Control of worker exposure contributing to exposure scenario [W-GES-CM(Low)]	
Workers related free short title	Catalysts manufacture:
Use descriptor covered	PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 3: [Use in closed batch process (synthesis or formulation). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8a: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities] PROC 8b: [Transfer of substance or preparation

	(charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 9: [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting] PROC 14: [Production of preparations or articles by tabletting, compression, extrusion, pelletisation. Industrial setting]
Processes, tasks, activities covered	PROC 1: for activities within; - RM delivery & handling includes activities: • Storage of solid RM • Transfer of RM from delivery containers into hopper or central supply system • Conveying RM (transport to machine for processing) - Catalyst Manufacture: • Dissolving • Precipitating • Filtrating • Forming • Drying - Fresh catalyst storage • Storage (fresh catalyst) PROC 2: for activities within; - RM delivery & handling includes activities: • Semi-bulk delivery • Storage of solid RM • Transfer of RM from delivery containers into hopper or central supply system • Conveying RM (transport to machine for processing) - Catalyst Manufacture: • Forming • Precipitating • Dissolving • Filtrating • Calcination (oxidation at elevated temperatures) • Screening - Maintenance & Cleaning (manufacturing): • Maintenance • Cleaning - Spent catalyst delivery and handling • Semi-bulk delivery • Storage - Regeneration • Drying • Calcination • Screening - Maintenance & Cleaning (regeneration): • Maintenance • Cleaning - Regenerated catalyst storage • Storage PROC 3: for activities within; - Catalyst Manufacture:

	• Precipitating • Filtrating • Impregnation (continuous/batch) • Calcination - Regeneration • Drying <u>PROC 4</u>: for activities within; - Catalyst Manufacture: • Filtrating - Regeneration • Drying <u>PROC 8a</u>: for activities within; - RM delivery & handling includes activities: • Semi-bulk delivery of solid RM (bags, drums) • Transfer of RM from delivery containers into hopper or central supply system - Catalyst Manufacture: • Dissolving • Filtrating - Fresh Catalyst Packaging: • Filling operations <u>PROC 8b:</u> for activities within for activities within; - RM delivery & handling includes activities: • Semi-bulk delivery of solid RM (bags, drums) • Transfer of RM from delivery containers into hopper or central supply system - Catalyst Manufacture: • Dissolving • Forming • Filtrating - Fresh Catalyst Packaging: • Filing operations - Spent catalyst delivery & handling includes activities: • Transfer • Conveying <u>PROC 9</u>: for activities within; - Fresh Catalyst Packaging: • Filling operations - Regenerated catalyst packaging: • Filling operations <u>PROC 14</u>: for activities within; - Catalyst Manufacture: • Forming
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Solid (Low dustiness)	
Amounts used	

Varying (risk limited by exposure not quantities)		
Frequency and duration of use/exposure		
Daily. > 4 hours		
Human factors not influenced by risk management		
Respiration volume under conditions of use		MEASE Default
Room size and ventilation rate		MEASE Default
Area of skin contact with the substance under conditions of use		MEASE Default
Body weight		70 kg
Other given operational conditions affecting workers exposure		
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact		
Technical conditions and measures at process level (source) to prevent release		
Activity controlled in accordance with PROC descriptor		
Technical conditions and measures to control dispersion from source towards the worker		
PROC 1	Local generic LEV not required	
PROC 2	Local generic LEV not required	
PROC 3	Local generic LEV not required	
PROC 4	Local generic LEV not required	
PROC 8a	Local generic LEV not required	
PROC 8b	Local generic LEV not required	
PROC 9	Local generic LEV not required	
PROC 14	Local generic LEV not required	
Organisational measures to prevent /limit releases, dispersion and exposure		
Best available techniques and good hygiene measures assumed		
Conditions and measures related to personal protection, hygiene and health evaluation		
Based on classification (all PROCs)		
Eye protection		Required (goggles or face shield)
Skin protection		Required (overalls and gloves)
Based on risk assessment (PROC related)		
PROC 1	Not required	
PROC 2	Not required	
PROC 3	Not required	
PROC 4	Not required	
PROC 8a	Not required	
PROC 8b	Not required	
PROC 9	Not required	
PROC 14	Not required	
2.6 Control of worker exposure contributing to exposure scenario [W-GES-CM(Liquid)]		
Workers related free short title		Catalysts manufacture:
Use descriptor covered		PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 3: [Use in closed batch process (synthesis or formulation). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 5: [Mixing or blending in batch processes for formulation of preparations and articles (multistage

	and/or significant contact) Industrial setting] PROC 8a: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 9: [Transfer of substance or preparation into small containers (dedicated filling line, including weighing). Industrial setting]
Processes, tasks, activities covered	PROC 1: for activities within; - Catalyst Manufacture: • Precipitating • Filtrating PROC 2: for activities within; - Catalyst Manufacture: • Precipitating • Filtrating - Maintenance & Cleaning (regeneration): • Maintenance • Cleaning - Spent catalyst delivery and handling • Semi-bulk delivery • Storage - Regeneration • Drying • Calcination • Screening - Regenerated catalyst storage • Storage PROC 3: for activities within; - Catalyst Manufacture: • Precipitating • Filtrating • Impregnation batch - Regeneration • Drying PROC 4: for activities within; - Catalyst Manufacture: • Filtrating - Regeneration • Drying PROC 5: for activities within; - Catalyst Manufacture: • Mixing • Blending PROC 8a and 8b: for activities within; - Catalyst Manufacture: • Filtrating PROC 8b (only): for activities within - Spent catalyst delivery & handling includes activities:

	• Transfer • Conveying PROC 9: for activities within; - Maintenance & Cleaning (manufacturing): • Cleaning
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Liquid (aqueous solution, slurry)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	Local generic LEV not required
PROC 2	Local generic LEV not required
PROC 3	Local generic LEV not required
PROC 4	Local generic LEV not required
PROC 5	Local generic LEV not required
PROC 8a	Local generic LEV not required
PROC 8b	Local generic LEV not required
PROC 9	Local generic LEV not required
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	Not required
PROC 2	Not required
PROC 3	Not required
PROC 4	Not required
PROC 5	Not required
PROC 8a	Not required
PROC 8b	Not required
PROC 9	Not required
3. Exposure and risk mitigation	

Environment

All tables:

* mean of agricultural soil and grassland (180 days)

**including a country-specific regional background;

Freshwater = median value of 2.9 µg dissolved Cu/L

Freshwater sediment = not applicable

Marine = median value of 1.1 µg dissolved Cu/L

Marine sediment = median value 16.1 mg Cu/kg dw

Soil = median value of 24.4 mg Cu/kg dw

Generic exposure: spERC: Metal compound formulation amended for catalyst manufacture

E-GES-CM2.1: Maximum tonnage 40 tonnes per annum, 350 days production [Tier 2]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.003	0.0054	0.7
	Sediment	mg Cu/kg dw	87.1	80	80	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg Cu/kg dw	676	8.0	24.1	0.04
Terrestrial	Soil	mg Cu/kg dw	64.6	0.0044	24.4	0.4
	Groundwater	mg Cu/l	-	0.000002	-	-

E-GES-CM3.1: Maximum tonnage 3250 tonnes per annum, 350 days production [Tier 3]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0045	0.0072	0.9
	Sediment	mg Cu/kg dw	87.1	29.5	29.5	0.3
Marine	Aquatic	mg Cu/l	-	-	-	-
	Sediment	mg Cu/kg dw	-	-	-	-
Terrestrial	Soil	mg Cu/kg dw	64.6	0.311	24.7	0.4
	Groundwater	mg Cu/l	-	0.02	-	-

E-GES-CM2.2: Maximum tonnage 500 tonnes per annum, 350 days production [Tier 2]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0026	0.0054	0.7
	Sediment	mg Cu/kg dw	87.1	80	80	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0003	0.0014	0.2
	Sediment	mg Cu/kg dw	676	8.01	24.1	0.04
Terrestrial	Soil	mg Cu/kg dw	64.6	18.6	43	0.7
	Groundwater	mg Cu/l	-	0.009	-	-

E-GES-CM3.2: Maximum tonnage 1100 tonnes per annum, 350 days production [Tier 3]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0001	0.003	0.4
	Sediment	mg Cu/kg dw	87.1	0.837	0.837	0.01

Marine	**Aquatic**	mg Cu/l	-	-	-	-
	Sediment	mg Cu/kg dw	-	-	-	-
Terrestrial	**Soil**	mg Cu/kg dw	64.6	36.1	60.5	0.9
	Groundwater	mg Cu/l	-	0.02	-	-

Worker exposure: Indoor activities the manufacture of catalysts containing **copper dinitrate**

RM DELIVERY & HANDLING INCLUDES ACTIVITIES:						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Semi-bulk delivery	**W-GES-CM(High)**	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	YES	NO	0.125
	W-GES-CM(Low)	**> 4**	**PROC 2**	NO	NO	0.035
		> 4	**PROC 8a**	NO	NO	0.55
		> 4	**PROC 8b**	NO	NO	0.125
Storage	**W-GES-CM(High)**	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	YES	NO	0.125
	W-GES-CM(Low)	**> 4**	**PROC 2**	NO	NO	0.035
		> 4	**PROC 1**	NO	NO	0.023
Transfer	**W-GES-CM(High)**	**> 4**	**PROC 8a**	YES	YES [10]	0.55
		> 4	**PROC 8b**	YES	YES [4]	0.338
	W-GES-CM(Med)	**> 4**	**PROC 2**	NO	NO	0.525
		> 4	**PROC 8a**	YES	NO	0.52
		> 4	**PROC 8b**	YES	NO	0.275
	W-GES-CM(Low)	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 8a**	NO	NO	0.55
		> 4	**PROC 8b**	NO	NO	0.125
Conveying	**W-GES-CM(High)**	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	YES	NO	0.125
		> 4	**PROC 8a**	YES	YES [10]	0.55
		> 4	**PROC 8b**	YES	YES [4]	0.338
	W-GES-CM(Med)	**> 4**	**PROC 8a**	YES	NO	0.52
		> 4	**PROC 8b**	YES	NO	0.275
	W-GES-CM(Low)	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 8a**	NO	NO	0.55
		> 4	**PROC 8b**	NO	NO	0.125
CATALYST MANUFACTURE MAY INVOLVE MANY ACTIVITIES:						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Dissolving	**W-GES-CM(Low)**	**> 4**	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 8a**	NO	NO	0.55

		> 4	PROC 8b	NO	NO	0.125
Precipitation	**W-GES-CM(Liquid)**	> 4	**PROC 1**	NO	NO	0.126
		> 4	**PROC 2**	NO	NO	0.252
		> 4	**PROC 3**	NO	NO	0.135
	W-GES-CM(Low)	> 4	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 3**	NO	NO	0.113
Filtrating	**W-GES-CM(Liquid)**	> 4	**PROC 1**	NO	NO	0.126
		> 4	**PROC 2**	NO	NO	0.252
		> 4	**PROC 3**	NO	NO	0.135
		> 4	**PROC 4**	NO	NO	0.301
		> 4	**PROC 8a**	NO	NO	0.30
		> 4	**PROC 8b**	NO	NO	0.261
	W-GES-CM(Low)	> 4	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 3**	NO	NO	0.113
		> 4	**PROC 4**	NO	NO	0.525
		> 4	**PROC 8a**	NO	NO	0.55
		> 4	**PROC 8b**	NO	NO	0.125
Drying	**W-GES-CM(High)**	> 4	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.125
	W-GES-CM(Med)	> 4	**PROC 2**	NO	NO	0.525
		> 4	**PROC 3**	YES	NO	0.113
		> 4	**PROC 8b**	YES	NO	0.275
	W-GES-CM(Low)	> 4	**PROC 1**	NO	NO	0.023
Mixing & blending	**W-GES-CM(High)**	> 4	**PROC 1**	NO	NO	0.023
	W-GES-CM(Med)	> 4	**PROC 2**	NO	NO	0.525
		> 4	**PROC 3**	YES	NO	0.113
		> 4	**PROC 5**	YES	NO	0.525
	W-GES-CM(Liquid)	> 4	**PROC 5**	NO	NO	0.0.30
Forming	**W-GES-CM(High)**	> 4	**PROC 14**	YES	YES [4]	0.275
	W-GES-CM(Med)	> 4	**PROC 14**	YES	NO	0.125
	W-GES-CM(Low)	> 4	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.035
		> 4	**PROC 8b**	NO	NO	0.125
		> 4	**PROC 14**	NO	NO	0.125
Impregnation (batch)	**W-GES-CM(Liquid)**	> 4	**PROC 3**	NO	NO	0.135
	W-GES-CM(Med)	> 4	**PROC 3**	YES	NO	0.113
Impregnation (continuous)	**W-GES-CM(Low)**	> 4	**PROC 3**	NO	NO	0.113
Calcination	**W-GES-CM(High)**	> 4	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	> 4	**PROC 1**	NO	NO	0.023
		> 4	**PROC 2**	NO	NO	0.525
		> 4	**PROC 3**	YES	NO	0.113
	W-GES-CM(Low)	> 4	**PROC 2**	NO	NO	0.035
Reduction	**W-GES-CM(High)**	> 4	**PROC 1**	NO	NO	0.023
Stabilisation	**W-GES-CM(High)**	> 4	**PROC 1**	NO	NO	0.023
Screening	**W-GES-CM(High)**	> 4	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	> 4	**PROC 2**	NO	NO	0.525
		> 4	**PROC 4**	YES	NO	0.525
	W-GES-CM(Low)	> 4	**PROC 2**	NO	NO	0.035

FRESH CATALYST PACKAGING:						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Filling operations	**W-GES-CM(High)**	**> 4**	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	**> 4**	**PROC 8a**	YES	NO	0.55
		> 4	**PROC 8b**	YES	NO	0.275
		> 4	**PROC 9**	YES	NO	0.525
	W-GES-CM(Low)	**> 4**	**PROC 8a**	NO	NO	0.55
		> 4	**PROC 8b**	NO	NO	0.125
		> 4	**PROC 9**	NO	NO	0.125
MAINTENANCE & CLEANING (MANUFACTURING):						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Maintenance	**W-GES-CM(High)**	**> 4**	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	**> 4**	**PROC 2**	NO	NO	0.525
	W-GES-CM(Low)	**> 4**	**PROC 2**	NO	NO	0.035
Cleaning	**W-GES-CM(High)**	**> 4**	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	**> 4**	**PROC 2**	NO	NO	0.525
		> 4	**PROC 4**	YES	NO	0.525
	W-GES-CM(Low)	**> 4**	**PROC 2**	NO	NO	0.035
	W-GES-CM(Liquid)	**> 4**	**PROC 9**	NO	NO	0.261
FRESH CATALYST STORAGE:						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Fresh catalyst storage	**W-GES-CM(Med)**	**> 4**	**PROC 1**	NO	NO	0.023
	W-GES-CM(Low)	**> 4**	**PROC 1**	NO	NO	0.023
Spent catalyst delivery & handling						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Storage & Semi-bulk delivery	**W-GES-CM(High)**	**> 4**	**PROC 2**	YES	NO	0.125
	W-GES-CM(Med)	**> 4**		NO	NO	0.525
	W-GES-CM(Low)	**> 4**		NO	NO	0.035
	W-GES-CM(Liquid)	**> 4**		NO	NO	0.252
Transfer & Conveying	**W-GES-CM(High)**	**> 4**	**PROC 8b**	YES	YES [4]	0.338
	W-GES-CM(Med)	**> 4**		YES	NO	0.275
	W-GES-CM(Low)	**> 4**		NO	NO	0.125
	W-GES-CM(Liquid)	**> 4**		NO	NO	0.261
Regeneration						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Drying	**W-GES-CM(High)**	**> 4**	**PROC 2**	YES	NO	0.125
		> 4	**PROC 3**	YES	NO	0.113
		> 4	**PROC 4**	YES	YES [4]	0.650
	W-GES-CM(Med)	**> 4**	**PROC 2**	NO	NO	0.525

		> 4	PROC 3	YES	NO	0.113
		> 4	PROC 4	YES	NO	0.525
	W-GES-CM(Low)	> 4	PROC 2	NO	NO	0.035
		> 4	PROC 3	NO	NO	0.113
		> 4	PROC 4	NO	NO	0.525
	W-GES-CM(Liquid)	> 4	PROC 2	NO	NO	0.252
		> 4	PROC 3	NO	NO	0.135
		> 4	PROC 4	NO	NO	0.301
Calcination	W-GES-CM(High)	> 4	PROC 1	NO	NO	0.023
		> 4	PROC 2	YES	NO	0.125
	W-GES-CM(Med)	> 4	PROC 1	NO	NO	0.023
		> 4	PROC 2	NO	NO	0.525
	W-GES-CM(Low)	> 4	PROC 1	NO	NO	0.023
		> 4	PROC 2	NO	NO	0.035
	W-GES-CM(Liquid)	> 4	PROC 1	NO	NO	0.126
		> 4	PROC 2	NO	NO	0.252
Screening	W-GES-CM(High)	> 4	PROC 2	YES	NO	0.125
	W-GES-CM(Med)	> 4	PROC 2	NO	NO	0.525
	W-GES-CM(Low)	> 4	PROC 2	NO	NO	0.035
	W-GES-CM(Liquid)	> 4	PROC 2	NO	NO	0.252
Regenerated Catalyst Packaging						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Filling operations	W-GES-CM(High)	> 4	PROC 9	YES	YES [4]	0.525
	W-GES-CM(Med)	> 4	PROC 9	YES	NO	0.525
	W-GES-CM(Low)	> 4	PROC 9	NO	NO	0.125
	W-GES-CM(Liquid)	> 4	PROC 9	NO	NO	0.261
Maintenance & Cleaning (regeneration)						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Maintenance & Cleaning	W-GES-CM(High)	> 4	PROC 2	YES	NO	0.125
	W-GES-CM(Med)	> 4	PROC 2	NO	NO	0.525
	W-GES-CM(Low)	> 4	PROC 2	NO	NO	0.035
	W-GES-CM(Liquid)	> 4	PROC 2	NO	NO	0.252
Regenerated catalyst storage						
Description	**GES**	**Duration of activity [h/d]**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Regenerated catalyst storage	W-GES-CM(High)	> 4	PROC 2	YES	NO	0.125
	W-GES-CM(Med)	> 4	PROC 2	NO	NO	0.525
	W-GES-CM(Low)	> 4	PROC 2	NO	NO	0.035
	W-GES-CM(Liquid)	> 4	PROC 2	NO	NO	0.252

4. Guidance to evaluate whether a site works inside the boundaries set by the ES

Environment

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Workers

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

It should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

9.3.1.3 Generic exposure scenario development – Catalyst 'In use' phase

The 'in-use' phase of the catalyst lifecycle may or may not take place at the site of manufacture, and includes the actual use and post-use (recovery/recycling) processes as outlined within the ECMA catalysts sector mapping information. For each of the processes

- Use,
- Recycling*

these activities may require a manufacture assessment under REACH for either* ***copper dinitrate* *or other substance generated, recovered and isolated as part of the DU. However, if these activities are deemed to be waste this may be considered outside of REACH.*

the environment and worker exposure scenarios are concerned with the underlying activities that determine the environmental emission routes or highlight any concerns for worker health. Therefore, each process step and expected activities are considered further, according to the mapping information supplied (see Annex 13), with respect to the potential for;

- emissions to air and waste water for the environment and
- dermal and inhalation exposure of workers.

9.3.1.3.1 Environmental Generic Exposure Scenario for Catalyst 'In-use' Phase [E-GES-CU]

The downstream use of catalysts containing copper compounds can be further divided into 'in-use' and 'recycling' steps; any regeneration (in-situ or ex-situ) has been considered as part of the manufacturing process of catalysts.

In-use, can be further broken down into 6 process steps of;

i) Reactor loading

ii) Use (in reactor)

iii) Reactor unloading

iv) Maintenance/cleaning

v) Spent/regenerated catalyst storage

vi) Recycling

i) Reactor loading can involve any of the typical activities listed as: batch loading (including inspection), continuous loading and liquid systems. All of these activities have the potential for release to the air compartments as particulates/dusts (solid RM) or from evaporation (liquid RMs) during transfer or spills. The main concern for the environmental releases of copper compounds will be emissions to air via particulates as the volatility of these compounds is not expected to be of concern. Air filters or extraction systems as RMMs are expected to be fitted to all locations where evaporation or particulate releases are likely to occur. Direct release to waste water is unlikely unless due to spillage/leakage during liquid storage. Such emission would not be routine and procedures should be in place to recover large spillages/leakages, with small scale spills/leaks inclusive of the cleaning and maintenance activities covered during catalyst manufacture.

ii) Use (in reactors) is considered a closed process and no intentional releases to the environment are considered likely.

iii) Reactor unloading can involve either continuous or batch processes. As for loading, the compartment of concern is air and, in all cases, filtration and dust extraction within the facilities where these process steps take place can be expected as normal practice.

iv) Maintenance activity is likely to result in emissions via air and waste water. The presence of air RMMs will depend on the location of the activity, but since air filters/dust extraction are assumed during manufacture processes where particulates are likely to be released [and require cleaning activities to take place], the logical assumption is that air RMMs will be present during the maintenance cleaning step. Waste water treatment is also as assumed to be present for this process step where releases to waste water occur.

v) Spent/regenerated catalyst storage involves the final storage prior to recovery or re-use and is considered to be largely contained with some potential releases to air (particulates) during transfer to and from storage and is covered within the handling activities.

In-situ regeneration *is an optional process (not routine for all catalysts manufacturers) and air is the only compartment of concern, with filtration devices present where applicable. This* *process is <u>not covered</u> in the assessment below as it is either a waste/recovery step (outside of REACH) or part of the manufacturing assessment and is covered in Section 9.3.1.2.3).*

vi) Recycling can be considered as either a recovery or waste activity and it is the responsibility of the downstream user to define which of these it is and ensure the correct regulatory measures are applied (see ECMA position paper, discussed 2012 in Section 9.3.1.2). In this GES, the recycling of catalysts containing copper compounds has been considered a recovery step and 4 potential process steps have been identified by the catalyst sector;

i) Spent catalyst delivery & handling

ii) Pyrometallurgical recycling

iii) Hydrometallurgical recycling

iv) End-product storage

i) Spent catalyst delivery & handling involves the following typical activities: semi-bulk delivery of spent catalyst (IBC, drums), storage of spent catalyst, emptying of containers of spent catalyst and conveying spent catalyst. The main release for these activities will be to air, which is managed by the presence of air filters where applicable.

ii) Pyrometallurgical recycling involves the following activities: screening, calcination (oxidation at elevated temperatures), smelting, filling, maintenance and cleaning. Again, the main releases are to air, which are managed by the presence of air filters where applicable. There is also the potential for releases to waste water during maintenance and cleaning activity. These are expected to pass through a waste water treatment processes.

iii) Hydrometallurgical recycling has been listed within the ECMA use mapping for the catalyst sector, but no information on the activities has been provided.

iv) End-product storage of the final product is considered not to result in any releases to the environment.

<u>Exposure pathways</u>

Multiple exposure scenarios (ES) for the DU of catalysts need to take account of the potential scale of use, ranging from the large industrial sites with on-site waste treatment to smaller sites where emissions to water pass to a municipal STP. It is also possible for some catalyst use to take place without emissions to waste water. Therefore, in considering the process steps outlined above for catalyst use, three ES are required that allow for;

- No waste water emissions
- Waste water to pass through a treatment process (on-site WWTP or off-site STP), and
- Waste water to pass through two waste water treatment steps (on-site WWTP with release via municipal STP).

Despite the limited routes of environmental exposure demonstrated within the mapping information, using the available guidance for the exposure assessments under REACH, the catalyst sector has listed the following ERC codes: 1[Production], 4 [Use], 6a [Use] and 6b [Use] as shown below;

Environmental Exposure	**ERC**			
	1	**4**	**6a**	**6b**
Life cycle stage (LCS)	Production	Use	Use	Use
Containment	Open/closed	Open/closed	Open/closed	Open/closed
Type of use in LCS	N/A	Processing aid	Intermediate	Reactive processing aid
Dispersion of emission sources	Industrial	Industrial	Industrial	Industrial
Indoor/outdoor	Indoor	Indoor	Indoor	Indoor
Release promotion during service life	N/A	N/A	N/A	N/A
Amount of substance used as input to emission calculation	100% M/I volume	100% M/I volume	100% M/I volume	100% M/I volume
Fraction used by largest customer - main source	1	1	1	1
Release times per year	20-300	20-300	20-300	20-300
Default release to air from process [%]	5	95*	5	0.1
Default release to water from process [%]	6	100**	2	5
Default release to soil from process [%]+	0.01	5	0.1	0.025
Dilution to be applied for PEC aquatic derivation (freshwater)	10 (18000 m^3/d)	10 (18000 m^3/d)	10 (18000 m^3/d)	10 (18000 m^3/d)

*- where substance highly volatile **- where substance highly soluble + - regional exposure only

ERC1 is intended for activities associated with production. This has already been considered in the production of copper dinitrate and is therefore not repeated here.

In considering the default values presented for ERC 4, copper compounds are neither volatile nor highly soluble. As catalyst use is likely to be part of a larger chemical process, where controls are likely to be equivalent to those in place during manufacture, it is questionable as to whether ERC 4 is appropriate for catalyst use. This is also supported by the mapping information, which suggests that waste water releases of copper compounds will be restricted to cleaning and maintenance activities, but where contact with the suggested 100% of the copper compounds used would not be practical. Also the use of catalysts includes recycling of the catalyst, which would not be necessary if 100% of the catalyst used was released via waste water. Therefore, the Tier 1 assessment of the catalysts in-use phase has *only* used the default ERC 6a and 6b assuming a reasonable worst-case of 220 release days per annum (allows for a generic 6 weeks of plant closure) with an on-site WWTP (minimum) or with further removal by discharge to an additional off-site STP.

Currently there is no spERC specific to the downstream use of catalysts but in previous copper compound assessments the 'Industrial use of metal compounds' spERC (version 1.1, 2010) developed by ARCHE consultants was used. This spERC is considered appropriate for both open and closed systems using both wet and dry processes and is based on information gathered for metal compounds used in various industrial activities [Industrial use of metal compounds in the following sectors: crystal manufacture, leather tanning, pigments, paints, coatings, plastics, rubber and textiles].

The spERC has been developed by considering how the existing appropriate RMMs can be used to achieve the necessary reduction in emissions. For air emission the spERC value is based on the findings that the RMMs for air are present in >50% of the sites including:

- Electrostatic precipitation
- Fabric or bag filters (most common)
- Ceramic filters
- Wet scrubbers (most common)
- Dry or semi-dry scrubbers

From the available data, the maximum 90th percentile reported site-specific release factor to air (after RMM) for the activities investigated was 0.1%

For the releases to waste water the spERC value is based on the RMMs for water present in >50% of the sites including:

- Chemical precipitation
- Sedimentation
- Filtration
- Electrolysis

The 50th percentile of the reported site-specific removal efficiency for 12 sites was 95% (50.00% – 99.95%). The maximum emission of the 90th percentiles of reported site-specific release factors to waste water was 0.6% (after on-site RMM).

This spERC has been developed further by ARCHE consulting and republished as version 2.1, which is further divided into 3 sector specific subsections;

- Eurometaux 2.5-6a.v2.1 - Industrial use of metal compounds in plastics and rubber industry sector,
- Eurometaux 2.5-6b.v2.1 - Industrial use of metal compounds in textile industry sector and
- Eurometaux 2.5-6c.v2.1 - Industrial use of metal compounds in glass, ceramics and crystal industry sector.

However, the information currently available from the copper compound catalyst DU does not allow for the specific refinement of the original spERC or the application of these refined spERC scenarios to DU of catalysts. Therefore, in the absence of a catalyst sector specific spERC it is considered that the approach set out in version 1.1 of ‘Industrial use of metal compounds’ spERC remains valid and has been used in the Tier 2 assessment below. Therefore, the exposure resulting from the generic scenarios is presented below:

Environmental Exposure	Generic exposure descriptors						
	E-GES-CU0	E-GES-CU1.1* (6a)	E-GES-CU1.2 (6a)	E-GES-CU1.1* (6b)	E-GES-CU1.2 (6b)	E-GES-CU2.1* (spERC)	E-GES-CU2.2 (spERC)
Life cycle stage (LCS)	Use	Use		Use		Use	
Containment	Open/closed	Open/closed		Open/closed		Open/closed	
Type of use in LCS	Industrial use of metal compounds	Intermediate		Reactive processing aid		Industrial use of metal compounds	
Dispersion of emission sources	Industrial	Industrial		Industrial		Industrial	
Indoor/outdoor	Indoor	Indoor		Indoor		Indoor	
EUSES Input parameters							
Amount of substance used as input to emission calculation	100% M/I volume	100% M/I volume		100% M/I volume		100% M/I volume	
Fraction used by largest customer - main source	1	1		1		1	
Release times per year	220	220		220		220	
On-site WWTP [Efficiency]	Not applicable	YES [92%]		YES [92%]		YES [92%]	
Off-site municipal STP [Efficiency]	Not applicable	NO	YES [92%]	NO	YES [92%]	NO	YES [92%]
Default release to air from process [%]	0.1**	5		0.1		0.1	
Default release to water from process [%]	Not applicable	2 (0.16 after WWTP)		5 (0.4 after WWTP)		0.6 (0.048 after WWTP)	
Default release to local soil from process [%]	0	0		0		0	
Dilution to be applied for PEC aquatic derivation (freshwater)	10 (20000 m^3/d)	10 (20000 m^3/d)		10 (20000 m^3/d)		10 (20000 m^3/d)	

*This scenario has been calculated assuming waste water treatment is on-site the results of which will also be considered for off-site STP treatment only.
**Due to low potential for volatilisation, spERC emission to air considered relevant for all air emissions where no water emissions are assumed.

The predicted maximum allowable usage of catalysts for sites meeting the conditions outlined above (expressed as copper tonnage) is presented in **Table 100** below.

Table 100: Maximum allowable tonnage of copper utilised by a single site using catalysts containing copper dinitrate

Maximum allowable use per site (220 day emission)	E-GES-CU0	E-GES-CU1.1(6a)	E-GES-CU1.2(6a)	E-GES-CU1.1(6b)	E-GES-CU1.2(6b)	E-GES-CU2.1 (spERC)	E-GES-CU2.2 (spERC)
Maximum allowable annual tonnage (tonnes per annum)	45000	10.375*	60 [B] 127.5[P]	4.15*	23 [B] 52 [P]	34.5*	190 [B] 432 [P]
Maximum allowable daily tonnage (tonnes Cu per day)	204.55	0.05*	0.27 [B] 0.58 [P]	0.019*	0.105 [B] 0.24 [P]	0.16*	0.86 [B] 1.96 [P]

* Maximum allowable tonnage for use is the same for on-site WWTP or off-site STP, as the threshold is triggered by the risk to the sediment compartment for these emission scenarios and not to soil.
[B] – on-site treatment at biological treatment plant
[P] – on-site treatment at physico-chemical treatment plant

The above GES values represent worst-case maximum tonnages (as copper) for catalysts used at a single site, where releases to air and waste water are within those defined by the ES. Therefore, in order to determine the acceptable tonnage for catalyst use containing copper dinitrate, individual sites will need to scale the values in accordance with the known copper content of the products being used. It may also be necessary to scale the specific usage further by applying different emission values where monitoring data or additional RMMs are available.

9.3.1.3.2 Worker Generic Exposure Scenario for Catalyst 'In-use' Phase [W-GES-CU]

For the purpose of assessing the exposure of workers to copper compounds, only the MEASE model outputs have been used and the results for all available PROCs presented in full in Annex 14. These outputs have been used to map the exposures for workers involved in the catalyst sector in accordance with the ECMA mapping (see Annex 13); the additional information provided by the members of the Copper Compound Consortium concentrated on the manufacture and not DU of catalyst products. Acceptable working conditions have been defined as those conditions where the risk characterisation was <1. However, the assessment presented can only be considered as illustrative and does not replace the requirement for a local on-site or task specific assessment, which remains the responsibility of the site owner or employer.

The information provided by the ECMA was confined to PROC codes and no indication of the physical form of the substance or preparation has been provided. Therefore, a GES for each of the substance forms (solid – high, medium and low dustiness, or liquid – aqueous solution or slurry) and associated PROCs has been assessed within the defined activities (see Table 101).

Table 101: Activities defined by PROC within the downstream use of catalysts exposure scenario

ES breakdown	Contributative ES (Short description of process or activity)	Process Category (PROC)	Containment
Reactor Loading	Batch loading (including inspection)	PROC 8b	open
		PROC 8b	closed
	Continuous loading	PROC 8b	closed
	Liquid systems	PROC 8b	closed
Use	Catalyst use in reactor	PROC 1 / PROC 2	closed
Reactor Unloading	Batch unloading	PROC 8b	open
	Continuous unloading	PROC 8b	closed
Maintenance/cleaning	Maintenance/cleaning	PROC 2 / PROC 4	open
Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage	PROC2	open
		PROC 2	closed
Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	PROC 2	closed
	Storage of spent catalyst	PROC 2	closed
	Emptying of containers of spent catalyst	PROC 8b	open
	Conveying spent catalyst	PROC 8b	open
		PROC 8b	closed
Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	PROC 2	closed
	Storage of spent catalyst	PROC 2	closed
	Emptying of containers of spent catalyst	PROC 8b	open
	Conveying spent catalyst	PROC 8b	open
Pyrometallurgical recycling	Screening	PROC 2	open
	Calcination (oxidation at elevated temperatures)	PROC 2 / PROC 1	closed
	Smelting	PROC 22	closed
	Filling	PROC 8b	open
	Maintenance	PROC 2	open
	Cleaning	PROC 2	open
Hydrometallurgical recycling	No information available		
Product storage	Final product storage	PROC2	open

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solid RM) or from evaporation (liquid RMs) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters:

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009).
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities, as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high. The outcome of downstream use is presented for each substance physical form.

9.3.1.4 Exposure Scenario for catalyst 'in – use' phase

GES4: Downstream use or 'in-use' phase of catalysts containing copper dinitrate.

1. Title GES - copper dinitrate used within catalyst products	
Life cycle	Use stage of copper dinitrate
Free short title	Downstream use of catalysts products containing copper dinitrate
Systematic title based on use descriptor	SU: SU 03 - Uses of substances as such or in preparations at industrial sites SU 09 – Manufacture of fine chemicals SU 08 - Manufacture of bulk, large scale chemicals (including petroleum products) SU 10 - Formulation [mixing] of preparations and/or re-packaging (excluding alloys) PC: PC 2 [Adsorbents] PC 19 [Intermediate] PC 20 [processing aids used in the chemical industry] PC 32 [Polymer preparations and compounds] ERC: ERC6a – intermediate ERC 6b – reactive processing aid spERC – Industrial use of metal compounds

	PROC: PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 22: [Potentially closed processing operations (with minerals) at elevated temperature]
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling
Processes, tasks, activities covered (workers)	Use; • Reactor loading • Use (in reactor) • Reactor unloading • Maintenance/cleaning • Spent/regenerated catalyst storage Recycling; • Spent catalyst delivery & handling • Pyrometallurgical recycling • Hydrometallurgical recycling • Product storage
2. Operational conditions and risk management measures (RMMs)	
2.1 Control of environmental exposure [E-GES-CU0]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	All scenarios where no emission to water is expected (ERC6a, ERC6b and spERC)
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling,
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	204.55 tonnes Cu per day
Maximum annual use at a site	45000 tonnes Cu per year
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	

None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No waste water released from use of catalyst. **Air:** 0.1% emission assumed (spERC value) irrespective of RMMs due to negligible volatility of copper.	
Organizational measures to prevent/limit release from site	
No releases to waste water.	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
No releases to waste water.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.2 Control of environmental exposure [E-GES-CU1.1(6a)]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	ERC6a – intermediate
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling,
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	0.05 tonnes Cu per day
Maximum annual use at a site	10.375 tonnes Cu per year
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs assumed; 2% emission followed by on-site WWTP <u>or</u> off-site STP with 92% removal. **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
On-site WWTP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant

Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.3 Control of environmental exposure [E-GES-CU1.2(6a)]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	ERC6a – intermediate
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling,
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	0.27 tonnes Cu per day [Biological WWTP] 0.58 tonnes Cu per day [Physico-chemical WWTP]
Maximum annual use at a site	60 tonnes Cu per year [Biological WWTP] 127.5 tonnes Cu per year [Physico-chemical WWTP]
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs assumed; 2% emission followed by on-site WWTP with further 92% removal, and discharge to off-site municipal STP (92% efficiency assumed). **Air:** No RMMs assumed; 5% emission.	
Organizational measures to prevent/limit release from site	
On-site WWTP with discharge to off-site municipal STP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated and results in restricted tonnage due to risk in soil compartment being triggered when municipal STP is used.
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling. Solids waste from municipal STP disposed of to land or in accordance with local waste regulations.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.4 Control of environmental exposure [E-GES-CU1.1(6b)]	

Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	ERC6b – reactive processing aid
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling,
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	0.019 tonnes Cu per day
Maximum annual use at a site	4.15 tonnes Cu per year
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs assumed; 5% emission followed by on-site WWTP or off-site STP with further 92% removal. **Air:** No RMMs assumed; 0.1% emission.	
Organizational measures to prevent/limit release from site	
On-site WWTP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.5 Control of environmental exposure [E-GES-CU1.2(6b)]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	ERC6b – reactive processing aid
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling,
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	

Amounts used on site	
Maximum daily use at a site	0.105 tonnes Cu per day [Biological WWTP] 0.24 tonnes Cu per day [Physico-chemical WWTP]
Maximum annual use at a site	23 tonnes Cu per year [Biological WWTP] 52 tonnes Cu per year [Physico-chemical WWTP]
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No RMMs assumed; 5% emission followed by on-site WWTP with further 92% removal, and discharge to off-site municipal STP (92% efficiency assumed). **Air:** No RMMs assumed; 0.1% emission.	
Organizational measures to prevent/limit release from site	
On-site WWTP with discharge to off-site municipal STP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated and results in restricted tonnage due to risk in soil compartment being triggered when municipal STP is used.
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling. Solids waste from municipal STP disposed of to land or in accordance with local waste regulations.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.6 Control of environmental exposure [E-GES-CU2.1(spERC)]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	spERC – Industrial use of metal compounds
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	0.16 tonnes Cu per day
Maximum annual use at a site	34.5 tonnes Cu per year
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]

Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
Various; closed-system, open-system, filtration, precipitation etc.,	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: The spERC emission factor of 0.6% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment is assumed to be on-site with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.1% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
On-site WWTP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	Not relevant
Discharge rate of the Municipal STP	Not relevant
Incineration of the sludge of the Municipal STP	Not relevant
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.7 Control of environmental exposure [E-GES-CU2.2(spERC)]	
Environmental related free short title	Catalyst use
Systematic title based on use descriptor (environment)	spERC – Industrial use of metal compounds
Processes, tasks, activities covered (environment)	Catalyst use: • Use, • Recycling.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC.
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used on site	
Maximum daily use at a site	0.86 tonnes Cu per day [Biological WWTP] 1.96 tonnes Cu per day [Physico-chemical WWTP]
Maximum annual use at a site	190 tonnes Cu per year [Biological WWTP] 432 tonnes Cu per year [Physico-chemical WWTP]
Frequency and duration of catalyst use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity, freshwater	10 (default)
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
Various; closed-system, open-system, filtration, precipitation etc.,	

Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: The spERC emission factor of 0.6% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment is assumed to be on-site with an efficiency of 92% Cu removal. Discharge via an additional off-site municipal STP (92% efficiency assumed). **Air:** The spERC emission factor of 0.1% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
On-site WWTP with discharge to off-site municipal STP	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated and results in restricted tonnage due to risk in soil compartment being triggered when municipal STP is used.
Conditions and measures related to external treatment of waste for disposal	
On-site WWTP waste is taken to a controlled offsite location for incineration, disposal or recycling. Solids waste from municipal STP disposed of to land or in accordance with local waste regulations.	
Conditions and measures related to external recovery of waste	
As applicable.	
2.8 Control of worker exposure contributing to exposure scenario (W-GES-CU(High))	
Workers related free short title	Downstream use of catalyst products
Use descriptor covered	PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 22: [Potentially closed processing operations (with minerals) at elevated temperature]
Processes, tasks, activities covered	**Use** • Reactor loading • Use (in reactor) • Reactor unloading • Maintenance/cleaning • Spent/regenerated catalyst storage **Recycling** • Spent catalyst delivery & handling • Pyrometallurgical recycling • Hydrometallurgical recycling • Product storage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Solid (High dustiness)	

Amounts used		
Varying (risk limited by exposure not quantities)		
Frequency and duration of use/exposure		
Daily. > 4 hours		
Human factors not influenced by risk management		
Respiration volume under conditions of use		MEASE Default
Room size and ventilation rate		MEASE Default
Area of skin contact with the substance under conditions of use		MEASE Default
Body weight		70 kg
Other given operational conditions affecting workers exposure		
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact		
Technical conditions and measures at process level (source) to prevent release		
Activity controlled in accordance with PROC descriptor		
Technical conditions and measures to control dispersion from source towards the worker		
PROC 1	Local generic LEV not required	
PROC 2	LEV required (LEV generic, ECETOC reference)	
PROC 4	LEV required (LEV generic, ECETOC reference)	
PROC 8b	LEV required (LEV generic, ECETOC reference)	
PROC 22	LEV required (LEV generic, ECETOC reference)	
Organisational measures to prevent /limit releases, dispersion and exposure		
Best available techniques and good hygiene measures assumed		
Conditions and measures related to personal protection, hygiene and health evaluation		
Based on classification (all PROCs)		
Eye protection		Required (goggles or face shield)
Skin protection		Required (overalls and gloves)
Based on risk assessment (PROC related)		
PROC 1	Not required	
PROC 2	Not required	
PROC4	RPE (APF 4) required	
PROC 8b	RPE (APF 4) required	
PROC 22	Not required	
2.9 Control of worker exposure contributing to exposure scenario [W-GES-CU(Med)]		
Workers related free short title		Downstream use of catalyst products
Use descriptor covered		PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 22: [Potentially closed processing operations (with minerals) at elevated temperature]
Processes, tasks, activities covered		**Use** • Reactor loading • Use (in reactor)

		• Reactor unloading • Maintenance/cleaning • Spent/regenerated catalyst storage **Recycling** • Spent catalyst delivery & handling • Pyrometallurgical recycling • Hydrometallurgical recycling • Product storage
Assessment Method		Estimation of exposure based on predicted data using MEASE
Product characteristic		
Specific to manufacture source: Solid (Medium dustiness)		
Amounts used		
Varying (risk limited by exposure not quantities)		
Frequency and duration of use/exposure		
Daily. > 4 hours		
Human factors not influenced by risk management		
Respiration volume under conditions of use		MEASE Default
Room size and ventilation rate		MEASE Default
Area of skin contact with the substance under conditions of use		MEASE Default
Body weight		70 kg
Other given operational conditions affecting workers exposure		
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact		
Technical conditions and measures at process level (source) to prevent release		
Activity controlled in accordance with PROC descriptor		
Technical conditions and measures to control dispersion from source towards the worker		
PROC 1	Local generic LEV not required	
PROC 2	Local generic LEV not required	
PROC 4	LEV required (LEV generic, ECETOC reference)	
PROC 8b	LEV required (LEV generic, ECETOC reference)	
PROC 22	LEV required (LEV generic, ECETOC reference)	
Organisational measures to prevent /limit releases, dispersion and exposure		
Best available techniques and good hygiene measures assumed		
Conditions and measures related to personal protection, hygiene and health evaluation		
Based on classification (all PROCs)		
Eye protection		Required (goggles or face shield)
Skin protection		Required (overalls and gloves)
Based on risk assessment (PROC related)		
PROC 1	Not required	
PROC 2	Not required	
PROC 4	Not required	
PROC 8b	Not required	
PROC 22	Not required	
2.10 Control of worker exposure contributing to exposure scenario [W-GES-CU(Low)]		
Workers related free short title		Downstream use of catalyst products
Use descriptor covered		PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling).

	Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 22: [Potentially closed processing operations (with minerals) at elevated temperature]
Processes, tasks, activities covered	**Use** • Reactor loading • Use (in reactor) • Reactor unloading • Maintenance/cleaning • Spent/regenerated catalyst storage **Recycling** • Spent catalyst delivery & handling • Pyrometallurgical recycling • Hydrometallurgical recycling • Product storage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Solid (Low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
PROC 1	Local generic LEV not required
PROC 2	Local generic LEV not required
PROC 4	Local generic LEV not required
PROC 8b	Local generic LEV not required
PROC 22	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)

Based on risk assessment (PROC related)	
PROC 1	Not required
PROC 2	Not required
PROC 4	Not required
PROC 8b	Not required
PROC 22	Not required

2.11 Control of worker exposure contributing to exposure scenario [W-GES-CU(Liquid)]	
Workers related free short title	Downstream use of catalyst products
Use descriptor covered	PROC 1: [Use in closed process, no likelihood of exposure. Industrial setting] PROC 2: [Use in closed, continuous process with occasional controlled exposure (e.g. sampling). Industrial setting] PROC 4: [Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting] PROC 8b: [Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities] PROC 22: [Potentially closed processing operations (with minerals) at elevated temperature]
Processes, tasks, activities covered	**Use** • Reactor loading • Use (in reactor) • Reactor unloading • Maintenance/cleaning • Spent/regenerated catalyst storage **Recycling** • Spent catalyst delivery & handling • Pyrometallurgical recycling • Hydrometallurgical recycling • Product storage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Specific to manufacture source: Liquid (aqueous solution, slurry)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily. > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	

PROC 1	Local generic LEV not required
PROC 2	Local generic LEV not required
PROC 4	Local generic LEV not required
PROC 8b	Local generic LEV not required
PROC 22	NOT APPLICABLE
Organisational measures to prevent /limit releases, dispersion and exposure	
Best available techniques and good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
PROC 1	Not required
PROC 2	Not required
PROC 4	Not required
PROC 8b	Not required
PROC 22	NOT APPLICABLE

3. Exposure and risk mitigation

Environment

All tables:

* mean of agricultural soil and grassland (180 days)

**including a country-specific regional background;

Freshwater = median value of 2.9 µg dissolved Cu/L

Freshwater sediment = not applicable

Marine = median value of 1.1 µg dissolved Cu/L

Marine sediment = median value 16.1 mg Cu/kg dw

Soil = median value of 24.4 mg Cu/kg dw

Generic exposure:

1. All – No water emissions

E-GES-CU0: Maximum tonnage 45000 tonnes per annum, 220 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg Cu/l	0.0078	0	2.9	0.37
	Sediment	mg Cu/kg dw	87.1	0	0	0
Marine	**Aquatic**	mg Cu/l	0.0056	0	0.0011	0.2
	Sediment	mg Cu/kg dw	676	0	16.1	0.02
Terrestrial	**Soil**	mg Cu/kg dw	64.6	33.513	57.9	0.9
	Groundwater	mg Cu/l	-	0.00534	-	-

2. ERC6a: Intermediate

E-GES-CU1.1(6a): Maximum tonnage 10.375 tonnes per annum, 220 days production

[on-site WWTP values]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.6	78.6	0.9
Marine	**Aquatic**	mg Cu/l	0.0056	0.0002	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.86	24.0	0.03
Terrestrial	**Soil**	mg Cu/kg dw	64.6	0.32	24.7	0.4
	Groundwater	mg Cu/l	-	0.0001	-	-

[off-site STP values]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.6	78.6	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0002	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.86	24.0	0.03
Terrestrial	Soil	mg Cu/kg dw	64.6	13.11	37.51	0.6
	Groundwater	mg Cu/l	-	0.009	-	-

E-GES-CU1.2(6a):
[Biological WWTP] Maximum tonnage 60 tonnes per annum, 220 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0007	0.004	0.5
	Sediment	mg Cu/kg dw	87.1	36.9	36.9	0.4
Marine	Aquatic	mg Cu/l	0.0056	0.00007	0.0012	0.2
	Sediment	mg Cu/kg dw	676	3.71	19.8	0.03
Terrestrial	Soil	mg Cu/kg dw	64.6	7.78	32.18	0.5
	Groundwater	mg Cu/l	-	0.01	-	-

[Physicochemical WWTP] Maximum tonnage 127.5 tonnes per annum, 220 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.4	78.4	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0002	0.001	0.2
	Sediment	mg Cu/kg dw	676	7.88	24.0	0.04
Terrestrial	Soil	mg Cu/kg dw	64.6	16.55	40.95	0.6
	Groundwater	mg Cu/l	-	0.01	-	-

3. ERC6b: Reactive processing aid
E-GES-CU1.1(6b): Maximum tonnage 4.15 tonnes per annum, 220 days production
[on-site WWTP values presented only]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.5	78.5	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0002	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.85	24.0	0.03
Terrestrial	Soil	mg Cu/kg dw	64.6	0.003	24.4	0.4
	Groundwater	mg Cu/l	-	0.0000009	-	-

[off-site STP values]

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.5	78.5	0.9
Marine	Aquatic	mg Cu/l	0.0056	0.0002	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.85	24.0	0.03
Terrestrial	Soil	mg Cu/kg dw	64.6	12.81	37.21	0.6
	Groundwater	mg Cu/l	-	0.009	-	-

E-GES-CU1.2(6b):
[Biological WWTP] Maximum tonnage 23 tonnes per annum, 220 days production

Compartment		Unit	PNEC	C_{local}	PEC**	RCR
Freshwater	Aquatic	mg Cu/l	0.0078	0.0007	0.004	0.5
	Sediment	mg Cu/kg dw	87.1	34.8	34.8	0.4

Marine	**Aquatic**	mg Cu/l	0.0056	0.00007	0.0012	0.2
	Sediment	mg Cu/kg dw	676	3.48	19.6	0.03
Terrestrial	**Soil**	mg Cu/kg dw	64.6	5.69	30.09	0.5
	Groundwater	mg Cu/l	-	0.004	-	-

[Physico-chemical WWTP] Maximum tonnage 52 tonnes per annum, 220 days production

Compartment		**Unit**	**PNEC**	**C_{local}**	**PEC****	**RCR**
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.7	78.7	0.9
Marine	**Aquatic**	mg Cu/l	0.0056	0.0002	0.001	0.2
	Sediment	mg Cu/kg dw	676	7.87	24.0	0.04
Terrestrial	**Soil**	mg Cu/kg dw	64.6	12.88	37.28	0.6
	Groundwater	mg Cu/l	-	0.009	-	-

4. spERC: Industrial use of metal compounds

E-GES-CU2.1(spERC U): Maximum tonnage 34.5 tonnes per annum, 220 days production

[on-site WWTP values]

Compartment		**Unit**	**PNEC**	**C_{local}**	**PEC****	**RCR**
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.3	78.3	0.90
Marine	**Aquatic**	mg Cu/l	0.0056	0.00016	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.83	23.9	0.04
Terrestrial	**Soil**	mg Cu/kg dw	64.6	0.02	24.42	0.4
	Groundwater	mg Cu/l	-	0.000007	-	-

[off-site STP values]

Compartment		**Unit**	**PNEC**	**C_{local}**	**PEC****	**RCR**
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.3	78.3	0.90
Marine	**Aquatic**	mg Cu/l	0.0056	0.00016	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.83	23.9	0.04
Terrestrial	**Soil**	mg Cu/kg dw	64.6	12.81	37.21	0.6
	Groundwater	mg Cu/l	-	0.009	-	-

E-GES-CU2.2(spERC U):

[Biological WWTP] Maximum tonnage 190 tonnes per annum, 220 days production

Compartment		**Unit**	**PNEC**	**C_{local}**	**PEC****	**RCR**
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0007	0.004	0.5
	Sediment	mg Cu/kg dw	87.1	34.5	34.5	0.4
Marine	**Aquatic**	mg Cu/l	0.0056	0.00007	0.0012	0.2
	Sediment	mg Cu/kg dw	676	3.46	19.6	0.03
Terrestrial	**Soil**	mg Cu/kg dw	64.6	5.74	30.14	0.5
	Groundwater	mg Cu/l	-	0.004	-	-

[Physico-chemical WWTP] Maximum tonnage 432 tonnes per annum, 220 days production

Compartment		**Unit**	**PNEC**	**C_{local}**	**PEC****	**RCR**
Freshwater	**Aquatic**	mg Cu/l	0.0078	0.0016	0.0045	0.6
	Sediment	mg Cu/kg dw	87.1	78.6	78.6	0.9
Marine	**Aquatic**	mg Cu/l	0.0056	0.00016	0.0013	0.2
	Sediment	mg Cu/kg dw	676	7.86	24.0	0.04
Terrestrial	**Soil**	mg Cu/kg dw	64.6	13.07	37.47	0.6
	Groundwater	mg Cu/l	-	0.009	-	-

Worker exposure: Indoor activities for the DU of catalysts containing **copper dinitrate**

ES breakdown	Contributative ES (Short description of process or activity)	PROC	LEV	RPE [APF]	RCR [Total Exposure]
W-GES-CU(High) > 4 hours/day					
Use	Catalyst use in reactor	PROC 1	NO	NO	0.023
Pyrometallurgical recycling	Calcination (oxidation at elevated temperatures)				
Use	Catalyst use in reactor	PROC 2	YES	NO	0.125
Maintenance/cleaning	Maintenance/cleaning				
Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage				
Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)				
	Storage of spent catalyst				
Pyrometallurgical recycling	Screening				
	Calcination (oxidation at elevated temperatures)				
	Maintenance				
	Cleaning				
Product storage	Final product storage				
Maintenance/cleaning	Maintenance/cleaning	PROC 4	YES	YES (4)	0.650
Reactor Loading	Batch loading (including inspection)	PROC 8b	YES	YES (4)	0.338
	Continuous loading				
	Liquid systems				
Reactor Unloading	Batch unloading				
	Continuous unloading				
Spent catalyst delivery & handling	Emptying of containers of spent catalyst				
	Conveying spent catalyst				
Pyrometallurgical recycling	Filling				
Pyrometallurgical recycling	Smelting	PROC 22	YES	NO	0.803
W-GES-CU(Med) > 4 hours/day					
ES breakdown	**Contributative ES (Short description of process or activity)**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Use	Catalyst use in reactor	PROC 1	NO	NO	0.023
Pyrometallurgical recycling	Calcination (oxidation at elevated temperatures)				
Use	Catalyst use in reactor	PROC 2	NO	NO	0.525
Maintenance/cleaning	Maintenance/cleaning				
Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage				
Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)				
	Storage of spent catalyst				
	Storage of spent catalyst				
Pyrometallurgical recycling	Screening				
	Calcination (oxidation at elevated temperatures)				
	Maintenance				
	Cleaning				
Product storage	Final product storage				
Maintenance/cleaning	Maintenance/cleaning	PROC 4	YES	NO	0.525

Reactor Loading	**Batch loading (including inspection)**	**PROC 8b**	YES	NO	0.275
	Continuous loading				
	Liquid systems				
Reactor Unloading	**Batch unloading**				
	Continuous unloading				
Spent catalyst delivery & handling	**Emptying of containers of spent catalyst**				
	Conveying spent catalyst				
Spent catalyst delivery & handling	**Emptying of containers of spent catalyst**				
	Conveying spent catalyst				
Pyrometallurgical recycling	**Filling**				
Pyrometallurgical recycling	**Smelting**	**PROC 22**	YES	NO	0.803
W-GES-CU(Low) > 4 hours/day					
ES breakdown	**Contributative ES (Short description of process or activity)**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Use	**Catalyst use in reactor**	**PROC 1**	NO	NO	0.023
Pyrometallurgical recycling	**Calcination (oxidation at elevated temperatures)**				
Use	**Catalyst use in reactor**	**PROC 2**	NO	NO	0.035
Maintenance/cleaning	**Maintenance/cleaning**				
Spent/regenerated catalyst storage	**Spent/regenerated catalyst product storage**				
Spent catalyst delivery & handling	**Semi-bulk delivery of spent catalyst (IBC, drums...)**				
	Storage of spent catalyst				
Pyrometallurgical recycling	**Screening**				
	Calcination (oxidation at elevated temperatures)				
	Maintenance				
	Cleaning				
Product storage	**Final product storage**				
Maintenance/cleaning	**Maintenance/cleaning**	**PROC 4**	YES	YES (4)	0.525
Reactor Loading	**Batch loading (including inspection)**	**PROC 8b**	NO	NO	0.125
	Continuous loading				
	Liquid systems				
Reactor Unloading	**Batch unloading**				
	Continuous unloading				
Spent catalyst delivery & handling	**Emptying of containers of spent catalyst**				
	Conveying spent catalyst				
Pyrometallurgical recycling	**Filling**				
Pyrometallurgical recycling	**Smelting**	**PROC 22**	YES	NO	0.803
W-GES-CU(Liquid) > 4 hours/day					
ES breakdown	**Contributative ES (Short description of process or activity)**	**PROC**	**LEV**	**RPE [APF]**	**RCR [Total Exposure]**
Use	**Catalyst use in reactor**	**PROC 1**	NO	NO	0.126
Pyrometallurgical recycling	**Calcination (oxidation at elevated temperatures)**				
Use	**Catalyst use in reactor**	**PROC 2**	NO	NO	0.251
Maintenance/cleaning	**Maintenance/cleaning**				

Spent/regenerated catalyst storage	**Spent/regenerated catalyst product storage**				
Spent catalyst delivery & handling	**Semi-bulk delivery of spent catalyst (IBC, drums...)**				
	Storage of spent catalyst				
Pyrometallurgical recycling	**Screening**				
	Calcination (oxidation at elevated temperatures)				
	Maintenance				
	Cleaning				
Product storage	**Final product storage**				
Maintenance/cleaning	**Maintenance/cleaning**	**PROC 4**	NO	NO	0.301
Reactor Loading	**Batch loading (including inspection)**	**PROC 8b**	NO	NO	0.261
	Continuous loading				
	Liquid systems				
Reactor Unloading	**Batch unloading**				
	Continuous unloading				
Spent catalyst delivery & handling	**Emptying of containers of spent catalyst**				
	Conveying spent catalyst				
Pyrometallurgical recycling	**Filling**				
Pyrometallurgical recycling	**Smelting**	**PROC 22**	NOT APPLICABLE		

4. Guidance to evaluate whether a site works inside the boundaries set by the ES

Environment

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Workers

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

It should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

9.3.1.5 Waste related measures

See Section **9.4**.

9.3.1.6 Exposure estimation

9.3.1.6.1 Environmental releases

Releases to the local environment as a result of catalyst manufacture and downstream uses are summarised below in Table 102 and Table 103.

No direct regional releases are presented as measured regional data have been used (see Section **9.6**).

Table 102: Summary of the releases to the environment for catalyst manufacture

ES Descriptor	Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]	Aquatic (wastewater with/without STP)	0.0766	Maximum tonnage – 40 tonnes Cu per annum.
	Air (direct + STP)*	0.0286	
	Soil (direct releases only)	0	
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]	Aquatic (wastewater)	6.22	Maximum tonnage – 3250 tonnes Cu per annum.
	Air (direct + STP)*	2.32	
	Soil (direct releases only)	0	
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]	Aquatic (wastewater)	0.957	Maximum tonnage – 500 tonnes Cu per annum.
	Air (direct + STP)*	0.357	
	Soil (direct releases only)	0	
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]	Aquatic (wastewater)	2.11	Maximum tonnage – 1100 tonnes Cu per annum.
	Air (direct + STP)*	0.786	
	Soil (direct releases only)	0	

* - local direct only, no emissions at STP due to lack of volatilisation.

Table 103: Summary of the releases to the environment for downstream use of catalyst products

ES Descriptor	Compartments	Release from point source (kg/d) (local exposure estimation)	Total release for regional exposure estimation (kg/d)	Justification
E-GES-CU1.1(ERC6a) [WWTP or STP]	Aquatic (wastewater with/without STP)	0.076	0.009	Maximum tonnage – 10.375 tonnes Cu per annum.
	Air (direct + STP)*	2.36	1.42	
	Soil (direct releases only)	0	0	
E-GES-CU1.2(6a) [Biological WWTP]	Aquatic (wastewater)	0.035	0.0526	Maximum tonnage – 60 tonnes Cu per annum.
	Air (direct + STP)*	13.6	8.22	
	Soil (direct releases only)	0	0	
E-GES-CU1.2(6a) [Physico-chemical WWTP]	Aquatic (wastewater)	0.074	0.112	Maximum tonnage – 127.5 tonnes Cu per annum.
	Air (direct + STP)*	29	17.5	
	Soil (direct releases only)	0	0	

ES Descriptor	Compartments	Release from point source (kg/d) (local exposure estimation)	Total release for regional exposure estimation (kg/d)	Justification
E-GES-CU1.1(ERC6b) [WWTP or STP]	Aquatic (wastewater)	0.076	0.009	Maximum tonnage – 41.5 tonnes Cu per annum.
	Air (direct + STP)*	0.019	0.011	
	Soil (direct releases only)	0	0	
E-GES-CU1.2(6b) [Biological WWTP]	Aquatic (wastewater with/without STP)	0.418	0.05	Maximum tonnage – 23 tonnes Cu per annum.
	Air (direct + STP)*	0.105	0.063	
	Soil (direct releases only)	0	0	
E-GES-CU1.2(6b) [Physico-chemical WWTP]	Aquatic (wastewater)	0.945	0.114	Maximum tonnage – 52 tonnes Cu per annum.
	Air (direct + STP)*	0.236	0.142	
	Soil (direct releases only)	0	0	
E-GES-CU2.1(spERC U) [WWTP or STP]	Aquatic (wastewater)	0.073	0.009	Maximum tonnage – 34.5 tonnes Cu per annum.
	Air (direct + STP)*	0.157	0.095	
	Soil (direct releases only)	0	0	
E-GES-CU2.1(spERC U) [Biological WWTP]	Aquatic (wastewater)	0.0332	0.05	Maximum tonnage – 190 tonnes Cu per annum.
	Air (direct + STP)*	0.864	0.52	
	Soil (direct releases only)	0	0	
E-GES-CU2.2(spERC U) [Physico-chemical WWTP]	Aquatic (wastewater with/without STP)	0.075	0.114	Maximum tonnage – 432 tonnes Cu per annum.
	Air (direct + STP)*	1.96	1.18	
	Soil (direct releases only)	0	0	

9.3.1.6.2 Exposure concentration in sewage treatment plants (STP)

Table 104: Predicted Exposure Concentrations (PEC) in sewage for catalyst manufacture

Compartments	Value	Justification
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	NA	Maximum tonnage 40 tonnes copper per annum.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	NA	
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	NA	Maximum tonnage 3250 tonnes copper per annum.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	NA	
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.068	Maximum tonnage 500 tonnes copper per annum.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	1980	
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]		
Concentration in sewage (PECstp)(in mg Cu/l)	0.077	Maximum tonnage 1100 tonnes copper per annum.
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	2250	

NA – not applicable (no STP)

Table 105: Predicted Exposure Concentrations (PEC) in sewage for downstream use of catalyst products

Compartments	Value	Justification
E-GES-CU0		
Concentration in sewage (PECstp)(in mg Cu/l)	Not applicable.	
Concentration in sewage sludge (in mg Cu/kg dw)		
E-GES-CU1.1(6a) [Biological WWTP <u>or</u> STP]		
Concentration in sewage (PECwwtp/stp)(in mg Cu/l)	0.0377	Maximum tonnage 10.375 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1100	
E-GES-CU1.2(6a) [Biological WWTP <u>and</u> STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.218	Maximum tonnage 60 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0175	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	580	
E-GES-CU1.2(6a) [Physico-chemical WWTP <u>and</u> STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	N/A	Maximum tonnage 127.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0371	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1080	
E-GES-CU1.1(6b) [Biological WWTP <u>or</u> STP]		
Concentration in sewage (PECwwtp/stp)(in mg Cu/l)	0.0377	Maximum tonnage 4.15 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1100	
E-GES-CU1.2(6b) [Biological WWTP <u>and</u> STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.209	Maximum tonnage 23 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0167	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	487	
E-GES-CU1.2(6b) [Physico-chemical WWTP <u>and</u> STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	N/A	Maximum tonnage 52 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0378	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1100	

Compartments	Value	Justification
E-GES-CU2.1(spERC U) [Biological WWTP or STP]		
Concentration in sewage (PECwwtp/stp)(in mg Cu/l)	0.0376	Maximum tonnage 34.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1100	
E-GES-CU2.2(spERC U) [Biological WWTP and STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	0.207	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0166	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	483	
E-GES-CU2.2(spERC U) [Physico-chemical WWTP and STP]		
Concentration in sewage (PECwwtp)(in mg Cu/l)	N/A	Maximum tonnage 432 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Concentration in sewage sludge (PECsludge-wwtp)(in mg Cu/kg dw)	Not calculated*	
Concentration in sewage (PECstp)(in mg Cu/l)	0.0377	
Concentration in sewage sludge (PECsludge-stp)(in mg Cu/kg dw)	1100	

* Not calculated since waste disposal is not to land but are disposed of to landfill or via incineration in accordance with waste regulations.

9.3.1.6.3 Exposure concentration in aquatic pelagic compartment

Table 106: Predicted Exposure Concentrations (PEC) in aquatic compartment for catalyst manufacture

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]			
Freshwater (in mg Cu/l)	0.003	0.005	Maximum tonnage 40 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0003	0.001	
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]			
Freshwater (in mg Cu/l)	0.0045	0.007	Maximum tonnage 3250 tonnes copper per annum.
Marine water (in mg Cu/l)	-	-	
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]			
Freshwater (in mg Cu/l)	0.003	0.005	Maximum tonnage 500 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0003	0.001	
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]			
Freshwater (in mg Cu/l)	0.0001	0.003	Maximum tonnage 1100 tonnes copper per annum.
Marine water (in mg Cu/l)	-	-	

Table 107: Predicted Exposure Concentrations (PEC) in aquatic compartment for downstream use of catalyst products

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-CU0			
Freshwater (in mg Cu/l)	0	2.9	Maximum tonnage 45000 tonnes copper per annum.
Marine water (in mg Cu/l)	0	0.0011	
E-GES-CU1.1(6a) [Biological WWTP or STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 10.375 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0002	0.0013	
E-GES-CU1.2(6a) [Biological WWTP and STP]			
Freshwater (in mg Cu/l)	0.0007	0.004	Maximum tonnage 60 tonnes copper per annum.
Marine water (in mg Cu/l)	0.00007	0.0012	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 127.5 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0002	0.001	
E-GES-CU1.1(6b) [Biological WWTP or STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 4.15 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0002	0.0013	
E-GES-CU1.2(6b) [Biological WWTP and STP]			
Freshwater (in mg Cu/l)	0.0007	0.004	Maximum tonnage 23 tonnes copper per annum.
Marine water (in mg Cu/l)	0.00007	0.0012	
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 52 tonnes copper per annum.
Marine water (in mg Cu/l)	0.0002	0.001	
E-GES-CU2.1(spERC U) [Biological WWTP or STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 34.5 tonnes copper per annum.
Marine water (in mg Cu/l)	0.00016	0.0013	
E-GES-CU2.2(spERC U) [Biological WWTP and STP]			
Freshwater (in mg Cu/l)	0.0007	0.004	Maximum tonnage 190 tonnes copper per annum.
Marine water (in mg Cu/l)	0.00007	0.0012	
E-GES-CU2.2(spERC U) [Physico-chemical WWTP and STP]			
Freshwater (in mg Cu/l)	0.0016	0.0045	Maximum tonnage 432 tonnes copper per annum.
Marine water (in mg Cu/l)	0.00016	0.0013	

9.3.1.6.4 Exposure concentration in sediments

Table 108: Predicted Exposure Concentrations (PEC) in sediments for catalyst manufacture

Compartments	Local concentration	PEC aquatic	Justification

		(local+regional)	
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]			
Freshwater sediments (in mg Cu/kg dw)	80	80	Maximum tonnage 40 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	8.0	24.1	
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]			
Freshwater sediments (in mg Cu/kg dw)	29.5	29.5	Maximum tonnage 3250 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	-	-	
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]			
Freshwater sediments (in mg Cu/kg dw)	80	80	Maximum tonnage 500 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	8.01	24.1	
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]			
Freshwater sediments (in mg Cu/kg dw)	0.837	0.837	Maximum tonnage 1100 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	-	-	

Table 109: Predicted Exposure Concentrations (PEC) in sediments for downstream use of catalyst products

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-CU0			
Freshwater sediments (in mg Cu/kg dw)	0	0	Maximum tonnage 45000 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	0	16.1	
E-GES-CU1.1(6a) [Biological WWTP or STP]			
Freshwater sediments (in mg Cu/kg dw)	78.6	78.6	Maximum tonnage 10.375 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.86	24.0	
E-GES-CU1.2(6a) [Biological WWTP and STP]			
Freshwater sediments (in mg Cu/kg dw)	36.9	36.9	Maximum tonnage 60 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	3.71	19.8	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]			

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
Freshwater sediments (in mg Cu/kg dw)	78.4	78.4	Maximum tonnage 127.5 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.86	24.0	
E-GES-CU1.1(6b) [Biological WWTP <u>or</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	78.5	78.5	Maximum tonnage 4.15 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.85	24.0	
E-GES-CU1.2(6b) [Biological WWTP <u>and</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	34.8	34.8	Maximum tonnage 23 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	3.48	19.6	
E-GES-CU1.2(6b) [Physico-chemical WWTP <u>and</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	78.7	78.7	Maximum tonnage 52 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.87	24.0	
E-GES-CU2.1(spERC U) [Biological WWTP <u>or</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	78.3	78.3	Maximum tonnage 34.5 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.83	23.9	
E-GES-CU2.2(spERC U) [Biological WWTP <u>and</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	34.5	34.5	Maximum tonnage 190 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	3.46	19.6	
E-GES-CU2.2(spERC U) [Physico-chemical WWTP <u>and</u> STP]			
Freshwater sediments (in mg Cu/kg dw)	78.6	78.6	Maximum tonnage 432 tonnes copper per annum.
Marine water sediments (in mg Cu/kg dw)	7.86	24.0	

9.3.1.6.5 Exposure concentrations in soil and groundwater

Table 110: Predicted Exposure Concentrations (PEC) in soil and groundwater for catalyst manufacture

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]			

Soil (mg Cu/kg dw)	0.004	24.4	Maximum tonnage 40 tonnes copper per annum.
Groundwater (mg Cu/l)	0.000002	-	
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]			
Soil (mg Cu/kg dw)	0.311	24.71	Maximum tonnage 3250 tonnes copper per annum.
Groundwater (mg Cu/l)	0.0002	-	
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]			
Soil (mg Cu/kg dw)	18.6	43.0	Maximum tonnage 500 tonnes copper per annum.
Groundwater (mg Cu/l)	0.0088	-	
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]			
Soil (mg Cu/kg dw)	36.1	60.5	Maximum tonnage 1100 tonnes copper per annum.
Groundwater (mg Cu/l)	0.0193	-	

Table 111: Predicted Exposure Concentrations (PEC) in soil and groundwater for downstream use of catalyst products

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-CU0			
Soil averaged (mg Cu/kg dw)	64.6	33.513	Maximum tonnage 45000 tonnes copper per annum.
Groundwater (mg Cu/l)	-	0.00534	
E-GES-CU1.1(6a) [Biological on-site WWTP]			
Soil averaged (mg Cu/kg dw)	0.32	24.7	Maximum tonnage 10.375 tonnes copper per annum.
Groundwater (mg Cu/l)	0.0001	-	
E-GES-CU1.1(6a) [off-site STP]			
Soil averaged (mg Cu/kg dw)	13.11	37.51	Maximum tonnage 10.375 tonnes copper per annum.
Groundwater (mg Cu/l)	0.009	-	
E-GES-CU1.2(6a) [Biological WWTP and STP]			
Soil averaged (mg Cu/kg dw)	7.78	32.18	Maximum tonnage 60 tonnes copper per annum.
Groundwater (mg Cu/l)	0.01	-	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]			
Soil averaged (mg Cu/kg dw)	16.55	40.95	Maximum tonnage 127.5 tonnes copper per annum.
Groundwater (mg Cu/l)	0.01	-	
E-GES-CU1.1(6b) [Biological on-site WWTP]			
Soil averaged (mg Cu/kg dw)	0.003	24.4	Maximum tonnage 4.15 tonnes copper per annum.
Groundwater (mg Cu/l)	0.0000009	-	
E-GES-CU1.1(6b) [off-site STP]			
Soil averaged (mg Cu/kg dw)	12.81	37.21	Maximum tonnage 4.15 tonnes copper per annum.
Groundwater (mg Cu/l)	0.009	-	
E-GES-CU1.2(6b) [Biological WWTP and STP]			

Compartments	Local concentration	PEC aquatic (local+regional)	Justification
Soil averaged (mg Cu/kg dw)	5.69	30.09	Maximum tonnage 23 tonnes copper per annum.
Groundwater (mg Cu/l)	0.004	-	
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]			
Soil averaged (mg Cu/kg dw)	12.88	37.28	Maximum tonnage 52 tonnes copper per annum.
Groundwater (mg Cu/l)	0.009	-	
E-GES-CU2.1(spERC U) [Biological on-site WWTP]			
Soil averaged (mg Cu/kg dw)	0.02	24.42	Maximum tonnage 34.5 tonnes copper per annum.
Groundwater (mg Cu/l)	0.000007	-	
E-GES-CU2.1(spERC U) [off-site STP]			
Soil averaged (mg Cu/kg dw)	12.81	37.21	Maximum tonnage 34.5 tonnes copper per annum.
Groundwater (mg Cu/l)	0.009	-	
E-GES-CU2.2(spERC U) [Biological WWTP and STP]			
Soil averaged (mg Cu/kg dw)	5.74	30.14	Maximum tonnage 190 tonnes copper per annum.
Groundwater (mg Cu/l)	0.004	-	
E-GES-CU2.2(spERC U) [Physico-chemical WWTP and STP]			
Soil averaged (mg Cu/kg dw)	13.07	37.47	Maximum tonnage 432 tonnes copper per annum.
Groundwater (mg Cu/l)	0.009	-	

9.3.1.6.6 Atmospheric compartment

Table 112: Annual average Predicted Exposure Concentration (PEC) in local air for catalyst manufacture

ES descriptor	Units	Local concentration	PEC air (local+regional)	Justification
E-GES-CM2.1 (no STP) [Tier 2 – spERC + default receiving water dilution]	mg Cu/m^3	0.000008	0.000008	Maximum tonnage 40 tonnes copper per annum.
E-GES-CM3.1 (no STP) [Tier 3 – spERC + realistic receiving water dilution]		0.00062	0.00062	Maximum tonnage 3250 tonnes copper per annum.
E-GES-CM2.2 [Tier 2 – spERC + default receiving water dilution]		0.0001	0.0001	Maximum tonnage 500 tonnes copper per annum.
E-GES-CM3.2 [Tier 3 – spERC + realistic receiving water dilution]		0.00021	0.00021	Maximum tonnage 1100 tonnes copper per annum.

Table 113: Predicted Exposure Concentration (PEC) in air for downstream use of catalyst products

ES descriptor	Units	Local concentration	PEC air (local+regional)	Justification

E-GES-CU0	mg Cu/m^3	0.0343	0.0343	Maximum tonnage 45000 tonnes copper per annum.
E-GES-CU1.1(6a) [Biological WWTP or STP]		0.0004	0.0004	Maximum tonnage 10.375 tonnes copper per annum.
E-GES-CU1.2(6a) [Biological WWTP and STP]		0.002	0.002	Maximum tonnage 60 tonnes copper per annum.
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]		0.005	0.005	Maximum tonnage 127.5 tonnes copper per annum.
E-GES-CU1.1(6b) [Biological WWTP or STP]		0.000003	0.000003	Maximum tonnage 4.15 tonnes copper per annum.
E-GES-CU1.2(6b) [Biological WWTP and STP]		0.00002	0.00002	Maximum tonnage 23 tonnes copper per annum.
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]		0.00004	0.00004	Maximum tonnage 52 tonnes copper per annum.
E-GES-CU2.1(spERC U) [Biological WWTP or STP]		0.00003	0.00003	Maximum tonnage 34.5 tonnes copper per annum.
E-GES-CU2.2(spERC U) [Biological WWTP and STP]		0.0001	0.0001	Maximum tonnage 190 tonnes copper per annum.
E-GES-CU2.2(spERC U) [Physico-chemical WWTP and STP]		0.0003	0.0003	Maximum tonnage 432 tonnes copper per annum.

9.3.1.6.7 Exposure concentration relevant for the food chain (Secondary poisoning)

Copper is an essential trace element, well regulated in all living organisms. Difference in copper uptake rates are related to essential needs, varying with the species, size, life stage and seasons. Copper homeostatic mechanisms are applicable across species with specific processes being active depending on the species and life stages. Simple estimations on secondary poisoning are therefore not adequate.

There is overwhelming evidence to show the absence of copper biomagnification across the trophic chain in the aquatic and terrestrial food chains. Differences in sensitivity among species are not related to the level in the trophic chain but to the capability of internal homeostasis and detoxification. Field evidence has further provided evidence on the mechanisms of action of copper in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning.

9.3.1.6.8 Workers exposure

ACUTE/SHORT TERM EXPOSURE

Not applicable, only long-term (worst-case) exposure assessments have been carried out for the catalysts sector workers.

LONG-TERM EXPOSURE

A summary of the long-term exposure values for workers involved in catalyst manufacture and/or downstream use of catalyst products is presented in Table 114 and Table 115.

Table 114: Summary of long-term exposure concentration to workers within catalyst manufacture

Routes of exposure	Concentrations	Justification
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Semi-bulk delivery, Storage, Conveying, Drying, Mixing, Calcination (manufacture & regeneration), Reduction, Stabilisation]. No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Semi-bulk delivery, Storage, Conveying, Spent catalyst storage, Drying (manufacture & regeneration), Calcination (manufacture & regeneration), Screening (manufacture & regeneration), Filling operations, Maintenance & Cleaning (manufacture & regeneration)] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 [Drying (regeneration)] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Drying (regeneration)] LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a [Semi-bulk delivery, Transfer activities, Filling operations] LEV + RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Semi-bulk delivery Transfer activities (manufacture & regeneration), Filling operations] LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.313	
W-GES-CM(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 [Forming] LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Fresh catalyst storage, Calcination (regeneration), Forming] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Transfer activities, Mixing, Calcination, Spent catalyst storage, Drying (manufacture & regeneration), Calcination (manufacture & regeneration), Screening (manufacture & regeneration), Maintenance & Cleaning (manufacture & regeneration)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Med)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 [Drying (manufacture & regeneration), Mixing, Calcination, Impregnation batch] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Drying (manufacture & regeneration), Screening, Cleaning] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 [Mixing & blending] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a [Semi-bulk delivery, Transfer activities, Conveying, Filling operations] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Semi-bulk delivery, Transfer activities (manufacture & regeneration), Conveying, Drying, Filling operations] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 [Filling operations (manufacture & regeneration)] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Med)		
Dermal systemic exposure (in mg Cu/d)	0.1	PROC 14 [Forming] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	240	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Semi-bulk delivery, Storage, Transfer activities, Conveying, Calcination (regeneration), Dissolving, Precipitating, Filtrating, Drying, Forming, Fresh catalyst storage] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Semi-bulk delivery, Storage, Transfer activities, Conveying, Dissolving, Filtrating, Forming, Spent catalyst storage (regeneration), Drying (regeneration), Calcination (manufacture & regeneration), Forming, Precipitating, Screening (manufacture & regeneration), Maintenance & Cleaning (manufacture & regeneration)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 [Precipitating, Filtrating, Drying (manufacture & regeneration), Mixing, Impregnation (continuous/batch), Calcination] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(Low)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Filtrating, Drying (regeneration)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a [Semi-bulk delivery, Transfer activities, Conveying, Dissolving, Filtrating, Filling operations] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Semi-bulk delivery, Transfer activities (manufacture & regeneration), Conveying, Dissolving, Filtrating, Forming, Filling operations] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 [Filling operations (manufacture & regeneration)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 [Forming] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Calcination (regeneration), Precipitation, Filtrating] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Filtrating, Spent catalyst storage (regeneration), Drying (regeneration), Calcination (regeneration), Precipitating, Screening (regeneration), Maintenance & Cleaning (regeneration)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 [Drying (regeneration), Precipitation, Filtrating, Impregnation (batch)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Drying (regeneration), Filtrating] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 [Mixing & blending] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
W-GES-CM(Liquid)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	240	PROC 8a [Filtrating] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Transfer activities (regeneration), Filtrating] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 [Filling operations (regeneration), Cleaning] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	

Table 115: Summary of long-term exposure concentration to workers within downstream use of catalyst products

Routes of exposure	Concentrations	Justification
W-GES-CU(High)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CU(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CU(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Maintenance/cleaning] LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
W-GES-CU(High)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.313	
W-GES-CU(High)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 [Pyrometallurgical recycling - smelting] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
W-GES-CU(Med)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CU(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CU(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Maintenance/cleaning] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CU(Med)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
W-GES-CU(Med)		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 [Pyrometallurgical recycling - smelting] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
W-GES-CU(Low)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CU(Low)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CU(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Maintenance/cleaning] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
W-GES-CU(Low)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
W-GES-CU(Low)		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 [Pyrometallurgical recycling - smelting] LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
W-GES-CU(Liquid)		
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
W-GES-CU(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
W-GES-CM(Liquid)		
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 [Maintenance/cleaning] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
W-GES-CU(Liquid)		

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
W-GES-CU(Liquid)		
Dermal systemic exposure (in mg Cu/d)		PROC 22 [Pyrometallurgical recycling - smelting] NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

9.3.1.6.9 Consumer exposure

Not applicable to the catalyst sector.

9.3.1.6.10 Indirect exposure of humans via the environment (oral)

See Section **9.4**.

9.3.2 Generic downstream use of copper dinitrate

9.3.2.1 Description of sectors

The known downstream uses (DU) of copper dinitrate compounds within the scope of REACH with industrial, professional and consumer (end use) uses are given in Table 116.

Table 116: Summary of downstream uses of copper compound

IUCLID identified use number and descriptor (IU)		Industrial		Professional (P)*	Consumer (C)*
		Formulation (F)	Use (I)		
1	Generic formulation step	√			
2	Formulation as an intermediate under SCC	√			
3	Absorbents	√			
4	Catalyst manufacture [see also Section 9.3.1.2]	√			
5	Catalyst use [see also Section 9.3.1.3]	√	√		
6	Ceramics	√	√	√	√
7	Coatings, inks	√	√	√	√
8	Cosmetics	√	√	√	**
9	Electroplating/Galvanic industry (e.g. use in metal surface treatment products)	√	√	√	√
10	Fertilisers	√	√	√	√
11	Glass	√	√	√	√
12	Laboratory chemicals/reagents, quality control	√	√		
13	Leather and textile dyes	√	√		√
14	Lubricants, greases, release products	√	√	√	√
15	Non-metal-surface treatments	√	√		√
16	Polishes and waxes	√	√	√	√
17	Process intermediate for manufacture of other	√	√		

IUCLID identified use number and descriptor (IU)		Industrial Formulation (F)	Industrial Use (I)	Professional (P)*	Consumer (C)*
	copper compounds e.g. catalysts				
18	Processing aids	√	√		
19	Putties, fillers, construction chemicals	√	√	√	√
20	Pyrotechnics (e.g. in fireworks)	√	√	√	√
21	Raw material for synthesis, production of other copper salts and fine chemicals	√	√		

* - results in wide dispersive emissions, linked to both professional and consumer use stages

** - Environment only. Consumer use of cosmetics is out of scope of REACH

Copper dinitrate is used in several product types that fall under the control of separate regulations, e.g. as a food and feed additive; in pharmaceuticals; in biocidal products and in plant protection products. As these uses fall outside the scope of REACH they are not considered any further in this assessment.

Copper dinitrate is also used as an ingredient of cosmetic products. As consumer use of cosmetics is outside the scope of REACH, this use has been excluded from this assessment.

Copper dinitrate may also be present at very low concentrations in various types of articles (see section 9.3.2.3.3 for further information). As there is never any intended release of the compound during service life, no consumer or environmental exposure assessments have been carried out for the articles concerned.

The following sections outline all available environmental and human exposure scenarios that can be used as a guide to inform the specific exposure scenarios for industrial, professional or consumer use as required under REACH.

9.3.2.2 GES descriptors for generic downstream use of copper dinitrate

In order to identify each generic exposure scenario (GES) of downstream use of copper dinitrate, the following descriptor codes have been developed. The environmental GES will all have the prefix **E-GES;** the worker GES will all have the prefix **W-GES** (industrial) or **PW-GES** (professional) and the consumer GES will have the prefix **C-GES**. All of these will then have '**DU**' for downstream use or '**WDU**' for wide dispersive use. WDU results from the end use, which can be equally applied to the professional or consumer DU. In order to define the specific release category or activities investigated within the individual GES title additional sub-categories have been added;

Scenario (GES5 – GES9)			Description
E-GES-DU	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data
	Waste water treatment	0	No waste water emission
		1	Waste water treated once at STP*
	Environmental release category (ERC)	(2)	Formulation of mixtures
		(3)	Formulation in materials
		(4)	Industrial use of processing aids in processes and products, not becoming part of articles
		(5)	Industrial use resulting in inclusion into or

Scenario (GES5 – GES9)			Description
			onto a matrix
		(6a)	Industrial use resulting in manufacture of another substance (use of intermediates)
		(6b)	Industrial use of reactive processing aids
		(6d)	Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers
		(7)	Industrial use of substances in closed systems
		(12a)	Industrial processing of articles with abrasive techniques (low releases)
		(spERC F)	Industrial formulation of metal compounds
		(spERC U)	Industrial use of metal compounds
E-GES-WDU	Environmental release category (ERC)	(ERC8a-c)	Wide dispersive indoor use of substance
		(ERC8d-f)	Wide dispersive outdoor use of substance
		(ERC9a)	Wide dispersive indoor use of substance in closed systems
		(ERC9b)	Wide dispersive outdoor use of substance in closed systems
W/PW-GES-DU	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry
C-GES-DU	Various products		

* - on-site WWTP can be introduced where applicable; STP presents a worst-case approach as this allows for an assessment of risk to the STP microorganisms, and the impact of sludge disposal to land.

The E-GES for downstream use will depend on the potential routes of exposure resulting from the activities within each of the identified exposure titles. Although for industrial uses, potential direct on-site exposure of the soil compartment has been identified within the exposure titles, this is considered to be largely due to accidental spillage (outside the scope of this risk assessment) and will result in limited and localised exposure. This is recognised by the REACH guidance and the available environmental release categories (ERC), where releases to soil are limited to outdoor use scenarios only. However, indirect exposure of the wider soil environment (industrial, natural and agricultural) that will occur as a result of emissions to air and waste water (STP sludge disposal) have been considered. For each exposure title, the predicted environmental concentrations (PEC) for the relevant compartments have been calculated using EUSES 2.0. These PEC values have then been compared to the relevant predicted no effect concentrations (PNEC) in order to determine the risk characterisation (PEC:PNEC) and define the maximum allowable tonnage (PEC:PNEC must not exceed 1).

Due to the generic nature of the exposure assessment of downstream uses and lack of specific information, only 2 environmental GES have been considered;

1. No waste water emissions (exposure via air only) and

2. Waste water release subject to a single waste treatment i.e. released via an STP.

For the GES without waste water emissions, only a single assessment has been carried out using the worst-case air emissions of 0.4% release. This is considered acceptable for the estimation of copper inputs into the environment following the use of copper dinitrate due to the lack of volatility. For the GES where waste water has been considered, this has been repeated for each of the ERC and spERCs identified as relevant to the current downstream use sectors for copper dinitrate.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of RMMs (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

The W/PW-GES for downstream use will depend on the level, route (dermal or inhalation) and length of exposure as derived by assuming a realistic but worst-case exposure challenge. MEASE calculation tools have been used to determine the acceptability of the exposure patterns undertaken by workers during downstream use by calculating the risk characterisation ratio for inhalation, dermal and total exposures (RCR must not exceed 1).

As for the environment, it should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of RMMs (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

9.3.2.3 Generic downstream use scenario development

All downstream use exposure scenario predictions are based on the standard EUSES 2.0 model for the environment and MEASE for the worker exposure in line with the available guidance for REACH.

The downstream uses of copper compounds are considered in terms of user; i.e. industrial (formulation and DU), professional or consumer, which influence the scale and route of the resulting environmental exposure;

- point source (local concentrations [industrial formulation and use]) and
- wide dispersive emissions (regional concentrations [professional and consumer use]).

The downstream use of copper dinitrate is considered to be extremely diverse and in order to provide an assessment that can be applied to all current and future uses of this compound; all potential activities (i.e. PROC codes where available) and routes of exposure (ERCs and spERCs) have been used.

The exposure outputs of this section provide an illustration of the potential exposures for any use pattern address as mapped for the individual user or site, when producing individual or site risk assessment. The approach taken has been to assume worst-case exposures i.e. long-term exposure of workers and consumers with threshold use tonnage calculated for the environment within the generic exposure assessments outlined below.

9.3.2.3.1 Environment generic exposure scenario for downstream use of copper dinitrate [E-GES-DU]

Industrial use: The ERC codes associated with industrial use are subdivided into either a) formulation processes [i.e. the copper compound is used in the formulation step of another chemical or product] or b) downstream use (DU) of the copper compound for a specific purpose. For the potential downstream use sectors of copper dinitrate, identified and agreed by the Copper Compound Consortium, the default exposure assessments have been carried out in addition to the metal compound spERCs for 'formulation' and 'use'. The resulting release estimates for the relevant ERCs and spERC codes are presented below:

a) Industrial – Formulation (GES5)

SCENARIO	E-GES-DU0	E-GES-DU1.1(2)	E-GES-DU1.1(3)	E-GES-DU2.1(spERC F)
Life cycle stage (LCS)	Use			
Containment	Open/closed			
Type of use in LCS	No waste water releases	Formulation of mixtures	Formulation in materials	Industrial formulation of metal compounds
Dispersion of emission sources	Industrial			
Indoor/outdoor	Indoor			
Amount of substance used as input to emission calculation	100% M/I volume			
Fraction used by largest customer - main source	1			
Release times per year	220			
Default release to air from process [%]	0.4	2.5	30	0.004
Default release to water from process [%]	N/A	2	0.2	0.5
Default release to soil from process [%]	N/A	0.01	0.1	N/A
Dilution to be applied for PEC aquatic derivation	ES S1* [Freshwater TGD default] - 10 (18000 m^3/d) ES S2* [Freshwater non-standard] - 100 (180000 m^3/d) ES S3* [Marine TGD default] - 100 (180000 m^3/d)			

*ES S1 - S3 = environmental exposure sub-scenarios with variable dilutions/receiving waters

b) Industrial - Downstream use (GES6)

SCENARIO	E-GES-DU1.1(4)	E-GES-DU1.1(5)	E-GES-DU1.1(6a)	E-GES-DU1.1(6b)	E-GES-DU1.1(6d)	E-GES-DU1.1(7)	E-GES-DU1.1(12a)+	E-GES-DU1.1(spERC U)
Life cycle stage (LCS)	Use							
Containment	Open/closed							
Type of use in LCS	Industrial use of processing aids in processes and products, not becoming part of articles	Industrial use resulting in inclusion into or onto a matrix	Industrial use resulting in manufacture of another substance (use of intermediates)	Industrial use of reactive processing aids	Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers	Industrial use of substances in closed systems	Industrial processing of articles with abrasive techniques (low releases)	Industrial use of metal compounds
Dispersion of emission sources	Industrial							
Indoor/outdoor	Indoor							
Amount of substance used as input to emission calculation	100% M/I volume							
Fraction used by largest customer - main source	1							
Release times per year	220							
Default release to air from process [%]	**100**	50	5	0.10	35	5	**2.5**	0.1
Default release to water from process [%]	100	50	2	5	0.005	5	2.5	0.6
Default release to soil from process [%]	5	1	0.1	0.025	0.025	5	2.5	N/A
Dilution to be applied for PEC aquatic derivation	ES S1* [Freshwater TGD default] - 10 (18000 m^3/d) ES S2* [Freshwater non-standard] - 100 (180000 m^3/d) ES S3* [Marine TGD default] - 100 (180000 m^3/d)							

+ - IUCLID implies this is only suitable for use against in-service exposure predictions, but the descriptor of 'type of use' refers to industrial use environmental releases

<u>Professional (GES7); consumer (GES8) and wide dispersive uses (GES9):</u> In relation to releases to water, the scenario for both indoor and outdoor wide dispersive uses are based on the assumption that they occur in the urban infrastructure, are collected in a central public sewage system and are then treated by an STP. For outdoor uses, this scenario can be considered as a reasonable worst case.

To assume that all releases occur on a paved surface of an urban infrastructure and are collected in a sewage system may be considered overly conservative, but this is balanced by the assumption that all releases to water are treated in an STP.

Direct releases to air and soil are not considered in the wide dispersive use scenario.

For wide dispersive uses, a daily wide dispersive use_(average over a year) should be calculated (tonnes/day) according to the REACH guidance. Consequently the same releases are used for the assessment of the risk for the environment and for man via the environment (and (top) predators) where applicable.

There are specific ERC codes linked to wide dispersive uses which are;

Professional and consumer uses:

- ERC8a-c: Wide dispersive indoor use of substance
- ERC8d-f: Wide dispersive outdoor use of substance
- ERC9a: Wide dispersive indoor use of substance in closed systems
- ERC9b: Wide dispersive outdoor use of substance in closed systems

Looking at individual downstream wide dispersive use in terms of defining safe threshold limits is not appropriate as <u>all</u> uses of copper should be considered in parallel as the resulting concentrations will be additive. Therefore, as shown by the VRA, measured levels of copper reported in STP effluent is a more appropriate method of addressing the wide dispersive uses from all uses where environmental releases of copper may occur.

Measured region-specific PEC data are available for STP effluents from 3 EU countries; Belgium, the Netherlands and UK that range between 0.011 and 0.054 mg total Cu/l. In addition, the highest PEC for the STP of 0.054 mg total Cu/l was reported in the UK, which was shown to be equivalent to 0.008 mg dissolved Cu/l.

9.3.2.3.2 <u>Worker Generic Exposure Scenario for downstream use of copper dinitrate [W/PW-GES-DU]</u>

For the purpose of assessing the exposure of workers (industrial and professional) to copper compounds, only the MEASE model outputs have been used and the results for all available PROCs are presented in full in Annex 14 (industrial) and Annex 15 (Professional). These outputs have been used to map the potential exposures for workers involved in the downstream use sectors in accordance with REACH guidance and descriptions, with additional information provided by the members of the Copper Compound Consortium. Acceptable working conditions are defined as those where the risk characterisation was calculated to be <1.

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solids) or from evaporation (liquids) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities, as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high.

9.3.2.3.3 Consumer Generic Exposure Scenario for downstream use of copper dinitrate [C-GES-DU]

Copper dinitrate is used in the following product types that have consumer applications that may result in low-level exposure:

- Coatings and inks
- Fertilisers
- Lubricants, greases, release products
- Polishes & wax blends
- Putties, fillers and construction products
- Pyrotechnics (e.g. in fireworks)

Copper dinitrate may be incorporated into the following types of articles, from which there is no intended release and therefore no significant potential for consumer exposure:

- Ceramics
- Electroplating and galvanic
- Glass
- Non-metal surface treatments

Copper dinitrate is also used during the production/processing of the following finished articles, which may therefore incidentally contain trace quantities of the substance.

- Leather and textile dyes

As there is no intended release from these articles, there is considered to be no significant potential for consumer exposure and they will not be considered any further in this assessment.

Copper dinitrate is also used in product types that fall under the control of separate regulations, e.g. consumer use of cosmetics, biocidal and plant protection products, food and feed ingredients. As such, these uses will not be considered any further in this assessment.

Exposure resulting from the use of consumer products containing copper and copper compounds was evaluated as a broad class under the VRA (2008). This evaluation is considered to be directly applicable to the requirements of REACH and has therefore been adopted without modification.

It was noted in the VRA (2008) that consumer exposure to copper may occur via dermal or oral routes or via inhalation. Dermal exposure occurs mainly through the use of toiletries and cosmetics or through the handling of with coins or wearing of jewellery. Additional dermal exposure is possible from the use of special paints or from copper-containing wood preservatives and pesticides. The latter use was not considered in the VRA, since this is the subject of a separate risk assessment. Oral exposure (other than from food and water) occurs in particular by ingestion of dietary supplements containing copper; inhalation exposure occurs through cigarette smoke. Internal exposure may also occur with the use of intra-uterine devices. Due to sparse information on the release of copper from consumer products and uncertainties in rates and frequency of use, the magnitude of most forms of consumer exposure could only be estimated approximately. A summary of consumer external exposure estimates (mg/person/day), from copper and copper compounds, for the general population is shown in Table 117.

Table 117: Summary of consumer external exposure estimates for the general population (VRA, 2008)

Articles/products	General Population (mg/person/day)	
	Typical	Reasonable Worst Case [RWC]
Cosmetics and toiletries		
Face cream	0.24	1.44
Hair care products	4.3×10^{-6}	1.4×10^{-5}
Other		
Cigarette smoking	none	5×10^{-4}
Handling of coins	0.14	0.28
Copper jewellery	none	0.41
Paints	none	4.03
Food supplements	none	2.00

As there is no intended release from these articles, there is considered to be no significant potential for consumer exposure and they will not be considered any further in this assessment.

9.3.2.4 Exposure scenarios for generic downstream uses of copper dinitrate

9.3.2.4.1 Industrial use

GES5: Industrial generic 'formulation' use of copper dinitrate.

1. Title GES – Industrial 'formulation' use of copper dinitrate	
Life cycle	Formulation (industrial) stage of copper dinitrate
Free short title	Generic downstream industrial 'formulation' of copper dinitrate
Systematic title based on use descriptor	SU: SU3 – Uses of substances as such or in preparations at industrial sites PC: PC 0: Other: Colouring agents, pigments PC 2: Adsorbents PC 3: Air care products PC 9a: Coatings and paints, thinners, paint removers PC 9b: Fillers, putties, plasters, modelling clay PC 12: Fertilisers PC 14: Metal surface treatment products, including galvanic and electroplating products PC 15: Non-metal-surface treatment products PC 18: Ink and toners PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 21: Laboratory chemicals PC 23: Leather tanning, dye, finishing, impregnation and care products PC 24: Lubricants, greases, release products PC 31: Polishes and wax blends PC 32: Polymer preparations and compounds PC 39: Cosmetics, personal care products ERC: ERC 2 – Formulation of mixtures ERC 3 – Formulation in materials spERC F – Industrial formulation of metal compounds PROC: PROC 1 – Use in closed process, no likelihood of exposure PROC 2 – Use in closed, continuous process with occasional controlled exposure PROC 3 – Use in closed batch process (synthesis or formulation) PROC 4 – Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5 – Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or

	significant contact) PROC 8a – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9 – Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14 – Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 19 – Hand mixing with intimate contact and only PPE available PROC 21 – Low energy manipulation of substances bound in materials and/or articles PROC 26 – Handling of solid inorganic substances at ambient temperature
Processes, tasks, activities covered (environment)	This scenario covers downstream formulation of preparations and/or materials during the following identified uses of copper dinitrate: Absorbents; Catalyst manufacture; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Laboratory chemicals/reagents, quality control; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected ERCs
Processes, tasks, activities covered (workers)	This scenario covers downstream formulation of preparations and/or materials during the following identified uses of copper dinitrate: Absorbents; Catalyst manufacture; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Laboratory chemicals/reagents, quality control; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected PROCs
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure [E-GES-DU0]	
Environmental related free short title	Generic downstream industrial 'formulation' of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 2 – 3 but without releases to water
Processes, tasks, activities covered (environment)	ERC 2 – 3 but without releases to water

Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC.
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	25 000 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	Not relevant
Dilution capacity	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No release to water **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Not relevant	
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.2 Control of environmental exposure [E-GES-DU1.1(ERC2)]	
Environmental related free short title	Generic downstream industrial ‘formulation’ of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 2 – Formulation of mixtures
Processes, tasks, activities covered (environment)	Mixing and blending of substances into chemical preparations in all types of formulating industries, such as paints and do-it- yourself products, pigment paste, fuels, household products (cleaning products), lubricants, etc.
Environmental Assessment Method	Predicted (modelled) local and regional (measured)

	concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	10 tonnes Cu per year
Maximum annual use at a site ES S2	17 tonnes Cu per year
Maximum annual use at a site ES S3	17 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 2 is taken: 2% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	

As applicable	
2.3 Control of environmental exposure [E-GES-DU1.1(ERC3)]	
Environmental related free short title	Generic downstream industrial 'formulation' of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 3 – Formulation in materials
Processes, tasks, activities covered (environment)	Mixing or blending of substances which will be physically or chemically bound into or onto a matrix (material) such as plastics additives in master batches or plastic compounds. For instance; plasticizers or stabilizers in PVC master-batches or products, crystal growth regulator in photographic films, etc.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	100 tonnes Cu per year
Maximum annual use at a site ES S2	170 tonnes Cu per year
Maximum annual use at a site ES S3	170 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 3 is taken: 0.2% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	

Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.4 Control of environmental exposure [E-GES-DU2.1(spERC F-Formulation)]	
Environmental related free short title	Generic downstream industrial 'formulation' of copper dinitrate
Systematic title based on use descriptor (environment)	spERC : formulation of metal compounds v1.1
Processes, tasks, activities covered (environment)	Mixing and blending of metal compounds into preparations in following formulating industries: catalyst, glass, pigments, paints, coatings plastics, rubber and stabilisers, water treatment chemicals.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	41 tonnes Cu per year
Maximum annual use at a site ES S2	67 tonnes Cu per year
Maximum annual use at a site ES S3	67 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m^3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	

Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: The spERC emission factor of 0.5% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 60% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment can be either onsite or offsite with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.004% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.5 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 1
Processes, tasks, activities covered	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default

Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	No LEV required
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.6 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 2
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional expose will arise e.g. through maintenance, sampling and equipment breakages
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	

Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.7 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 3
Processes, tasks, activities covered	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	

Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.8 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 4
Processes, tasks, activities covered	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure

Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.9 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 5

Processes, tasks, activities covered	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required

2.10 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 8a
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in non- dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required

Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.11 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 8b
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)

Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.12 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 9
Processes, tasks, activities covered	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	

Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.13 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 14
Processes, tasks, activities covered	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)

High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.14 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 19
Processes, tasks, activities covered	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	

Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV available
Medium dustiness	No LEV available
High dustiness	No LEV available
Aqueous solution	No LEV available
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	RPE required : Inhalation APF = 10
High dustiness	RPE required : Inhalation APF = 40
Aqueous solution	No RPE required
2.15 Control of workers exposure for contributing exposure scenario [W-GES-DU(Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 21
Processes, tasks, activities covered	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (Low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	

Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
2.16 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 26
Processes, tasks, activities covered	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, un-packaging, mixing/blending and weighing of metal powders or other minerals
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	

Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
3. Exposure and risk estimation	

Environment

ES1 – Freshwater dilution factor = 10

ES2 – Freshwater dilution factor = 100

ES3 – Marine dilution factor = 100

E-GES-DU0: No releases to water with worst case spERC air emission factor: 0.4%

Compartment	Unit	PNEC	$PEC_{Regional}$	C_{local}	PEC	RCR
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	33.51	57.91	0.90

E-GES-DU1.1: ERC 2

Compartment	Unit	PNEC	$PEC_{Regional}$	C_{local}	PEC	RCR
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.43
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.71	12.71	0.15
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.71	28.81	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.67	44.07	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	33.45	57.85	0.90

E-GES-DU1.1: ERC 3						
Compartment	**Unit**	**PNEC**	**$PEC_{Regional}$**	**C_{local}**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.43
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.71	12.71	0.15
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.71	28.81	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.67	44.07	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	33.45	57.85	0.90

E-GES-DU2.1: spERCs F						
Compartment	**Unit**	**PNEC**	**$PEC_{Regional}$**	**C_{local}**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.6	5.5	0.70
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.43
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	76.64	76.64	0.88
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.52	12.52	0.14
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.52	28.62	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	20.15	44.55	0.69
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	32.93	57.33	0.89

Workers

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**PPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 1**	No	No	0.023
W-GES-DU(Med)		Medium		No	No	0.023
W-GES-DU(Low)		Low		No	No	0.023
W-GES-DU(Liquid)	Liquid			No	No	0.126

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 2	Yes	No	0.125
W-GES-DU(Med)		Medium		No	No	0.525
W-GES-DU(Low)		Low		No	No	0.035
W-GES-DU(Liquid)	Liquid			No	No	0.252

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 3	Yes	No	0.113
W-GES-DU(Med)		Medium		Yes	No	0.113
W-GES-DU(Low)		Low		No	No	0.113
W-GES-DU(Liquid)	Liquid			No	No	0.135

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 4	Yes	Yes APF = 4	0.65
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.525
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 5	Yes	Yes APF = 4	0.650
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.525
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 8a	Yes	Yes APF = 10	0.55
W-GES-DU(Med)		Medium		Yes	No	0.55
W-GES-DU(Low)		Low		No	No	0.55
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 8b**	Yes	Yes APF = 4	0.338
W-GES-DU(Med)		Medium		Yes	No	0.275
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 9**	Yes	Yes APF = 4	0.525
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 14**	Yes	Yes APF = 4	0.275
W-GES-DU(Med)		Medium		Yes	No	0.125
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 19**	No	Yes APF = 40	0.728
W-GES-DU(Med)		Medium		No	Yes APF = 10	0.603
W-GES-DU(Low)		Low		No	No	0.603
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form		PROC	Worker protection required		RCR
				LEV	PPE	Combined Exposure
W-GES-DU(Low)	Solid	Low	**PROC 21**	No	No	0.603

GES	Physical form	PROC	Worker protection required	RCR

				LEV	PPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 26**	Yes	Yes APF = 4	0.553
W-GES-DU(Med)		Medium		Yes	No	0.823
W-GES-DU(Low)		Low		Yes	No	0.373

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Environment

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Workers

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

It should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

GES6: Industrial generic downstream use of copper dinitrate.

1. Title GES – Industrial use of copper dinitrate	
Life cycle	Use (industrial) stage of copper dinitrate
Free short title	Generic downstream industrial use of copper dinitrate
Systematic title based on use descriptor	SU: *Generic DU:* SU3 – Uses of substances as such or in

	preparations* at industrial sites *Additional specific DU (where applicable according to IUCLID, see Section 9.3.2.1)* Adsorbents [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Catalyst manufacture [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Catalyst use [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Ceramics [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement; SU 19: Building and construction work] Coatings, inks [SU 7: Printing and reproduction of recorded media; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Cosmetics [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 0: Other: cosmetics] Electroplating and galvanic [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 14: Manufacture of basic metals, including alloys; SU 16: Manufacture of computer, electronic and optical products, electrical equipment] Fertiliser [SU 1: Agriculture, forestry and fishing; SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Glass [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement] Laboratory chemicals/reagent, quality control [SU 24: Scientific research and development] Leather and textile dyes [SU 5: Manufacture of textiles, leather, fur] Lubricants and greases, release products [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Non-metal surface treatments [SU 15: Manufacture of fabricated metal products, except machinery and equipment] Polishes and waxes [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Process intermediate for manufacture of other copper compounds e.g. catalysts [SU 8: Manufacture of bulk,

	large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Processing aids [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals] Putties, fillers, construction chemicals [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 19: Building and construction work] Pyrotechnics [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Raw material for production of other compounds and fine chemicals [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] PC: Adsorbents [PC 2: Adsorbents; PC 3: Air care products; PC 19: Intermediate; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents] Catalyst manufacture [PC 2: Adsorbents; PC 19: Intermediate; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents] Catalyst use [PC 2: Adsorbents; PC 19: Intermediate; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents; PC 32: Polymer preparations and compounds] Ceramics [PC 0: Other: Colouring agents, pigments] Coatings, inks [PC 9a: Coatings and paints, thinners, paint removers; PC 18: Ink and toners] Cosmetics [PC 39: Cosmetics, personal care products] Electroplating and galvanic [PC 14: Metal surface treatment products, including galvanic and electroplating products] Fertiliser [PC 12: Fertilisers] Glass [PC 0: Other: Colouring agents, pigments] Laboratory chemicals/reagent, quality control [PC 19: Intermediate; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents; PC 21: Laboratory chemicals] Leather and textile dyes [PC 23: Leather tanning, dye, finishing, impregnation and care products] Lubricants and greases, release products [PC 24: Lubricants, greases, release products] Non-metal surface treatments [PC 15: Non-metal-surface treatment products] Polishes and waxes [PC 31: Polishes and wax blends] Process intermediate for manufacture of other copper compounds e.g. catalysts [PC 19: Intermediate] Processing aids [PC 2: Adsorbents; PC 19: Intermediate; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents] Putties, fillers, construction chemicals [PC 9b: Fillers, putties, plasters, modelling clay]

	Pyrotechnics [PC 0: Other: Colouring agents, pigments] Raw material for production of other compounds and fine chemicals [PC 19: Intermediate] <u>ERC</u>: ERC 4 – Industrial use of processing aids in processes and products, not becoming part of articles ERC 5 – Industrial use resulting in inclusion into or onto a matrix ERC 6a – Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b – Industrial use of reactive processing aids ERC 6d – Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers ERC 7 – Industrial use of substances in closed systems ERC 12a – Industrial processing of articles with abrasive techniques (low releases) spERC U – Industrial use of metal compounds <u>PROC</u>: PROC 1 – Use in closed process, no likelihood of exposure PROC 2 – Use in closed, continuous process with occasional controlled exposure PROC 3 – Use in closed batch process (synthesis or formulation) PROC 4 – Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5 – Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7 – Industrial spraying PROC 8a – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9 – Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10 – Roller application or brushing of adhesive and other coating Industrial or non-industrial setting PROC 13 – Treatment of articles by dipping and pouring PROC 14 – Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15 – Use as laboratory reagent PROC 17 – Lubrication at high energy conditions and in partly open process PROC 19 – Hand mixing with intimate contact and only PPE available PROC 20 – Heat and pressure transfer fluids in dispersive, professional use but closed systems PROC 21 – Low energy manipulation of substances bound in materials and/or articles

	PROC 22 – Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature PROC 24 – High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25 – Other hot work operations with metals PROC 26 – Handling of solid inorganic substances at ambient temperature
Processes, tasks, activities covered (environment)	This scenario covers downstream uses of copper dinitrate: Absorbents; Catalyst manufacture; Catalyst use; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Laboratory chemicals/reagents, quality control; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected ERCs
Processes, tasks, activities covered (workers)	This scenario covers downstream uses of copper dinitrate: Absorbents; Catalyst manufacture; Catalyst use; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Laboratory chemicals/reagents, quality control; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected PROCs
2. Operational conditions and risk management measures	
2.1 Control of environmental exposure [E-GES-DU0]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 4 – 7 but without releases to water
Processes, tasks, activities covered (environment)	ERC 4 – 7 but without releases to water
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC.
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	25 000 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]

Environment factors not influenced by risk management	
Receiving surface water flow rate	Not relevant
Dilution capacity	Not relevant
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: No release to water **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Not relevant	
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.2 Control of environmental exposure [E-GES-DU1.1(ERC4)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 4 – Industrial use of processing aids
Processes, tasks, activities covered (environment)	Industrial use of processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example, solvents used in chemical reactions or the 'use' of solvents during the application of paints, lubricants in metal working fluids, anti-set off agents in polymer moulding/casting.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	0.2 tonnes Cu per year
Maximum annual use at a site ES S2	0.3 tonnes Cu per year
Maximum annual use at a site ES S3	0.3 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d

Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 4 is taken: 100% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.3 Control of environmental exposure [E-GES-DU1.1(ERC5)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 5 – Industrial inclusion into or onto a matrix
Processes, tasks, activities covered (environment)	Industrial use of substances as such or in preparations (non- processing aids), which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyes in textile fabrics and leather products, metals in coatings applied through plating and galvanizing processes. The category covers substances in articles with a particular function and also substances remaining in the article after having been used as processing aid in an earlier life cycle stage (e.g. heat stabilisers in plastic processing).
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	

Amounts used	
Maximum annual use at a site ES S1	0.40 tonnes Cu per year
Maximum annual use at a site ES S2	0.65 tonnes Cu per year
Maximum annual use at a site ES S3	0.65 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 5 is taken: 50% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.4 Control of environmental exposure [E-GES-DU1.1(ERC6a)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 6a – Industrial use of intermediates
Processes, tasks, activities covered (environment)	Use of intermediates in primarily the chemical industry using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions, for the synthesis (manufacture) of other substances. For instance

	the use of chemical building blocks (feedstock) in the synthesis of agrochemicals, pharmaceuticals, monomers, etc.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	10 tonnes Cu per year
Maximum annual use at a site ES S2	17 tonnes Cu per year
Maximum annual use at a site ES S3	17 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 6a is taken: 2% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.5 Control of environmental exposure [E-GES-DU1.1(ERC6b)]	

Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 6b – Industrial use of reactive processing aids
Processes, tasks, activities covered (environment)	Industrial use of reactive processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example the use of bleaching agents in the paper industry.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	4 tonnes Cu per year
Maximum annual use at a site ES S2	6.5 tonnes Cu per year
Maximum annual use at a site ES S3	6.5 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 6b is taken: 5% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	

Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.6 Control of environmental exposure [E-GES-DU1.1(ERC6d)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 6d – Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers
Processes, tasks, activities covered (environment)	Industrial use of chemicals (cross-linking agents, curing agents) in the production of thermosets and rubbers, polymer processing. For instance the use of styrene in polyester production or vulcanization agents in the production of rubbers.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	4100 tonnes Cu per year
Maximum annual use at a site ES S2	5000 tonnes Cu per year
Maximum annual use at a site ES S3	5000 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 6d is taken: 0.005% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	

Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.7 Control of environmental exposure [E-GES-DU1.1(ERC7)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 7 – Industrial use of substances in closed systems
Processes, tasks, activities covered (environment)	Industrial use of substances in closed systems. Use in closed equipment, such as the use of liquids in hydraulic systems, cooling liquids in refrigerators and lubricants in engines and dielectric fluids in electric transformers and oil in heat exchangers. No intended contact between functional fluids and products foreseen and thus low emissions via waste water and waste air to be expected.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	4 tonnes Cu per year
Maximum annual use at a site ES S2	6.5 tonnes Cu per year
Maximum annual use at a site ES S3	6.5 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 7 is taken: 5% This value is not taking into account RMM so a	

92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.8 Control of environmental exposure [E-GES-DU1.1(ERC12a)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC 12a – Industrial processing of articles with abrasive techniques (low release)
Processes, tasks, activities covered (environment)	Substances included into or onto articles and materials are released (intended or not) from the article matrix as a result of processing by workers. These processes are typically related to PROC 21, 24, 25. Processes where the removal of material is intended, but the expected release remains low, include for example: cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries.
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	8 tonnes Cu per year
Maximum annual use at a site ES S2	13 tonnes Cu per year
Maximum annual use at a site ES S3	13 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	

None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: At least one waste water treatment either onsite or offsite is required with an efficiency of 92% Cu removal. Default emission value from ERC 12a is taken: 2.5% This value is not taking into account RMM so a 92% reduction is still applied. **Air:** 0.4% emission assumed irrespective of ERC. This value is taken from the worst case metal spERCs (Use of metals and metal compounds in metallic coating v1.1). Due to negligible volatility of copper the default ERC values for air emissions are unreasonably high.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.9 Control of environmental exposure [E-GES-DU2.1(spERC U-Use)]	
Environmental related free short title	Generic industrial use of copper dinitrate
Systematic title based on use descriptor (environment)	spERC U: use of metal compounds v1.1
Processes, tasks, activities covered (environment)	Industrial use of metal compounds in following sectors: crystal manufacture, leather tanning, pigments, paints, coatings, plastics, rubber and textiles. In the absence of a catalyst sector specific spERC it is considered that the approach set out in version 1.1 of 'Industrial use of metal compounds' spERC remains valid and has been used in the Tier 2 assessment (see Section 9.3.1.3.1).
Environmental Assessment Method	Predicted (modelled) local and regional (measured) concentrations of copper are used for calculation of the PEC
Product characteristics	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Maximum annual use at a site ES S1	35 tonnes Cu per year
Maximum annual use at a site ES S2	190 tonnes Cu per year
Maximum annual use at a site ES S3	190 tonnes Cu per year
Frequency and duration of use	
Pattern of release to the environment	220 days per year [For GES only]

Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity 1, freshwater	10 (default)
Dilution capacity 2, freshwater	100
Dilution capacity, marine	100 (default)
Other given operational conditions affecting environmental exposure	
None	
Technical conditions and measures at process level (source) to prevent release	
None	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Waste water: The spERC emission factor of 0.6% is the maximum of the 90th percentiles of reported site-specific release factors to waste water. > 50% of the sites have RMM for water. It is assumed that the 90th percentile used for the spERC is from a site without RMM for water. Therefore an additional treatment step is added. The waste water treatment can be either onsite or offsite with an efficiency of 92% Cu removal. **Air:** The spERC emission factor of 0.1% is the maximum of the 90th percentiles of reported site-specific release factors to air.	
Organizational measures to prevent/limit release from site	
None	
Conditions and measures related to municipal sewage treatment plant	
Municipal Sewage Treatment Plant (STP)	92% removal assumed
Discharge rate of the Municipal STP	Default: 200 l per capita (10000 capita per STP)
Incineration of the sludge of the Municipal STP	None assumed, disposal to land calculated as default setting
Conditions and measures related to external treatment of waste for disposal	
Waste is taken to a controlled offsite location for incineration, disposal or recycling	
Conditions and measures related to external recovery of waste	
As applicable	
2.10 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 1
Processes, tasks, activities covered	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	

Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	No LEV required
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.11 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 2
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	

Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.12 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 3
Processes, tasks, activities covered	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	

Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.13 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 4
Processes, tasks, activities covered	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default

Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.14 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 5
Processes, tasks, activities covered	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default

Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.15 Control of workers exposure for contributing exposure scenario [W-GES-DU(Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 7
Processes, tasks, activities covered	Air dispersive techniques Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	

Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	RPE required : Inhalation APF = 4
2.16 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 8a
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in non- dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	

Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.17 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 8b
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	

Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.18 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 9
Processes, tasks, activities covered	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	

Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.19 Control of workers exposure for contributing exposure scenario [W-GES-DU(Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 10
Processes, tasks, activities covered	Low energy spreading of e.g. coatings Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required

Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.20 Control of workers exposure for contributing exposure scenario [W-GES-DU(Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 13
Processes, tasks, activities covered	Immersion operations Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	

Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.21 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 14
Processes, tasks, activities covered	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)

Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.22 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 15
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	

Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.23 Control of workers exposure for contributing exposure scenario [W-GES-DU(Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 17
Processes, tasks, activities covered	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.24 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low, Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate

Use descriptor covered	PROC 19
Processes, tasks, activities covered	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV available
Medium dustiness	No LEV available
High dustiness	No LEV available
Aqueous solution	No LEV available
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	RPE required : Inhalation APF = 10
High dustiness	RPE required : Inhalation APF = 40
Aqueous solution	No RPE required
2.25 Control of workers exposure for contributing exposure scenario [W-GES-DU(Liquid)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 20
Processes, tasks, activities covered	Motor and engine oils, brake fluids Also in these applications, the lubricant may be exposed to high energy

	conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.26 Control of workers exposure for contributing exposure scenario [W-GES-DU(Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 21
Processes, tasks, activities covered	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (Low dustiness)	
Amounts used	

Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
2.27 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 22
Processes, tasks, activities covered	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default

Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
2.28 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 23
Processes, tasks, activities covered	Sand and die casting, tapping and casting melted solids, dressing of melted solids, hot dip galvanising, raking of melted solids in paving Exposure related to dust and fumes to be expected
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	

Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
2.29 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 24
Processes, tasks, activities covered	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	

Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
2.30 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 25
Processes, tasks, activities covered	Welding, soldering, gouging, brazing, flame cutting Exposure is predominantly expected to fumes and gases.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)

High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
2.31 Control of workers exposure for contributing exposure scenario [W-GES-DU(High, Med, Low)]	
Workers related free short title	Generic exposure for workers exposed to copper dinitrate
Use descriptor covered	PROC 26
Processes, tasks, activities covered	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, un-packaging, mixing/blending and weighing of metal powders or other minerals
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	

Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
3. Exposure and risk estimation	

Environment
ES1 – Freshwater dilution factor = 10
ES2 – Freshwater dilution factor = 100
ES3 – Marine dilution factor = 100

E-GES-DU0: No releases to water with worst case spERC air emission factor: 0.4%

Compartment	Unit	PNEC	$PEC_{Regional}$	C_{local}	PEC	RCR
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	33.51	57.91	0.90

E-GES-DU1.1: ERC 4

Compartment	Unit	PNEC	$PEC_{Regional}$	C_{local}	PEC	RCR
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.42
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.26
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	11.22	11.22	0.13
Marine sediment ES 3	mg Cu/kg dw	676	16.1	11.22	27.32	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.67	44.07	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	29.49	53.89	0.83

E-GES-DU1.1: ERC 5

Compartment	Unit	PNEC	$PEC_{Regional}$	C_{local}	PEC	RCR
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.42
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.15	12.15	0.14
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.15	28.25	0.04
Terrestrial	mg Cu/kg dw	64.6	24.4	19.66	44.06	0.68

ES 1						
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	31.95	56.35	0.87

E-GES-DU1.1: ERC 6a						
Compartment	**Unit**	**PNEC**	**$PEC_{Regional}$**	**C_{local}**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.43
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.71	12.71	0.15
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.71	28.81	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.67	44.07	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	33.45	57.85	0.90

E-GES-DU1.1: ERC 6b or ERC 7						
Compartment	**Unit**	**PNEC**	**$PEC_{Regional}$**	**C_{local}**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.42
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.15	12.15	0.14
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.15	28.25	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.66	44.06	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	31.95	56.35	0.87

E-GES-DU1.1: ERC 6d						
Compartment	**Unit**	**PNEC**	**$PEC_{Regional}$**	**C_{local}**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.6	5.5	0.70
Freshwater ES 2	µg Cu/l	7.8	2.90	0.3	3.2	0.41
Marine ES 3	µg Cu/l	5.6	1.10	0.3	1.4	0.25
Freshwater sediment ES 1	mg Cu/kg dw	87	0	76.64	76.64	0.88
Freshwater sediment ES 2	mg Cu/kg dw	87	0	9.35	9.35	0.11
Marine sediment ES 3	mg Cu/kg dw	676	16.1	9.35	25.45	0.04

Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	25.65	50.05	0.77
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	31.28	55.68	0.86

E-GES-DU1.1: ERC 12a						
Compartment	**Unit**	**PNEC**	**PEC$_{Regional}$**	**C$_{local}$**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.5	5.4	0.69
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.42
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	74.77	74.77	0.86
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.15	12.15	0.14
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.15	28.25	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	19.66	44.06	0.68
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	31.95	56.35	0.87

E-GES-DU2.1: spERCs U						
Compartment	**Unit**	**PNEC**	**PEC$_{Regional}$**	**C$_{local}$**	**PEC**	**RCR**
Freshwater ES 1	µg Cu/l	7.8	2.90	2.6	5.5	0.71
Freshwater ES 2	µg Cu/l	7.8	2.90	0.4	3.3	0.42
Marine ES 3	µg Cu/l	5.6	1.10	0.4	1.5	0.27
Freshwater sediment ES 1	mg Cu/kg dw	87	0	78.51	78.51	0.90
Freshwater sediment ES 2	mg Cu/kg dw	87	0	12.34	12.34	0.14
Marine sediment ES 3	mg Cu/kg dw	676	16.1	12.34	28.44	0.04
Terrestrial ES 1	mg Cu/kg dw	64.6	24.4	20.66	45.06	0.70
Terrestrial ES 2 and 3	mg Cu/kg dw	64.6	24.4	32.46	56.86	0.88

Workers

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 1**	No	No	0.023
W-GES-DU(Med)		Medium		No	No	0.023

W-GES-DU(Low)		Low		No	No	0.023
W-GES-DU(Liquid)	Liquid			No	No	0.126

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 2**	Yes	No	0.125
W-GES-DU(Med)		Medium		No	No	0.525
W-GES-DU(Low)		Low		No	No	0.035
W-GES-DU(Liquid)	Liquid			No	No	0.252

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 3**	Yes	No	0.113
W-GES-DU(Med)		Medium		Yes	No	0.113
W-GES-DU(Low)		Low		No	No	0.113
W-GES-DU(Liquid)	Liquid			No	No	0.135

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 4**	Yes	Yes APF = 4	0.650
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.525
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 5**	Yes	Yes APF = 4	0.650
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.525
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	**Physical form**	**PROC**	**Worker protection required**		**RCR**
			LEV	**RPE**	**Combined Exposure**
W-GES-DU(Liquid)	Liquid	**PROC 7**	Yes	Yes APF = 4	0.501

GES	**Physical form**	**PROC**	**Worker protection required**	**RCR**

				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 8a**	Yes	Yes APF = 10	0.55
W-GES-DU(Med)		Medium		Yes	No	0.55
W-GES-DU(Low)		Low		No	No	0.55
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 8b**	Yes	Yes APF = 4	0.338
W-GES-DU(Med)		Medium		Yes	No	0.275
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 9**	Yes	Yes APF = 4	0.525
W-GES-DU(Med)		Medium		Yes	No	0.525
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
W-GES-DU(Liquid)	Liquid	**PROC 10**	No	No	0.301

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
W-GES-DU(Liquid)	Liquid	**PROC 13**	No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 14**	Yes	Yes APF = 4	0.275
W-GES-DU(Med)		Medium		Yes	No	0.125
W-GES-DU(Low)		Low		No	No	0.125
W-GES-DU(Liquid)	Liquid			No	No	0.261

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 15**	Yes	No	0.513
W-GES-DU(Med)		Medium		No	No	0.513
W-GES-DU(Low)		Low		No	No	0.113
W-GES-DU(Liquid)	Liquid			No	No	0.126

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
W-GES-DU(Liquid)	Liquid	**PROC 17**	No	No	0.35

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 19**	No	Yes APF = 40	0.728
W-GES-DU(Med)		Medium		No	Yes APF = 10	0.603
W-GES-DU(Low)		Low		No	No	0.603
W-GES-DU(Liquid)	Liquid			No	No	0.301

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
W-GES-DU(Liquid)	Liquid	**PROC 20**	No	No	0.252

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(Low)	Solid	Low	**PROC 21**	No	No	0.603

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	**PROC 22**	Yes	No	0.803
W-GES-DU(Med)		Medium		Yes	No	0.803
W-GES-DU(Low)		Low		Yes	No	0.803

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 23	Yes	No	0.303
W-GES-DU(Med)		Medium		Yes	No	0.303
W-GES-DU(Low)		Low		Yes	No	0.303

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 24	Yes	Yes APF = 4	0.378
W-GES-DU(Med)		Medium		Yes	No	0.703
W-GES-DU(Low)		Low		Yes	No	0.503

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 25	Yes	No	0.303
W-GES-DU(Med)		Medium		Yes	No	0.303
W-GES-DU(Low)		Low		Yes	No	0.303

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
W-GES-DU(High)	Solid [Dustiness]	High	PROC 26	Yes	Yes APF = 4	0.553
W-GES-DU(Med)		Medium		Yes	No	0.823
W-GES-DU(Low)		Low		Yes	No	0.373

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Environment

Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool)

Scaling of the release to air and water environment includes:

Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility.

Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7.

It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Workers

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

It should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

9.3.2.4.2 Professional use: [Worker only]

GES7: Professional generic downstream use of copper dinitrate.

1. Title GES – Professional downstream use of copper dinitrate	
Life cycle	Use stage of copper dinitrate
Free short title	Generic professional use of copper dinitrate
Systematic title based on use descriptor	SU: *Generic DU:* SU22 – Professional use *Additional specific DU (where applicable according to IUCLID, see Section 9.3.2.1):* Ceramics [SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement; SU 19: Building and construction work] Coatings/Inks [SU 7: Printing and reproduction of recorded media; SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Cosmetics [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 0: Other: Cosmetics] Electroplating and galvanic [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 14: Manufacture of basic metals, including alloys; SU 16: Manufacture of computer, electronic and optical products, electrical equipment] Fertiliser [SU 1: Agriculture, forestry and fishing; SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Glass [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys), SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement] Lubricants and greases, release products [SU 10:

	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Polishes and waxes [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] Putties, fillers, construction chemicals [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 19: Building and construction work] Pyrotechnics [SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)] PC: Ceramics [PC 0: Other: Colouring agents, pigments] Coatings/Inks [PC 9a: Coatings and paints, thinners, paint removers; PC 18: Ink and toners] Cosmetics [PC 39: Cosmetics, personal care products] Electroplating and galvanic [PC 14: Metal surface treatment products, including galvanic and electroplating products] Fertiliser [PC 12: Fertilisers] Glass [PC 0: Other: Colouring agents, pigments] Lubricants and greases, release products [PC 24: Lubricants, greases, release products] Polishes and waxes [PC 31: Polishes and wax blends] Putties, fillers, construction chemicals [PC 9b: Fillers, putties, plasters, modelling clay] Pyrotechnics [PC 0: Other: Colouring agents, pigments] ERC: Not applicable see ‘Wide dispersive uses’ PROC: PROC 1* [Use in closed process, no likelihood of exposure. Industrial setting] {*refer to industrial DU MEASE assessment} PROC 2 – Use in closed, continuous process with occasional controlled exposure PROC 3 – Use in closed batch process (synthesis or formulation) PROC 4 – Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5 – Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9 – Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10 – Roller application or brushing PROC 11 – Non industrial spraying PROC 13 – Treatment of articles by dipping and pouring PROC 14 – Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15 – Use as laboratory reagent

	PROC 17 – Lubrication at high energy conditions and in partly open process PROC 19 – Hand mixing with intimate contact and only PPE available PROC 20 – Heat and pressure transfer fluids in dispersive, professional use but closed systems PROC 21 – Low energy manipulation of substances bound in materials and/or articles PROC 22 – Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting PROC 25 – Other hot work operations with metals PROC 26 – Handling of solid inorganic substances at ambient temperature
Processes, tasks, activities covered (environment)	Professional downstream use of copper dinitrate in; Absorbents; Catalyst manufacture; Catalyst use; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Intermediate in the production of copper containing metal powders; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected ERCs
Processes, tasks, activities covered (workers)	Downstream use of copper dinitrate in; Absorbents; Catalyst manufacture; Catalyst use; Ceramics; Coatings/Inks; Cosmetics; Electroplating and galvanic; Fertilisers; Glass; Intermediate in the production of copper containing metal powders; Leather and textile dyes; Lubricants and greases, release products; Non-metal-surface treatments; Polishes and waxes; Process intermediate for manufacture of other copper compounds e.g. catalysts; Processing aids; Putties, fillers, construction chemicals; Pyrotechnics; Raw material for production of other compounds and fine chemicals. All possible processes, tasks and activities described by the selected PROCs
2. Operational conditions and risk management measures	
2.1 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 2
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.2 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 3
Processes, tasks, activities covered	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.3 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 4
Processes, tasks, activities covered	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.4 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 5
Processes, tasks, activities covered	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.5 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 8a
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in non- dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.6 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 8b
Processes, tasks, activities covered	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	

Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.7 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 9
Processes, tasks, activities covered	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	

Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 4
Aqueous solution	No RPE required
2.8 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 10
Processes, tasks, activities covered	Low energy spreading of e.g. coatings including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	

Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.9 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 11
Processes, tasks, activities covered	Air dispersive techniques Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours. Less than 4 hours required for high dustiness exposure.	
Human factors not influenced by risk management	

Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	LEV required (LEV generic, median estimate)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	RPE required : Inhalation APF = 10
2.10 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 13
Processes, tasks, activities covered	Immersion operations Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance	MEASE Default

under conditions of use		
Body weight	70 kg	
Other given operational conditions affecting workers exposure		
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact		
Technical conditions and measures at process level (source) to prevent release		
Activity controlled in accordance with PROC descriptor		
Technical conditions and measures to control dispersion from source towards the worker		
Aqueous solution	No LEV required	
Organisational measures to prevent /limit releases, dispersion and exposure		
Good hygiene measures assumed		
Conditions and measures related to personal protection, hygiene and health evaluation		
Based on classification (all PROCs)		
Eye protection	Required (goggles or face shield)	
Skin protection	Required (overalls and gloves)	
Based on risk assessment (PROC related)		
Aqueous solution	No RPE required	
2.11 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]		
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate	
Use descriptor covered	PROC 14	
Processes, tasks, activities covered	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.	
Assessment Method	Estimation of exposure based on predicted data using MEASE	
Product characteristic		
Solid (High, medium and low dustiness) and liquid (aqueous solution)		
Amounts used		
Varying (risk limited by exposure not quantities)		
Frequency and duration of use/exposure		
Daily > 4 hours		
Human factors not influenced by risk management		
Respiration volume under conditions of use	MEASE Default	
Room size and ventilation rate	MEASE Default	
Area of skin contact with the substance under conditions of use	MEASE Default	
Body weight	70 kg	
Other given operational conditions affecting workers exposure		
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact		
Technical conditions and measures at process level (source) to prevent release		

Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	RPE required : Inhalation APF = 10
Aqueous solution	No RPE required
2.12 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 15
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	

Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Medium dustiness	No LEV required
High dustiness	LEV required (LEV generic, ECETOC reference)
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
Aqueous solution	No RPE required
2.13 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 17
Processes, tasks, activities covered	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	

Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.14 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low, Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 19
Processes, tasks, activities covered	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness) and liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV available
Medium dustiness	No LEV available
High dustiness	No LEV available
Aqueous solution	No LEV available
Organisational measures to prevent /limit releases, dispersion and exposure	

Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	RPE required : Inhalation APF = 10
High dustiness	RPE required : Inhalation APF = 40 and limit time to max 4 h/day
Aqueous solution	No RPE required
2.15 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Liquid]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 20
Processes, tasks, activities covered	Motor and engine oils, brake fluids Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Liquid (aqueous solution)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Aqueous solution	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	

Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Aqueous solution	No RPE required
2.16 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-Low]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 21
Processes, tasks, activities covered	Substances included into or onto articles and materials with high or intended release during their service life from outdoor use; such as brake pads in trucks or cars. This also includes releases from the article matrix as a result of processing by workers.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (Low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	No LEV required
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
2.17 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-	

High, Med, Low]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 22
Processes, tasks, activities covered	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	RPE required : Inhalation APF = 4
Medium dustiness	RPE required : Inhalation APF = 4
High dustiness	RPE required : Inhalation APF = 4
2.18 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate

Use descriptor covered	PROC 25
Processes, tasks, activities covered	Welding, soldering, gouging, brazing, flame cutting Exposure is predominantly expected to fumes and gases.
Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, ECETOC reference)
Medium dustiness	LEV required (LEV generic, ECETOC reference)
High dustiness	LEV required (LEV generic, ECETOC reference)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	No RPE required
High dustiness	No RPE required
2.19 Control of professional workers exposure for contributing exposure scenario [PW-GES-DU-High, Med, Low]	
Workers related free short title	Generic exposure for professional workers exposed to copper dinitrate
Use descriptor covered	PROC 26
Processes, tasks, activities covered	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, un-packaging, mixing/blending and weighing of metal powders or other minerals

Assessment Method	Estimation of exposure based on predicted data using MEASE
Product characteristic	
Solid (High, medium and low dustiness)	
Amounts used	
Varying (risk limited by exposure not quantities)	
Frequency and duration of use/exposure	
Daily > 4 hours	
Human factors not influenced by risk management	
Respiration volume under conditions of use	MEASE Default
Room size and ventilation rate	MEASE Default
Area of skin contact with the substance under conditions of use	MEASE Default
Body weight	70 kg
Other given operational conditions affecting workers exposure	
Worst case assumptions from MEASE: Wide dispersive use, direct handling and extensive contact	
Technical conditions and measures at process level (source) to prevent release	
Activity controlled in accordance with PROC descriptor	
Technical conditions and measures to control dispersion from source towards the worker	
Low dustiness	LEV required (LEV generic, median estimate)
Medium dustiness	LEV required (LEV generic, median estimate)
High dustiness	LEV required (LEV generic, median estimate)
Organisational measures to prevent /limit releases, dispersion and exposure	
Good hygiene measures assumed	
Conditions and measures related to personal protection, hygiene and health evaluation	
Based on classification (all PROCs)	
Eye protection	Required (goggles or face shield)
Skin protection	Required (overalls and gloves)
Based on risk assessment (PROC related)	
Low dustiness	No RPE required
Medium dustiness	RPE required : Inhalation APF = 4
High dustiness	RPE required : Inhalation APF = 10
3. Exposure and risk estimation	
Professional workers	

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 2	No	No	0.04
PW-GES-DU(Med)		Medium		Yes	No	0.13
PW-GES-DU(High)		High		Yes	No	0.53
PW-GES-DU(Liquid)	Liquid			No	No	0.25

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 3	No	No	0.11
PW-GES-DU(Med)		Medium		Yes	No	0.11
PW-GES-DU(High)		High		Yes	No	0.11
PW-GES-DU(Liquid)	Liquid			No	No	0.14

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 4	Yes	No	0.13
PW-GES-DU(Med)		Medium		Yes	No	0.53
PW-GES-DU(High)		High		Yes	Yes APF = 10	0.53
PW-GES-DU(Liquid)	Liquid			No	No	0.35

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 5	Yes	No	0.13
PW-GES-DU(Med)		Medium		Yes	No	0.53
PW-GES-DU(High)		High		Yes	Yes APF = 10	0.53
PW-GES-DU(Liquid)	Liquid			No	No	0.35

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 8a	No	No	0.55
PW-GES-DU(Med)		Medium		Yes	No	0.55
PW-GES-DU(High)		High		Yes	Yes APF = 10	0.55
PW-GES-DU(Liquid)	Liquid			No	No	0.30

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 8b	No	No	0.53
PW-GES-DU(Med)		Medium		Yes	No	0.28
PW-GES-DU(High)		High		Yes	Yes APF = 4	0.65
PW-GES-	Liquid			No	No	0.30

DU(Liquid)						

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 9	No	No	0.53
PW-GES-DU(Med)		Medium		Yes	No	0.53
PW-GES-DU(High)		High		Yes	Yes APF = 4	0.53
PW-GES-DU(Liquid)	Liquid			No	No	0.30

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
PW-GES-DU(Liquid)	Liquid	PROC 10	No	No	0.30

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
PW-GES-DU(Liquid)	Liquid	PROC 11	Yes	Yes APF = 10	0.70

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure
PW-GES-DU(Liquid)	Liquid	PROC 13	No	No	0.30

GES	Physical form		PROC	Worker protection required		RCR
				LEV	RPE	Combined Exposure
PW-GES-DU(Low)	Solid [Dustiness]	Low	PROC 14	Yes	No	0.13
PW-GES-DU(Med)		Medium		Yes	No	0.53
PW-GES-DU(High)		High		Yes	Yes APF = 10	0.53
PW-GES-DU(Liquid)	Liquid			No	No	0.35

GES	Physical form	PROC	Worker protection required		RCR
			LEV	RPE	Combined Exposure

PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 15**	No	No	0.11
PW-GES-DU(Med)		Medium		No	No	0.51
PW-GES-DU(High)		High		Yes	No	0.51
PW-GES-DU(Liquid)	Liquid			No	No	0.14

GES	**Physical form**	**PROC**	**Worker protection required**		**RCR**
			LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Liquid)	Liquid	**PROC 17**	Yes	No	0.35

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 19**	No	No	0.60
PW-GES-DU(Med)		Medium		No	Yes APF = 10	0.60
PW-GES-DU(High)		High		No	Yes APF = 40 Restricted to < 4 h/d	0.81
PW-GES-DU(Liquid)	Liquid			No	No	0.30

GES	**Physical form**	**PROC**	**Worker protection required**		**RCR**
			LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Liquid)	Liquid	**PROC 20**	No	No	0.25

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 21**	No	No	0.06

GES	**Physical form**		**PROC**	**Worker protection required**		**RCR**
				LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 22**	Yes	Yes APF = 4	0.35
PW-GES-DU(Med)		Medium		Yes	Yes APF = 4	0.35
PW-GES-DU(High)		High		Yes	Yes APF = 4	0.35

GES	Physical form		PROC	Worker protection required		RCR
				LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 25**	Yes	No	0.50
PW-GES-DU(Med)		Medium		Yes	No	0.50
PW-GES-DU(High)		High		Yes	No	0.50

GES	Physical form		PROC	Worker protection required		RCR
				LEV	**RPE**	**Combined Exposure**
PW-GES-DU(Low)	Solid [Dustiness]	Low	**PROC 26**	Yes	No	0.78
PW-GES-DU(Med)		Medium		Yes	Yes APF = 4	0.55
PW-GES-DU(High)		High		Yes	Yes APF = 10	0.55

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Workers

Scaling considering duration and frequency of use. Collect process occupational exposure monitoring data.

It should be noted that the evaluation of worker safety presented in this document is based on standardised (default) assumptions on levels of emission associated with generic processes, the behaviour of a compound in a particular working environment and the presumed efficiency of Risk Management Measures (e.g. LEV; RPE). These standardised assumptions may not accurately reflect the conditions that prevail within a specific workplace. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

Predictions for inhalation exposure in the workplace may be further refined using the modelling approach set out in the VRA (2008), Chapter 4.1.2, Human Health Effects.

9.3.2.4.3 Consumer use: [Generic only]

GES9: Consumer generic downstream use of copper dinitrate.

1. Title GES – Consumer downstream use of copper dinitrate	
Life cycle	Use stage of copper dinitrate
Free short title	Consumer exposure to copper dinitrate present in products.
Sector of use – Main	
Product categories (PC)	PC 0, 9a, 9b, 12, 14, 15, 18, 23, 24, 31, 39
Article categories (AC)	*No intended release* A-1 A-2 A-3 A-4 A-5
Processes, tasks, activities covered	
This scenario covers consumer end use of the following product types containing copper dinitrate: • Ceramics • Coatings and inks • Electroplating and galvanic • Fertilisers • Glass	

- Leather and textile dyes
- Lubricants, greases, release products
- Non-metal surface treatments
- Polishes and wax blends
- Putties, fillers, construction products
- Pyrotechnics

2. Operational conditions and risk management measures

2.1 Control of consumer exposure for contributing exposure scenario [C-GES-DU]

Product characteristics

Consumer products containing copper dinitrate are typically in liquid/slurry form.

Sintered products are solid, with low dustiness.

Concentrations of copper dinitrate in consumer products are invariably low.

Exposure Assessment

Consumer exposure scenario for combined occupational and consumer assessment:

The consumer exposure assessments are not directly relevant to these workers. It is also assumed that workers in the copper/Copper dinitrate industries are unlikely to take copper in dietary supplements. Therefore, for the purpose of combining occupational and consumer exposures for this group, a separate consumer scenario is considered following the Cu VRA. As a typical consumer scenario for workers, it will be assumed that they are exposed via the dermal route to 0.14 mg Cu/day to coins and to 4.3×10^{-6} mg Cu/day via hair-care products. As a RWC consumer scenario for workers, it will be assumed that workers are exposed via the dermal route to 0.28 mg Cu/day to coins, to 1.4×10^{-5} mg Cu/day via hair-care products and via the inhalation route to 0.001 mg Cu/person/day by smoking cigarettes.

Consumer exposure scenario:

The exposure estimation for consumer exposure only can be found below.

3. Exposure and risk estimation

Routes of exposure

The most relevant routes of exposure are summarised below. Selection of the worst-case exposure route is based on consumer estimations from the Cu VRA (2008).

	Inhalation	Dermal	Oral
Massive or sintered copper/copper compound products.	Not relevant	Dermal contact to handling of coins, copper jewellery	Not relevant
Preparations containing copper powder/copper compounds.	Inhalation exposure through unintentional use cigarette smoking	Dermal contact to face cream, hair-care products, paint	Oral exposure through food supplements
Worst-case exposure considered in generic consumer exposure scenario.	Inhalation exposure through unintentional use cigarette smoking	Dermal exposure through paint	Oral exposure through food supplements
External exposure (mg/person/day)	Typical: none Reasonable worst case: 0.0005	Typical: none Reasonable worst case: 4.03	Typical: none Reasonable worst case: 2

Long Term Exposure

	Unit	Exposure concentration	Justification
Internal dermal + inhalation systemic (occupational)	mg/kg bw/d	1.9×10^{-2}	Reasonable worst-case internal exposure estimate from Cu VRA
Risk characterisation ratio (combined dermal and inhalation)	-	0.46	Based on DNEL for repeated dose effects (see section 5.11).

9.3.2.4.4 Wide dispersive use: [Environment only]

GES9: Wide dispersive uses [environmental releases only] from generic professional and consumer downstream use of copper dinitrate.

1. Title GES – Wide dispersive use of copper dinitrate	
Life cycle	Use (wide dispersive use) stage of copper dinitrate
Free short title	Generic wide dispersive use of copper dinitrate
Systematic title based on use descriptor	SU: SU21 – Consumer use SU22 – Professional use PC: Ceramics [PC 0: Other: Colouring agents, pigments] Coatings/Inks [PC 9a: Coatings and paints, thinners, paint removers; PC 18: Ink and toners] Cosmetics [PC 39: Cosmetics, personal care products] Electroplating and galvanic [PC 14: Metal surface treatment products, including galvanic and electroplating products] Fertiliser [PC 12: Fertilisers] Glass [PC 0: Other: Colouring agents, pigments] Lubricants and greases, release products [PC 24: Lubricants, greases, release products] Polishes and waxes [PC 31: Polishes and wax blends] Putties, fillers, construction chemicals [PC 9b: Fillers, putties, plasters, modelling clay] Pyrotechnics [PC 0: Other: Colouring agents, pigments] ERC: ERC8a-c: Wide dispersive indoor use of substance ERC8d-f: Wide dispersive outdoor use of substance ERC9a: Wide dispersive indoor use of substance in closed systems ERC9b: Wide dispersive outdoor use of substance in closed systems PROC: Not applicable, see Professional and Consumer uses.
Processes, tasks, activities covered (environment)	Wide dispersive use of copper dinitrate All possible processes, tasks and activities described by the selected ERCs
Processes, tasks, activities covered (workers)	Wide dispersive use of copper dinitrate All possible processes, tasks and activities described by the selected PROCs
2. Operational conditions and risk management measures	
2.0 Control of environmental exposure [E-GES-WDU]	
Environmental related free short title	Generic wide dispersive use of copper dinitrate
Systematic title based on use descriptor (environment)	ERC8 ERC9
Processes, tasks, activities covered (environment)	ERC8 ERC9

Environmental Assessment Method	Environmental Assessment based on measured regional concentrations (fertiliser use) and concentrations of copper in municipal STPs (other uses).
Product characteristics	
Copper dinitrate can be in any form in a substance or article.	
Amounts used	
Maximum annual use on EU scale	Downstream wide dispersive use in terms of defining safe threshold limits is not appropriate as all uses of copper should be considered in parallel as the resulting concentrations will be additive. Therefore, as shown by the VRA, measured levels of copper reported in STP effluent is a more appropriate method of addressing the wide dispersive uses from all uses where environmental releases of copper may occur. With specific regard to fertiliser use, regional concentrations of copper developed for all environmental compartments in the VRA already include inputs from fertilisers and give no cause for concern.
Frequency and duration of use	
Pattern of release to the environment	365 days per year
Environment factors not influenced by risk management	
Receiving surface water flow rate	18000 m3/d
Dilution capacity	Flow rate of receiving surface water should be sufficiently high to dilute the effluent concentration of the STP below the PNEC for water and sediment.
Other given operational conditions affecting environmental exposure	
Indoor or outdoor use of products containing copper dinitrate is possible.	
Conditions and measures related to municipal sewage treatment plant	
Presence of municipal sewage treatment plant	
Conditions and measures related to external treatment of waste for disposal	
At the end of the lifecycle the article should be correctly disposed of. Waste from articles containing copper dinitrate should be disposed of correctly in accordance to local regulations.	
Conditions and measures related to external recovery of waste	
Not relevant	
3. Exposure and risk estimation	
Not applicable	
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES	
Environment Scaling tool: Metals EUSES IT tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool) Scaling of the release to air and water environment includes: Refining of the release factor to air and waste water and/or and the efficiency of the air filter and waste water treatment facility. Scaling of the PNEC for aquatic environment by using a tiered approach for correction for bioavailability and background concentration (C_{local} approach). See Annex 1-7. It should be noted that the PEC values and associated maximum allowable tonnages presented in this document have been modelled on the basis of standardised (default) assumptions on levels of emission associated with a generic process, fate and behaviour of a compound in a localised environment and the	

presumed efficiency of Risk Management Measures (e.g. on-site waste water treatment plants and municipal sewage treatment plants). These standardised assumptions may not accurately reflect the conditions that prevail at a particular site. As such, the information presented in this document should be regarded as a guidance tool only. It remains the responsibility of the user to ensure that a compound is used safely within the context of their site and in full consultation with the relevant local authorities.

9.3.2.5 Waste related measures

See Section 9.4.

9.3.2.6 Exposure estimation

9.3.2.6.1 Environmental releases

Releases to the local environment as a result of industrial downstream uses of copper dinitrate are summarised below in Table 118. No direct regional releases are presented as measured regional data have been used (see Section 9.4).

Table 118: Summary of the releases* to the environment resulting from the industrial formulation and downstream uses of copper dinitrate [GES5/GES6]

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
E-GES-DU0 [GES5/GES6]		
Aquatic (without STP)	N/A	Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Aquatic (after STP)	N/A	
Air (direct + STP)*	454.55	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 2) [GES5]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.18	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.55	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.31	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 3) [GES5]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	1.82	
Soil (direct releases only)	0	

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
ES2 & 3		
Aquatic (without STP)	1.55	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	3.09	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 4) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.00	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.36	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.11	
Air (direct + STP)*	0.01	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 5) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.01	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.48	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.01	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 6a) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.18	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.55	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.31	
Soil (direct releases only)	0	

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
E-GES-DU1.1(ERC 6b) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.07	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.48	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.12	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 6d) [GES6]		
ES1		
Aquatic (without STP)	0.93	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	74.55	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.14	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.09	
Air (direct + STP)*	90.91	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 7) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.07	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.48	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.12	
Soil (direct releases only)	0	
E-GES-DU1.1(ERC 12a) [GES6]		
ES1		
Aquatic (without STP)	0.91	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.15	
Soil (direct releases only)	0	

Compartments	Release from point source (kg/d) (local exposure estimation)	Justification
ES2 & 3		
Aquatic (without STP)	1.48	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.24	
Soil (direct releases only)	0	
E-GES-DU2.1(spERC F - Formulation) [GES5]		
ES1		
Aquatic (without STP)	0.93	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.07	
Air (direct + STP)*	0.01	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.52	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.01	
Soil (direct releases only)	0	
E-GES-DU2.1(spERC U - Use) [GES6]		
ES1		
Aquatic (without STP)	0.95	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Aquatic (after STP)	0.08	
Air (direct + STP)*	0.16	
Soil (direct releases only)	0	
ES2 & 3		
Aquatic (without STP)	1.50	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Aquatic (after STP)	0.12	
Air (direct + STP)*	0.25	
Soil (direct releases only)	0	

* - local direct only, no emissions at STP due to lack of volatilisation.

9.3.2.6.2 Exposure concentration in sewage treatment plants (STP)

Table 119: Predicted Exposure Concentrations (PEC) in sewage resulting from the industrial downstream uses of copper dinitrate [GES5/GES6]

ES	Endpoint (units)	Value	Justification
E-GES-DU1.1(ERC 2) [GES5]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	2002.56	

ES	Endpoint (units)	Value	Justification
E-GES-DU1.1(ERC 3) [GES5]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	2002.56	
E-GES-DU1.1(ERC 4) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.05	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1766.97	
E-GES-DU1.1(ERC 5) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1914.21	
E-GES-DU1.1(ERC 6a) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	2002.56	
E-GES-DU1.1(ERC 6b) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1914.21	

ES	Endpoint (units)	Value	Justification
E-GES-DU1.1(ERC 6d) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1207.43	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.05	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1472.47	
E-GES-DU1.1(ERC 7) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1914.21	
E-GES-DU1.1(ERC 12a) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1177.98	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1914.21	
E-GES-DU2.1(spERC F - Formulation) [GES5]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1207.43	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1973.11	
E-GES-DU2.1(spERC U - Use) [GES6]			
ES1	Concentration in sewage (PECstp)(in mg Cu/l)	0.04	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
	Concentration in sewage sludge (in mg Cu/kg dw)	1236.88	
ES2 & 3	Concentration in sewage (PECstp)(in mg Cu/l)	0.06	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
	Concentration in sewage sludge (in mg Cu/kg dw)	1943.66	

9.3.2.6.3 Exposure concentration in aquatic pelagic compartment

Table 120: Predicted Exposure Concentrations (PEC) in aquatic compartment resulting from the industrial downstream uses of copper dinitrate [GES5/GES6]

Compartments	Units	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-DU0 [GES5/GES6]				
Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).				
E-GES-DU1.1(ERC 2) [GES5]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00043	0.0033	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00043	0.0015	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 3) [GES5]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00043	0.0033	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00043	0.0015	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 4) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.

Compartments	Units	Local concentration	PEC aquatic (local+regional)	Justification
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00038	0.0033	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00038	0.0015	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 5) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00041	0.0033	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00041	0.0015	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6a) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00043	0.0033	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine water dilution 100]				
Marine water	mg Cu/l	0.00043	0.0015	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6b) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00041	0.0033	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC aquatic (local+regional)	Justification
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00041	0.0015	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6d) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0026	0.0055	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00031	0.0032	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00031	0.0014	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 7) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0025	0.0054	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00041	0.0033	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00041	0.0015	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 12a) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0026	0.0054	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00041	0.0033	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00041	0.0015	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC aquatic (local+regional)	Justification
E-GES-DU2.1(spERC F - Formulation) [GES5]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0026	0.0055	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00042	0.0033	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00042	0.0027	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU2.1(spERC U - Use) [GES6]				
[ES1 – freshwater dilution 10]				
Freshwater	mg Cu/l	0.0026	0.0055	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Freshwater	mg Cu/l	0.00041	0.0033	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Marine water	mg Cu/l	0.00041	0.0015	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

9.3.2.6.4 Exposure concentration in sediments

Table 121: Predicted Exposure Concentrations (PEC) in sediments following the industrial downstream uses of copper dinitrate [GES5/GES6]

Compartments	Units	Local concentration	PEC sediment (local+regional)	Justification
E-GES-DU0 [GES5/GES6]				
Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).				
E-GES-DU1.1(ERC 2) [GES5]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.71	12.71	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC sediment (local+regional)	Justification
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.71	28.81	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 3) [GES5]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.71	12.71	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.71	28.81	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 4) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	11.22	11.22	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	11.22	27.32	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 5) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.15	12.15	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.15	28.25	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC sediment (local+regional)	Justification
E-GES-DU1.1(ERC 6a) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.71	12.71	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.71	28.81	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6b) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.15	12.15	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.15	28.25	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6d) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	76.64	76.64	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	9.35	9.35	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	9.35	25.45	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC sediment (local+regional)	Justification
E-GES-DU1.1(ERC 7) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.15	12.15	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.15	28.25	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 12a) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	74.77	74.77	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.15	12.15	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.15	28.25	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU2.1(spERC F - Formulation) [GES5]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	76.64	76.64	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.52	12.52	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.52	28.62	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

Compartments	Units	Local concentration	PEC sediment (local+regional)	Justification
E-GES-DU2.1(spERC U - Use) [GES6]				
[ES1 – freshwater dilution 10]				
Sediment (freshwater)	mg Cu/kg dw	78.51	78.51	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
[ES2 – freshwater dilution 100]				
Sediment (freshwater)	mg Cu/kg dw	12.34	12.34	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
[ES3 – marine dilution 100]				
Sediment (marine)	mg Cu/kg dw	12.34	28.44	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

9.3.2.6.5 Exposure concentrations in soil and groundwater

Table 122: Predicted Exposure Concentrations (PEC) in soil and groundwater resulting from the industrial downstream uses of copper dinitrate [GES5/GES6]

Compartment	Local concentration	PEC soil/groundwater (local+regional)	Justification
E-GES-DU0 [GES5/GES6]			
Soil averaged (mg Cu/kg dw)	33.510	5.71	Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.003	-	
E-GES-DU1.1(ERC 2) [GES5]			
ES1			
Soil averaged (mg Cu/kg dw)	19.674	44.07	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	33.446	57.85	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 3) [GES5]			
ES1			
Soil averaged (mg Cu/kg dw)	19.795	44.07	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	33.651	57.85	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	

Compartment	Local concentration	PEC soil/groundwater (local+regional)	Justification
E-GES-DU1.1(ERC 4) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.661	44.06	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	29.492	56.35	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 5) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.661	44.06	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	31.950	56.35	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 6a) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.674	44.07	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	33.446	57.85	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 6b) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.666	44.06	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	31.958	56.35	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 6d) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	25.649	50.05	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.024	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	31.279	55.68	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.026	-	

Compartment	Local concentration	PEC soil/groundwater (local+regional)	Justification
E-GES-DU1.1(ERC 7) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.666	44.06	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	31.958	56.35	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU1.1(ERC 12a) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	19.672	44.06	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	31.966	56.35	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU2.1(spERC F - Formulation) [GES5]			
ES1			
Soil averaged (mg Cu/kg dw)	20.153	44.55	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	32.933	57.33	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	
E-GES-DU2.1(spERC U - Use) [GES6]			
ES1			
Soil averaged (mg Cu/kg dw)	20.656	45.06	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Groundwater (mg Cu/l)	0.021	-	
ES2 & 3			
Soil averaged (mg Cu/kg dw)	32.459	56.86	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Groundwater (mg Cu/l)	0.027	-	

9.3.2.6.6 Atmospheric compartment

Table 123: Predicted Exposure Concentration (PEC) in air resulting from the industrial downstream uses of copper dinitrate [GES5/GES6]

ES	Local concentration	PEC air (local+regional)	Justification
E-GES-DU0 [GES5/GES6]			
Annual average (mg Cu/m3)	0.076	0.076	Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).

ES	Local concentration	PEC air (local+regional)	Justification
E-GES-DU1.1(ERC 2) [GES5]			
ES1			
Annual average (mg Cu/m3)	0.000030	0.000030	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000052	0.000052	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 3) [GES5]			
ES1			
Annual average (mg Cu/m3)	0.000305	0.000305	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000518	0.000518	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 4) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000001	0.000001	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000001	0.000001	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 5) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000001	0.000001	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000002	0.000002	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6a) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000030	0.000030	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000052	0.000052	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6b) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000012	0.000012	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.

ES	Local concentration	PEC air (local+regional)	Justification
ES2 & 3			
Annual average (mg Cu/m3)	0.000020	0.000020	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6d) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.012491	0.012491	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.015233	0.015233	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 7) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000012	0.000012	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000020	0.000020	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 12a) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000024	0.000024	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000040	0.000040	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU2.1(spERC F - Formulation) [GES5]			
ES1			
Annual average (mg Cu/m3)	0.000001	0.000001	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000002	0.000002	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU2.1(spERC U - Use) [GES6]			
ES1			
Annual average (mg Cu/m3)	0.000027	0.000027	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3			
Annual average (mg Cu/m3)	0.000042	0.000042	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).

9.3.2.6.7 Exposure concentration relevant for the food chain (Secondary poisoning)

Copper is an essential trace element, well-regulated in all living organisms. Difference in copper uptake rates are related to essential needs, varying with the species, size, life stage and seasons. Copper homeostatic mechanisms are applicable across species with specific processes being active depending on the species, life stages. Simple estimations on secondary poisoning are therefore not adequate.

There is overwhelming evidence to show the absence of copper biomagnification across the trophic chain in the aquatic and terrestrial food chains. Differences in sensitivity among species are not related to the level in the trophic chain but to the capability of internal homeostasis and detoxification. Field evidence has further provided evidence on the mechanisms of action of copper in the aquatic and terrestrial environment and the absence of a need for concern for secondary poisoning.

9.3.2.6.8 Workers exposure

ACUTE/SHORT TERM EXPOSURE

Not applicable to downstream industrial uses as worst-case assumptions have considered long-term exposure only.

LONG-TERM EXPOSURE: INDUSTRIAL

A summary of the predicted long-term exposure values for workers involved in the industrial downstream use of copper dinitrate are presented in Table 124.

Table 124: Summary of long-term exposure concentration to workers involved in the industrial downstream use of copper dinitrate

a) Industrial formulation [GES5]

1. W-GES-DU(High) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	

1. W-GES-DU(High) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV + RPE (APF 10) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.313	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 LEV + RPE (APF 40) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.45	

2. W-GES-DU(Med) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	

2. **W-GES-DU(Med)** [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 No LEV RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.72	

3. **W-GES-DU(Low)** [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	

3. W-GES-DU(Low) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	990	PROC 21 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.27	

4. W-GES-DU(Liquid) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	

4. W-GES-DU(Liquid) [GES5]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 26 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

b) Industrial downstream use [GES6]

1. W-GES-DU(High) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)		PROC 7 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV + RPE (APF 10) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.313	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV + RPE (APF 4) required.

1. W-GES-DU(High) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 LEV + RPE (APF 40) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
Dermal systemic exposure (in mg Cu/d)	990	PROC 23 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	
Dermal systemic exposure (in mg Cu/d)	990	PROC 24 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.275	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.45	

2. W-GES-DU(Med) [GES6]

Routes of exposure	Concentrations	Justification
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 7 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

2. W-GES-DU(Med) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 No LEV RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
Dermal systemic exposure (in mg Cu/d)	990	PROC 23 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	
Dermal systemic exposure (in mg Cu/d)	990	PROC 24 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.6	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.72	

3. W-GES-DU(Low) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	

3. **W-GES-DU(Low)** [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)		PROC 7 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 21 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.7	
Dermal systemic exposure (in mg Cu/d)	990	PROC 23 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	

3. W-GES-DU(Low) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	990	PROC 24 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.4	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.2	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.27	

4. W-GES-DU(Liquid) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	120	PROC 1 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 7 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 10 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	

4. W-GES-DU(Liquid) [GES6]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 13 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 17 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 20 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 22 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 23 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 24 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 25 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 26 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

LONG-TERM EXPOSURE: PROFESSIONAL

A summary of the predicted long-term exposure values for workers involved in the professional downstream use of copper dinitrate are presented in Table 125.

Table 125: Summary of long-term exposure concentration to professional workers involved in the downstream use of copper dinitrate [GES7]

1. PW-GES-DU(High) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV + RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV + RPE (APF 10) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV + RPE (APF 10) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV + RPE (APF 4) required
Inhalation exposure (in mg Cu/m^3)/8h workday	0.625	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 11 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV + RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	594	PROC 19 LEV - NOT AVAILABLE

1. PW-GES-DU(High) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Inhalation exposure (in mg Cu/m^3)/8h workday	0.75	RPE (APF 40) required. Restricted to < 4 h/d.
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.4	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV + RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.45	

2. PW-GES-DU(Med) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE

2. PW-GES-DU(Med) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 11 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 LEV - NOT AVAILABLE RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 21 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.4	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.45	

3. PW-GES-DU(Low) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.

3. PW-GES-DU(Low) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	480	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 10 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 11 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 13 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)		PROC 17 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)	990	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.5	
Dermal systemic exposure (in mg Cu/d)		PROC 20 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

3. PW-GES-DU(Low) [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	99	PROC 21 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	990	PROC 22 LEV + RPE (APF 4) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.25	
Dermal systemic exposure (in mg Cu/d)	990	PROC 25 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.4	
Dermal systemic exposure (in mg Cu/d)	990	PROC 26 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.675	

4. PW-GES-DU(Liquid)] [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 2 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)	120	PROC 3 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 4 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 5 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8a No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 8b No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 9 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 10 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 11 LEV + RPE (APF 10) required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.45	

4. PW-GES-DU(Liquid)] [GES7]		
Routes of exposure	**Concentrations**	**Justification**
Dermal systemic exposure (in mg Cu/d)	240	PROC 13 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 14 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.1	
Dermal systemic exposure (in mg Cu/d)	120	PROC 15 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.01	
Dermal systemic exposure (in mg Cu/d)	240	PROC 17 LEV required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 19 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.05	
Dermal systemic exposure (in mg Cu/d)	240	PROC 20 No RMM required.
Inhalation exposure (in mg Cu/m^3)/8h workday	0.001	
Dermal systemic exposure (in mg Cu/d)		PROC 22 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 25 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		
Dermal systemic exposure (in mg Cu/d)		PROC 26 NOT APPLICABLE
Inhalation exposure (in mg Cu/m^3)/8h workday		

9.3.2.6.9 Consumer exposure

The most relevant routes of exposure are summarised below in Table 126. Selection of the worst-case exposure route is based on consumer estimations from the Cu VRA (2008).

Table 126: Consumer exposure to copper dinitrate

Exposure	Exposure concentration	Justification
External exposure (mg/person/day)		
Dermal	0 4.03	Typical Reasonable worst case
Inhalation	0 0.0005	Typical Reasonable worst case
Oral	0 2	Typical Reasonable worst case
Long Term (mg/kg bw/d)		
Internal dermal + inhalation systemic (occupational)	1.9×10^{-2}	Reasonable worst-case internal exposure estimate from Cu VRA
Risk characterisation ratio (combined dermal and inhalation)	0.46	Based on NOAEL for repeated dose effects of 4.075 mg/kg bw/day and an assessment factor of 100 (VRA, 2008).

9.3.2.6.10 Indirect exposure of humans via the environment

See Section 9.4.1.

9.4 Waste related measures

9.4.1 Municipal waste (MW)

The potential for release of copper to the environment from waste material associated with the use of copper metal and copper compounds was considered as part of the VRA (2008). It should be borne in mind that the tonnage of copper metal used in the EU is much greater than the cumulative tonnage of copper compounds and that the latter therefore contribute only a small proportion of the releases discussed below.

9.4.1.1 Releases after disposal

The main copper containing waste streams in the EU and where possible the associated copper emissions to the environment were assessed from National databases and completed with international literature. The revised TGD (TGD, 2003) includes some sections on waste disposal and was taken as the starting point for the approach, developed by the contractors in the framework of the Targeted Risk Assessment on cadmium in Ni-Cd batteries (TRAR, 2005) to assess emissions from Municipal Solid Waste (MSW). The latter approach was discussed in depth and the methodology was agreed by the Member States at the technical meeting level. This methodology has been used as a starting point for the calculation of the copper emissions associated with the waste management of MSW.

Although the estimates on waste streams are merely indicative, waste from electric and electronic equipment (WEEE) seems to be the largest fraction of Cu waste (188-250 kt) followed by construction and demolition waste (C/D) (129-167 kt), Municipal Solid waste (MSW) (59-83 kt), Industrial waste (65-71 kt) and end-of-life vehicles waste ELV (53-73 kt) which is the most uncertain waste estimate. The figures reported reflect the Western European countries (which is quite similar to the EU-15). Industrial waste is landfilled in hazardous landfills and/or incinerated. Also the non-recycled fraction of WEEE waste, C/D waste and ELV waste are put into dedicated landfills.

With regard to the emissions and the evaluation of potential risks only those emissions associated with the MSW stream have been quantified. Current emissions were estimated based on an overall average European situation (25 % incineration and 75 % landfill).

Emissions of copper from incineration of MSW are expected to occur through air if no adequate flue gas treatment is in place, water (in case wet scrubbers are used) and the disposal and/or re-use of incineration residues. The emission associated with copper in MSW landfills is related to the generation and eventual discharge of leachate into the environment. In the EU-15 countries approximately 157,241 kt wet weight (110,069 kt dry wt.) of MSW is landfilled or incinerated each year. As a reasonable worst case estimate of the total copper content in MSW (90th percentile) the value of 1,048 g Cu/tonne dry wt. has been taken forward in the calculations yielding a total copper load of 115 kt. This value is higher than the range reported ICSG (2004) and Bertram *et al.,* (2002) of 59-83 kt of copper. This can be explained by the fact that the estimates in these studies are based on average values and not on the 90th percentile. The incineration of 38,700 kt wet weight (27,090 kt dwt) of MSW in the EU (i.e. 25 % of total MSW) results in copper emissions to air of 2.5 tonnes per year. Emissions to water and sludge were calculated to be 30.9 tonnes and 355 tonnes, respectively. It is assumed that the generated sludges are landfilled in hazardous landfill and not spread on the soil. Copper stored in incinerator residues (8,243 kt of bottom ash and 1,049 kt of fly ash) is estimated to be 28 kt per year. The average modelled copper concentration of bottom ash and fly ash is 3,227 mg/kg dwt and 1,335 mg/kg dry wt.

For the landfill scenarios it has been estimated that the reasonable worst case copper concentration in leachate is 119 µg/l (90th percentile of measured values). Landfilling of 118,541 kt wet weight (82,979 dry wt.) of MSW per year (i.e. 75 % of EU total) results in copper emissions of 2.4 tonnes to groundwater and 6.2 tonnes to surface water. The contamination of the groundwater compartment due to fugitive emissions of landfills has not been further evaluated since this is out of the scope of the risk assessment.

A further 15.4 tonnes is concentrated in sludge following the treatment of leachates. It is assumed that the sludge of the STP is spread over soil.

Interestingly, the relative contribution of waste incineration plants and landfill facilities to the total EU emissions (see above) is minor (0.4%).

9.4.1.2 Local PECs from releases after disposal

Besides the quantification of regional emissions from waste management strategies, local default scenarios have been developed. The local PEC calculations for a local typical incinerator scenario emitting in a large river (dilution factor of 1,000) results in a PEClocal water of 3.2 µg/l. In a realistic worst case scenario (dilution factor of 100) a local PEC_{water} of 6.1 µg/l is derived. These result in PEC_{local} sediment values of 77 and 162 mg/kg dwt, respectively. The PEClocal air for a generic MSW incineration plant is 8.8 ng/m^3. The PEClocal soil due to air deposition is 24.4 mg/kg dry wt.

The local PEC calculations for a local landfill emitting a leachate with a copper concentration of 119 µg/l directly to the surface water or indirectly through an STP results in a local

PEC_{water} of 3.36 and 2.94 µg/l, respectively. These yield PEC_{local} sediment values of 81 and 70 mg/kg dwt.

9.4.2 Hazardous waste (HW)

The assessment of measured waste emissions associated with metals described in the ECHA guidance document (ECHA, Chapter R.18, 2012) involves applying a generic methodology along with proposed defaults to determine the risks associated with metals. However, this approach can lead to overestimations of the risks, especially when materials are produced in large quantities and should only be used in the absence of real data. Reviews of scientific literature, analysis of questionnaires sent to manufacturers and detailed waste reports for numerous metals (Ag, Cd, Co, Sb, Pb, Ni, Zn) were compiled by ARCHE (ARCHE, 2012) with the aim of obtaining more realistic risk measures and refining the currently used default values. The majority of these refinements were applied to the municipal waste (MW) stream, which ARCHE then used to define an exposure scenario for the assessment of the generic release of metals from hazardous waste (HW) facilities including incinerators.

To achieve this, a collection of measured data and a thorough understanding of operational conditions and Risk Management Measures (RMM) of HW facilities were required. To obtain this information, both the Landfill and Waste Incineration (WI) Directives were consulted. All current operational HW landfills have to be compliant with the Landfill Directive which aims to prevent or reduce negative effects on the environment from the landfilling of waste. Where required additional technical guidance and general principles of the IPPC Directive are also applied. Furthermore, the Waste Incineration (WI) Directive also aims to reduce negative effects caused by emissions of waste into the air, soil, surface water and groundwater, thus lessening the risk to human health. From 2002 onwards, this directive was transpositioned into national legislation across Europe and all incinerators now have to comply with the provisions in this directive.

Quantitative information regarding the landfilling and incineration of HW has been derived using the EUROSTAT database. This provided information about HW statistics in Europe and illustrated that Europe is a net exporter of HW with a total of 77 million tonnes being treated in the EU member states in 2008. The database also demonstrated the most important waste categories in 2008, including mineral waste (28.6%) and combustion wastes (13.2%), which gave rise to the overall HW generation.

The significant emission from metals being landfilled is leachate, a medium by which soluble materials, such as metal ions, can be transported into the environment. To avoid this, leachate is collected and treated during every landfill process. According to available waste reports, the leachate volumes produced during the operational phase of HW landfill are comparable to the generic MW landfill described in other reports and so these data can then be used to calculate risks from HW facilities. As for the incineration process of waste, a best available techniques reference document (BREF) finalised in 2006 under the IPPC Directive details the process of dedicated incineration.

Operators of these HW incinerators and landfills have an obligation to report their emissions data to their local authorities. Due to a lack of a central online European database, ARCHE in collaboration with DHI contacted the local authorities and associations from throughout Europe in an attempt to collect and analyse emission data. Reports were submitted by; Belgium, Denmark and Finland, France, Germany, Italy, The Netherlands and the United Kingdom, which although limited were considered to represent realistic worst-case data with regard to inhabitant density and industrialisation. Landfill emission data were collected from both external and internal on-site landfills from metal producing companies (see **Table 127**).

External landfill: Specialised external HW landfills exist in the highly industrialised countries such as Belgium, Denmark, Finland, France, Germany, Italy and the UK. From these a total of 48 leachate metal concentration data sets from different landfills were made available to ARCHE. However, since data from on-site landfills at metal production facilities will reflect the emission resulting from predominantly metal related waste disposal, these have been used for the development of ARCHE's reasonable worst-case HW scenario. This is preferable to the data from external HW landfills, since they accept all forms of hazardous waste.

On-site landfill: Twelve metal production companies from 8 different European countries reported the measured metal leachate concentrations from their on-site landfills. The highest measured metal concentrations in leachates were observed by companies who undertake dust reduction management techniques by recycling the leachate as either a dampening spray for the landfill area or as a transport medium for slurry.

Table 127: Measured copper (Cu) levels in HW leachate collected at landfill sites across Europe

Endpoint	Leachate measured Cu levels (µg/l)	
	External landfill	On-site landfill
Median	97	47
50P	100	NR
90P	1139.3	528
Max	4000	570
Min	9.35	3.5
Data points	44	7

ARCHE's report states that these data are likely to overestimate the metal release compared to external HW landfills and have used them as a benchmarking exercise only.

Emission data for HW incinerators are less readily available but helpful suggestions were provided for ARCHE by the EURTIS secretariat and BDSAV who illustrated the importance of use of measured data for HW incinerators. Metals entering the HW incineration process are distributed among various output fractions such as stack emissions (flue gas), waste water, fly ash and slags and filter cake. **Table 128** gives the percentage distribution data of copper between the different residues and releases averaged over a test period in a HW incinerator.

Table 128: Percentage distribution of copper in a HW incineration process (WI BREF, 2006)

Output fraction		%Cu
Solid residue for disposal	Slag	75.9
	Fly ash	22.4
	Filter cake	1.69
Release to the environment	To water effluent	0.01
	To air	< 0.01

The routes of environmental exposure resulting from HW incinerators to effluent and air have been quantified at many sites across Europe. **Figure 9** shows the concentrations of copper in the effluent wastewater of different merchant HW incinerators. The annual average for all plants is lower than 0.25 mg/l, which sufficiently meets the discharge limit of 0.5 mg Cu/l.

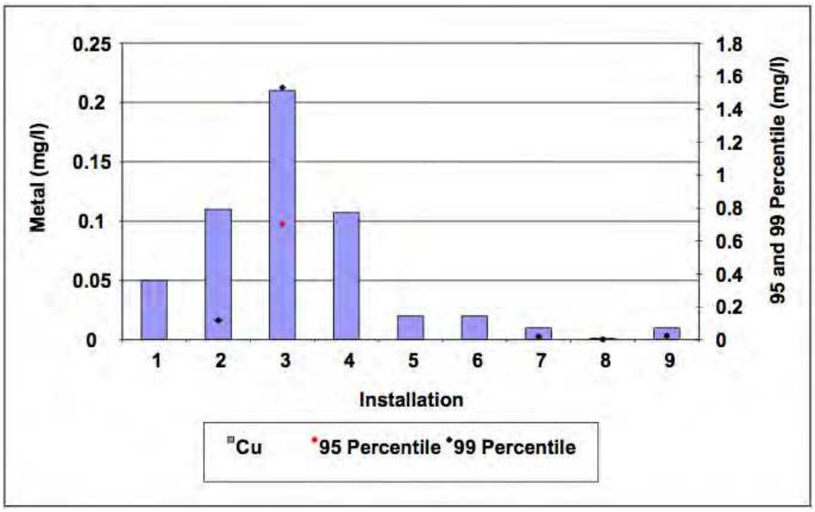

Figure 9: Annual average discharges of copper at EU HW incinerators (WI BREF, 2006)[19]

Unfortunately the data presented in **Table 128** suggest that the 0.2 % release factor to air given in the current ECHA environmental emission guidance (Chapter R.18) would over predict the air emissions of copper resulting from HW incineration. However, individual metal emission data to air are very limited since European and often national regulations only report grouped data. For example Cu is frequently reported together with Sb, As, Pb, Cr, Co, Mn, Ni, V, and Sn as a sum parameter. The average mass flow of all metal emissions to air from merchant HW incinerators in Europe is 1.3 g/T of incinerated waste. According to the French HW incinerators reported in CITEPA-OMINEA (2011) under the section 'Incinération de déchets industriels' copper emission to air is given as 0.09 g metal/T waste incinerated.

[19] Adapted from ARCHE (2011) Figure 3 Graph of annual average discharges of various metals to water at European hazardous waste incinerators (WI BREF, 2006); installations are numbered 1-9

9.4.2.1 Data selection for HW landfill and incinerators for use in HW exposure scenario data

A. Landfill leachate data selection

A box whisker plot for the 44 data points for copper in HW leachate is displayed in **Figure 10**. These emission values demonstrated that leachate concentrations can be significantly different based on different circumstances, such as meteorological conditions or the amount of waste being landfilled (see **Figure 10**). It was considered that using the 90th percentile endpoint to define the generic exposure scenario would result in a large overestimation of the risks, since not all landfill leachates are discharged via a municipal STP. Some HW leachate fractions are collected on-site and go through treatment at specialised wastewater treatment plants (WWTP) or even recycled at the site [for dust reduction measures]. Therefore, data analysis was carried out using the statistical software package STATISTICA, which gave the median value of 100 µg Cu/l, and the 25th and 75th percentile values were 25 and 467 µg Cu/l, respectively. STATISTICA considered all data points above 965 µg Cu/l as outliers.

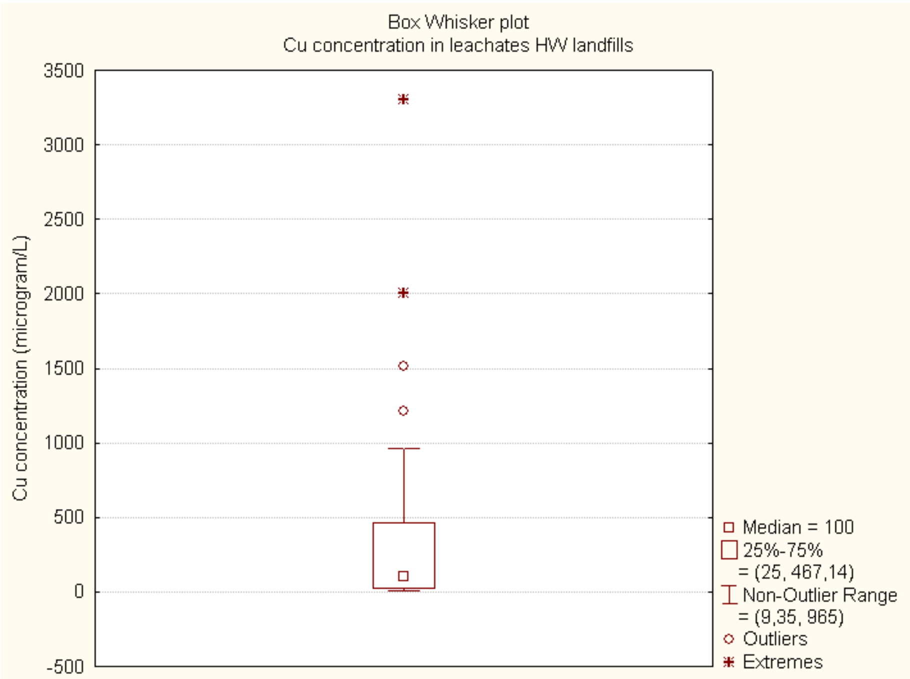

Figure 10: Box whisker plot for copper concentration in leachates from hazardous waste landfills

In **Figure 10**, the measured copper concentration values represent the copper leached out from all copper sources present in the HW landfill sites. The median value of 100 µg Cu/l was taken forward by ARCHE in the calculations and risk characterisation for the HW landfill scenario. This is higher than the median leachate concentration obtained during the data collection of on-site landfill information, which was 47 µg Cu/l.

B. Incinerator effluent data selection

For HW incinerators, the median, 90th percentile, minimum and maximum metal concentrations have been defined for copper concentrations in effluent water of HW incineration facilities after treatment (see **Table 129**). The median value (22.2 µg/l) was taken forwards for use in the exposure and risk characterisation calculations.

Table 129: Median, 90P, Min, Max and number of data points for copper (Cu) concentrations from effluent of HW incinerators after treatment

Endpoint	Cu levels (µg/l)
Median	22.2
90P	110
Min	0
Max	210
Data points	11

C. Incinerator air emissions data selection

As air emissions are currently reported as sum values a split has to be made to allocate the metal specific contribution for copper. However, the only copper data currently available for HW incinerators are from the CITEPA-OMINEA report (2011) and reports 0.09 g Cu/T waste incinerated, which is 13.9% of the combined metal contribution released. Whilst it has been noted that the distributions of metals for the French HW incinerators may not be typical of other EU HW incinerators, the French scenario has been taken as an example in absence of other data to calculate the contribution of copper from European HW incineration. The impact of waste types, amounts and flue gas treatment may differ between countries, which could affect specific metal content in the air.

The percentage contribution of 13.9% has been applied to the combined metal data in order to predict the levels of copper in air in mg/Nm^3 across the available EU incineration sites. These data have then been converted to kg/day assuming 60000 tonnes of waste is incinerated per year over 330 days, which results in a median 1500000 m^3 of flue gas being produced per day (see **Table 130**). The median value was used with EUSES to derive the predicted environmental concentrations (PECs) of copper.

Table 130: Median, 90P, Min, Max and number of data points for daily copper (Cu) emissions to air from HW incinerators

Endpoint	Cu (kg/day)
Median	0.0033
90P	0.0417
Min	0.0003
Max	0.1184
Data points	11

9.4.2.2 Risk Assessment of HW Landfills

When calculating risks of hazardous waste landfills, it can be assumed that during operation, a HW leachate landfill is similar to a MW landfill in terms of leachate generation. Thus, consistent with the recommendation from the ECHA guidance, the HW landfills were treated similarly to the MW landfills and the dilution factor will be the same. The ARCHE Waste Reports (2011-2012) established that the total leachate production was 100 m^3 per day and diluted in a STP and then in a standard river, resulting in a total dilution factor of 200 (DF = 20*10). It was assumed that the leachate is produced 365 days/year and the default copper sludge removal rate of 92% was applied in order to calculate the emissions from the STP to surface waters. The sludge disposal to soil step in EUSES was not used due to the possibly high concentrations of all kind of organic and inorganic pollutants. The results are shown in **Table 131**.

Table 131: Risk characterisations results for HW Landfill effluent containing copper

Compartment	Units	PEC*	PNEC	PEC:PNEC
STP	µg/l	0.0004	0.23	0.002
Aquatic	µg/l	2.9	7.8	0.375
Sediment	mg/kg dw	68.33	87	0.785

* - all PECs are worst-case values and include regional (background concentration), sediment PEC:PNEC should be reduced further to 0.01 after taking account of AVS.

It can be concluded from the above table that no unacceptable aquatic risks have been identified for the HW landfill waste route for copper containing material. No metal emissions to the air were recorded from a HW landfill due to low volatility of metal at ambient temperatures. Also the sludge from an STP treating leachates from a hazardous waste landfill is not considered to be applied to soil. Since both the aerial deposition and sludge application route are not relevant for HW landfills no terrestrial scenario has been developed.

9.4.2.3 Risk Assessment of HW Incinerators

Assessment of risks from hazardous waste incinerators differs from the MW incineration as the dilution factor is different, due to a reduced wastewater generation. A typical generic HW incineration plant can process 60,000 tonnes of waste per year and generates 0.2 m^3 effluent per ton waste (WI BREF, 2006). Assuming a plant operates 330 days/year this will result in an effluent flow of 36 m^3/day being discharged in a standard river of 18,000 m^3/day, giving a total dilution factor of 496. All effluent from these plants is assumed to be treated on site and not discharged to a municipal STP before discharge in surface water. The results of the risk characterisation for this scenario are presented in **Table 132**.

Table 132: Risk characterisations results for HW incinerator effluent containing copper

Compartment	Units	PEC*	PNEC	PEC:PNEC
Aquatic	µg/l	2.9	7.8	**0.376**
Sediment	mg/kg dw	68.42	87	**0.786**

* - all PECs are worst-case values and include regional (background concentration), sediment PEC:PNEC should be reduced further to 0.011 after taking account of AVS.

Risks to the terrestrial compartment have been calculated using the median local air emission value of 0.0033 kg Cu/d based on the assumption that 13% of total metal emissions to the air by HW incinerators will be copper. The outcome of these calculations is presented in **Table 133**.

Table 133: Risk characterisations for copper in soil resulting from HW incinerator emissions to air

Compartment	Units	PEC*	PNEC	PEC:PNEC
Soil	mg/kg dw	24.4	88	0.277

* - PEC includes regional (background concentration)

Table 134 shows the concentration of copper in air 100 m from the incinerator is not expected to pose any risks to human health.

Table 134: Risk characterisations for copper for MvE inhalation

$C_{local\ air}$ (100m)	Units	PEC	DNEL inhalation	RCR inhalation
Copper dust	µg/ m^3	0.00083	1000	0.00000083
Copper fume			100	0.0000083

These results can conclude that the legislation currently in place in the Landfill Directive and the Waste Incineration Directive is accepted as protective against environmental releases from hazardous waste treatment facilities releasing copper to the environment.

9.5 Indirect exposure of humans via the environment

Indirect exposure of humans via the environment was assessed as part of the Cu VRA (2008) for copper derived from both copper metal and copper compounds.

9.5.1 Local environment

Local indirect exposure was assessed by taking the regional environmental assessment as a base level and adding an additional amount arising from airborne deposition and plant uptake. Copper from fruit and vegetables, locally grown, was included in this assessment with other foodstuffs assumed to be sourced regionally.

Airborne concentrations and deposition rates were taken from the environment risk assessment calculated using the EUSES methodology. The contribution to dietary intake in the local environment was rather low due to the impact of industrial air pollution control measures and the effective homeostatic control of copper uptake by plants. Median additional daily intake is estimated at 0.14 mg/day and 90P-RWC at 0.25 mg/day.

The values taken forward to risk characterisation are summarised in Table 135.

Table 135: Summary of values for the local environment taken forward for risk characterisation

Exposure	Typical	RWC
External exposure through inhalation (mg/person/day) Basis: TGD default 24 h inhalation volume (20 m^3)	0.057	0.093

External exposure through dietary intake (mg/person/day) Intake additional to regional dietary intake	0.14	0.25

9.5.2 Regional environment

9.5.2.1 Inhalation

Inhalation exposure constitutes a quantitatively insignificant route for the general population, and the overall regional exposure assessment will be insensitive to error in 'regional' inhalation exposure. Taking a default inhalation volume of 20 m^3/day and a conservative exposure level of 100 ng/m^3 gives an inhalation intake of 0.002 mg/day.

9.5.2.2 Dietary

Indirect exposure to copper arises mainly through ingestion of food and drinking water. The literature covering dietary exposure is extensive and comprises studies based on market basket or duplicate diet designs. Studies published between 1989 and 2004 covering ten member states were consulted for the regional exposure assessment. It is notable that the results are highly consistent independent of study design or location. Median daily intakes for adults are 1.2 mg/day with a 10P-RWC of 0.6 mg/day (relevant to assessing potentials for copper deficiency) and a 90P-RWC of 2 mg/day (relevant to assessing potentials for copper excess). The elderly may have slightly lower intakes than younger adults. The intake of children is age-dependent.

Table 136: Summary of typical and RWC dietary exposure data (mg/day)

Age Years	Typical	10P-RWC	90P-RWC
ADULTS			
predominantly <60	1.2	0.4-1.0	2.0
>60	1.02	≤0.4 (0.6)*	≤2.0
CHILDREN			
<15 months	0.60		
2 yrs	0.45	0.40	0.50
2-3 yrs	0.70	0.45	0.95
5-9 yrs	0.60		
11-14 yrs	1.46	0.88	2.04
14-19 yrs	1.10-1.50	0.72-0.87	1.49-2.12

(*) 10P- RWC of 0.4 is considered anomalous and a value of 0.6 is used.

The 10^{th} percentile values are reflected against copper deficiencies. Typical and 90^{th} percentile RWC values are carried forward to the risk characterisation – assessment of effects from copper excess.

9.5.2.3 Drinking water

There is greater uncertainty concerning copper intakes from drinking water. Typically, copper levels in drinking water are very low with an estimated median intake of 0.11 mg/day and a 90P-RWC of 0.13 mg/day, less where bottled water is consumed.

However, copper may leach from copper pipes into water depending on a number of factors including the physico-chemical properties of the water, the condition of the distribution network and standing time. Therefore, a detailed assessment of copper levels in drinking water has been done. Data obtained after stagnation (first draw) are taken as a basis for acute exposures and data that most closely reflects representative daily consumption was used in chronic exposure estimates.

9.5.2.3.1 Acute exposure

Acute exposure was estimated based on the consumption of 'corrosive - first-draw water' (after stagnation of the water in the drinking water tube) as obtained from literature. A conservative typical and RWC estimates of 0.72 mg/litre and of 2.11 mg/litre respectively are carried forward for risk characterisation.

9.5.2.3.2 Chronic exposure

From literature, median copper levels in drinking water tubes were assessed and used for determining the 'chronic' copper exposure estimates from drinking water tubes.

A summary of the findings is provided in Table 137. The table shows median copper intake from consumption of 'moderately corrosive' water typically around 0.75 mg/day with a 90P-RWC of 2.2 mg/day.

Table 137: Medium copper intake from consumption of 'moderately corrosive' water

Exposure group	Exposure estimate (mg/day) (mean concentration (mg/litre) in parentheses)	
	Typical	RWC
Low exposure		
Consumption of bottled water	<0.01 (<0.005)	0.03 (0.015)
Typical exposure		
Basis: non-corrosive water, exposure = 10% of dietary exposure	0.11 (0.055)	0.13 (0.065)
Exposure to moderately corrosive water		
Zeitz *et al.*, (2003)	0.75 (0.6-0.9)	2.2 (1.9-2.4)
Berlin	(0.375)	(1.10)
Exposure from corrosive water		
Pettersson and Rasmussen (1999, 2003)	1.2	3.1
Malmo & Upsalla	(0.61)	(1.57)

9.5.2.4 Ingestion of dust by children

Young children also incur exposure through ingestion of dust by hand to mouth contact. This exposure may consist of a mixture of house dust and garden dust and is considered to be relevant to the exposure of children and adolescents.

Exposure estimates are calculated using the IEUBK dust ingestion data and the copper in household dust data in UK cities with a median value of 250 mg/kg for the city of Birmingham and an assumed RWC of 1000 mg/kg (see Table 138).

Table 138: Dust and copper ingestion by children (age dependent ingestion values from IEUBK model)

Age	Dust ingested (mg/day)	Copper ingested (µg/day)	
		Typical [1]	RWC [2]
0-1 yrs	85	21	85
1-4 yrs	135	34	135
6-7 yrs	85	21	85
7-12 yrs	34	8.5	34
12 yr old	13.5	3.4	13.5

[1] Basis: copper in dust = 250 mg/kg
[2] Basis: copper in dust = 1000 mg/kg

9.5.2.5 Overall regional exposure

Table 139, Table 140, Table 141 and Table 142 summarize the exposures for adults and children from air, food, drinking water and dust. Values for typical exposure and for a RWC case (moderately corrosive water) were carried forward to the risk characterisation.

Table 139: Estimates of total oral exposure to copper (mg/day)

Exposure group	Predominantly < 60 yr				Predominantly > 60 yr			
	typical		RWC		typical		RWC	
Dietary exposure	1.2		2		1.01		2	
Total exposure estimate additional exposure from drinking [(1)]	lower	upper	lower	upper	lower	upper	lower	upper
Low	1.2	1.2	2	2	1	1	2	2
Typical	1.3	1.3	2	2.1	1.1	1.1	2.1	2.1
moderately corrosive	2	3.4	2.8	4.2	1.8	3.2	2.8	4.2
corrosive	2.4	4.3	3.2	5.1	2.2	4.1	3.2	5.1

Table 140: Estimated typical oral copper intake for children and adolescents

Age Years	Food mg Cu/day	Typical water			Dust mg Cu/day	Total mg Cu/day
		l/day	mg Cu/l	mg Cu/day		
<1.3	0.6	0.81	0.055	0.045	0.021	0.67
2	0.45	0.81	0.055	0.045	0.034	0.53
2 to 3	0.7	0.81	0.055	0.045	0.034	0.78
5 to 9	0.6	1.52	0.055	0.084	0.021	0.70
11 to 14	1.46	1.52	0.055	0.084	0.006	1.55
14 to 19	1.1	1.52	0.055	0.084	0.003	1.19

14 to 19	1.5	1.52	0.055	0.084	0.003	1.59

Table 141: Estimated 10P-RWC oral copper intake for children and adolescents

Age Years	Food mg Cu/day	10th percentile RWC (Bottled water)			Dust mg Cu/day	Total mg Cu/day
		l/day	mg Cu/l	mg Cu/day		
<1.3	0.6	0.81	0.005	0.004	0.021	0.63
2	0.4	0.81	0.005	0.004	0.034	0.44
2 to 3	0.45	0.81	0.005	0.004	0.034	0.49
5 to 9	0.6	1.52	0.005	0.008	0.021	0.63
11 to 14	0.88	1.52	0.005	0.008	0.006	0.89
14 to 19	0.72	1.52	0.005	0.008	0.003	0.73
14 to 19	0.87	1.52	0.005	0.008	0.003	0.88

Table 142: Estimated 90P-RWC oral copper intake for children and adolescents

Age Years	Food mg Cu/day	Typical water			Dust mg Cu/day	Total mg Cu/day
		l/day	mg Cu/l	mg Cu/day		
<1.3	0.6	0.81	0.055	0.045	0.021	0.67
2	0.45	0.81	0.055	0.045	0.034	0.53
2 to 3	0.7	0.81	0.055	0.045	0.034	0.78
5 to 9	0.6	1.52	0.055	0.085	0.021	0.70
11 to 14	1.46	1.52	0.055	0.085	0.006	1.55
14 to 19	1.1	1.52	0.055	0.085	0.003	1.19
14 to 19	1.5	1.52	0.055	0.085	0.003	1.59

Indirect exposure of humans to copper via the environment was assessed as part of the Cu VRA. The resulting predicted exposures are summarised in the following table.

Table 143: Indirect exposure of humans via the environment

Route of exposure	Unit	Value	Justification
Inhalation – Local	mg/person /day	0.093	Reasonable worst-case values taken from Cu VRA (2008). Basis: TGD default 24 h inhalation volume (20 m^3).
	mg/person /day	0.057	Typical values taken from Cu VRA (2008). Basis: TGD default 24 h inhalation volume (20 m^3). Value used in combined exposure and taken forward to risk characterisation.
Dietary intake – Local	mg/person /day	2.35	Reasonable worst-case values taken from Cu VRA (2008). Regional dietary intake included (2.1 mg/person/day).

Route of exposure	Unit	Value	Justification
	mg/person /day	1.44	Typical values taken from Cu VRA (2008). Regional dietary intake included (1.3 mg/person/day). Value used in combined exposure and taken forward to risk characterisation.

The risk characterisation for indirect exposure of humans via the environment from the Cu VRA is summarized in Section 0.

9.5.3 Combined exposure

The estimated combined exposure to copper taken forward for risk characterisation for workers and the general population has been evaluated within the Cu VRA (2008) and are summarised in Table 144 and Table 145. The VRA combined exposure assessment is based on worst-case exposure estimates from the copper industry as a whole, which exceed those associated with the copper compound sector alone. Therefore, the approach and outcome presented within the VRA are considered to be conservative when applied to exposures related to copper compounds.

For workers, the RWC estimate is derived by combining the RWC occupational exposure with the typical indirect exposure (higher typical food + typical drinking water) and the typical consumer exposure. The typical estimate is derived by combining the typical occupational exposure with the RWC indirect exposure (higher RWC food + typical drinking water) and the RWC consumer exposure. RWC consumer exposure sources for workers include the use of hair care products, handling of coins and smoking.

Table 144: Combined exposure data carried forward for risk characterisation for workers - Typical scenarios

Risk characterisation	External Inhalation Cu(mg/ p/day)	External Dermal Cu(mg/p/day)	External Oral Cu(mg/p/day)
WORKERS EXPOSURE*			
Smelting and Refining FURNACE OPERATION			
All smelting, converter and anode furnace operation (site specific data, except where indicated below) Pooled ECI-07 anode furnace opn (incl. tapping) anode furnace opn using RPE (incl. tapping) SAMPLING PLANT(site specific data) Pooled RAW MATERIAL HANDLING (site specific data) Pooled	 0.3-2.3 1.2 8.5 0.85 0.4-3.2 1.9 0.2-2.9 0.2	 60 60 60 60 60 60 60 60	
PRODUCTION OF BILLETS (Process Code 6), SAND AND DIE CASTINGS (Process Code 7), WIREROD			
All operations (site specific data) Pooled data (Process Code 8)	0.3-2.4 1.2	60 60	

Risk characterisation	External Inhalation Cu(mg/ p/day)	External Dermal Cu(mg/p/day)	External Oral Cu(mg/p/day)
FURTHER PROCESSING			
All operations (site specific data) Pooled data	0.3-1 0.4	60 60	
RPE COPPER POWDER PRODUCTION			
ECI-97– operation specific -pooled	3.4-5.9 4.2	259 259	
ECI-105– operation specific *** -pooled	19.5-69 55.9	259 259	
ECI-106– operation specific ** - operation specific using RPE -pooled -pooled using	7.7-97.0 0.6-8.3 26 2.2	259 259 259 259	
Intermediate use of copper for copper compounds production			
ECI-91	6.8	230	
ECI-93	3.0	207	
ECI-110	1.0	207	
ECI-112	1.2	66	
Pooled	2.3	181	
CONSUMER EXPOSURE	0.001	0.28	
MAN EXPOSED VIA THE ENVIRONMENT-LOCAL	0.093		2.35

*assuming a respiratory volume of 10 m^3 for a worker/day, *** site closed, *** additional risk reduction measures have been implemented*

Table 145: Combined exposure data carried forward for risk characterisation for workers – RWC scenarios

Risk characterisation	External Inhalation Cu(mg/p/day)	External Dermal Cu(mg/p/day)	External Oral Cu(mg/p/day)
WORKERS EXPOSURE*			
Smelting and Refining			
FURNACE OPERATION All smelting, converter and anode furnace operation (site specific data, except where indicated below) Pooled	 1.7-8.4 5.4	 85 85	
ECI-07 anode furnace opn (incl. tapping) anode furnace opn using RPE (incl. tapping)	 15.5 1.55	 85	
SAMPLING PLANT (site specific data) Pooled	1.9-6.0 5.5	85 85	
RAW MATERIAL HANDLING (site specific data) Pooled	0.7-10.3 2.9	85 85	
PRODUCTION OF BILLETS (Process Code 6), SAND AND DIE CASTINGS (Process Code 7), WIREROD (Process Code 8)			

All operations (site specific data) Pooled data	2.3-12.4 6.0	85 85	
FURTHER PROCESSING			
All operations site specific data (using RPE) Pooled data	2.0-24.5 (1.3) 3.0	85 85	
COPPER POWDER PRODUCTION			
ECI-97– operation specific -pooled ECI-105***– operation specific -pooled ECI-106**– operation specific - operation specific using RPE -pooled -pooled using RPE	8.2-9.7 9.2 102-982 190 36.9-111.6 2.2-16 112.6 11.3	952 952 952 952 952 952 952 952	
Intermediate use of copper for copper compounds production			
ECI-91 ECI-93 ECI-110 ECI-112 Pooled	14.3 8.0 7.6 3.1 8.2	845 760 760 243 663	
CONSUMER EXPOSURE	0	0.14	
MAN EXPOSED VIA THE ENVIRONMENT-LOCAL	0.057		1.44

*assuming a respiratory volume of 10 m3 for a worker/day, ** site closed, *** additional risk reduction measures have been implemented

For the general population, the typical estimate is derived by combining the typical indirect exposure with the typical consumer exposure. The RWC estimate is derived by combining the RWC indirect exposure with the RWC consumer exposure excluding the use of supplements. The use of supplements has been excluded in order not to combine indirect exposure for areas with high levels of copper in drinking water with the use of copper supplements thereby avoiding unreasonably conservative exposure scenarios.

Table 146: Combined exposure data carried forward for risk characterisation for the general population – Typical scenarios

Risk characterisation	External Inhalation Cu(mg/p/day)	External Dermal Cu(mg/p/day)	External Oral Cu(mg/p/day)
Consumer exposure	0	0.38	0
Man exposed via the environment –regional	0.002	0	1.2-4.3
Man exposed via the environment –local	0.057	0	1.34-4.44

Table 147: Combined exposure data carried forward for risk characterisation for the general population – RWC scenarios

Risk characterisation	External Inhalation Cu(mg/p/day)	External Dermal Cu(mg/p/day)	External Oral Cu(mg/p/day)
Consumer exposure	0.0005	6.16	2
Man exposed via the environment –regional	0.002	0	2.0-5.1
Man exposed via the environment –local	0.093	0	2.25-5.35

9.6 Regional exposure concentrations

All data have been taken from the agreed values presented within the copper VRA (2008).

The frequency distributions of ambient copper exposure concentrations in the European surface waters, sediment, sewage treatment plants and soils were assessed in order to derive the predicted environmental concentrations (PEC) from the collected monitoring data in accordance to the TGD. Using well defined quality criteria, only high quality data were retained (e.g. soils and sediments extracted through aqua regia). If different data were available from one site, the site-specific 90th percentile value was derived and the region-specific PEC was defined as the average of the 90P values. If not sufficient site- specific data were available, the 90P of the individual data was used as region-specific PEC.

The assessment of the copper exposure concentrations in surface waters, sediments, STPs and soils is based on national monitoring databases, international databases and literature. Ambient monitoring data integrate both the natural background and the concentration added by anthropogenic activities. In addition, only a small fraction of the copper present in the environment is available for biological uptake. Therefore (1) natural background concentrations, (2) ambient concentrations and (3) the bioavailable metal fraction of the exposure concentrations will be considered when applicable.

9.6.1 Freshwater

The assessment of the copper exposure concentrations in surface waters is based on dissolved copper levels but total copper levels are also reported when available.

Reliable region-specific dissolved Cu PEC values, derived for Austria, Belgium Flanders, Belgium Walloon, Denmark, Finland Barentz area, Germany Elbe, Ireland, Portugal, The Netherlands, Sweden, England, Wales and Scotland ranged between 0.5 and 4.7 µg Cu/l with a median of 2.9 µg Cu/l. Additional reliable region-specific Cu PEC values, based on total measurements, derived for Finland, France, Germany Hessischen Landesambt & Northern Ireland, ranged between 1.8 and 7 µg Cu/l. The distributions of the fraction of copper dissolved in the surface waters, derived from 2 extensive databases (Elbe Germany & the Netherlands) were quite similar with median values of respectively 48 and 59 %.

Dissolved copper background levels around Europe ranged between 0.8 and 5.3 µg dissolved Cu/l according to Zuurdeeg (2002). In the FOREGS data base[20], the ambient copper baseline level for rivers ranged between 0.1 and 14 µg dissolved Cu/L with a 10th-90th percentile range between 0.23 and 2.45 µg dissolved Cu/l. Average measured or estimated background levels of copper in European countries ranged between 0.3 and 1.9 µg dissolved Cu/l with a median value of 0.84 µg dissolved Cu/l. The typical value of 0.84 µg/l for dissolved copper does confirm the median value of 0.88 µg/l that was generated in the FOREGS Geochemical Mapping Programme.

[20] FOREGS Geochemical Baseline mapping program -2005 website http://www.gsf.fi/publ/foregsatlas/map_compare.html

9.6.1.1 River and lake sediment

Reliable region-specific PEC sediment values derived for Belgium Flanders, France Artois Picardia, France Rhone-Mediterranean, Sweden, The Netherlands and Spain and ranged between 46 and 88 mg Cu/kg dwt with a median value of 67.5 mg Cu/kg dwt.

Reported copper background levels around Europe in literature ranged between 16 and 32 mg Cu/kg dwt with a median value of 21 mg Cu/kg dwt. In the FOREGS-database the ambient baseline levels for copper in freshwater sediment ranged between 1.0 and 998 mg/kg, with a 10th/90th percentile of 4 and 44 mg/kg and a 50th percentile of 14 mg/kg. Taking into account the high quality of the data set, this value is accepted as a typical background concentration for Cu in European freshwater sediments (EU-regional scale).

From a literature search as well as novel experimental data, it was recognised that the copper fraction (as well as other divalent metals) bound to sulphides, present in anaerobic sediments, does not contribute to the toxicological relevant sediment fraction. Therefore, to better understand the copper fraction actually bioavailable in sediment, Acid Volatile Sulphide measurement, carried out in Europe were assessed. The database contained 226 data essentially from Flanders and the Netherlands and some additional data from other EU countries (Italy, Germany, Sweden and UK). Statistical analysis of these data revealed a median AVS concentration in Europe of 8.1 µmol AVS/g dry weight and a 10th percentile of 0.77 µmol AVS/g dry weight. In lack of data, the 10th percentile was considered as a reasonable worst case and thus, in case of lack of bioavailability data, the PEC bioavailable is calculated as PEC total – the AVS reasonable worst case

9.6.2 Coastal water

Exposure data were obtained for the coastal areas of Belgium, The Netherlands, Norway, Denmark, Sweden and UK sampled between 1984 and 2005. The 90th percentiles ranged between 0.8 and 2.7 µg Cu/l. with a median 90th percentiles of 1.1 µg Cu/l. The value of 2.7 µg Cu/l was derived for older data (84-85) and is therefore not considered as representative for current regional marine waters. The data represent coastal areas of the N. Sea, the Baltic, the Kattegat and the Skagerrak.

9.6.2.1 Coastal sediment

Sediment concentrations were obtained for the coastal zones of Belgium, Denmark, Germany, Ireland, The Netherlands, Norway, Sweden and UK. RWC PEC values range between 4 and 55 mg Cu/kg dwt with a median RWC PEC value of 16 mg Cu/kg dwt.

9.6.3 STP

Reliable region-specific total PEC values for STPs, obtained from Belgium, the Netherlands and UK ranged between 11 and 54 µg Cu/l based on total copper levels. In addition, an STP PEC value of 8 µg dissolved Cu/l was derived for the UK, i.e., the country characterised by the highest total copper values in STPs (54 µg/l). Dissolved copper concentrations in STPs were not available for other countries. The representativeness of this limited data set was further confirmed from a comparison of copper levels in sludge across Europe as reported from a European database.

9.6.4 Soil

Reliable country-specific PEC values for agricultural soils, derived for Austria, Belgium, Finland, France, Germany, Ireland, Northern Italy, The Netherlands, Norway and Sweden ranged between 16 and 58 mg Cu/kg dw, with a median of 31.2 mg Cu/kg dw.

Reliable country-specific PEC values for forest soils, derived for Austria, Germany, Ireland, The Netherlands, and Portugal, ranged between 7 and 40 mg Cu/kg dwt with a median of 24 mg Cu/kg dwt.

Reliable country-specific PEC values for grassland soils, derived for Austria, Germany, Ireland and The Netherlands, Spain ranged between 28 and 44 mg Cu/kg dry weight with a median of 32.8 mg Cu/kg dwt.

The 10th and 90th percentile of the copper baseline levels around Europe as derived in the FOREGS program are respectively 3 -33 mg Cu/kg dwt. The median of the FOREGS database is 12 mg Cu/kg dwt.

Average copper concentrations in the earth crust and soils are estimated to respectively range between 24 -55 mg Cu/kg dwt and 20-30 mg Cu/kg dwt.

Table 148: Overview of regional monitoring data

Compartment	Measured PEC_{region} Median *(Min-Max)*	Investigated countries** for the measured PEC_{region}	Natural background levels Median *(Min-Max)*
Rivers and lakes (µg dissolved Cu/L)	2.9 (0.5-4.7)	Au, B, Dk, Fi, Fr, D, Ire, P, Nl, Sw, UK, Sp	0.9 (0.2-2.45)
River and lake sediment (mg/kg dry weight)	67 (46-88)*	B, Fr, Fi, Nl, UK, Sp	14 (4-44)
Coastal waters (µg dissolved Cu/L)	1.1 (0.8-2.7)	N. Sea, Atlantic, Baltic	0.05-0.4
Coastal sediments (mg/kg dry weight)	16.1 (4-55)	N. Sea, Atlantic, Baltic	
Effluent sewage treatment plants (µg total Cu/L)	15.1 (11-54)	B, Nl, UK	
Forest soils (mg/kg dry weight)	24.4 (7-40)	Au, De, Ire, Nl, Sp	12 (3-33)
Grassland soils (mg/kg dry weight)	32.8 (28-44)	Au, De, Ire, Nl, Sp	12 (3-33)
Agricultural soils (mg/kg dry weight)	31.2 (16-58)	Au, Be, Fi, Fr, De, Ire, It, Nl, No, Sw	12 (3-33)

* Measurements on acid Volatile sulphides are available for Flanders, The Netherlands, UK, and Finland as well as for a dataset of wade-able streams in Europe. The analysis clearly indicated that at a regional scale, copper is fully bound to AVS and thus non-available.

It is useful to mention that these measured PECs are related to releases of ‘copper-ions’ from uses of copper as well as copper-compounds. The PECs also include releases from copper compounds used as biocidal and plant-protection products and are therefore ‘over-estimating’ the PEC, relevant to this ‘copper compound’ dossier. Table **149** provides a summary of the copper concentrations in the different environmental compartments as determined from the EUSES 2.0 model steady state calculations and as obtained from the measured monitoring data across Europe as part of the VRA (2008). This comparison shows a higher concentration obtained from modelling data than from measured data, especially for agricultural soils and sediments. This discrepancy can be explained by the steady state modelling in EUSES.

Table 149: Comparison of measured versus modelled environmental concentrations

$PEC_{compartment}$	*Natural/pristine ambient background (median measured)*	*Modelled (EUSES 2.0) PEC*		*Measured PEC*	
		*EU continental scale**	*EU regional scale Selected region (Netherlands)**	*EU-15 (regional median PEC (min-max)*	
Air PEC_{add} **(ng/m^3)**	NA	1.7E-5	**1.12E-4**	air	NA
Agricultural soil $PEC_{add/total}$ **(mg/kg dw)**	12	18.4	78.8	agr. soil grassland	31.2 (16.1-57.5) 32.8 (28.0-44.0)
Natural soil PEC_{total} **(mg/kg dw)**	12	13.6	22.7	forest soil	**24.4** (7.3-40.2)
Freshwater PEC_{total} **(dissolved; µg/l)**	0.88	1.65	4.4	freshwater	**2.9** (0.5-4.7)
Sediment PEC_{total} **(mg/kg dw)**	14	32.8	Steady state: 100.7	sediment	**67.5** (45.8-88.3)

*NA: not available; * including the EU median natural background concentrations*

A refined analysis of the accumulation profile of copper in agricultural soils showed that, considering the current release patterns, it would take 5000 years before agricultural soil concentrations have reached steady state.

Considering the availability of large monitoring data-sets on copper across Europe, the measured data have been retained for the final risk characterisations. Values in **bold** are used as ambient background values for the assessment of the local exposures.

10 RISK CHARACTERISATION

This section provides a summary of the risk characterisation based on the available effects data presented within the Voluntary Risk Assessment on copper metal, Dicopper oxide, copper (II) oxide, copper oxychloride and copper sulphate. The copper VRA has been prepared in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances. For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Voluntary Risk Assessment Report (VRA) that can be obtained from the ECHA website.

This CSR only considers the production and uses of copper dinitrate. Massive copper and copper powders are assessed in the copper registration dossier.

The following sections present the risk characterisation ratios (RCR) calculated within the parameters outlined within Chapter 9 for the generic exposure scenarios (GES) investigated for production, formulation (catalyst manufacture) and downstream use. These RCR are limited to the GES investigated, each of which have been presented as a reasonable worst-case (RWC) illustration of the potential risk from the predicted environmental, worker and consumer exposure to 'copper' as a result of copper dinitrate production and use. In all cases, it is the responsibility of the specific production/manufacturing site and/or employer and/or downstream user (DU) to ensure that the human and environmental risk associated with each life-cycle stage of copper dinitrate has been assessed and all relevant control measures put in place or communicated downstream as required.

In order to identify each generic exposure scenario (GES) the following descriptor codes have been developed. The environmental GES will all have the prefix **E-GES** and the worker GES will all have the prefix **W-GES** (industrial), **PW-GES** (professional) and **C-GES** (consumer). Further descriptors are given within each relevant sector.

For the purpose of assessing the exposure of workers to copper compounds, only the MEASE model outputs have been used and the results for all available PROCs presented in full in Annexes 14 and 15.

10.1 PRODUCTION – Manufacture of copper dinitrate

The following risk characterisation ratios (RCR) are presented for the generic exposure scenarios (GES) defined within Section 9.2.2. In order to identify each GES the following descriptor codes have been developed. The Environmental Generic Exposure Scenarios [**E-GES**] and the Worker Generic Exposure Scenarios [**W-GES**] for production are denoted by the letter '**P**', with further notation to identify the specific release category or activities investigated within the individual GES title;

Scenario			**Description**
E-GES-P	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data
	Waste water treatment	0	No waste water emission
		1	Waste water treated on-site WWTP*
		2	Waste water treated on (WWTP*) and off-site (STP)
W-GES-P	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry

* On-site WWTP can involve biological or physico-chemical treatment; therefore, the impact of copper exposure on sewage sludge microorganisms has to be carried out. Where unacceptable exposure levels of a biological treatment WWTP dictate the maximum copper tonnage (within manufactured catalyst product) a second estimate of maximum tonnage will be presented assuming a non-biological treatment process.

10.1.1 Human health

10.1.1.1 Workers

Acceptable working conditions for the production of copper compounds in all sectors have been derived for all relevant PROC codes in the GES. However, the assessment presented can only be considered as illustrative and does not replace the requirement for a local on-site or task specific assessment, which remain the responsibility of the site owner or employer.

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solids) or from evaporation (liquids) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,

- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high.

Table 150: (Semi) Quantitative risk characterisation for industrial workers involved in the production of copper compound; copper dinitrate

GES1: Production of copper dinitrate is produced from reacting cupric oxide (CuO) [or other copper compound] and nitric acid					
ES [+ RMMs]	**Route**	**UNITS**	**Exposure concentrations (EC)**	**DN(M)EL[21]**	**RCR[22]**
W-GES-P(High) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-P(High) PROC 2 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-P(High)PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-P(High) PROC 8b + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.313	1	0.313
	Combined routes				0.338
W-GES-P(Med) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-P(Med) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-P(Med) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Med) PROC 8b + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275
W-GES-P(Low) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023

[21] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[22] *Equal to the ratio of the relevant EC (reported in column 4) to the relevant D(M)NEL (reported in column 5)*

GES1: Production of copper dinitrate is produced from reacting cupric oxide (CuO) [or other copper compound] and nitric acid					
ES [+ RMMs]	**Route**	**UNITS**	**Exposure concentrations (EC)**	**DN(M)EL[21]**	**RCR[22]**
W-GES-P(Low) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.01	1	0.035
	Combined routes				0.023
W-GES-P(Low) PROC 3 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-P(Low) PROC 8b No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0. 1
	Combined routes				0.125
W-GES-P(Liquid) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.125
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.126
W-GES-P(Liquid) PROC 2 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.252
W-GES-P(Liquid) PROC 3 No RMM required	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.135
W-GES-P(Liquid) PROC 8b No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261

GES2: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid					
ES [+ RMMs]	**Route**	**UNITS**	**Exposure concentrations (EC)**	**DN(M)EL[23]**	**RCR[24]**
W-GES-P(High) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-P(High) PROC 2 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-P(High)PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-P(High) PROC 4 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.650
W-GES-P(High) PROC 5 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.650
W-GES-P(High) PROC 8a	Dermal	mg Cu/d	480	136.67	0.05

[23] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[24] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

GES2: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid					
ES [+ RMMs]	**Route**	**UNITS**	**Exposure concentrations (EC)**	**DN(M)EL[23]**	**RCR[24]**
+ LEV + RPE (APF 4)	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-P(High) PROC 8b + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.313	1	0.313
	Combined routes				0.338
W-GES-P(High) PROC 9 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.55
	Combined routes				0.525
W-GES-P(High) PROC 26 + LEV + RPE (APF 4)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.45	1	0.45
	Combined routes				0.553
W-GES-P(Med) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-P(Med) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Med) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-P(Med) PROC 4 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Med) PROC 5 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Med) PROC 8a + LEV	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-P(Med) PROC 8b + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275
W-GES-P(Med) PROC 9 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Med) PROC 26 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.72	1	0.72
	Combined routes				0.823
W-GES-P(Low) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-P(Low) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.01	1	0.035
	Combined routes				0.023
W-GES-P(Low) PROC 3 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1

GES2: Copper dinitrate is manufactured by dissolution of copper metal in nitric acid					
ES [+ RMMs]	**Route**	**UNITS**	**Exposure concentrations (EC)**	**DN(M)EL[23]**	**RCR[24]**
	Combined routes				0.113
W-GES-P(Low) PROC 4 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Low) PROC 5 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-P(Low) PROC 8a No RMM required	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-P(Low) PROC 8b No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0. 1
	Combined routes				0.125
W-GES-P(Low) PROC 9 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0. 1
	Combined routes				0.125
W-GES-P(Low) PROC 26 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.27	1	0.27
	Combined routes				0.373
W-GES-P(Liquid) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.125
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.126
W-GES-P(Liquid) PROC 2 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.252
W-GES-P(Liquid) PROC 3 No RMM required	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.135
W-GES-P(Liquid) PROC 4 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-P(Liquid) PROC 5 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-P(Liquid) PROC 8a No RMM required	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-P(Liquid) PROC 8b No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-P(Liquid) PROC 9 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-P(Liquid) PROC 26 + LEV + RPE (APF 4)	Dermal	N/A			
	Inhalation				
	Combined routes				

10.1.1.2 Consumers

Not applicable.

10.1.1.3 Indirect exposure of humans via the environment

See Section 10.5.

10.1.2 Environment

In considering all of the available information, all three defined production scenarios (E-GES) have been used to determine the maximum tonnage for copper dinitrate using EUSES 2.0. All scenarios are based on the assumptions outlined by ERC 1 for production and the spERC for Manufacture of metal compounds v1.1b;

i) E-GES-P1.0/2.0 – assuming no waste water releases as a result of production processes [applicable to GES1].

ii) E-GES-P1.1/2.1 - all waste waters are treated on site (WWTP) prior to release directly to receiving waters [applicable to GES1 and GES2].

iii) E-GES-P1.2/2.2 [applicable to GES2] – assuming that all waste waters are also treated at an on-site WWTP prior to release to a municipal off-site STP.

The maximum predicted tonnage of copper considered acceptable, within the confines of the exposure scenarios outlined within Section **9.2.2.1**, have been calculated using EUSES 2.0. However, the maximum tonnage for E-GES-P1.2 and 2.2 has been shown to be limited by unacceptable effects against sewage sludge microorganisms where biological treatment processes are assumed. Whilst the majority of on-site WWTP will involve physico-chemical treatment processes, the use of biological treatment plants on-site cannot be dismissed due to a lack of information for the industry as a whole. Therefore, the risk threshold for sewage sludge microorganisms exposed to copper as a result of production has been considered since retaining the functionality of the waste treatment (92% minimum copper removal) process is essential to the exposure scenarios investigated. However, in order to illustrate the maximum production tonnages of copper compound, where on-site treatment is carried out using physico-chemical treatment processes, a second calculation has been carried out.

No assessment of secondary poisoning in the aquatic or terrestrial compartments is considered necessary due to the following;

- copper is an essential trace element,
- copper is well regulated in all living organisms and
- there is no evidence of copper biomagnification across the trophic chain in either the aquatic or terrestrial food chains.

10.1.2.1 Aquatic compartment (including sediment and secondary poisoning)

Table 151: Risk characterisation for the aquatic compartment for production

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-P1.0/2.0 [GES1]					
Not applicable no direct releases to water.					
E-GES-P1. 1 [GES1 & GES2]					
Freshwater	mg Cu/l	0.0055	0.0078	0.7	Maximum tonnage 5.75 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dwt	78.7	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	24.0	676	0.04	
E-GES-P2. 1 [GES1 & GES2]					
Freshwater	mg Cu/l	0.0055	0.0078	0.7	Maximum tonnage 1725 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dwt	78.8	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	23.98	676	0.04	
E-GES-P1.2 [WWTP – physico-chemical] [GES2]					
Freshwater	mg Cu/l	0.0055	0.0078	0.7	Maximum tonnage 71.25 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dwt	78.7	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	24.0	676	0.04	
E-GES-P1.2 [WWTP – biological] [GES2]					
Freshwater	mg Cu/l	0.0041	0.0078	0.5	Maximum tonnage 32 tonnes copper per annum. Risk threshold limit is on-site WWTP microorganisms.
Sediment (freshwater)	mg Cu/kg dwt	35.3	87.1	0.4	
Marine water	mg Cu/l	0.0012	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	19.6	676	0.03	
E-GES-P2.2 [WWTP – physico-chemical] [GES2]					
Freshwater	mg Cu/l	0.0055	0.0078	0.7	Maximum tonnage 21000 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dwt	77.9	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	23.92	676	0.04	
E-GES-P2.2 [WWTP – biological] [GES2]					
Freshwater	mg Cu/l	0.004	0.0078	0.5	Maximum tonnage 9450 tonnes copper per annum. Risk threshold limit is on-site WWTP microorganisms.
Sediment (freshwater)	mg Cu/kg dwt	35	87.1	0.4	
Marine water	mg Cu/l	0.0012	0.0056	0.2	
Sediment (marine)	mg Cu/kg dwt	19.62	676	0.03	

*- Local concentrations include background levels.

10.1.2.2 Terrestrial compartment

Table 152: Risk characterisation for the terrestrial compartment for production

Compartments	PEC*	PNEC	PEC/PNEC	Discussion
	mg Cu/kg dwt			
E-GES-P1.0 [GES1]				
Agricultural soil	44.8	64.6	0.7	Maximum tonnage 900 tonnes copper per annum. Risk threshold limit is the soil compartment.
Grassland	59.8		0.9	
E-GES-P2.0 [GES1]				
Agricultural soil	42.6	64.6	0.7	Maximum tonnage 134000 tonnes copper per annum. Risk threshold limit is the soil compartment.
Grassland	56.1		0.9	
E-GES-P1.1 [GES1 & GES2]				
Agricultural soil	24.53	64.6	0.4	Maximum tonnage 5.75 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	24.63		0.4	
E-GES-P2.1 [GES1 & GES2]				
Agricultural soil	24.64	64.6	0.4	Maximum tonnage 1725 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	24.81		0.4	
E-GES-P1.2 [WWTP – physico-chemical] [GES2]				
Agricultural soil	44.2	64.6	0.7	Maximum tonnage 71.25 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	34.5		0.5	
E-GES-P1.2 [WWTP – biological] [GES2]				
Agricultural soil	33.28	64.6	0.5	Maximum tonnage 32 tonnes copper per annum. Risk threshold limit is on-site WWTP microorganisms.
Grassland	28.92		0.4	
E-GES-P2.2 [WWTP – physico-chemical] [GES2]				
Agricultural soil	45.1	64.6	0.7	Maximum tonnage 21000 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	36.5		0.6	
E-GES-P2.2 [WWTP – biological] [GES2]				
Agricultural soil	33.72	64.6	0.5	Maximum tonnage 9450 tonnes copper per annum. Risk threshold limit is on-site WWTP microorganisms.
Grassland	29.84		0.5	

*- Local concentrations include background levels.

10.1.2.3 Atmospheric compartment

The air levels predicted for compound manufacture have been detailed in Section **9.2.5.1.6**. However, copper is not considered to pose a risk to the atmospheric compartment and has not been considered further.

10.1.2.4 Microbiological activity in sewage treatment systems

Not applicable.

10.1.2.5 Site specific environmental risk assessments

Production sites for copper dinitrate; CCCP12, CCCP15, CCCP16 and CCCP17 have each supplied annual tonnage data (undisclosed-confidential) for which the following risk characterisations have been predicted. These data are based on EUSES 2.0 model predictions using all available input data regarding production tonnage, on-site RMMs and emission routes (via WWTP/STP). For each site, a Tier 2 exposure assessment has been carried out using the conditions outlined by the spERC (metal compound manufacture) as each site has supplied information to confirm that it complies with the RMMs required.

In order to maintain confidentiality, the tonnage and production days for each site are not shown.

Table 153: Environmental risk characterisation for production site CCCP12

Tier 2: EUSES 2.0 calculations with spERC assumptions				
Compartment		**Unit**	**PNEC**	**RCR**
Freshwater	**Aquatic**	mg/l	0.0078	0.4
	Sediment	mg/kg dwt	18.93	0.003
Marine	**Aquatic**	mg/l	0.0056	0.2
	Sediment	mg/kg dwt	146.96	0.1
Terrestrial	**Soil**	mg/kg dwt	69.82	0.4
	Groundwater	mg/l	-	-

Table 154: Risk characterisation for production site CCCP15

Tier 2: EUSES 2.0 calculations with spERC assumptions				
Compartment		**Unit**	**PNEC**	**RCR**
Freshwater	**Aquatic**	mg/l	0.0078	0.4
	Sediment	mg/kg dwt	18.93	0.003
Marine	**Aquatic**	mg/l	0.0056	0.2
	Sediment	mg/kg dwt	146.96	0.1
Terrestrial	**Soil**	mg/kg dwt	69.82	0.4
	Groundwater	mg/l	-	-

Table 155: Risk characterisation for production site CCCP16

Tier 2: EUSES 2.0 calculations with spERC assumptions				
Compartment		**Unit**	**PNEC**	**RCR**
Freshwater	**Aquatic**	mg/l	0.0078	0.4
	Sediment	mg/kg dwt	18.93	0.01
Marine	**Aquatic**	mg/l	0.0056	0.2
	Sediment	mg/kg dwt	146.96	0.1
Terrestrial	**Soil**	mg/kg dwt	69.82	0.4
	Groundwater	mg/l	-	-

Table 156: Risk characterisation for production site CCCP17

Tier 2: EUSES 2.0 calculations with spERC assumptions				
Compartment		**Unit**	**PNEC**	**RCR**
Freshwater	**Aquatic**	mg/l	0.0078	0.372
	Sediment	mg/kg dwt	18.93	0.0005
Marine	**Aquatic**	mg/l	0.0056	0.196
	Sediment	mg/kg dwt	146.96	0.11
Terrestrial	**Soil**	mg/kg dwt	69.82	0.35
	Groundwater	mg/l	-	-

These data show that the production activities associated with the manufacture of this copper compound are not expected to result in unacceptable environmental effects.

10.2 DOWNSTREAM USE – [FORMULATION] Manufacture of catalysts containing copper dinitrate [GES3]

The following risk characterisation ratios (RCR) are presented for the generic exposure scenarios (GES) defined within Section **9.3.1.2**. In order to identify each GES the following descriptor codes have been developed. The Environmental Generic Exposure Scenarios [**E-GES**] and the Worker Generic Exposure Scenarios [**W-GES**] for catalyst manufacture are denoted by '**CM**', with further notation to identify the specific release category or activities investigated within the individual GES title;

Scenario [GES3]			**Description**
E-GES-CM	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data (default dilution in receiving waters)
		3	Tier 3 - spERC/measured data (realistic dilution in receiving waters)
	Waste water treatment	0	No waste water emission
		1	Waste water treated on-site WWTP*
		2	Waste water treated on (WWTP*) and off-site (STP)
W-GES-CM	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry

** On-site WWTP is assumed to be physico-chemical treatment; therefore, the impact of copper exposure on sewage sludge microorganisms has not been carried out. Should an on-site biological treatment plant be in use, this assessment should be added by the catalyst user.*

10.2.1 Human health

Copper is an essential trace element for all biological organisms, including humans. The essentiality of copper arises from its incorporation into a large number of proteins and is demonstrated in a range of physiological functions where copper plays a critical role. With essential elements such as copper, homeostatic control mechanisms exist in order to maintain a constant internal environment within a range that is essential to good health. With respect to oral intake of copper, the major homeostatic control mechanisms involve regulation at both the site of intestinal absorption and biliary excretion via first-pass metabolism in the liver. Failure to maintain copper homeostasis may lead to adverse effects resulting from either deficiency or excess.

Therefore, the consequences of both high and low copper intakes are considered for risk characterisation.

10.2.1.1 Workers

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solid) or from evaporation (liquids) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high.

Table 157: (Semi) Quantitative risk characterisation for workers involved in catalyst manufacture [GES3]

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[25]	RCR[26]
W-GES-CM(High) PROC 1 [Semi-bulk delivery, Storage, Conveying, Drying, Mixing, Calcination (manufacture & regeneration), Reduction, Stabilisation]. **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m³	0.01	1	0.01
	Combined routes				0.023
W-GES-CM(High) PROC 2 [Semi-bulk delivery, Storage, Conveying, Spent catalyst storage, Drying (manufacture & regeneration), Calcination	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m³	0.1	1	0.1
	Combined routes				0.125

[25] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[26] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[25]	RCR[26]
(manufacture & regeneration), Screening (manufacture & regeneration), Filling operations, Maintenance & Cleaning (manufacture & regeneration)] **+ LEV**					
W-GES-CM(High) PROC 3 [Drying (regeneration)] **+ LEV**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-CM(High) PROC 4 [Drying (regeneration)] **+ LEV + RPE (APF 4)**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.650
W-GES-CM(High) PROC 8a [Semi-bulk delivery Transfer activities, Filling operations] **+ LEV + RPE (APF 10)**	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-CM(High) PROC 8b [Semi-bulk delivery, Transfer activities (manufacture & regeneration), Filling operations] **+ LEV + RPE (APF 4)**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.313	1	0.313
	Combined routes				0.338
W-GES-CM(High) PROC 14 [Forming] **+ LEV + RPE (APF 4)**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275
W-GES-CM(Med) PROC 1 [Fresh catalyst storage Calcination (regeneration)] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-CM(Med) PROC 2 [Transfer activities, Mixing, Calcination, Spent catalyst storage, Drying (manufacture & regeneration), Calcination (manufacture & regeneration), Screening(manufacture & regeneration), Maintenance & Cleaning (manufacture & regeneration)] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-CM(Med) PROC 3 [Drying (manufacture & regeneration), Mixing, Calcination, Impregnation batch] **+ LEV**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-CM(Med) PROC 4 [Drying (manufacture & regeneration), Screening, Cleaning] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-CM(Med) PROC 5 [Mixing & blending] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-CM(Med) PROC 8a	Dermal	mg Cu/d	480	136.67	0.05

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[25]	RCR[26]
[Semi-bulk delivery, Transfer activities, Conveying, Filling operations] + LEV	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-CM(Med) PROC 8b [Semi-bulk delivery, Transfer activities (manufacture & regeneration), Conveying, Drying, Filling operations] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275
W-GES-CM(Med) PROC 9 [Filling operations (manufacture & regeneration)] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-CM(Med) PROC 14 [Forming] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-CM(Low) PROC 1 [Semi-bulk delivery, Storage, Transfer activities, Conveying, Calcination (regeneration), Dissolving, Precipitating, Filtrating, Drying, Fresh catalyst storage] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-CM(Low) PROC 2 [Semi-bulk delivery, Storage, Transfer activities, Conveying, Dissolving, Filtrating, Forming, Spent catalyst storage (regeneration), Drying (regeneration), Calcination (manufacture & regeneration), Forming, Precipitating, Screening (manufacture & regeneration), Maintenance & Cleaning (manufacture & regeneration)] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.035
W-GES-CM(Low) PROC 3 [Precipitating, Filtrating, Drying (manufacture & regeneration), Mixing, Impregnation (continuous/batch), Calcination] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-CM(Low) PROC 4 [Filtrating, Drying (regeneration)] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-CM(Low) PROC 8a [Semi-bulk delivery, Transfer activities, Conveying, Dissolving, Filtrating, Filling operations] **No RMM required**	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-CM(Low) PROC 8b [Semi-bulk delivery, Transfer activities (manufacture & regeneration), Conveying,	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[25]	RCR[26]
Dissolving, Filtrating, Forming, Filling operations] **No RMM required**					
W-GES-CM(Low) PROC 9 [Filling operations (manufacture & regeneration)] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-CM(Low) PROC 14 [Forming] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-CM(Liquid) PROC 1 [Calcination (regeneration), Precipitation, Filtrating] **No RMM required**	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.126
W-GES-CM(Liquid) PROC 2 [Filtrating, Spent catalyst storage (regeneration), Drying (regeneration), Calcination (regeneration), Precipitating, Screening (regeneration), Maintenance & Cleaning (regeneration)] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.252
W-GES-CM(Liquid) PROC 3 [Drying (regeneration), Precipitation, Filtrating, Impregnation (batch)] **No RMM required**	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.135
W-GES-CM(Liquid) PROC 4 [Drying (regeneration), Filtrating] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-CM(Liquid) PROC 5 [Mixing & blending] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-CM(Liquid) PROC 8a [Filtrating] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-CM(Liquid) PROC 8b [Transfer activities (regeneration), Filtrating] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-CM(Liquid) PROC 9 [Filling operations (regeneration), Cleaning] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261

10.2.1.2 Consumers

Not applicable, catalyst manufacture is considered to take place within an industrial process.

10.2.1.3 Indirect exposure of humans via the environment

See Section 10.5.

10.2.2 Environment

In considering all of the available information, two scenarios (E-GES) for catalyst manufacture have been defined and used to determine the maximum tonnage for catalyst manufacture for a single site using EUSES 2.0. Both scenarios are based on the assumptions outlined by the spERC for Manufacture of metal containing catalysts (ECMA 1.1a, v2.0) modified by measured data provided by catalyst manufacturers (see additional adjustment as outlined in Section **9.3.1.2.1**), as a Tier 2 (default receiving waters) and Tier 3 (realistic receiving waters) assessment.:

i) E-GES-CM2.1/3.1 – assuming that all waste waters are treated on site (WWTP) prior to release directly to receiving waters, and

ii) E-GES-CM2.2/3.2 – assuming that all waste waters are treated at an on-site WWTP prior to release to a municipal off-site STP.

Note: A Tier 1 assessment using default ERC values has not been presented, as the information available for copper compound containing catalysts suggests that this would not be applicable.

The maximum predicted tonnage of copper considered acceptable within the confines of the exposure scenarios outlined in Section **9.3.1.2.1** have been calculated using EUSES 2.0.

No assessment of secondary poisoning in the aquatic or terrestrial compartments is considered necessary due to the following:

- copper is an essential trace element,
- copper is well regulated in all living organisms and
- there is no evidence of copper biomagnification across the trophic chain in either the aquatic or terrestrial food chains.

10.2.2.1 Aquatic compartment (including sediment)

Table 158: Risk characterisation for the aquatic compartment for catalysts manufacture [GES3]

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-CM2.1 [no STP]					
Freshwater	mg Cu/l	0.0054	0.0078	0.7	Maximum tonnage 40 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dw	80	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.1	676	0.04	
E-GES-CM3.1 [no STP]					

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
Freshwater	mg Cu/l	0.0072	0.0078	0.9	Maximum tonnage 3250 tonnes copper per annum. Risk threshold limit is freshwater aquatic compartment.
Sediment (freshwater)	mg Cu/kg dw	29.5	87.1	0.3	
E-GES-CM2.2					
Freshwater	mg Cu/l	0.0054	0.0078	0.7	Maximum tonnage 500 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Sediment (freshwater)	mg Cu/kg dw	80	87.1	0.9	
Marine water	mg Cu/l	0.0014	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.1	676	0.04	
E-GES-CM3.2					
Freshwater	mg Cu/l	0.003	0.0078	0.4	Maximum tonnage 1100 tonnes copper per annum. Risk threshold limit is terrestrial (soil) compartment.
Sediment (freshwater)	mg Cu/kg dw	0.837	87.1	0.01	

*- Local concentrations include background levels.

10.2.2.2 Terrestrial compartment

Table 159: Risk characterisation for the terrestrial compartment for catalyst manufacture [GES3]

Compartments	PEC*	PNEC	PEC/PNEC	Discussion
	mg Cu/kg dw			
E-GES-CM2.1 [WWTP – physico-chemical]				
Agricultural soil	24.4	64.6	0.4	Maximum tonnage 40 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	24.4		0.4	
E-GES-CM2.1 [WWTP – biological]				
Agricultural soil	24.7	64.6	0.4	Maximum tonnage 3250 tonnes copper per annum. Risk threshold limit is freshwater aquatic compartment.
Grassland	25.0		0.4	
E-GES-CM2.2 [WWTP – physico-chemical]				
Agricultural soil	43.0	64.6	0.7	Maximum tonnage 500 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
Grassland	31.9		0.5	
E-GES-CM2.2 [WWTP – biological]				
Agricultural soil	60.5	64.6	0.9	Maximum tonnage 1100 tonnes copper per annum. Risk threshold limit is agricultural soil due to the assumption that sludge from STP is spread on land.
Grassland	39.0		0.6	

*- Local concentrations include background levels.

10.2.2.3 Atmospheric compartment

The air levels predicted for catalyst manufacture have been detailed in Section **9.3.1.6.6**. However, copper is not considered to pose a risk to the atmospheric compartment and has not been considered further.

10.2.2.4 Microbiological activity in sewage treatment systems

Both scenarios investigated for catalyst manufacture involve at least an on-site WWTP, which may or may not be biological in nature and for some sites connection to an off-site municipal STP has been assumed.

Table 160: Risk characterisation for sewage sludge microorganisms for catalyst manufacture [GES3]

Compartments	PEC	PNEC	PEC/PNEC	Discussion
	mg Cu/l			
E-GES-CM2.1/3.1 [no STP]				
Not applicable since no biological activity to protect.				
E-GES-CM2.2				
STP	0.0383	0.23	0.2	Maximum tonnage 500 tonnes copper per annum. Risk threshold limit is freshwater sediment compartment.
E-GES-CM3.2				
STP	0.0842	0.23	0.4	Maximum tonnage 1100 tonnes copper per annum. Risk threshold limit is agricultural soil due to the assumption that sludge from STP is spread on land.

10.3 DOWNSTREAM USE – Catalysts containing copper dinitrate [GES4]

The following risk characterisation ratios (RCR) are presented against the generic exposure scenarios (GES) defined within section **9.3.1.3**. In order to identify each GES the following descriptor codes have been developed. The Environmental Generic Exposure Scenarios [**E-GES**] and the Worker Generic Exposure Scenarios [**W-GES**] for catalyst use are denoted by '**CU**', with further notation to identify the specific release category or activities investigated within the individual GES title;

Scenario [GES4]			**Description**
E-GES-CU	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data
	Waste water treatment	0	No waste water emission
		1	Waste water treated at either on-site WWTP* <u>or</u> off-site STP
		2	Waste water treated on (WWTP*) and off-site (STP)
		(2)	Formulation - Not included into matrix
		(6a)	Use - Intermediate
		(6b)	Use - Reactive processing aid
		spERC	As given in text
W-GES-CU	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry

* - on-site WWTP can involve biological or physico-chemical treatment; therefore, the impact of copper exposure on sewage sludge microorganisms has to be carried out. Where unacceptable exposure levels of a biological treatment WWTP dictate the maximum copper tonnage (within catalyst product) a second estimate of maximum copper tonnage will be presented assuming a non-biological treatment process.

The 'in-use' phase of the catalyst lifecycle may or may not take place at the site of manufacture, and includes the actual use and post-use (recovery/recycling) processes as outlined within the ECMA catalysts sector mapping information (with specific amendments assigned by Copper Compound Consortium members). For each of the processes:

- Use,
- Recycling.

The environment and worker exposure scenarios are concerned with the underlying activities that determine the environmental emission routes or highlight any concerns for worker health. Therefore, each process step and expected activities are considered further, according to the mapping information supplied (see Annex 13), with respect to the potential for;

- emissions to air and waste water for the environment and
- dermal and inhalation exposure of workers.

10.3.1 Human health

Copper is an essential trace element for all biological organisms, including humans. The essentiality of copper arises from its incorporation into a large number of proteins and is demonstrated in a range of physiological functions where copper plays a critical role. With essential elements such as copper, homeostatic control mechanisms exist in order to maintain a constant internal environment within a range that is essential to good health. With respect to oral intake of copper, the major homeostatic control mechanisms involve regulation at both the site of intestinal absorption and biliary excretion via first-pass metabolism in the liver. Failure to maintain copper homeostasis may lead to adverse effects resulting from either deficiency or excess.

Therefore, the consequences of both high and low copper intakes are considered for risk characterisation.

10.3.1.1 Workers

Acceptable working conditions for the downstream use of catalyst products containing copper dinitrate have been established for the activities defined by the ECMA mapping (see Annex 13). However, the assessment presented can only be considered as illustrative and does not replace the requirement for a local on-site or task specific assessment, which remains the responsibility of the site owner or employer.

The information provided by the ECMA was confined to PROC codes and no indication of the physical form of the substance or preparation has been provided. Therefore, a GES for each of the substance forms (solid – high, medium and low dustiness; or liquid – aqueous solution or slurry) and associated PROC codes have been considered within the following Table 161.

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solids) or from evaporation (liquids) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high.

Table 161: (Semi) Quantitative risk characterisation for workers involved in the downstream use of catalyst products containing copper dinitrate [GES4]

SOLID – High dustiness	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[27]	RCR[28]
W-GES-CU(High) PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m3	0.01	1	0.01
	Combined routes				0.023
W-GES-CU(High) PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.1	1	0.1
	Combined routes				0.125
W-GES-CU(High) PROC 4 [Maintenance/cleaning] **+ LEV + RPE (APF 4)**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.625	1	0.625
	Combined routes				0.650
W-GES-CU(High) PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] **+ LEV + RPE (APF 4)**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.313	1	0.313
	Combined routes				0.338
W-GES-CU(High) PROC 22 [Pyrometallurgical recycling - smelting] **+ LEV**	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m3	0.7	1	0.7
	Combined routes				0.803

[27] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[28] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

SOLID – Medium dustiness	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[29]	RCR[30]
W-GES-CU(Med) PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m3	0.01	1	0.01
	Combined routes				0.023
W-GES-CU(Med) PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.5	1	0.5
	Combined routes				0.525
W-GES-CU(Med) PROC 4 [Maintenance/cleaning] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.5	1	0.5
	Combined routes				0.525
W-GES-CU(Med) PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] **+ LEV**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.25	1	0.25
	Combined routes				0.275
W-GES-CU(Med) PROC 22 [Pyrometallurgical recycling - smelting] **+ LEV**	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m3	0.7	1	0.7
	Combined routes				0.803

29 *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

30 *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

SOLID – Low dustiness	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[31]	RCR[32]
W-GES-CU(Low) PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m3	0.01	1	0.01
	Combined routes				0.023
W-GES-CU(Low) PROC 2 [Use - catalyst use in reactor, Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.01	1	0.01
	Combined routes				0.035
W-GES-CU(Low) PROC 4 [Maintenance/cleaning] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.5	1	0.5
	Combined routes				0.525
W-GES-CU(Low) PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] **No RMM required**	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m3	0.1	1	0. 1
	Combined routes				0.125
W-GES-CU(Low) PROC 22 [Pyrometallurgical recycling - smelting] **+ LEV**	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m3	0.7	1	0.7
	Combined routes				0.803

[31] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[32] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

SOLID – Liquid	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[33]	RCR[34]
W-GES-CU(Liquid) PROC 1 [Use - catalyst use in reactor, Pyrometallurgical recycling - calcination (oxidation at elevated temperatures)] **No RMM required**	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m3	0.001	1	0.001
	Combined routes				0.126
W-GES-CU(Liquid) PROC 2 [Use - catalyst use in reactor Maintenance/cleaning, Spent catalyst storage, Spent catalysts delivery and handling – semi-bulk delivery (IBC, drums etc,.) and storage, Pyrometallurgical recycling – screening, Pyrometallurgical recycling – calcination (oxidation at elevated temperatures), Pyrometallurgical recycling – maintenance and cleaning, Final products - storage] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.025
	Inhalation	mg Cu/m3	0.001	1	0.1
	Combined routes				0.252
W-GES-CU(Liquid) PROC 4 [Maintenance/cleaning] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.025
	Inhalation	mg Cu/m3	0.05	1	0.05
	Combined routes				0.301
W-GES-CU(Liquid) PROC 8b [Reactor loading - batch loading (including inspection), Reactor loading – continuous loading, Reactor loading –liquid systems, Reactor unloading – batch unloading, Reactor unloading – continuous unloading, [Reactor activities]Spent catalyst delivery and handling – emptying containers of spent catalysts, conveying spent catalyst, Pyrometallurgical recycling - filling] **No RMM required**	Dermal	mg Cu/d	240	13.67	0.025
	Inhalation	mg Cu/m3	0.01	1	0.01
	Combined routes				0.261

[33] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

[34] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

10.3.1.2 Consumers

Catalyst downstream use is expected to be part of an industrial process, therefore, consumer exposure has not been considered within this scenario.

10.3.1.3 Indirect exposure of humans via the environment

See Section 10.5.

10.3.2 Environment

Multiple exposure scenarios (ES) for the DU of catalysts need to take account of the potential scale of use, ranging from the large industrial sites with on-site waste treatment to smaller sites where emissions to water pass to a municipal STP. It is also possible for some catalyst use to take place without emissions to waste water. Therefore, in considering the process steps outlined above for catalyst use, three ES are required that allow for;

- No waste water emissions [E-GES-CU0]
- Waste water to pass through a single treatment process (on-site WWTP or off-site STP) [E-GES-CU1], and
- Waste water to pass through two waste water treatment steps (on-site WWTP with release via municipal STP) [E-GES-CU2].

The maximum predicted tonnage of copper considered, within the confines of the exposure scenarios outlined within Section **9.3.1.3.1** have been calculated using EUSES 2.0. The maximum tonnage has been shown to be limited by unacceptable effects against sewage sludge microorganisms where biological treatment processes are assumed. Whilst the majority of on-site WWTP will involve physico-chemical treatment processes, the use of biological treatment plants on-site cannot be dismissed due to a lack of information from catalyst downstream users. Therefore, the risk threshold for sewage sludge microorganisms exposed to copper as a result of catalyst use has been considered, since retaining the functionality of the waste treatment (92% minimum copper removal) process is essential to the exposure scenarios investigated. However, in order to illustrate the maximum tonnages of copper used within manufactured catalyst products where on-site treatment is carried out using physico-chemical treatment processes, a second calculation has been carried out.

The following ERCs have been assigned to catalyst production and use processes: 1[Production], 4 [Use], 6a [Use] and 6b [Use]. ERC1 is intended for activities associated with production and has not been repeated here. ERC 4 is not considered appropriate for copper compounds, as they are neither volatile nor highly soluble. Therefore, the tier 1 assessment for the catalysts in-use phase has used the default emissions for ERC 6a and 6b, assuming a reasonable worst-case of 220 release days per annum (allows for a generic 6 weeks of plant closure) with an on-site WWTP (minimum) or with further removal by discharge to an additional off-site STP.

In addition to the ERC codes, there is also an ‘Industrial use of metal compounds’ spERC available (developed by ARCHE consultants), which may be used to assess **copper dinitrate** exposure resulting from downstream use of catalysts. This spERC is considered appropriate for both open and closed systems using both wet and dry processes and is based on information gathered for metal compounds used in various industrial activities [Industrial use of metal compounds in following sectors: crystal manufacture, leather tanning, pigments, paints, coatings, plastics, rubber and textiles].

No assessment of secondary poisoning in the aquatic or terrestrial compartments is considered necessary due to the following;

- copper is an essential trace element,
- copper is well regulated in all living organisms and
- there is no evidence of copper biomagnification across the trophic chain in either the aquatic or terrestrial food chains.

10.3.2.1 Aquatic compartment (including sediment)

Table 162: Risk characterisation for the aquatic compartment for downstream use of catalyst products containing copper dinitrate [GES4]

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-CU0					
Freshwater	mg Cu/l	0.003	0.0078	0.4	Maximum tonnage 45000 tonnes copper per annum. Risk threshold limit is agricultural soil compartment.
Sediment (freshwater)	mg Cu/kg dw	8.79	87.1	0.1	
Marine water	mg Cu/l	0.001	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	17.2	676	0.03	
E-GES-CU1.1(6a) [on-site WWTP or off-site STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 10.375 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.6	87.1	0.9	
Marine water	mg Cu/l	0.0013	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.0	676	0.03	
E-GES-CU1.2(6a) [Biological WWTP and STP]					
Freshwater	mg Cu/l	0.003	0.0078	0.5	Maximum tonnage 60 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Sediment (freshwater)	mg Cu/kg dw	36.9	87.1	0.4	
Marine water	mg Cu/l	0.001	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	19.8	676	0.03	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 127.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.4	87.1	0.9	
Marine water	mg Cu/l	0.001	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.0	676	0.04	
E-GES-CU1.1(6b) [on-site WWTP or off-site STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 4.15 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.5	87.1	0.9	
Marine water	mg Cu/l	0.0013	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.0	676	0.03	
E-GES-CU1.2(6b) [Biological WWTP and STP]					
Freshwater	mg Cu/l	0.0036	0.0078	0.5	Maximum tonnage 23 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Sediment (freshwater)	mg Cu/kg dw	34.8	87.1	0.4	
Marine water	mg Cu/l	0.001	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	19.6	676	0.03	
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 52 tonnes copper per annum. Risk threshold limit is
Sediment (freshwater)	mg Cu/kg dw	78.7	87.1	0.9	

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
Marine water	mg Cu/l	0.001	0.0056	0.2	freshwater sediment.
Sediment (marine)	mg Cu/kg dw	24.0	676	0.04	
E-GES-CU2.1(spERC) [on-site WWTP or off-site STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 34.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.3	87.1	0.90	
Marine water	mg Cu/l	0.0013	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	13.9	676	0.04	
E-GES-CU2.2(spERC) [Biological WWTP and STP]					
Freshwater	mg Cu/l	0.0036	0.0078	0.5	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Sediment (freshwater)	mg Cu/kg dw	34.5	87.1	0.4	
Marine water	mg Cu/l	0.001	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	19.6	676	0.03	
E-GES-2.2(spERC) [Physico-chemical WWTP and STP]					
Freshwater	mg Cu/l	0.0045	0.0078	0.6	Maximum tonnage 432 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.6	87.1	0.9	
Marine water	mg Cu/l	0.0013	0.0056	0.2	
Sediment (marine)	mg Cu/kg dw	24.0	676	0.04	

*- Local concentrations include background levels.

10.3.2.2 Terrestrial compartment

Table 163: Risk characterisation for the terrestrial compartment for downstream use of catalyst products containing copper dinitrate [GES4]

Compartments	PEC*	PNEC	PEC/PNEC	Discussion
	mg Cu/kg dw			
E-GES-CU0				
Agricultural soil	44.8	64.6	0.7	Maximum tonnage 45000 tonnes copper per annum. Risk threshold limit is agricultural soil compartment.
Grassland	59.8		0.9	
E-GES-CU1.1(6a) [on-site WWTP]				
Agricultural soil	24.64	64.6	0.4	Maximum tonnage 10.375 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	24.81		0.38	
E-GES-CU1.1(6a) [off-site STP]				
Agricultural soil	42.90	64.6	0.7	Maximum tonnage 10.375 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	32.11		0.5	
E-GES-CU1.2(6a) [Biological WWTP and STP]				
Agricultural soil	34.22	64.6	0.5	Maximum tonnage 60 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Grassland	30.14		0.5	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]				
Agricultural soil	45.3	64.6	0.7	Maximum tonnage 127.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	36.6		0.6	
E-GES-CU1.1(6b) [on-site WWTP]				
Agricultural soil	24.4	64.6	0.4	Maximum tonnage 4.15 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	24.4		0.4	
E-GES-CU1.1(6b) [off-site STP]				
Agricultural soil	42.7	64.6	0.7	Maximum tonnage 4.15 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	31.7		0.5	
E-GES-CU1.2(6b) [Biological WWTP and STP]				
Agricultural soil	32.52	64.6	0.5	Maximum tonnage 23 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Grassland	27.66		0.4	

Compartments	PEC*	PNEC	PEC/PNEC	Discussion
	mg Cu/kg dw			
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]				
Agricultural soil	42.8	64.6	0.7	Maximum tonnage 52 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	31.76		0.5	
E-GES-CU2.1(spERC) [on-site WWTP]				
Agricultural soil	24.4	64.6	0.4	Maximum tonnage 34.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	24.4		0.4	
E-GES-CU2.1(spERC) [off-site STP]				
Agricultural soil	42.7	64.6	0.7	Maximum tonnage 34.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	31.71		0.5	
E-GES-CU2.2(spERC) [Biological WWTP and STP]				
Agricultural soil	32.52	64.6	0.5	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
Grassland	27.76		0.4	
E-GES-CU2.2(spERC) [Physico-chemical WWTP and STP]				
Agricultural soil	42.9	64.6	0.7	Maximum tonnage 432 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Grassland	32.04		0.5	

*- Local concentrations include background levels.

10.3.2.3 Atmospheric compartment

The air levels predicted for catalyst manufacture and use have been detailed in sections **9.3.1.6.6**. However, copper is not considered to pose a risk to the atmospheric compartment and has not been considered further.

10.3.2.4 Microbiological activity in sewage treatment systems

Both scenarios investigated for catalyst manufacture involve at least an on-site WWTP, which may or may not be biological in nature and for some sites connection to an off-site municipal STP has been assumed. Only biological waste water treatment has to be considered in terms of risk to copper from catalysts containing copper dinitrate (see Table 164).

Table 164: Risk characterisation for sewage sludge microorganisms for downstream use of catalyst products containing copper dinitrate [GES4]

Compartments	PEC	PNEC	PEC/PNEC	Discussion
	mg Cu/l			
E-GES-CU0				
Not applicable				
E-GES-CU1.1(6a) [Biological WWTP or STP]				
WWTP	0.0377	0.23	0.2	Maximum tonnage 10.375 tonnes copper per annum. Risk threshold limit is freshwater sediment.
STP				
E-GES-CU1.2(6a) [Biological WWTP and STP]				
WWTP	0.218	0.23	0.9	Maximum tonnage 60 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
STP	0.0175		0.08	
E-GES-CU1.2(6a) [Physico-chemical WWTP and STP]				
WWTP	N/A	0.23	N/A	Maximum tonnage 127.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
STP	0.0371		0.2	

Compartments	PEC	PNEC	PEC/PNEC	Discussion
	mg Cu/l			
E-GES-CU1.1(6b) [Biological WWTP or STP]				
WWTP STP	0.0377	0.23	0.2	Maximum tonnage 4.15 tonnes copper per annum. Risk threshold limit is freshwater sediment.
E-GES-CU1.2(6b) [Biological WWTP and STP]				
WWTP	0.209	0.23	0.9	Maximum tonnage 23 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
STP	0.0167		0.07	
E-GES-CU1.2(6b) [Physico-chemical WWTP and STP]				
WWTP	N/A	0.23	N/A	Maximum tonnage 52 tonnes copper per annum. Risk threshold limit is freshwater sediment.
STP	0.0378		0.2	
E-GES-CU2.1(spERC) [Biological WWTP or STP]				
WWTP STP	0.0376	0.23	0.2	Maximum tonnage 34.5 tonnes copper per annum. Risk threshold limit is freshwater sediment.
E-GES-CU2.2(spERC) [Biological WWTP and STP]				
WWTP	0.207	0.23	0.9	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is WWTP microorganism.
STP	0.0166		0.07	
E-GES-CU2.2(spERC) [Physico-chemical WWTP and STP]				
WWTP	N/A	0.23	N/A	Maximum tonnage 432 tonnes copper per annum. Risk threshold limit is freshwater sediment.
STP	0.0377		0.2	

10.4 DOWNSTREAM USE – [GENERIC] All downstream users of copper dinitrate [GES5-10]

The following risk characterisation ratios (RCR) are presented against the generic exposure scenarios (GES) defined within Section **9.3.2.3**. In order to identify each GES the following descriptor codes have been developed. The environmental GES [**E-GES**] and the industrial worker [**W-GES**]**,** Professional GES [**PW-GES**] or consumer [**C-GES**] for downstream use are denoted by '**DU**', with further notation to identify the specific release category or activities investigated within the individual GES title;

Scenario [GES5-10]			**Description**
E-GES-DU*	Tier	1	Tier 1 – defaults from ERC codes
		2	Tier 2 – spERC/measured data
	Waste water treatment	0	No waste water emission**
		1	Waste water treated at off-site STP
		(PROC)	Codes as given in accordance with REACH guidance
W/PW-GES-DU***	Substance form	(High)	Solid, high dustiness
		(Med)	Solid, medium dustiness
		(Low)	Solid, low dustiness
		(Liquid)	Liquid, aqueous solution or slurry

* - **WDU** or 'wide dispersive use' also defined in Section **9.3.2.3.1** for environment only.
** - uses worst-case emission to air for estimate of PEC in soil from copper deposition.
*** - **C-GES-DU** – consumer use also defined in Section **9.3.2.3.1** for human exposures only.

The ‘in-use’ phase of copper dinitrate has been considered in accordance with all ERCs, available spERC F [Metal compound formulation – ARCHE consultants] and spERC U [Metal compound use – ARCHE consultants] and PROC codes with respect to the potential for:

- emissions to air and waste water for the environment and
- dermal and inhalation exposure of workers.

10.4.1 Human health

Copper is an essential trace element for all biological organisms, including humans. The essentiality of copper arises from its incorporation into a large number of proteins and is demonstrated in a range of physiological functions where copper plays a critical role. With essential elements such as copper, homeostatic control mechanisms exist in order to maintain a constant internal environment within a range that is essential to good health. With respect to oral intake of copper, the major homeostatic control mechanisms involve regulation at both the site of intestinal absorption and biliary excretion via first-pass metabolism in the liver. Failure to maintain copper homeostasis may lead to adverse effects resulting from either deficiency or excess.

Therefore, the consequences of both high and low copper intakes are considered for risk characterisation.

10.4.1.1 Workers: Industrial and Professional

Acceptable working conditions for the downstream use of copper compounds in all sectors have been derived for all available PROC codes However, the assessment presented can only be considered as illustrative and does not replace the requirement for a local on-site or task specific assessment, which remains the responsibility of the site owner or employer.

All of the activities have been assessed in terms of inhalation [due to the release of particulates/dusts (solids) or from evaporation (liquids) during transfer or spills] and dermal exposures [direct contact during handling or spills]. Exposure via ingestion is not considered relevant to normal working practices. The exposure estimations have been carried out according to MEASE using the following worst-case default parameters;

- Content in preparation: > 25%,
- Duration of exposure (minutes): > 240 min,
- Pattern of use: Wide dispersive use,
- Pattern of exposure control: Direct handling,
- Contact level: Extensive contact level,
- RMM efficiency based on: ECETOC (2009),
- No gloves.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

No distinction has been made between indoor or outdoor activities as this is not possible within MEASE. However, where the requirement for LEV is triggered it will be assumed that this includes outdoor working practices as the risk of inhalation must be considered high (see Table 165 and Table 166).

Table 165: (Semi) Quantitative risk characterisation for industrial workers involved in the downstream formulation and use of copper dinitrate [GES5/GES6]

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
W-GES-DU(High) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-DU(High) PROC 2 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-DU(High) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-DU(High) PROC 4 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.650
W-GES-DU(High) PROC 5 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.650
W-GES-DU(High) PROC 8a + LEV + RPE (APF 10)	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
W-GES-DU(High) PROC 8b + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.313	1	0.313
	Combined routes				0.338
W-GES-DU(High) PROC 9 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(High) PROC 14 + LEV + RPE (APF 4)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275

35 *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in 5.11.*

36 *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
W-GES-DU(High) PROC 19 + LEV + RPE (APF 40)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.728
W-GES-DU(High) PROC 22 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.7	1	0.7
	Combined routes				0.803
W-GES-DU(High) PROC 23 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.2
	Combined routes				0.303
W-GES-DU(High) PROC 24 + LEV + RPE (APF 4) [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.275	1	0.275
	Combined routes				0.378
W-GES-DU(High) PROC 25 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.2
	Combined routes				0.303
W-GES-DU(High) PROC 26 + LEV + RPE (APF 4)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.45	1	0.45
	Combined routes				0.553
W-GES-DU(Med) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-DU(Med) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Med) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-DU(Med) PROC 4 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Med) PROC 5 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Med) PROC 8a + LEV	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
W-GES-DU(Med) PROC 8b + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.275
W-GES-DU(Med) PROC 9 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Med) PROC 14 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-DU(Med) PROC 19 + LEV + RPE (APF 10)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.603
W-GES-DU(Med) PROC 22 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.7	1	0.7
	Combined routes				0.803
W-GES-DU(Med) PROC 23 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.2
	Combined routes				0.303
W-GES-DU(Med) PROC 24 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.6	1	0.6
	Combined routes				0.703
W-GES-DU(Med) PROC 25 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.2
	Combined routes				0.303
W-GES-DU(Med) PROC 26 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.72	1	0.72
	Combined routes				0.823
W-GES-DU(Low) PROC 1 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.023
W-GES-DU(Low) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.035
W-GES-DU(Low) PROC 3 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.113
W-GES-DU(Low) PROC 4	Dermal	mg Cu/d	240	136.67	0.025

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
No RMM required	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Low) PROC 5 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.525
W-GES-DU(Low) PROC 8a No RMM required	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0. 5
	Combined routes				0.55
W-GES-DU(Low) PROC 8b No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0. 1
	Combined routes				0.125
W-GES-DU(Low) PROC 9 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-DU(Low) PROC 14 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.125
W-GES-DU(Low) PROC 19 No RMM required	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.603
W-GES-DU(Low) PROC 21 No RMM required	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.603
W-GES-DU(Low) PROC 22 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.7	1	0.7
	Combined routes				0.803
W-GES-DU(Low) PROC 23 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.2
	Combined routes				0.303
W-GES-DU(Low) PROC 24 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.4	1	0.4
	Combined routes				0.503
W-GES-DU(Low) PROC 25 + LEV [GES6 only]	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.2	1	0.4
	Combined routes				0.303
W-GES-DU(Low) PROC 26 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.27	1	0.27

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
	Combined routes				0.373
W-GES-DU(Liquid) PROC 1 No RMM required	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.126
W-GES-DU(Liquid) PROC 2 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.1
	Combined routes				0.252
W-GES-DU(Liquid) PROC 3 No RMM required	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.135
W-GES-DU(Liquid) PROC 4 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-DU(Liquid) PROC 5 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-DU(Liquid) PROC 7 + LEV + RPE (APF 4) [GES6 only]	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.501
W-GES-DU(Liquid) PROC 8a No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-DU(Liquid) PROC 8b No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-DU(Liquid) PROC 9 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-DU(Liquid) PROC 10 No RMM required [GES6 only]	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-DU(Liquid) PROC 13 No RMM required [GES6 only]	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.261
W-GES-DU(Liquid) PROC 14 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined				0.261

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL[35]	RCR[36]
	routes				
W-GES-DU(Liquid) PROC 17 No RMM required [GES6 only]	Dermal	mg Cu/d	120	13.67	0.250
	Inhalation	mg Cu/m^3	0.01	1	0.1
	Combined routes				0.350
W-GES-DU(Liquid) PROC 19 No RMM required	Dermal	mg Cu/d	240	136.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.301
W-GES-DU(Liquid) PROC 20 No RMM required [GES6 only]	Dermal	mg Cu/d	240	136.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.252

Table 166: (Semi) Quantitative risk characterisation for professional workers involved in the downstream use of copper dinitrate [GES7]

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL	RCR
PW-GES-DU(High) PROC 2 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(High) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.51
PW-GES-DU(High) PROC 4 + LEV + RPE (APF 10)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(High) PROC 5 + LEV + RPE (APF 10)	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(High) PROC 8a + LEV.+ RPE (APF 10) required	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
PW-GES-DU(High) PROC 8b + LEV + RPE (APF 4) required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.625	1	0.625
	Combined routes				0.65
PW-GES-DU(High) PROC 9 + LEV + RPE (APF 4) required.	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(High) PROC 14	Dermal	mg Cu/d	240	136.67	0.025

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL	RCR
+ LEV + RPE (APF 10) required.	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(High) PROC 15 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.51
PW-GES-DU(High) PROC 19 LEV - NOT AVAILABLE + RPE (APF 40) required. *Restricted to < 4 h/d.*	Dermal	mg Cu/d	594	136.67	0.062
	Inhalation	mg Cu/m^3	0.75	1	0.75
	Combined routes				0.81
PW-GES-DU(High) PROC 22 + LEV + RPE (APF 4) required.	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.35
PW-GES-DU(High) PROC 25 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.4	1	0.4
	Combined routes				0.50
PW-GES-DU(High) PROC 26 + LEV + RPE (APF 10) required.	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.45	1	0.45
	Combined routes				0.55
PW-GES-DU(Med) PROC 2 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.13
PW-GES-DU(Med) PROC 3 + LEV	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.11
PW-GES-DU(Med) PROC 4 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(Med) PROC 5 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(Med) PROC 8a + LEV	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
PW-GES-DU(Med) PROC 8b + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.28
PW-GES-DU(Med) PROC 9	Dermal	mg Cu/d	240	136.67	0.025

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL	RCR
+ LEV	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(Med) PROC 14 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(Med) PROC 15 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.51
PW-GES-DU(Med) PROC 19 + LEV + RPE (APF 10)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.60
PW-GES-DU(Med) PROC 22 + LEV + RPE (APF 4)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.35
PW-GES-DU(Med) PROC 25 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.4	1	0.4
	Combined routes				0.50
PW-GES-DU(Med) PROC 26 + LEV + RPE (APF 4)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.45	1	0.45
	Combined routes				0.55
PW-GES-DU(Low) PROC 2 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.04
PW-GES-DU(Low) PROC 3 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.11
PW-GES-DU(Low) PROC 4 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.13
PW-GES-DU(Low) PROC 5 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.13
PW-GES-DU(Low) PROC 8a No RMM required	Dermal	mg Cu/d	480	136.67	0.05
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.55
PW-GES-DU(Low) PROC 8b No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL	RCR
	Combined routes				0.53
PW-GES-DU(Low) PROC 9 No RMM required	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.53
PW-GES-DU(Low) PROC 14 + LEV	Dermal	mg Cu/d	240	136.67	0.025
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.13
PW-GES-DU(Low) PROC 15 No RMM required	Dermal	mg Cu/d	120	136.67	0.013
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.11
PW-GES-DU(Low) PROC 19 LEV NOT AVAILABLE	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.5	1	0.5
	Combined routes				0.60
PW-GES-DU(Low) PROC 21 No RMM required	Dermal	mg Cu/d	99	136.67	0.01
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.06
PW-GES-DU(Low) PROC 22 + LEV + RPE (APF 4)	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.25	1	0.25
	Combined routes				0.35
PW-GES-DU(Low) PROC 25 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.4	1	0.4
	Combined routes				0.50
PW-GES-DU(Low) PROC 26 + LEV	Dermal	mg Cu/d	990	136.67	0.103
	Inhalation	mg Cu/m^3	0.675	1	0.675
	Combined routes				0.78
PW-GES-DU(Liquid) PROC 2 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.25
PW-GES-DU(Liquid) PROC 3 No RMM required	Dermal	mg Cu/d	120	13.67	0.125
	Inhalation	mg Cu/m^3	0.01	1	0.01
	Combined routes				0.14
PW-GES-DU(Liquid) PROC 4 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.35
PW-GES-DU(Liquid) PROC 5 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.1	1	0.1

ES [+ RMMs]	Route	UNITS	Exposure concentrations (EC)	DN(M)EL	RCR
	Combined routes				0.35
PW-GES-DU(Liquid) PROC 8a No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 8b No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 9 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 10 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 11 + LEV + RPE (APF 10) required.	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.45	1	0.45
	Combined routes				0.70
PW-GES-DU(Liquid) PROC 13 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 14 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.1	1	0.1
	Combined routes				0.35
PW-GES-DU(Liquid) PROC 15 No RMM required	Dermal	mg Cu/d	120	13.67	0.01
	Inhalation	mg Cu/m^3	0.01	1	0.125
	Combined routes				0.14
PW-GES-DU(Liquid) PROC 17 + LEV	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 19 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.05	1	0.05
	Combined routes				0.30
PW-GES-DU(Liquid) PROC 20 No RMM required	Dermal	mg Cu/d	240	13.67	0.251
	Inhalation	mg Cu/m^3	0.001	1	0.001
	Combined routes				0.25

10.4.1.2 Consumers [GES8]

A number of consumer products contain small amounts of copper dinitrate, but the available data indicate that the quantitative role of consumer products in copper exposure is minimal. Copper in dietary supplements is the only source that may make an appreciable contribution to copper intake and this source is considered only in the RWC estimate. Therefore, despite the uncertainties in the consumer exposure assessment, even substantial errors are likely to have little effect on the outcome. However, this scenario cannot be considered as a stand-alone scenario because consumers will always be exposed simultaneously to some copper via food and drinking water.

No risks are predicted for consumer exposure.

10.4.1.3 Indirect exposure of humans via the environment

See Section 10.5.

10.4.2 Environment

10.4.2.1 Industrial downstream uses [GES5/GES6]

Multiple exposure scenarios (ES) for the DU of copper dinitrate need to take account of the potential scale of use, ranging from the large industrial sites with on-site waste treatment to smaller sites where emissions to water pass to a municipal STP. It is also possible for some uses to take place without emissions to waste water. Therefore, in considering the process steps outlined in Section **9.3.2.3** for industrial scale downstream use, two ES are required that allow for:

- No waste water emissions [E-GES-DU0]
- Waste water to pass through a single treatment process (on-site WWTP or off-site STP) [E-GES-DU1.1/2.1],

The maximum predicted tonnage of copper considered acceptable, within the confines of the ERC or spERC codes outlined in section 9.3.2, have been calculated using EUSES 2.0.

No assessment of secondary poisoning in the aquatic or terrestrial compartments is considered necessary due to the following:

- copper is an essential trace element,
- copper is well regulated in all living organisms and
- there is no evidence of copper biomagnification across the trophic chain in either the aquatic or terrestrial food chains.

10.4.2.2 Aquatic compartment (including sediment)

Table 167: Risk characterisation for the aquatic compartment for downstream use of copper dinitrate [GES5/GES6]

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-DU0 [GES5/GES6]					
Freshwater	Aquatic compartment not applicable				Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)					
Marine water					
Sediment (marine)					
E-GES-DU1.1(ERC 2 & 6a) [GES5/GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.43	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.71	87.1	0.15	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.81	676	0.04	
E-GES-DU1.1(ERC 3) [GES5]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.43	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.71	87.1	0.15	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.81	676	0.04	
E-GES-DU1.1(ERC 4) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.42	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	11.22	87.1	0.13	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.26	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	27.32	676	0.04	

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-DU1.1(ERC 5) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.42	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.15	87.1	0.14	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.25	676	0.04	
E-GES-DU1.1(ERC 6b & 7) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.42	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.15	87.1	0.14	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.25	676	0.04	
E-GES-DU1.1(ERC 6d) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0055	0.0078	0.70	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	76.64	87.1	0.88	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0032	0.0078	0.41	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	9.35	87.1	0.11	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0014	0.0056	0.25	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	25.45	676	0.04	
E-GES-DU1.1(ERC 12a) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0054	0.0078	0.69	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	74.77	87.1	0.86	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.42	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.15	87.1	14	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.25	676	0.04	

Compartments	UNITS	PEC*	PNEC	PEC/PNEC	Discussion
E-GES-DU2.1(spERC Formulation)					
[ES1 – freshwater dilution 10] [GES5]					
Freshwater	mg Cu/l	0.0055	0.0078	0.70	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	76.64	87.1	0.88	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.43	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.52	87.1	0.14	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0027	0.0056	0.27	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.62	676	0.04	
E-GES-DU2.1(spERC Use) [GES6]					
[ES1 – freshwater dilution 10]					
Freshwater	mg Cu/l	0.0055	0.0078	0.71	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
Sediment (freshwater)	mg Cu/kg dw	78.51	87.1	0.90	
[ES2 – freshwater dilution 100]					
Freshwater	mg Cu/l	0.0033	0.0078	0.42	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (freshwater)	mg Cu/kg dw	12.34	87.1	0.14	
[ES3 – marine dilution 100]					
Marine water	mg Cu/l	0.0015	0.0056	0.27	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).
Sediment (marine)	mg Cu/kg dw	28.44	676	0.04	

*- Local concentrations include background levels.

10.4.2.3 Terrestrial compartment

Table 168: Risk characterisation for the terrestrial compartment for downstream use of copper dinitrate [GES5/GES6]

Compartments	PEC*	PNEC	PEC/PNEC	Discussion
	mg Cu/kg dw			
E-GES-DU0 [GES5/GES6]				
ES1	5.71	64.6	0.90	Maximum tonnage of 25000 tonnes of copper per annum. Risk threshold limit is the terrestrial compartment (soil).
E-GES-DU1.1(ERC 2 & 6a) [GES5/GES6]				
ES1	44.07	64.6	0.68	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	57.85		0.90	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 3) [GES5]				
ES1	44.07	64.6	0.68	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	57.85		0.90	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 4) [GES6]				
ES1	44.06	64.6	0.68	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	56.35		0.83	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 5) [GES6]				
ES1	44.06	64.6	0.68	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	56.35		0.87	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6b & 7) [GES6]				
ES1	44.06	64.6	0.68	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	56.35		0.87	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6d) [GES6]				
ES1	50.05	64.6	0.77	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	55.68		0.86	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 12a) [GES6]				
ES1	44.06	64.6	0.68	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	56.35		0.87	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU2.1(spERC Formulation) [GES5]				
ES1	44.55	64.6	0.69	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	57.33		0.89	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU2.1(spERC Use) [GES6]				
ES1	45.06	64.6	0.70	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	56.86		0.88	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

*- Mean local concentrations in soil include background levels.

10.4.2.4 Atmospheric compartment

The air levels predicted for downstream use of copper dinitrate have been detailed in Section **9.3.2.6.6**. However, copper is not considered to pose a risk to the atmospheric compartment and has not been considered further.

10.4.2.5 Microbiological activity in sewage treatment systems

Where waste waters have been considered, treatment has been assumed to be via an off-site municipal STP.

Table 169: Risk characterisation for sewage sludge microorganisms for downstream use of copper dinitrate [GES5/GES6]

Compartments	PEC	PNEC	PEC/PNEC	Discussion
	mg Cu/l			
E-GES-DU0 [GES5/GES6]				
Not applicable – no waste water releases.				
E-GES-DU1.1(ERC 2 & 6a) [GES5/GES6]				
ES1	0.04	0.23	0.16	Maximum tonnage 10 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.27	Maximum tonnage 17 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 3) [GES5]				
ES1	0.04	0.23	0.16	Maximum tonnage 100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.27	Maximum tonnage 170 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 4) [GES6]				
ES1	0.04	0.23	0.16	Maximum tonnage 0.2 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.05		0.24	Maximum tonnage 0.3 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 5) [GES6]				
ES1	0.04	0.23	0.16	Maximum tonnage 0.4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.26	Maximum tonnage 0.65 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6b & 7) [GES6]				
ES1	0.04	0.23	0.16	Maximum tonnage 4 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.26	Maximum tonnage 6.5 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 6d) [GES6]				
ES1	0.04	0.23	0.16	Maximum tonnage 4100 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.05		0.20	Maximum tonnage 5000 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU1.1(ERC 12a) [GES6]				
ES1	0.04	0.23	0.17	Maximum tonnage 8 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.27	Maximum tonnage 13 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).

Compartments	PEC	PNEC	PEC/PNEC	Discussion
	mg Cu/l			
E-GES-DU2.1(spERC Formulation) [GES5]				
ES1	0.04	0.23	0.16	Maximum tonnage 41 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06		0.26	Maximum tonnage 67 tonnes copper per annum. Risk threshold limit the terrestrial compartment (soil).
E-GES-DU2.1(spERC Use) [GES6]				
ES1	0.04	0.23	0.17	Maximum tonnage 35 tonnes copper per annum. Risk threshold limit is freshwater sediment.
ES2 & 3	0.06 [0.21]		0.90	Maximum tonnage 190 tonnes copper per annum. Risk threshold limit is the terrestrial compartment (soil).

10.4.2.6 Wide dispersive uses: Professional and consumer downstream use [GES9]

The General Case

The scenario for both indoor and outdoor wide dispersive uses (with the exception of fertiliser end-use) is based on the assumption that emissions occur in the context of the urban infrastructure, are collected in a central public sewage system and are then treated by an STP. For outdoor uses, this scenario can be considered as a reasonable worst case.

To assume that all releases occur on a paved surface of an urban infrastructure and are collected in a sewage system may be considered overly-conservative, but this is balanced by the assumption that all releases to water are treated in an STP.

With the exception of the end-use of fertilisers, direct releases to air and soil are considered not to be applicable to the wide dispersive use scenario.

The exposure scenarios have considered all possible wide dispersive uses as outlined by (see Section 9.3.2):

- ERC8a-c: Wide dispersive indoor use of substance.
- ERC8d-f: Wide dispersive outdoor use of substance.
- ERC9a: Wide dispersive indoor use of substance in closed systems.
- ERC9b: Wide dispersive outdoor use of substance in closed systems.

Unlike for local site specific point source assessments, an estimate of the maximum allowable tonnage from wide dispersive use could not be derived for individual dicopper chloride trihydroxide uses/products. However, there are measured region-specific PEC data available for STP effluents from three EU countries: Belgium, the Netherlands and UK that range between 0.011 and 0.054 mg total Cu/l. In addition, the highest PEC for the STP of 0.054 mg total Cu/l was reported in the UK, which was shown to be equivalent to 0.008 mg dissolved Cu/l.

These data suggest that emissions to receiving water courses with dilutions ≥10 ≤15 would be sufficient to remove any concern for the aquatic environment as a result of wide dispersive uses of products containing dicopper chloride trihydroxide.

This approach and these data have been presented and accepted within the VRA (2008) for the consideration of all copper inputs across the EU.

Fertiliser Use

The derivation of regional background concentrations for use in environmental exposure assessment is discussed in Section 9.5 for all environmental compartments. The derived concentrations are based on a large monitoring data-set evaluated in the context of the Copper Voluntary Risk Assessment (VRA, 2008). The resulting measured concentrations are presented in **Table 149**.

As established in the VRA, environmental background concentrations of copper measured at the regional level include a component associated with inputs from anthropogenic sources such as fertilisers. This accounts for the raised copper concentrations seen in agricultural soils, compared to those in forest soils (see **Table 149**). Nonetheless, the risk characterisation exercise conducted in the VRA confirms that all 90th percentile RCR values for copper in soil on the regional scale are smaller than 1 and that there is therefore no predicted risk. Similarly, measured regional concentrations for freshwater, marine water and their associated sediments also confirm that there is no risk to these compartments (VRA, 2008).

In view of the above, it is considered that any attempt to separately quantify local inputs from the use of copper compounds in fertilisers would result in "double-counting" that would over-estimate the risk, which is adequately assessed at the regional level. It is therefore concluded that the use of copper compounds in fertilisers gives no cause for concern at rates typically applied in the European Union.

10.5 Indirect exposure of humans via the environment

10.5.1 Acute effects

The most likely potential source of acute exposure is from the leaching of copper into 'corrosive' drinking water. No risks are predicted for acute exposure.

10.5.2 Repeat dose effects

Internal exposure values and toxic effects were compared. The major source of variability is the uncertainty concerning copper exposure from drinking water. No risks are predicted for local or regional indirect exposure.

10.6 Overall exposure (combined for all relevant emission/release sources)

10.6.1 Human health (combined for all exposure routes)

Two relevant combinations of contributing exposure scenarios are considered (see Table 170):

- General population: indirect and consumer exposure (Combination 1).
- Workers: occupational, local indirect and consumer exposure (Combination 2)

Table 170: Identification of relevant combination of exposure scenarios

Contributing Exposure scenarios	Combination 1	Combination 2
Occupational		X
Consumer	X	X
Man exposed indirect via the environment	X	X

Following the Cu VRA (2008), the RWC estimate for combination 1 is derived by combining the RWC local indirect exposure via the environment with the RWC consumer exposure excluding the use of supplements. The use of supplements has been excluded in order not to combine indirect exposure for areas with high levels of copper in drinking water with the use of copper supplements thereby avoiding unreasonably conservative exposure scenarios. Consumer exposure sources identified in the VRA for workers include the use of hair-care products, handling of coins and smoking.

The worst-case/maximum (>4 hours daily exposure estimates, minimum RMMs, maximum exposure) acceptable combined (inhalation + dermal) RCR estimates for all worker defined GES exposures are also presented in Table 171. These are seen to range between 0.023 and 0.85 and do not include the potential RWC consumer RCR estimate. This is because the addition of these two values is not considered appropriate due to the generic worker exposure assessments with copper dinitrate representing absolute worst-case and not RWC exposures, as have been defined for the consumer exposure estimates. Therefore, the RCR values presented for the worker GES are likely to present significant over-prediction of worker exposure when compared to actual working conditions where gloves, LEV and other precautions may be in place as a matter of routine.

PLEASE NOTE: As this substance is classified on the basis of its potential to cause skin corrosivity and serious eye damage, it is ESSENTIAL that gloves and eye protection (goggles/face shield) should be worn when handling.

Table 171: Risk characterisation for combined relevant emission

ES title [including RMMs]	SOLID: High Dust			SOLID: Medium Dust			SOLID: Low Dust			LIQUID		
	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE
Relevant combination of exposure scenario: Combination 1 ES: GES8												
C-GES-DU(PROC 0)	0.89	NO	NO	0.89	NO	NO	0.89	NO	NO	0.89	NO	NO
Relevant combination of exposure scenario: Combination 2 [Industrial workers] ES: GES1-7												
W-GES-CM/CU/DU(F/U)(PROC 1)	0.023	NO	NO	0.023	NO	NO	0.023	NO	NO	0.126	NO	NO
W-GES-CM/CU/DU(F/U)(PROC 2)	0.125	YES	NO	0.525	NO	NO	0.035	NO	NO	0.252	NO	NO
W-GES-CM(PROC 0)				0.113	YES	NO	0.113	NO	NO	0.135	NO	NO
W-GES-P/CU/DU(F/U)(PROC 3)	0.113	YES	NO									
W-GES-CM(F/U)(PROC 4)				0.525	YES	NO	0.525	NO	NO	0.301	NO	NO
W-GES-CU/DU(F/U)(PROC 4)	0.650	YES	YES (AFP 4)									
W-GES- CM/DU(F/U)(PROC 5)	0.650	YES	YES (AFP 4)	0.525	YES	NO	0.525	NO	NO	0.301	NO	NO
W-GES-DU(U)(PROC 7)										0.50	NO	NO
W-GES- CM/DU(F/U)(PROC 8a)	0.55	YES	YES (AFP 10)	0.55	YES	NO	0.55	NO	NO	0.301	NO	NO
W-GES-CM/CU/DU(F/U)(PROC 8b)	0.338	YES	YES (AFP 4)	0.275	YES	NO	0.125	NO	NO	0.261	NO	NO
W-GES-CM/CU(PROC 9)				0.525	YES	NO	0.125	NO	NO	0.261	NO	NO
W-GES-DU(F/U) (PROC 9)	0.525	YES	YES (AFP 4)									
W-GES-DU(U)(PROC 10)										0.301	NO	NO
W-GES-DU(U)(PROC 13)										0.261	NO	NO
W-GES-CM/DU(F/U)(PROC 14)	0.275	YES	YES (AFP 4)	0.125	YES	NO	0.125	NO	NO	0.261	NO	NO
W-GES-DU(U)(PROC 15)	0.513	YES	NO	0.513	NO	NO	0.113	NO	NO	0.126	NO	NO
W-GES-DU(U)(PROC 17)										0.350	NO	NO
W-GES-DU(F/U)(PROC 19)	0.728	YES	YES (AFP 40)	0.603	YES	YES (AFP 10)	0.603	NO	NO	0.301	NO	NO
W-GES-DU(U)(PROC 20)										0.252	NO	NO
W-GES-DU(F/U)(PROC 21)							0.603	NO	NO			
W-GES-CU/DU(U)(PROC 22)	0.803	YES	NO	0.803	YES	NO	0.803	YES	NO			
W-GES-DU(U)(PROC 23)	0.303	YES	NO	0.303	YES	NO	0.303	YES	NO			

ES title [including RMMs]	SOLID: High Dust			SOLID: Medium Dust			SOLID: Low Dust			LIQUID		
	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE
W-GES-DU(U)(PROC 24)	0.378	YES	YES (AFP 4)	0.703	YES	NO	0.503	YES	NO			
W-GES-DU(U)(PROC 25)	0.303	YES	NO	0.303	YES	NO	0.303	YES	NO			
W-GES-DU(F/U)(PROC 26)	0.553	YES	YES (AFP 4)	0.823	YES	NO	0.373	YES	NO			
Relevant combination of exposure scenario: Combination 2 [Professional workers] ES: GES7 [Downstream professional use]												
PW-GES-DU(PROC 2)	0.53	YES	NO	0.13	YES	NO	0.04	NO	NO	0.25	NO	NO
PW-GES-DU(PROC 3)	0.51	YES	NO	0.11	YES	NO	0.11	NO	NO	0.14	NO	NO
PW-GES-DU(PROC 4)	0.53	YES	YES (AFP 10)	0.53	YES	NO	0.13	YES	NO	0.35	NO	NO
PW-GES-DU(PROC 5)	0.53	YES	YES (AFP 10)	0.53	YES	NO	0.13	YES	NO	0.35	NO	NO
PW-GES-DU(PROC 8a)	0.55	YES	YES (AFP 10)	0.55	YES	NO	0.55	NO	NO	0.30	NO	NO
PW-GES-DU(PROC 8b)	0.65	YES	YES (AFP 4)	0.28	YES	NO	0.53	NO	NO	0.30	NO	NO
PW-GES-DU(PROC 9)	0.53	YES	YES (AFP 4)	0.53	YES	NO	0.53	NO	NO	0.30	NO	NO
PW-GES-DU(PROC 10)										0.30	NO	NO
PW-GES-DU(PROC 11)										0.70	YES	YES (AFP 10)
PW-GES-DU(PROC 13)										0.30	NO	NO
PW-GES-DU(PROC 14)	0.53	YES	YES (AFP 10)	0.53	YES	NO	0.13	YES	NO	0.35	NO	NO
PW-GES-DU(PROC 15)	0.51	YES	NO	0.51	NO	NO	0.11	NO	NO	0.14	NO	NO
PW-GES-DU(PROC 17)										0.30	YES	NO
PW-GES-DU(PROC 19) *LEV not available, Restricted to < 4 h/d.	0.85	N/A*	YES (AFP 40)	0.60	N/A*	YES (AFP 10)	0.78	N/A*	NO	0.30	NO	NO
PW-GES-DU(PROC 20)										0.25	NO	NO

ES title [including RMMs]	SOLID: High Dust			SOLID: Medium Dust			SOLID: Low Dust			LIQUID		
	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE	RCR	LEV	RPE
PW-GES-DU(PROC 21)							0.60	NO	NO			
PW-GES-DU(PROC 22)	0.35	YES	YES (AFP 4)	0.35	YES	YES (AFP 4)	0.06	YES	YES (AFP 4)			
PW-GES-DU(PROC 25)	0.50	YES	NO	0.50	YES	NO	0.35	YES	NO			
PW-GES-DU(PROC 26)	0.55	YES	YES (AFP 10)	0.55	YES	YES (AFP 4)	0.50	YES	NO			

10.6.2 Environment (combined for all emission sources)

The regional risk characterisation from the Cu VRA shows that there is no unacceptable risk on a regional level from the production and use of copper and copper compounds.

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ANNEXES

ANNEX 1: Freshwater PNEC: Overview of the NOEC values and physico-chemical parameters for freshwater fish

NOECs are expressed as measured µg Cu/L , FT= flow through, S= static, R= renewal; H= Hardness; d= days ; Cb= copper background concentration expressed as measured µg Cu/L

Footnotes see Annex 3

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Ictalurus punctatus	fry	60 d	growth	**13**	FT	3	T: 22°C; pH: 7.65; H: 186.3 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Ictalurus punctatus	fry	60 d	mortality	**13**	FT	3	T: 22°C; pH: 7.65; H: 186.3 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Noemacheilus barbatulus	adult (8.7 - 12.1 cm)	64 d	mortality	**120**	FT	2	T 11.9°C; pH: 8.26; H: 249 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Solbe & Cooper, 1976
Oncorhynchus kisutch	parr	61 d	growth	**22**	FT	/	T: 9.5 °C; pH: 7.15; H: 24.4 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus kisutch	fry	60 d	growth	**21**	FT	/	T: 16.7 °C; pH: 7.4; H: 31.8 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus kisutch	parr	61 d	growth	**28**	FT	/	T: 8.7 °C; pH: 7.0; H: 28.7 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus kisutch	parr	61 d	mortality	**24**	FT	/	T: 9.5 °C; pH: 7.15; H: 24.4 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Oncorhynchus kisutch	fry	60 d	mortality	**18**	FT	/	T: 16.7 °C; pH: 7.4; H: 31.8 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus mykiss	fry (0.12 g; 2.6 cm)	60 d	growth	**2.2**	FT	0.45*	T: 9.8 °C; pH: 7.5; H: 24.6 mg/l CaCO3; DOC: 0.2 mg/l (12)	Well + deionised water	Marr *et al.,* 1996
Oncorhynchus mykiss	parr	61 d	growth	**45**	FT	/	T: 9.5 °C; pH: 7.2; H: 24.4 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus mykiss	eggs	63 d	growth	**16**	FT	3	T: 12 °C; pH: 7.65; H: 120 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Seim *et al.,* 1984
Oncorhynchus mykiss	parr	61 d	mortality	**24**	FT	/	T: 9.5 °C; pH: 7.15; H: 24.4 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus mykiss	parr	61 d	mortality	**28**	FT	/	T: 8.7 °C; pH: 7.0; H: 28.7 mg/l CaCO3; DOC: 2.9 mg/l (11)	River (Chehalis River)	Mudge *et al.,* 1993
Oncorhynchus mykiss	embryo	45 d	Growth	**11.4**	FT	3	T: 10.8 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Oncorhynchus mykiss	embryo	45 d	mortality	**11.4**	FT	3	T: 10.8 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Catostomus commersoni	embryo	40 d	Growth	**12.9**	FT	3	T: 14.9 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Catostomus commersoni	embryo	40 d	mortality	**12.9**	FT	3	T: 14.9 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Esox lucius	embryo	35 d	Growth	**34.9**	FT	3	T: 15.6 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Esox lucius	embryo	35 d	mortality	**34.9**	FT	3	T: 15.6 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Perca fluviatilis	juvenile (3.8 - 4.3 g)	30 d	growth	**39**	FT	1	T: 17.5 °C; pH: 7.8; H: 194 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	Collvin, 1985
Perca fluviatilis	juvenile (3.8 g)	30 d	mortality	**188**	FT	3	T: 15.1 °C; pH: 7.8; H: 178 mg/l CaCO3; DOC: 1mg/l (7)	Tap	Collvin, 1984
Pimephales notatus	fry (15 - 16 mm) -second generation	30 d	growth	**44**	FT	4.3	T: 25 °C; pH: 8.1; H: 201 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + demineralised tap	Horning & Neiheisel, 1979
Pimephales notatus	fry (15 - 16 mm)	60 d	growth	**71.8**	FT	4.3	T: 25 °C; pH: 8.1; H: 201 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + demineralised tap	Horning & Neiheisel, 1979
Pimephales notatus	fry (15 - 16 mm)	60 d	mortality	**71.8**	FT	4.3	T: 25 °C; pH: 8.1; H: 201 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + demineralised tap	Horning & Neiheisel, 1979
Pimephales promelas	fry (10 - 15 mm)	330 d	growth	**33**	FT	3.5	T: 21°C; pH: 8.0; H: 198 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount, 1968

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Pimephales promelas	fry (10 - 20 mm)	327 d	growth	**10.6**	FT	4.4	T: 22°C; pH: 6.9; H: 31.4 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount & Stephan, 1969
Pimephales promelas	larvae (4 weeks old)	187 d	growth	**59.5**	FT	4.2	T: 23°C; pH: 7.85; H: 202 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + demineralised tap	Pickering *et al.,* 1977
Pimephales promelas	embryo-larval	32 d	growth	**4.8**	FT	1.25*	T: 25°C; pH: 7.05; H: 44 mg/l CaCO3; DOC: 1 mg/l (13)	Lake (Lake Superior)	Spehar & Fiandt, 1985
Pimephales promelas	fry (10 - 15 mm)	330 d	mortality	**33**	FT	3.5	T: 21°C; pH: 8.0; H: 198 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount, 1968
Pimephales promelas	fry (10 - 20 mm)	327 d	mortality	**10.6**	FT	4.4	T: 22°C; pH: 6.9; H: 31.4 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount & Stephan, 1969
Pimephales promelas	larvae	28 d	mortality	**61**	FT	0.6	T: 21°C; pH: 8.17; H: 202 mg/l CaCO3; DOC: 1.3 mg/l (9)	Ground water	Scudder *et al.,* 1988
Pimephales promelas	embryo-larval	32 d	mortality	**4.8**	FT	1.25*	T: 25°C; pH: 7.05; H: 44 mg/l CaCO3; DOC: 1 mg/l (13)	Lake (Lake Superior)	Spehar & Fiandt, 1985
Pimephales promelas	juvenile (32 - 38 mm; 5 months old)	270 d	reproduction	**66**	FT	7	T: 23°C; pH: 8.1; H: 274 mg/l CaCO3; DOC: 2 mg/l (3)	River	Brungs *et al.,* 1976
Pimephales promelas	fry (10 - 15 mm)	330 d	reproduction	**14.5**	FT	3.5	T: 21°C; pH: 8.0; H: 198 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount, 1968

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Pimephales promelas	fry (10 - 20 mm)	327 d	reproduction	**10.6**	FT	4.4	T: 22°C; pH: 6.9; H: 31.4 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Mount & Stephan, 1969
Pimephales promelas	larvae (4 weeks old)	187 d	reproduction	**25.5**	FT	4.2	T: 23°C; pH: 7.9; H: 202 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Pickering *et al.,* 1977
Pimephales promelas	larvae (4 weeks old)	97 d	reproduction	**23**	FT	4.2	T: 23°C; pH: 7.9; H: 202 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Pickering *et al.,* 1977
Pimephales promelas	larvae (4 weeks old)	7 d	reproduction	**22.5**	FT	4.2	T: 23°C; pH: 7.9; H: 202 mg/l CaCO3; DOC: 0.55 mg/l (14)	Spring + deionised tap	Pickering *et al.,* 1977
Salvelinus fontinalis	embryo	60 d	Growth	**22.3**	FT	/	T: 5.6 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Salvelinus fontinalis	embryo	60 d	mortality	**22.3**	FT	/	T: 5.6 °C; pH: 7.6; H: 45 mg/l CaCO3; DOC: 1.0 mg/l (13)	Lake (Lake Superior)	McKim *et al.,* 1978
Salvelinus fontinalis	Alevins/juveniles	189 d	Growth	**9.5**	FT	/	T: 10.6 °C; pH: 7.5; H: 45 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	McKim & Benoit, 1971
Salvelinus fontinalis	Alevins/juveniles	189 d	mortality	**9.5**	FT	/	T: 10.6 °C; pH: 7.5; H: 45 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	McKim & Benoit, 1971
Salvelinus fontinalis	yearling	244 d	growth	**17.4**	FT	/	T: 10.6 °C; pH: 7.5; H: 45 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	McKim & Benoit, 1971

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Salvelinus fontinalis	fry	30 d	Growth	**7**	FT	3	T: 10 °C; pH: 6.85; H: 37.5 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Salvelinus fontinalis	fry	30 d	growth	**21**	FT	3	T: 10 °C; pH:6.9; H: 187 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Salvelinus fontinalis	yearling	244 d	mortality	**17.4**	S	1.9	T: 10.6 °C; pH: 7.45; H: 45 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	McKim & Benoit, 1971
Salvelinus fontinalis	fry	60 d	mortality	**13**	FT	3	T: 10 °C; pH: 6.85; H: 37.5 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Salvelinus fontinalis	fry	30 d	mortality	**21**	FT	3	T: 10 °C; pH:6.9; H: 187 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Salvelinus fontinalis	yearling	244 d	reproduction	**17.4**	FT	1.9	T: 10.6 °C; pH: 7.45; H: 45 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	McKim & Benoit, 1971
Salvelinus fontinalis	fry	60 d	reproduction	**7**	FT	3	T: 10 °C; pH: 6.85; H: 37.5 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976
Salvelinus fontinalis	fry	30 d	reproduction	**49**	FT	3	T: 10 °C; pH:6.9; H: 187 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Sauter *et al.,* 1976

ANNEX 2: Freshwater PNEC: Overview of the NOEC values and physico-chemical parameters for freshwater invertebrates

NOECs are expressed as measured µg Cu/L , FT= flow through, S= static, R= renewal; H= Hardness; d= days ; Cb= copper background concentration expressed as measured µg Cu/L

Footnotes see Annex 3

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**10**	R	0.5*	T: 23°C; pH: 7.6; H: 85 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstitued	Cerda & Olive, 1993
Ceriodaphnia dubia	neonates (< 24 h)	7 d	mortality	**20**	R	0.5*	T: 23°C; pH: 7.6; H: 85 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstitued	Cerda & Olive, 1993
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**10**	S	1.5*	T: 25°C; pH: 9.0; H: 98 mg/l CaCO3; DOC: 2.9 mg/l (2)	River (New River)	Belanger & Cherry, 1990
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**20**	S	1.5*	T: 25°C; pH: 8.0; H: 114 mg/l CaCO3; DOC: 2 mg/l (3)	River (Amy Bayou)	Belanger & Cherry, 1990
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**20**	S	1.5*	T: 25°C; pH: 9.0; H: 114 mg/l CaCO3; DOC: 2 mg/l (3)	River (Amy Bayou)	Belanger & Cherry, 1990
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**20**	S	1.5*	T: 25°C; pH: 6.0; H: 182 mg/l CaCO3; DOC: 3 mg/l (4)	River (Clinch River)	Belanger & Cherry, 1990
Ceriodaphnia dubia	neonates (< 8 h)	7 d	mortality	**19**	S	/	T: 25°C; pH: 7.0; H: 22 mg/l CaCO3; DOC: 2 mg/l (3)	River	Jop *et al.,* 1995

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Ceriodaphnia dubia	neonates (< 8 h)	7 d	mortality	**4**	S	/	T: 25°C; pH: 6.95; H: 20 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstituted	Jop *et al.,* 1995
Ceriodaphnia dubia	neonates (< 24 h)	7 d	mortality	**122**	R	3.4	T: 25°C; pH: 8.25; H: 100 mg/l CaCO3; DOC: 5.7 mg/l (5)	River (Lester River)	Spehar & Fiandt, 1985
Ceriodaphnia dubia	neonates (2-8 h)	7 d	reproduction	**6.3**	S	1.5	T: 25°C; pH: 8.15; H: 94 mg/l CaCO3; DOC: 2.9 mg/l (2)	River (New River)	Belanger *et al.,* 1989
Ceriodaphnia dubia	neonates (2-8 h)	7 d	reproduction	**24.1**	S	4.7	T: 25°C; pH: 8.31; H: 179 mg/l CaCO3; DOC: 3 mg/l (4)	River (Clinch River)	Belanger *et al.,* 1989
Ceriodaphnia dubia	neonates (< 8 h)	7 d	reproduction	**4**	S	/	T: 25°C; pH: 6.3-7.6; H: 20 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstituted	Jop *et al.,* 1995
Ceriodaphnia dubia	neonates (< 8 h)	7 d	reproduction	**10**	S	/	T: 25°C; pH: 6.6-7.4; H: 22 mg/l CaCO3; DOC: 2 mg/l (3)	River	Jop *et al.,* 1995
Ceriodaphnia dubia	neonates (< 24 h)	7 d	reproduction	**31.6**	S	3.4	T: 25°C; pH: 8.25; H: 100 mg/l CaCO3; DOC: 5.7 mg/l (5)	River (Lester River)	Spehar & Fiandt, 1985
Daphnia magna	neonates	21 d	growth	**12.6**	R	2.6	T: 20°C; pH: 8.1; H: 225 mg/l CaCO3; DOC: 2 mg/l (3)	Lake (Lake Ijssel)	Van Leeuwen *et al.,* 1988
Daphnia magna	neonates	21 d	mortality	**36.8**	R	2.6	T: 20°C; pH: 8.1; H: 225 mg/l CaCO3; DOC: 2 mg/l (3)	Lake (Lake Ijssel)	Van Leeuwen *et al.,* 1988

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Daphnia magna	neonates	21 d	population growth	**36.8**	FT	2.6	T: 20°C; pH: 8.1; H: 225 mg/l CaCO3; DOC: 2 mg/l (3)	Lake (Lake Ijssel)	Van Leeuwen *et al.,* 1988
Daphnia magna	neonates	21 d	reproduction	**28**	R	0.5*	T: 20°C; pH: 6.31; H: 10 mg/l CaCO3; DOC: 2.72 mg/l	Lake	Heijerick *et al.,* 2002
Daphnia magna	neonates	21 d	reproduction	**21.5**	R	0.5*	T: 20°C; pH: 6.1; H: 12.4 mg/l CaCO3; DOC: 2.34 mg/l	Lake	Heijerick *et al.,* 2002
Daphnia magna	neonates	21 d	reproduction	**71.4**	R	0.5*	T: 20°C; pH: 8.3; H: 238 mg/l CaCO3; DOC: 8.24 mg/l	Lake	Heijerick *et al.,* 2002
Daphnia magna	neonates	21 d	reproduction	**68.8**	R	0.5*	T: 20°C; pH: 8.06; H: 191 mg/l CaCO3; DOC: 1.99 mg/l	River	Heijerick *et al.,* 2002
Daphnia magna	neonates	21 d	reproduction	**106**	R	0.5*	T: 20°C; pH: 7.55; H: 132 mg/l CaCO3; DOC: 6.13 mg/l	River	Heijerick *et al.,* 2002
Daphnia magna	neonates	21 d	reproduction	**181**	R	0.5*	T: 20°C; pH: 7.5; H: 134 mg/l CaCO3; DOC: 20.4 mg/l	Lake	Heijerick *et al.,* 2002
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**4**	R	0.5*	T: 20°C; pH: 8.6; H: 57.5 mg/l CaCO3; DOC: 0.1 mg/l (6)	Deionized reconstituted	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**20**	R	0.5*	T: 20°C; pH: 8.5; H: 57.5 mg/l CaCO3; DOC: 0.475 mg/l (6)	Deionized reconstituted + DOC	Winner, 1985

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**30**	R	0.5*	T: 20°C; pH: 8.7; H: 57.5 mg/l CaCO3; DOC: 0.85 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**5**	R	0.5*	T: 20°C; pH: 8.7; H:115 mg/l CaCO3; DOC: 0.1 mg/l [(6)]	Deionized reconstituted	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**20**	R	0.5*	T: 20°C; pH: 8.55; H: 115 mg/l CaCO3; DOC: 0.475 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**40**	R	0.5*	T: 20°C; pH: 8.55; H:115 mg/l CaCO3; DOC: 0.85 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**10**	R	0.5*	T: 20°C; pH: 8.55; H: 230 mg/l CaCO3; DOC: 0.175 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**15**	R	0.5*	T: 20°C; pH: 8.6; H: 230 mg/l CaCO3; DOC: 0.475 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Daphnia pulex	neonates (< 24 h)	42 d	mortality	**20**	R	0.5*	T: 20°C; pH: 8.6; H: 230 mg/l CaCO3; DOC: 0.85 mg/l [(6)]	Deionized reconstituted + DOC	Winner, 1985
Brachionus calyciflorus	neonates (< 2 h)	2 d	reproduction	**8.2**	S	0.3	T: 25°C; pH: 6.0; H: 100 mg/l CaCO3; DOC: 4.9 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006 (13)
Brachionus calyciflorus	neonates (< 2 h)	2 d	reproduction	**31.2**	S	0.3	T: 25°C; pH: 6.0; H: 100 mg/l CaCO3; DOC: 14.5 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006 (13)

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Brachionus calyciflorus	neonates (< 2 h)	2 d	reproduction	**47.8**	S	0.3	T: 25°C; pH: 7.8; H: 100 mg/l CaCO3; DOC: 4.84 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006 (13)
Brachionus calyciflorus	neonates (< 2 h)	2 d	reproduction	**103**	S	0.3	T: 25°C; pH: 7.8; H: 100 mg/l CaCO3; DOC: 14.7 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006 (13)
Gammarus pulex	mixed sizes (1.5-14 mm)	100 d	population response	**11**	FT	2.6	T: 11°C; pH: 8.0; H: 103 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	Maund *et al.,* 1992
Hyalella azteca	2 - 3 weeks old	10 d	mortality	**50**	S	/	T: 20°C; pH: 7.65; H: 36 mg/l CaCO3; DOC: 1 mg/l (8)	Spring	Deaver & Rodgers, 1996
Hyalella azteca	2 - 3 weeks old	10 d	mortality	**50**	S	/	T: 20°C; pH: 7.8; H: 50 mg/l CaCO3; DOC: 1 mg/l (8)	Spring	Deaver & Rodgers, 1996
Hyalella azteca	2 - 3 weeks old	10 d	mortality	**82**	S	/	T: 20°C; pH: 8.05; H: 64 mg/l CaCO3; DOC: 1 mg/l (8)	Spring	Deaver & Rodgers, 1996
Hyalella azteca	2 - 3 weeks old	10 d	mortality	**82**	S	/	T: 20°C; pH: 7.5; H: 22 mg/l CaCO3; DOC: 1 mg/L (8)	Spring	Deaver & Rodgers, 1996
Hyalella azteca	2 - 3 weeks old	10 d	mortality	**30**	S	/	T: 20°C; pH: 6.95; H: <10 mg/l CaCO3; DOC: 1 mg/l (8)	Spring	Deaver & Rodgers, 1996
Hyalella azteca	<7 days old	35 d	mortality	**32**	R	3	T: 22°C; pH: 7.6; H: 128 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	Othman & Pascoe, 2002

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Chironomus riparius	eggs (< 12 h)	10 d	growth	**16.9**	R	0.5*	T: 20°C; pH: 6.8; H: 151 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstituted	Taylor *et al.,* 1991
Clistoronia magnifica	larvae 1st generation	240 d	Life cycle	**8.3**	FT	/	T: 15°C; pH: 7.3; H: 26 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Nebeker *et al.,* 1984
Clistoronia magnifica	larvae-2nd generation	240 d	Life cycle	**13**	FT	/	T: 15°C; pH: 7.3; H: 26 mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Nebeker *et al.,* 1984
Paratanytarsus parthenogeneticus	larvae (7 days old)	16 d	growth	**40**	/	0.5*	T: 23°C; pH: 6.9; H: 25 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstituted	Hatakeyama & Yasuno, 1981
Paratanytarsus parthenogeneticus	larvae (7 days old)	16 d	reproduction	**40**	/	0.5*	T: 23°C; pH: 6.9; H: 25 mg/l CaCO3; DOC: 0.5 mg/l (1)	Reconstituted	Hatakeyama & Yasuno, 1981
Dreissenia polymorpha	18-22 mm	63-77 d	Filtration rate	**13**	S	3	T: 15°C; pH: 7.9; H: 150 mg/l CaCO3; DOC: <7.34 mg/l (10)	Lake (Lake Markermeer)	Kraak *et al.,* 1994
Dreissenia polymorpha	18-22 mm	27 d	Filtration rate	**21**	R	/	T: 13.4°C; pH: 7.8; H: 296 mg/l CaCO3; DOC: 1.0 mg/l (7)	Tap	Mersch *et al.,* 1993
Villosa iris	glochidia	30 d	mortality	**19.1**	FT	3.2	T: 20.8°C; pH: 8.4; H: 152 mg/l CaCO3; DOC: 3.0 mg/l (4)	River (Clinch River)	Jacobson *et al.,* 1997

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Test type	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Campeloma decisum	11 to 27 mm snail	42 d	mortality	**8**	FT	1.9	T: 15°C; pH: 8.15; H: 44.9 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	Arthur & Leonard, 1970
Campeloma decisum	11 to 27 mm snail	42 d	mortality	**8**	FT	1.9	T: 15°C; pH: 8.15; H: 44.9 mg/l CaCO3; DOC: 1 mg/l (7)	Tap	Arthur & Leonard, 1970
Juga plicifera	mature	30 d	mortality	**6**	FT	0.5*	T: 15°C; pH: 7.1; H: 21mg/l CaCO3; DOC: 1.3 mg/l (9)	Well	Nebeker *et al.,* 1986

ANNEX 3: Freshwater PNEC: Overview of the NOEC values and physico-chemical parameters for freshwater algae/higher plants.

NOECs are expressed as measured µg Cu/L , FT= flow through, S= static, R= renewal; H= Hardness; d= days ; Cb= copper background concentration expressed as measured µg Cu/L

Footnotes see Annex 3

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Chlamydomonas reinhardtii	Inoculum: 1,000 c/ml	10 d	growth	**22**	FT	0.5*	T: 24°C; pH: 6.6; H: 25 mg/l CaCO3; DOC: 0.5 mg/l [1]	Reconstituted	Schäfer *et al.,* 1994
Chlamydomonas reinhardtii	Inoculum: 10,000 c/ml	3 d	growth	**178**	S	0.5*	T: 20°C; pH: 6.02; H: 23 mg/l CaCO3; DOC: 9.84 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlamydomonas reinhardtii	Inoculum: 10,000 c/ml	3 d	growth	**108**	S	0.5*	T: 20°C; pH: 7.03; H: 23 mg/l CaCO3; DOC: 9.84 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlamydomonas reinhardtii	Inoculum: 10,000 c/ml	3 d	growth	**96**	S	0.5*	T: 20°C; pH: 8.11; H: 23 mg/l CaCO3; DOC: 9.84 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**108.3**	S	0.5*	T: 20°C; pH: 6.03; H: 97 mg/l CaCO3; DOC: 5.17 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**407.4**	S	0.5*	T: 20°C; pH: 6.04; H: 99 mg/l CaCO3; DOC: 15.5 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**55.6**	S	0.5*	T: 20°C; pH: 7.92; H: 388 mg/l CaCO3; DOC: 5.0 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**36.4**	S	0.5*	T: 20°C; pH: 7.04; H: 242 mg/l CaCO3; DOC: 1.5 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**172.9**	S	0.5*	T: 20°C; pH: 7.97; H: 389 mg/l CaCO3; DOC: 15.8 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**98.9**	S	0.5*	T: 20°C; pH: 7.03; H: 244 mg/l CaCO3; DOC: 10.8 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**85.4**	S	0.5*	T: 20°C; pH: 7.01; H: 486 mg/l CaCO3; DOC: 10.0 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**161.9**	S	0.5*	T: 20°C; pH: 8.75; H: 243 mg/l CaCO3; DOC: 9.9 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**282.9**	S	0.5*	T: 20°C; pH: 7.05; H: 244 mg/l CaCO3; DOC: 19.10 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**187.8**	S	0.5*	T: 20°C; pH: 6.01; H: 389 mg/l CaCO3; DOC: 5.0 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**510.2**	S	0.5*	T: 20°C; pH: 6.05; H: 390 mg/l CaCO3; DOC: 15.2 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**31**	S	0.5*	T: 20°C; pH: 7.88; H: 98 mg/l CaCO3; DOC: 5.3 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**188**	S	0.5*	T: 20°C; pH: 7.88; H: 99 mg/l CaCO3; DOC: 15.7 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**404.1**	S	0.5*	T: 20°C; pH: 5.5; H: 244 mg/l CaCO3; DOC: 10.3 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**158.7**	S	0.5*	T: 20°C; pH: 7.07; H: 25 mg/l CaCO3; DOC: 10.3 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**83.9**	S	0.5*	T: 20°C; pH: 7.03; H: 244 mg/l CaCO3; DOC: 10.8 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Chlorella vulgaris	Inoculum: 10,000 c/ml	3 d	growth	**132.3**	S	0.5*	T: 20°C; pH: 7.04; H: 246 mg/l CaCO3; DOC: 10.2 mg/l	Reconstituted	De Schamphelaere *et al.,* 2006
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**52.9**	S	0.5*	T: 20°C; pH: 6.74; H: 10.0 mg/l CaCO3; DOC: 2.72 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**61.8**	S	0.5*	T: 20°C; pH: 7.0; H: 12.4 mg/l CaCO3; DOC: 2.34 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**94.7**	S	0.5*	T: 20°C; pH: 6.14; H: 7.9 mg/l CaCO3; DOC: 12 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**17.9**	S	0.5*	T 20°C; pH: 7.66; H: 48.7 mg/l CaCO3; DOC: 2.52 mg/l	Lake	Heijerick *et al.,* 2002

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**49**	S	0.5*	T: 20°C; pH: 8.0; H: 220 mg/l CaCO3; DOC: 6.42 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**35.4**	S	0.5*	T: 20°C; pH: 7.84; H: 238 mg/l CaCO3; DOC: 8.24 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**23.1**	S	0.5*	T: 20°C; pH: 7.93; H: 191 mg/l CaCO3; DOC: 1.99 mg/l	River	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**19.3**	S	0.5*	T: 20°C; pH: 7.93; H: 191 mg/l CaCO3; DOC: 1.99 mg/l	River	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**56.4**	S	0.5*	T: 20°C; pH: 7.69; H: 132 mg/l CaCO3; DOC: 6.13 mg/l	River	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**164**	S	0.5*	T: 20°C; pH: 7.84; H: 166 mg/l CaCO3; DOC: 17.8 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**65.5**	S	0.5*	T: 20°C; pH: 7.35; H: 134 mg/l CaCO3; DOC: 20.4 mg/l	Lake	Heijerick *et al.,* 2002
Pseudokirchneriella subcapitata	Inoculum: 10,000 c/ml	3 d	growth	**15.7**	S	0.5*	T: 20°C; pH: 8.16; H: 169 mg/l CaCO3; DOC: 1.7 mg/l	Lake	Heijerick *et al.,* 2002
Lemna minor	Double fronded colonies	7 d	growth	**30**	S	0.5*	T: 25°C; pH: 6.5; H : 26.8 mg/l CaCO3; DOC: 0.5 mg/l [(1)]	artificial	Teisseire *et al.,* 1998

Footnote Cb : * = estimated

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference

Footnotes: DOC concentrations:

(1): DOC estimation of reconstituted water is 0.5 mg/l (De Schamphelaere and Janssen, 2002 (0.3 mg DOC/L); Ryan eta al., 2004 (0.4-0.5 mg DOC/L); Karman *et al.,* 2004 (<0.1 mg DOC/L); Hollis *et al.,* 1997 (0.4-0.6 mg DOC/L).

(2): DOC estimation for New River (USA) water extracted from the United States Geological Survey records (USGS). The USGS database reports TOC concentration of 3.65 mg/l, and assuming a DOC/TOC ratio of 0.8.

(3): DOC estimation for unknown river/lake water or for which no reliable DOC concentration could be estimated is 2.0 mg/l (Santore *et al.,* 2002)

(4): DOC estimation for Clinch River (USA) water extracted from the United States Geological Survey records (USGS). The USGS database reports TOC concentration of 3.7 mg/l, and assuming a DOC/TOC ratio of 0.8.

(5): DOC estimation for Lester River (USA) water extracted from the United States Geological Survey records (USGS). The USGS database reports TOC concentration of 7.1 mg/l, and assuming a DOC/TOC ratio of 0.8.

(6): DOC estimation for deionized water (= 0.1 mg/l according to Santore *et al.,* 2002) with addition of artificial humic acids (no addition; 0.15 mg/l; 0.75 mg/l; 1.5 mg/l). Conversion from humic acid content to organic carbon content was performed after using a factor of 2.

(7): DOC estimation for tap water is 1.0 mg/l (Santore *et al.,* 2002)

(8): DOC estimation for spring water is 1.0 mg/l (Santore *et al.,* 2002)

(9): DOC estimation for well water is 1.3 mg/l (Santore *et al.,* 2002)

(10): DOC level of Markermeer (origin of the test water) was used as a basis for the DOC estimation; the Markermeer water was however filtered extensively over a sand bed to reduce the TOC (pers. communication)) and the resulting DOC value is therefore < 7.3 mg/L.

(11): DOC estimation for Chehalis River (USA) water extracted from the United States Geological Survey records (USGS). The USGS database reports TOC concentration of 3.6 mg/l, and assuming a DOC/TOC ratio of 0.8.

Organism	Age/size of organisms	Exposure time	Endpoint	NOEC (µg/l)	Testtype	Cb (µg Cu/l)	Physico-chemical conditions	Medium	Reference

(12): DOC estimation for ultrapure deionized water (0.1 mg/l Santore *et al.,* 2002) and well water (1.3 mg/l according to Santore *et al.,* 2002) in a ratio of 90%/10% is 0.45 mg/l.

(13): DOC estimation for Lake Superior water is 1.0 mg/l (Santore *et al.,* 2002)

ANNEX 4: Marine PNEC: High quality NOEC values for fish and related chemistry of the test waters.

e: value was estimated; m: value was measured and reported; NR : Background concentration not reported, but since results are based on measured concentrations, this does not affect the validity of the final result

NOEC values between brachets are not included in the derivation of a species mean NOEC, because they are not the most sensitive biological endpoint for the species

Species	Age and/or size of test organism	Test duration	Effect parameter	NOEC Value (µg/l)	Administration of test substance	Cu background	DOC mg/L	Salinity (g/l)	Test water	Reference
Atherinops affinis	early blastula embryo	12 days	embryo abnormalities	(123)	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	hatchability	(123)	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	young abnormalities	63	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	embryo abnormalities	(115)	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	hatchability	(115)	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	young abnormalities	68	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	embryo abnormalities	55	static	<3m	2.0e	33	filtered natural seawater	Anderson *et al.,* 1991

Species	Age and/or size of test organism	Test duration	Effect parameter	NOEC Value (µg/l)	Administration of test substance	Cu background	DOC mg/L	Salinity (g/l)	Test water	Reference
Atherinops affinis	early blastula embryo	12 days	hatchability	55	static	<3m	2.0e	33	natural seawater	Anderson *et al.,* 1991
Atherinops affinis	early blastula embryo	12 days	young abnormalities	55	static	<3m	2.0e	33	natural seawater	Anderson *et al.,* 1991
Cyprinodon variegates	Egg	7 days	hatchability	(109)	flowthrough	<0.4m	1.19m	23.5-27	natural seawater	Hurd, K., 2006b
Cyprinodon variegates	Embryo-larval stages	32 days	Survival	(109)	flowthrough	<0.4m	1.19m	23.5-27	natural seawater	Hurd, K., 2006b
Cyprinodon variegates	Embryo-larval stages	32 days	Embryo development (weight)	57.8	flowthrough	<0.4m	1.19m	23.5-27	natural seawater	Hurd, K., 2006b
Cyprinodon variegates	Embryo-larval stages	32 days	Embryo development (length)	57.8	flowthrough	<0.4m	1.19m	23.5-27	natural seawater	Hurd, K., 2006b

ANNEX 5: Marine PNEC: High quality NOEC values for invertebrates and related chemistry of the test waters.

e: value was estimated; m: value was measured and reported; NR : Background concentration not reported, but since results are based on measured concentrations, this does not affect the validity of the final result

NOEC values between brachets are not included in the derivation of a species mean NOEC, because they are not the most sensitive biological endpoint for the species

Species	**Age and/or size of test organism**	**Test duration**	**Effect parameter**	**NOEC Value (µg/l)**	**Administration of test substance**	**Cu background ($\mu g\ l^{-1}$)**	**DOC (mg/L)**	**Salinity (g/l)**	**Test water**	**Reference**
Penaeus mergulensis	Juvenile	14 days	growth	33	Flow through	<1m	2.0e	20	natural seawater	Ahsanullah, M. Et al 1995
Penaeus monodon	Juvenile	14 days	growth	145	Flow through	<1m	2.0e	20	natural seawater	Ahsanullah, M. Et al 1995
Tisbe furcata	Life cycle	100 days max	Survival and reproduction	19.1	Static renewal	NR	2.0e	34	Natural seawater	Bechmann R.K., 1994
Artemia franciscana	Cysts	48 hours	Hatching success	6.6	Static	0.2m	0.48m	Not reported	Artificial seawater	Brix, 2006
Mytilus edulis	Embryo	48 hours	Development	6.2	Flow through	1.8m	1.51m	32	natural seawater	Brooks, S. 2006
Crassostreas gigas	Embryo	24 hour	Development	10.89	Flow through	2.8m	2.19m	31.1 - 34.2	natural seawater + 0.1 mg DOC/L, added as humic acids	Brooks, S. 2006

Species	Age and/or size of test organism	Test duration	Effect parameter	NOEC Value (µg/l)	Administration of test substance	Cu background (µg l^{-1})	DOC (mg/L)	Salinity (g/l)	Test water	Reference
Crassostreas gigas	Embryo	24 hour	Development	10.42	Flow through	2.5m	3.36m	31.1 - 34.2	natural seawater, + 0.81 mg DOC/L, added as humic acids	Brooks, S. 2006
Crassostreas gigas	Embryo	24 hour	Development	12.83	Flow through	3.0m	3.36m	31.1 - 34.2	natural seawater+ 1.02 mg DOC/L, added as humic acids	Brooks, S. 2006
Crassostreas gigas	Embryo	24 hour	Development	19.53	Flow through	3.6m	3.88m	31.1 - 34.2	natural seawater, + 1.85 mg DOC/L, added as humic acids	Brooks, S. 2006
Crassostreas gigas	Embryo	24 hour	Development	28.19	Flow through	1.1m	4.66m	31.1 - 34.2	natural seawater; + 2.77 mg DOC/L, added as humic acids	Brooks, S. 2006
Crassostreas gigas	Embryo	24 hour	Development	47.13	Flow through	3.2m	5.19m	31.1 - 34.2	natural seawater,+ 3.13 mg DOC/L, added as	Brooks, S. 2006

Species	Age and/or size of test organism	Test duration	Effect parameter	NOEC Value (µg/l)	Administration of test substance	Cu background (µg l^{-1})	DOC (mg/L)	Salinity (g/l)	Test water	Reference
									humic acids	
Placopecten magellanicus	Adult	8 weeks	gonad development	10.0	Flow through	2.5-3.4m	2.0e	25	Natural seawater	Gould, 1988
Eurytemora affinis	<24 hrs	8 days	Mortality, fecundity and maturation	51.1	Semi-static	<3m	2.0e	14 - 17	natural estuarine water	Hall, L., 1997
Paracentrotus lividus	Embryo	48 hours	Development	8.8	Static	<0.4m	1.83m	34.4	natural seawater	Hurd, K. 2006a
Mercenaria mercenaria	Larvae	96 hours	Development	7.0	Static	1m	0.5e	26.5	Artificial seawater	LaBreche, 2002
Paracentrotus lividus	Embryo	48 hours	Development	16.5	Static	0.32 – 1.45m	2.0e	35	natural seawater	Lorenzo, J. 2006
Neanthes arenaceodentata	3-4 week larva	28 days	growth	13.5	Flow through	2±1m	2.0m	32	filtered natural seawater	Pesch *et al.,* 1986
Neanthes arenaceodentata	3-4 week larva	28 days	growth	12.1	Flow through	2±1m	2.0m	32	filtered natural seawater	Pesch *et al.,* 1986
Mytilus edulis	1.0-1.5 cm individuals	10 days	growth rate	6.0	daily renewal of solutions	2.0 – 2.4m	2.0m	not reported	Filtered seawater	Redpath, K.J. 1985

Species	Age and/or size of test organism	Test duration	Effect parameter	NOEC Value (µg/l)	Administration of test substance	Cu background (µg l^{-1})	DOC (mg/L)	Salinity (g/l)	Test water	Reference
Goniastrea aspera	Larvae	72 hours	Motility	14.2	Static	1.2m	2.0e	not reported	Natural seawater	Reichelt-Brushett, 2004
Acropora tenuis	Larvae	48 hours	Settlement success	17.3	Static	0.63m	2.0e	not reported	Natural seawater	Reichelt-Brushett, 2000
Lobophytum compactum	Eggs/sperm	5 hours	Fertilisation success	36.0	Static	NR	2.0e	not reported	Natural seawater	Reichelt-Brushett, 2005
Protothaca staminea	5.2 to 5.8 cm total length	30 days	Mortality	18	Flow through	0.35m	2.0e	32	natural seawater	Roesijida, G. 1980
Mytilus galloprovincialis	Embryo	48 hours	Development	5.9	Static	0.6m	0.9m	Not reported	Filtered seawater	Rosen, 2005
Mytilus galloprovincialis	Embryo	48 hours	Development	7.5	Static	1.5m	0.9m	Not reported	Filtered seawater	Rosen, 2005
Mytilus galloprovincialis	Embryo	48 hours	Development	9.2	Static	0.7m	1.5m	Not reported	Filtered seawater	Rosen, 2005
Mytilus galloprovincialis	Embryo	48 hours	Development	9.7	Static	1.0m	0.9m	Not reported	Filtered seawater	Rosen, 2005
Tisbe battagliai	<24 hrs	21 days	Survival	18	Semi-Static	2.0m	2.79m	35	natural seawater	Williams, T. 2006
Tisbe battagliai	<24 hrs	21 days	Development	18	Semi-Static	2.0m	2.79m	35	natural seawater	Williams, T. 2006

Species	**Age and/or size of test organism**	**Test duration**	**Effect parameter**	**NOEC Value (µg/l)**	**Administration of test substance**	**Cu background (µg l^{-1})**	**DOC (mg/L)**	**Salinity (g/l)**	**Test water**	**Reference**
Tisbe battagliai	<24 hrs	21 days	Reproduction	18	Semi-Static	2.0m	2.79m	35	natural seawater	Williams, T. 2006
Pandalus danae	Larvae	>42 days	Mortality	9.9	Flow through	0.47m	2.0e	29.8-30.6	natural seawater	Young *et al.*, 1979
Pandalus danae	Larvae	>42 days	Development	9.9	Flow through	0.47m	2.0e	29.8-30.6	natural seawater	Young *et al.*, 1979

ANNEX 6: Marine PNEC: High quality NOEC values for marine algae and related chemistry of the test waters.

e: value was estimated; m: value was measured and reported; NR : Background concentration not reported, but since results are based on measured concentrations, this does not affect the validity of the final result

NOEC values between brachets are not included in the derivation of a species mean NOEC, because they are not the most sensitive biological endpoint for the species

Species	**Age and/or size of test organism**	**Test duration**	**Effect parameter**	**NOEC value (µg/l)**	**Administration of test substance**	**Cu background (µg/l)**	**DOC**	**Salinity (g/l)**	**Test water**	**Reference**
Macrocystis pyrifera, motile zoospore	Zoospores	19 days	sporophyte growth	10.2	static renewal	<0.6m	2.0e	35-37	artificial filtered seawater	Anderson *et al.,* 1990
Macrocystis pyrifera, motile zoospore	Zoospores	19 days	germination	(50.1)	static renewal	<0.6m	2.0e	35-37	artificial filtered seawater	Anderson *et al.,* 1990
Macrocystis pyrifera, motile zoospore	Zoospores	19 days	germ tube growth	10.2	static renewal	<0.6m	2.0e	35-37	artificial filtered seawater	Anderson *et al.,* 1990
Fucus vesiculosis	Zoospore	14 days	Growth	11	flow through	4.2m	1.67m	30.9	natural filtered seawater	Brooks, S., 2006d
Fucus vesiculosis	zoospore	14 days	Growth	18.5	flow through	2.3m	2.11m	31	natural filtered seawater,+ 0.56 mg DOC/L added as humic acids	Brooks, S., 2006d

Species	**Age and/or size of test organism**	**Test duration**	**Effect parameter**	**NOEC value (µg/l)**	**Administration of test substance**	**Cu background**	**DOC**	**Salinity (g/l)**	**Test water**	**Reference**
Fucus vesiculosis	zoospore	14 days	Growth	32	flow through	2.9m	2.56m	31.4	natural filtered seawater,,+ 1.65 mg DOC/L added as humic acids	Brooks, S., 2006d
Fucus vesiculosis	zoospore	14 days	Growth	46	flow through	2.8m	2.88m	30.9	natural filtered seawater,,+ 2.03 mg DOC/L added as humic acids	Brooks, S., 2006d
Phaeodactylum tricornutum	10^3 cells/ml	72 hours	Growth rate	2.9	static	NR	1.0m	31	natural filtered seawater	Simpson, 2003
Skeletonema costantum		72 hours	Growth rate	7.5	static	<0.4m	2.19m	31	natural filtered seawater	Smyth, D. 2006a
Phaeodactylum tricornutum	10^4 cells/ml	72 hours	Growth rate	5.7	static	<0.4m	2.19m	31	natural filtered seawater	Smyth, D. 2006b

ANNEX 7: Freshwater sediment PNEC : Overview of the selected high quality chronic toxicity values for freshwater sediments (the values indicated in bold have been used in the final PNEC derivation (selected based on maximizing bioavailability = no or low AVS concentration)

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Tubifex tubifex	oligochaete	28 d	reproduction	**67.25**	measured	static	Artificial sediment: Sala Bolognese Silt + clay (< 63 um) 69.7%, OC 1.41 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	survival	**67.25**	measured	static	Artificial sediment :Sala Bolognese Silt + clay (< 63 um) 69.7%, OC 1.41 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	reproduction	**231.7**	measured	static	Lake Maggiore Silt + clay (< 63 um) 65.2%, OC 1.56 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	reproduction	**62.64**	measured	static	Artificial sediment: Ca Bosco plus food supplement Silt + clay (< 63 um) 62.5%, OC 1.03 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	survival	**385.8**	measured	static	Lake Maggiore Silt + clay (< 63 um) 65.2%, OC 1.56 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	survival	**101.4**	measured	static	Artificial sediment: Ca Bosco plus food supplement Silt + clay (< 63 um) 62.5%, OC 1.03 %	Vecchi *et al.,* 1999.

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Tubifex tubifex	oligochaete	28 d	survival	**69.1**	measured	static	Artificial sediment: Ca Bosco minus food supplement Silt + clay (< 63 um) 71.5%, OC 1,05 %	Vecchi *et al.,* 1999.
Tubifex tubifex	oligochaete	28 d	survival	**138.5**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	reproduction	**79.3**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	Growth	**79.3**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	survival	988.3	measured	Static renewal	Artificial OECD substrate: AVS 8.04 mmol/kg; OC 3.33%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	reproduction	459.2	measured	Static renewal	Artificial OECD substrate: AVS 8.04 mmol/kg; OC 3.33%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	growth	163	measured	Static renewal	Artificial OECD substrate: AVS 8.04 mmol/kg; OC 3.33%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	survival	937	measured	Static renewal	Artificial OECD substrate: AVS 14.39 mmol/kg; OC 3.33%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	survival	**580.9**	measured	Static renewal	Artificial OECD substrate: AVS 0.59 mmol/kg; OC 9.81%	De Schamphelaere *et al.,* 2005
Tubifex tubifex	oligochaete	28 d	Reproduction	**580.9**	measured	Static renewal	Artificial OECD substrate: AVS 0.59 mmol/kg; OC 9.81%	De Schamphelaere *et al.,* 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Tubifex tubifex	oligochaete	28 d	growth	**580.9**	measured	Static renewal	Artificial OECD substrate: AVS 0.59 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	survival	1267	measured	Static renewal	Artificial OECD substrate: AVS 5.43 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	1037	measured	Static renewal	Artificial OECD substrate: AVS 5.43 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	growth	1036.5	measured	Static renewal	Artificial OECD substrate: AVS 5.43 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	survival	1357	measured	Static renewal	Artificial OECD substrate: AVS 15.15 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	480.9	measured	Static renewal	Artificial OECD substrate: AVS 15.15 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	Growth	271.6	measured	Static renewal	Artificial OECD substrate: AVS 15.15 mmol/kg; OC 9.66%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	survival	**54**	measured	Static renewal	Natural Brakel sediment: AVS 0.27 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	**18.3**	measured	Static renewal	Natural Brakel sediment: AVS 0.27 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	growth	**18.3**	measured	Static renewal	Natural Brakel sediment: AVS 0.27 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Tubifex tubifex	oligochaete	28 d	survival	**95.3**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	**56.1**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	Growth	**32.2**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	**98.3**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	Growth	**53**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	reproduction	1856	measured	Static renewal	Natural Leuven sediment: AVS 56.4 mmol/kg; OC 24.8%	De Schamphelaere *et al.*, 2005
Tubifex tubifex	oligochaete	28 d	Growth	1,855.60	measured	Static renewal	Natural Leuven sediment: AVS 56.4 mmol/kg; OC 24.8%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	growth	**53.2**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	survival	292.5	measured	Static renewal	Artificial OECD substrate: AVS 4.87 mmol/kg; OC 3.29%	De Schamphelaere *et al.*, 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Hyalella azteca	amphipod	28 d	growth	292.5	measured	Static renewal	Artificial OECD substrate: AVS 4.87 mmol/kg; OC 3.29%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	582.6	measured	Static renewal	Artificial OECD substrate: AVS 12.33 mmol/kg; OC 3.29%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	**337.6**	measured	Static renewal	Artificial OECD substrate: AVS 0.27 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28d	Growth	**538.6**	measured	Static renewal	Artificial OECD substrate: AVS 0.27 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	739.5	measured	Static renewal	Artificial OECD substrate: AVS 5.30 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	growth	492.7	measured	Static renewal	Artificial OECD substrate: AVS 5.30 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	849.5	measured	Static renewal	Artificial OECD substrate: AVS 8.97 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	Growth	512.2	measured	Static renewal	Artificial OECD substrate: AVS 8.97 mmol/kg; OC 9.66%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	**171**	measured	Static renewal	Natural Brakel sediment: AVS 0.18 mmol/kg; OC 2.83%	De Schamphelaere *et al.,* 2005
Hyalella azteca	amphipod	28 d	survival	**141**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.,* 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Hyalella azteca	amphipod	28 d	Growth	**21.8**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	survival	**140**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	Growth	**49.9**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	survival	3,158	measured	Static renewal	Natural Leuven sediment: AVS 58.6 mmol/kg; OC 18.9%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	growth	1,531	measured	Static renewal	Natural Leuven sediment: AVS 58.6 mmol/kg; OC 18.9%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	survival	1,495	measured	Static renewal	Natural Ijzer sediment: AVS 18.25 mmol/kg; OC 6.48%	De Schamphelaere *et al.*, 2005
Hyalella azteca	amphipod	28 d	growth	244.8	measured	Static renewal	Natural Ijzer sediment: AVS 18.25 mmol/kg; OC 6.48%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	**59.5**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	**59.5**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	89.2	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Chironomus riparius	Chironomidae	28 d	survival	589.3	measured	Static renewal	Artificial OECD substrate: AVS 4.02 mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	318	measured	Static renewal	Artificial OECD substrate: AVS 4.02 mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	318	measured	Static renewal	Artificial OECD substrate: AVS 4.02 mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	553.6	measured	Static renewal	Artificial OECD substrate: AVS 16.21 mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	553.6	measured	Static renewal	Artificial OECD substrate: AVS 16.21; mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	553.6	measured	Static renewal	Artificial OECD substrate: AVS 16.21; mmol/kg; OC 3.33%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	**292**	measured	Static renewal	Artificial OECD substrate: AVS 0.30 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	**292**	measured	Static renewal	Artificial OECD substrate: AVS 0.30 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	**505.9**	measured	Static renewal	Artificial OECD substrate: AVS 0.30 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	934.1	measured	Static renewal	Artificial OECD substrate: AVS 4.05 mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005

Species	**Taxonomic group**	**Test duration**	**Effect parameter**	**NOEC (mg/kg dry weight)**	**Analysis of concentrations**	**Administration of test substance**	**Physico-chemical conditions of sediments**	**Reference**
Chironomus riparius	Chironomidae	28 d	emergence	934.1	measured	Static renewal	Artificial OECD substrate: AVS 4.05; mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	452.6	measured	Static renewal	Artificial OECD substrate: AVS 4.05; mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	1,417	measured	Static renewal	Artificial OECD substrate: AVS 12.60; mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	1,417	measured	Static renewal	Artificial OECD substrate: AVS 12.60; mmol/kg; OC 9.81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	1,417	measured	Static renewal	Artificial OECD substrate: AVS 12.60; mmol/kg; OC 9..81%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	**177.1**	measured	Static renewal	Natural Brakel sediment: AVS 0.15 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	**75.4**	measured	Static renewal	Natural Brakel sediment: AVS 0.15 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	**54.2**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	**54.4**	measured	Static renewal	Natural Kraenepoel 1 sediment: AVS 0.28 mmol/kg; OC 2.12%	De Schamphelaere *et al.*, 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Chironomus riparius	Chironomidae	28 d	survival	**85.4**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	**55.5**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	survival	2,113	measured	Static renewal	Natural Ijzer sediment: AVS 15.57 mmol/kg; OC 6.48%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	emergence	1,320	measured	Static renewal	Natural Ijzer sediment: AVS 15.57 mmol/kg; OC 6.97%	De Schamphelaere *et al.*, 2005
Chironomus riparius	Chironomidae	28 d	growth	776.5	measured	Static renewal	Natural Ijzer sediment: AVS 15.57 mmol/kg; OC 6.97%	De Schamphelaere *et al.*, 2005
Lumbriculus variegatus	oligochaete	28 d	biomass	**80.5**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005
Lumbriculus variegatus	oligochaete	28 d	biomass	**91.8**	measured	Static renewal	Natural Kraenepoel 2 sediment: AVS 0.10 mmol/kg; OC 1.96%	De Schamphelaere *et al.*, 2005
Lumbriculus variegatus	oligochaete	28 d	biomass	416.3	measured	Static renewal	Natural Ijzer sediment: AVS 16.50 mmol/kg; OC 6.97%	De Schamphelaere *et al.*, 2005
Gammarus pulex	amphipod	35 d	survival	**94.7**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005
Gammarus pulex	amphipod	35 d	growth	**94.7**	measured	Static renewal	Artificial OECD substrate: AVS 0.05 mmol/kg; OC 2.62%	De Schamphelaere *et al.*, 2005

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Gammarus pulex	amphipod	35 d	survival	**97.4**	measured	Static renewal	Natural Brakel sediment: AVS 0.21 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Gammarus pulex	amphipod	35 d	growth	**30.6**	measured	Static renewal	Natural Brakel sediment: AVS 0.21 mmol/kg; OC 2.83%	De Schamphelaere *et al.*, 2005
Gammarus pulex	amphipod	35 d	survival	1,268.00	measured	Static renewal	Natural Ijzer sediment: AVS 17.50 mmol/kg; OC 6.48%	De Schamphelaere *et al.*, 2005
Gammarus pulex	amphipod	35 d	growth	789	measured	Static renewal	Natural Ijzer sediment: AVS 17.50 mmol/kg; OC 6.6.97%	De Schamphelaere *et al.*, 2005
Hyalella azteca	Amphipod	28 d	Survival	**59.3**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hyalella azteca	Amphipod	28 d	Survival	**66.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hyalella azteca	Amphipod	28 d	Survival	**155.1**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hyalella azteca	Amphipod	28 d	Growth	**59.3**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003

Species	**Taxonomic group**	**Test duration**	**Effect parameter**	**NOEC (mg/kg dry weight)**	**Analysis of concentrations**	**Administration of test substance**	**Physico-chemical conditions of sediments**	**Reference**
Hyalella azteca	Amphipod	28 d	Growth	**66.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hyalella azteca	Amphipod	28 d	Growth	**52.3**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hexagenia spp	Hexagenia	21 d	Survival	**39.2**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hexagenia spp	Hexagenia	21 d	Survival	**33.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hexagenia spp	Hexagenia	21 d	Survival	**44.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hexagenia spp	Hexagenia	21 d	Growth	**23.4**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Hexagenia spp	Hexagenia	21 d	Growth	**29.2**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003

Species	Taxonomic group	Test duration	Effect parameter	NOEC (mg/kg dry weight)	Analysis of concentrations	Administration of test substance	Physico-chemical conditions of sediments	Reference
Hexagenia spp	Hexagenia	21 d	Growth	**44.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Survival	**237.8**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Survival	**246.9**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Survival	**270.5**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Reproduction	**127.8**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Reproduction	**129**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003
Tubifex tubifex	Oligochaete	28 d	Reproduction	**270.5**	measured	Static	Sediment: reference sediment Long point (Lake Erie 0.5 % TOC)	Milani *et al.*, 2003

ANNEX 8: Terrestrial PNEC : Overview of the NOEC values for soil invertebrates

Values selected for the effects assessment are underlined. See IUCLID/RAR (2008) for reasons on the selection.

NOEC indices: m: mortality, r: reproduction (based on cocoon production (cp), juvenile production (jp)); h: hatching success, g: growth, ab: abundance, f: fragmentation, lb: litter breakdown, mi: maturity index; ri: Instantaneous rate of population increase.

Estimated background copper concentrations and CEC** are indicated in italics.

*measured concentration-C_b

** If the CEC was missing from a test with plants/invertebrates/micro-organisms, then it was estimated from % clay, pH and %organic matter using an experimentally derived regression model: CEC=(30+4.4 pH)*clay/100+(-34.66+29.72 pH)*OM/100; the clay is the % clay in the soil (Helling *et al.,* 1964; regression based on CEC measured at various pH values on 60 different soils; CEC refers to the soil pH).

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Allobophora chlorotica	Sandy soil	4.8-5.2	04-Jun	02-Apr	12	05-Sep	0	28	$NOEC_{r(cp)}$	28		40	
									Ma, 1988				
Allobophora caliginosa	Non-EU sandy soil				*10.7*		0	14	$NOEC_m$	500		510.7	
Allobophora caliginosa	Non-EU sandy soil				*10.7*		0	14	$NOEC_{r(cp)}$	50		60.7	
									Martin, 1986				
Aporrectodea caliginosa	Sandy soil	4.8-5.2	04-Jun	02-Apr	*10.7*		0	28	$NOEC_{r(cp)}$	27		37.7	
									Ma, 1988				

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Aporrectodea caliginosa	Non-EU soil	7.05	21.6		*10.7*		0	42	$NOEC_g$	25		35.7	
Aporrectodea caliginosa	Non-EU soil	7.05	21.6		*10.7*		0	56	$NOEC_{r(cp)}$	70		80.7	
									Khalil *et al.,* 1996a and b				
Cognettia sphagnetorum	LUFA 2.2 + peat + fungus	4.1	66	5.1	*10.7*	*60.6*	0	63	$NOEC_g$	20		30.7	
Cognettia sphagnetorum	LUFA 2.2 + peat + fungus	4.1	66	5.1	*10.7*	*60.6*	0	35	$NOEC_g$	63		73.7	
Cognettia sphagnetorum	LUFA 2.2 + peat + algae	4.1	66	5.1	*10.7*	*60.6*	0	63	$NOEC_g$	441		451.7	
Cognettia sphagnetorum	LUFA 2.2 + peat + algae	4.1	66	5.1	*10.7*	*60.6*	0	42	$NOEC_g$	312		322.7	
Cognettia sphagnetorum	LUFA 2.2 + peat + fungus	4.1	66	5.1	*10.7*	*60.6*	0	70	$NOEC_f$	23		33.7	
Cognettia sphagnetorum	LUFA 2.2 + peat + algae	4.1	66	5.1	*10.7*	*60.6*	0	70	$NOEC_f$	455		465.7	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Augustsson and Rundgren, 1998				
Dendrobaena rubida	Sand+cattle dung	4.5	7.7-11.7		3.6		28	90	$NOEC_h$	100		103.6	
Dendrobaena rubida	Sand+cattle dung	5.5	7.7-11.7		<0.5		28	90	$NOEC_h$	100		100	
Dendrobaena rubida	Sand+cattle dung	5.5	7.7-11.7		<0.5		28	90	$NOEC_{r(cp)}$	100		100	
Dendrobaena rubida	Sand+cattle dung	6.5	7.7-11.7		1.3		28	90	$NOEC_h$	100		101.3	
Dendrobaena rubida	Sand+cattle dung	6.5	7.7-11.7		1.3		28	90	$NOEC_{r(cp)}$	100		101.3	
									Bengtsson *et al.,* 1986				
Eisenia andrei	OECD soil	6.2	10	20	*3.2*	*15.1*	0	84	$NOEC_g$	<u>56</u>		<u>59.2</u>	
									Van Dis *et al.,* 1988				
Eisenia andrei	OECD soil	6.3-7.1	10	20	*3.2*	*16.6*	0	28	$NOEC_{r(cp)}$	<u>120</u>		<u>123.2</u>	
									Van Gestel *et al.,* 1989				
Eisenia andrei	OECD soil	6.2	10	20	6.1	*15.1*	0	84	$NOEC_g$	<u>56</u>		<u>62</u>	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Van Gestel *et al.,* 1991				
Eisenia andrei	Forest soil	5.6	<1	4	*3.7*	*2.9*	3	28		188*		192	
Eisenia andrei	Forest soil	5.6	<1	4	*3.7*	*2.9*	3	28	$NOEC_r$	188*		192	
									Svendsen & Weeks, 1997a				
Eisenia andrei	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_{r(cp)}$	100		103.2	
Eisenia andrei	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_{r(jp)}$	100		103.2	
Eisenia andrei	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_g$		≥ 320		≥ 323.2
Eisenia andrei	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_{r(cp)}$	3.2		8.4	
Eisenia andrei	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_g$		≥ 320		≥ 325.2[a]
									Kula and Larink, 1997				
Eisenia fetida	OECD soil	6.3	10	20	2.4	*15.4*	0	56	$NOEC_m$	200		202.4	
Eisenia fetida	OECD soil	6.3	10	20	2.4	*15.4*	0	56	$NOEC_{r(cp)}$	10		12.4	
									Spurgeon *et al.,* 1994				

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Eisenia fetida	OECD soil	6.1	10	20	*3.2*	*14.8*		21	$NOEC_{r(cp)}$	29		32.3	
Eisenia fetida	OECD soil	6.1	10	20	*3.2*	*14.8*		21	$NOEC_g$	725		728.2	
Eisenia fetida	OECD soil	6.1	10	20	*3.2*	*14.8*		14	$NOEC_m$	293		296.2	
									Spurgeon and Hopkin, 1995				
Eisenia fetida	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_{r(cp)}$	10		13.2	
Eisenia fetida	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_{r(jp)}$	32		35.2	
Eisenia fetida	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_g$		≥ 320		≥ 323.2
Eisenia fetida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_{r(cp)}$	10		15.2	
Eisenia fetida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_{r(jp)}$	32		37.2	
Eisenia fetida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_g$		≥ 320		≥ 325.2
									Kula and Larink, 1997				
Eisenia fetida	OECD soil	6	10	20	*3.2*	*14.5*	0	28	$NOEC_m$		≥ 320		≥ 323.2

Organism	**Medium**	**pH**	**OM**	**clay**	**Cb**	**CEC**	**Equil. Period**	**Durat.**	**Endpoint**	**Added NOEC**		**Total NOEC**	
										NOEC or EC_{10}	**Unbounded NOEC**	**NOEC or EC_{10}**	**Unbounded NOEC**
			%	**%**	**mg/kg_{dw}**	**cmol/kg**	**days**	**days**		**mg/kg_{dw}**	**mg/kg_{dw}**	**mg/kg_{dw}**	**mg/kg_{dw}**
Eisenia fetida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	28	$NOEC_m$		≥ 320		≥ 325.2
									Kula and Larink, 1998				
Eisenia fetida	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_m$		≥ 1,400		≥ 1,415
Eisenia fetida	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_g$	700		715	
Eisenia fetida	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_r$	100		115	
									Scott-Fordsmand *et al.,* 2000				
Enchytraeus albidus	OECD soil	6 42	10	20	*3.2*	*14.5*	0	42	$NOEC_{r-P-}$ $NOEC_{r-F1}$		<175.7 <175.7		<178.9 <178.9
									Lock and Janssen (2002)				
Eisenia fetida	natural soil	/	/	/	*10.7*	/	0	14	$NOEC_m$	650		660.7	
									Liang and Zhou, 2003]				
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	28	$NOEC_m$		≥ 3000		≥ 3003.2

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	28	$NOEC_r$	200		203.2	
Folsomia candida	OECD soil	5	10	20	*3.2*	*11.5*	2	28	$NOEC_m$	40		43.2	
Folsomia candida	OECD soil	5	10	20	*3.2*	*11.5*	2	28	$NOEC_r$	200		203.2	
Folsomia candida	OECD soil	4.5	10	20	*3.2*	*10*	2	28	$NOEC_m$		≥ 3000		≥ 3003.2
Folsomia candida	OECD soil	4.5	10	20	*3.2*	*10*	2	28	$NOEC_r$	1,000		1,003.20	
									Sandifer & Hopkin, 1996				
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	28	$NOEC_r$	200		203.2	
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	42	$NOEC_r$	200		203.2	
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	28	$NOEC_m$		≥ 3,000		≥ 3,003
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	28	$NOEC_m$	1,000		1,003.20	
Folsomia candida	OECD soil	6	10	20	*3.2*	*14.5*	2	42	$NOEC_m$	1,000		1,003.20	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Sandifer & Hopkin, 1997				
Folsomia candida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	21	$NOEC_g$	200		205.2	
Folsomia candida	LUFA 2.2	5.8	3.9	5.1	*5.2*	*8.3*	0	21	$NOEC_r$	400		405.2	
Folsomia candida	OECD	6	10	20	*3.2*	*14.5*	0	56	$NOEC_g$	800		803.2	
Folsomia candida	OECD	6	10	20	*3.2*	*14.5*	0	56	$NOEC_r$	400		403.2	
									Rundgren and Van Gestel, 1988				
Folsomia fimetaria	LUFA 2.2	5.5	3.91	5	*5.2*	*7.8*	1	21	$NOEC_m$	800		805.2	
Folsomia fimetaria	LUFA 2.2	5.5	3.91	5	*5.2*	*7.8*	1	21	$NOEC_m$		≥1,000		≥1,005
Folsomia fimetaria	LUFA 2.2	5.5	3.91	5	*5.2*	*7.8*	1	21	$NOEC_g$	542		547.2	
Folsomia fimetaria	LUFA 2.2	5.5	3.91	5	*5.2*	*7.8*	1	21	$NOEC_g$	845		850.2	
Folsomia fimetaria	LUFA 2.2	5.5	3.91	5	*5.2*	*7.8*	1	21	$NOEC_g$	400		405.2	
									Scott-Fordsmand *et al.,* 1997				
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_m$	1,000		1,015	
Folsomia fimetaria	Sandy	6.5-	3.9-	13-	15	*16.6*	1	21	$NOEC_m$	600		615	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	clay	7.0	5.5	16									
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_m$	1,000		1,015	
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_g$	1,000		1,015	
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_g$	1,000		1,015	
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_g$	1,000		1,015	
Folsomia fimetaria	Sandy clay	6.5-7.0	3.9-5.5	13-16	15	*16.6*	1	21	$NOEC_r$	400		415	
									Scott-Fordsmand *et al.,* 2000a				
Folsomia fimetaria	Sandy clay Hygum	6.7 6.7	4.5 4.5	13.8 13.8	19 19	*15.6* *15.6*	0 0	21 21	$EC10_r$	122		141	
Folsomia candida	Sandy clay Hygum	6.7							$EC10_r$	<31			<50
		6.7							Pedersen *et al.,* 2000				
Folsomia fimetaria	Sandy	6.7							$EC10_r$	698		717	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC: NOEC or EC_{10}	Added NOEC: Unbounded NOEC	Total NOEC: NOEC or EC_{10}	Total NOEC: Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	clay												
	Hygum	6.7								776		795	
		6.7	4.5							888		907	
		4.5								648		667	
		4.5								688		707	
		4.5							Pedersen *et al.,* 2001				
Folsomia candida	artificial OECD soil	4.5	13.8						$NOEC_{ri}$	796.8		800	
		13.8							Herbert *et al.,* 2004.				
Hypoaspis aculeifer	LUFA 2.2	13.8							$NOEC_r$	174		179.2	
Hypoaspis aculeifer	LUFA 2.2	13.8							$NOEC_m$		≥ 1,000		≥ 1,005
		13.8	19						Krogh and Axelsen, 1998				
Isotoma viridis	LUFA 2.2	19							$NOEC_g$	50		55.2	
Isotoma viridis	OECD	19							$NOEC_g$	400		403.2	
		19							Rundgren and Van Gestel, 1988				

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Lumbricus rubellus	Sandy loam	19	15.6						$NOEC_m$	150		162	
		15.6							Ma, 1982				
Lumbricus rubellus	Loamy sand	15.6							$NOEC_r$	40*		54	
Lumbricus rubellus	Loamy sand	15.6							$NOEC_{lb}$	40*		54	
Lumbricus rubellus	Loamy sand	15.6	1						$NOEC_g$	117*		131	
Lumbricus rubellus	Loamy sand	7							$NOEC_m$	117*		131	
Lumbricus rubellus	Calcareous sandy loam	35							$NOEC_{lb}$	50*		63	
Lumbricus rubellus	Calcareous sandy loam	84	21						$NOEC_g$		≥ 360		≥ 373
Lumbricus rubellus	Calcareous sandy loam	21							$NOEC_m$	123*		136	
		21							Ma, 1984				
Lumbricus rubellus	Sandy soil	21							$NOEC_{r(c}$	80		90.7	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC: NOEC or EC_{10}	Added NOEC: Unbounded NOEC	Total NOEC: NOEC or EC_{10}	Total NOEC: Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									p)				
		21							Ma, 1988				
Lumbricus rubellus	Forest soil								$NOEC_g$	73*		76	
Lumbricus rubellus	Forest soil	6	10	20	3.2	*14.5*	7	28	$NOEC_m$	150*		153	
									Svendsen & Weeks, 1997b				
Lumbricus rubellus	Clay loam	5.8	3.9	5.1	5.2	*8.3*	0	21	$NOEC_g$	139.6		154	
		5.8	3.9	5.1	5.2	*8.3*	0	21	Spurgeon *et al.,* (2004)				
Octalasium cyaneum	brown soil								$NOEC_m$	100		153	
Octalasium cyaneum	peaty soil	5.8	3.9	5.1	5.2	*8.3*	0	56	$NOEC_m$	1,200		1,214	
		6	10	20	3.2	*14.59*	0	56	Jäggy & Streit, 1982				
Plectus acuminatus	OECD								$NOEC_{r(jp)}$	32		35.2	
		7.3	8	17	12	*25.3*	0	84	Kammenga *et al.,* 1996				
Platynothrus peltifer	LUFA 2.2								$NOEC_{r(jp)}$	63		68.2	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Platynothrus peltifer	LUFA 2.2	4.8	5.7	2	*14*	*7.2*	0	42	$NOEC_{r(jp)}$	63		68.2	
Platynothrus peltifer	LUFA 2.2	4.8	5.7	2	*14*	*7.2*	0	42	$NOEC_{r(jp)}$	63		68.2	
		4.8	5.7	2	14	7.2	0	42	Van Gestel and Doornekamp, 1998				
Folsomia candida	loamy sand	4.8	5.7	2	14	7.2	0	42	$NOEC_r$		< 29.7		<31.7
	Gudow	7.3	3.4	17	13	16.9	0	42					
Folsomia candida	Sandy loam	7.3	3.4	17	13	16.9	0	42	$NOEC_r$	174		191	
	Nottingham	7.3	3.4	17	13	16.9	0	42					
Folsomia candida	loamy sand								$NOEC_r$	28.2		31	
	Houthalen	4.8-5.2	04-Jun	02-Apr	10.7		0	28					
Folsomia candida	loamy sand								$NOEC_r$	279		293	
	Rhydtalog	5.6	<1	4	3	2.9	5	110					
Folsomia candida	Sandy clay loam	5.6	<1	4	3	2.9	5	110	ED_r	1390		1460	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC: NOEC or EC_{10}	Added NOEC: Unbounded NOEC	Total NOEC: NOEC or EC_{10}	Total NOEC: Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	Zegveld												
Folsomia candida	Loamy sand Kovlinge	7.2-7.8	9.6-9.95	41	14.4	44.2	14	294	$NOEC_r$	55.5		61.5	
Folsomia candida	Sandy clay Souli	4.78 4.5	5.4 72		53 14		0 0	30 14	$NOEC_r$	53.1		84.1	
Folsomia candida	loamy sand Montpellier	5.5	10	20	3.2	13	5h	21	$NOEC_r$	172		177	
Folsomia candida	Clay Aluminusa	5.8	3.9	5.1	5.2	8.3	0	70	$NOEC_r$	276		297	
Folsomia candida	Sandy clay loam Woburn	5.8 5.8	3.9 3.9	5.1 5.1	5.2 5.2	8.3 8.3	0 0	70 70	$NOEC_r$	244		266	
Folsomia candida	Silt loam Ter Munck	3	8.2	7	2	5.8	7	28	$NOEC_r$	237		259	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Folsomia candida	Silty clay loam Vault de lugny	3.4 3.4	8.3 3	13 5	17 2	6.7 1.9	7 7	28 28	$NOEC_r$	534		555	
Folsomia candida	Silty clay loam Rots	4.2 4.7	20.7 37.3	13 24	14 70	15.2 35.3	7 7	28 28	$NOEC_r$	160		174	
Folsomia candida	Clay Souli	4.8 4.8	2.6 0.7	7 38	6 31	2.4 11.2	7 7	28 28	$NOEC_r$	887		921	
Folsomia candida	Silt loam Marknesse	5.2 5.4	1.2 1.4	9 51	5 21	2.5 22.6	7 7	28 28	$NOEC_r$	453		471	
Folsomia candida	Loam Barcelona	6.4 6.8	7 1.6	21 15	22 22	23.4 8.9	7 7	28 28	$NOEC_r$	139		227	
Folsomia candida	Clay Brécy	7.3 7.4	2.5 2	38 27	21 14	26.2 20	7 7	28 28	$NOEC_r$	632		663	
Folsomia candida	Loam Guadalajara	7.4 7.5	4.2 2	46 26	34 18	36.3 20.1	7 7	28 28	$NOEC_r$	538		545	
Folsomia candida	Sandy	7.5	2.4	21	88	14.3	7	28	$NOEC_r$	493		511	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	clay Hygum	7.5	2.4	50	31	23.5	7	28					
Folsomia candida	Loamy sand Wageningen A	7.5	0.6	25	7	16.9	7	28	$NOEC_r$	27.9		45.4	
Folsomia candida	Loamy sand Wageningen D	5.4	3.3	23	21	6.7	7	28	$NOEC_r$	48		65.4	
Folsomia candida	Sand Woburn salt	4.3 5	2.2 2.3	9 9	19 19	1.2 1.9	7 7	28 28	$NOEC_r$				
Folsomia candida	Sand Woburn cake	6.5 6.5	0.2 0.3	8 8	13 35	8.4 11.6	7 7	28 28	$NOEC_r$	132		167	
Eisenia fetida	loamy sand Gudow	3 3.4	8.2 8.3	7 13	2 17	5.8 6.7	7 7	28 28	$NOEC_r$	177		179	
Eisenia fetida	Sandy loam	4.7	37.3	24	70	35.3	7	28	$NOEC_r$	93.6		110.6	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	Nottingham	4.8	2.6	7	6	2.4	7	28					
Eisenia fetida	Sandy clay loam	4.8	0.7	38	31	11.2	7	28	$NOEC_r$	56.4		126	
	Zegveld	5.1	3.8	9	8	4.7	7	28					
Eisenia fetida	Loamy sand	5.2	1.2	9	5	2.5	7	28	$NOEC_r$	48.2		54	
	Kovlinge	5.4	1.4	51	21	22.6	7	28					
Eisenia fetida	Sandy clay	6.4	7	21	22	23.4	7	28	$NOEC_r$	179		210	
	Souli	6.8	1.6	15	22	8.9	7	28					
Eisenia fetida	Sandy loam	7.3	2.3	38	21	26.2	7	28	$NOEC_r$	86.8		95	
	Kovlinge	7.4	2	27	14	20	7	28					
Eisenia fetida	Loamy sand	7.4	4.2	46	34	36.3	7	28	$NOEC_r$	54.9		60	
	Montpellier	7.5	2	26	18	20.1	7	28					
Eisenia fetida	Clay	7.5	2.4	50	31	23.5	7	28	$NOEC_r$		< 91.9		< 113
	Aluminus	5.4	3.3	23	21	6.7	7	28					

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	a												
Eisenia fetida	Sandy clay loam Woburn	5 6.45			5.7 2.3	7.88 16.74	7 7	28 28	$NOEC_r$	177		199	
Eisenia fetida	Silt loam Ter Munck	5			5.7	7.88	7	28	$ED10_r$	91.8		114	
Eisenia fetida	Silty clay loam Vault de lugny	7.3	2.3	38	21	26.2	7	28	$NOEC_r$	303		324	
Eisenia fetida	Silty clay loam Rots	7.4	2	27	14	20	7	28	$NOEC_r$	289		303	
Eisenia fetida	Clay Souli	7.4	4.2	46	34	36.3	7	28	$NOEC_r$	287		321	
Eisenia fetida	Silt loam Marknesse	7.5	2	26	18	20.1	7	28	$NOEC_r$	153		171	
Eisenia fetida	Clay	7.5	2.4	50	31	23.5	7	28	$NOEC_r$	164		195	

Organism	Medium	pH	OM	clay	Cb	CEC	Equil. Period	Durat.	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	days	days		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	Brécy												
Eisenia fetida	Sandy clay	5.4	3.3	23	21	6.7	7	28	$NOEC_r$	<u>91.6</u>		<u>112.6</u>	
	Hygum												
Eisenia fetida	Lufa 2.2	5			5.7	7.88	7	28	NOEC	<u>81.9</u>		<u>87.6</u>	
Eisenia fetida	OECD	6.45			2.3	16.74	7	28	NOEC	<u>186</u>		<u>188</u>	
Eisenia andrei	Lufa 2.2	5			5.7	7.88	7	28	NOEC	<u>154</u>		<u>159</u>	
									Criel *et al.*, 2005				

ANNEX 9: Terrestrial PNEC : Overview of the NOEC values for plants

Values selected for the effects assessment are underlined. See IUCLID/RAR (2008) for reasons on the selection.

NOEC indices: m = mortality; y = yield (based on root (r), shoot (s), leaves (l), stem (st), grain (g), tubers (tub) or total plant (tp) dry weight); rep = reproductive dry matter; sb = seed biomass; ; se=seedling emergence; rl = root length. Estimated background copper concentrations and CEC** are indicated in italics.

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg$_{dw}$	cmol/kg	d	d		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
Polygonum convolvulus = Fallopia convolvulus	Field soil: clayey sand	6.4	1.7	11.1	12	*9.2*	11	105	NOEC$_m$	125		137	
Polygonum convolvulus	Field soil: clayey sand	6.4	1.7	11.1	12	*9.2*	11	34	NOEC$_{y(tp)}$	200		212	
Polygonum convolvulus	Field soil: clayey sand	6.4	1.7	11.1	12	*9.2*	11	34	NOEC$_{rep}$	200		212	
Polygonum convolvulus	Field soil: clayey sand	6.4	1.7	11.1	12	*9.2*	11	105	NOEC$_{sb}$	200		212	
									Kjær and Elmegaard, 1996				
Fallopia convolvulus	Field soil : Hygum site	6.7	4.5	13.8	22	*15.7*	84	35	NOEC$_{y(s)}$	200		222	
Fallopia convolvulus	Field soil : Hygum site	6.7	4.5	13.8	22	*15.7*	84	35	NOEC$_{y(r)}$	200		222	
									Pedersen *et al.,* 2000				

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Vigna mungo	Unspecified	6.2			*10.7*			45	$NOEC_{y(st)}$	50		60.7	
Vigna mungo	Unspecified	6.2			*10.7*			45	$NOEC_{y(l)}$	100		110.7	
									Kalyanaraman and Sivagurunathan, 1993				
Triticum aestivum	Loamy sand	7.8	0.2		*10.7*			To flag leaf stage	$NOEC_{y(s)}$	40		50.7	
Triticum aestivum	Loamy sand	7.8	0.2		*10.7*			To maturity	$NOEC_{y(g)}$	40		50.7	
									Chhibba *et al.,* 1994				
Citrus reticulata	Sandy soil	5.8	0.8		*10.7*	1.78	45	220	$NOEC_{y(s)}$		<50		<60.7
Citrus reticulata	Sandy soil	5.8	0.8		*10.7*	1.78	45	220	$NOEC_{y(s)}$		<50		<60.7
Citrus limon	Sandy soil	5.8	0.8		*10.7*	1.78	45	220	$NOEC_{y(s)}$		<50		<60.7
Citrus limon	Sandy soil	5.8	0.8		*10.7*	1.78	45	220	$NOEC_{y(s)}$		<50		<60.7

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Alva *et al.,* 1993				
Avena sativa	Loamy fine sand	6.5			*10.7*		14	49	$NOEC_{y(s)}$		<100		<110.7
Avena sativa	Loamy fine sand	7.1			*10.7*		14	49	$NOEC_{y(s)}$		<100		<110.7
Avena sativa	Loamy fine sand	6.7			*10.7*		14	49	$NOEC_{y(s)}$		<100		<110.7
Avena sativa	Loamy fine sand	6.5			*10.7*		14	49	$NOEC_{y(r)}$	100		110.7	
Avena sativa	Loamy fine sand	6.7			*10.7*		14	49	$NOEC_{y(r)}$	100		110.7	
Avena sativa	Loamy fine sand	7.1			*10.7*		14	49	$NOEC_{y(r)}$	100		110.7	
									Rhoads *et al.,* 1992				
Avena sativa	Clay soil	5.6	1.6	12	6	*8.7*		150	$NOEC_{y(g)}$	200		206	
Avena sativa	Clay soil	5.4	2.4	40	7	*24.7*		150	$NOEC_{y(g)}$	200		207	
Avena sativa	Clay soil	5.2	3.2	58	58	*34.8*		150	$NOEC_{y(g)}$	200		258	
Avena sativa	Sandy soil	5	3.4	4	4	*6*		150	$NOEC_{y(g)}$	200		204	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Avena sativa	Sandy soil	5.4	6.8	5	19	*11.3*		150	$NOEC_{y(g)}$	200		219	
Avena sativa	Sandy soil	4.6	19.4	4	21	*22*		150	$NOEC_{y(g)}$		≥ 400		≥ 421
									De Haan *et al.,* 1985				
Avena sativa	Peaty muck	7	56		86		21	31	$NOEC_{y(s)}$		≥ 4705*		≥ 4791
Glycine max	Peaty muck	7	56		86		21	46	$NOEC_{y(s)}$	1946*		2032	
									Roth *et al.,* 1971				
Lolium perenne	Loamy soil	7.5	3.1	12.8	*10.7*	*14*		102	$NOEC_{y(s)}$	95.3		106	
Lolium perenne	Loamy soil	7.5	3.1	12.8	*10.7*	*14*		102	$NOEC_{y(r)}$	95.3		106	
									Jarvis, 1978				
Hordeum vulgare	Forest soil	7.6	3.8	8	17.2	*12.4*	0	14	$NOEC_{g(s)}$ $NOEC_{g(r)}$ $NOEC_{se}$	304.8 20.2 111.8		322 37.4 129	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC: NOEC or EC_{10}	Added NOEC: Unbounded NOEC	Total NOEC: NOEC or EC_{10}	Total NOEC: Unbounded NOEC
			%	%	mg/kg$_{dw}$	cmol/kg	d	d		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
Hordeum vulgare	Artificial soil	7.8	0.3	0	0	*0.6*	0	14	$NOEC_{g(s)}$	11.2		11.2	
									$NOEC_{g(r)}$	1		1	
									$NOEC_{se}$	11		11	
									Ali *et al.*, 2004				
Hordeum vulgare	Sandy loam Nottingham	3.4	8.3	13	17	6.7	7	4	$EC10_{rl}$	58		75	
Hordeum vulgare	Loamy sand Houthalen	3.4	3.2	5	2	1.9	7	4	$EC10_{rl}$	16		18	
Hordeum vulgare	Loamy sand Rhydtalog	4.2	20.7	13	14	15.2	7	4	$NOEC_{rl}$	30		44	
Hordeum vulgare	Sandy clay loam Zegveld	4.7	37.3	24	70	35.3	7	4	$NOEC_{rl}$	80		150	
Hordeum vulgare	Loamy sand Kovlinge I	4.8	2.6	7	6	2.4	7	4	$NOEC_{rl}$	45		51	
Hordeum vulgare	Sandy clay Souli I	4.8	0.7	38	31	11.2	7	4	$NOEC_{rl}$	77		108	
Hordeum vulgare	Sandy loam Kovlinge II	5.1	3.8	9	8	4.7	7	4	$NOEC_{rl}$	37		45	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Hordeum vulgare	Loamy sand Montpellier	5.2	1.2	9	5	2.5	7	4	$EC10_{rl}$	38		43	
Hordeum vulgare	Clay Aluminosa	5.4	1.4	51	21	22.6	7	4	$NOEC_{rl}$	252		273	
Hordeum vulgare	Sandy clay loam Woburn	6.4	7	21	22	23.4	7	4	$NOEC_{rl}$	144		166	
Hordeum vulgare	Silt loam Ter Munck	6.8	1.6	15	22	8.9	7	4	$NOEC_{rl}$	55		77	
Hordeum vulgare	Silty clay loam Vault de Lugny	7.3	2.3	38	21	26.2	7	4	$NOEC_{rl}$	154		175	
Hordeum vulgare	Silty clay loam Rots	7.4	2	27	14	20	7	4	$NOEC_{rl}$	47		61	
Hordeum vulgare	Clay Souli II	7.4	4.2	46	34	36.3	7	4	$EC10_{rl}$	120		154	
Hordeum vulgare	Silt loam Marknesse	7.5	2	26	18	20.1	7	4	$NOEC_{rl}$	37		55	
Hordeum vulgare	Loam Barcelona	7.5	2.4	21	88	14.3	7	4	$NOEC_{rl}$	77		165	
Hordeum vulgare	Clay	7.5	2.4	50	31	23.5	7	4	$NOEC_{rl}$	44		75	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
	Brecy												
Hordeum vulgare	Loam Guadalajara	7.5	0.6	25	7	16.9	7	4	$NOEC_{rl}$		<37		<44
Hordeum vulgare	Sandy clay Hygum	5.4	3.3	23	21	6.7	7	4	$NOEC_{rl}$	114		135	
Hordeum vulgare	Loamy sand Wageningen A	4.3	2.2	9	19	1.2	7	4	$NOEC_{l}$		<70		<89
Hordeum vulgare	Loamy sand Wageningen D	5	2.3	9	19	1.9	7	4	$NOEC_{rl}$		>138		>157
Hordeum vulgare	Sand Woburn salt	6.5	1.7	8	13	8.4	7	4	$NOEC_{rl}$	44		57	
Hordeum vulgare	Sand Woburn cake	6.5	2.5	8	35	11.6	7	4	$NOEC_{rl}$		<50		<85
Lycopersicon esculentum	Sandy loam Nottingham	3.4	8.3	13	17	6.7	7	28	$NOEC_{y(s)}$	19		36	
Lycopersicon esculentum	Loamy sand Houthalen	3.4	3.2	5	2	1.9	7	28	$NOEC_{y(s)}$		<20		<22

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Lycopersicon esculentum	Loamy sand Rhydtalog	4.2	20.7	13	14	15.2	7	28	$NOEC_{y(s)}$	<u>357</u>		<u>371</u>	
Lycopersicon esculentum	Sandy clay loam Zegveld	4.7	37.3	24	70	35.3	7	28	$NOEC_{y(s)}$	<u>628</u>		<u>698</u>	
Lycopersicon esculentum	Loamy sand Kovlinge I	4.8	2.6	7	6	2.4	7	28	$NOEC_{y(s)}$	<u>85</u>		<u>91</u>	
Lycopersicon esculentum	Sandy clay Souli I	4.8	0.7	38	31	11.2	7	28	$NOEC_{y(s)}$	<u>43</u>		<u>74</u>	
Lycopersicon esculentum	Sandy loam Kovlinge II	5.1	3.8	9	8	4.7	7	28	$NOEC_{y(s)}$	<u>197</u>		<u>205</u>	
Lycopersicon esculentum	Sandy loam Montpellier	5.2	1.2	9	5	2.5	7	28	$NOEC_{y(s)}$		<41		<46
Lycopersicon esculentum	Clay Aluminosa	5.4	1.4	51	21	22.6	7	28	$NOEC_{y(s)}$	<u>176</u>		<u>197</u>	
Lycopersicon esculentum	Sandy clay loam Woburn	6.4	7	21	22	23.4	7	28	$NOEC_{y(s)}$	<u>91</u>		<u>113</u>	
Lycopersicon esculentum	Silt loam Ter Munck	6.8	1.6	15	22	8.9	7	28	$NOEC_{y(s)}$	<u>198</u>		<u>220</u>	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Lycopersicon esculentum	Silty clay loam Vault de Lugny	7.3	2.3	38	21	26.2	7	28	$NOEC_{y(s)}$	311		332	
Lycopersicon esculentum	Silty clay loam Rots	7.4	2	27	14	20	7	28	$NOEC_{y(s)}$	660		674	
Lycopersicon esculentum	Clay Souli II	7.4	4.2	46	34	36.3	7	28	$NOEC_{y(s)}$	628		662	
Lycopersicon esculentum	Silt loam Marknesse	7.5	2	26	18	20.1	7	28	$NOEC_{y(s)}$	227		245	
Lycopersicon esculentum	Loam Barcelona	7.5	2.4	21	88	14.3	7	28	$NOEC_{y(s)}$	315		403	
Lycopersicon esculentum	Clay Brecy	7.5	2.4	50	31	23.5	7	28	$NOEC_{y(s)}$	100		131	
Lycopersicon esculentum	Loam Guadalajara	7.5	0.6	25	7	16.9	7	28	$NOEC_{y(s)}$	313		320	
Lycopersicon esculentum	Sandy clay Hygum	5.4	3.3	23	21	6.7	7	28	$NOEC_{y(s)}$	106		127	
Lycopersicon esculentum	Loamy sand Wageningen A	4.3	0.2	9	19	1.2	7	28	$NOEC_{y(s)}$		<70		<89

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Lycopersicon esculentum	Loamy sand Wageningen D	5	0.3	9	19	1.9	7	28	$NOEC_{y(s)}$	71		90	
									Rooney et al.(2004)				
Lycopersicon esculentum	loamy fine sand (thermic Typic Paleudult)	4.8-5.5	2.7	9	*10.7*	*7.9*	14	42	$NOEC_{y(s)}$		<175		<185.7
		5.9-6.5											
		6.5-6.6	2.7	9	*10.7*	*9.2*	14	42		175		185.7	
		7.1-7.4											
			2.7	9	*10.7*	*9.6*	14	42		350		360.7	
			2.7	9	*10.7*	*10.5*	14	42		350		360.7	
									Rhoads *et al.,* (1989)				
Oryza sativa	Oxysol	6	1.5		1			28	$NOEC_{y(s)}$	66		67	
Phaseolus vulgaris	Oxysol	6	1.5		1			21	$NOEC_{y(s)}$	40		41	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Zea mays	Oxysol	6	1.5		1			21	$NOEC_{y(s)}$	56		57	
Glycine max	Oxysol	6	1.5		1			28	$NOEC_{y(s)}$	13		14	
Triticum aestivum	Oxysol	6	1.5		1			28	$NOEC_{y(s)}$	63.5		64.5	
									Fageria, 2001				
Medicago sativa	Silty loam	7.1	0.3		39				$NOEC_{y(stp}$	1,500		1,539	
Medicago sativa	clayey	7.8	1.8		37				$NOEC_{y(stp}$	1,253		1,290	
Medicago sativa	Silty loam	6.1	14.5		40				$NOEC_{y(stp}$	860		900	
Medicago sativa	Sandy loam	7.5	1.1		57				$NOEC_{y(stp}$	821		878	
Medicago sativa	loamy	5.3	12		4				$NOEC_{y(stp}$	816		820	
									Gonzales, 1991				
Zea mays	Peat soil	5.2	75		76		20	21	$NOEC_{y(s)}$		<200		<276
									McBride, 2001				

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
Senecio vulgaris	regolithic acidic	4.1	1.9	17.5	158	10.1	28	>105	$LC10_m$	67		225	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{rep}$	28		186	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{se}$	181		339	
Poa annua	regolithic acidic	4.1	1.9	17.5	158	10.1	28	210	$LC10_m$	379		537	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{rep}$	42		200	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{se}$	158		316	
Andryala integrifolia	regolithic acidic	4.1	1.9	17.5	158	10.1	28	>175	$LC10_m$	76		234	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{rep}$	/		/	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{se}$	78		236	
Hypochoeris radicata	regolithic acidic	4.1	1.9	17.5	158	10.1	28	196	$LC10_m$	192		350	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$EC10_{rep}$	192		350	
	regolithic acidic	4.1	1.9	17.5	158	10.1	28		$E10C_{se}$	181		339	

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Brun *et al.,* (2003)				
Cleopatra mandarin	fine sand (Typic Quartzipsamments) from topsoil (0-15 cm) of an orange grove	5			*10.7*		90	106	$NOEC_{y(r)}$		>200		>210.7
		5			*10.7*		90	106	$NOEC_{y(s)}$		>200		>210.7
		6			*10.7*		90	106	$NOEC_{y(r)}$	100		110.7	
		6			*10.7*		90	106	$NOEC_{y(s)}$	100		110.7	
		7			*10.7*		90	106	$NOEC_{y(r)}$		>200		>210.7
		7			*10.7*		90	106	$NOEC_{y(s)}$		>200		>210.7
Swingle citrumelo		5			*10.7*		90	106	$NOEC_{y(r)}$	50		60.7	
		5			*10.7*		90	106	$NOEC_{y(s)}$		>200		>210.7
		6			*10.7*		90	106	$NOEC_{y(r)}$	100		110.7	
		6			*10.7*		90	106	$NOEC_{y(s)}$		>200		>210.7
		7			*10.7*		90	106	$NOEC_{y(r)}$	100		110.7	
		7			*10.7*		90	106	$NOEC_{y(s)}$		>200		>210.7

Organism	Medium	pH	OM	clay	C_b	CEC	Equil. Period	Duration	Endpoint	Added NOEC		Total NOEC	
										NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
			%	%	mg/kg_{dw}	cmol/kg	d	d		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Mozaffari *et al.,* (1996)				

ANNEX 10: Terrestrial PNEC : Overview of the NOEC values for micro-organism

Values selected for the effects assessment are underlined. See IUCLID/RAR (2008) for reasons

** If the CEC was missing from a test with plants/invertebrates/micro-organisms, then it was estimated from % clay, pH and %organic matter using an experimentally derived regression model: CEC=(30+4.4 pH)*clay/100+(-34.66+29.72 pH)*OM/100; the clay is the % clay in the soil (Helling *et al.,* 1964; regression based on CEC measured at various pH values on 60 different soils; CEC refers to the soil pH).

Estimated background copper concentrations and CEC** are indicated in italics.

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	phosphatase activity	sandy loam	5.1	5.7	9	6.5		540	438		445	
$CuCl_2$	phosphatase activity	silty loam	7.4	2.4	19	22		540	170		192	
$CuCl_2$	phosphatase activity	clay	6.8	3.2	60	52		540	960		1,012	
$CuCl_2$	phosphatase activity	sandy peat	4.3	12.8	5	5.5		540	58		64	
									Doelman & Haanstra, 1989			
$CuCl_2$	urease activity	silty loam	7.4	2.4	19	22		540	340		362	
$CuCl_2$	urease activity	clay	6.8	3.2	60	52		540	520		572	
$CuCl_2$	urease activity	sandy peat	4.3	12.8	5	5.5		540	210		216	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Doelman & Haanstra, 1986			
$CuCl_2$	respiration	sand	7.7	1.6	2	4	*4.4*	490	150		154	
$CuCl_2$	respiration	sandy loam	5.1	5.7	9	6.5		301		<150		<156.5
$CuCl_2$	respiration	silty loam	7.4	2.4	19	22		630		≥ 8,000		≥ 8,022
$CuCl_2$	respiration	clay	6.8	3.2	60	52		560		≥ 8,000		≥ 8,052
$CuCl_2$	respiration	sandy peat	4.3	12.8	5	5.5	*14.5*	574	400		406	
									Doelman & Haanstra, 1984			
$CuCl_2$	arylsulphatase activity	sandy loam	5.1	5.7	9	6.5		540	347		354	
$CuCl_2$	arylsulphatase activity	silty loam	7.4	2.4	19	22		540	289		311	
$CuCl_2$	arylsulphatase activity	clay	6.8	3.2	60	52		540	2,669		2,721	
$CuCl_2$	arylsulphatase activity	sandy peat	4.3	12.8	5	5.5		540	3,323		3,329	
									Haanstra & Doelman, 1991			
$CuSO_4$	N-mineralisation	sandy loam	5.9	3.4	16	33	*13.8*	21	100		133	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuSO_4$	N-mineralisation	sandy loam	7.3	3.4	16	33	*16.3*	21		<100		<133
$CuSO_4$	nitrification	sandy loam	5.9	3.4	16	33	*13.8*	21	100		133	
$CuSO_4$	nitrification	sandy loam	7.3	3.4	16	33	*16.3*	21	100		133	
									Quraishi & Cornfield, 1973			
$CuSO_4$	ammonification (aeroob)	sandy loam	7.1	3.4	17	33	*16.5*	21	1,000		1,033	
$CuSO_4$	nitrification	sandy loam	7.1	3.4	17	33	*16.5*	21	1,000		1,033	
$CuSO_4$	ammonification (anaeroob)	sandy loam	7.1	3.4	17	33	*16.5*	21		≥ 10,000		≥ 10,033
									Premi & Cornfield, 1969			
$CuCl_2$	glutamic acid decomposition	sand	7.7	1.6	2	4		540		<55		<59

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
$CuCl_2$	glutamic acid decomposition	silty loam	7.4	2.4	19	22	16.5	540	55		77	
$CuCl_2$	glutamic acid decomposition	clay	6.8	3.2	60	52	41.6	540	55		107	
$CuCl_2$	glutamic acid decomposition	sandy peat	4.3	12.8	5	5.5	14.5	540	400		406	
									Haanstra & Doelman, 1984			
$CuSO_4$	amidase activity	clay	7.5		17.7	*10.7*		84	200		210.7	
$CuSO_4$	amidase activity	sand	7.4		2.2	*10.7*		84		≥ 2,000		≥ 2,010.7
									Hemida *et al.,* 1997			
$CuSO_4$	N-mineralisation	silty loam	6.9	2.2		9.4	*27.3*	84		<100		<109
									Chang & Broadbent, 1982			
$CuSO_4$	respiration	silty loam	6.9	2.3		9.4	*27.3*	90		<40.6		<50

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
									Chang and Broadbent (1981)			
$CuSO_4$	ethylene production	Hanford soil	7.15	8.16	18	*10.7*		7	10		20.7	
									Arshad & Frankenberger, 1991			
$CuSO_4$	microbial biomass	Lösslehm	6.1	2.7		50		30	100		150	
$CuSO_4$	microbial biomass	Auengleye	7.5	4.9		80		30	100		180	
$CuSO_4$	microbial biomass	Aueboden	7.2	3.3		50		30	100		150	
									Beck, 1981			
Cu-salt	respiration	Grassland soil	6.3	10.1	29.8	32	61.4	49		>768		>800
	Microbial biomass C	Grassland soil	6.3	10.1	29.8	32	61.4	49	<u>118</u>		<u>150</u>	
	Microbial biomass N	Grassland soil	6.3	10.1	29.8	32	61.4	49	<u>468</u>		<u>500</u>	
	N-mineralisation	Grassland soil	6.3	10.1	29.8	32	61.4	49	<u>268</u>		<u>300</u>	
									Khan and Scullion, 2002			

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
$Cu(NO_3)_2$	denitrification	silty loam	6.75	3.1	28.1	*10.7*	*22.1*	21	100		110.7	
									Bollag & Barabasz, 1979			
$CuSO_4$	ATP content	forest soil	4.5	80		*10.7*		182	337		347.7	
$CuSO_4$	ATP content	sandy loam	7.8	4.4		*10.7*		182	197		207.7	
$CuSO_4$	respiration	forest soil	4.5	80		*10.7*		182	763		773.7	
									Frostegard *et al.,* 1993			
$CuSO_4$	dehydrogenase activity	alluvial soil	7.1	1.9		3		182	10		13	
		Sandy soil	6.9	3		0.9		182		<10		<10.9
									Maliszewska *et al.,* 1985			
$CuCl_2$	respiration	sandy loam	5.2	2.4	8	*10.7*		28		<50		<60.7
									Saviozzi *et al.,* 1997			
$CuCl_2$	respiration	forest soil: sandy clay loam	7			*10.7*		20	50		60.7	
$CuCl_2$	urease activity	forest soil: sandy clay	7			*10.7*		20	200		210.7	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
		loam										
									Skujins *et al.,* 1986			
$Cu(NO3)_2$	phosphatase activity	Loam	6.1	20.4	32	*10.7*		7		<635		<640.7
$Cu(NO3)_2$	phosphatase activity	Silt loam	6.3	13.8	2.5	*10.7*		7		<635		<640.7
$Cu(NO3)_2$	sulphatase activity	loam	6.1	20.4	32	*10.7*		7		<635		<640.7
$Cu(NO3)_2$	sulphatase activity	silt loam	6.3	13.8	2.5	*10.7*		7		<635		<640.7
$Cu(NO3)_2$	substrate induced respiration	loam	6.1	20.4	32	*10.7*	*48.5*	7	<u>635</u>		<u>645.7</u>	
$Cu(NO3)_2$	substrate induced respiration	silt loam	6.3	13.8	2.5	*10.7*	*22.7*	7	<u>635</u>		<u>645.7</u>	
$Cu(NO3)_2$	substrate induced respiration	Loamy sand	5.8	7.8	3	*10.7*		7		<635		<640.7
									Speir *et al.,* 1999			

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	Nitrification	Sandy loam Nottingham	3.4	8.3	13	17	6.7	28	200		217	
$CuCl_2$	Nitrification	Sandy clay loam Zegveld	4.7	37.3	24	70	35.3	4	1200		1270	
$CuCl_2$	Nitrification	Loamy sand Kovlinge I	4.8	2.6	7	6	2.4	28	25		31	
$CuCl_2$	nitrification	Sandy clay Souli I	4.8	0.7	38	31	11.2	28	25		56	
$CuCl_2$	nitrification	Sandy loam Kovlinge II	5.1	3.8	9	8	4.7	14	50		58	
$CuCl_2$	nitrification	Clay Aluminosa	5.4	1.4	51	21	22.6	28	100		121	
$CuCl_2$	nitrification	Sandy clay loam Woburn	6.4	7	21	22	23.4	4	300		322	
$CuCl_2$	nitrification	Silt loam Ter	6.8	1.6	15	22	8.9	7	200		222	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
		Munck										
$CuCl_2$	nitrification	Silty clay loam Vault de Lugny	7.3	2.3	38	21	26.2	4	800		821	
$CuCl_2$	nitrification	Silty clay loam Rots	7.4	2	27	14	20	7	400		414	
$CuCl_2$	nitrification	Clay Souli II	7.4	4.2	46	34	36.3	14	600		634	
$CuCl_2$	nitrification	Silt loam Marknesse	7.5	2	26	18	20.1	7	800		818	
$CuCl_2$	nitrification	Loam Barcelona	7.5	2.4	21	88	14.3	11	300		388	
$CuCl_2$	nitrification	Clay Brécy	7.5	2.4	50	31	23.5	4	400		431	
$CuCl_2$	nitrification	Loam Guadalajara	7.5	0.6	25	7	16.9	7	52		59	
$CuCl_2$	nitrification	Sandy clay Hygum	5.4	3.3	23	21	6.7	14	127		148	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
$CuCl_2$	nitrification	Loamy sand Wageningen A	4.3	2.2	9	19	1.2	18		<12		<29
$CuCl_2$	nitrification	Loamy sand Wageningen D	5	2.3	9	19	1.9	18	<u>65</u>		<u>84</u>	
$CuCl_2$	nitrification	Sand Woburn salt	6.5	0.2	8	13	8.4	14	<u>100</u>		<u>113</u>	
$CuCl_2$	nitrification	Sand Woburn cake	6.5	0.3	8	35	11.6	14	<u>50</u>		<u>85</u>	
$CuCl_2$	Glucose respiration	Loamy sand Gudow	3	8.2	7	2	5.8	4	<u>1200</u>		<u>1202</u>	
$CuCl_2$	Glucose respiration	Sandy loam Nottingham	3.4	8.3	13	17	6.7	4	<u>150</u>		<u>167</u>	
$CuCl_2$	Glucose respiration	Loamy sand Houthalen	3.4	3	5	2	1.9	4	<u>50</u>		<u>52</u>	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	Glucose respiration	Loamy sand Rhydtalog	4.2	20.7	13	14	15.2	4	600		614	
$CuCl_2$	Glucose respiration	Sandy clay loam Zegveld	4.7	37.3	24	70	35.3	4	100		170	
$CuCl_2$	Glucose respiration	Loamy sand Kovlinge I	4.8	2.6	7	6	2.4	4	25		31	
$CuCl_2$	Glucose respiration	Sandy clay Souli I	4.8	0.7	38	31	11.2	4	100		131	
$CuCl_2$	Glucose respiration	Sandy loam Kovlinge II	5.1	3.8	9	8	4.7	4	50		58	
$CuCl_2$	Glucose respiration	Loamy sand Montpellier	5.2	1.2	9	5	2.5	4	25		30	
$CuCl_2$	Glucose respiration	clay Aluminosa	5.4	1.4	51	21	22.6	4	400		421	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
$CuCl_2$	Glucose respiration	Sandy clay loam Woburn	6.4	7	21	22	23.4	4	300		321	
$CuCl_2$	Glucose respiration	Silt loam Ter Munck	6.8	1.6	15	22	8.9	4	50		72	
$CuCl_2$	Glucose respiration	Silt clay loam Vault de Lugny	7.3	2.3	38	21	26.2	4	102		123	
$CuCl_2$	Glucose respiration	Silt clay loam Rots	7.4	2	27	14	20	4	200		214	
$CuCl_2$	Glucose respiration	Clay Souli II	7.4	4.2	46	34	36.3	4	89		123	
$CuCl_2$	Glucose respiration	Silt loam Marknesse	7.5	2	26	18	20.1	4	23		41	
$CuCl_2$	Glucose respiration	loam Barcelona	7.5	2.4	21	88	14.3	4	300		388	
$CuCl_2$	Glucose respiration	clay Brécy	7.5	2.4	50	31	23.5	4	200		231	
$CuCl_2$	Glucose respiration	loam Guadalajara	7.5	0.6	25	7	16.9	4	50		57	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	Glucose respiration	Sandy clay Hygum	5.4	3.3	23	21	6.7	4	170		191	
$CuCl_2$	Glucose respiration	Loamy sand Wageningen A	4.3	2.2	9	19	1.2	4	12		31	
$CuCl_2$	Glucose respiration	Loamy sand Wageningen D	5	2.3	9	19	1.9	4	25		44	
$CuCl_2$	Glucose respiration	Sand Woburn salt	6.5	0.2	8	13	8.4	4	100		113	
$CuCl_2$	Glucose respiration	Sand Woburn cake	6.5	0.3	8	35	11.6	4	27		62	
$CuCl_2$	Maize respiration	Loamy sand Gudow	3	8.2	7	2	5.8	28	2400		2402	
$CuCl_2$	Maize respiration	Sandy loam Nottingham	3.4	8.3	13	17	6.7	28	1200		1217	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	Maize respiration	Loamy sand Rhydtalog	4.2	20.7	13	14	15.2	28	1200		1214	
$CuCl_2$	Maize respiration	Sandy clay loam Zegveld	4.7	37.3	24	70	35.3	28	300		370	
$CuCl_2$	Maize respiration	Loamy sand Kovlinge I	4.8	2.6	7	6	2.4	28	50		56	
$CuCl_2$	Maize respiration	Sandy clay Souli II	4.8	0.7	38	31	11.2	28	200		231	
$CuCl_2$	Maize respiration	Sandy loam Kovlinge II	5.1	3.8	9	8	4.7	28	100		108	
$CuCl_2$	Maize respiration	Loamy sand Montpellier	5.2	1.2	9	5	2.5	28	50		55	
$CuCl_2$	Maize respiration	Clay Aluminosa	5.4	1.4	51	21	22.6	28	400		421	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg_{dw}	cmol/kg		mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}	mg/kg_{dw}
$CuCl_2$	Maize respiration	Sandy clay loam Woburn	6.4	7	21	22	23.4	28	150		172	
$CuCl_2$	Maize respiration	Silt loam Ter Munck	6.8	1.6	15	22	8.9	28	50		72	
$CuCl_2$	Maize respiration	Silty clay loam Vault de Lugny	7.3	2.3	38	21	26.2	28	400		421	
$CuCl_2$	Maize respiration	clay Souli II	7.4	4.2	46	34	36.3	28	600		634	
$CuCl_2$	Maize respiration	Silt loam Marknesse	7.5	2	26	18	20.1	28	150		168	
$CuCl_2$	Maize respiration	Loam Barcelona	7.5	2.4	21	88	14.3	28	150		238	
$CuCl_2$	Maize respiration	Sandy clay Hygum	5.4	3.3	23	21	6.7	28		>804		>825
$CuCl_2$	Maize respiration	Loamy sand Wageningen A	4.3	2.2	9	19	1.2	28	51		70	

Test substance	Process	Medium	pH	%OM	%clay	C_b	CEC	Duration	Added NOEC		Total NOEC	
									NOEC or EC_{10}	Unbounded NOEC	NOEC or EC_{10}	Unbounded NOEC
						mg/kg$_{dw}$	cmol/kg		mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$	mg/kg$_{dw}$
$CuCl_2$	Maize respiration	Loamy and Wageningen D	5	2.3	9	19	1.9	28	83		102	
$CuCl_2$	Maize respiration	Sand Woburn salt	6.5	0.2	8	13	8.4	28		>200		>213
$CuCl_2$	Maize respiration	Sand Woburn cake	6.5	0.3	8	35	11.6	28	100		135	
									Smolder and Oorts, 2004			

ANNEX 11:Copper compound environmental exposure assessment – EUSES INPUT

Input data: EUSES		
Substance properties*		
SUBSTANCE IDENTIFICATION	Copper	
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight	99	[g.mol-1]
Melting point	350	[oC]
Boiling point	350	[oC]
Vapour pressure at test temperature	1.00E-09	[Pa]
Temperature at which vapour pressure was measured	20	[oC]
Vapour pressure at 25 [oC]	1.41E-09	[Pa]
Octanol-water partition coefficient	N/A	[log10]
Water solubility at test temperature	1.00E+05	[mg.l-1]
Temperature at which solubility was measured	20	[oC]
Water solubility at 25 [oC]	1.07E+05	[mg.l-1]
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS		
SOLIDS-WATER		
Chemical class for Koc-QSAR	Non-hydrophobics	
Organic carbon-water partition coefficient	N/A	[l.kg-1]
Solids-water partition coefficient in soil	2.12E+03	[l.kg-1]
Solids-water partition coefficient in sediment	2.44E+04	[l.kg-1]
Solids-water partition coefficient suspended matter	3.02E+04	[l.kg-1]
Solids-water partition coefficient in raw sewage sludge*	3.02E+04	[l.kg-1]
Solids-water partition coefficient in settled sewage sludge	N/A	[l.kg-1]
Solids-water partition coefficient in activated sewage sludge	N/A	[l.kg-1]
Solids-water partition coefficient in effluent sewage sludge	N/A	[l.kg-1]
Soil-water partition coefficient	3.18E+03	[m3.m-3]
Suspended matter-water partition coefficient	7.56E+03	[m3.m-3]
Sediment-water partition coefficient	1.22E+04	[m3.m-3]

N/A – not applicable for metals or not available
*Note: Degradation is not relevant for metals

ANNEX 12:Generic exposure mapping for copper compound production

Summary information

ES title	ES breakdown	Contributive ES (Short description of process or activity)	Use descriptors: Sector of use (SU)	Use descriptors: Process Category (PROC)	Use descriptors: Product category (PC)	Use descriptors: Environmental Release Category (ERC)	Life Cycle Stage(s): Manufacture	Life Cycle Stage(s): Formulation	Life Cycle Stage(s): End use: Industrial	Life Cycle Stage(s): End use: Professional	Life Cycle Stage(s): End use: Consumer	Level of containment
Production of Copper compound	**Compound manufacture**	Production processes	SU 9, 8 (10)	PROC 4 / PROC 5	N/A	ERC1	x		X			open/closed
		Chemical synthesis; i.e. oxidating	SU 9, 8 (10)	PROC 1 / PROC 3	N/A	ERC1	x		X			open/closed
		Precipitating	SU 9, 8 (10)	PROC 3	N/A	ERC1	x		X			open/closed
		Centrifugation	SU 9, 8 (10)	PROC 3	N/A	ERC1	x		X			open/closed
		Drying	SU 9, 8 (10)	PROC 2 / PROC 3	N/A	ERC1	x		X			open/closed
		Mixing	SU 9, 8 (10)	PROC 2 / PROC 3	N/A	ERC1	x		X			open/closed
		Forming	SU 9, 8 (10)	PROC 14	N/A	ERC1	x		X			open/closed
		Calcination	SU 9, 8 (10)	PROC 1 / PROC 3	N/A	ERC1	X		X			open/closed
		Impregnation	SU 9, 8 (10)	PROC 3	N/A	ERC1	X		X			open/closed
		Compaction, tabletting and screening	SU 9, 8 (10)	PROC 2 / PROC 3	N/A	ERC1	X		X			open/closed
	Fresh product packaging	Filling operations (transfer to transport containers)	SU 9, 8 (10)	PROC 2 / PROC 3 / PROC 4 / PROC 8b / PROC 9	N/A	ERC1	X		X			open/closed
	Maintenance & cleaning	Maintenance & cleaning (Production)	SU 9, 8 (10)	PROC 26	N/A	ERC1	X		X			open/closed

Environmental information

ES title	ES breakdown	Contributative ES (Short description of process or activity)	E Exposure Modifier						E RMM			
			Duration and frequency (exposure time)	Work pattern		Compartments			Air Filtration	Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)	Waste treatment	Waste water treatment
						Air	Soil	Water				
Production of Copper compound	Compound manufacture	Production processes	365			x		x				x
		Chemical synthesis; oxidating	365			x		x				x
		Precipitating	365			x		x				x
		Centrifugation	365			x		x				x
		Drying	365			x		x				x
		Mixing	365			x		x				x
		Forming	365			x		x				x
		Calcination	365			x		x				x
		Impregnation	365			x		x				x
		Compaction, tabletting and screening	365			x						
	Fresh product packaging	filling operations (transfer to transport containers)	365			x		x				x
	Maintenance & cleaning	Maintenance & cleaning (Production)	365			x		x				x

Worker information

ES title	ES breakdown	Contributative ES (Short description of process or activity)	HH Exposure routes			HH Exposure Modifier				Indoor		PPE			
			Inhalation	Dermal	Ingestion	Duration and frequency (exposure time)	Work pattern		Outdoor or Indoor Operation	with GEV	with LEV	Respiratory protection	Eye protection (goggles)	Protection of hands (gloves)	Other technical measures
Production of Copper compound	Compound manufacture	Receipt of RM	x	x		8h	8h/d	220 days/year	Outdoor / indoor		x	To be determined			
		Transfer of RM to intermediate storage	x	x		8h	8h/d	220 days/year	Indoor		x				
		Storage of RM	x	x		8h	8h/d	220 days/year	Outdoor / indoor		x				
		Transfer of RM to process	x	x		8h	8h/d	220 days/year	Indoor		x				
		Production processes	x	x		8h	8h/d	220 days/year	Indoor		x				
		Chemical synthesis; oxidating	x	x		8h	8h/d	220 days/year	Indoor		x				
		Precipitating	x	x		8h	8h/d	220 days/year	Indoor		x				
		Centrifugation	x	x		8h	8h/d	220 days/year	Indoor		x				
		Drying	x	x		8h	8h/d	220 days/year	Indoor		x				
		Mixing	x	x		8h	8h/d	220 days/year	Indoor		x				
		Forming	x	x		8h	8h/d	220 days/year	Indoor		x				
		Calcination	x	x		8h	8h/d	220 days/year	Indoor		x				
		Impregnation	x	x		8h	8h/d	220 days/year	Indoor		x				
		Compaction, tabletting and screening	x	x		8h	8h/d	220 days/year	Indoor		x				
	Fresh product packaging	filling operations (transfer to transport containers)	x	x		8h	8h/d	220 days/year	Indoor		x				
	Maintenance & cleaning	Maintenance & cleaning (Production)	x	x		8h	8h/d	220 days/year	Indoor		x				

ANNEX 13:Catalysts sector mapping information – According to ECMA

a) Summary information

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors				Life Cycle Stage(s)					Level of containment
			Sector of use (SU)	Process Category (PROC)	Product category (PC)	Environ-mental Release Category (ERC)	Manufacture	Formulation	End use			
									Industrial	Professional	Consumer	
Catalyst Manufacture	RM delivery & handling	Bulk delivery of solid RM (e.g. tank, silo, car)	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 8b			x	x	X			closed
		Semi-bulk delivery of solid RM (bags, drums...)	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 8b			x	x	X			closed
		Delivery of liquid RM	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 8b			x	x	X			closed
		Storage of solid RM	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 2			x	x	X			closed

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors: Sector of use (SU)	Use descriptors: Process Category (PROC)	Use descriptors: Product category (PC)	Use descriptors: Environ-mental Release Category (ERC)	Life Cycle Stage(s): Manufacture	Life Cycle Stage(s): Formulation	End use: Industrial	End use: Professional	End use: Consumer	Level of containment
		Storage of liquid RM	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 2			x	x	X			closed
		Transfer of RM from delivery containers into hopper or central supply system	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC1 / ERC6A	x	x	X			open
				PROC 8b			x	x	X			closed
		Conveying RM (transport to machine for processing)	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			open
				PROC 8b			x	x	X			closed
	Catalyst Manufacture	Dissolving	SU 9, 8 (10)	PROC 3	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			closed
		Precipitating	SU 9, 8 (10)	PROC 3	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			closed
		Filtrating	SU 9, 8 (10)	PROC 4	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			open
			SU 9, 8 (10)	PROC 2 / PROC 3	PC19, 21	ERC1 / ERC2 / ERC6A	x	x	X			closed
		Drying	SU 9, 8 (10)	PROC 2 / PROC 3	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			closed

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors: Sector of use (SU)	Use descriptors: Process Category (PROC)	Use descriptors: Product category (PC)	Use descriptors: Environ-mental Release Category (ERC)	Life Cycle Stage(s): Manufacture	Life Cycle Stage(s): Formulation	End use: Industrial	End use: Professional	End use: Consumer	Level of containment
		Mixing	SU 9, 8 (10)	PROC 3	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			closed
		Forming	SU 9, 8 (10)	PROC 14	PC19, 20	ERC1 / ERC2 / ERC6A	x	x	X			open
		Impregnation continuous	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	x	x	X			closed
		Impregnation batch	SU 9, 8 (10)	PROC 3 / PROC 4	PC19, 20	ERC1 / ERC6A	x	x	X			open
		Calcination (oxidation at elevated temperatures)	SU 9, 8 (10)	PROC 2 / PROC 1	PC19, 20	ERC1 / ERC6A	X					closed
		Reduction	SU 9, 8 (10)	PROC 1	PC19, 20	ERC1 / ERC6A	X					closed
		Stabilisation	SU 9, 8 (10)	PROC 1 / PROC 2 / PROC 3	PC19, 20	ERC1 / ERC2 / ERC6A	X	x				closed
		screening (adjusting particle size distribution)	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC2 / ERC6A	X	x				open
				PROC 1			X	x				closed
	Fresh Catalyst Packaging	filling operations (transfer to transport containers)	SU 9, 8 (10)	PROC 9	PC19, 20	ERC1 / ERC2 / ERC6A	X	x				open
				PROC 9			X	x				closed

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors				Life Cycle Stage(s)					Level of containment
			Sector of use (SU)	Process Category (PROC)	Product category (PC)	Environ-mental Release Category (ERC)	Manufacture	Formulation	End use			
									Industrial	Professional	Consumer	
	Maintenance & Cleaning (manufacturing)	maintenance	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	X	x				open
		cleaning	SU 9, 8 (10)	PROC2	PC19, 20	ERC1 / ERC6A	X	x				open
	Fresh catalyst storage	final product storage	SU 9, 8 (10)	PROC2	PC19, 20	ERC1 / ERC6A	X	x	X			open
				PROC 2			X	x	X			closed
Catalyst use	Reactor Loading	Batch loading (including inspection)	SU 8	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			open
				PROC 8b					X			closed
		Continuous loading	SU 8	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
		Liquid systems	SU 8	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
	Use	Catalyst use in reactor	SU 8	PROC 1	PC19, 20	ERC4, ERC6A, ERC6B	X		X			closed
	In-situ Regeneration	Optional	SU 8	PROC 1 / PROC 3	PC19, 20	ERC4, ERC6A, ERC6B	X					closed
	Reactor Unloading	Batch unloading	SU 8	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			open

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors				Life Cycle Stage(s)					Level of containment
			Sector of use (SU)	Process Category (PROC)	Product category (PC)	Environ-mental Release Category (ERC)	Manufacture	Formulation	End use: Industrial	End use: Professional	End use: Consumer	
		Continuous unloading	SU 8	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
	Maintenance	Maintenance	SU 8	PROC 2	PC19, 20	ERC4, ERC6A, ERC6B	X		X			open
	Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage	SU 8	PROC2	PC19, 20	ERC4, ERC6A, ERC6B			X			open
				PROC 2					X			closed
Ex-situ regeneration	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	SU 9, 8 (10)	PROC 2	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
		Storage of spent catalyst	SU 9, 8 (10)	PROC 2	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
		Emptying of containers of spent catalyst	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			open
		Conveying spent catalyst	SU 9, 8 (10)	PROC 8b	PC19, 20	ERC4, ERC6A, ERC6B			X			open
				PROC 8b					X			closed
	Regeneration	Drying	SU 9, 8 (10)	PROC 2 / PROC 3 / PROC 4	PC19, 20	ERC4, ERC6A, ERC6B			X			closed
		Calcination (oxidation at elevated	SU 9, 8 (10)	PROC 2 / PROC 1	PC19, 20	ERC4, ERC6A,	X					closed

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors: Sector of use (SU)	Use descriptors: Process Category (PROC)	Use descriptors: Product category (PC)	Use descriptors: Environ-mental Release Category (ERC)	Life Cycle Stage(s): Manufacture	Life Cycle Stage(s): Formulation	End use: Industrial	End use: Professional	End use: Consumer	Level of containment
		temperatures)				ERC6B						
		Screening (adjusting particle size distribution)	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	X					open
				PROC 2			X					closed
	Regenerated Catalyst Packaging	Filling operations (transfer to transport containers)	SU 9, 8 (10)	PROC 9	PC19, 20	ERC1 / ERC6A	X					open
	Maintenance & Cleaning (regeneration)	Maintenance	SU 9, 8 (10)	PROC 2	PC19, 20	ERC1 / ERC6A	X					open
		Cleaning	SU 9, 8 (10)	PROC2	PC19, 20	ERC1 / ERC6A	X					open
	Regenerated catalyst storage	Regenerated catalyst storage	SU 9, 8 (10)	PROC2	PC19, 20	ERC1 / ERC6A			X			closed
Recycling	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)		PROC 2	PC19, 20	ERC1 / ERC6A			X			closed
		Storage of spent catalyst		PROC 2	PC19, 20	ERC1 / ERC6A			X			closed
		Emptying of containers of spent catalyst		PROC 8b	PC19, 20	ERC1 / ERC6A			X			open
		Conveying spent catalyst		PROC 8b	PC19, 20	ERC1 / ERC6A			X			open
	Pyrometallurgical recycling	Screening		PROC 2	PC19, 20	ERC1 / ERC6A	X					open

ES title	ES breakdown	Contributative ES (Short description of process or activity)	Use descriptors				Life Cycle Stage(s)					Level of containment
			Sector of use (SU)	Process Category (PROC)	Product category (PC)	Environ-mental Release Category (ERC)	Manufacture	Formulation	End use			
									Industrial	Professional	Consumer	
[redacted]		Calcination (oxidation at elevated temperatures)		PROC 2 / PROC 1	PC19, 20	ERC1 / ERC6A	X					closed
		Smelting		PROC 22		ERC1 / ERC6A	X					closed
		Filling		PROC 8b		ERC1 / ERC6A	X					open
		Maintenance		PROC 2		ERC1 / ERC6A	X					open
		Cleaning		PROC 2		ERC1 / ERC6A	X					open
	Hydrometallurgical recycling	No information										
	Product storage	Final product storage	SU 9, 8 (10)	PROC2	PC19, 20		X					open

b) Environmental Exposure information

ES title	ES breakdown	Contributative ES (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	Work pattern		Compartments			Air Filtration	Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)	Waste treatment	Waste water treatment
						Air	Soil	Water				
Catalyst Manufacture	RM delivery & handling	Bulk delivery of solid RM (e.g. tank, silo, car)	2h/week to 1h/month			Yes	Yes	No	Yes		particulates from air filtration	
			2h/week to 1h/month			Yes	Yes	No				
		Semi-bulk delivery of solid RM (bags, drums...)	2h/week to 1h/month			Yes	Yes	No	Yes		particulates from air filtration	
			2h/week to 1h/month			Yes	Yes	No				
		Delivery of liquid RM	2h/week to 1h/month			Yes	Yes	No				
			2h/week to 1h/month			Yes	Yes	No				
		Storage of solid RM	24h/24	7d/7	350d/y	Yes	No	No				
			24h/24	7d/7	350d/y	No	No	No				
		Storage of liquid RM	24h/24	7d/7	350d/y	Yes	No	Yes				
			24h/24	7d/7	350d/y	No	No	Yes				

ES title	ES breakdown	Contributative ES (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	Work pattern		Compartments: Air	Soil	Water	Air Filtration	Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)	Waste treatment	Waste water treatment
		Transfer of RM from delivery containers into hopper or central supply system	5 min to 2*3h/d	7d/7	350d/y	Yes	No	No	Yes		packaging, particulates from air filtration	
			5 min to 2*3h/d	7d/7	350d/y	Yes	No	No				
		Conveying RM (transport to machine for processing)	24h/24	7d/7	350d/y	Yes	No	No	Yes		particulates from air filtration	
			24h/24	7d/7	350d/y	No	No	No				
	Catalyst Manufacture	Dissolving	NA	NA	NA	NA	NA	NA	NA			
		Precipitating	NA	NA	NA	NA	NA	NA	NA			
		Filtrating	24h/24	7d/7	350d/y	No	No	Yes			filtrate	Yes (specify type)
			24h/24	7d/7	350d/y	No	No	Yes			filtrate	Yes (specify type)
		Drying	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	

ES title	ES breakdown	Contributative ES (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	Work pattern		Compartments			Air Filtration	Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)	Waste treatment	Waste water treatment
						Air	Soil	Water				
		Mixing	NA	NA	NA	NA	NA	NA	NA			
		Forming	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	
		Impregnation continuous	NA	NA	NA	NA	NA	NA	NA			
		Impregnation batch	24h/24	7d/7	350d/y	Yes	No	No	Yes		particulates from air filtration	Yes (specify type)
		Calcination (oxidation at elevated temperatures)	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	
		Reduction	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	
		Stabilisation	24h/24	7d/7	350d/y	Yes	No	No		Yes	particulates from air filtration	
		screening (adjusting particle size distribution)	24h/24	7d/7	350d/y	Yes	No	No	Yes		undersized/oversized	
			24h/24	7d/7	350d/y	No	No	No			undersized/oversized	
	Fresh Catalyst Packaging	filling operations (transfer to transport containers)	24h/24	7d/7	350d/y	Yes	No	No	Yes		particulates from air	

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	Work pattern		Compartments			Air Filtration	Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)	Waste treatment	Waste water treatment
						Air	Soil	Water				
											filtration	
			24h/24	7d/7	350d/y	No	No	No				
	Maintenance & Cleaning (manufacturing)	maintenance				Yes	Yes	Yes			yes	
		cleaning	1 h/d	7d/w	350d/y	Yes	Yes	Yes			liquid & solid residues	
	Fresh catalyst storage	final product storage	24h/24	7d/7	350d/y	Yes	No	No				
			24h/24	7d/7	350d/y	No	No	No				
Catalyst use	Reactor Loading	Batch loading (including inspection)	24h/d	2d/y	from 3 months to 10 years	Yes	Yes	No	Sometimes	No	Packaging	No
			24h/d	2d/y	from 3 months to 10 years	No	No	No	Yes	No	Packaging	No
		Continuous loading										
		Liquid systems	NA	NA	NA	NA	NA	NA				
	Use	Catalyst use in reactor	NA	NA	NA	NA	NA	NA				

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	**E Exposure Modifier**						**E RMM**			
			duration and frequency (exposure time)	**Work pattern**		**Compartments**			**Air Filtration**	**Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)**	**Waste treatment**	**Waste water treatment**
						Air	**Soil**	**Water**				
	In-situ Regeneration	Optional	24h/d	2d/y to 7d/7	every 2 years to 365d/y	Yes	No	No	Yes	Sometimes	yes	Yes
	Reactor Unloading	Batch unloading	24h/d	2d/y	from 3 months to 10 years	Yes	Yes	No	Sometimes	No	yes	No
		Continuous unloading	24h/d	7d/w	350d/y	Yes	Yes	No			yes	
	Maintenance	Maintenance			from 3 months to 10 years	Yes	Yes	Yes			yes	
	Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage	24h/24	7d/7	350d/y	Yes	No	No				
			24h/24	7d/7	350d/y	No	No	No				
Ex-situ regeneration	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	8h/day	5d/w	220d/y	Yes	Yes	No				
		Storage of spent catalyst	24h/24	7d/7	350d/y	No	No	No				
		Emptying of containers of spent catalyst	3*2h/d	7d/7	350d/y	Yes	No	No	Yes	NA	packaging, particulates from air filtration	NA
		Conveying spent catalyst	24h/24	7d/7	350d/y	Yes	No	No	Yes	NA	particulates from air filtration	NA

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	**E Exposure Modifier**						**E RMM**			
			duration and frequency (exposure time)	**Work pattern**		**Compartments**			**Air Filtration**	**Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)**	**Waste treatment**	**Waste water treatment**
						Air	**Soil**	**Water**				
			24h/24	7d/7	350d/y	No	No	No	NA	NA	NA	NA
	Regeneration	Drying	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	Yes
		Calcination (oxidation at elevated temperatures)	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	Yes
		Screening (adjusting particle size distribution)	24h/24	7d/7	350d/y	Yes	No	No	Yes	NA	undersized/oversized	NA
			24h/24	7d/7	350d/y	No	No	No	Yes	NA	undersized/oversized	NA
	Regenerated Catalyst Packaging	Filling operations (transfer to transport containers)	24h/24	7d/7	350d/y	Yes	No	No	Yes	NA	particulates from air filtration	NA
	Maintenance & Cleaning (regeneration)	Maintenance	24h/24	7d/7	350d/y	Yes	Yes	Yes	NA	NA	yes	NA
		Cleaning	1 h/d	7d/w	350d/y	Yes	Yes	Yes	NA	NA	liquid & solid residues	Yes
	Regenerated catalyst storage	Regenerated catalyst storage	24h/24	7d/7	350d/y	No	No	No	NA	NA	NA	NA
Recycling	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	8h/day	5d/w	220d/y	Yes	No	No	NA	NA	NA	NA

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	**Work pattern**		**Compartments: Air**	**Soil**	**Water**	**Air Filtration**	**Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)**	**Waste treatment**	**Waste water treatment**
[redacted]		Storage of spent catalyst	24h/24	7d/7	350d/y	No	No	No	NA	NA	NA	NA
		Emptying of containers of spent catalyst	3*2h/d	7d/7	350d/y	Yes	No	No	Yes	NA	packaging, particulates from air filtration	NA
		Conveying spent catalyst	24h/24	7d/7	350d/y	Yes	No	No	Yes	NA	particulates from air filtration	NA
	Pyrometallurgical recycling	Screening	24h/24	7d/7	350d/y	Yes	No	No	Yes	NA	oversized, particulates from air filtration	NA
		Calcination (oxidation at elevated temperatures)	24h/24	7d/7	350d/y	Yes	No	No	Yes	Yes	particulates from air filtration	Yes
		Smelting	24h/24	7d/7	350d/y	Yes	No	No	Yes		particulates from air filtration	
		Filling	24h/24	7d/7	350d/y	Yes	No	No	Yes		particulates from air filtration	
		Maintenance	24h/24	7d/7	350d/y	Yes	Yes	Yes	NA	NA	yes	NA
		Cleaning	1 h/d	7d/7	350d/y	Yes	Yes	Yes	NA	NA	liquid & solid residues	Yes

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	E Exposure Modifier						E RMM			
			duration and frequency (exposure time)	**Work pattern**		**Compartments**			**Air Filtration**	**Gas Treatment (scrubbers, solvent recovery, incineration, DeNOx)**	**Waste treatment**	**Waste water treatment**
						Air	**Soil**	**Water**				
[redacted]	Hydrometallurgical recycling	No information										
	Product storage	Final product storage	NA	NA	NA	No	No	No	NA	NA	NA	NA

c) Worker exposure information

ES title	ES breakdown	Contributative ES (Short description of process or activity)	HH Exposure routes			HH Exposure Modifier				Indoor		PPE			
			Inhalation	Dermal	Ingestion	Duration and frequency (exposure time)	Work pattern		Outdoor or Indoor Operation	with GEV	with LEV	Respiratory protection	Eye protection (LEP/goggles)	Protection of hands (gloves)	Other technical measures
Catalyst Manufacture	RM delivery & handling	Bulk delivery of solid RM (e.g. tank, silo, car)	X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	Yes	No	No	Yes	Yes	
			X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	Yes	No	No	Yes	Yes	
		Semi-bulk delivery of solid RM (bags, drums...)	X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	Yes	No	No	Yes	Yes	packaging type
			X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	Yes	No	No	Yes	Yes	
		Delivery of liquid RM	X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	No	No	No	Yes	Yes	bulk, drums
			X	X	NA	2h/week to 1h/month	8h/shift	220 days/year	Both	No	No	No	Yes	Yes	
		Storage of solid RM	X	X	NA	NA	NA	NA	Both	Yes	No	No	Sometimes	Sometimes	Packaging type (bulk, bags,)
			X	X	NA	NA	NA	NA	Both	Yes	No	No	Sometimes	Sometimes	
		Storage of liquid RM	X	X	NA	NA	NA	NA	Both	No	No	NA	NA	NA	bulk, drums
			X	X	NA	NA	NA	NA	Both	No	No	NA	NA	NA	
		Transfer of RM from delivery containers into	X	X	NA	5 min to 4h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	bulk, bags, drums

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	**HH Exposure routes**			**HH Exposure Modifier**						**PPE**			
			Inhalation	**Dermal**	**Ingestion**	**Duration and frequency (exposure time)**	**Work pattern**		**Outdoor or Indoor Operation**	**Indoor** with GEV	**Indoor** with LEV	**Respiratory protection**	**Eye protection (LEP/goggles)**	**Protection of hands (gloves)**	**Other technical measures**
		hopper or central supply system	X	X	NA	NA	NA	NA	Indoor	No	No	Yes	No	Yes	
		Conveying RM (transport to machine for processing)	X	X	NA	0.25h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	
			X	X	NA	NA	NA	NA	Indoor	No	No	Yes	No	Yes	
	Catalyst Manufacture	Dissolving	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Precipitating	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Filtrating	X	X	NA	0.5-2h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	No	Yes	Yes	wet process so limited dust
			X	X	NA	0.5-2h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	No	Yes	Yes	wet process so limited dust
		Drying	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Mixing	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Forming	X	X	NA	2h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	No	Yes	Yes	
		Impregnation continuous	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	**HH Exposure routes**			**HH Exposure Modifier**						**PPE**			
			Inhalation	**Dermal**	**Ingestion**	**Duration and frequency (exposure time)**	**Work pattern**		**Outdoor or Indoor Operation**	**Indoor**		**Respiratory protection**	**Eye protection (LEP/goggles)**	**Protection of hands (gloves)**	**Other technical measures**
										with GEV	**with LEV**				
		Impregnation batch	X	X	NA	0.5-2h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Sometimes	Yes	Yes	can be dusty or wet process
		Calcination (oxidation at elevated temperatures)	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Reduction	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Stabilisation	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		screening (adjusting particle size distribution)	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	
			NA	NA	NA	NA	NA	NA	Indoor	Yes	Yes				
	Fresh Catalyst Packaging	filling operations (transfer to transport containers)	X	X	NA	4h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	bulk, bags, drums
			NA	NA	NA	NA	NA	NA	Indoor	Yes	Yes				
	Maintenance & Cleaning (manufacturing)	maintenance	X	X	NA	variable from 0 to whole shift depending on function (operator or maintenance personnel)			Indoor	Yes	No	Sometimes	Yes	Yes	Suits, flushing, rinsing, purging, isolation (blinding)
		cleaning	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Yes	No	Yes	Yes	Yes	flushing, rinsing, purging, isolation

ES title	ES breakdown	Contributative ES (Short description of process or activity)	HH Exposure routes			HH Exposure Modifier						PPE			
			Inhalation	Dermal	Ingestion	Duration and frequency (exposure time)	Work pattern		Outdoor or Indoor Operation	Indoor		Respiratory protection	Eye protection (LEP/goggles)	Protection of hands (gloves)	Other technical measures
										with GEV	with LEV				
															(blinding)
	Fresh catalyst storage	final product storage	NA	NA	NA	NA	NA	NA	Both	Yes	No				Packaging type (bulk, bags,)
			NA	NA	NA	NA	NA	NA	Both	Yes	No				
Catalyst use	Reactor Loading	Batch loading (including inspection)	X	X	NA	8h-12/shift	8h-12/shift	220d/y	Both	No	May be	Yes	Yes	Yes	inside reactor: respirator with independent air supply, outside on platform: P3-mask
			X	X	NA	8h-12/shift	8h-12/shift	220d/y	Outdoor	No	Yes	Yes	Yes	Yes	inside reactor: respirator with independent air supply, outside on platform: P3-mask
		Continuous loading	X	X	NA	1h to 2h/wk	8h/shift	220d/y	Outdoor	No	No				Filling under vacuum continuously as demanded.

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	HH Exposure routes			HH Exposure Modifier						PPE			
			Inhalation	Dermal	Ingestion	Duration and frequency (exposure time)	Work pattern		Outdoor or Indoor Operation	Indoor		Respiratory protection	Eye protection (LEP/goggles)	Protection of hands (gloves)	Other technical measures
										with GEV	with LEV				
		Liquid systems	NA	NA	NA	NA	NA	NA		No	No				
	Use	Catalyst use in reactor	NA	NA	NA	NA	NA	NA	Outdoor	No	No	NA	NA	NA	
	In-situ Regeneration	Optional	NA	NA	NA	NA	NA	NA	Outdoor	No	No	NA	NA	NA	
	Reactor Unloading	Batch unloading	X	X	NA	8h-12/shift	8h-12/shift	220d/y	Outdoor	No	May be	Yes	Yes	Yes	gravity or vacuum, under N2
		Continuous unloading	X	X	NA	NA	NA	NA	Outdoor	No	No	NA	NA	NA	
	Maintenance	Maintenance	X	X	NA	variable from 0 to whole shift depending on function (operator or maintenance personnel)			Indoor	Yes	No	Sometimes	Yes	Yes	Suits, flushing, rinsing, purging, isolation (blinding)
	Spent/regenerated catalyst storage	Spent/regenerated catalyst product storage	NA	NA	NA	NA	NA	NA	Both	No	No	NA	NA	NA	Packaging type (bulk, IBC, bags, drums...)
			NA	NA	NA	NA	NA	NA	Both	No	No	NA	NA	NA	Packaging type (bulk, IBC, bags, drums...)
Ex-situ regeneration	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	NA	NA	NA	NA	NA	NA	Both	Some-times	No	No	No	No	packaging type

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	**HH Exposure routes**			**HH Exposure Modifier**						**PPE**			
			Inhalation	**Dermal**	**Ingestion**	**Duration and frequency (exposure time)**	**Work pattern**		**Outdoor or Indoor Operation**	**Indoor**		**Respiratory protection**	**Eye protection (LEP/goggles)**	**Protection of hands (gloves)**	**Other technical measures**
										with GEV	**with LEV**				
		Storage of spent catalyst	NA	NA	NA	NA	NA	NA	Both	Some-times	No	No	No	No	packaging type
		Emptying of containers of spent catalyst	X	X	NA	2h/shift	8h/shift	220 days/year	Indoor	Some-times	Yes	Sometimes	Sometimes	Yes	packaging type
		Conveying spent catalyst	X	X	NA	0.25h/shift	8h/shift	220 days/year	Indoor	Some-times	Some-times	Yes	Sometimes	Yes	
			NA	NA	NA	NA	NA	NA	Indoor	Some-times	Some-times	Yes	Sometimes	Yes	
	Regeneration	Drying	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Calcination (oxidation at elevated temperatures)	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Screening (adjusting particle size distribution)	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Some-times	Yes	Yes	Yes	Yes	
			NA	NA	NA	NA	NA	NA	Indoor	Some-times	Yes	Yes	Yes	yes	
	Regenerated Catalyst Packaging	Filling operations (transfer to transport containers)	X	X	NA	4h/shift	8h/shift	220 days/year	Indoor	Some-times	Yes	Yes	Yes	Yes	bags, drums
	Maintenance & Cleaning (regeneration)	Maintenance	X	X	NA	variable from 0 to whole shift depending on function (operator or maintenance personnel)			Indoor	Some-times	No	Sometimes	Yes	Yes	Suits, flushing, rinsing, purging, isolation (blinding)

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	HH Exposure routes			HH Exposure Modifier						PPE			
			Inhalation	Dermal	Ingestion	Duration and frequency (exposure time)	Work pattern		Outdoor or Indoor Operation	Indoor: with GEV	Indoor: with LEV	Respiratory protection	Eye protection (LEP/goggles)	Protection of hands (gloves)	Other technical measures
		Cleaning	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Yes	No	Yes	Yes	Yes	flushing, rinsing, purging, isolation (blinding)
	Regenerated catalyst storage	Regenerated catalyst storage	NA	NA	NA	NA	NA	NA	Both	Some-times	No	NA	NA	NA	packaging type
Recycling	Spent catalyst delivery & handling	Semi-bulk delivery of spent catalyst (IBC, drums...)	NA	NA	NA	NA	NA	NA	Outdoor	No	No	No	No	No	packaging type
		Storage of spent catalyst	NA	NA	NA	NA	NA	NA	Both	No	No	No	No	No	packaging type
		Emptying of containers of spent catalyst	X	X	NA	4h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Sometimes	Sometimes	Yes	packaging type
		Conveying spent catalyst	X	X	NA	0.25h/shift	8h/shift	220 days/year	Indoor	Yes	No	Sometimes	Sometimes	Yes	
	Pyrometallurgical recycling	Screening	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	
		Calcination (oxidation at elevated temperatures)	NA	NA	NA	NA	NA	NA	Indoor	No	No	NA	NA	NA	
		Smelting	NA	NA	NA	NA	NA	NA	Indoor	Yes	Yes	Yes	Yes	Yes	
		Filling	X	X	NA	4h/shift	8h/shift	220 days/year	Indoor	Yes	Yes	Yes	Yes	Yes	moulds
		Maintenance	X	X	NA	variable from 0 to whole shift depending on function (operator or maintenance personnel)			Indoor	Yes	No	Sometimes	Yes	Yes	Suits, flushing, rinsing,

ES title	ES breakdown	**Contributative ES** (Short description of process or activity)	HH Exposure routes: Inhalation	HH Exposure routes: Dermal	HH Exposure routes: Ingestion	HH Exposure Modifier: Duration and frequency (exposure time)	HH Exposure Modifier: Work pattern		HH Exposure Modifier: Outdoor or Indoor Operation	HH Exposure Modifier: Indoor with GEV	HH Exposure Modifier: Indoor with LEV	PPE: Respiratory protection	PPE: Eye protection (LEP/goggles)	PPE: Protection of hands (gloves)	Other technical measures
[redacted]															purging, isolation (blinding)
		Cleaning	X	X	NA	1h/shift	8h/shift	220 days/year	Indoor	Yes	No	Yes	Yes	Yes	flushing, rinsing, purging, isolation (blinding)
	Hydrometallurgical recycling	No information													
	Product storage	Final product storage	NA	NA	NA	NA	NA	NA	Both	No	No	NA	NA	NA	

ANNEX 14:Industrial Worker GES MEASE Outputs for copper compounds [All Appropriate PROC codes]

Key

Acceptable	Unacceptable

a) Indoor, without LEV

PROC	solid, low dustiness	solid, medium dustiness	solid, high dustiness	aqueous solution

	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1	0.01	120	0.01	120	0.01	120	0.001	120
2	0.01	240	0.5	240	1	240	0.001	240
3	0.1	120	1	120	1	120	0.01	120
4	0.5	240	5	240	25	240	0.05	240
5	0.5	240	5	240	25	240	0.05	240
6								
7							20	240
8a	0.5	480	5	480	50	480	0.05	240
8b	0.1	240	5	240	25	240	0.01	240
9	0.1	240	5	240	20	240	0.01	240
10							0.05	240
11							20	240
12							0.001	120
13							0.01	240
14	0.1	240	1	240	10	240	0.01	240
15	0.1	120	0.5	120	5	120	0.01	120
16							0.01	120
17							0.1	240
18							0.1	240
19	0.5	990	5	990	25	990	0.05	240
20							0.001	240
21	0.5	990						
22	7	990	7	990	7	990		
23	2	990	2	990	2	990		
24	2	990	3	990	5.5	990		
25	2	990	2	990	2	990		
26	1.5	990	4	990	10	990		
27a	5	990	5	990	5	990		

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
27b	0.1	990	0.5	990	2.5	990	0.1	240

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
1	0.01	0.01254325	0.01	0.012543248	0.01	0.01254325	0.001	0.12540495
2	0.01	0.0250865	0.5	0.025086496	1	0.0250865	0.001	0.25080991
3	0.1	0.01254325	1	0.012543248	1	0.01254325	0.01	0.12540495
4	0.5	0.0250865	5	0.025086496	25	0.0250865	0.05	0.25080991
5	0.5	0.0250865	5	0.025086496	25	0.0250865	0.05	0.25080991
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	20	0.25080991
8a	0.5	0.05017299	5	0.050172992	50	0.05017299	0.05	0.25080991
8b	0.1	0.0250865	5	0.025086496	25	0.0250865	0.01	0.25080991
9	0.1	0.0250865	5	0.025086496	20	0.0250865	0.01	0.25080991
10	0	0	0	0	0	0	0.05	0.25080991
11	0	0	0	0	0	0	20	0.25080991
12	0	0	0	0	0	0	0.001	0.12540495
13	0	0	0	0	0	0	0.01	0.25080991
14	0.1	0.0250865	1	0.025086496	10	0.0250865	0.01	0.25080991
15	0.1	0.01254325	0.5	0.012543248	5	0.01254325	0.01	0.12540495
16	0	0	0	0	0	0	0.01	0.12540495
17	0	0	0	0	0	0	0.1	0.25080991

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
18	0	0	0	0	0	0	0.1	0.25080991
19	0.5	0.1034818	5	0.103481797	25	0.1034818	0.05	0.25080991
20	0	0	0	0	0	0	0.001	0.25080991
21	0.5	0.1034818	0	0	0	0	0	0
22	7	0.1034818	7	0.103481797	7	0.1034818	0	0
23	2	0.1034818	2	0.103481797	2	0.1034818	0	0
24	2	0.1034818	3	0.103481797	5.5	0.1034818	0	0
25	2	0.1034818	2	0.103481797	2	0.1034818	0	0
26	1.5	0.1034818	4	0.103481797	10	0.1034818	0	0
27a	5	0.1034818	5	0.103481797	5	0.1034818	0	0
27b	0.1	0.1034818	0.5	0.103481797	2.5	0.1034818	0.1	0.25080991

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0.02254325	0.02254325	0.02254325	0.12640495
2	0.0350865	0.5250865	1.0250865	0.25180991
3	0.11254325	1.01254325	1.01254325	0.13540495
4	0.5250865	5.0250865	25.0250865	0.30080991
5	0.5250865	5.0250865	25.0250865	0.30080991
6	0	0	0	0
7	0	0	0	20.2508099
8a	0.55017299	5.05017299	50.050173	0.30080991
8b	0.1250865	5.0250865	25.0250865	0.26080991
9	0.1250865	5.0250865	20.0250865	0.26080991
10	0	0	0	0.30080991
11	0	0	0	20.2508099
12	0	0	0	0.12640495
13	0	0	0	0.26080991
14	0.1250865	1.0250865	10.0250865	0.26080991
15	0.11254325	0.51254325	5.01254325	0.13540495
16	0	0	0	0.13540495
17	0	0	0	0.35080991
18	0	0	0	0.35080991
19	0.6034818	5.1034818	25.1034818	0.30080991
20	0	0	0	0.25180991
21	0.6034818	0	0	0
22	7.1034818	7.1034818	7.1034818	0
23	2.1034818	2.1034818	2.1034818	0
24	2.1034818	3.1034818	5.6034818	0
25	2.1034818	2.1034818	2.1034818	0
26	1.6034818	4.1034818	10.1034818	0
27a	5.1034818	5.1034818	5.1034818	0
27b	0.2034818	0.6034818	2.6034818	0.35080991

b) Indoor, with LEV

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1								
2					0.1	240		
3			0.1	120	0.1	120		
4			0.5	240	2.5	240		
5			0.5	240	2.5	240		
6								
7							1	240
8a			0.5	480	5	480		
8b			0.25	240	1.25	240		
9			0.5	240	2	240		
10								
11							4.5	240
12								
13								
14			0.1	240	1	240		
15					0.5	120		
16								
17								
18								
19			5	990	25	990		
20								
21								
22	0.7	990	0.7	990	0.7	990		
23	0.2	990	0.2	990	0.2	990		

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
24	0.4	990	0.6	990	1.1	990		
25	0.2	990	0.2	990	0.2	990		
26	0.27	990	0.72	990	1.8	990		
27a	0.9	990	0.9	990	0.9	990		
27b					0.45	990		

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0.1	0.0250865	0	0
3	0	0	0.1	0.012543248	0.1	0.01254325	0	0
4	0	0	0.5	0.025086496	2.5	0.0250865	0	0
5	0	0	0.5	0.025086496	2.5	0.0250865	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	1	0.25080991
8a	0	0	0.5	0.050172992	5	0.05017299	0	0
8b	0	0	0.25	0.025086496	1.25	0.0250865	0	0
9	0	0	0.5	0.025086496	2	0.0250865	0	0
10	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	4.5	0.25080991
12	0	0	0	0	0	0	0	0

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
13	0	0	0	0	0	0	0	0
14	0	0	0.1	0.025086496	1	0.0250865	0	0
15	0	0	0	0	0.5	0.01254325	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
19	0	0	5	0.103481797	25	0.1034818	0	0
20	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0
22	0.7	0.1034818	0.7	0.103481797	0.7	0.1034818	0	0
23	0.2	0.1034818	0.2	0.103481797	0.2	0.1034818	0	0
24	0.4	0.1034818	0.6	0.103481797	1.1	0.1034818	0	0
25	0.2	0.1034818	0.2	0.103481797	0.2	0.1034818	0	0
26	0.27	0.1034818	0.72	0.103481797	1.8	0.1034818	0	0
27a	0.9	0.1034818	0.9	0.103481797	0.9	0.1034818	0	0
27b	0	0	0	0	0.45	0.1034818	0	0

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0	0	0	0
2	0	0	0.1250865	0
3	0	0.11254325	0.11254325	0
4	0	0.5250865	2.5250865	0
5	0	0.5250865	2.5250865	0
6	0	0	0	0
7	0	0	0	1.25080991
8a	0	0.55017299	5.05017299	0
8b	0	0.2750865	1.2750865	0
9	0	0.5250865	2.0250865	0
10	0	0	0	0
11	0	0	0	4.75080991
12	0	0	0	0
13	0	0	0	0
14	0	0.1250865	1.0250865	0
15	0	0	0.51254325	0
16	0	0	0	0
17	0	0	0	0
18	0	0	0	0
19	0	5.1034818	25.1034818	0
20	0	0	0	0
21	0	0	0	0
22	0.8034818	0.8034818	0.8034818	0
23	0.3034818	0.3034818	0.3034818	0
24	0.5034818	0.7034818	1.2034818	0
25	0.3034818	0.3034818	0.3034818	0
26	0.3734818	0.8234818	1.9034818	0
27a	1.0034818	1.0034818	1.0034818	0
27b	0	0	0.5534818	0

c) Indoor, with LEV and PPE APF 4

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initia Inhal Expo Estin (mg/
1							
2							
3							
4					0.625	240	
5					0.625	240	
6							
7							
8a					1.25	480	
8b					0.313	240	
9					0.5	240	
10							
11							
12							
13							
14					0.25	240	
15							
16							
17							
18							
19			1.25	990	6.25	990	
20							
21							
22							
23							
24					0.275	990	
25							
26					0.45	990	
27a	0.225	990	0.225	990	0.225	990	
27b							

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhal Expo Estin
1	0	0	0	0	0	0	
2	0	0	0	0	0	0	
3	0	0	0	0	0	0	
4	0	0	0	0	0.625	0.0250865	
5	0	0	0	0	0.625	0.0250865	
6	0	0	0	0	0	0	

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initia Inhal Expo Estin (mg/r
7	0	0	0	0	0	0	
8a	0	0	0	0	1.25	0.05017299	
8b	0	0	0	0	0.313	0.0250865	
9	0	0	0	0	0.5	0.0250865	
10	0	0	0	0	0	0	
11	0	0	0	0	0	0	
12	0	0	0	0	0	0	
13	0	0	0	0	0	0	
14	0	0	0	0	0.25	0.0250865	
15	0	0	0	0	0	0	
16	0	0	0	0	0	0	
17	0	0	0	0	0	0	
18	0	0	0	0	0	0	
19	0	0	1.25	0.103481797	6.25	0.1034818	
20	0	0	0	0	0	0	
21	0	0	0	0	0	0	
22	0	0	0	0	0	0	
23	0	0	0	0	0	0	
24	0	0	0	0	0.275	0.1034818	
25	0	0	0	0	0	0	
26	0	0	0	0	0.45	0.1034818	
27a	0.225	0.1034818	0.225	0.103481797	0.225	0.1034818	
27b	0	0	0	0	0	0	

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0.6500865	0
5	0	0	0.6500865	0
6	0	0	0	0
7	0	0	0	0.50080991
8a	0	0	1.30017299	0
8b	0	0	0.3380865	0
9	0	0	0.5250865	0
10	0	0	0	0
11	0	0	0	1.37580991
12	0	0	0	0
13	0	0	0	0
14	0	0	0.2750865	0
15	0	0	0	0
16	0	0	0	0
17	0	0	0	0
18	0	0	0	0
19	0	1.3534818	6.3534818	0
20	0	0	0	0
21	0	0	0	0
22	0	0	0	0
23	0	0	0	0
24	0	0	0.3784818	0
25	0	0	0	0
26	0	0	0.5534818	0
27a	0.3284818	0.3284818	0.3284818	0
27b	0	0	0	0

d) Indoor, with LEV and PPE APF 10

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initia Inhal Expo Estin (mg/
1							
2							
3							
4							
5							
6							
7							
8a					0.5	480	
8b							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19			0.5	990	2.5	990	
20							
21							
22							
23							
24							
25							
26							
27a							
27b							

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhal Expo Estin
1	0	0	0	0	0	0	
2	0	0	0	0	0	0	
3	0	0	0	0	0	0	
4	0	0	0	0	0	0	
5	0	0	0	0	0	0	
6	0	0	0	0	0	0	

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initia Inhal Expo Estin (mg/r
7	0	0	0	0	0	0	
8a	0	0	0	0	0.5	0.05017299	
8b	0	0	0	0	0	0	
9	0	0	0	0	0	0	
10	0	0	0	0	0	0	
11	0	0	0	0	0	0	
12	0	0	0	0	0	0	
13	0	0	0	0	0	0	
14	0	0	0	0	0	0	
15	0	0	0	0	0	0	
16	0	0	0	0	0	0	
17	0	0	0	0	0	0	
18	0	0	0	0	0	0	
19	0	0	0.5	0.103481797	2.5	0.1034818	
20	0	0	0	0	0	0	
21	0	0	0	0	0	0	
22	0	0	0	0	0	0	
23	0	0	0	0	0	0	
24	0	0	0	0	0	0	
25	0	0	0	0	0	0	
26	0	0	0	0	0	0	
27a	0	0	0	0	0	0	
27b	0	0	0	0	0	0	

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8a	0	0	0.55017299	0
8b	0	0	0	0
9	0	0	0	0
10	0	0	0	0
11	0	0	0	0.70080991
12	0	0	0	0
13	0	0	0	0
14	0	0	0	0
15	0	0	0	0
16	0	0	0	0
17	0	0	0	0
18	0	0	0	0
19	0	0.6034818	2.6034818	0
20	0	0	0	0
21	0	0	0	0
22	0	0	0	0
23	0	0	0	0
24	0	0	0	0
25	0	0	0	0
26	0	0	0	0
27a	0	0	0	0
27b	0	0	0	0

e) Indoor, with LEV and PPE APF 40

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		a
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalat Exposu Estima (mg/m3
1							
2							
3							
4							
5							
6							
7							
8a							
8b							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19					0.625	990	
20							
21							
22							
23							
24							
25							
26							
27a							
27b							

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		a
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalat Exposu Estima
1	0	0	0	0	0	0	
2	0	0	0	0	0	0	
3	0	0	0	0	0	0	
4	0	0	0	0	0	0	
5	0	0	0	0	0	0	
6	0	0	0	0	0	0	

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		a
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhala Exposu Estima (mg/m3
7	0	0	0	0	0	0	
8a	0	0	0	0	0	0	
8b	0	0	0	0	0	0	
9	0	0	0	0	0	0	
10	0	0	0	0	0	0	
11	0	0	0	0	0	0	
12	0	0	0	0	0	0	
13	0	0	0	0	0	0	
14	0	0	0	0	0	0	
15	0	0	0	0	0	0	
16	0	0	0	0	0	0	
17	0	0	0	0	0	0	
18	0	0	0	0	0	0	
19	0	0	0	0	0.625	0.1034818	
20	0	0	0	0	0	0	
21	0	0	0	0	0	0	
22	0	0	0	0	0	0	
23	0	0	0	0	0	0	
24	0	0	0	0	0	0	
25	0	0	0	0	0	0	
26	0	0	0	0	0	0	
27a	0	0	0	0	0	0	
27b	0	0	0	0	0	0	

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8a	0	0	0	0
8b	0	0	0	0
9	0	0	0	0
10	0	0	0	0
11	0	0	0	0
12	0	0	0	0
13	0	0	0	0
14	0	0	0	0
15	0	0	0	0
16	0	0	0	0
17	0	0	0	0
18	0	0	0	0
19	0	0	0.7284818	0
20	0	0	0	0
21	0	0	0	0
22	0	0	0	0
23	0	0	0	0
24	0	0	0	0
25	0	0	0	0
26	0	0	0	0
27a	0	0	0	0
27b	0	0	0	0

ANNEX 15: Professional Worker GES MEASE Outputs for copper compounds [All Appropriate PROC codes]

Key:

Acceptable	Unacceptable

a) Indoor, without LEV

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1								
2	0.01	240	1	240	5	240	0.001	240
3	0.1	120	1	120	5	120	0.01	120
4	1	240	5	240	50	240	0.1	240
5	1	240	5	240	50	240	0.1	240
6								
7								
8a	0.5	480	5	480	50	480	0.05	240
8b	0.5	240	5	240	50	240	0.05	240
9	0.5	240	5	240	20	240	0.05	240
10							0.05	240
11							20	240
12								
13							0.05	240
14	1	240	5	240	50	240	0.1	240
15	0.1	120	0.5	120	5	120	0.01	120
16								
17							1	240

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	**Dermal Exposure Estimate (mg/day)**	**Initial Inhalation Exposure Estimate (mg/m3)**	**Dermal Exposure Estimate (mg/day)**	**Initial Inhalation Exposure Estimate (mg/m3)**	**Dermal Exposure Estimate (mg/day)**	**Initial Inhalation Exposure Estimate (mg/m3)**	**Dermal Exposure Estimate (mg/day)**
18								
19	0.5	990	5	990	50	990	0.05	240
20							0.001	240
21	0.05	99						
22	10	990	10	990	10	990		
23								
24								
25	4	990	4	990	4	990		
26	3	990	8	990	20	990		
27a								
27b								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	**RCR Dermal Exposure Estimate**	**RCR Inhalation Exposure Estimate**	**RCR Dermal Exposure Estimate**	**RCR Inhalation Exposure Estimate**	**RCR Dermal Exposure Estimate**	**RCR Inhalation Exposure Estimate**	**RCR Dermal Exposure Estimate**
1	0	0	0	0	0	0	0	0
2	0.01	0.0250865	1	0.025086496	5	0.0250865	0.001	0.25080991
3	0.1	0.01254325	1	0.012543248	5	0.01254325	0.01	0.12540495
4	1	0.0250865	5	0.025086496	50	0.0250865	0.1	0.25080991
5	1	0.0250865	5	0.025086496	50	0.0250865	0.1	0.25080991
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
8a	0.5	0.05017299	5	0.050172992	50	0.05017299	0.05	0.25080991
8b	0.5	0.0250865	5	0.025086496	50	0.0250865	0.05	0.25080991
9	0.5	0.0250865	5	0.025086496	20	0.0250865	0.05	0.25080991
10	0	0	0	0	0	0	0.05	0.25080991
11	0	0	0	0	0	0	20	0.25080991
12	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0.05	0.25080991
14	1	0.0250865	5	0.025086496	50	0.0250865	0.1	0.25080991
15	0.1	0.01254325	0.5	0.012543248	5	0.01254325	0.01	0.12540495
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	1	0.25080991
18	0	0	0	0	0	0	0	0
19	0.5	0.1034818	5	0.103481797	50	0.1034818	0.05	0.25080991
20	0	0	0	0	0	0	0.001	0.25080991
21	0.05	0.01034818	0	0	0	0	0	0
22	10	0.1034818	10	0.103481797	10	0.1034818	0	0
23	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0
25	4	0.1034818	4	0.103481797	4	0.1034818	0	0
26	3	0.1034818	8	0.103481797	20	0.1034818	0	0
27a	0	0	0	0	0	0	0	0
27b	0	0	0	0	0	0	0	0

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0.00	0.00	0.00	0.00
2	0.04	1.03	5.03	0.25
3	0.11	1.01	5.01	0.14
4	1.03	5.03	50.03	0.35
5	1.03	5.03	50.03	0.35
6	0.00	0.00	0.00	0.00
7	0.00	0.00	0.00	0.00
8a	0.55	5.05	50.05	0.30
8b	0.53	5.03	50.03	0.30
9	0.53	5.03	20.03	0.30
10	0.00	0.00	0.00	0.30
11	0.00	0.00	0.00	20.25
12	0.00	0.00	0.00	0.00
13	0.00	0.00	0.00	0.30
14	1.03	5.03	50.03	0.35
15	0.11	0.51	5.01	0.14
16	0.00	0.00	0.00	0.00
17	0.00	0.00	0.00	1.25
18	0.00	0.00	0.00	0.00
19	0.60	5.10	50.10	0.30
20	0.00	0.00	0.00	0.25
21	0.06	0.00	0.00	0.00
22	10.10	10.10	10.10	0.00
23	0.00	0.00	0.00	0.00
24	0.00	0.00	0.00	0.00
25	4.10	4.10	4.10	0.00
26	3.10	8.10	20.10	0.00
27a	0.00	0.00	0.00	0.00
27b	0.00	0.00	0.00	0.00

b) Indoor, with LEV

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1								
2			0.1	240	0.5	240		
3			0.1	120	0.5	120		
4	0.1	240	0.5	240	5	240		
5	0.1	240	0.5	240	5	240		
6								
7								
8a			0.5	480	5	480		
8b			0.25	240	2.5	240		
9			0.5	240	2	240		
10								
11							4.5	240
12								
13								
14	0.1	240	0.5	240	5	240		
15					0.5	120		
16								
17							0.05	240
18								
19			5	990	50	990		
20								
21								
22	1	990	1	990	1	990		
23								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
24								
25	0.4	990	0.4	990	0.4	990		
26	0.675	990	1.8	990	4.5	990		
27a								
27b								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
1	0	0	0	0	0	0	0	0
2	0	0	0.1	0.025086496	0.5	0.0250865	0	0
3	0	0	0.1	0.012543248	0.5	0.01254325	0	0
4	0.1	0.0250865	0.5	0.025086496	5	0.0250865	0	0
5	0.1	0.0250865	0.5	0.025086496	5	0.0250865	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
8a	0	0	0.5	0.050172992	5	0.05017299	0	0
8b	0	0	0.25	0.025086496	2.5	0.0250865	0	0
9	0	0	0.5	0.025086496	2	0.0250865	0	0
10	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	4.5	0.25080991
12	0	0	0	0	0	0	0	0

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
13	0	0	0	0	0	0	0	0
14	0.1	0.0250865	0.5	0.025086496	5	0.0250865	0	0
15	0	0	0	0	0.5	0.01254325	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0.05	0.25080991
18	0	0	0	0	0	0	0	0
19	0	0	5	0.103481797	50	0.1034818	0	0
20	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0
22	1	0.1034818	1	0.103481797	1	0.1034818	0	0
23	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0
25	0.4	0.1034818	0.4	0.103481797	0.4	0.1034818	0	0
26	0.675	0.1034818	1.8	0.103481797	4.5	0.1034818	0	0
27a	0	0	0	0	0	0	0	0
27b	0	0	0	0	0	0	0	0

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0.00	0.00	0.00	0.00
2	0.00	0.13	0.53	0.00
3	0.00	0.11	0.51	0.00
4	0.13	0.53	5.03	0.00
5	0.13	0.53	5.03	0.00
6				
7				
8a	0.00	0.55	5.05	0.00
8b	0.00	0.28	2.53	0.00
9	0.00	0.00	0.00	0.00
10	0.00	0.00	0.00	0.00
11	0.00	0.00	0.00	4.75
12	0.00	0.00	0.00	0.00
13	0.00	0.00	0.00	0.00
14	0.13	0.53	5.03	0.00
15	0.00	0.00	0.51	0.00
16	0.00	0.00	0.00	0.00
17	0.00	0.00	0.00	0.30
18	0.00	0.00	0.00	0.00
19	0.00	5.10	50.10	0.00
20	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00
22	1.10	1.10	1.10	0.00
23	0.00	0.00	0.00	0.00
24	0.00	0.00	0.00	0.00
25	0.50	0.50	0.50	0.00
26	0.78	1.90	4.60	0.00
27a	0.00	0.00	0.00	0.00
27b	0.00	0.00	0.00	0.00

c) Indoor, with LEV and PPE APF 4

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1								
2								
3								
4					1.25	240		
5					1.25	240		
6								
7								
8a					1.25	480		
8b					0.625	240		
9					0.5	240		
10								
11							1.125	240
12								
13								
14					1.25	240		
15								
16								
17								
18								
19			1.25	990	12.5	990		
20								
21								
22	0.25	990	0.25	990	0.25	990		
23								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
24								
25								
26			0.45	990	1.125	990		
27a								
27b								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	1.25	0.0250865	0	0
5	0	0	0	0	1.25	0.0250865	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
8a	0	0	0	0	1.25	0.05017299	0	0
8b	0	0	0	0	0.625	0.0250865	0	0
9	0	0	0	0	0.5	0.0250865	0	0
10	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	1.125	0.25080991
12	0	0	0	0	0	0	0	0

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
13	0	0	0	0	0	0	0	0
14	0	0	0	0	1.25	0.0250865	0	0
15	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
19	0	0	1.25	0.103481797	12.5	0.1034818	0	0
20	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0
22	0.25	0.1034818	0.25	0.103481797	0.25	0.1034818	0	0
23	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
26	0	0	0.45	0.103481797	1.125	0.1034818	0	0
27a	0	0	0	0	0	0	0	0
27b	0	0	0	0	0	0	0	0

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0.00	0.00	0.00	0.00
2	0.00	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00
4	0.00	0.00	1.28	0.00
5	0.00	0.00	1.28	0.00
6	0.00	0.00	0.00	0.00
7	0.00	0.00	0.00	0.00
8a	0.00	0.00	1.30	0.00
8b	0.00	0.00	0.65	0.00
9	0.00	0.00	0.53	0.00
10	0.00	0.00	0.00	0.00
11	0.00	0.00	0.00	1.38
12	0.00	0.00	0.00	0.00
13	0.00	0.00	0.00	0.00
14	0.00	0.00	1.28	0.00
15	0.00	0.00	0.00	0.00
16	0.00	0.00	0.00	0.00
17	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00
19	0.00	1.35	12.60	0.00
20	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00
22	0.35	0.35	0.35	0.00
23	0.00	0.00	0.00	0.00
24	0.00	0.00	0.00	0.00
25	0.00	0.00	0.00	0.00
26	0.00	0.55	1.23	0.00
27a	0.00	0.00	0.00	0.00
27b	0.00	0.00	0.00	0.00

d) Indoor, with LEV and PPE APF 10

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
1								
2								
3								
4					0.5	240		
5					0.5	240		
6								
7								
8a					0.5	480		
8b								
9								
10								
11							0.45	240
12								
13								
14					0.5	240		
15								
16								
17								
18								
19			0.5	990	5	990		
20								
21								
22								
23								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
24								
25								
26					0.45	990		
27a								
27b								

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0.5	0.0250865	0	0
5	0	0	0	0	0.5	0.0250865	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
8a	0	0	0	0	0.5	0.05017299	0	0
8b	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
*11	0	0	0	0	0	0	0.45	0.25080991
12	0	0	0	0	0	0	0	0

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		aqueous solution	
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)
13	0	0	0	0	0	0	0	0
14	0	0	0	0	0.5	0.0250865	0	0
15	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
19	0	0	0.5	0.103481797	5	0.1034818	0	0
20	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
*26	0	0	0	0	0.45	0.1034818	0	0
27a	0	0	0	0	0	0	0	0
27b	0	0	0	0	0	0	0	0

* - median estimates

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
1	0.00	0.00	0.00	0.00
2	0.00	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00
4	0.00	0.00	0.53	0.00
5	0.00	0.00	0.53	0.00
6	0.00	0.00	0.00	0.00
7	0.00	0.00	0.00	0.00
8a	0.00	0.00	0.55	0.00
8b	0.00	0.00	0.00	0.00
9	0.00	0.00	0.00	0.00
10	0.00	0.00	0.00	0.00
11	0.00	0.00	0.00	0.70
12	0.00	0.00	0.00	0.00
13	0.00	0.00	0.00	0.00
14	0.00	0.00	0.53	0.00
15	0.00	0.00	0.00	0.00
16	0.00	0.00	0.00	0.00
17	0.00	0.00	0.00	0.00
18	0.00	0.00	0.00	0.00
19	0.00	0.60	5.10	0.00
20	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00
22	0.00	0.00	0.00	0.00
23	0.00	0.00	0.00	0.00
24	0.00	0.00	0.00	0.00
25	0.00	0.00	0.00	0.00
26	0.00	0.00	0.55	0.00
27a	0.00	0.00	0.00	0.00
27b	0.00	0.00	0.00	0.00

e) Indoor, with LEV and PPE APF 40

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		a
	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalation Exposure Estimate (mg/m3)	Dermal Exposure Estimate (mg/day)	Initial Inhalat Exposu Estima (mg/m3
17					0.25	480	
18							
19					1.25*	990*	
20							
21							
22							
23							
24							
25							
26							
27a							
27b							

*- shorten exposure time to 60 - 240 min = 0.75 mg/m^3 & 594 mg/day

PROC	solid, low dustiness		solid, medium dustiness		solid, high dustiness		
	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhalation Exposure Estimate	RCR Dermal Exposure Estimate	RCR Inhala Expos Estim
17	0	0	0	0	0.25	0.05017299	
18	0	0	0	0	0	0	
19	0	0	0	0	1.25**	0.103482**	
20	0	0	0	0	0	0	
21	0	0	0	0	0	0	
22	0	0	0	0	0	0	
23	0	0	0	0	0	0	
24	0	0	0	0	0	0	
25	0	0	0	0	0	0	
26	0	0	0	0	0	0	
27a	0	0	0	0	0	0	
27b	0	0	0	0	0	0	

**- shorten exposure time to 60 - 240 min = 0.75 & 0.06208908

PROC	Combined exposure low dustiness	Combined exposure medium dustiness	Combined exposure high dustiness	Combined exposure aqueous solution
17	0.00	0.00	0.30	0.00
18	0.00	0.00	0.00	0.00
19	0.00	0.00	1.35***	0.00
20	0.00	0.00	0.00	0.00
21	0.00	0.00	0.00	0.00
22	0.00	0.00	0.00	0.00
23	0.00	0.00	0.00	0.00
24	0.00	0.00	0.00	0.00
25	0.00	0.00	0.00	0.00
26	0.00	0.00	0.00	0.00
27a	0.00	0.00	0.00	0.00
27b	0.00	0.00	0.00	0.00

***- shorten exposure time to 60 - 240 min = 0.81