



Extended Safety Data Sheet (eSDS) for Copper massive produced

Prepared by the European Copper Institute (ECI)

Copper massive is NOT classified and therefore there is no regulatory obligation to distribute this e-SDS

Version: 1

Revision date: 20 July 2015

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SECTION 0: Introduction to this e-SDS

Copper in massive form (particle size >1mm) does not meet the criteria for classification in accordance with Regulations (EC) No 1272/2008 and 67/548/EEC. No safety measures are therefore needed for copper in massive form.

During production of copper in massive forms (e.g. cathodes) and during specific industrial uses (e.g. melting), safety measures may however be needed due to the potential occurrence of hazardous copper-bearing materials (dusts, mists, fumes) and soluble copper compounds in and around industrial settings. This SDS therefore focusses on safety data and safety measures of relevance to the production and industrial uses of copper massive.

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Substance name:	Copper massive (particle size >1mm)
Chemical formula:	Cu
Trade name:	Oxygen free copper OFE-OK®, OF-OK® Outokumpu High purity copper Cu99,995; Cu99,999; Cu99,9999 Deoxidized copper Cu-DHP, CuP, XLP/PHC, HCP Electrolytic Tough Pitch Copper ETP (min. 99,90 % Cu; max. 400 ppm oxygen) Silver bearing oxygen free copper CuAg0,045(OF), CuAg0,04(OF), CuAg0,05(OF), CuAg0,10(OF), CuAg0,25(OF), CuAg0,45(OF), CuAg0,8(OF), CuAg1,0(OF), Silver bearing deoxidized copper CuAg0,10P, CuAg0,04P Zirconium bearing copper ZrK
CAS number:	7440-50-8
EINECS number:	231-159-6
Index number:	Not assigned
ECHA Registration number:	01-2119480154-42-0096

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Uses of copper in massive and powder forms can be summarised as

Downstream and Formulation stages – Industrial

DM1 - Production of copper fire-refined ingots, and unwrought shapes (billets, slabs and cakes, etc)

DM2 - Production of copper particulates and powders (including catalyst pellets) – e.g. by thermal, hydrometallurgical and electrochemical processes

F1. Production of alloys, in which copper is the main constituent, as well as where it is a minor alloying element (e.g. in

stainless steel, in alloy particulates, in alloy shapes, etc)

F2. Production of copper-powder containing preparations (e.g. brazing paste, pigment paints, etc)

Uses of copper as such or in preparation, including production of articles

U1. Production of copper containing articles (finished and semi-finished products - e.g. wire rod, wires, bars, sections, tubes, strip/sheet, cables and cast products)

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- U2. Production of articles made from copper and copper containing particulates (e.g. sintered products)
- U3. Use as an intermediate in the production of other copper containing substances
- U4. Use as brazing paste (handling of preparation by industrial workers)
- U5. Use as catalyst (handling of powder by industrial workers)

Service life stage (article or preparation in sealed container) –consumers, professional /industrial workers

- S1. Use of article (handling by consumer) - e.g. handling of coins
- S2. Use of article (handling by professional worker) - e.g. installation of roofs and tubes
- S3. Use as spray coating agent (handling of preparation in sealed container)
- S4. Use of article made from copper and copper-containing particulates - e.g. brake pads

End-of-life stage4

- EoL1. Of industrial wastes -e.g. recycling and recovery as raw material
- EoL2. Of private wastes e.g. collecting, recovery, and disposal

The following exposure scenarios, developed in the REACH Chemical Safety Report for Copper, are relevant to the production and identified uses of copper in massive forms:

Scenario Number	Exposure scenario title as presented in Annex I
1	Raw material and scrap handling of massive metal
20	Raw material and scrap handling of fines, milling to fines
2	Smelting and fire refining
3	Electrolytic Refining
30	Hydro-metallurgical copper production
23	Melting and casting
13	Continuous Dipping
13	Hot processes
9	Heat Treatment
25	Electro deposition
11	Coating & Electroplating
26	Surface treatment
27	Compaction & Sintering & Injection moulding
28	Metallization and Thermal Spraying
5	Low energy mechanical processing of cold metal
12	Welding
16	Etching
18	Handling of articles by consumer and professional worker

1.2.2. Uses advised against:

There are no uses advised against.

1.3. Details of the supplier of the safety data sheet

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Company Name

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Tel. + 358 2 6266111

Fax + + 358 2 6265300

E-mail address author/competent person responsible for the SDS: info.pori@luvata.com

1.4. Emergency telephone number (could be e.g. the anti-poison of the destination country)

Myrkytystietokeskus, Stenbäckinkatu 11, 00290 Helsinki Tel. +358 9 4711

SECTION 2: HAZARDS IDENTIFICATION of copper in massive form

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 (Classification, Labelling and Packaging))

Not classified

2.1.2 Classification according to Directive 67/548/EEC (Dangerous Substances Directive)

Not classified

2.2 Label elements

2.2.1 Labelling according to Regulation (EC) No. 1272/2008

None

2.2.2 Labelling according to Directive 67/548/EEC

None

2.3 Other hazards

The substance does not meet the criteria for a PBT or vPvB substance.

Copper is not expected to contribute to ozone depletion, ozone formation, global warming or acidification.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Main component – Cu

Name: Copper massive

CAS: 7440-50-8

EINECS: 231-159-6

Concentration: ≥ 99.9%

Classification impurities: none

SECTION 4: FIRST AID MEASURES applicable to production and uses of copper in massive forms

4.1 Description of first aid measures

Copper in massive form is not hazardous.

During production and some uses, the following hazardous derivatives may occur/be formed: respirable copper-bearing particles and soluble copper compounds. This section also considers potential hazards of copper-bearing materials and copper compounds (referred to as "copper"), relevant to the production and use of copper massive.

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General advice

Get medical attention if any discomfort develops.
Show this safety data sheet to the doctor in attendance.

Following inhalation

In case of exposure to fumes, fine particulates, powders, flakes: move to fresh air, lay patient down, get medical attention if discomfort persists.

Following skin contact

Use general hygiene measures for contact with the material: wash with soap and warm water.

In case of contact with molten product, cool rapidly with water and seek immediate medical attention. Do not attempt to remove molten product from skin because skin will tear easily. Cuts or abrasions should be treated promptly with thorough cleansing of the affected area.

Following eye contact

Use general measures if eye irritations occur. Do not rub eyes. Remove any contact lenses.
Flush eyes thoroughly with water, taking care to rinse under eyelids. If discomfort continues, consult a physician.

After ingestion

In case of significant oral intake (several mg Cu), rinse mouth and give 200-300 ml water to drink.
Do not induce vomiting.
Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

Gastro-intestinal symptoms are the first symptoms for high oral intakes of soluble copper compounds. Vomiting may occur.

The most critical organ for delayed effects from "copper" excess is the liver.

Nose-lung irritation may be a symptom occurring after inhalation of copper containing fumes/dusts/mists.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

Massive Copper itself is non-flammable. Use fire fighting measures appropriate to surrounding materials.

5.1.2 Unsuitable extinguishing media

Extinguishing media which may be used where molten copper is present: sand, sodium chlorite

Extinguishing media which must not be used where molten copper is present: water or halogenated extinguishing media.

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5.2 Special hazards arising from the substance or mixture

Respirable dust.

5.3 Advice for firefighters

General protection is needed: wear a self-contained breathing apparatus and a fully protective suit and gloves. Dispose of fire debris and contaminated fire fighting media in accordance with official regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Copper in massive form is not hazardous.

During production and some uses, hazardous "copper" may be formed and therefore accidental releases of respirable copper-bearing particles and soluble copper compounds are considered.

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Avoid formation of dust.

Ensure adequate ventilation.

Avoid inhalation of dust and fumes.

Wear suitable protective equipment.

6.1.2 For emergency responders:

Avoid formation of dust.

Ensure adequate ventilation.

Avoid inhalation of dust and fumes.

Wear suitable protective equipment.

Keep unprotected persons away.

6.2 Environmental precautions

-Liquids containing powder should be absorbed in vermiculite, dry sand, or earth before putting into a suitable container for recycling or disposal as hazardous waste.

-Collect dust, particulates, powders, flakes using a vacuum cleaner with a HEPA filter. Place in a suitable container for recycling or disposal as hazardous waste.

-Although the substance is not classified as dangerous to the environment, in the event of an accidental release the product should be prevented from reaching the sewage system or any water course, and from penetrating the ground/soil. Dispose of spilled material in accordance with the relevant local regulations. See Section 13 for disposal considerations.

6.3 Methods and material for containment and cleaning up

Avoid dust formation.

Sweep all spilled material or use an appropriate industrial vacuum cleaner.

Collect spilled material in suitable containers or closed plastic bags for recovery or disposal.

Dispose spilled material or contaminated material as waste. See section 13 for disposal considerations.

6.4 Reference to other sections

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For more information on exposure controls/personal protection or disposal considerations, check Sections 8 to 13 of this Safety Data Sheet.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures

Copper is not classified in massive forms and no protective measures are needed for safe handling

7.1.2 Advice on general occupational hygiene

Avoid contact with molten material. Do not use water on molten metal.

Melting, burning, sawing, brazing, grinding or machining operations may generate fumes and dusts.

Avoid generation and spreading of dust. Avoid inhalation of dust and small particles and contact with eyes.

Provide adequate ventilation.

Observe good industrial hygiene practices.

7.2 Conditions for safe storage, including any incompatibilities

Avoid direct contact with strong acids.

7.3 Specific end use(s)

Check the identified uses in section 1.2 of this safety data sheet.

For more information see the relevant Exposure Scenario, Annex I and check section 2.1: Control of workers exposure.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION – of relevance to industrial settings

An overview of the assigned protection factors (APFs) of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE (www.ebrc.de/mease.html).

8.1 Control parameters of relevance to industrial settings (occurrence of dusts, mist, fumes)

The following current national occupational exposure limit values for copper and copper compounds apply:

Country	Occupational exposure limit	Maximum exposure time	Document number – Date	Basis	Link to the legislation
UK	0.2 mg Cu (fume)/m ³ 1 mg Cu (dust and mist)/m ³	8h TWA (dust and mist)/m ³	2007	Copper	Health and Safety Executive- http://www.hse.gov.uk/coshh/table1.pdf
Finland	0.1 mg Cu (alveolar)/m ³ 1 mg Cu (dust and mist)/m ³	8h TWA	2009	Copper	The Ministry of Social Affairs and Health- http://pre20090115.stm.fi/hm1113394626349/passthru.pdf

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Belgium	0.2 mg Cu (fume)/m ³ 1 mg Cu (dust and mist)/m ³	8h TWA	2007	Copper	Service public fédéral Emploi, Travail et Concertation sociale- http://www.emploi.belgique.be/WorkArea/showcontent.aspx?id=23914
France	0.2 mg Cu (fume)/m ³ 1 mg Cu (dust)/m ³	8h TWA	2008	Copper	INSTITUT NATIONAL DE RECHERCHE ET DE SÉCURITÉ- http://en.inrs.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParReference/ED%20984/\$File/ED984.pdf

8.1.2 PNECs and DNELs

Exposure pattern	Route	Descriptor	DNEL / PNEC
Human –Long-term systemic effects	Oral, dermal and inhalation	Internal dose DNEL (Derived No Effect Level) Using absorption factors of 25% for oral, 100% for inhalation (respirable) and 0.03% for dermal exposure routes	0.041mg Cu/kg B wt/d
Human Short-term –systemic effects	Oral, dermal and inhalation	Internal dose DNEL (Derived No Effect Level) Using absorption factors of 25% for oral, 100% for inhalation (respirable) and 0.03% for dermal exposure routes	0.082mg Cu/kg B wt/d
Human Short-term – effects-drinking water	Oral	A NOAEL for drinking water	4 mg/l
Environmental	Freshwater	PNEC (Predicted No Effect Concentration) Includes a default bio-availability correction	7.8 µg dissolved Cu/L ⁽¹⁾
Environmental	Marine water	PNEC (Predicted No Effect Concentration) Includes a default bio-availability correction	5.2 µg dissolved Cu/L ⁽¹⁾
Environmental	Sediment freshwater	PNEC (Predicted No Effect Concentration) Includes a default bio-availability correction	87 mg Cu/kg dry wt ⁽¹⁾
Environmental	Sediment estuarine	PNEC (Predicted No Effect Concentration)	288 mg Cu/kg dry wt ⁽¹⁾
Environmental	Sediment marine	PNEC (Predicted No Effect Concentration)	676 mg Cu/kg dry wt ⁽¹⁾
Environmental	Soil	PNEC (Predicted No Effect Concentration) Includes a default bio-availability correction	65.5 mg Cu/kg dry wt ⁽¹⁾
Environmental	STP	PNEC (Predicted No Effect Concentration)	230 dissolved Cu/L

(1) Default PNEC values are given. These can be refined if information on local environment is available (see section 12.1)

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8.2 Exposure controls for industrial settings

See section 2.1 of the individual exposure scenarios in Annex I for a detailed description of the required exposure control measures. Any control measures and associated efficiency values are based on actual measured data at the workplace or on the MEASE tool for occupational exposure assessment (<http://www.ebrc.de/ebrc/ebrc-mease.php>).

For appropriate air monitoring, "total" and "respirable" copper levels should be assessed. An Excel sheet that allows the systemic internal human health exposure levels to be calculated is available from: <http://www.eurocopper.org/copper/reach.html>

The environmental assessment uses the Metal EUSES calculator for Downstream Uses which can be freely downloaded from <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>. For environmental monitoring, the physico-chemical characteristics of the local receiving environment should preferably be monitored (see section 12)

8.2.1 Appropriate engineering controls at industrial settings

Prevent formation of dust where possible. Ensure appropriate ventilation/exhaustion at machinery and places where dust can be generated.

Any deposit of dust which cannot be avoided should be regularly removed preferably using appropriate industrial vacuum cleaners or central vacuum systems.

Waste air should be released into the atmosphere only after it has passed through suitable dust separators.

Waste water generated during the production process or cleaning operations should be collected and should preferably be treated in an on-site waste water treatment plant which ensures efficient removal of copper.

8.2.2 Individual protection measures, such as personal protective equipment

8.2.2.1 Eye/face protection:

As a precautionary measure, the wearing of suitable safety glasses is advised.

8.2.2.2 Skin protection:

Copper is not classified as hazardous to skin (see section 11 for more details).

8.2.2.3 Respiratory protection

Melting, grinding or machining operations as well as packaging may generate fumes and dusts.

Avoid generation and spreading of dust - Use local ventilation to keep levels below established threshold values. A suitable particle filter mask is recommended where needed (see annex 1).

8.2.2.4 Thermal hazards

Not applicable. Copper does not have any self-heating or auto-flammable properties.

8.2.3 Environmental exposure controls

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

(a) Appearance Solid, copper colour. The particle size >1mm

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(b) Odour	Odourless.
(c) Odour threshold	Not applicable as odourless
(d) pH	Not applicable to an inorganic solid.
(e) Melting point	1059 1069°C
(f) Initial boiling point and boiling range	Not applicable to a solid that melts >300°C
(g) Flash point	Not applicable to an inorganic solid
(h) Evaporation rate	Not applicable to an inorganic solid.
(i) Flammability (solid, gas)	Non-flammable.
(j) Upper/lower flammability or explosive limits	Not applicable
(k) Vapour pressure	Not applicable to a solid that melts at >300°C
(l) Vapour density	Not applicable to an inorganic solid.
(m) Relative density	8.78g/cm ³ at 20°C
(n) Solubility(ies)	Insoluble – copper needs to be transformed into a copper compound to become soluble.
(o) Partition coefficient n-octanol/water	Not applicable to inorganic substances.
(p) Auto-ignition temperature	No auto ignition
(q) Decomposition temperature	Decomposition and/or melting starts at 1059°C
(r) Viscosity	Not applicable to an inorganic solid
(s) Explosive properties	Non-explosive. The substance does not contain chemical groups associated with explosive properties
(t) Oxidising properties	Non-oxidising substance.

9.2 Other information

Not applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable. See section 9.

10.2 Chemical stability

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Under normal conditions of use and storage, the product is stable.

10.3 Possibility of hazardous reactions

Reaction with H⁻ equivalents releases soluble copper compounds.

10.4 Conditions to avoid

Avoid dust formation and contact with acids.

10.5 Incompatible materials

Strong acids

10.6 Hazardous decomposition products

The element Cu⁰ does not decompose but may be transformed into other metal forms (e.g. Cu²⁺) –see section 10.3 .

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The toxicological information was obtained from the Risk Assessment Report on copper and copper compounds, assessed by the EC Technical Committee for New and Existing Substances (TCNES) and the EC Scientific Committee on Health and Environmental Risks (SCHER) (see: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp), and supplemented with recent information gathered for the REACH registration. The additional information confirms the hazard profile derived for copper massive as well as the DNELs derived.

Most of the available hazard data are related to exposure of soluble copper compounds (e.g. copper sulphate) and fine copper flakes, coated with zinc stearates (particle size around 5µm). For the hazard profile of copper in massive forms, information on solubility, bioaccessibility and bioavailability is combined with the hazard profile of soluble copper compounds in a read-across approach to assess its potential hazards.

Toxicity endpoints	Description of effects
Absorption	<p>Copper is an essential element and therefore, the concentration of copper in the body is strictly and efficiently regulated by homeostatic mechanisms. The major control mechanism is gastrointestinal absorption and biliary excretion into faeces. Liver has an important role in the maintenance of the copper homeostasis. The failure to maintain homeostasis may lead to adverse effects resulting either from deficiency or excess.</p> <p><u>INHALATION:</u> Copper massive and its marketed downstream use products have a d50 particle size >10 µm and therefore do not meet the criteria for acute inhalation classification. In specific cases (e.g. during production), dusts, mists and fumes may be produced. The absorption of the respirable</p>

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fraction (fumes) is considered to be complete (100%). Absorption of the “inhalable” fraction depends on the particle size and the Multiple Path Model of Particle Deposition (MPPD))¹ can be used to quantify the particle dependent absorption.

ORAL: The solubility of copper massive forms in gastric fluid is low. In-vitro bio-accessibility of soluble copper compounds, copper powders and copper massive forms (various sizes) in gastric fluid (in accordance to ASTM D5517-07), demonstrated that, **for massive forms, the release of copper ions in gastric fluids, was only < 0.1% of its total potential release (Rodriguez et al., 2010).**

Following administration of soluble copper compounds, a dose dependent adsorption of copper ions has been drawn from true pooled fitted data (exposure-specific absorption). The essential nutritive value of copper-ions drives this homeostasis with a copper absorption ranging between 20 % (high copper intake - near toxicity) to 80 % (low copper intake - near deficiency) for soluble copper compounds. Considering the most reliable human data currently available (Turnlund *et al* , 1989; 1998; 2005 and Harvey *et al* , 2003; 2005), **for a given soluble copper dose in the Gastro Intestinal Tract, oral absorption of copper in humans can be calculated based on the mean result for two functions:**

$$\text{Equation 1 } \text{oral absorption\%} = -15.0 \ln(x) + 63.2$$

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

$$x = \text{copper intake (mg/day)}$$

DERMAL: A dermal absorption of 0.3% for soluble and insoluble copper substances in solution or suspension is observed from in- vitro percutaneous tests on human skin (Roper 2003; Cage 2003). **For the dry exposure scenarios applicable to copper powders, the dermal absorption value of 0.03% applies.**

Acute toxicity

ORAL: At high levels, solubilised copper-ions may induce gastro-Intestinal effects. Acute oral effects, assessed from animal studies using CuO (Sanders, 2002a), copper sulphate (Lheritier, 1994) and coated copper flakes (Sanders, 2001a) are available. Comparison of the toxicity profiles demonstrates the importance of solubility/bio-accessibility for read-across of toxicity data among copper-bearing substances. The available animal data combined with in-vitro bio-accessibility data permitted the assessment of the acute toxicity of copper in powder and massive form.

The assessment concluded that, according to the Regulations (EC) No 1272/2008 and 67/548/EEC, copper sulphate and coated copper flakes meet the criteria as acute harmful by oral intake (LD50 rats > 300 mg/kg body weight). The assessment further concluded that, according to Regulations (EC) No 1272/2008 and 67/548/EEC, copper (massive and powder forms) and CuO do not meet the criteria for classification after oral intake (LD50 > 2000 mg/kg body weight).

Acute gastrointestinal effects associated with copper sulphate additions to drinking water were investigated in humans (Araya *et al* , 2001 and 2003) and a NOAEL of 4mg Cu/L was derived. At higher doses (6 to 8 mg Cu as CuSO₄/L, administered as a bolus on an empty stomach) nausea was the most frequently reported symptom (10% at 6 mg/L and 18% at 8 mg/L) and generally occurred within 15

¹ MPPD from : Asharian and Freijer, 1999

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	<p>minutes of administration. Other gastrointestinal symptoms (vomiting, diarrhoea and abdominal pain) were reported less frequently and abdominal pain showed no relationship to concentration.</p> <p><u>INHALATION:</u> Available acute inhalation toxicity data on coated copper flakes (Wesson, 2001) and copper oxychloride (Wesson, 2003) demonstrate that these soluble materials need to be classified as "harmful by inhalation" (LD50 rats 1-5 g/m³ air). The inhalation toxicity was characterized by local damage at the site of predominant deposition of particles (effect on respiratory tract and in lungs).</p> <p>Copper massive has a particle size >10 µm and down-stream uses do not lead to particles with d₅₀ <10µm. Therefore, according to Regulations (EC) No 1272 and 67/548/EEC, these do not meet the criteria for classification as harmful by inhalation.</p> <p><u>DERMAL:</u> Consideration of available acute dermal toxicity data on copper (coated copper flakes Sanders, 2001b)) and copper compounds (copper sulphate (Lheritier, 1993) and copper oxide (Sanders, 2002b) (LD50>2000 mg/kg body weight) against EU classification criteria, according to Regulations (EC) No 1272/2008 and 67/548/EEC, leads to the conclusion that copper nor any of the tested copper compounds require classification for acute lethal effects after dermal exposure.</p> <p>The classification criteria, for very fine and soluble "copper" bearing substances, according to the regulations (EC) No 1272/2008 and 67/548/EEC on acute toxicity, lead to a classification as "harmful if swallowed and if inhaled".</p> <p>The classification criteria, for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on acute toxicity, are therefore not met.</p>
STOT single exposure	<p>The effects following acute toxicity (oral and inhalation – see above) have been used for the classification as harmful. The local oral and inhalation effects resulted in mortality.</p> <p>The classification criteria, for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on STOT-SE are therefore not met.</p>
Skin/eye irritation/corrosion	<p>Animal data (coated copper flakes (Sanders, 2001c) and CuO (Sanders, 2002c)) have demonstrated that, according to Regulations (EC) No 1272 and 67/548/EEC, "copper" is not a skin irritant.</p> <p>Animal studies with coated copper flakes (Sanders 2001d) and CuO (Sanders, 2002d) induced slight reversible eye irritation effects. Following the criteria, according to the Regulations (EC) No 1272 and 67/548/EEC, the coated copper flakes and CuO are not considered as an eye irritant.</p> <p>The classification criteria, for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on skin/eye irritation are therefore not met.</p>
Respiratory Skin Sensitisation	<p>Animal data (coated copper flakes (Sanders 2001e) and CuO (Sanders 2002e)) have demonstrated that, according to Regulations (EC) No 1272/2008 and 67/548/EEC, "copper" is not a skin sensitizer.</p> <p>The classification criteria, for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on sensitization are therefore not met.</p>

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Genotoxicity	<p>Public domain data indicate that copper sulphate is negative <i>in vitro</i> 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 <i>in vitro</i> mammalian cell tests show that copper sulphate is genotoxic only at high, cytotoxic concentrations (up to 250 mg/l).</p> <p>Two <i>in vivo</i> genotoxicity studies performed on a soluble copper compound (copper sulphate), in accordance to respectively OECD 486 and EU B.12 were negative (Ward, 1994 and Riley, 1994).</p> <p>The classification criteria for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on germ cell mutagen are therefore not met.</p>
Carcinogenicity	<p>All available studies on the carcinogenicity of copper are public domain studies but study qualities are limited due to shorter exposure periods (<2 years) and small group sizes (Carlton et al., 1973; Burki and Okita, 196 and Harrison et al., 1954). However, using these studies in a weight of evidence approach, it was concluded that copper compounds do not raise concerns with respect to carcinogenic activity.</p> <p>The classification criteria for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on carcinogenicity are therefore not met.</p>
Toxicity for reproduction	<p>A high quality study (Mylchreest, 2005) indicate that the no observed-adverse effect level (NOAEL) for reproductive toxicity of a soluble copper compound (copper sulphate pent hydrate) in rats is > 1500 mg/kg food or >24 mg Cu/kg bw/d, the highest dose tested. At the highest dose, slight non-reproductive toxicity effects (transient effect on spleen weight) were observed.</p> <p>The classification criteria for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 and 67/548/EEC on reproductive toxicity are therefore not met.</p>
Repeated dose toxicity and STOT-RE	<p>NOAEL_{oral} rat = 16 mg Cu /kg body weight/day (Hebert C.D., 1993). Following repeated administration of CuSO₄ in the feed for 13 weeks produced effects in the forestomach, liver and kidney. Inflammation of the liver occurred in male and female animals at 260 mg CuSO₄/kgBW/day and above. The incidence and severity of the effects were dose-dependent. This study was used in the subsequent calculation of an oral and systemic DNEL (including a Safety factor of 100 and an oral absorption of 25%) of 0.041 mg Cu/kg body weight/day.</p> <p>The classification criteria, for copper in massive form and copper powder, according to Regulations (EC) No 1272/2008 on Specific Target Organ Toxicity are therefore not met.</p>

SECTION 12: ECOLOGICAL INFORMATION

The ecotoxicological information was obtained from the Risk Assessment report on copper and copper compounds, assessed by the EC Technical Committee for New and Existing Substances (TCNES) and the EC Scientific Committee on Health and Environmental Risks (SCHER) (see: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp), and supplemented with recent information gathered for the REACH registration. The additional information confirms the hazard profile derived for copper massive and refined the PNECs derived for the some compartments (soil and marine waters).

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Most of the available hazard data are related to exposure of soluble copper compounds (e.g. copper sulphate). For the hazard profile of copper massive forms (assessed from a sphere of 1mm diameter), information on solubility and bioavailability are combined with the hazard profile of soluble copper compounds in a read-across approach to assess its potential hazards.

12.1 Ecotoxicity

Environmental bioavailability

In accordance to the CLP guidance (2009), the environmental bio-availability of a copper massive form (1 mm sphere) in freshwater environments was assessed from transformation/dissolution tests (OECD 29). The data demonstrate higher release at lower pH. The data also demonstrate a linear relationship between the releases and the exposed surface area. The non-abrasive release of dissolved copper ions to the aqueous transformation/dissolution medium (7 days, 100 mg/L loading, pH6), was 6.7 µg Cu/l corresponding to a surface –specific release of 0.15 µg Cu/mm² (Rodriguez et al., 2007).

Acute aquatic toxicity test results and environmental classification:

The acute toxicity of soluble copper ions was assessed from studies on soluble copper compounds. From a literature search 451 high quality L (E)C50 values 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*). The data were treated and summarized in accordance with the CLP guidance (2009) to derive the pH dependent acute reference value. The lowest species-specific geometric mean L(E) C50 reference was obtained for an invertebrate (*Ceriodaphnia dubia*) at pH 5.5-6.5 with an acute L(E)C50 of 25.0 µg Cu/L (Van Sprang et al., 2010).

To assess the environmental classification of copper in massive form, the copper release from the 7 days transformation/dissolution data of copper in massive forms (6.7 µg Cu/L at 100mg/L, pH6) was combined with the acute reference value for the copper ions (25 µg Cu/L) (Van Sprang et al., 2010).

The assessment demonstrates that, according to Regulations (EC) No 1272/2008 and 67/548/EEC, copper massive forms do not need to be classified for acute environmental hazards.

In accordance with the EU CLP guidelines (2009), chronic classification applies if the substance is persistent or bio-accumulative. For “copper” it has been demonstrated that the bio-available copper-ions are rapidly removed from the water column (Rader, 2010) – see also section 12.2. Copper is an essential nutrient, copper concentrations are very strongly regulated and copper is not bio-magnified across the food-web – see also section 12.3. The “bio-accumulation” criteria therefore do not apply the “copper”.

Based on the assessment (see section 12.2 and 12.3), according to Regulations (EC) No 1272/2008 and 67/548/EEC, Copper massive does not meet the classification for chronic aquatic toxicity.

For more details – see copper Chemical Safety Report (2010)

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Chronic freshwater toxicity test results and PNEC derivation:

The chronic toxicity of soluble copper ions was assessed from studies on soluble copper compounds. 139 individual NOEC/EC10 values resulting in 27 different species-specific soluble Cu-ions NOEC values, covering different trophic levels (fish, invertebrates and algae) were used for the PNEC derivation. The large intra-species variability in the reported single species NOECs was related to the influence of test media characteristics (e.g., pH, dissolved organic carbon (DOC), hardness) on the bioavailability and thus toxicity of copper. Species-specific NOECs were therefore calculated after normalizing the NOECs towards a series of realistic environmental conditions in Europe (typical EU scenario's, with well-defined pH, hardness and DOC). Such normalization was done by using chronic copper bioavailability models (Biotic Ligand Models), developed and validated for three taxonomic groups (fish, invertebrates and algae) and additional demonstration of the applicability of the models to a range of other species. The species-specific BLM-normalized NOECs were used for the derivation of log-normal Species Sensitivity Distributions (SSD) and HC5 values (the median fifth percentile of the SSD), using statistical extrapolation methods to derive a PNEC. The data allow the derivation of PNECs for the typical EU scenario ranging between 7.8 to 22.1 µg dissolved Cu/L. Additional BLM scenario calculations for a wide range of surface waters across Europe further demonstrated that the HC5 of 7.8 µg dissolved Cu/L, is protective for 90% of the EU surface waters and can thus be considered as a reasonable worst case for Europe in a generic context.

Copper threshold values were also derived for three high quality mesocosm studies, representing lentic and lotic systems. The mesocosm studies included the assessment of direct and indirect effects to large variety of taxonomic group and integrate potential effects from uptake from water as well as from food. The results confirm the BLM normalized single species threshold values.

Conclusion: a value of 7.8 µg dissolved Cu/L is the default chronic freshwater PNEC, to be used to assess local risks. The assessment can be refined if information on local water chemistry (dissolved organic carbon, pH, calcium, magnesium, sodium and alkalinity) is available.

For more details – see Copper Risk Assessment Report (2008) and Copper Chemical Safety Report (2010)

Chronic marine waters toxicity test results and PNEC derivation

The chronic toxicity of soluble copper ions was assessed from studies on soluble copper compounds. 51 high-quality chronic NOEC/EC10 values, resulting in 24 different species-specific soluble Cu-ions NOEC values covering different trophic levels (fish, invertebrates, algae), were retained for the PNEC derivation. NOEC values were related to the Dissolved Organic Carbon (DOC) concentrations of the marine test media. Species-specific NOECs were therefore calculated after DOC normalizing of the NOECs. These species-specific NOECs were used for the derivation of species sensitivity distributions (SSD) and HC5 values, using statistical extrapolation methods. The organic carbon normalisation was carried out at a DOC level typical for coastal areas (2 mg/l) and resulted in an HC5 value of 5.2 µg Cu/L.

For more details – see Copper Risk Assessment Report (2008)

A Copper threshold value was also recently derived from a high quality marine mesocosm study (Foekema et al., 2010). The mesocosm studies included the assessment of direct and indirect effects to large variety of taxonomic group and integrate potential effects from uptake from water as well as from food. The results confirm the DOC normalized single species threshold values.

Conclusion: a value of 5.2 µg dissolved Cu/L is the default chronic marine water PNEC, to be used to assess local risks. The assessment can be refined if the dissolved organic carbon concentration of the local environment is available.

For more details – see Copper Chemical Safety Report (2010)

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Chronic freshwater sediment toxicity test results and PNEC derivation:

The sediment PNEC included using a weight of evidence approach considering different sources and tiered approaches of information: (1) sediment ecotoxicity data from spiking sediments with of soluble copper compound, (2) pelagic ecotoxicity data in combination with water-sediment partitioning coefficients (K_d values) derived through different approaches and (3) mesocosm/field ecotoxicity.

High-quality chronic benthic NOECs for six benthic species, representing 62 NOEC values were retained for the PNEC derivation. NOEC values were related to sediment characteristics (e.g., Organic Carbon (OC) and Acid Volatile Sulphides (AVS)), influencing the bioavailability and thus toxicity of copper to benthic organisms. The derivation of the freshwater HC_{5 sediment} for copper was therefore based on the OC-normalized dataset, containing only low-AVS sediments.

An HC-5 of 1741 mg Cu/kg OC, corresponding to 87 mg Cu/kg dry weight for a sediment with 5 % O.C. (TGD default value) is used.

Conclusion: a value of 87 mg Cu/kg dry weight is the default chronic freshwater sediment PNEC, to be used to assess local risks. The assessment can be refined if the organic carbon concentration and the Acid Volatile Sulphide concentrations of the local sediment is available.

For more details – see Copper Risk Assessment Report (2008) and Copper Chemical Safety Report (2010)

Chronic terrestrial toxicity test results and PNEC derivation:

Chronic terrestrial toxicity is derived from spiking of soils with soluble copper compounds. A high-quality dataset of 252 individual chronic NOEC/EC₁₀ values from 28 different species and processes representing different trophic levels (i.e., decomposers, primary producers, primary consumers) has been retained for the PNEC derivation. The observed intra-species differences in toxicity data were related to differences in bioavailability: the latter related to differences in soil properties and to differences in ageing and application mode and rate.

The soil property best explaining the variability in toxicity for most of the endpoints was the eCEC (effective Cation Exchange Capacity). To account for the observed difference between lab-spiked soils and field-contaminated soils, a conservative leaching-ageing factor of 2 was agreed based on test data from the mechanistic research on ageing and ionic strength (leaching) effects. For the normalisation of the ecotoxicity data, first the leaching-ageing factor was applied on all added NOEC/EC₁₀ values. These adjusted values, after addition of the respective Cu background concentrations, were subsequently normalised to a wide range of EU soils using the relevant regression (bio) availability models, generating soil-type specific HC₅ values and a derivation of the PNEC. Species Sensitivity Distributions were constructed using the normalised NOEC/EC₁₀ data. HC₅ values from log-normal distributions ranging between 65.5 and 150 mg Cu/kg dry weight were obtained (Oorts et al., 2010).

A total of eight single species studies were 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 five multi-species studies were available, three of which studied the effects of copper in freshly spiked soils and two in field contaminated aged soils. Invertebrates, plants and micro-organisms were studied. Single-species and multi-species field studies indicate that effects did not occur at an exposure level at the HC₅value.

See Copper Risk assessment Report

Conclusion: a value of 65.5 mg Cu/kg dry weight is the default chronic soil PNEC, to be used to assess local risks. The assessment can be refined if the pH and Cation Exchange Capacity of the local soil is available.

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For more details – see copper Chemical Safety Report (2010)

For more information on how the environmental classification was derived and how to assess bio-availability, contact your supplier.

12.2 Persistence and degradability

“Copper” cannot be degraded, but may be transformed between different phases, chemical species, and oxidation states.

In accordance to the EU 2009 CLP guidance, the fate of the copper ion under “environmentally relevant” conditions was modelled, using the Ticket Unit World Model. Rapid removal from the water column was also assessed using data from one mesocosm and three field studies (Rader et al., 2010). The assessment demonstrated the rapid removal of copper-ions, delivered as soluble copper compounds, from the water column under “normal environmental conditions”. Rapid removal of a substance from the water column is defined as 70% removal within 28 days. Literature data demonstrates the strong binding of copper-ions to sediment materials and especially the anaerobic CuS complexes are very stable (Simpson et al., 1998; Sundelin and Erickson, 2001). The remobilisation of Cu-ions to the water column is therefore not expected. The assessment therefore demonstrates that “copper” does not meet the criterion as “persistent”.

12.3 Bioaccumulative potential

The Guidance states the following on Bioaccumulation: *“Metals that are essential nutrients are actively regulated: removal and sequestration processes that minimise toxicity are complemented by an ability to up-regulate concentrations for essentiality. As a result, the “bioaccumulative” criterion is not applicable to these metals.”*

12.4 Mobility in soil

Copper-ions bind strongly to the soil matrix. The binding depends on the soil properties. A median water-soil partitioning coefficient (Kp) of 2120 L/kg has been derived for soils (more details see Copper Risk Assessment Report, 2008 and Copper Chemical Safety Report, 2010).

12.5 Results of PBT and vPvB assessment

The PBT and vPvB criteria of Annex XIII to the Regulation do not apply to inorganic substances, such as copper and its inorganic compounds.

Copper is not PBT or vPvB.

12.6 Other adverse effects

Copper is not expected to contribute to ozone depletion, ozone formation, global warming or acidification.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility.

SECTION 14: TRANSPORT INFORMATION

Copper massive do not need to be classified for transportation.

RID/ADR: not restricted

ADNR/ADN: not restricted

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IATA/ICAO: not restricted

IMO/IMDG: not restricted

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance

15.1.1 Worldwide Chemical Inventories

EC inventory (EU): 231-159-6	ENCS (Japan): listed
TSCA (USA): listed	ECL(Korea): listed
DSL(Canada): listed	PICCS (Philippines): listed
AICS (Australia): listed	IECSC(China): listed
NZIoC (New Zealand): listed	

Copper is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.

15.1.2 Other regulatory information

15.2. Chemical safety assessment

A chemical safety assessment has been carried out for the substance.

SECTION 16: OTHER INFORMATION

The data herein are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish any legally valid contractual relationship.

Version 2010-12-01: New extended Safety Data Sheet in compliance with regulation (EC) No. 1907/2006 ("REACH"). The information provided in this SDS is consistent with the information provided in the REACH Chemical Safety Report (CSR) for Copper metal. Further information can be obtained from the Manager of the Copper REACH Consortium at the European Copper Institute

For contact details:

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Abbreviations

TCNES: EC Technical Committee for New and Existing Substances (TCNES)

SCHER: EC Scientific Committee on Health and Environmental Risks

REACH: EC Regulation on Registration, Evaluation and Authorisation of Chemicals (**Regulation (EC) No 1907/2006 as amended**)

LD50: Lethal dose to 50% of the test organisms

LC50: Lethal concentration to 50% of the test organisms

LC10: Lethal concentration to 10% of the test organisms

EC10: Effective concentration to 10% of the test organisms

NOEC: No Observed Effect Concentration = highest concentration tested without effects

DNEL: Derived No-Effect Level

SSD: Species Sensitivity Distribution= distribution of the species-specific NOEC or (L(E)C10 values for all species tested.

HC-5: The concentration without effect for 95% of the species = statistically derived environmental threshold value.

PNEC: Predicted No-effects Concentration

DOC: Dissolved Organic Carbon

OC: Organic Carbon

CEC: Cationic Exchange Capacity

AVS = Acid Volatile Sulphide.

References

The list of full references can be obtained upon request

Disclaimer:

Luvata Pori Oy provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. Furthermore, this Safety Data Sheet (including its Annex) is based on the requirements of Regulation (EC) No 1907/2006 (REACH) based on information as available as at October 1, 2010. Further information received following the timetable prescribed by REACH and the guidance policies set out in the REACH Implementation Programs may be added as it becomes available.

**Annex I to Extended Safety Data Sheet (eSDS) for copper massive prepared by ECI
(EU commission regulation N° 1907/2006/EC and amendments) November 2010**

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