



FENIX
METALS LIMITED

Safety Data Sheet

Solder (containing lead)

Safety Data Sheet according to the REACH Regulation (EC) 1907/2006, and the CLP Regulation (EC) 1272/2008. Revisions from the previous major version are indicated by a vertical line at the left margin.

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier

Solder sticks, bars, ingots, pellets and solid wire of alloys:

90Sn, 30 Fluks⁽¹⁾, 33 Fluks⁽¹⁾, 35 Fluks⁽¹⁾, 40 Fluks⁽¹⁾, 40GAR, 45GAR, 50GAR, 22 Hafnia, 28 Hafnia, 30 Hafnia, 33 Hafnia, 37 Hafnia, 38 Hafnia, 40 Hafnia, 50 Hafnia, 60 Hafnia, 30HK⁽¹⁾, 40HK⁽¹⁾, 50HK⁽¹⁾, 63 STARLI HQ, 63 STARLI X, 63 STARLI Refresher, Bera ReGalvanising⁽⁵⁾, Bera Super LT⁽¹⁾, Capillary wire⁽¹⁾, LC10, LS4 (L)⁽⁴⁾, Meta 25⁽¹⁾, Meta 28⁽¹⁾, Meta 30⁽¹⁾, Meta 33⁽¹⁾, Meta 35⁽¹⁾, Meta 40⁽¹⁾, Meta 45⁽¹⁾, Meta 50⁽¹⁾, Meta-Zinc⁽¹⁾⁽³⁾, Meta-Zinc 40⁽¹⁾⁽³⁾, Selectralloys 6337ST2, UOS-015⁽¹⁾⁽²⁾, Pb60Sn39Bi1⁽³⁾, Sn5Ag1Pb⁽⁴⁾, Sn5Ag1,5Pb⁽⁴⁾, Sn7Pb93, Sn17Pb83, Sn20Pb80, Sn20Sb4Pb76⁽¹⁾, Sn25, Sn25Pb75, Sn26Sb1,2⁽¹⁾, Sn27⁽¹⁾, Sn27Pb73, Sn28⁽¹⁾, Sn29,5Bi0,5Pb70⁽³⁾, Sn30^(sometimes 1), Sn30Pb70, Sn30Sb1.6Pb⁽¹⁾, Sn33Pb67, Sn33^(sometimes 1), Sn35Pb65, Sn37Sb3Pb60⁽¹⁾, Sn40^(sometimes 1), Sn40Pb60, Sn40 Low Bi, Sn40Sb2Pb⁽¹⁾, Sn40Pb55Zn5⁽⁵⁾, Sn45Pb55, Sn45Pb55GAR, Sn50, Sn50Pb50, Sn60, Sn60Cu1⁽²⁾, Sn60Pb40, Sn60Pb38Cu2⁽²⁾, Sn61.9Pb38.1, Sn62Ag2Pb⁽⁴⁾, Sn62Ag2Pb36⁽⁴⁾, Sn62Pb36Ag2⁽⁴⁾, Sn62Pb36Ag2P⁽⁴⁾, Sn62SbNi⁽¹⁾⁽²⁾, Sn63Pb37, Sn80Pb20, S-Pb49Sn48Bi3⁽³⁾, S-Pb55Sn45, S-Pb58Sn40Sb2⁽¹⁾, S-Pb60Sn40, S-Pb65Sn35, S-Pb69Sn30Sb1⁽¹⁾, S-Pb70Sn30, S-Pb74Sn25Sb1⁽¹⁾, S-Pb78Sn20Sb2⁽¹⁾, S-Pb80Sn20, S-Pb85Sn15, S-Pb90Sn10, S-Pb93Sn5Ag2⁽⁴⁾, S-Pb95Sn5, S-Pb95Ag5⁽⁴⁾, S-Pb98Sn2, S-Pb98Ag2⁽⁴⁾, S-Sn50Pb50, S-Sn50Pb50E, S-Sn50Pb50Sb⁽¹⁾, S-Sn50Pb49Cu1⁽²⁾, S-Sn60Pb40, S-Sn60Pb40E, S-Sn60Pb40Sb⁽¹⁾, S-Sn60Pb38Bi2⁽³⁾, S-Sn60Pb39Cu1⁽²⁾, S-SnSn62Pb36Ag2⁽⁴⁾, S-Sn63Pb37, S-Sn63Pb37E, S-Sn63Pb37Sb⁽¹⁾.

⁽¹⁾ contains antimony.

⁽²⁾ contains copper.

⁽³⁾ contains bismuth.

⁽⁴⁾ contains silver.

⁽⁵⁾ contains zinc.

This data sheet does not apply to powders or other finely divided forms of the product.

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

Soldering and surface coating for electronic, electrical, plumbing and engineering applications at temperatures up to 500°C. Manufacture of solder powder.

Details of Exposure Scenarios are given in section 16.

1.3 Details of the supplier of the safety data sheet

Fenix Metals Sp. z o.o.

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(office hours only), (office hours only)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

The components of the product are not classified as hazardous under the Dangerous Substances Directive 67/548/EEC or the Classification Labelling and Packaging Regulation (EC) 1272/2008.

The product is not classified as dangerous under the Dangerous Preparations Directive 1999/45/EC or the Classification Labelling and Packaging Regulation (EC) 1272/2008.

2.2 Label elements

Dangerous Preparations Directive 1999/45/EC - none required.

Classification Labelling and Packaging Regulation (EC) 1272/2008 - none required.

2.3 Other hazards

Burns from contact with molten product.

Lead in massive form is not a significant health hazard. However, melting or activities generating lead dust, fume or vapour can result in sufficient lead entering your body to be hazardous to your health. Oxidation products (including lead compounds) may also form on the surface of metallic lead. Lead is heavy and care should be taken when lifting and handling. See section 11 for more information on the health hazards of lead compounds.

SECTION 3: Composition/Information on Ingredients

3.2 Mixtures

Declarable components: none.

Other components:

| Substance: | Weight (%) | EC No: | CAS No: | Registration No: |
|--|------------|-----------|-----------|--|
| Tin | 0-95 | 231-141-8 | 7440-31-5 | 01-2119486474-28-0024 Some of this substance is exempted from the registration requirements in accordance with Article 2.7(d), as it is a recovered substance. |
| Lead | 5-99 | 231-100-4 | 7439-92-1 | 01-2119513221-59-0085 Some of this substance is exempted from the registration requirements in accordance with Article 2.7(d), as it is a recovered substance. |
| Antimony (products marked ⁽¹⁾) | <5 | 231-146-5 | 7439-92-1 | 05-2114310155-65 |
| Copper (products marked ⁽²⁾) | <5 | 231-159-6 | 7440-50-8 | No registration number is given for this substance, because it is exempted from the registration requirements in accordance with Article 2.7(d), as it is a recovered substance; |
| Bismuth (products marked ⁽³⁾) | <5 | 231-177-4 | 7440-69-9 | 05-2114310315-65 |
| Silver (products marked ⁽⁴⁾) | 0.5-10 | 231-131-3 | 7440-22-4 | 05-2114130135-65 |
| Zinc (products marked ⁽⁵⁾) | 2.5-25 | 231-175-3 | 7440-66-6 | |

SECTION 4: First Aid Measures

The measures below are unlikely to be relevant whilst lead is in its solid metallic state. However, they are relevant if the metal is melted and in the event of exposure to fumes, vapour or dust or oxidation products that may form on the surface.

4.1 Description of first aid measures

| | |
|---------------------|---|
| Inhalation | Remove to fresh air. Seek medical attention. |
| Ingestion | Rinse out mouth and give plenty of water to drink. Seek medical attention. |
| Eye contact | Check for contact lenses and remove if present. Wash the eyes thoroughly with water. Seek medical advice if irritation persists. |
| Skin contact | Remove contaminated clothing. Wash skin immediately with soap and water. Seek medical advice if irritation persists. In case of contact with molten metal, cool skin rapidly with cold water. |

4.2 **Most important symptoms and effects, both acute and delayed**

Symptoms of lead poisoning include weakness, irritability, asthenia, nausea, abdominal pain with constipation, and anaemia.

For antimony, acute or delayed effects are not anticipated.

For high oral intakes of soluble copper compounds, the first symptoms are gastro-intestinal. 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.

Symptoms of acute silver poisoning:

Direct contact may cause mild local irritation of the skin or eyes. Inhalation of fumes or dusts of silver may be irritating to mucous membranes and upper respiratory tract. Exposure to high concentrations of smoke or dust may cause lung damage and pulmonary oedema. Ingestion of silver compounds can cause irritation of the gastrointestinal tract.

Symptoms of chronic silver poisoning:

Prolonged exposure to the smoke or dust causes a metallic taste in the mouth, loss of appetite, headache and general infirmity. It can also cause a bluish or grayish discoloration of the skin, eyes and mucous membranes (Argyria). It may take several years before it develops. The stains are permanent.

4.3 **Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. Symptoms of lead poisoning may occur after several hours; get medical attention.

SECTION 5: Firefighting Measures

5.1 **Extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Suitable extinguishing agents: CO₂, dry powder, sand or water spray. Do not use full water jets or foam.

5.2 **Special hazards arising from the substance or mixture**

Fire may cause hazardous combustion products, including lead fumes and lead oxide.

5.3 **Advice for fire fighters**

Use a self-contained breathing apparatus. Wear protective clothing. Do not allow runoff into drains, surface waters or groundwater.

SECTION 6: Accidental Release Measures

The product as supplied in solid form is not hazardous if spilled or released, although normal hygiene measures should be taken if the product is manually handled. This section applies to accidental release of materials, such as dross, dust or fume, arising from use of the product, as a result of fire or from other causes.

6.1 **Personal precautions, protective equipment and emergency procedures**

Persons not providing assistance should be kept away from the contaminated area. Ensure adequate ventilation. Avoid dust formation and inhalation of dust and fumes. Avoid contact with skin, eyes and clothing. Wear suitable respiratory protective equipment if exposure levels are expected to exceed OELs.

6.2 **Environmental precautions**

Do not discharge into drains, surface waters or groundwater. In case of entry into waterways, soil or drains, inform the responsible authorities.

6.3 **Methods and materials for containment and cleaning up**

Pieces can be picked up. Collect spilled material by vacuum cleaning or by sweeping in damped condition and keep in closed containers. Avoid raising dust. Label containers and send for recovery or disposal (see section 13).

6.4 **Reference to Other Sections**

See section 8: Exposure Controls/Personal Protection.
See section 13: Disposal Considerations.

SECTION 7: Handling and Storage

7.1 **Precautions for safe handling**

Wear protective clothing (see Section 8). Do not let molten metal contact water. Ensure that product and any tools are dry before contact with molten metal. Avoid generation of dust and fume. Provide good ventilation of working area (local exhaust ventilation, if necessary). Do not eat, drink or smoke until handling has ceased and hands and face have been washed. See section 16 for relevant Exposure Scenarios.

7.2 **Conditions for safe storage, including any incompatibilities**

No special measures required. Do not store together with foodstuffs or animal feedstocks. Do not store with acids or alkalis. Do not store with combustible materials. Keep out of the reach of children.

7.3 **Specific end uses(s)**

See section 16 for specific Exposure Scenarios.

SECTION 8. Exposure Controls/Personal Protection

8.1 Control parameters

Occupational exposure standards:

| | | |
|------------------------|---|--|
| UK EH40 | Lead | 0.15mg/m ³ 8hr TWA |
| | Tin (inorganic compounds) | 2mg/m ³ 8hr TWA, 4mg/m ³ 15min STEL |
| | Antimony (metal & compounds) | 0.5mg/m ³ 8hr TWA |
| | Silver (metallic) | 0.1mg/m ³ 8hr TWA |
| | Copper (dust) | 1mg/m ³ 8hr TWA, 2mg/m ³ 15min STEL |
| | (fume) | 0.2mg/m ³ 8hr TWA |
| France ED 984 | Plomb | 0.1mg/m ³ VME |
| | Etain | pas catalogué |
| | Antimoine | 0.5mg/m ³ VME |
| | Argent (métallique) | 0.1mg/m ³ VME |
| | Cuivre (poussière) (fumé) | 1mg/m ³ VME, 2mg/m ³ VLCT (ou VLE) 0.2mg/m ³ VME |
| Germany TRGS900 | Blei (TRGS 505) (einetembare Fraktion) | 0.1mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 4 |
| | Zinn(IV) Verbindungen, anorganische (einetembare Fraktion) | 2mg/m ³ Grenzwert |
| | Zinn(II) Verbindungen, anorganische (einetembare Fraktion) | 8mg/m ³ Grenzwert |
| | Antimon (einetembare Fraktion) | 0.5mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 4 |
| | Antimonverbindungen (ausgenommen Antimonwasserstoff und Diantimontrioxid) (einetembare Fraktion) | 0.5mg/m ³ Grenzwert |
| | Diantimontrioxid (einetembare Fraktion) | 0.1mg/m ³ Grenzwert |
| | Silber | 0.1mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 8 |
| | Kupfer und seine Verbindungen (einetembare Fraktion) | 1mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 4 |
| | Kupfer-Rauch (alveolengängige Fraktion) | 0.1mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 4 |
| | Zinkhaltige Rauch (einetembare Fraktion) | 1mg/m ³ Grenzwert Spitzenbegrenzung, Überschreitungsfaktor 2 |

In countries other than the UK, France and Germany, different exposure limits may apply.

Biological action levels - inorganic lead:

| | |
|----------------|---|
| EU | 70µg/dL |
| UK | 60µg/dL |
| | 30µg/dL for women of reproductive capacity. |
| Germany | 40µg/dL |
| | 30µg/dL for women of reproductive capacity. |
| France | 40 µg/dL |
| | 30 µg/dL (for woman of reproductive capacity) |

DN(M)ELs for workers - lead:

| Exposure pattern | Route | Descriptors | DNEL/DMEL | Most sensitive endpoint |
|------------------------------|---------------------------------|-------------|-----------|---|
| Acute - systemic effects | Dermal (mg/kg bw /day) | NA | NA | NA |
| | Inhalation (mg/m ³) | NA | NA | NA |
| Acute - local effects | Dermal (mg/kg) | NA | NA | NA |
| | Inhalation (mg/m ³) | NA | NA | NA |
| Long-term - systemic effects | Systemic (µg lead /dL blood) | NOAEL | 40 µg/dl | Adult neurological function. |
| | | NOAEL | 10 µg/dl | Developmental effect on foetus of pregnant women. |
| Long-term - local effects | Dermal (mg/kg) | NA | NA | NA |
| | Inhalation (mg/m ³) | NA | NA | NA |

PNECs - lead

| Exposure pattern | Route | Descriptor | PNEC |
|-----------------------------|------------------------------|------------|---|
| Long-term – chronic effects | Freshwater | PNEC | 3.1 g Pb/L (dissolved) |
| Long-term- chronic effects | Marine | PNEC | 3.5 g Pb/L (dissolved) |
| Long-term – chronic effects | Freshwater Sediment | PNEC | 174.0 mg Pb/kg dw ⁽¹⁾ 41.0 mg Pb/kg dw ⁽²⁾ |
| Long-term – chronic effects | Marine Sediment | PNEC | 164.0 mg Pb/kg dw |
| Long-term – chronic effects | Soil | PNEC | 212.0 mg Pb/kg dw |
| Long-term – chronic effects | STP (Sewage Treatment Plant) | PNEC | 0.1 mg Pb/L |

(1) without bioavailability correction

(2) with bioavailability correction

PNECs and DNELs - antimony:

| Exposure pattern | Route | Descriptor | DNEL/PNEC |
|------------------------------|-----------------------|------------|-----------------------|
| Long-term - systemic effects | Dermal | DNEL | 281 mg/kg bw/day |
| Long-term - local effects | Inhalation | DNEL | 0.5 mg/m ³ |
| | Freshwater | PNEC | 0.113 mg Sb/L |
| | Marine | PNEC | 0.0113 mg Sb/L |
| | Sediment - freshwater | PNEC | 7.8 mg Sb/kg ww |
| | Sediment - marine | PNEC | 1.56 mg Sb/kg ww |
| | Soil | PNEC | 37 mg Sb/kg dw |
| | STP | PNEC | 2.55 mg Sb/L |

PNECs and DNELs - copper:

| Exposure pattern | Route | Descriptors | DNEL/PNEC |
|---|-----------------------------|--|------------------------|
| Human long-term systemic effects | Oral, dermal and inhalation | Internal dose DNEL using absorption factors of 25% for oral, 100% for inhalation (respirable) and 0.03% for dermal exposure routes | 0.041mg Cu/kg B wt/day |
| Human short-term systemic effects | Oral, dermal and inhalation | Internal dose DNEL using absorption factors of 25% for oral, 100% for inhalation (respirable) and 0.03% for dermal exposure routes | 0.082mg Cu/kg B wt/day |
| Human short-term effects - drinking water | Oral | NOAEL for drinking water | 4mg/L |

| | | | |
|---------------|------------------------|--|--------------------------------------|
| Environmental | Fresh water | PNEC. Includes a default bio-availability correction | 7.8 µg dissolved Cu/L ⁽¹⁾ |
| Environmental | Marine water | PNEC. Includes a default bio-availability correction | 5.2 µg dissolved Cu/L ⁽¹⁾ |
| Environmental | Sediment - fresh water | PNEC. Includes a default bio-availability correction | 87 mg Cu/kg dry wt ⁽¹⁾ |
| Environmental | Sediment - estuarine | PNEC | 288 mg Cu/kg dry wt ⁽¹⁾ |
| Environmental | Sediment - marine | PNEC | 676 mg Cu/kg dry wt ⁽¹⁾ |
| Environmental | Soil | PNEC. Includes a default bio-availability correction | 65.5 mg Cu/kg dry wt ⁽¹⁾ |
| Environmental | STP | PNEC | 230 g dissolved Cu/L |

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

PNEC and DNELs - bismuth

PNEC STP 17.5 mg/L

DNELs:

Worker: Long-term exposure - systemic effects, Inhalation - DNEL: 13.1 mg/m³

General population: Long-term exposure - systemic effects, oral DNEL: 13.3 mg/kg bw/day

PNEC and DNELs - silver

DNELs (derived from the levels causing changes in the body - by inhalation, exposure to prolonged and severe):

Employees:

soluble silver compounds 0.01mg Ag/m³*

Poorly soluble / insoluble silver compounds 0.1mg Ag/m³**

General Public:

soluble silver compounds 0.004mg Ag/m³*

Poorly soluble / insoluble silver compounds 0.04mg Ag/m³**

DNELs (derived from the levels causing changes in the body - after ingestion, exposure to long-term):

Employees:

soluble silver compounds 0.02mg Ag/kg body weight/day*

Poorly soluble / insoluble silver compounds 0.12mg Ag/kg body weight/day**

General Public:

soluble silver compounds 0.002mg Ag/kg body weight/day*

Poorly soluble / insoluble silver compounds 0.12mg Ag/kg body weight/day**

* value only for calculations

** value appropriate for the metallic silver

PNEC freshwater: 0.04µg Ag/L (Soluble Ag)

PNEC marine: 0.86µg Ag/L (Soluble Ag)

PNEC sediment freshwater: 438mg Ag/kg dw

PNEC sediment marine: 438mg Ag/kg dw

PNEC soil: 0.794mg Ag/kg ww

PNEC STP: 0.025mg Ag/L (Soluble Ag)

PNECs and DNELs - zinc

DNELs for employees

Inhalation exposure

DNEL = 2.5 mg/m³ (inhalation exposure to water-soluble salts of zinc)

DNEL = 5 mg/m³ (inhalation exposure to poorly soluble or insoluble zinc salts).

Oral Exposure

DNEL = 50 mg Zn / day (i.e., 0.63 mg Zn / kg body weight) (exposure to oral water-soluble salts of zinc)

DNEL. = 50 mg Zn / day (i.e. 0.83 mg Zn / kg body weight) (exposure to oral slightly soluble or insoluble zinc salts)

Dermal exposure

DNEL = 500 mg Zn / day (i.e. 8.3 mg Zn / kg body weight) (Dermal exposure to water-soluble salts of zinc)

DNEL = 5000 mg Zn / day (i.e., 83 mg Zn / kg body weight) (Dermal exposure to poorly soluble or insoluble zinc salts)

DNELs for the general population

DNEL = 1.3 mg/m³ (inhalation exposure to water-soluble salts of zinc)

DNEL = 2.5 mg/m³ (inhalation exposure to poorly soluble or insoluble zinc salts)

PNECs

| Test organism | Value | Assessment factor |
|---|-----------------------|-------------------|
| Aquatic organisms in fresh water | 20.6µg dissolved Zn/L | 1 |
| Aquatic organisms in sea water | 6.1µg dissolved Zn/L | 3 |
| Organisms inhabiting freshwater sediment | 117.8mg/kg dry weight | 1 |
| Organisms inhabiting marine sediment | 56.5mg/kg dry weight | 1 |
| Organisms inhabiting the soil | 35.6mg/kg dry weight | 1 |
| Organisms of biological waste water treatment plant | 52mg/L | 100 |

8.2 Exposure controls

See full details in generic Exposure Scenario for lead metal and other specific Exposure Scenarios, attached as Annex and listed in section 16.

8.2.1 Organisational measures

Prevent formation of dust where possible. Local exhaust ventilation should be provided where necessary to keep exposure levels within required limits. Any deposit of dust which cannot be avoided must be regularly removed, preferably by vacuum cleaning. Do not eat, drink, smoke or sniff whilst working. Wash skin thoroughly before breaks and after work. Keep product and waste away from foodstuffs, beverages and feed. Immediately remove all contaminated clothing. Wash hands before breaks and at the end of work. Store protective clothing separately from employees' own clothing.

Personal Hygiene

Ensure workers follow simple hygiene rules (e.g. do not bite nails and keep them cut short, avoid touching or scratching face with dirty hands or gloves); Ensure workers do not wipe away sweat with hands or arms; Ensure workers use disposable tissues rather than a handkerchief; Prohibit drinking, eating and smoking in production areas, or access to eating and non-production areas in working clothes; Ensure workers wash hands, arms, faces and mouths (but preferably shower) and change into clean clothing before entering eating areas; For high exposure workplaces, separate rooms for cleaning hands, removal of clothes, showers and clean clothes may be necessary; Ensure workers handle dirty working clothes with care; Allow no personal belongings to be taken into production areas, or items that have been used in production areas to be taken home. Ensure general shop cleanliness is maintained by frequent washing/vacuuming. Clean every workplace at the end of every shift.

Blood lead monitoring

Set in place a certified monitoring regime which covers all site activities; Define a policy for submitting workers to regular blood lead monitoring, including increased frequency for workers undertaking high-risk jobs and workers with elevated blood lead levels; Ensure all workers have a blood test prior to working on site. Set an "action level" that is typically 5 µg/dL below the exposure limit deemed to be safe. If the action level is exceeded, appropriate measures are to be taken, to prevent further increases in blood lead. If the safe threshold is exceeded, continue or begin ban on overtime, ensure strict hygiene procedures are followed, undertake detailed inspections to ensure correct use of personal protective equipment, undertake detailed inspections to ensure recommended workplace procedures are followed, move employee to workplace where exposure is expected to be lower or remove from lead environment altogether, further increase blood lead sampling frequency, and continue frequent sampling until results are below the first action level.

8.2.2 Personal Protection Equipment

Respiratory protection

Suitable respiratory protective device recommended. In case of brief or low level exposure, use dust mask or half mask with particle filter P2. Assess the need to wear respiratory protective equipment in production areas. Consider use of effective masks accompanied by a compliance policy (ensure proper shaving. Ensure workers do not remove RPE in production areas in order to communicate). Where masks are used, employ formal mask cleaning and filter changing strategies.

Hand protection

Protective gloves. Material of gloves: neoprene or leather. Insulating gloves should be worn when handling molten or hot metal.

Eye protection

A face shield, safety goggles or safety glasses should be worn when handling molten metal.

Skin Protection

Wear protective work clothing. For workers in areas of significant exposure, provide sufficient working clothes to enable daily change into clean clothes. In such cases all work clothing should be cleaned by the employer on a daily basis and is not permitted to leave the work site.

8.2.3 Environmental Protection

One or more of the following measures may if necessary be taken to reduce emissions to water:

- Chemical precipitation: used primarily to remove the metal ions
- Sedimentation
- Filtration: used as final clarification step
- Electrolysis: for low metal concentration
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater

One or more of the following measures may if necessary be taken to reduce emissions to air:

- Electrostatic precipitators using wide electrode spacing: Wet electrostatic precipitators:
- Cyclones, but as primary collector Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values Membrane filtration techniques can achieve
- Ceramic and metal mesh filters. PM10 particles are removed
- Wet scrubbers

Lead removal from treatment works should be at least the minimum default 84% removal used in the CSR. Solid material collected from on-site treatment must be sent for metal recovery or treated as hazardous waste. Waste water treatment sludge must be recycled, incinerated or landfilled and not used as agricultural fertiliser.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance: Grey or silvery metallic solid

Odour: None

Odour threshold: Not applicable

pH: Not applicable

Melting point: 178°C to 325°C, depending on grade.

Boiling point: >600°C

Flashpoint: Not applicable

Evaporation rate: Not applicable

Flammability: Not flammable

Upper/lower flammability limits: Not applicable

Vapour pressure: Not applicable

Vapour density: Not applicable

Relative density: 7.5g/mL to 11.2g/mL, depending on grade.

Solubility in water: Lead - 185 mg/l at 20°C
Antimony - 18.2 mg/L at T° 20°C (ISO 6341 medium – loading 2 g Sb/L-pH 4.6)
Copper - insoluble, needs to be transformed into a copper compound to become soluble
Silver - 0.03 mg / L

Solubility in other solvents: Not applicable

Partition coefficient (log Kow): Not applicable

Autoignition temperature: Not applicable

Decomposition temperature: Not applicable

Viscosity: Not applicable

Explosive properties: Not explosive

Oxidising properties: Not oxidising

9.2 Other information

None.

SECTION 10: Stability and Reactivity

10.1 Reactivity

Tin, lead, antimony, copper and silver are not reactive substances and no reactive hazards are expected.

10.2 Chemical stability

Expected to be stable under normal conditions of storage and use.

10.3 Possibility of hazardous reactions

No hazardous reactions are expected under normal conditions of use.

Combustion or hot processes can result in the formation of dross or ashes containing lead oxides and antimony trioxide. Inhalation of these should be avoided.

10.4 Conditions to avoid

Avoid dust formation. See section 7.2 Conditions for safe storage.

10.5 Incompatible materials

Acids, alkalis, strong oxidizing agents, chlorine, chlorinated hydrocarbons, oxidizers. Tin reacts strongly with cupric nitrate and with fused ammonium nitrate below 200°C. Reactions with acids or bases can liberate hydrogen, which is extremely flammable.

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

Lead in massive form is not a significant health hazard. However the following information is relevant if you swallow any lead or breathe in lead dust, fume or vapour.

The application of read-across from diantimony trioxide (ATO) CAS#1309-64-4 to antimony metal has been verified based on the relative bioaccessibility of antimony ions specific to each endpoint and route of exposure. This read-across approach is applied to the following endpoints:

- Adsorption/desorption
- Acute toxicity
- Irritation (skin, eye, respiratory tract)
- Corrosivity
- Sensitisation
- Repeated dose toxicity (oral, inhalation, dermal, other routes)
- Mutagenicity
- Carcinogenicity (oral, inhalation, dermal, other routes)
- Toxicity for reproduction

For copper, 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.

Data for the components of this product are conclusive although insufficient for classification. Based on available data, the classification criteria are not met. The conventional method for classifying mixtures is therefore not applicable.

The following information is not required by the classification criteria:

Absorption

Lead

Lead is slowly absorbed by ingestion and inhalation and poorly absorbed through the skin. If absorbed, it will accumulate in the body with low rates of excretion, leading to long-term build up. Part of risk management is to take worker blood samples for analysis to ensure that exposure levels are acceptable.

Antimony

- Oral = 1% (ECB, 2008)
- Dermal = 0.26% (negligible) (ECB, 2008)
- inhalation = 6.82 % (ECB, 2008)

Copper

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.

INHALATION: 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 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)) 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 with 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) and 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:

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

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

x= 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

Lead

Lead in massive form is not considered to be acutely toxic. It is not easily inhaled or ingested, and if it is accidentally ingested passes through the gastrointestinal system without significant absorption into the body. Lead is not easily absorbed through the skin.

Antimony

Based on read-across from ATO, antimony has a low acute toxicity:

Oral LD₅₀ rat > 20,000 mg/kg bw (Fleming, 1938; Gross et al, 1955; Myers et al, 1978)

Dermal LD₅₀ rabbit > 8,300 mg/kg bw (Gross et al, 1955)

Inhalation LC₅₀ rat > 5,200 mg/l (Leuschner, 2006)

Based on read-across from ATO, antimony does not require classification as STOT, single exposure, oral and inhalation since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and no effects were observed at the guidance value.

Copper

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 Regulation (EC) No 1272/2008 and Directive 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 Regulation (EC) No 1272/2008 and Directive 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 minutes of administration. Other gastrointestinal symptoms (vomiting, diarrhoea and abdominal pain) were

reported less frequently and abdominal pain showed no relationship to concentration.

Acute toxicity inhalation: copper massive has a particle size $>10\ \mu\text{m}$ and down-stream uses do not lead to particles with $d_{50} <10\ \mu\text{m}$. Therefore, according to Regulation (EC) No 1272 and Directive 67/548/EEC, these do not meet the criteria for classification as harmful by inhalation.

INHALATION: 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" (LD_{50} 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).

Copper massive has a particle size $>10\ \mu\text{m}$ and down-stream uses do not lead to particles with $d_{50} <10\ \mu\text{m}$. Therefore, according to Regulation (EC) No 1272 and Directive 67/548/EEC, these do not meet the criteria for classification as harmful by inhalation.

DERMAL: 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)) ($\text{LD}_{50} >2000$ mg/kg body weight) against EU classification criteria, according to Regulation (EC) No 1272/2008 and Directive 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.

The classification criteria, for very fine and soluble "copper" bearing substances, according to the Regulation (EC) No 1272/2008 and Directive 67/548/EEC on acute toxicity, lead to a classification as "harmful if swallowed and if inhaled".

The classification criteria, for copper in massive form and copper powder, according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC on acute toxicity, are therefore not met.

Bismuth

Bismuth Oral LD_{50} rat >2000 mg/kg, per OECD method 401.

Tin has no toxicity at 2000 mg/kg (oral); animal data suggest that the oral absorption of tin is low. No toxicity at 4.75 mg/L (max achievable aerosol concentration) in acute inhalation study.

Silver

Toxic concentrations and doses:

- LD_{50} (rat): $> 2\ 000$ mg / kg body weight (silver);
- LD_{50} (rat, oral): 3702 mg / kg body weight (Ag_2O);
- LC_{50} (rat, inhalation): no data;
- LD_{50} (rat skin): no data.

Zinc

Ingestion:

Harmful. May cause gastrointestinal tract irritation with nausea, vomiting, diarrhoea, loss of appetite, abdominal pain, fever and chills. May affect central and autonomic nervous system, with ataxia, drowsiness impaired motor coordination, dizziness, irritation, aching muscles. Can cause changes in the blood.

Inhalation:

Exposure to zinc dust or fumes may cause respiratory irritation. Exposure to inhalation of zinc fumes may cause the so-called foundry fever with a sweet taste in the mouth, fever chills, headache, weakness, excessive sweating, strong thirst, leg pain, and chest, breathing problems and vomiting.

Skin corrosion/irritation

Tin

Not irritating (rabbit) – OECD 404.

Lead

Studies have shown that sparingly soluble inorganic lead compounds are not corrosive and this lack of effect is expected also for metallic lead.

Antimony

Based on read-across from ATO, antimony is not a corrosive agent.

Copper

Animal data (coated copper flakes (Sanders, 2001c) and CuO (Sanders, 2002c)) have demonstrated that, according to Regulation (EC) No 1272 and Directive 67/548/EEC, "copper" is not a skin irritant.

Silver

Direct contact may cause mild local skin irritation.

Zinc

The substance is not classified as hazardous in this class.

May cause skin irritation. After prolonged exposure, may cause dermatitis.

Serious eye damage/irritation

Tin

Not irritating (rabbit) – OECD 405.

Copper

Animal studies with coated copper flakes (Sanders 2001d) and CuO (Sanders, 2002d) induced slight reversible eye irritation effects. Following the criteria, according to the Regulation (EC) No 1272 and Directive 67/548/EEC, the coated copper flakes and CuO are not considered as an eye irritant.

Silver

Direct contact may cause mild local eye irritation.

Zinc

May cause irritation on exposure to fumes and dust.

Sensitisation

There is no evidence that tin, lead, antimony, bismuth or zinc cause respiratory or skin sensitisation.

Copper

Animal data (coated copper flakes (Sanders 2001e) and CuO (Sanders 2002e)) have demonstrated that, according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC, "copper" is not a skin sensitizer.

Silver

There have been a few cases of allergic skin inflammation on contact with powdered silver, silver solutions or dental amalgams.

Repeated dose toxicity

Tin

No information available.

Lead

Lead is a cumulative poison and may be absorbed into the body through ingestion or inhalation. Although inhalation and ingestion of lead in massive form are unlikely, poor hygiene practises may result in hand to mouth transfer which maybe significant over a prolonged period of time. Inorganic lead compounds have been documented in observational human studies to produce toxicity in multiple organ systems and body function including the haemotopoetic (blood) system, kidney function, reproductive function and the central nervous system.

Antimony

NOAEC_{inhalation} = 0.51 mg/m³ (Newton et al, 1994)

NOAEL_{oral} = 1686 mg/kg/day (Hext et al, 1999)

The NOAEC was determined in a study with a high background incidence of lung inflammation in controls, therefore there is considerable uncertainty regarding the reliability of this numerical value. The NOAEC is based on impaired lung clearance that was observed at 4.50 mg/m³.

Based on read-across from ATO, antimony does not require classification as STOT, repeated exposure, oral since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and the NOAEL is above the guidance value.

Based on read-across from ATO, antimony does not require classification as STOT, repeated exposure, inhalation since there is an absence of consistent identifiable toxic effects other than the non-specific PSP overload, which is an adaptive response not triggering a STOT classification.

Bismuth: NOAEL oral rat = 1000mg/kg.

Carcinogenicity

Tin

Not carcinogenic. Both the Ames test and in vitro chromosome aberration test (CHO cells) are negative.

Lead

There is some evidence that inorganic lead compounds may have a carcinogenic effect, and they have been classified by IARC as probably carcinogenic to humans (Group 2A). However, it is considered that this classification does not apply to lead in massive form, given the very low bioavailability of metallic lead. Carcinogenicity studies of lead metal powder have been negative. Epidemiology studies of workers exposed to inorganic lead compounds have found a limited association with stomach cancer. IARC has concluded that lead metal is possibly carcinogenic to humans (Group 2B).

Antimony

Antimony metal does not require classification according to Regulation (EC) 1272/2008. However, as a consequence of the read across from ATO to antimony metal, antimony metal powder requires the same inhalation carcinogenicity classification. NOAEC: 0.51 mg/m³ / Target organ: respiratory: lung

Copper

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, 1969 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.

Zinc

The substance is not classified as hazardous in this class.

Mutagenicity

Tin

Ames test: Not mutagenic – OECD 471.

In vitro mammalian cytogenicity: Not mutagenic – OECD 473.

In vitro gene mutation in mammalian cells: Not mutagenic – OECD 476.

Lead

The evidence for genotoxic effects of highly soluble inorganic lead compounds is contradictory, with numerous studies reporting both positive and negative effects. Responses appear to be induced by indirect mechanisms, mostly at very high concentrations that lack physiological relevance.

Antimony

Based on read-across from ATO, antimony is not expected to cause systemic mutagenicity in vivo after oral administration. Negative in vivo results on chromosome aberrations and micronuclei were obtained in two different species via oral application – mouse (Elliot et al., 1998) and rat (Whitwell, 2006), (Kirkland et al., 2007). An in vivo UDS assay in rats was also negative (Elliot et al., 1998). The classification criteria according to Regulation (EC) 1272/2008 as germ cell mutagen are also not met.

Copper

Public domain data indicate 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 g/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).

Two in vivo 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).

The classification criteria for copper in massive form and copper powder, according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC on germ cell mutagen are therefore not met.

Zinc

The substance is not classified as hazardous in this class.

Toxicity for reproduction

Tin

For tin, both the Ames test and in vitro chromosome aberration test (CHO cells) are negative.

Lead

Exposure to high levels of inorganic lead compounds may cause adverse effects on male and female fertility, including adverse effects on sperm quality. Prenatal exposure to inorganic lead compounds is also associated with adverse effects on neurobehavioural development in children.

Antimony

For antimony, based on the available long-term toxicity studies in rodents (Omura et al, 2002) and the relevant information on the toxicokinetic behaviour in rats, it is concluded that diantimony trioxide and, based on read-across from ATO, also antimony does not present a reproductive toxicity hazard, because of the lack of absorption and systemic distribution, and a correspondingly negligible exposure of reproductive organs in male and female mammalian species to diantimony trioxide. For these reasons, no classification for reproductive toxicity is required.

The reference Schroeder R.E. (2003) was identified as key study for developmental toxicity and will be used for classification and labelling. This study suggests that the NOAEC for developmental toxicity is > 6.3 mg antimony trioxide/m³. Thus, classification as developmental toxicant according to Regulation (EC) 1272/2008 is similarly not required for antimony metal.

Copper

A high quality study (Mylchreest, 2005) indicates that the 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.

The classification criteria for copper in massive form and copper powder, according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC on reproductive toxicity are therefore not met.

Bismuth

For bismuth, OECD method 476 gives a negative result for genotoxicity in vivo.

Zinc

The substance is not classified as hazardous in this class.

STOT-single exposure

Tin

No effects.

Copper

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.

The classification criteria, for copper in massive form and copper powder, according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC on STOT-SE are not met.

Silver

Inhalation of silver smoke and dust may irritate mucous membranes and upper respiratory tract. Exposure to high concentration of smoke/dust may damage the lungs and cause pneumothorax.

Ingesting silver compounds may irritate the stomach.

STOT-repeated exposure

Tin

Repeated dose toxicity (oral gavage) NOEL >1000 mg/kg/day (rat). 28 day subacute study – OECD 407.

Copper

NOAELoral rat = 16mg Cu /kg bw/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/kg bw/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 0.041mg Cu/kg bw/day.

The classification criteria, for copper in massive form and copper powder, according to Regulation (EC) No 1272/2008 on Specific Target Organ Toxicity are therefore not met.

Silver

Prolonged exposure to silver smoke/dust may cause blue or grey discolouration on eyes, nose, lips, throat and skin. This occurs over time and it may take several years before such discolouration occurs. It is irreversible.

Aspiration hazard

The product is a solid and aspiration hazards are not expected to occur.

SECTION 12: Ecological Information

The environmental effects of lead have been assessed using read-across from studies with similar inorganic lead compounds.

12.1 Toxicity

12.1.1 Tin

Short term toxicity to fish 96 h LC₅₀: >12.4µg/L (NOEC 12.4µg/L) *Pimephales promelas* (total tin from aged solutions of tin) – OECD 203.

Long term toxicity to aquatic invertebrates 7 days: LC₅₀ (mortality) >3200µg/L, EC₅₀ (reproduction) 1303µg/L (total tin from aged tin solutions) – *Daphnia magna* – EPA 1002.0.

Toxicity to algae EC₅₀ (72 h): >19.2µg/L (total tin from aged tin solutions) - *Pseudokirchnerella subcapitata* – OECD 201.

12.1.2 Lead

Reliable acute aquatic toxicity data (tests conducted with soluble lead salts; all toxicity data reported as dissolved lead).

| Test organism | Endpoint | Range of values |
|---|-------------------------------------|---|
| Fish: <i>Pimephales promelas</i> , <i>Oncorhynchus mykiss</i> | 96h-LC ₅₀ | pH 5.5 – 6.5: 40.8 – 810.0 g Pb/L pH >6.5 – 7.5: 52.0 – 3,598.0 g Pb/L pH > 7.5 – 8.5: 113.8 – 3,249.0 g Pb/L |
| Invertebrates: <i>Daphnia magna</i> , <i>Ceriodaphnia dubia</i> | 486h-LC ₅₀ | pH 5.5 – 6.5: 73.6 – 655.6 g Pb/L pH >6.5 – 7.5: 28.8 – 1,179.6 g Pb/L pH > 7.5 – 8.5: 26.4 – 3,115.8 g Pb/L |
| Algae: <i>Pseudokirchneriella subcapitata</i> , <i>Chlorella kesslerii</i> | 72h-ErC ₅₀ (growth rate) | pH 5.5 – 6.5: 72.0 – 388.0 g Pb/L pH >6.5 – 7.5: 26.6 – 79.5 g Pb/L pH > 7.5 – 8.5: 20.5 – 49.6 g Pb/L |

Tests were conducted according to international accepted test guidelines or scientifically acceptable methods.

Reliable chronic toxicity test results (tests conducted with soluble lead salts; all toxicity data reported as dissolved lead)

| Test organisms | Range of values (EC ₁₀ , NOEC) |
|---|---|
| <i>Aquatic freshwater toxicity data</i> | |

| | |
|---|-----------------------------|
| Fish: <i>Oncorhynchus mykiss</i> , <i>Salmo salar</i> , <i>Pimephales promelas</i> , <i>Salvelinus fontinalis</i> , <i>Ictalurus punctatus</i> , <i>Lepomis macrochirus</i> , <i>Salvelinus namaycush</i> , <i>Cyprinus carpio</i> , <i>Acipenser sinensis</i> | 17.8 – 1,558.6 g Pb/L |
| Invertebrates: <i>Hyalella azteca</i> , <i>Lymnaea palustris</i> , <i>Ceriodaphnia dubia</i> , <i>Lymnaea stagnalis</i> , <i>Philodina rapida</i> , <i>Daphnia magna</i> , <i>Alona rectangular</i> , <i>Diaphanosoma birgei</i> , <i>Chironomus tentans</i> , <i>Brachionus calyciflorus</i> , <i>Chironomus riparius</i> , <i>Baetis tricaudatus</i> . | 1.7 – 963.0 g Pb/L |
| Algae: <i>Pseudokirchneriella subcapitata</i> , <i>Chlorella kesslerii</i> , <i>Chlamydomonas reinhardtii</i> . | 6.1 – 190.0 g Pb/L |
| Higher plants: <i>Lemna minor</i> | 85.0 – 1,025.0 g Pb/L |
| The most sensitive toxicity endpoint was 1.7 g Pb/L for <i>C. dubia</i> (reproduction) and <i>L. stagnalis</i> (growth). Symptoms of toxicity were effects on survival, growth, reproduction, hatching, (population) growth rate and malformation during development. Toxicity of dissolved lead in freshwater is dependent on the physico-chemistry of the freshwater (mainly dissolved organic carbon, pH, hardness). | |
| Aquatic marine toxicity data | |
| Fish: <i>Cyprinodon variegatus</i> | 229.6 – 437.0 g Pb/L |
| Invertebrates: <i>Mytilus trossulus</i> , <i>Americamysis bahia</i> , <i>Mytilus galloprovincialis</i> , <i>Neanthes arenaceodentata</i> , <i>Strongylocentrotus purpuratus</i> , <i>Paracentrotus lividus</i> , <i>Dendraster excentricus</i> , <i>Tisbe battagliai</i> , <i>Crassostrea gigas</i> | 9.2 – 1,409.6 g Pb/L |
| Algae: <i>Skeletonema costatum</i> , <i>Phaeodactylum tricornutum</i> , <i>Dunaliella tertiolecta</i> . | 52.9 – 1,234.0 g Pb/L |
| Higher plants: <i>Champia parvula</i> | 11.9 g Pb/L |
| The most sensitive toxicity endpoint was 9.2 g Pb/L for <i>M. trossulus</i> (malformation). Symptoms of toxicity include effects on survival, growth, growth rate, reproduction and malformation during development | |
| Sediment freshwater toxicity data | |
| Invertebrates: <i>Tubifex tubifex</i> , <i>Ephoron virgo</i> , <i>Hyalella azteca</i> , <i>Gammarus pulex</i> , <i>Lumbriculus variegatus</i> , <i>Hexagenia limbata</i> , <i>Chironomus tentans</i> | 573.0 – 3,390.0 mg Pb/kg dw |
| The most sensitive toxicity endpoint was 573.0 mg Pb/kg dw for <i>T. tubifex</i> (reproduction). Symptoms of toxicity include effects on survival, growth, and reproduction. Toxicity of lead in freshwater sediment is dependent on the acid volatile sulphide content (AVS) of the freshwater sediment. | |
| Sediment marine toxicity data | |
| Invertebrates: <i>Neanthes arenaceodentata</i> , <i>Leptocheirus plumulosus</i> | 680.0 – 1,291.0 mg Pb/kg dw |
| The most sensitive toxicity endpoint was 680.0 mg Pb/kg dw for <i>N. arenaceodentata</i> (growth). Symptoms of toxicity include effects on survival, growth, and reproduction | |
| Terrestrial toxicity data (values were determined in different topsoils with contrasting properties and spiked with soluble lead salts): | |
| Invertebrates: <i>Folsomia candida</i> , <i>Proisotoma minuta</i> , <i>Sinella curviseta</i> , <i>Eisenia fetida</i> , <i>Eisenia andrei</i> , <i>Dendrobaena rubida</i> , <i>Lumbricus rubellus</i> , <i>Aporrectodea caliginosa</i> | 34.0 – 2,445.0 mg Pb/kg dw |
| Plants: <i>Hordeum vulgare</i> , <i>Zea mays</i> , <i>Echinochloa crus-galli</i> , <i>Lolium perenne</i> , <i>Sorghum bicolor</i> , <i>Triticum aestivum</i> , <i>Oryza sativa</i> and <i>Avena sativa</i> , <i>Raphanus sativus</i> , <i>Lycopersicon esculentum</i> , <i>Lactuca sativa</i> , <i>Cucumis sativus</i> , <i>Picea rubens</i> , <i>Pinus taeda</i> | 57.0 – 6,774.0 mg Pb/kg dw |
| Micro-organisms: denitrification, N-mineralization, nitrification, basal respiration, substrate-induced respiration | 97.0 – 7,880.0 mg Pb/kg dw |
| The most sensitive toxicity endpoint was 34.0 mg Pb/kg for <i>F. candida</i> (reproduction). Symptoms of toxicity include effects on survival, growth, hatching, yield, reproduction, and microbe mediated processes. Toxicity of lead in soils is dependent on 1) the ageing processes and 2) the Cation Exchange Capacity (eCEC) of the soil. | |

Tests were conducted according to international accepted test guidelines or scientifically acceptable methods.

Toxicity data for micro-organisms (for STP) (tests conducted with soluble lead salts):

| Test Organisms | Effects | Range of values (EC ₁₀ , NOEC) |
|-----------------------|---------------------|---|
| Bacterial populations | Respiration | 1.06 - 2.92 mg Pb/L |
| | Ammonia uptake rate | 2.79 - 9.59 mg Pb/L |
| Protozoan community | Mortality | 1.0 – 7.0 mg Pb/L |

Tests were conducted according to international accepted test guidelines or scientifically acceptable methods.

For an overview of PNECs for the different compartments, check section 8.1.2.

12.1.3 Antimony

Antimony metal and antimony containing compounds will dissolve and generate antimony ions (Vangheluwe et al., 2001). The environmental section will therefore discuss the fate of antimony in general.

| Acute aquatic toxicity test results: | | |
|--|--------------------------------------|---|
| Marine fish [Pagrus major] | 96 h LC ₅₀ | 6.9 mg Sb/L (Takayanagi, 2001) |
| Freshwater fish [Pimephales promelas] | 96 h LC ₅₀ | 14.4 mg Sb/L (Brooke et al, 1986) |
| Invertebrates [Chlorohydra viridissima] | 96 h LC ₅₀ | 1.77 mg Sb/L (TAI, 1990) |
| Algae [Pseudokirchneriella subcapitata] | 72 h ErC ₅₀ (growth rate) | > 36.6 mg Sb/L (Heijerick et al, 2004) |
| Chronic aquatic toxicity test results: | | |
| Fish [Pimephales promelas] | 28 d NOEC/LOEC (growth; length) | 1.13/2.31 mg Sb/L (Kimball, 1978) |
| Invertebrates [Daphnia magna] | 21 d NOEC/LOEC (reproduction) | 1.74/3.13 mg Sb/L (Heijerick et al, 2003) |
| Algae [Pseudokirchneriella subcapitata] | 72 h NOEC/LOEC (growth rate) | 2.11/4.00 mg Sb/L (Heijerick et al, 2004) |
| Chronic sediment toxicity test results: | | |
| Midge [Chironomus riparius] | 14-d NOEC (growth) | 78 mg Sb/kg ww (Heijerick et al, 2005) |
| Chronic terrestrial toxicity test results (values were determined in a soil spiked with Sb ₂ O ₃ and aged for 31 weeks before testing): | | |
| Soil invertebrates | NOEC | 999 mg Sb/kg dw (Moser, 2007) |
| Plants | NOEC | 999 mg Sb/kg dw (Smolders et al., 2007) |
| Soil microorganisms | NOEC | 2930 mg Sb/kg dw (Smolders et al., 2007) |
| Toxicity tests for microorganisms (for STP): | | |
| Aquatic microorganisms | NOEC | 2.55 mg Sb/L (EPAS, 2005) |
| Inhibition of nitrification | NOEC | 27 mg Sb/L (EPAS, 2005) |

12.1.4 Copper

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 6.7µg Cu/L corresponding to a surface-specific release of 0.15µg 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, Chlamydomonas 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 100 mg/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 Regulation (EC) No 1272/2008 and Directive 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 Regulation (EC) No 1272/2008 and Directive 67/548/EEC, Copper massive does not meet the classification for chronic aquatic toxicity.

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 scenarios, 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 and 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.

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.

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.

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 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 HC₅ sediment for copper was therefore based on the OC-normalized dataset, containing only low-AVS sediments.

An HC₅ 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.

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 150mg 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 HC₅ value. See Copper Risk assessment Report

Conclusion: a value of 65.5mg 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.

12.1.5 Bismuth

Fish toxicity LC₅₀ > 100 mg/L. Duration of exposure 96 h, method OECD 203.

Daphnia toxicity LC₅₀ > 100 mg/L. Duration of exposure 48 h, method OECD 202.

Algae toxicity LC₅₀ > 100 mg/L. Duration of exposure 72 h, method OECD 201.

Bacteria toxicity EC₁₀ 175,4 mg/L. Duration of exposure 3 h, method OECD 209.

12.1.6 Silver

Based on available data, the classification criteria regarding toxicity of silver to the environment are not met. Data on acute and chronic toxicity of silver ions in the aquatic environment are available for a wide range of freshwater and saltwater species. In most studies, the toxicity of silver ions as the test material was used very well soluble in water, silver nitrate.

Fish:

Acute toxicity:

LC₅₀ (96h), *Pimephales promelas*: 1.2g Ag/L

LC₅₀ (96h), *Oncorhynchus mykiss*: 1.48mg Ag/L

LC₅₀ (96h), *Salmo gairdneri*: 6.5g Ag/L (soft water)

LC₅₀ (96h), *Salmo gairdneri*: 13mg Ag/L (hard water)

Chronic toxicity:

EC₁₀ (217d), *Salmo trutta*: 0.19mg Ag/L

EC₁₀ (217d), *Salmo trutta*: 1.23mg Ag/L

EC₁₀ (196d), *Oncorhynchus mykiss*: 0.17mg Ag/L

NOEC (32d), *Pimephales promelas*: 0.351mg Ag/L (stunting)

EC₁₀ (32d), *Pimephales promelas*: 0.39mg Ag/L (stunting)

EC₁₀ (32d), *Pimephales promelas*: 0.44mg Ag/L (mortality)

Crustaceans:

Acute toxicity:

LC₅₀ (48 h), *Daphnia magna*: 0.22mg Ag/L

LC₅₀ (48 h), *Ceriodaphnia dubia*: 0.76mg Ag/L

Chronic Toxicity

EC₁₀ (7d), *Ceriodaphnia dubia*: 2.48mg Ag/L (for reproduction)

EC₁₀ (21d), *Daphnia magna*: 2.14mg Ag/L (stunting)

NOEC (7d), *Ceriodaphnia reticulata*: 1mg Ag/L (for reproduction)

Algae:

Acute toxicity:

EC₁₀ (24h), *Chlamydomonas reinhardtii*: 0.54mg Ag/L (growth inhibition)

EC₁₀ (24h), *Pseudokirchneriella subcapitata*: 0.41mg Ag/L (growth inhibition)

Chronic Toxicity

NOEC (14 d), *Champi parvula*: 1.2gAg/L

Predicted concentrations of silver do not cause changes in the environment:

PNEC (surface water): 0.04mg/ L
PNEC (sea water): 0.86mg/L
PNEC (sediment surface): 1.2mg/kg of sludge (dry weight)
PNEC (marine sediments): 1.2mg/kg of sludge (dry weight)

12.1.7 Zinc

Acute toxicity to aquatic environment

The effect on freshwater organisms depends on pH:

For water with low pH: 0.413 mg Zn / L (based on the lowest value for *Ceriodaphnia dubia*);

For water and a neutral / high pH: 0.136 mg Zn / L (based on the lowest value for *Selenastrum capricornutum*).

See also Section 8.

Chronic toxicity to aquatic environment

The effect on freshwater organisms depends on pH:

For water at pH 8.0: 19 mg Zn / L (based on data for *Pseudokirchneriella subcapitata*)

For water at pH 6.0, 82 mg Zn / L (based on data for *Daphnia magna*).

12.2 Persistence and degradability

12.2.1 Tin

Not applicable.

12.2.2 Lead

Lead is naturally occurring and ubiquitous in the environment. Lead is obviously persistent in the sense that they do not degrade to CO₂, water, and other elements of less environmental concern. In the water compartment, lead is rapidly and strongly bound to the suspended solids of the water column. This binding and subsequent settling to the sediment allows for rapid metal removal of lead from the water column. Insignificant remobilization of lead from sediment is expected.

12.2.3 Antimony

Antimony cannot be degraded, but may be transformed between different phases, chemical species, and oxidation states. Antimony is therefore considered to be persistent (P) and very persistent (vP) like any other metal.

12.2.4 Copper

“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”.

12.2.5 Silver

Silver is a persistent substance.

12.2.6 Zinc

Not applicable.

12.3 Bioaccumulative potential

12.3.1 Tin

The potential for bioaccumulation of tin is low.

12.3.2 Lead

Available BCF/BAF data for the aquatic environment show a distinct inverse relationship with the exposure concentration demonstrating that lead is homeostatically regulated by aquatic organisms. A median BAF within environmentally relevant concentrations of 1,552 L/kg ww is observed in aquatic organisms. In the soil compartment no bioaccumulation is expected. The BAFs are not significantly affected by the lead concentration in the soil. A median BAF value for soil dwelling organisms is 0.10 kg dw/kg ww. Available information on transfer of lead through the food chain indicates that lead does not biomagnify in aquatic or terrestrial food chains.

12.3.3 Antimony

Bioaccumulation of antimony by both aquatic and terrestrial organisms is low. A BCF of 40 has been determined for aquatic organisms and a BSAF of 1 for earthworms. Therefore, antimony is not considered bioaccumulative (B) or very bioaccumulative (vB) based on the definitive criteria.

12.3.4 Copper

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.”.

12.3.5 Silver
According to the Chemical Safety Report for silver, there are several studies on various organisms. To develop a safety assessment for silver account was taken of the study carried out on carps (*Cyprinus carpio*), in which fish were exposed to 0.2mg Ag/L for 30 days. The bioconcentration factor (BCF) or coefficient of concentration in the body in relation to its concentration in the ambient aquatic environment for carp was 70. The value of BCF in fish ≥ 500 indicates a capacity for bioconcentration.

12.3.6 Zinc
Because of the homeostatic mechanisms of absorption and excretion, it is estimated that zinc does not bioaccumulate.

12.4 Mobility in soil

12.4.1 Tin
Tin is a water-insoluble, involatile metal. Mobility is expected to be low.
Log Kd: 2.1 - 4.3L/kg.

12.4.2 Lead
Lead metal (non-classified) is sparingly soluble in water and with its relatively high Kd value, is expected to be absorbed onto soils and sediments. Typical log Kd-values of 5.2, 5.7 and 3.8 have been determined for freshwater sediment, marine sediment and soil, respectively.

12.4.3 Antimony
For antimony, a log Kp of 2.07 has been determined for soil.

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

12.4.5 Silver
Silver ions react in the soil with CO_3^{2-} , S^{2-} , SO_3^{2-} and Cl^- to form extremely sparingly soluble compounds, which therefore remain in the upper layer of soil.

12.4.6 Zinc
No data available.

12.5 Results of PBT and vPvB assessment

The PBT and vPvB criteria in Annex XIII of the REACH Regulation do not apply to inorganic substances.

The criterion for persistence is not applicable for inorganic lead. Under conditions of a standard EUSES lake lead meets the criteria for rapid removal from the water column (>70% in 28 days). Bioaccumulation criterion is not applicable to inorganic substances such as lead. However, lead is considered to be toxic, since the most sensitive NOECs, HC5-50 and PNEC values are lower than 10 g Pb/L.

12.6 Other adverse effects

Silver is one of the most toxic metals for bacteria.

Lead metal (non-classified) 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 disposed of according to national legislation complying with the European Waste Directive 2008/98/EC. Do not allow waste to reach drains, ground water, soil or sewage system. Do not send to landfill.

SECTION 14: Transport information

| | | |
|------|--|-----------------------------------|
| 14.1 | UN Number: | Not classified as dangerous goods |
| 14.2 | UN Proper shipping name: | Not classified as dangerous goods |
| 14.3 | Transport hazard class(es): | Not classified as dangerous goods |
| 14.4 | Packing group: | Not classified as dangerous goods |
| 14.5 | Environmental hazards: | Not classified as dangerous goods |
| 14.6 | Special precautions for user: | None |
| 14.7 | Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: | Not transported in bulk |

SECTION 15: Regulatory Information

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

Regulations exist in most countries to control the use of lead-containing materials at work.

The components of this product are not subject to authorisation or restriction.

15.2 Chemical Safety Assessment

Chemical safety assessments have been carried out for the components of this product.

SECTION 16: Other Information

Revision information

Revisions from the previous major version are indicated by a vertical line at the left margin.

Exposure Scenarios

The following Exposure Scenarios are provided in the annex to this safety data sheet:

| | |
|---------------------------------------|--|
| Generic Exposure Scenario: Lead Metal | |
| Exposure Scenario Pb No. 2: | Secondary lead production |
| Exposure Scenario Pb No. 6: | Use of lead metal in production of a range of lead articles |
| Exposure Scenario Pb No. 8: | Lead powder production (includes solder powder) |
| Exposure Scenario Pb No. 10: | Professional use of lead solder |
| Exposure Scenario Pb No. 16: | Professional use of inert anodes (includes consumable anodes) |
| Exposure Scenario Pb No. 22: | Consumer use of solder |
| Exposure Scenario Sn No. 2: | Industrial use of tin in manufacture of solders and other tin-containing alloys with similar melting temperatures, including their use in other articles and manufacturing processes |
| Exposure Scenario Sn No. 3: | Industrial use of tin solders (including the manufacture of electronic and electrical articles) |
| Exposure Scenario Sn No. 7: | Industrial use of tin in tin coatings - electrolytic plating |
| Exposure Scenario Sn No. 8: | Industrial use of tin and tin alloys in tin coatings - hot dip and thermal spraying |
| Exposure Scenario Sn No. 9: | Industrial use of tin in primary and secondary recovery |
| Exposure Scenario Sn No. 11: | Consumer exposure to tin metal or tin-containing products |
| Exposure Scenario Sn No. 12: | Professional exposure to tin metal or tin-containing products |
| Exposure Scenario Sb No. 5: | Use of antimony metal in preparations (including solder) |
| Exposure Scenario Ag No. 2: | Use of silver metal in re-melting and alloying. |
| Exposure Scenario Ag No. 4: | Use of silver metal in electronics, contact materials and electroplating. |
| Exposure Scenario Ag No. 7: | Professional uses of silver metal, silver alloys or silver containing articles. |
| Exposure Scenario Cu No. 02: | Generic scenario for controlling environmental exposure |

List of Abbreviations

| | |
|-------------------|---|
| BAF | Bioaccumulation factor |
| BCF | Bioconcentration factor |
| bw | Body weight |
| CAS No | Chemical Abstract Service Registry Number |
| CLP | Classification Labelling and Packaging Regulation (EC) 1272/2008 |
| DN(M)EL | Derived No-Effect Level or Derived Minimal Effect Level |
| d ₅₀ | Median diameter |
| dw | Dry weight |
| EC ₁₀ | Effective Concentration, 10% |
| EC ₅₀ | Effective Concentration, 50% |
| EC ₅₀ | Effective Concentration, 50% |
| EC No. | European Commission number |
| ECB | European Chemicals Bureau |
| ErC ₅₀ | Effective Concentration, reduction of growth rate, 50% |
| EUSES | European Union System for the Evaluation of Substances |
| HC ₅ | 5th percentile of the SSD (Species Sensitivity Distribution) |
| HC ₅₀ | 50th percentile of the SSD (Species Sensitivity Distribution) |
| IARC | International Agency for Research on Cancer |
| IBC Code | International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk |
| Kd or Kp | Water-soil partition coefficient |
| LC ₅₀ | Lethal Concentration, 50% |
| LD ₅₀ | Lethal Dose, 50% |
| LOEC | Lowest observed effect concentration |
| MARPOL 73/78 | International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978 |
| NA | Not applicable |
| NOAEL | No Observed Adverse Effect Level |

| | |
|------------------|--|
| NOEC | No Observed Effect Concentration |
| NOEL | No Observed Effect Level |
| OEL | Occupational Exposure Limit |
| PNEC | Predicted No-Effect Level |
| PBT | Persistent, bio-accumulative, toxic |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) 1907/2006 |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| STOT | Specific Target Organ Toxicity |
| STOT-SE | Specific Target Organ Toxicity - Single Exposure |
| STP | Sewage treatment plant |
| TCL ₀ | Lowest concentration with toxic effect |
| TDL ₀ | Lowest dose with toxic effect |
| TWA | Time Weighted Average |
| VLCT | Valeur Limite Courte Terme |
| VLE | Valeur Limite d'Exposition |
| VME | Valeur Moyenne d'Exposition |
| vPvB | Very Persistent Very Bio-accumulative |
| ww | Wet weight |

Method of evaluation

This product has not been tested. Judgements on the expected toxicity of lead have been made based upon consideration of similar substances.

Data for the components of this product are conclusive although insufficient for classification. Based on available data, the classification criteria are not met

Classification according to CLP Regulation

Classification Labelling and Packaging Regulation (EC) 1272/2008 - Not classified as hazardous.

Legal Statement

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Annex - Exposure Scenarios

ES Pb No. 2: Secondary lead production

| 1. Title | |
|--|--|
| Identified Use | Use of lead-batteries and scrap in secondary lead production |
| Systemic title based on use descriptor | SU 0, SU 14; ERC 1; AC 0; PC 7 |
| 2. Operational conditions and risk management measures | |
| Involved PROCs | Involved Tasks |
| PROC 8b, 26 | Raw material handling: storage, transport and handling of batteries and other lead scrap |
| PROC 2 | Shredding and sorting: for batteries, separation of sulphuric acid, shredding (breaking), grid-separation, elution of PbO-paste, also sorting of other lead scrap |
| PROC 4 | Desulphurisation: sulphur removal from PbO-paste |
| PROC 22 | Melting and smelting: melting of grids, smelting and reduction of paste |
| PROC23 | Refining and casting: refining of lead, casting of ingots |
| PROC21 | Storage, shipment and transport: storage and shipment of finished goods, intra-facility transport |
| PROC0 | Repair, cleaning and maintenance |
| 2.1 Control of workers exposure | |
| Product characteristic | Raw material is principally lead scrap, used lead batteries, drosses and battery oxides. These materials will have varying levels of dustiness. The product is massive lead metal, usually as ingots. |
| Amounts used | Not restricted |
| Frequency and duration of use/exposure | Full shift exposure (8 hours) for all workplaces (not restricted). |
| Human factors not influenced by risk management | See section 8 of the SDS, above (hygiene measures affecting lead blood levels) |
| Other given operational conditions affecting workers exposure | Indoor handling, room volume >1000 m ³ |
| Technical conditions and measures at process level (source) to prevent release | Enclosed system for melting of grids, smelting and reduction of paste. |
| Technical conditions and measures to control dispersion from source towards the worker | Controls give 78% minimum worker exposure reduction. Risk Management Measures include enclosure of process equipment, dilution ventilation and/or local exhaust ventilation. Pass waste air through cleaning equipment. Separation of workers via control room for melting of grids, smelting and reduction of paste. Protective gloves to be worn. |
| Organisational measures to prevent /limit releases, dispersion and exposure | See section 8 of the core SDS, above. |
| Conditions and measures related to personal protection, hygiene and health evaluation | Minimum Respiratory Protective Equipment (RPE) is FFP 2 mask, except in cases where adequate ventilation/emission control in place (see also section 8). |
| 2.2 Control of environmental exposure | |
| Amounts used | 19,300 tonnes/annum/site |
| Frequency and duration of use | Continuous use/release, up to 345 days/year |
| Environment factors not influenced by risk management | Dilution factor (Freshwater): 10 Dilution factor (Marine): 100 |
| Other given operational conditions affecting environmental exposure | Not applicable |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | See section 8 of the SDS, above. |
| | Estimated fraction released to water (g/tonne): 0.018 |
| | Estimated fraction released to air (g/tonne): 154.65 |

| | |
|---|---|
| Organisational measures to prevent/limit release from site | See section 8 of the SDS, above. |
| Conditions and measures related to external treatment of waste for disposal | <p>Pb-bearing wastes resulting from the processes described above are generated in the form of solids (e.g. slags, matte). These should be treated by a licensed waste treatment operator (landfilled or incinerated) according to relevant waste regulation.</p> <p><i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the lead content of the waste is elevated enough, internal or external recovery/recycling might be considered.</i></p> <p>Fraction of daily/annual use expected in waste: <i>primary producers = 0.22 % secondary producers = 0.73 % compound producers = 0.02 % battery manufacturers = 1.25E-8 % lead sheet manufacturers = 0.19 %</i></p> <p>Appropriate waste codes: <i>02 01 10*, 06 03 15*, 06 04 05*, 06 05 02*, 10 04 01*, 10 04 02*, 10 04 04*, 10 04 05*, 10 04 06*, 10 04 07*, 10 04 99, 10 05 99, 10 10 10, 10 10 11*, 12 01 03*, 15 01 04*, 15 01 10*, 15 02 02*, 16 01 04*, 16 01 06*, 16 01 19, 16 06 01*, 16 06 02*, 16 08 02*, 16 08 03*, 16 11 03*, 17 04 03, 17 04 07*, 17 04 09*, 17 09 04*, 19 01 11*, 19 02 05*, 19 08 11*, 19 08 13*, 19 08 14, 19 10 02*, 19 12 03*, 19 12 11*</i></p> <p>Suitable disposal: <i>Keep separate and dispose of to either</i> - <i>Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.</i> <i>Hazardous landfill operated under Directive 1999/31/EC.</i></p> <p><i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2013)</i></p> |

3 Exposure estimation

| Health Exposure Estimations (based on measures outlined in section 2.1) | | Predicted Blood Lead Levels (Maximum) | Derived No-Effect Level | Risk Characterisation Ratio |
|--|---|---|------------------------------------|-----------------------------|
| | Blood lead concentrations for male workers (maximum): | 38.08 µg/dL | 40.0 µg/dL | 0.95 |
| Environmental Exposure Estimations (based on measures outlined in section 2.2) | | Predicted Exposure Concentrations (Maximum) | Predicted No Effect Concentrations | |
| | Freshwater: | 0.84 µg/l | 3.1 µg/l | 0.27 |
| | Marine: | 0.051 µg/l | 3.5 µg/l | 0.015 |
| | Freshwater sediment: | 166.07 mg/kg dw | 174.0 mg/kg dw | 0.95 |
| | Marine water sediment: | 60.95 mg/kg dw | 164.2 mg/kg dw | 0.37 |
| | Terrestrial: | 29.30 mg/kg dw | 212.0 mg/kg dw | 0.14 |
| | Sewerage treatment plant: | 12 µg/l | 100 µg/l | 0.12 |

4 Guidance to DU to evaluate whether they work inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his implemented risk management measures are adequate. Detailed guidance for evaluation of ES can be acquired via your supplier or from the ECHA website (guidance R14, R16). For environmental exposure, a DU-Scaling tool (free download: <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>) is available. For human health, exposure (as measured blood lead levels) must be below the DNEL. For female workers these DNEL are 30µg/dL or 10µg/dL (for female workers of reproductive capacity).

ES Pb No. 6: Use of Lead metal in production of a range of lead articles (e.g. cast, rolled and extruded production, ammunition and lead shot)

| 1. Title | |
|--|---|
| Identified Use | Use of lead metal in the production of cast, rolled and extruded products, e.g. weights, foil, string, rope, bars, shot, sheathing and cables. |
| Systemic title based on use descriptor | SU 15, SU 17, SU 19; PC 7, PC 38; AC 7, AC1, AC 2, AC 3; ERC1, 2, 3, 5, 10a |
| 2. Operational conditions and risk management measures | |
| Involved PROCs | Involved Tasks |
| PROC 26 | Raw material handling |
| PROC22, 23 | Melting |
| PROC 23 | Refining and Casting |
| PROC 14 | Extrusion |
| PROC 24 | Milling/Rolling |
| PROC 21 | Sawing/Slitting |
| PROC 25 | Soldering/Manufacture of Solder |
| PROC 21, 22, 23, 24, 25, 4, 5 | Production of lead shot |
| PROC 21 | Ammunition Manufacture (i.e. assembly of ammunition) |
| PROC 23 | Addition of coating metal to bath |
| PROC 23 | Hot dip coating |
| PROC 21 | Storage and Shipment |
| 2.1 Control of workers exposure | |
| Product characteristic | Raw material are lead ingots, bars, or other forms of massive lead (1-99% purity). Raw materials can also include lead powder and paste. Finished lead articles are in solid form. |
| Amounts used | Not restricted |
| Frequency and duration of use/exposure | 4 – 8 hour shifts for all workplaces. |
| Human factors not influenced by risk management | See section 8 of the SDS, above (hygiene measures affecting lead blood levels). |
| Other given operational conditions affecting workers exposure | Indoor handling, room volume >20m ³ for raw material handling, >60m ³ for melting and >1000m ³ for all other workplaces. |
| Technical conditions and measures at process level (source) to prevent release | Enclosed systems required for melting, refining and casting and possibly soldering/production of lead shot. Open systems/no direct handling required for remaining workplaces. |
| Technical conditions and measures to control dispersion from source towards the worker | Controls give 78% minimum worker exposure reduction. Risk Management Measures include enclosure of process equipment, dilution ventilation and/or local exhaust ventilation. Pass waste air through cleaning equipment. LEV typically required for all processes other than storage and shipment. |
| Organisational measures to prevent /limit releases, dispersion and exposure | See section 8 of the core SDS, above. |
| Conditions and measures related to personal protection, hygiene and health evaluation | Minimum Respiratory Protective Equipment (RPE) is FFP 2 mask, except in cases where adequate ventilation/emission control in place (see also section 8). Leather or thermal-protective gloves required for all processes other than milling/rolling, sawing/slitting and storage and shipment. |
| 2.2 Control of environmental exposure | |
| Amounts used | Not restricted. |
| Frequency and duration of use | Continuous use/release, up to 300 days/year. |
| Environment factors not influenced by risk management | Flow rate of receiving surface water is 37 m ³ /s. |
| Other given operational conditions affecting environmental exposure | Not applicable. |

| | | | |
|--|---|-------------------|--|
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | See section 8 of the SDS, above. | | |
| | Estimated emissions released to water: | 20 kg/annum/site | |
| | Estimated emissions released to air: | 100 kg/annum/site | |
| Organisational measures to prevent/limit release from site | See section 8 of the SDS, above. | | |
| Conditions and measures related to external treatment of waste for disposal | <p>Pb-bearing wastes resulting from the processes described above are generated in the form of solids (e.g. dross, slags). These should be treated by a licensed waste treatment operator (landfilled or incinerated) according to relevant waste regulation.</p> <p><i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the lead content of the waste is elevated enough, internal or external recovery/recycling might be considered.</i></p> <p>Fraction of daily/annual use expected in waste: <i>primary producers = 0.22 % secondary producers = 0.73 % compound producers = 0.02 % battery manufacturers = 1.25E-8 % lead sheet manufacturers = 0.19 %</i></p> <p>Appropriate waste codes: <i>02 01 10*, 06 03 15*, 06 04 05*, 06 05 02*, 10 04 01*, 10 04 02*, 10 04 04*, 10 04 05*, 10 04 06*, 10 04 07*, 10 04 99, 10 05 99, 10 10 10, 10 10 11*, 12 01 03*, 15 01 04*, 15 01 10*, 15 02 02*, 16 01 04*, 16 01 06*, 16 01 19, 16 06 01*, 16 06 02*, 16 08 02*, 16 08 03*, 16 11 03*, 17 04 03, 17 04 07*, 17 04 09*, 17 09 04*, 19 01 11*, 19 02 05*, 19 08 11*, 19 08 13*, 19 08 14, 19 10 02*, 19 12 03*, 19 12 11*</i></p> <p>Suitable disposal: <i>Keep separate and dispose of to either</i> - <i>Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.</i> <i>Hazardous landfill operated under Directive 1999/31/EC.</i></p> <p><i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2013)</i></p> | | |

3 Exposure estimation

| Health Exposure Estimations (based on measures outlined in section 2.1) | | Predicted Blood Lead Levels (Maximum) | Derived No-Effect Level | Risk Characterisation Ratio |
|--|---|--|------------------------------------|-----------------------------|
| | Blood lead concentrations for male workers (maximum): | 33.7 µg/dL | 40.0 µg/dL | 0.84 |
| Environmental Exposure Estimations (based on measures outlined in section 2.2) | | Predicted Exposure Concentrations (Maximum) | Predicted No Effect Concentrations | |
| | Freshwater: | 0.622 µg/l | 3.1 µg/l | 0.27 |
| | Marine: | 0.049 µg/l | 3.5 µg/l | 0.015 |
| | Freshwater sediment: | 103.5 mg/kg dw | 174.0 mg/kg dw | 0.59 |
| | Marine water sediment: | 57.1 mg/kg dw | 164.2 mg/kg dw | 0.35 |
| | Terrestrial: | 28.3 mg/kg dw | 212.0 mg/kg dw | 0.14 |
| | Sewerage treatment plant: | The site is assumed not to be connected with an off-site STP | | |

4 Guidance to DU to evaluate whether they work inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his implemented risk management measures are adequate. Detailed guidance for evaluation of ES can be acquired via your supplier or from the ECHA website (guidance R14, R16). For environmental exposure, a DU-Scaling tool (free download: <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>) is available. For human health, exposure (as measured blood lead levels) must be below the DNEL. For female workers these DNEL are 30µg/dL or 10µg/dL (for female workers of reproductive capacity).

ES Pb No. 8: Lead Powder Production

| 1. Title | | | | |
|--|---|---|--------------|---|
| Identified Use | Use of lead metal in the production of powders (Solder) | | | |
| Systemic title based on use descriptor | SU 15, SU 17; PC 0; AC 0; ERC 1, ERC 10a, ERC 11a | | | |
| 2. Operational conditions and risk management measures | | | | |
| Involved PROCs | Involved Tasks | | | |
| PROC 26 | Raw material handling | | | |
| PROC 22, 25 | Manufacture of Solder (molten lead alloy) | | | |
| PROC 27a, 27b | Powder Production: Blowing of molten lead alloy with different gases | | | |
| PROC 27a, 27b, 26 | Powder Production: Ultrasonic atomisation (Solder falling onto an ultrasonic horn) and Centrifugal atomisation (Solder falling onto a spinning disc) | | | |
| PROC 21 | Storage and Shipment | | | |
| 2.1 Control of workers exposure | | | | |
| Product characteristic | Raw material are lead or lead alloy ingots, bars, or other forms of massive lead with a lead content usually in the range 36-99%. | | | |
| Amounts used | Not restricted | | | |
| Frequency and duration of use/exposure | Full shift exposure (8 hours) for all workplaces. | | | |
| Human factors not influenced by risk management | See section 8 of the SDS, above (hygiene measures affecting lead blood levels) | | | |
| Other given operational conditions affecting workers exposure | Indoor handling, room volume >150 m ³ Outdoor handling for raw material processes. | | | |
| Technical conditions and measures at process level (source) to prevent release | Enclosed systems are required for all workplaces other than Raw Material Handling and Storage and Shipment. | | | |
| Technical conditions and measures to control dispersion from source towards the worker | Controls give 78% minimum worker exposure reduction. Risk Management Measures include enclosure of process equipment, negative draft exhaust systems and/or local exhaust ventilation. Pass waste air through cleaning equipment. | | | |
| Organisational measures to prevent /limit releases, dispersion and exposure | See section 8 of the core SDS, above. | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | Minimum Respiratory Protective Equipment (RPE) is FFP 2 mask, except in cases where adequate ventilation/emission control in place (see also section 8). Leather gloves are required for all workplaces other than Raw Handling and Storage and Shipment. | | | |
| 2.2 Control of environmental exposure | | | | |
| Amounts used | Not restricted | | | |
| Frequency and duration of use | Continuous use/release, up to 300 days/year | | | |
| Environment factors not influenced by risk management | No emissions to the environment. | | | |
| Other given operational conditions affecting environmental exposure | Not applicable | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | See section 8 of the SDS, above. | | | |
| | <table border="1"> <tr> <td>Estimated fraction released to water (g/tonne):</td> <td rowspan="2">No emissions</td> </tr> <tr> <td>Estimated fraction released to air (g/tonne):</td> </tr> </table> | Estimated fraction released to water (g/tonne): | No emissions | Estimated fraction released to air (g/tonne): |
| Estimated fraction released to water (g/tonne): | No emissions | | | |
| Estimated fraction released to air (g/tonne): | | | | |
| Organisational measures to prevent/limit release from site | See section 8 of the SDS, above. | | | |

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| <p>Conditions and measures related to external treatment of waste for disposal</p> | <p>Pb-bearing wastes resulting from the processes described above are generated in the form of solids (e.g. dross, slags). These should be treated by a licensed waste treatment operator (landfilled or incinerated) according to relevant waste regulation.</p> <p><i>Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the lead content of the waste is elevated enough, internal or external recovery/recycling might be considered.</i></p> <p>Fraction of daily/annual use expected in waste:</p> <p>primary producers = 0.22 % secondary producers = 0.73 % compound producers = 0.02 % battery manufacturers = 1.25E-8 % lead sheet manufacturers = 0.19 %</p> <p>Appropriate waste codes: 02 01 10*, 06 03 15*, 06 04 05*, 06 05 02*, 10 04 01*, 10 04 02*, 10 04 04*, 10 04 05*, 10 04 06*, 10 04 07*, 10 04 99, 10 05 99, 10 10 10, 10 10 11*, 12 01 03*, 15 01 04*, 15 01 10*, 15 02 02*, 16 01 04*, 16 01 06*, 16 01 19, 16 06 01*, 16 06 02*, 16 08 02*, 16 08 03*, 16 11 03*, 17 04 03, 17 04 07*, 17 04 09*, 17 09 04*, 19 01 11*, 19 02 05*, 19 08 11*, 19 08 13*, 19 08 14, 19 10 02*, 19 12 03*, 19 12 11*</p> <p>Suitable disposal: <i>Keep separate and dispose of to either</i></p> <ul style="list-style-type: none"> - <i>Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.</i> - <i>Hazardous landfill operated under Directive 1999/31/EC.</i> <p><i>A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2013)</i></p> |
|--|--|

3 Exposure estimation

| Health Exposure Estimations (based on measures outlined in section 2.1) | | Predicted Blood Lead Levels (Maximum) | Derived No-Effect Level | Risk Characterisation Ratio |
|--|---|---|------------------------------------|-----------------------------|
| | Blood lead concentrations for male workers (maximum): | 16.0 µg/dL | 40.0 µg/dL | 0.4 |
| Environmental Exposure Estimations (based on measures outlined in section 2.2) | | Predicted Exposure Concentrations (Maximum) | Predicted No Effect Concentrations | |
| | Freshwater: | No Emissions | 3.1 µg/l | N/A |
| | Marine: | No Emissions | 3.5 µg/l | N/A |
| | Freshwater sediment: | No Emissions | 174.0 mg/kg dw | N/A |
| | Marine water sediment: | No Emissions | 164.2 mg/kg dw | N/A |
| | Terrestrial: | 0.19 mg/kg dw | 212.0 mg/kg dw | 0.14 |
| | Sewerage treatment plant: | No Emissions | 100 µg/l | N/A |

4 Guidance to DU to evaluate whether they work inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his implemented risk management measures are adequate. Detailed guidance for evaluation of ES can be acquired via your supplier or from the ECHA website (guidance R14, R16). For environmental exposure, a DU-Scaling tool (free download: <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>) is available. For human health, exposure (as measured blood lead levels) must be below the DNEL. For female workers these DNEL are 30µg/dL or 10µg/dL (for female workers of reproductive capacity).

ES Pb No. 10: Professional Use of Lead Solder

| 1. Title | | | | |
|---|---|---------------------------------------|-------------------------|-----------------------------|
| Identified Use | Professional Use of Lead Solder | | | |
| Systemic title based on use descriptor | PC 7, PC 38; SU 10, SU 14, SU 16, SU 17, SU 0; AC 3, AC 7; ERC 0, ERC 2, ERC 3, ERC 5, ERC 8a. | | | |
| 2. Operational conditions and risk management measures | | | | |
| Involved PROCs | Involved Tasks | | | |
| PROC 0, PROC 3, PROC 4, PROC 5, PROC 15, PROC 25 | Use of low temperature melting solders for electrical appliance assemblage or repair and pipe joining or assembly of stained glass articles. | | | |
| 2.1 Control of workers exposure | | | | |
| Product characteristic | Ingots, wire or powder of metallic alloy containing lead (typically range of 37-75%). | | | |
| Amounts used | Based on maximum professional use of 20 kg per shift. | | | |
| Frequency and duration of use/exposure | Use of lead solders is assumed to occur 0.5 - 3 hours per day, five days per week | | | |
| Human factors not influenced by risk management | See section 8 of the SDS, above (hygiene measures affecting lead blood levels) | | | |
| Other given operational conditions affecting workers exposure | No limitations assessed | | | |
| Technical conditions and measures at process level (source) to prevent release | None needed. | | | |
| Technical conditions and measures to control dispersion from source towards the worker | Ensure good ventilation where possible. | | | |
| Organisational measures to prevent /limit releases, dispersion and exposure | See section 8 of the core SDS, above. | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | For operations covered by this scenario, gloves should ideally be worn. | | | |
| 2.2 Control of environmental exposure | | | | |
| Overview | No environmental emissions during professional use. | | | |
| Conditions and measures related to recovery of articles at the end of service life | Soldered articles are expected to be recovered and recycled (by a licensed recovery operator in accordance with relevant legislation), owing to the intrinsic values of the substrates and the solders. | | | |
| 3 Exposure estimation | | | | |
| Health Exposure estimations (based on measures outlined in section 2.1) | | Predicted Blood Lead Levels (Maximum) | Derived No Effect Level | Risk Characterisation Ratio |
| | Solder, electrical, stained glass, plumbing | 2.55 µg/dL | 40µg/dL | 0.06 |
| | Solder, industrial (bars) | 6.2 µg/dL | 40µg/dL | 0.16 |
| Environmental Exposure estimations (based on measures outlined in section 2.2) | Not applicable | | | |
| 4 Guidance to DU to evaluate whether they work inside the boundaries set by the ES | | | | |
| <p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his implemented risk management measures are adequate. Detailed guidance for evaluation of ES can be acquired via your supplier or from the ECHA website (guidance R14, R16). For environmental exposure, a DU-Scaling tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool) is available. For human health, exposure (as measured blood lead levels) must be below the DNEL. For female workers these DNEL are 30µg/dL or 10µg/dL (for female workers of reproductive capacity).</p> | | | | |

ES Pb No. 16: Professional use of inert anodes

| | |
|--|--|
| <p><i>Exposure Scenario Format (16) addressing service life resulting from downstream use (article handled by worker)</i></p> | |
| <p>1. Title:</p> | |
| <p>Free short title: Use of Lead Anodes</p> | <p><i>Short free text (in supply chain specific language) describing the scope of the exposure scenario</i></p> <p>Use of lead anodes for electro-winning and electroplating processes</p> |
| <p>Systematic title based on use descriptor for article service life: Lead used as a barrier against weather, radiation or sound.</p> | <p><i>List descriptors for service life covered in the exposure scenario</i></p> <p>Installation, use, maintenance and recovery for recycling of lead anodes.</p> |
| <p>Systematic title based on use descriptor for downstream use leading to inclusion in article</p> <p>Lead installed as a component of building construction</p> | <p><i>Description of the preceding downstream use; make reference to the relevant exposure scenario if the downstream user needs to take measures to limit/reduce exposure from subsequent life cycle stages.</i></p> <p>Lead metal (usually containing lead alloyed with metals that may include tin, calcium and/or silver) are used as anodes in industrial scale electrochemical processes. This exposure scenario deals solely with the lead component of lead alloy anodes and the term “lead anodes” is taken to include lead alloy anodes.</p> <p>Inert lead anodes are commonly used in large scale electro-winning metal processes wherein high current is applied to electrolyte solutions containing dissolved metals (e.g. zinc or copper). These metals are deposited upon the cathode whereas electrolysis of water occurs at the lead anode. Inert lead anodes are relatively stable except for the generation of oxidation products that must be periodically removed. Inert lead anodes used in electro-winning, as a function of the specific process technology being used, have life spans from one to ten or more years before replacement is required.</p> <p>Consumable lead anodes are used as a source of metal in electroplating operations wherein a lead anode serves as a source of metal to coat metal conductors, including sheet, wire or strip with lead or lead-containing alloy. Such electrochemical methods essentially result in the deposition of a lead or lead alloy coating via electrochemical means as an alternative to “hot dipping” materials into a kettle of molten metal. By their very nature consumable anodes have much shorter life spans and must be replaced more frequently.</p> <p>For both types of anodes the primary mode of worker exposure to lead is via dermal contact. For inert anodes this would occur during installation of anodes, periodic cleaning of anodes and (at end of service life) recovery of used anodes for subsequent recycling and reuse. For consumable anodes dermal exposure will occur during anode installation and removal of spent anode material for recovery.</p> <p>Both processes will also generate waste lead-containing sludges and, in the case of consumable anodes, lead containing electrolyte. Since electrolytes are highly corrosive in nature, direct worker contact is not expected. Sludges recovered from use of either anode type will contain lead and other waste materials. Contact</p> |

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| | with sludges, or dust from dried sludges, is possible when these process wastes are processed for metal recovery. |
| Processes, tasks activities covered | <i>Additional free text specification of the activities or tasks covered (if needed);</i> TRA AC7_n, TARIC 7804 |
| Assessment Method | <i>Assessment methods applied to create the final exposure scenario (specify the routes if relevant)</i> Exposure assessment is made by expert judgement and measurements made of the dermal transfer of lead from lead sheet to the hands of human volunteers during scientific studies conducted under the auspices of the Voluntary Risk Assessment for Lead. The impact of chronic exposures upon the blood lead levels of adults and children are estimated using computer models specific to assessing lead exposure impacts as also described in the Voluntary Risk Assessment for Lead: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp . The vapour pressure of lead at ambient temperatures ($\sim 10^{-23}$ Pa) essentially negates opportunities for inhalation exposure during routine handling of clean lead anodes. |
| 2. Operational conditions and risk management measures | |
| <i>Brief description of overall operational conditions referring to article categories (AC), process category (PROC) and environmental release categories (ERC)</i> Handling of lead and lead alloy anode materials (TRA AC7_n) generally entails low energy manipulation (PROC 21) of anodes as they are received at the production facility, placed within or removed from electrochemical baths or occasionally cleaned to remove oxidation by-products. Contact with lead anodes while in use is not expected owing to the corrosive nature of the electrolyte. Sludge removal from electrochemical baths can be done by automated closed systems (PROC 1) or during periodic scheduled manual maintenance (PROC 8b). | |
| 2.1 Control of workers' exposure | |
| Product (article) characteristic | |
| <i>Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; fraction of substance amount available for exposure with regard to inhalation and skin contact.</i> Lead and lead alloy anodes can be of varying composition, shape and size as a function of the electrochemical process being applied. Anodes can be pure (>99%) lead or alloyed with materials such as silver, tin or calcium. The range of lead concentrations in such alloys is typically 5-98%. Depending upon the process being employed anodes can be flat plates, round, oval or ribbed rods, balls or hollow cylinders. The mass of anodes can be from a few tens of grams to over 1000kg. Dermal contact with anodes would typically entail the fingers and palms of both hands, although protective gloves are expected to be worn during maintenance activity due to the corrosive nature of the electrolytes in electrochemical processes. Sludges not recovered by automated systems would be in the form of dense slurries. The composition of the slurry will vary as a function of process and anode composition but will generally be characterized by the presence of multiple hazardous and/or corrosive materials. Protective footwear, clothing, gloves, eye protection and sometimes respiratory protection are worn during manual sludge removal. | |
| Amounts (contained in articles) present at workplace | |
| <i>Amounts used at a workplace; note: often this information is not needed for assessment of worker's exposure</i> The amount of lead and lead alloy anodes in use can vary between a few kilograms and many tonnes, with a lead content of typically 5-98%. | |
| Frequency and duration of use/exposure | |
| <i>Duration (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure</i> Daily contact with lead anodes is expected at high volume metal production facilities. Contact with anodes would be intermittent throughout the course of an 8 hour work day, 5 days per week. | |

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| Human factors not influenced by risk management |
| <i>Particular conditions e.g. body parts potentially exposed, increased breathing volume in a certain situation of work</i> Handling, installation, maintenance and replacement of lead anodes would entail dermal contact with the palms and fingers of both hands (840 cm ²). Sludge removal would be at infrequent intervals dependant on the purity of consumable anodes and the nature and intensity of the process. |
| Other given operational conditions affecting workers exposure |
| <i>Other operational conditions e.g. room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature (processing of article under elevated temperature) or abrasive (dust forming) conditions</i> Dermal transfer rates would not be affected by operational conditions. |
| Conditions and measures at level of article production to prevent release during service life |
| <i>Measures taken by down stream users (processing the substance into the article), for example: sufficient storage time of articles before delivery to avoid exposure during transportation</i> Generally not applicable. |
| Technical conditions and measures to prevent release (at source) from processing of articles |
| <i>Process design aiming to prevent releases and hence exposure of workers; this also includes conditions ensuring rigorous containment; specify efficacy of containment (e.g. residual losses or exposure)</i> Generally not applicable. Sludges removed during scheduled maintenance activity are kept in lidded containers to prevent aerosol formation. |
| Technical conditions and measures to control dispersion from source towards the worker |
| <i>Engineering controls, e.g. exhaust ventilation, general ventilation; specify efficacy of measure</i> Generation of lead-containing aerosols will be minimal during electrochemical processes. Electrolyte mist formation is common and necessitates ventilation controls or other measures to limit airborne corrosive mists. Although not implemented for the purpose of removing lead-containing aerosols, these ventilation controls serve to remove any low-level lead-containing aerosols that might be generated (e.g. small quantities of lead corrosion by-products aerosolised by mist generation). |
| Organisational measures to prevent /limit releases, dispersion and exposure |
| <i>Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions.</i> Workers engaged in the handling of lead anodes are trained in hygiene measures to minimize the impacts of dermal exposure. In someof situations, other sources of lead exposure will be present in the work environment (e.g. at copper production facilities and full training in hygiene practices and other measures recommended to minimize lead exposure are to be expected. Due to other exposure sources, workers will often be included in detailed medical surveillance programs for lead exposure. |
| Conditions and measures related to personal protection, hygiene and health evaluation |
| <i>Personal protection, .e.g. wearing of gloves, full body dermal protection, goggles, respirator; specify efficacy of measure</i> Gloves are usually worn during the handling of anodes. Protective clothing, footwear, gloves, eye protection and sometimes full face respirators are worn during sludge removal due to its numerous hazardous constituents. |
| 2.2 Control of environmental exposure |
| No risk management measures related to the environment are taken, as this ES does not include intended release to the environment. |
| Conditions and measures related to disposal of articles at end of service life |
| <i>Type of suitable treatment for waste generated by uses, e.g. municipal waste incineration, specify efficacy of treatment;</i> Lead and lead alloy anodes used in electrochemical applications are recycled at the end of service life. Sludges are similarly processed for recovery. |

Conditions and measures related to recovery of articles at the end of service life

Specify type of collection system and suitable recovery operation for waste generated by consumer uses, e.g. recycling schemes for substances in batteries, vehicles, household appliances, electronic articles, paper article, metal articles; specify efficacy of measure, including re-collection rate; provide corresponding instructions regarding separation of waste to be communicated to consumers

The intrinsic value of lead and alloying elements and ease of recovery of used lead anodes ensures virtually complete recovery.

3. Exposure estimation and reference to its source

Estimation of exposure and risk characterisation ratios (for all route of exposure for workers and all compartment for the environment) resulting from the conditions described above (entries 2.1 and 2.2) and the substance properties; make reference to the exposure assessment tool applied;

Lead exposure during lead and lead alloy anode installation will primarily be mediated by dermal transfer and subsequent hand to mouth activity to yield lead ingestion.

The assessment method applied here was developed for, and is extensively described in, the Voluntary Risk Assessment for Lead available on-line at: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp

There is limited quantitative data available to document the extent of dermal transfer that occurs as a result of worker contact with lead sheet. However, studies conducted for the Voluntary Risk Assessment for Lead measured the transfer of lead to the hands of human volunteers under controlled laboratory conditions.

Under controlled laboratory conditions, dermal transfer of lead in a variety of different contact scenarios (picking up weighted lead objects or controlled pressure pressing of the hand on lead metal ingots) varied as a function of contact frequency. For example, after 1, 5 or 10 contact events the geometric mean of lead transferred to the hand was 0.04, 0.37 and 0.61 $\mu\text{g}/\text{cm}^2$, respectively. The upper 90th percentile associated with these contact scenarios was 0.21, 1.39 and 1.84 $\mu\text{g}/\text{cm}^2$. Contact with oxidised lead surfaces is associated with somewhat higher rates of dermal loading of approximately 3 $\mu\text{g}/\text{cm}^2$ of affected skin. For risk assessment purposes, worker contact will be with both clean and oxidised lead surfaces - the quantity of lead transfer from lead surfaces is thus estimated as 3 $\mu\text{g}/\text{cm}^2$ of affected skin as a worst case assumption.

Given the extremely low uptake of lead through the skin (0.01%), dermal loading of hand skin surfaces is only of concern in connection to hand to mouth activity and the subsequent ingestion of lead. Extrapolation of hand dermal transfer to develop an estimate of systemic exposure resulting from subsequent hand to mouth contact and ingestion is detailed in the Voluntary Risk Assessment for Lead. For the purposes of these extrapolations 1/3 of the hand surface area is available for hand to mouth transfer and a transfer efficiency of 13% is assumed. Quantitative estimates of lead ingestion can then be made and computer simulation models of lead toxicokinetics in humans then used to translate the amount of lead ingested into an estimate of the likely impact of the modeled exposure upon the lead levels of the blood of workers. As a baseline estimate, the palms of both hands (840 cm^2) will be susceptible to dermal transfer and predicted to have a lead loading of 2520 μg . One third of this is available for dermal transfer (280 μg) and a dermal transfer efficiency of 13% yields a predicted intake of 108 μg . On a chronic basis this level of lead intake would be expected to increase blood lead levels by 5.5 $\mu\text{g}/\text{dL}$.

Occasional increases in exposure would occur during scheduled maintenance activity and disposal of sludges. Such activities are sufficiently infrequent so as to be secondary to the daily exposures expected from dermal contact.

Assuming a baseline blood lead level of 2.0 $\mu\text{g}/\text{dL}$, an increase in blood lead levels to 7.5 $\mu\text{g}/\text{dL}$ is predicted. For pregnant women (DNEL 10 $\mu\text{g}/\text{dL}$) this results in a Risk Characterisation ratio of 0.75. For other adults, the DNEL applied varies as a function of whether medical surveillance programs are in place or not (DNEL's of 40 and 20 $\mu\text{g}/\text{dL}$, respectively). Many workers occupationally exposed to anodes are expected to be under medical surveillance programs due to the presence of other lead exposure sources at some metal production facilities. For these individuals a Risk Characterisation ratio of 0.19 is calculated. For workers not under active lead medical surveillance, the calculated Risk Characterisation ratio is 0.38.

Only one environmental reasonable worst case scenario has been applied to all ES for professional users. This is due to the fact, based upon the regional (diffuse) emissions inventory and the regional monitoring data contained within the CSR for this substance, that no risk has been determined in any environment compartment (see below) on a regional or continental scale. This takes into account cumulative emissions from all identified uses of this substance. Given this generic conclusion, no specific environmental emissions data on the uses covered by this

ES are included.

| Compartment | Unit | PNEC | PEC regional | RCR |
|---|----------|------|--------------|------|
| Fresh water | µg/l | 2.67 | 0.61 | 0.23 |
| Marine water | µg/l | 2.67 | 0.046 | 0.02 |
| Fresh water sediment (without bioavailability correction) | mg/kg dw | 174 | 100.1 | 0.58 |
| Marine water sediment | mg/kg dw | 174 | 53.2 | 0.31 |
| Terrestrial | mg/kg dw | 147 | 28.3 | 0.19 |

Alternatively: *Include a link to a website from where the information described above can be retrieved.*

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of determinants (and a suitable algorithm) which together ensure control of risk, but which have some flexibility in the respective values for each determinant. This section may also include a link to a suitable calculation tool.

Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here

Communication of the risks of exposure to lead, and the factors that dictate exposure is appropriate. In particular, minimizing dermal transfer through wearing of gloves and/or use of appropriate hygiene measures should be emphasized. Sludge removal, although infrequent, represents an additional exposure route and appropriate training and PPE should be provided.

Additional good practice advice beyond the REACH CSA

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH

Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.

Users of consumable anodes to produce lead-containing products would be expected to inform down stream users of the presence of lead in their products.

ES Pb No. 22: Consumer use of Solder

| 1. Title: | |
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| <p>Free short title Use of solders (Identified Use 22)</p> | <p><i>Short free text (in supply chain specific language) describing the scope of the exposure scenario</i></p> <p>Use of electrical and plumbing solders to repair/assemble either electrical equipment or piping systems. Solder can also be used to join lead comes in the manufacture of stained glass windows.</p> |
| <p>Systematic title based on use descriptor for article service life Use of solder to make electrical connections, to join metal pipes or to assemble glass sections into stained glass windows</p> | <p><i>List descriptors for service life covered in the exposure scenario</i></p> <p>Example uses of lead solder can be found below:</p> <ol style="list-style-type: none"> 1. Electrical connections to be made that require electrically conductive metals with a low temperature melting point that form a stable and durable connection resistant to vibration and extremes of temperature. 2. Connections between metal pipes that are durable, flexible and resistant to corrosion. Use in potable water systems is prohibited. 3. Stable and ductile connections between lead comes used in stained glass decorative articles. |
| <p>Systematic title based on use descriptor for downstream use leading to inclusion in article Use of low temperature melting solders for electrical appliance assemblage or repair and pipe joining or assembly of stained glass articles.</p> | <p><i>Description of the preceding downstream use; make reference to the relevant exposure scenario if the downstream user needs to take measures to limit/reduce exposure from subsequent life cycle stages.</i></p> <p>Lead based solders are usually lead-tin alloys with low melting points used to make electrical connections or to join metal pipes or lead objects. Solder itself is generally produced in wire-like rolls that contain both the solder alloy and flux agents that enhance liquid metal fluidity and inhibit the formation of oxidation by-products. The solder bond formed is resistant to corrosion and possesses adequate tensile strength, shear strength and creep strength. Lead solder for use in making stained glass windows is produced in strips referred to as came.</p> <p>The lead-tin alloys used in solders are generally a eutectic mixture that melts at a temperature lower than its constituents, the melting point being such that connections between pipes or electrical components can be made without causing thermal damage to the items being joined. Electrical connections are made using an electrical soldering iron that generates heat by passing electrical current through a high resistance heating element. Wires or other electrical components to be joined are heated to a point where solder will liquefy, be drawn into the items to be joined by capillary action and then quickly harden. Electrical heating is also used in the melting of lead solder (for joining comes) in the assembly of stained glass decorative articles.</p> <p>Gas torches (e.g. propane torches) are often used to heat pipe materials prior to the formation of a soldered joint. Solder used to join the pipes is similarly drawn into the pipe joint by capillary action and is then allowed to harden. The reliance upon capillary action to form soldered joints or connections requires the application of heat to the items being joined and indirect transfer of heat to the solder – direct application of heat to solder does not yield the formation of a stable connection via capillary action.</p> |

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|---|--|
| Processes, tasks activities covered | <p><i>Additional free text specification of the activities or tasks covered (if needed); if ECETOC TRA is used, here the relevant product subcategories can be flagged.</i></p> <p>TRA PC38_n PC 7, ERC 10a, 11a, AC 7, 3, 2</p> |
| Assessment Method* | <p><i>Assessment methods applied to create the final exposure scenario (specify the routes if relevant)</i></p> <p>This exposure scenario presents a generic expert judgement approach to assess consumer exposures to lead during soldering processes. Two modes of exposure are expected –dermal transfer and inhalation. Handling of solder will yield dermal contact and transfer of lead to the skin. Lead on the skin of the hands may be transferred to the mouth by hand to mouth activity and subsequently ingested. This exposure pathway is assessed via expert judgement based upon dermal transfer studies extensively described in, the Voluntary Risk Assessment for Lead available on-line at: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp</p> <p>Under controlled laboratory conditions, dermal transfer of lead in a variety of different contact scenarios (picking up weighted lead objects or controlled pressure pressing of the hand on lead metal ingots) varied as a function of contact frequency. For example, after 1, 5 or 10 contact events the geometric mean of lead transferred to the hand was 0.04, 0.37 and 0.61 µg/cm², respectively. For risk assessment purposes, the quantity of lead transfer from clean lead surfaces is estimated as 1 µg/cm² of affected skin</p> <p>Possible inhalation exposure is also assessed based upon the properties of lead solders and the expected vapour pressure of lead at the temperatures associated with soldering.</p> |
| 2. Operational conditions and risk management measures | |
| <p><i>Brief description of overall operational conditions referring to article categories (AC) and environmental release categories (ERC)</i></p> | |
| <p>Solders have a TRA code of TRA PC38_n. Environmental releases are not expected as a result of soldering activity.</p> | |
| 2.1 Control of consumers exposure | |
| Product (article) characteristic | |
| <p><i>Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; fraction of substance amount available for exposure with regard to inhalation, skin contact and sucking;</i></p> <p>Solders contain lead in concentrations that can range from 10 – 90% - the most commonly used solders are 60 - 75% lead since this composition provides a melting point near the eutectic low (approx. 200 °C). Solder is normally provided in form and wire and use of solder would generally entail repeated dermal contacts with the fingertips. 36 cm² of exposed skin is thus expected during soldering operations. Lead came used in assembling stained glass decorative articles is provided as a strip of lead metal which similarly would be manipulated with the fingertips.</p> <p>Inhalation exposure will be dictated by the vapour pressure of lead and lead release during soldering operations. For the purposes of this assessment, solder will be assumed to have a maximum temperature of 220 °C, a temperature sufficient to both cause melting of solder and low enough to facilitate the capillary action upon which soldering is reliant without causing thermal degradation of flux agents that facilitate the soldering process. This approximate temperature will not be exceeded in stained glass work since higher temperatures would cause thermal distortions, discolorations and/or cracking of the glass sections being joined together.</p> | |

The vapour pressure (in torr) at this temperature will be:

$$\text{Log}_{10}P = (-0.2185 \times 43880.6/493) + 7.677369$$

$$\text{Log}_{10}P = -11.77$$

$$P = 1.70 \times 10^{-12} \text{ torr}$$

The preceding calculation indicates that the vapour pressure of lead at soldering temperatures is extremely low and below the detection limits of standard analytical methods. Inhalation exposure will thus not be considered further as an exposure route.

Amounts used

Amount of substance contained in the article;

The lead content of solders will range from 10 – 90% and is usually in the range of 60 – 75%. The amount of lead used will vary significantly with individual applications. Soldering electrical connections will use a gram or less whereas several grams may be used in soldering pipes. Stained glass decorative items can vary significantly in size – small decorative items would contain gram quantities of lead. Making large stained glass windows could require lead solder in kg quantities.

Frequency and duration of use/exposure from service life

Duration of e.g. inhalation of releases from indoor construction products; frequency and duration of e.g. skin contact to textiles or furniture;

No significant consumer inhalation exposure is normally associated with use of lead solder due to the low vapour pressure of lead at the melting temperature of solder. Dermal contact and transfer is thus expected to be the main mode of exposure.

Use of electrical or plumbing solders is expected to be infrequent and restricted to the occasional repair or assembly of electrical articles or pipes. Use of lead came for preparation of stained glass articles is a common hobby – for the purpose of this assessment work with lead came will be assumed to occur several hours a day for up to 5 days per week.

For the preceding scenarios, it is assumed that the use of lead solder/came to result in dermal transfer to the fingertips and all of the lead on the fingertips is available for hand to mouth transfer. The transfer efficiency of lead from the fingertips to the mouth is assumed to be 13%. Physiologically-based pharmacokinetic models are then used to calculate an incremental increase in blood lead for each of the preceding application scenarios. The results of these calculations are summarised in the following table.

| | Dermal Contact Area | Hand surface area involved | Lead transferred from clean lead surface | Predicted increase for lead in blood |
|-------------------|---------------------|----------------------------|--|--------------------------------------|
| Electrical Solder | Fingertips | 36 cm ² | 36 µg (4.7 µg ingestion once per month) | 0.025 µg/dL |
| Plumbing Solder | Fingertips | 36 cm ² | 36 µg (4.7 µg ingestion once per month) | 0.025 µg/dL |
| Stained Glass | Fingertips | 36 cm ² | 36 µg (4.7 µg ingestion five days per week) | 0.55 µg/dL |

Published scientific literature validating the estimates above was not found, but a case study in the United States characterised lead exposure in a home workshop maintained by an electronic components repair technician. Air lead levels during the repair process were below limits of detection and surface contamination (lead in dust) of work surfaces was not found. Dermal exposure was not quantified, but is not likely to have been significant given lack of lead in work surface dust samples. Limited studies of hobbyists producing stained glass articles have found blood lead levels comparable to general population averages and are consistent with the small increase predicted here.

Human factors not influenced by risk management

Particular conditions of use, e.g. body parts potentially exposed, children potentially exposed

Dermal contact (fingertips) is the primary mode of exposure. Children are not expected to engage in the activities

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|---|
| described here. |
| Other given operational conditions affecting consumers exposure from article service life |
| <i>Other operational conditions e.g. room volume, air exchange rate</i> None |
| Conditions and measures at level of article production to prevent release during service life |
| <i>Measures taken by down stream users (processing the substance into the article), for example: i) dyeing program and compatibility of fibre and dye in textile finishing; ii) compatibility of flame retardant and polymer type; iii) pre-wash of textiles to remove substances from finishing iv) sufficient storage time before delivery in order reduce residual releases of components not sufficiently fixed in the article matrix</i> None |
| Conditions and measures related to information and behavioural advice to consumers |
| <i>Usually not applicable related to articles</i> Lead solder/came should be labelled as hazardous with a particular emphasis upon potential toxicity to children. Case studies exist of elevated blood lead levels in children resulting from chewing on lead solder rolls. Lead solder should be appropriately labelled so as to encourage storage in locations to which children will not have access. Lead plumbing solders should not be used for the joining of potable water pipes and warnings against such applications would be appropriate. |
| Conditions and measures related to personal protective equipment and hygiene |
| <i>Usually not applicable related to articles</i> Not applicable under most circumstances. Practical guidance with respect to maintaining clean work areas and proper hygiene is advised when frequent use occurs (e.g. for stained glass hobbyists). |
| 2.2 Control of environmental exposure |
| No risk management measures related to the environment are taken, as this ES does not include intended release to the environment. |
| Conditions and measures related to disposal of articles at end of service life |
| <i>Type of suitable treatment for waste generated by consumer uses, e.g. municipal waste incineration, specify efficacy of treatment;</i> Electronic articles are expected to be recovered for recycling. Metal pipes in buildings are similarly expected to be recovered and recycled due to their intrinsic value. Lead came in stained glass would be expected to be recovered for recycling because of its value and since recycling of glass is increasingly common |
| 3. Exposure estimation and reference to its source |
| <i>Estimation of exposure and risk characterisation ratios (for all route of exposure for consumer and all compartment for the environment) resulting from the conditions described above (entries 2.1 and 2.2) and the substance properties; make reference to the exposure assessment tool applied;</i> Incremental increases in blood lead levels for consumers from specific products were calculated by estimating lead intake via all relevant exposure routes under reasonable worst case exposure assumptions resulting from product use. Exposure scenarios were adapted as appropriate to the characteristics of the subpopulation (e.g. children) under evaluation. The impact of this additional lead intake was assessed by calculating the potential incremental increase of lead in blood using the computer model most appropriate for the potentially affected subpopulation and comparing predicted blood lead levels to sub-population specific DNEL's for calculation of Risk Characterisation Ratios. Wherever possible, model predictions were compared to observational studies of exposure or lead in blood increases associated with specific consumer uses. The DNEL's used for different sub-sets of the population are listed below. Note that the DNEL for adult consumers is lower than the DNEL for occupational settings where workers are under medical surveillance. In the absence of medical surveillance, an assessment factor of 2 is applied to the occupational DNEL and is equivalent to a reduction of acceptable external exposure by a factor of 5. |

DNELs Used for Consumer Exposure Assessment

| Subpopulation | DNEL | Health Basis of DNEL |
|------------------|----------|--|
| Individual Child | 10 mg/dL | Impaired cognitive development |
| Pregnant Woman | 10 mg/d | Developmental toxicity affecting cognitive development |
| Adult | 20 mg/dL | Neuropsychological function |

Exposures associated with the use of lead solders for electrical or plumbing applications are expected to produce increments in blood lead below limits of detections (i.e. an increase in baseline blood lead of from 2.0 to 2.025 µg/dL is expected. The RCR's for pregnant women and men would thus be 0.2 and 0.1 respectively. Children are not expected to conduct electrical or plumbing soldering activity.

A larger, but still small, incremental increase in blood lead would be associated with preparation of stained glass, increasing lead in blood from baseline to 2.55 µg/dL. The RCR for pregnant women and men would be 0.26 and 0.13 respectively.

Only one environmental reasonable worst case scenario has been applied to all ES for consumers. This is due to the fact that, based upon the regional (diffuse) emissions inventory and the regional monitoring data contained within the CSR for this substance, no risk has been determined for any environment compartment (see below) on a regional or continental scale. This takes into account cumulative emissions from all identified uses of this substance. Given this generic conclusion no specific environmental emissions data on the uses covered by this ES are included

| Compartment | Unit | PNEC | PEC regional | RCR |
|---|----------|------|--------------|------|
| Fresh water | µg/l | 2.67 | 0.61 | 0.23 |
| Marine water | µg/l | 2.67 | 0.046 | 0.02 |
| Fresh water sediment (without bioavailability correction) | mg/kg dw | 174 | 100.1 | 0.58 |
| Marine water sediment | mg/kg dw | 174 | 53.2 | 0.31 |
| Terrestrial | mg/kg dw | 147 | 28.3 | 0.19 |

Alternatively: Include a link to a website from where the information described above can be retrieved. The preceding summary has been extracted from dermal transfer studies contained within the Voluntary Risk Assessment Report for Lead at: http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of determinants (and a suitable algorithm) which together ensure control of risk, but which have some flexibility in the respective values for each determinant. This section may also include a link to a suitable calculation tool.

Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here

Hobbyists engaged in the making of stained glass articles might be advised to have annual measures of lead in blood on a precautionary basis.

ES Sn No.2: Industrial use of tin in the manufacture of tin solders and other tin based alloys with similar melting temperatures, including their use in other articles and manufacturing processes.

| | |
|--|---|
| 1. Title | |
| Free short title | <i>Industrial use of tin in the manufacture of solders and other tin containing alloys with similar melting temperatures, including their use in other articles and manufacturing processes</i> |
| Systematic title based on use descriptor | <i>Industrial use of tin in the manufacture of base metals and alloys for the manufacture of solder (PROC 1, 5, 8a, 8b, 9, 14, 19, 21, 22, 23, 26, 27a) for use in vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators ERC 2 (formulation of preparations), 3 (formulation in materials), 10a (wide dispersive outdoor use of long-life articles and materials with low release) and 12a (industrial processing of articles with abrasive techniques (high release))</i> |
| Processes, tasks activities covered | <ul style="list-style-type: none"> • <i>Handling and transport of massive metal</i> • <i>Handling or use of molten metal bath</i> • <i>Alloy production</i> • <i>Manual casting</i> • <i>Machine casting of ingot, bar or billets. Continuous casting of billet, rod or strip</i> • <i>Rolling</i> • <i>Extrusion</i> • <i>Wire drawing and spooling</i> • <i>Other cold working processes e.g. stamping forging, swaging</i> • <i>Annealing or other heat treating processes</i> • <i>Drilling, boring, milling and turning</i> • <i>Atomising/Other powder forming processes</i> • <i>Sieving</i> • <i>Weighing and packing of powder</i> • <i>Open powder containers and adding powder to paste mixing vessel</i> • <i>Mixing paste</i> • <i>Filling paste containers with product</i> • <i>Centrifugal and manual casting of metal into rubber moulds</i> • <i>Manual casting – investment casting</i> • <i>Rolling or roll bonding</i> • <i>Grinding, polishing or buffing</i> • <i>Pressing and sintering of powder</i> |
| 2. Operational conditions and risk management measures | |
| <i>The industrial use of tin in manufacture of solders and other tin containing alloys with similar melting temperatures, including their use in other articles and manufacturing processes involves a number of tasks as detailed above. These tasks are both open and closed processes and are performed at a number of temperatures (from ambient to 600 °C) with different levels of exposure (from 15 mins to >4 hours over a 8 hour shift).</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | |
| <p><i>For the following uses/PROC codes, the substance is available as a solid with low dustiness:</i></p> <ul style="list-style-type: none"> • <i>PROC 1, 5, 14 and 21</i> <p><i>For the following uses/PROC codes, the substance is available as a solid with medium dustiness:</i></p> <ul style="list-style-type: none"> • <i>PROC 8a, 22, 23, 26 and 27</i> <p><i>For the following uses/PROC codes, the substance is available as a liquid:</i></p> <ul style="list-style-type: none"> • <i>PROC 19</i> | |

Frequency and duration of use/exposure

All process occur for the following duration:

- Handling and transport of massive metal: 15 mins - 4 hours
- Handling or use of molten metal bath: 1-4 hours
- Alloy production: 1-4 hours
- Manual casting: >4 hours
- Machine casting of ingot, bar or billets. Continuous casting of billet, rod or strip: 1 – 4 hours
- Cold rolling: >4 hours
- Extrusion: > 4 hours
- Wire drawing and spooling: >4 hours
- Other cold working processes (e.g. stamping or forging): >4 hours
- Annealing or other heat treating processes: <1 hour
- Drilling, boring, milling and turning: >4 hours
- Atomising/Other powder forming processes: >4 hours
- Sieving: > 4 hours
- Weighing and packing of powder: >4 hours
- Open powder containers and adding powder to paste mixing vessel: 15 mins - 1 hour
- Mixing paste: 1 – 4 hours
- Filling paste containers with product: >4 hours
- Centrifugal and manual casting of metal into rubber moulds: >4 hours
- Manual casting – investment casting: >4 hours
- Stamping: > 4 hours
- Rolling or roll bonding: > 4 hours
- Grinding or polishing or buffing: 1-4 hours

Human factors not influenced by risk management

Not applicable.

Other given operational conditions affecting workers exposure

All processes occur indoor at the following temperatures:

- Handling and transport of massive metal: Ambient
- Handling or use of molten metal bath: <400 °C
- Alloy production: up to 600 °C
- Manual casting: <350 - >550 °C
- Machine casting of ingot, bar or billets. Continuous casting of billet, rod or strip: <350 - >550 °C
- Cold rolling: <150 °C
- Extrusion: <150 °C
- Wire drawing and spooling: <60 °C
- Other cold working processes (e.g. stamping or forging): Ambient
- Annealing or other heat treating processes: <150 °C
- Drilling, boring, milling and turning: Ambient
- Atomising/Other powder forming processes: <350 °C
- Sieving: Ambient
- Weighing and packing of powder: Ambient
- Pressing and sintering of powder: >400 °C
- Open powder containers and adding powder to paste mixing vessel: Ambient
- Mixing paste: <50 °C
- Filling paste containers with product: Ambient
- Centrifugal and manual casting of metal into rubber moulds: <300°C
- Manual casting – investment casting: <400 °C
- Rolling or roll bonding: <150 °C

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| Technical conditions and measures at process level (source) to prevent release |
| <i>Not applicable</i> |
| Technical conditions and measures to control dispersion from source towards the worker |
| <p><i>Local Exhaust Ventilation is required for the following tasks:</i></p> <ul style="list-style-type: none"> • <i>Handling or use of molten metal bath</i> • <i>Alloy production</i> • <i>Manual casting (larger scale facilities)</i> • <i>Machine casting of ingot, bar or billets. Continuous casting of billet, rod or strip (larger scale facilities)</i> • <i>Extrusion</i> • <i>Atomising/Other powder forming processes</i> • <i>Sieving</i> • <i>Weighing and packing of powder</i> • <i>Open powder containers and adding powder to paste mixing vessel</i> • <i>Centrifugal and manual casting of metal into rubber moulds</i> • <i>Manual casting – investment casting</i> |
| Organisational measures to prevent /limit releases, dispersion and exposure |
| <i>Not applicable</i> |
| Conditions and measures related to personal protection, hygiene and health evaluation |
| <ul style="list-style-type: none"> • <i>Handling or use of molten metal bath – workers must wear suitable protective gloves. Eye protection (goggles) must be worn in all areas where there is a risk from molten metal. Respiratory protective equipment must be used when handling dross</i> • <i>Alloy production – workers must wear suitable protective gloves and eye protection (goggles). Suitable respiratory protective equipment must be used when working on dusty processes</i> • <i>Manual casting – workers must wear gloves and eye protection (goggles)</i> • <i>Machine casting of ingot, bar or billets. Continuous casting of billet, rod or strip – workers must wear suitable protective gloves and eye protection (goggles)</i> • <i>Cold rolling – workers must wear suitable protective gloves</i> • <i>Extrusion - workers must wear suitable protective gloves. Eye protection (goggles) must be worn if risk of hotshortness or working with molten alloy charging of the container</i> • <i>Annealing or other heat treatment processes - workers must wear suitable protective gloves</i> • <i>Drilling, boring, milling and tuning – workers must wear eye protection (goggles)</i> • <i>Atomising/Other powder forming processes – workers must wear suitable protective gloves and respiratory protective equipment. Eye protection must be used when working with molten metal</i> • <i>Sieving – workers must wear suitable protective gloves and respiratory protective equipment</i> • <i>Weighing and packing of powder- workers must wear suitable protective gloves and respiratory protective equipment</i> • <i>Pressing and sintering of powder – workers must wear suitable protective gloves and eye protection (goggles). Suitable respiratory protective equipment must be worn if workers are exposed to powder during the loading process</i> • <i>Open powder containers and adding powder to paste mixing vessel – workers must wear suitable protective gloves and respiratory protective equipment</i> • <i>Mixing paste – workers must wear suitable protective gloves</i> • <i>Filling paste containers with product – workers must wear suitable protective gloves</i> • <i>Centrifugal and manual casting of metal into rubber moulds – workers must wear suitable protective gloves and eye protection (goggles)</i> • <i>Manual casting (investment casting) - workers must wear suitable protective gloves and eye protection (goggles)</i> |
| 2.2 Control of environmental exposure |
| Amounts used |
| <i>Modelled EU tonnage 20000tpa. Modelled site tonnage 600 tpa</i> |
| Frequency and duration of use |
| <i>Continuous, 225 days/year</i> |

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| Environment factors not influenced by risk management |
| <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m³/d and 2000 m³/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |
| Other given operational conditions affecting environmental exposure |
| <i>Open and closed systems, wet and dry processes</i> |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| <i>SPERC fact sheet – Formulation of massive metal or metal powder in alloys, version 1.1 Modelled release factors to air 0.007% (after RMM), water 0.003% (after on-site RMM), soil 0%.</i> |
| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health. A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |
| Additional good practice advice beyond the REACH CSA |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i> |

ES Sn No. 3: Industrial use of tin solders

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| 1. Title | |
| Free short title | <i>Industrial use of tin solders (including the manufacture of electronic and electrical articles)</i> |
| Systematic title based on use descriptor | <i>Industrial use of tin solder for the manufacture of computer, electronic and optical products, electrical equipment, general manufacturing and building and construction work (PROC 8a, 8b, 9, 22, 23, 25, 26)</i> <i>ERC 5 (industrial use resulting in inclusion into or onto a matrix)</i> |
| Processes, tasks activities covered | <ul style="list-style-type: none"> • <i>Handling of solder alloys</i> • <i>Handling and transport of metal pastes</i> • <i>Re-melting of tin alloy</i> • <i>Hand soldering with soldering iron</i> • <i>Machine soldering with soldering iron</i> • <i>Hand soldering and tinning with gas torch</i> • <i>Machine soldering with gas torch</i> • <i>Wave soldering</i> • <i>Reflow soldering</i> • <i>Printing of paste (for reflow soldering)</i> • <i>Oven or furnace soldering up to 425 °C</i> • <i>Induction soldering</i> • <i>Resistance soldering</i> • <i>Laser soldering</i> |
| 2. Operational conditions and risk management measures | |
| <i>The industrial use of tin in the industrial use of tin solders involves a number of tasks as detailed above. These tasks are both open and closed processes and are performed at a number of temperatures (from ambient to 400 °C) with different levels of exposure (from <1 hour to up to 8 hours).</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | |
| <i>For all PROC codes covered by this Exposure Scenario the substance is available as a solid with medium dustiness.</i> | |
| Frequency and duration of use/exposure | |
| <p><i>All process occur for the following duration:</i></p> <ul style="list-style-type: none"> • <i>Handling of solder alloys: <1 hour</i> • <i>Handling and transport of metal pastes:<1 hour</i> • <i>Re-melting of tin alloy:<1 hour</i> • <i>Hand soldering with soldering iron: 1-4 hours</i> • <i>Machine soldering with soldering iron: 1-4 hours</i> • <i>Hand soldering with gas torch: <1 hour</i> • <i>Machine soldering with gas torch: <1 hour</i> • <i>Wave soldering: <1 hour</i> • <i>Reflow soldering: <1 hour</i> • <i>Printing of paste (for reflow soldering): up to 8 hours</i> • <i>Oven or furnace soldering: 1-4 hours</i> • <i>Induction soldering: < 1hour</i> • <i>Resistance soldering: < 1 hour</i> • <i>Laser soldering: < 1 hour</i> | |
| Human factors not influenced by risk management | |
| <i>Not applicable.</i> | |

| |
|---|
| Other given operational conditions affecting workers exposure |
| <p>All processes occur indoor at the following temperatures:</p> <ul style="list-style-type: none"> • Handling of solder alloys: ambient • Handling and transport of metal pastes: ambient • Re-melting of tin alloy: <400 °C • Hand soldering with soldering iron: ≤400 °C • Machine soldering with soldering iron: ≤400 °C • Hand soldering with gas torch: ≤400 °C • Machine soldering with gas torch: ≤400 °C • Wave soldering: ≤300 °C • Reflow soldering: ≤250 °C • Printing of paste (for reflow soldering): ambient • Oven or furnace soldering >425 °C • Induction soldering: ≤400 °C • Resistance soldering: ≤400 °C • Laser soldering: ≤400 °C |
| Technical conditions and measures at process level (source) to prevent release |
| Not applicable |
| Technical conditions and measures to control dispersion from source towards the worker |
| <p>Local Exhaust Ventilation is required for the following tasks:</p> <ul style="list-style-type: none"> • Re-melting of tin alloy: Required for larger scale operations only. • Hand soldering with soldering iron • Machine soldering with soldering iron • Hand soldering with gas torch: LEV is not required however this activity should be performed with adequate ventilation. • Machine soldering with gas torch • Wave soldering • Reflow soldering • Oven or furnace soldering • Induction soldering • Resistance soldering • Laser soldering |
| Organisational measures to prevent /limit releases, dispersion and exposure |
| Not applicable |
| Conditions and measures related to personal protection, hygiene and health evaluation |
| <ul style="list-style-type: none"> • Handling of solder alloys – workers must wear suitable protective gloves • Handling and transport of metal pastes –workers must wear suitable protective gloves if handling paste • Re-melting of tin alloy – workers must wear suitable protective gloves and eye protection(goggles). Suitable respiratory protective equipment must be worn when removing dross • Hand soldering with soldering iron – workers must wear suitable eye protection (goggles) • Machine soldering with soldering iron – workers must wear suitable protective eye protection (goggles) if in close proximity to machine soldering. • Hand soldering with gas torch – workers must wear suitable protective gloves and eye protection(goggles) • Machine soldering with gas torch – workers must wear suitable protective gloves and eye protection (goggles) • Wave soldering – workers must wear suitable protective gloves and eye protection (goggles). Suitable respiratory protective equipment may be worn when removing dross • Reflow soldering – workers must wear suitable protective gloves • Printing of paste (for reflow soldering) – workers must wear suitable protective gloves and eye protection (goggles) • Oven or furnace soldering – workers must wear suitable protective gloves and eye protection (goggles) |

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| <ul style="list-style-type: none"> • Induction soldering – workers must wear suitable protective gloves and eye protection (goggles) • Resistance soldering - workers must wear suitable protective gloves and eye protection (goggles) • Laser soldering - workers must wear suitable protective gloves and eye protection (goggles) |
| 2.2 Control of environmental exposure |
| Amounts used |
| <i>Modelled EU tonnage 17500tpa. Modelled site tonnage 600 tpa</i> |
| Frequency and duration of use |
| <i>Continuous, 215 days/year</i> |
| Environment factors not influenced by risk management |
| <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |
| Other given operational conditions affecting environmental exposure |
| <i>Not applicable</i> |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| <i>SPERC fact sheet – Use of metals and metal compounds in metallic coatings, version 1.1 Modelled release factors to air 0.4% (after RMM), water 0.6%(after on-site RMM)), soil 0%.</i> |
| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health. A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |
| Additional good practice advice beyond the REACH CSA |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i> |

ES Sn No. 7: Industrial use of tin in tin coatings - electrolytic plating

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| 1. Title | |
| Free short title | <i>Industrial use of tin in tin coatings - electrolytic plating</i> |
| Systematic title based on use descriptor | <i>Industrial use of tin in tin plating using electrolytic plating for the manufacture of tin plate for food cans, beverage cans, aerosols, closures, general line containers, battery blanks, electronic shielding, Automotive fillers, copper pipes, food processing equipment; manufacture of tin nickel for: electronics, domestic building and leisure, precision and general engineering, chemical process and food industries, medical and dentistry uses, energy uses; manufacture of tin zinc for automotive roofing; manufacture of tin copper for red and yellow bronze/white bronze speculum; manufacture of copper-tin-zinc for decorative and electronics (PROC 3, 8a, 8b, 9, 13, 14, 21, 22, 23, 26) for use in vehicles, machinery, mechanical appliances, electrical/electronic articles and metal articles</i> <i>ERC 2 (formulation of preparations), 3 (formulation in materials) and 5 (industrial use resulting in inclusion into or onto a matrix)</i> |
| Processes, tasks activities covered | <ul style="list-style-type: none"> <i>Electrolytic tinning/plating</i> |
| 2. Operational conditions and risk management measures | |
| <i>The industrial use of tin in tin coatings (electrolytic plating) involves the task detailed above. This task is both an open and closed process and is performed at >100 850 °C) and at > 4 hours exposure</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | |
| <i>For the majority of the uses/PROC codes covered by this Exposure Scenario the substance is available as a solid with low dustiness.</i> | |
| <i>For the following uses/PROC codes, the substance is available as a liquid:</i> | |
| <ul style="list-style-type: none"> <i>manufacture of Copper-Tin-Zinc - Decorative & Electronics – PROC 3</i> | |
| Frequency and duration of use/exposure | |
| <i>All process occur for the following duration:</i> | |
| <ul style="list-style-type: none"> <i>Electrolytic tinning/plating: >4 hours</i> | |
| Human factors not influenced by risk management | |
| <i>Not applicable.</i> | |
| Other given operational conditions affecting workers exposure | |
| <i>All processes occur indoor at the following temperatures:</i> | |
| <ul style="list-style-type: none"> <i>Electrolytic tinning/plating: <100 °C</i> | |
| Technical conditions and measures at process level (source) to prevent release | |
| <i>Not applicable</i> | |
| Technical conditions and measures to control dispersion from source towards the worker | |
| <i>Local Exhaust Ventilation is not required for this task</i> | |
| Organisational measures to prevent /limit releases, dispersion and exposure | |
| <i>Not applicable</i> | |
| Conditions and measures related to personal protection, hygiene and health evaluation | |
| <ul style="list-style-type: none"> <i>Electrolytic tinning/plating – gloves and eye protection (goggles) must be worn</i> | |

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| 2.2 Control of environmental exposure |
| Amounts used |
| <i>Modelled EU tonnage 20000tpa. Modelled site tonnage 4500 tpa</i> |
| Frequency and duration of use |
| <i>Continuous, 215 days/year</i> |
| Environment factors not influenced by risk management |
| <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |
| Other given operational conditions affecting environmental exposure |
| <i>Not applicable</i> |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| <i>SPERC fact sheet – Use of metals and metal compounds in metallic coatings, version 1.1 Modelled release factors to air 0.4% (after RMM), water 0.6% (after on-site RMM), soil 0%.</i> |
| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health. A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |
| Additional good practice advice beyond the REACH CSA |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i> |

ES Sn No. 8: Industrial use of tin and tin alloys in tin coatings - hot dip and thermal spraying

| 1. Title | |
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| Free short title | <i>Industrial use of tin and tin alloys in tin coatings – hot dip and thermal spraying</i> |
| Systematic title based on use descriptor | <i>Industrial use of tin in tin coatings using hot dip and thermal spraying for zinc galvanising (PROC 3, 8a, 8b, 9, 13, 22, 23, 26) and the manufacture and use of alloy for thermal spray (PROC 7, 14, 19, 21, 22, 23, 26, 27a for use in vehicles, machinery, mechanical appliances, electrical/electronic articles and metal articles) ERC 2 (formulation of preparations), 3 (formulation in materials) and 5 (industrial use resulting in inclusion into or onto a matrix)</i> |
| Processes, tasks activities covered | <ul style="list-style-type: none"> • <i>Handling and transport of massive metal</i> • <i>Handling or use of molten metal bath >400 °C</i> • <i>Alloy production</i> • <i>Manual casting of alloys</i> • <i>Machine casting of alloys</i> • <i>Hot dipping and immersion soldering</i> • <i>Solder coating processes for fine wires</i> • <i>Handling of alloy</i> • <i>Spraying</i> |
| 2. Operational conditions and risk management measures | |
| <i>The industrial use of tin in tin coatings (hot dip and thermal spraying) involves a number of tasks as detailed above. These tasks are both open and closed processes and are performed at a number of temperatures up to 475 °C with different levels of exposure (from 1-4 hours to up to 4 hours).</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | |
| <p><i>For the majority of the uses/PROC codes covered by this Exposure Scenario the substance is available as a solid with low dustiness.</i></p> <p><i>For the following uses/PROC codes, the substance is available as a solid with medium dustiness:</i></p> <ul style="list-style-type: none"> • <i>Manufacture and Use of Alloy for thermal spray – PROC 19, 22, 23, 26, 27a.</i> <p><i>For the following uses/PROC codes, the substance is available as a liquid:</i></p> <ul style="list-style-type: none"> • <i>Zinc Galvanising – PROC 3, 8a, 8b, 9, 13.</i> • <i>Manufacture and Use of Alloy for thermal spray – PROC 7.</i> | |
| Frequency and duration of use/exposure | |
| <p><i>All process occur for the following duration:</i></p> <ul style="list-style-type: none"> • <i>Handling and transport of massive metal: 1-4 hours</i> • <i>Handling or use of molten metal bath >400 °C: up to 4 hours</i> • <i>Alloy production: 1-4 hours</i> • <i>Machine casting of alloys: 1-4 hours</i> • <i>Mould casting of alloys: 1-4 hours</i> • <i>Hot dipping and immersion soldering: >4 hours</i> • <i>Solder coating processes for fine wires: 1-4 hours</i> • <i>Handling of alloy: 1-4 hours</i> • <i>Spraying: 1-4 hours</i> | |
| Human factors not influenced by risk management | |
| <i>Not applicable.</i> | |

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| Other given operational conditions affecting workers exposure |
| <p>All processes occur indoor at the following temperatures:</p> <ul style="list-style-type: none"> • Handling and transport of massive metal: Ambient • Handling or use of molten metal bath >400 °C: up to 550 °C • Alloy production: up to 500 °C • Machine casting of alloys: up to 500 °C • Mould casting of alloys: up to 500°C • Hot dipping and immersion soldering: up to 475 °C • Solder coating processes for fine wires: up to 450 °C • Handling of alloy: Ambient • Spraying: up to 400 °C |
| Technical conditions and measures at process level (source) to prevent release |
| <i>Not applicable</i> |
| Technical conditions and measures to control dispersion from source towards the worker |
| <p>Local Exhaust Ventilation is required for the following tasks:</p> <ul style="list-style-type: none"> • Handling or use of molten metal bath >400 °C • Alloy production • Permanent mould casting • Hot dipping (Galvanising) • Immersion tinning or solder coating, includes tern coating • Solder coating processes for fine wires • Spraying |
| Organisational measures to prevent /limit releases, dispersion and exposure |
| <i>Not applicable</i> |
| Conditions and measures related to personal protection, hygiene and health evaluation |
| <ul style="list-style-type: none"> • Handling and transport of massive metal – workers must wear suitable protective gloves and eye protection (goggles) • Handling or use of molten metal bath >400 °C – workers must wear suitable protective gloves, eye protection (goggles) and respiratory protective equipment • Alloy production – workers must wear suitable protective gloves, eye protection (goggles) and respiratory protective equipment • Manual casting of alloys - workers must wear suitable protective gloves and eye protection (goggles) • Machine casting of alloys - workers must wear suitable protective gloves and eye protection (goggles) • Hot dipping and immersion soldering – workers must wear suitable protective gloves and eye protection (goggles) • Solder coating processes for fine wires – workers must wear suitable protective gloves • Spraying - workers must wear suitable protective gloves and eye protection (goggles). Suitable respiratory protective equipment must be worn if LEV is insufficient |
| 2.2 Control of environmental exposure |
| Amounts used |
| <i>Modelled EU tonnage 50 tpa. Modelled site tonnage 5 tpa</i> |
| Frequency and duration of use |
| <i>Continuous, 215 days/year</i> |
| Environment factors not influenced by risk management |
| <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |

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| Other given operational conditions affecting environmental exposure |
| <i>Not applicable</i> |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| <i>SPERC fact sheet – Use of metals and metal compounds in metallic coatings, version 1.1 Modelled release factors to air 0.4% (after RMM), water 0.6%(after on-site RMM)), soil 0%.</i> |
| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health. A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |
| Additional good practice advice beyond the REACH CSA |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i> |

ES Sn No. 9: Industrial use of tin in primary and secondary recovery

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| 1. Title | |
| Free short title | <i>Industrial use of tin in primary and secondary recovery</i> |
| Systematic title based on use descriptor | <i>Industrial manufacture of basic metals, including alloys through primary end-of-life recovery (PROC 1, 2, 3, 4, 8b, 9, 22, 23, 26). ERC 1 (manufacture of substances)</i> |
| Processes, tasks activities covered | <ul style="list-style-type: none"> • <i>Scrap metal handling</i> • <i>Scrap metal processing i.e. shredding, separation, etc.</i> • <i>Handling of other scrap material</i> • <i>Secondary smelting</i> • <i>Pyrochemical refining</i> • <i>Liquidation refining</i> • <i>Vacuum distillation</i> • <i>Electrolytic refining</i> |
| 2. Operational conditions and risk management measures | |
| <i>The industrial use of tin in primary and secondary recovery involves a number of tasks as detailed above. These tasks are both open and closed processes and are performed at a number of temperatures (from <70 to <1200 °C) with exposure at >4 hours.</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | |
| <i>For the majority of the uses/PROC codes covered by this Exposure Scenario the substance is available as a solid with medium dustiness except for PROC 1 and 2 where the substance is available as a liquid.</i> | |
| Frequency and duration of use/exposure | |
| <p><i>All process occur for the following duration:</i></p> <ul style="list-style-type: none"> • <i>Scrap metal handling: >4 hours</i> • <i>Scrap metal processing i.e. shredding, separation, etc: >4 hours</i> • <i>Handling of other scrap material: >4 hours</i> • <i>Secondary smelting: >4 hours</i> • <i>Pyrochemical refining: >4 hours</i> • <i>Liquidation refining: >4 hours</i> • <i>Vacuum distillation: >4 hours</i> • <i>Electrolytic refining: >4 hours</i> | |
| Human factors not influenced by risk management | |
| <i>Not applicable.</i> | |
| Other given operational conditions affecting workers exposure | |
| <p><i>All processes occur indoor at the following temperatures:</i></p> <ul style="list-style-type: none"> • <i>Scrap metal handling: Ambient</i> • <i>Scrap metal processing i.e. shredding, separation, etc: up to 150 °C</i> • <i>Handling of other scrap material: Ambient</i> • <i>Secondary smelting: up to 1200 °C</i> • <i>Pyrochemical refining: up to 660 °C</i> • <i>Liquidation refining: up to 300 °C</i> • <i>Vacuum distillation: up to 1400 °C</i> • <i>Electrolytic refining: up to 70 °C</i> | |
| Technical conditions and measures at process level (source) to prevent release | |
| <i>Not applicable</i> | |

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| Technical conditions and measures to control dispersion from source towards the worker |
| Local Exhaust Ventilation is required for the following tasks: <ul style="list-style-type: none"> • Secondary smelting • Pyrochemical refining • Liquidation refining • Vacuum distillation |
| Organisational measures to prevent /limit releases, dispersion and exposure |
| Not applicable |
| Conditions and measures related to personal protection, hygiene and health evaluation |
| <ul style="list-style-type: none"> • Scrap metal handling – gloves and eye protection (goggles) must be worn. Respiratory protective equipment must be worn when handling dusty material or in a dusty environment • Scrap metal processing i.e. shredding, separation, etc – gloves and eye protection (goggles) must be worn. Respiratory protective equipment must be worn when handling dusty material or in a dusty environment • Handling of other scrap material – gloves, eye protection (goggles) and respiratory protective equipment must be worn • Secondary smelting – gloves, eye protection (goggles) and respiratory protective equipment must be worn • Pyrochemical refining – gloves and eye protection (goggles) must be worn. Respiratory protective equipment must be worn when removing drosses or working close to molten alloy • Liquidation refining – gloves and eye protection (goggles) must be worn. Respiratory protective equipment must be worn when removing drosses or working close to molten alloy • Vacuum distillation – gloves and eye protection (goggles) must be worn. Respiratory protective equipment must be worn when working with hot, open furnace • Electrolytic refining – gloves and eye protection (goggles) must be worn |
| 2.2 Control of environmental exposure |
| Amounts used |
| Modelled EU tonnage 15000 tpa. Modelled site tonnage 12000 tpa |
| Frequency and duration of use |
| Continuous, 220 days/year |
| Environment factors not influenced by risk management |
| Default data for receiving water and for the municipal sewage treatment plant are 18 000 m ³ /d and 2000 m ³ /d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed. |
| Other given operational conditions affecting environmental exposure |
| Open and closed systems, wet and dry processes |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| SPERC fact sheet – Manufacture and recycling of massive metal and metal powder, version 1.2 Modelled release factors to air 0.03% (after RMM), water 0.01% (after on-site RMM), soil 0%. |
| Conditions and measures related to municipal sewage treatment plant |
| EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land. |
| Conditions and measures related to external treatment of waste for disposal |
| External treatment and disposal of waste should comply with applicable local and/or national regulations. |
| Conditions and measures related to external recovery of waste |
| External recovery and recycling of waste should comply with applicable local and/or national regulations. |

3. Exposure estimation and reference to its source

All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health.

A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.

Additional good practice advice beyond the REACH CSA

Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.

ES Sn No. 11: Consumer exposure to tin metal or tin containing products

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| 1. Title | |
| Free short title | <i>Consumer exposure to tin metal or tin containing products</i> |
| Systematic title based on use descriptor | <i>Consumer use of base metals, alloys and metal surface treatment products in vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators and metal articles ERC 8c (wide dispersive indoor use resulting in inclusion into or onto a matrix), 8f (wide dispersive outdoor use resulting in inclusion into or onto a matrix), 10a (wide dispersive outdoor use of long-life articles and materials with low release) and 11a (wide dispersive indoor use of long-life articles and materials with low release)</i> |
| 2. Operational conditions and risk management measures | |
| <i>The consumer use of tin or tin containing products occurs via consumer interaction with tin-containing articles</i> | |
| 2.1 Control of consumers exposure | |
| Product characteristic | <i>Consumers will be exposed to tin via 'massive solid' articles in articles such as vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators</i> |
| Amounts used | <i>No information available</i> |
| Frequency and duration of use/exposure | <i>No information available</i> |
| Human factors not influenced by risk management | <i>No information available</i> |
| Other given operational conditions affecting consumers exposure | <i>Not applicable</i> |
| Conditions and measures related to information and behavioural advice to consumers | <i>Not applicable</i> |
| Conditions and measures related to personal protection and hygiene | <i>Not applicable</i> |
| 2.2 Control of environmental exposure | |
| Amounts used* | <i>Based on a EU tonnage of 15000 tpa and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 3 tpa/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of tin containing products and articles.</i> |
| Frequency and duration of use | <i>Continuous, 365 days/year</i> |
| Environment factors not influenced by risk management | <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |
| Other given operational conditions affecting environmental exposure | <i>ERC – highest emission from relevant ERC Modelled release factors to air 15%, water 3.2%, soil 3.2%.</i> |

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| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>Consumer exposure to tin is likely to occur via the use of articles A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |

ES Sn No. 12: Professional exposure to tin metal or tin containing products

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| 1. Title | |
| Free short title | <i>Professional exposure to tin metal or tin containing products</i> |
| Systematic title based on use descriptor | <i>Professional use to tin or tin containing products as base metals, alloys and metal surface treatment products in vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators and metal articles (PROC 4, 9, 14, 21, 22, 23, 25, 26) ERC 8c (wide dispersive indoor use resulting in inclusion into or onto a matrix), 8f (wide dispersive outdoor use resulting in inclusion into or onto a matrix), 10a (wide dispersive outdoor use of long-life articles and materials with low release) and 11a (wide dispersive indoor use of long-life articles and materials with low release)</i> |
| Processes, tasks activities covered | <i>No information available</i> |
| 2. Operational conditions and risk management measures | |
| <i>The professional use of tin or tin containing products includes both open and closed processes</i> | |
| 2.1 Control of workers exposure | |
| Product characteristic | <i>For the uses/PROC codes covered by this Exposure Scenario the substance is available as a solid with low dustiness</i> |
| Frequency and duration of use/exposure | <i>No information available</i> |
| Human factors not influenced by risk management | <i>Not applicable.</i> |
| Other given operational conditions affecting workers exposure | <i>No information available</i> |
| Technical conditions and measures at process level (source) to prevent release | <i>Not applicable</i> |
| Technical conditions and measures to control dispersion from source towards the worker | <i>No information available</i> |
| Organisational measures to prevent /limit releases, dispersion and exposure | <i>Not applicable</i> |
| Conditions and measures related to personal protection, hygiene and health evaluation | <i>No information available</i> |
| 2.2 Control of environmental exposure | |
| Amounts used | <i>Based on a EU tonnage of 15000 tpa and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 3 tpa/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of tin containing products and articles.</i> |
| Frequency and duration of use | <i>Continuous, 365 days/year</i> |
| Environment factors not influenced by risk management | <i>Default data for receiving water and for the municipal sewage treatment plant are 18 000 m³/d and 2000 m³/d, respectively (resulting dilution factor 10). For marine assessments an additional tenfold dilution is assumed.</i> |

| |
|---|
| Other given operational conditions affecting environmental exposure |
| <i>Not applicable</i> |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil |
| <i>ERC – highest emission from relevant ERC Modelled release factors to air 15%, water 3.2%, soil 3.2%.</i> |
| Conditions and measures related to municipal sewage treatment plant |
| <i>EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 90.3% to sludge, 9.7% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.</i> |
| Conditions and measures related to external treatment of waste for disposal |
| <i>External treatment and disposal of waste should comply with applicable local and/or national regulations.</i> |
| Conditions and measures related to external recovery of waste |
| <i>External recovery and recycling of waste should comply with applicable local and/or national regulations.</i> |
| 3. Exposure estimation and reference to its source |
| <i>All exposure estimates for human health show risk characterisation ratios below the value of 1 and so all uses covered by this Exposure Scenario are considered to be safe for human health. A quantitative risk assessment is not required for the environment as there is no basis for setting a PNEC. In addition, this substance is not classified as hazardous to the environment. A qualitative assessment has been applied. A review of these RMMs indicates that if the user complies with the following generic statements, risks to the environment can be considered to be adequately controlled: Avoid release to the environment.</i> |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| <i>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate.</i> |
| Additional good practice advice beyond the REACH CSA |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i> |

Exposure Scenario Sb No. 5: Use of antimony metal in preparations (including solder)

| 1. Title | | | | |
|---|---|------------------------|------------------------------|-------------------------|
| Systematic title based on use descriptor | SU22 (Professional uses) PC11, PC38 AC2, AC7 (appropriate PROCs and ERCs are given in section 2 below) | | | |
| Processes, tasks and/or activities covered | Processes, tasks and/or activities covered are described in Section 2 below. | | | |
| Assessment Method | For occupational assessment either measured data or MEASE was used. Environmental assessment uses EUSES. | | | |
| 2. Operational conditions and risk management measures | | | | |
| Task | Involved tasks | Involved PROCs | Involved ERC | |
| Handling of preparations at ambient temperature | Handling of solder | 21 | 10a, 10b, 11a, 11b, 12a, 12b | |
| Use of preparations at elevated temperatures | Soldering | 25 | | |
| 2.1 Control of workers exposure | | | | |
| Product characteristic | | | | |
| Task | Used in preparation | Content in preparation | Physical form | Emission potential |
| Handling of preparations at ambient temperature | not restricted | | massive object | very low |
| Use of preparations at elevated temperatures | Yes | <5% | molten | Low (temperature based) |
| Amounts used | | | | |
| Not restricted. | | | | |
| Frequency and duration of use/exposure | | | | |
| Duration of exposure is not restricted for any task. | | | | |
| Human factors not influenced by risk management | | | | |
| The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours). | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| Process temperature for task "Use of preparation at elevated temperatures" is up to 500°C. Operational conditions are not restricted or not relevant for other tasks. | | | | |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| No containment for any task is required. | | | | |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| Dilution ventilation is required for all tasks. | | | | |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| Check section 7.1.2, section 8.2.2.2 and section 11 in the core SDS for further information | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| No respiratory protective equipment is required for any task. Check section 8 in the core SDS for further information. | | | | |
| 2.2 Control of environmental exposure | | | | |
| Amounts used | | | | |
| Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of Sb metal containing products and articles. | | | | |
| Frequency and duration of use | | | | |
| Continuous use/release, 365 days/year | | | | |

| | | | | | | |
|---|--|------------------------------------|---|---------------------------------------|----------------------|-----------------|
| Environment factors not influenced by risk management | | | | | | |
| Default data for receiving water and for the municipal sewage treatment plant are 18 000 m ³ /d and 2000 m ³ /d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed. | | | | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | | | | | | |
| For local assessment of diffuse inputs of Sb metal all emissions are assumed to go to a local sewage treatment works. Over 95% of use of Sb containing products and articles has a release to water ≤3.2% based on the ERC. This has therefore been selected as the release fraction. Modelled release factors to water 3.2% before STP (ERC). | | | | | | |
| Conditions and measures related to municipal sewage treatment plant | | | | | | |
| EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1% to sludge, 20.9% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land. | | | | | | |
| Conditions and measures related to external treatment of waste for disposal | | | | | | |
| Check section 13 in the core SDS for further information. | | | | | | |
| 3. Exposure estimation and reference to its source | | | | | | |
| Occupational exposure | | | | | | |
| The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m ³ . | | | | | | |
| Task | Method used for inhalation exposure assessment | Inhalation exposure estimate (RCR) | Method used for dermal exposure assessment | Dermal exposure estimate (RCR) | | |
| Handling of preparations at ambient temperature | MEASE | 0.050 mg/m ³ (0.10) | Dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described in above exposure scenario section 2 and in section 8 and section 11 of the core SDS. | | | |
| Use of preparations at elevated temperatures | MEASE | 0.20 mg/m ³ (0.40) | | | | |
| Environmental emissions | | | | | | |
| Local PEC | | | | | | |
| Air mg.m-3 (RCR) | Fresh water mg/l (RCR) | Marine water mg/l (RCR) | Sediment freshwater mg/kg wwt (RCR) | Sediment marine water mg/kg wwt (RCR) | Soil mg/kg wwt (RCR) | STP mg/l (RCR) |
| 2.6E-06 (NA) | 5.87E-03 (0.052) | 7.15E-04 (0.063) | 5.71 (0.73) | 0.70 (0.45) | 9.03 (0.28) | 5.5E-02 (0.022) |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES | | | | | | |
| Occupational exposure / Environmental emissions | | | | | | |
| The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. Detailed guidance for evaluation of ES can be acquired via your supplier or from the ECHA website (guidance R14, R16). If measured data are not available, scaling tool for human health part is: MEASE (free download via: www.ebrc.de/mease.html). For environmental exposure: DU-Scaling tool (free download via: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool). | | | | | | |

ES Ag No. 2: Use of silver metal in re-melting and alloying

| Exposure Scenario Format (1) addressing uses carried out by workers | | | | |
|---|---|---|---------------------------------|--------------------|
| 1. Title | | | | |
| Free short title | Use of silver metal in re-melting and alloying as alloying agent (incl. brazes and solders), massive silver objects (including investment bars, jewellery, tableware, decoration), biomedical, dentistry or therapy applications | | | |
| Systematic title based on use descriptor | SU3 (Industrial uses), SU14, SU15 PC7, PC38 AC2, AC7 (appropriate PROCs and ERCs are given in Section 2 below) | | | |
| Processes, tasks and/or activities covered | Processes, tasks and/or activities covered are described in Section 2 below. | | | |
| Assessment Method | The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenarios addendum of the chemical safety report. | | | |
| 2. Operational conditions and risk management measures | | | | |
| Workplace | Involved tasks | Involved PROCs | Environment | ERC |
| Raw material handling | weighing, mixing, sieving, production of suspension | 3, 4, 8b, 21 | | |
| Production and handling of powders | weighing, mixing, milling, sieving | 5, 26, 27b | | |
| Melting and casting | melting, casting, refining | 22, 23 | | |
| Mechanical treatment | sawing, milling, grinding, rolling, etching, polishing, brushing, cutting, coiling | 10, 14, 21, 24 | | |
| Annealing | annealing (including any heat treatment above the recrystallisation temperature) | 1 (22 is considered as conducted in closed system) | | |
| Final handling | assembly, surface treatment, polishing, stamping | 14, 21 | | |
| Packaging of massive objects | packaging | 21 | | |
| Brazing and soldering | brazing and soldering | 25 | | |
| Welding (not part of this exposure scenario) Please refer to the exposure scenario "Welding in industrial and/or professional settings". | | 25 | | |
| 2.1 Control of workers exposure | | | | |
| Product characteristic | | | | |
| According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions is assumed to be involved with a medium emission. | | | | |
| Workplace | Use in preparation | Content in preparation | Physical form | Emission potential |
| Raw material handling | not restricted | | granules, scrap, massive silver | very low – low |
| Production and handling of powders | | | powder | high |
| Melting and casting | | | molten | high |
| Mechanical treatment | | | massive | medium |
| Annealing | | | massive | very low |

| | | | | |
|--|------------------------------|---------------------------|--|---------------------|
| Final handling | | massive | very low | |
| Packaging of massive objects | | massive | very low | |
| Brazing and soldering | | molten | low | |
| Amounts used | | | | |
| The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential. | | | | |
| Frequency and duration of use/exposure | | | | |
| Workplace | Duration of exposure | | | |
| Raw material handling | 480 minutes (not restricted) | | | |
| Production and handling of powders | 480 minutes (not restricted) | | | |
| Melting and casting | 480 minutes (not restricted) | | | |
| Mechanical treatment | 480 minutes (not restricted) | | | |
| Annealing | 480 minutes (not restricted) | | | |
| Final handling | 480 minutes (not restricted) | | | |
| Packaging of massive objects | 480 minutes (not restricted) | | | |
| Brazing and soldering | 480 minutes (not restricted) | | | |
| Human factors not influenced by risk management | | | | |
| The shift breathing volume during all process steps is assumed to be 10 m ³ /shift (8 hours). | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| Workplace | Room volume | Outdoor or indoor use | Process temperature | Process pressure |
| Raw material handling | >1,000 m ³ | indoors | ambient | not restricted |
| Production and handling of powders | >1,000 m ³ | indoors | ambient | not restricted |
| Melting and casting | >1,000 m ³ | indoors | up to 1300°C | not restricted |
| Mechanical treatment | >1,000 m ³ | indoors | ambient | not restricted |
| Annealing | >1,000 m ³ | indoors | ambient | not restricted |
| Final handling | >1,000 m ³ | indoors | ambient | not restricted |
| Packaging of massive objects | >1,000 m ³ | indoors | ambient | not restricted |
| Brazing and soldering | >1,000 m ³ | indoors | < 950°C | not restricted |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| Workplace | Level of containment | | Level of segregation | |
| Raw material handling | not required | | enclosed space | |
| Production and handling of powders | not required | | enclosed space | |
| Melting and casting | closed furnace | | enclosed space | |
| Mechanical treatment | not required | | not required | |
| Annealing | closed system | | enclosed space | |
| Packaging of massive objects | not required | | not required | |
| Brazing and soldering | not required | | not required | |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| Workplace | Level of separation | Localised controls (LC) | Efficiency of LC (according to MEASE)* | Further information |
| Raw material handling | not required | local exhaust ventilation | 78 % | - |
| Production and handling of powders | not required | local exhaust ventilation | 78 % | - |

| Melting and casting | not required | local exhaust ventilation | 78 % | - |
|---|--|--|--|---|
| Mechanical treatment | not required | local exhaust ventilation | 78 % | - |
| Annealing | not required | not required | na | - |
| Final handling | not required | not required | na | - |
| Packaging of massive objects | not required | not required | na | - |
| Brazing and soldering | not required | local exhaust ventilation | 78 % | - |
| *It has to be assured that localised controls like local exhaust ventilation systems are inspected and maintained at appropriate frequencies to guarantee the functionality and efficiency. | | | | |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air. | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| Workplace | Specification of respiratory protective equipment (RPE) | RPE efficiency (assigned protection factor, APF) | Specification of gloves | Further personal protective equipment (PPE) |
| Raw material handling | not required | na | Gloves are optional for process steps at ambient temperature, thermal protective gloves should be used for hot processes | standard working clothes (overall) and safety shoes |
| Production and handling of powders | FFP3 mask | APF=20 | | |
| Melting and casting | not required | na | | |
| Mechanical treatment | FFP2 mask | APF=10 | | |
| Annealing | not required | na | | |
| Final handling | not required | na | | |
| Packaging of massive objects | not required | na | | |
| Brazing and soldering | not required (please note that the release of fine particles cannot be excluded during brazing and soldering, if exposures of workers to brazing and/or soldering fumes are likely to occur appropriate RPE should be selected) | na | | |
| Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. | | | | |
| For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. | | | | |
| The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. | | | | |
| An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE. | | | | |
| 2.2 Control of environmental exposure | | | | |
| Product characteristics | | | | |
| Product related conditions, e.g. the concentration of the substance in a preparation; package design affecting exposure | | | | |

| | | | | |
|---|--|------------------------------------|---|--------------------------------|
| Amounts used | | | | |
| Daily and annual amount per site (for point sources); annual amount for wide disperse use | | | | |
| Frequency and duration of use | | | | |
| Intermittent (< 12 time per year) or continuous use/release | | | | |
| Environment factors not influenced by risk management | | | | |
| Flow rate of receiving surface water | | | | |
| Other given operational conditions affecting environmental exposure | | | | |
| Other operational conditions, e.g. indoor or outdoor use of products; process conditions related to temperature and pressure | | | | |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| Process design aiming to prevent releases and hence exposure of the environment; this also includes conditions ensuring rigorous containment; specify effectiveness of containment (e.g. residual losses) | | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | | | | |
| Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions to minimise emissions; specify efficacy of measures; specify the size of industrial sewage treatment plant (m3/d), degradation efficacy and sludge treatment (if applicable). | | | | |
| Organizational measures to prevent/limit release from site | | | | |
| Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions. | | | | |
| Conditions and measures related to municipal sewage treatment plant | | | | |
| Size of municipal sewage system/treatment plant (m3/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable) | | | | |
| Conditions and measures related to external treatment of waste for disposal | | | | |
| Type of suitable treatment for waste generated by workers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste: specify efficacy of treatment | | | | |
| Conditions and measures related to external recovery of waste | | | | |
| Specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery outside waste incinerators; specify efficacy of measure; | | | | |
| 3. Exposure estimation and reference to its source | | | | |
| Occupational exposure | | | | |
| The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective derived no-effect level (DNEL). For inhalation exposure, the RCR is based on the DNEL for metallic silver of 0.1 mg/m3. | | | | |
| Workplace | Method used for inhalation exposure assessment (refer to introduction) | Inhalation exposure estimate (RCR) | Method used for dermal exposure assessment | Dermal exposure estimate (RCR) |
| Raw material handling | analogous data | 0.047 mg/m3 (0.472) | Due to the negligible dermal absorption of metallic silver, the dermal route is not a relevant exposure path for metallic silver and a DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario. | |
| Production and handling of powders | analogous data | 0.06 mg/m3 (0.6) | | |
| Melting and casting | analogous data | 0.016 mg/m3 (0.16) | | |
| Mechanical treatment | MEASE | 0.066 mg/m3 (0.66) | | |
| Annealing | MEASE | 0.001 mg/m3 (0.01) | | |
| Final handling | MEASE | 0.050 mg/m3 (0.50) | | |
| Packaging of massive objects | MEASE | 0.050 mg/m3 (0.50) | | |
| Brazing and soldering | analogous data | 0.016 mg/m3 (0.16) | | |

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The glossary of MEASE can be considered for the classification of the dustiness of a specific material.

DNEL_{inhalation}: 0.1 mg/m³

Environmental emissions

ES Ag No. 4: Use of silver metal in electronics, contact materials and electroplating

| Exposure Scenario Format (1) addressing uses carried out by workers | | | | |
|---|---|------------------------|---|--------------------|
| 1. Title | | | | |
| Free short title | Use of silver metal in contact and fuse materials (incl. absorber rods), as electroplating agent, as coating and in electronics (incl. sintering/calcination processes and production of photovoltaic cells). | | | |
| Systematic title based on use descriptor | SU3 (Industrial uses), SU9, SU14, SU16 PC14 AC2 (appropriate PROCs and ERCs are given in Section 2 below). | | | |
| Processes, tasks and/or activities covered | Processes, tasks and/or activities covered are described in Section 2 below. | | | |
| Assessment Method | The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenarios addendum of the chemical safety report. | | | |
| 2. Operational conditions and risk management measures | | | | |
| Workplace | Involved tasks | Involved PROCs | Environment | ERC |
| Raw material handling | weighing, mixing, blending, sieving, filling | 3, 4, 5, 8a, 8b, 9, 26 | | |
| Processes in closed systems | sputtering, screen printing (solar cells) | 1, 2 | | |
| Mechanical treatment | pressing, rolling, cutting | 14, 21, 24 | | |
| Hot processes | sintering, melting, casting, heat treatment, extrusion, soldering | 22, 23, 25 | | |
| Wet process | electrolytic dissolution of silver, drying, electroplating | 2, 3, 4, 27b | | |
| Finishing | milling, cutting, shaping, sawing, grinding, brushing, polishing, assembly | 14, 21, 24 | | |
| Production and handling of powders | powder production, atomisation, packaging | 26, 27a, 27b | | |
| Packaging of massive objects | packaging | 21 | | |
| Welding (not part of this exposure scenario) | | 25 | | |
| Please refer to the exposure scenario "Welding in industrial and/or professional settings". | | | | |
| 2.1 Control of workers exposure | | | | |
| Product characteristic | | | | |
| According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions is assumed to be involved with a medium emission. | | | | |
| Workplace | Use in preparation | Content in preparation | Physical form | Emission potential |
| Raw material handling | not restricted | | various (powder, silver alloy, silver crystals, massive silver, granules) | high |
| Processes in closed systems | not restricted | | various | high |
| Mechanical treatment | not restricted | | massive, powder | low - high |

| | | | |
|------------------------------------|----------------|-------------------------|----------------|
| Hot processes | not restricted | molten | high |
| Wet process | not restricted | wetted powder, solution | low – very low |
| Finishing | not restricted | massive | medium |
| Production and handling of powders | not restricted | powder | high |
| Packaging of massive objects | not restricted | massive | very low |

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential.

Frequency and duration of use/exposure

| Workplace | Duration of exposure |
|------------------------------------|------------------------------|
| Raw material handling | 480 minutes (not restricted) |
| Processes in closed systems | 480 minutes (not restricted) |
| Mechanical treatment | 480 minutes (not restricted) |
| Hot processes | 480 minutes (not restricted) |
| Wet process | 480 minutes (not restricted) |
| Finishing | 480 minutes (not restricted) |
| Production and handling of powders | 480 minutes (not restricted) |
| Packaging of massive objects | 480 minutes (not restricted) |

Human factors not influenced by risk management

The shift breathing volume during all process steps is assumed to be 10 m³/shift (8 hours).

Other given operational conditions affecting workers exposure

| Workplace | Room volume | Outdoor or indoor use | Process temperature | Process pressure |
|------------------------------------|-----------------------|-----------------------|---------------------|------------------|
| Raw material handling | >1,000 m ³ | indoors | ambient | not restricted |
| Processes in closed systems | >1,000 m ³ | indoors | not restricted | not restricted |
| Mechanical treatment | >1,000 m ³ | indoors | not restricted | not restricted |
| Hot processes | >1,000 m ³ | indoors | up to 1300°C | not restricted |
| Wet process | >1,000 m ³ | indoors | not restricted | not restricted |
| Finishing | >1,000 m ³ | indoors | not restricted | not restricted |
| Production and handling of powders | >1,000 m ³ | indoors | ambient | not restricted |
| Packaging of massive objects | >1,000 m ³ | indoors | ambient | not restricted |

Technical conditions and measures at process level (source) to prevent release

| Workplace | Level of containment | Level of segregation |
|------------------------------------|----------------------------|----------------------|
| Raw material handling | not required | enclosed space |
| Processes in closed systems | closed, continuous process | enclosed space |
| Mechanical treatment | closed press | enclosed space |
| Hot processes | closed furnace | enclosed space |
| Wet process | closed reactor | not required |
| Finishing | not required | not required |
| Production and handling of powders | not required | enclosed space |
| Packaging of massive objects | not required | not required |

| Technical conditions and measures to control dispersion from source towards the worker | | | | |
|---|--|--|---|--|
| Workplace | Level of separation | Localised controls (LC) | Efficiency of LC (according to MEASE)* | Further information |
| Raw material handling | not required | local exhaust ventilation | 78 % | - |
| Processes in closed systems | not required | local exhaust ventilation | 78 % | - |
| Mechanical treatment | not required | not required | na | - |
| Hot processes | not required | local exhaust ventilation | 78 % | - |
| Wet process | not required | local exhaust ventilation | 78 % | - |
| Finishing | not required | local exhaust ventilation | 78 % | - |
| Production and handling of powders | not required | local exhaust ventilation | 78 % | - |
| Packaging of massive objects | not required | not required | na | - |
| *It has to be assured that localised controls like local exhaust ventilation systems are inspected and maintained at appropriate frequencies to guarantee the functionality and efficiency. | | | | |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air. | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| Workplace | Specification of respiratory protective equipment (RPE) | RPE efficiency (assigned protection factor, APF) | Specification of gloves | Further personal protective equipment (PPE) |
| Raw material handling | FFP3 mask | APF=20 | Gloves are optional for process steps at ambient temperature, thermal protective gloves should be used for hot processes. | standard working clothes (overall) and safety shoes. |
| Processes in closed systems | FFP2 mask during manual operations | APF=10 | | |
| Mechanical treatment | FFP3 mask | APF=20 | | |
| Hot processes | not required (please note that the release of fine particles cannot be excluded during soldering, if exposure of workers to soldering fumes is likely to occur appropriate RPE should be selected) | na | | |
| Wet process | not required | na | | |
| Finishing | FFP2 mask | APF=10 | | |
| Production and handling of powders | FFP3 mask | APF=20 | | |
| Packaging of massive objects | not required | na | | |
| Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. | | | | |
| For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. | | | | |
| The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the | | | | |

| | | | | |
|---|--|------------------------------------|---|--------------------------------|
| management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. | | | | |
| An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE. | | | | |
| 2.2 Control of environmental exposure | | | | |
| Product characteristics | | | | |
| Product related conditions, e.g. the concentration of the substance in a preparation; package design affecting exposure. | | | | |
| Amounts used | | | | |
| Daily and annual amount per site (for point sources); annual amount for wide disperse use. | | | | |
| Frequency and duration of use | | | | |
| Intermittent (< 12 time per year) or continuous use/release. | | | | |
| Environment factors not influenced by risk management | | | | |
| Flow rate of receiving surface water. | | | | |
| Other given operational conditions affecting environmental exposure | | | | |
| Other operational conditions, e.g. indoor or outdoor use of products; process conditions related to temperature and pressure. | | | | |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| Process design aiming to prevent releases and hence exposure of the environment; this also includes conditions ensuring rigorous containment; specify effectiveness of containment (e.g. residual losses). | | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | | | | |
| Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions to minimise emissions; specify efficacy of measures; specify the size of industrial sewage treatment plant (m3/d), degradation efficacy and sludge treatment (if applicable). | | | | |
| Organizational measures to prevent/limit release from site | | | | |
| Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions. | | | | |
| Conditions and measures related to municipal sewage treatment plant | | | | |
| Size of municipal sewage system/treatment plant (m3/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable). | | | | |
| Conditions and measures related to external treatment of waste for disposal | | | | |
| Type of suitable treatment for waste generated by workers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste: specify efficacy of treatment. | | | | |
| Conditions and measures related to external recovery of waste | | | | |
| Specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery outside waste incinerators; specify efficacy of measure. | | | | |
| 3. Exposure estimation and reference to its source | | | | |
| Occupational exposure | | | | |
| The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective derived no-effect level (DNEL). For inhalation exposure, the RCR is based on the DNEL for metallic silver of 0.1 mg/m3. | | | | |
| Workplace | Method used for inhalation exposure assessment (refer to introduction) | Inhalation exposure estimate (RCR) | Method used for dermal exposure assessment | Dermal exposure estimate (RCR) |
| Raw material handling | analogous data | 0.06 mg/m3 (0.6) | Due to the negligible dermal absorption of metallic silver, the dermal route is not a relevant exposure path for metallic silver and a DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario. | |
| Processes in closed systems | MEASE | 0.022 mg/m3 (0.22) | | |
| Mechanical treatment | analogous data | 0.056 mg/m ³ (0.56) | | |
| Hot processes | analogous data | 0.016 mg/m3 (0.16) | | |
| Wet process | analogous data | 0.0883 mg/m3 (0.883) | | |
| Finishing | MEASE | 0.066 mg/m3 (0.66) | | |
| Production and handling of powders | analogous data | 0.06 mg/m3 (0.6) | | |
| Packaging of massive objects | MEASE | 0.05 mg/m3 (0.5) | | |

| |
|--|
| Environmental emissions |
| |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES |
| Occupational exposure |
| <p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The glossary of MEASE can be considered for the classification of the dustiness of a specific material.</p> <p>DNEL_{inhalation}: 0.1 mg/m³</p> |
| Environmental emissions |
| |

ES Ag No. 7: Professional uses of silver metal, silver alloys or silver containing articles

| Modified Exposure Scenario Format (3) addressing service life resulting from downstream use (article/preparation handled by worker) | | | | |
|---|---|-----------------------|--|--|
| 1. Title | | | | |
| Free short title | Use of massive (silver) objects (e.g. investment bars, decoration, tableware), silver alloys and silver plated/containing articles (e.g. photovoltaic cells) | | | |
| Systematic title based on use descriptor | SU22 (Professional uses) PC38 AC2, AC3, AC7 (appropriate PROCs and ERCs are given in Section 2 below) | | | |
| Processes, tasks and/or activities covered | Processes, tasks and/or activities covered are described in Section 2 below. | | | |
| Assessment Method | The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenarios addendum of the chemical safety report. | | | |
| 2. Operational conditions and risk management measures | | | | |
| Task | Involved tasks | Involved PROCs | Environment | ERCs |
| Handling of objects/articles at ambient temperature | handling | 21 | | |
| Soldering/brazing | soldering, brazing | 25 | | |
| 2.1 Control of workers exposure | | | | |
| Product (article) characteristic | | | | |
| According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions is assumed to be involved with a medium emission. | | | | |
| Task | Content in article/preparation | Release potential | Emission potential | |
| Handling of objects/articles at ambient temperature | not restricted | very low | very low | |
| Soldering/brazing | not restricted | low | low | |
| Amounts (contained in articles) present at workplace | | | | |
| The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential. | | | | |
| Frequency and duration of use/exposure | | | | |
| Task | Duration of exposure | | | |
| Handling of objects/articles at ambient temperature | 480 minutes (not restricted) | | | |
| Soldering/brazing | 480 minutes (not restricted) | | | |
| Human factors not influenced by risk management | | | | |
| The shift breathing volume during all process steps is assumed to be 10 m ³ /shift (8 hours). | | | | |
| Other given operational conditions affecting workers exposure | | | | |
| Task | Room volume | Outdoor or indoor use | Process temperature | Process pressure |
| Handling of objects/articles at ambient temperature | not restricted | not restricted | Not considered relevant for occupational exposure assessment of the conducted processes. | |
| Soldering/brazing | not restricted | not restricted | < 950°C | Not considered relevant for occupational exposure assessment of the conducted processes. |

| Technical conditions and measures at process level (source) to prevent release | | | | |
|--|--|--|--|---|
| Task | Level of containment | | Level of segregation | |
| Handling of objects/articles at ambient temperature | not required | | not required | |
| Soldering/brazing | not required | | not required | |
| Technical conditions and measures to control dispersion from source towards the worker | | | | |
| Task | Level of separation | Type of ventilation | Efficiency of ventilation (according to MEASE) | Further information |
| Handling of objects/articles at ambient temperature | not required | not required | na | - |
| Soldering/brazing | not required | not required | na | - |
| Organisational measures to prevent /limit releases, dispersion and exposure | | | | |
| Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air. | | | | |
| Conditions and measures related to personal protection, hygiene and health evaluation | | | | |
| Task | Specification of respiratory protective equipment (RPE) | RPE efficiency (assigned protection factor, APF) | Specification of gloves | Further personal protective equipment (PPE) |
| Handling of objects/articles at ambient temperature | not required | na | not required | - |
| Soldering/brazing | Where brazing is carried out in a confined space then a suitable fume filter face mask should be used providing there is no question of depletion of oxygen in the atmosphere. Under these circumstances a helmet fed with fresh air or self contained breathing apparatus is to be preferred (Heathcote, 1981). | APF>20 | | - |
| <p>Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.</p> <p>For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.</p> <p>The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p> | | | | |
| 2.2 Control of environmental exposure | | | | |
| Product characteristics | | | | |
| Product related conditions, e.g. the concentration of the substance in a preparation; package design affecting exposure | | | | |
| Amounts used | | | | |
| Daily and annual amount per site (for point sources); annual amount for wide disperse use | | | | |
| Frequency and duration of use | | | | |
| Intermittent (< 12 time per year) or continuous use/release | | | | |
| Environment factors not influenced by risk management | | | | |
| Flow rate of receiving surface water | | | | |

| | | | | |
|--|--|------------------------------------|---|--------------------------------|
| Other given operational conditions affecting environmental exposure | | | | |
| Other operational conditions, e.g. indoor or outdoor use of products; process conditions related to temperature and pressure | | | | |
| Technical conditions and measures at process level (source) to prevent release | | | | |
| Process design aiming to prevent releases and hence exposure of the environment; this also includes conditions ensuring rigorous containment; specify effectiveness of containment (e.g. residual losses) | | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | | | | |
| Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions to minimise emissions; specify efficacy of measures; specify the size of industrial sewage treatment plant (m ³ /d), degradation efficacy and sludge treatment (if applicable). | | | | |
| Organizational measures to prevent/limit release from site | | | | |
| Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions. | | | | |
| Conditions and measures related to municipal sewage treatment plant | | | | |
| Size of municipal sewage system/treatment plant (m ³ /d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable) | | | | |
| Conditions and measures related to external treatment of waste for disposal | | | | |
| Type of suitable treatment for waste generated by workers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste: specify efficacy of treatment | | | | |
| Conditions and measures related to external recovery of waste | | | | |
| Specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery outside waste incinerators; specify efficacy of measure; | | | | |
| 3. Exposure estimation and reference to its source | | | | |
| Occupational exposure | | | | |
| The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective derived no-effect level (DNEL). For inhalation exposure, the RCR is based on the DNEL for metallic silver of 0.1 mg/m ³ . | | | | |
| Task | Method used for inhalation exposure assessment (refer to introduction) | Inhalation exposure estimate (RCR) | Method used for dermal exposure assessment | Dermal exposure estimate (RCR) |
| Handling of objects/articles at ambient temperature | qualitative assessment (non abrasive handling of massive silver objects is assumed to result in negligible exposure) | (<<1) | Due to the negligible dermal absorption of metallic silver, the dermal route is not a relevant exposure path for metallic silver and a DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario. | |
| Soldering/brazing | MEASE | < 0.05 mg/m ³ (< 0.5) | | |
| Environmental emissions | | | | |
| | | | | |
| 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES | | | | |
| Occupational exposure | | | | |
| The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The glossary of MEASE can be considered for the classification of the dustiness of a specific material. | | | | |
| DNEL _{inhalation} : 0.1 mg/m ³ | | | | |
| Environmental emissions | | | | |
| | | | | |

ES Cu No. 02: Generic scenario for controlling environmental exposure

| Contributing exposure scenario (02) generic scenario for controlling environmental exposure | | | | | |
|--|------|--------------|--------------------------|-----|--|
| ERC 1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b | | | | | |
| Product characteristic | | | | | |
| Solid, liquid (powder solutions), concentration ranges >0% - <100% | | | | | |
| Amounts used | | | | | |
| 31,000 Tonnes/year (generic value). Higher tonnages can be covered through scaling (see section on DU compliance checking). In the VRAR, safe use could be demonstrated using site-specific assessments for tonnages up to 366,000 Tonnes/year (reference year 2002-2006) using site-specific emission factors, site-specific dilution factors, additional municipal sewage treatments and site-specific bio-availability corrections where relevant. | | | | | |
| Frequency and duration of use | | | | | |
| 365 days/year. Sites with smaller number of emission days can be covered through scaling. | | | | | |
| Environment factors not influenced by risk management | | | | | |
| Flow rate of receiving surface water is set at the worst-case level 18,000 m ³ /day (EUSES default). For the generic scenario, this results in a dilution factor of 10. For the marine scenarios, a default dilution factor of 100 was used. In the VRAR, dilution factors up to 1,000 are demonstrated. Sites with deviating flow can be covered through scaling | | | | | |
| Technical conditions and measures at process level (source) to prevent release | | | | | |
| | | | | | |
| Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil | | | | | |
| <p>Release to air: The median sector-specific release factor for producers of 4.52 g/tonnes for air was selected as a reasonable worst case for the whole industry (all sectors considered). The factor includes fume/dust collection and abatement system where relevant (such as hot processes). Options are electrostatic precipitators, fabric or bag filters, ceramic filters, wet scrubbers, dry- or semi-dry scrubbers. High dust removal/filtration efficiency between 95% and 99.9% is required for stack emissions. For raw material storage and handling: spraying with water is needed for small particles.</p> <p>Release to water: The median sector-specific release factor for producers of 0.89 g/tonnes for water was selected as a reasonable worst case for the whole industry (all sectors considered). It is assumed that there is on-site wastewater treatment and that the waste-water is not connected to municipal sewage treatment plant.</p> | | | | | |
| Organizational measures to prevent/limit release from site | | | | | |
| <ul style="list-style-type: none"> Regular inspection/maintenance of workplace to prevent fugitive releases. Housekeeping and hygiene procedures: work area, equipment and floors regularly cleaned, water spraying to suppressant dust formation Competence and training: activities should only be executed by specialists or authorized personnel, regular training and instruction of workers, procedures for process control to minimise release/exposure In case of dust formation, regular monitoring | | | | | |
| Conditions and measures related to municipal sewage treatment plant | | | | | |
| <p>In the scaling tool, the EUSES default settings were used but can be adapted to site-specific information.</p> <p>The presence of a municipal sewage treatment plant was not assumed but can be included if relevant. A copper removal rate of 80% can be considered for municipal sewage treatment plant if relevant. Justification for this value can be found in the VRAR of Copper (2008).</p> <p>The default scenario of use of municipal sludge on agricultural soil was used.</p> | | | | | |
| Conditions and measures related to external treatment of solid waste for disposal | | | | | |
| Solid wastes generated from industrial sites are disposed as "hazardous wastes". | | | | | |
| Conditions and measures related to external recovery of solid waste | | | | | |
| Copper is a valuable material and therefore, the generation of waste is minimized The use of copper scrap is key element of the industrial copper production/use process. | | | | | |
| Exposure Assessment - Environment | | | | | |
| Compartment | Unit | PEC regional | PEC local (incl. PECreg) | RCR | Justification |
| Environmental release factor to aquatic (after on-site STP) | g/g | NR | 0,89E-6 | NR | This is value is the maximum 50 th percentile observed in one sector with more than two company data points. The few sites with higher release factor to wastewater can be covered through scaling. |

| | | | | | |
|---|--|--------|---------|------|--|
| Environmental release factor to air (direct + STP) | g/g | NR | 4.52E-6 | NR | This is value is the maximum 50 th percentile observed in one sector. The few sites with higher release factor to wastewater can be covered through scaling. |
| Exposure concentration in sewage treatment plant (STP) effluent | mg/L | 0 | 0.0075 | 0.03 | Calculation based on EUSES in case municipal STP is present. |
| Exposure concentration in aquatic pelagic (freshwater) | mg/L | 0.0029 | 0.0055 | 0.7 | Calculation based on EUSES |
| Exposure concentration in aquatic pelagic (marine) | mg/L | 0.0011 | 0.0032 | 0.2 | Calculation based on EUSES |
| Exposure concentration in sediment (freshwater) | mg/kg dw | 67 | 145.21 | 0.9 | Calculation based on EUSES. For the RCR full binding of the regional Cu-PEC to Acid Volatile Sulphides (AVS) and thus, no-availability of the regional Cu-PEC is considered. Justification provided in the copper VRAR |
| Exposure concentration in sediment (marine) | mg/kg dw | 16.1 | 28.9 | 0.05 | Calculation based on EUSES |
| Exposure concentration in agricultural soil | mg/kg dw | 24.4 | 24.4 | 0.4 | Calculation based on EUSES |
| Oral exposure concentration predator | 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, 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 tropic 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. | | | | |
| Oral exposure concentration top predator | | | | | |
| Exposure concentration in earthworm | | | | | |

Note that the regional risk characterisation also demonstrates safe use (see Cu VRAR and follows automatically from local risk characterisation).

Guidance to DU to evaluate whether he works inside the boundaries set by the ES

If a DU has OC/RMMs outside the OC/RMM specifications in the ES, then the DU can evaluate whether he works inside the boundaries set by the ES through scaling.

Environment

The Metal EUSES calculator for DUs can be freely downloaded from the <http://www.eurocopper.org/copper/reach.html> or <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>.

In the registrant-interface, the generic default OCs and RMMs can be entered. Some of them are very relevant for metals, such as the possibility to provide measured regional concentrations and solid-water partition coefficients.

In the simple and easy-to-use DU-interface, key OC and RMM can be changed according to the site-specific OC and RMMs of the DU. This includes general parameters as release factors, dilution, presence/absence of municipal sewage treatment plant, etc... It also allows the DU to enter bioavailability-corrected PNECs (Predicted No Effect Concentrations).

In the background, the full EUSES model is run to calculate exposure and risks. The resulting risk characterisation ratios allow the DU to assess safe use. In this way, the DU scaling tool enables the DU to check compliance with the ES if his OCs or RMMs differ from those in the ES.

Additional good practice advice (for environment) beyond the REACH CSA

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH. Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

- Environmental Management System (ISO 14001, EMAS)
- Reduce the fugitive emissions where possible
- Release to water: Direct cooling water and effluents are treated to remove dissolved Cu. Options: chemical precipitation, sedimentation, filtration or electrolysis. Copper removal efficiency of the on-site treatment varies between 90% and 99.9%. Alternatively, waste-waters can be connected to municipal sewage treatment plants.

Exposure assessment - indirect exposure of humans via the environment

| External exposure through | Unit | Value | Justification |
|---------------------------|----------------|-------|--|
| Inhalation – Local | mg/person /day | 0.093 | Reasonable worst-case values taken from Cu VRAR (2008) basis: TGD default 24 hr inhalation volume (20m3) |

| | | | |
|------------------------|----------------|-------|--|
| | mg/person /day | 0.057 | Typical values taken from Cu VRAR (2008) basis: TGD default 24 hr inhalation volume (20m3) 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 VRAR (2008) regional dietary intake included |
| | mg/person /day | 1.44 | Typical values taken from Cu VRAR (2008) regional dietary intake included Value used in combined exposure and taken forward to risk characterisation. |