

## ***Introductory note and Summary of changes of the Copper REACH Registration Dossier by section of the Copper Chemical Safety Report***

### **Introductory note to the Chemical Safety Report**

The data retained for the classification and labelling of copper compounds and for the PNEC/DNEL derivation under the copper Voluntary Risk Assessment (VRA) form the back-bone for the classification and PNEC/DNEL derivations of copper and copper compounds under REACH.

The approach, data-selection, data treatment and choice of assessment factors are based on the copper VRA Report, discussed and agreed at the level of the competent Authorities for Biocides and Existing Substance Regulations.

### **Introductory note to copper Voluntary Risk Assessment**

In response to a request from the European Commission to “start preparing the initial assessments for substances on the EU working list as these were considered as Community priorities in the context of the industry voluntary initiatives for high production volume chemicals” the copper industry committed to undertake a Voluntary Risk Assessment (VRA) for copper and the copper compounds on the EU working list: Cu, CuO, Cu<sub>2</sub>O, CuSO<sub>4</sub> and Cu<sub>2</sub>Cl(OH)<sub>3</sub>. This initiative was endorsed by the EU CAs in 2001. A comprehensive VRA dossier was compiled in co-operation with expert consultants from the University of Birmingham/ICON for human health toxicity, from BR. Stern and Associates for human health deficiency, and from Euras/Ecolas for the environment. It is based on the principles of Regulation 793/93, 1488/94 and the detailed methodology laid down in the revised Technical Guidance Document on Risk Assessment for New and Existing Substances. Methodological experiences gained through other metal Risk Assessments, e.g. the incorporation of bioavailability for zinc, were incorporated as appropriate. Additional up to date scientific information was integrated into the assessment where scientifically relevant (i.e. the use of bioavailability models for water, sediment and soil, plus information on copper as an essential nutrient). A broad cross section of the European copper industry has been fully involved in the process and has submitted a significant amount of proprietary data.

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

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

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

Since the initial submission of the dossier in 2005, comments have been received from several Member States. The current 2008 version reflects comments made by the Member States in writing

and during the TCNES meetings. To ensure the transparency and quality of the dossier, the current version and the responses to Member States comments have been refined in close co-operation with the Review Country (Italy – Istituto Superiori di Sanità).

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

All reports and assessments related to the copper VRA are available from:  
<https://echa.europa.eu/copper-voluntary-risk-assessment-reports>.

## Summary of changes of the Copper REACH Registration Dossier

*[This note summarises the main changes included in the Copper Dossier since the first registration in 2010 up to the latest submission update in January 2018. The changes are described by section of the Copper Chemical Safety Report. This note is for information proposes only.]*

<b>Version 1</b>	2010	
<b>Version 2</b>	January 2013	Major update – see note below
<b>Version 3</b>	January 2017	Major update – see note below
<b>Version 3.1</b>	January 2018	Minor update – adjustment of ecotoxicity reference values in (section 7) and addition of new transformation-dissolution test data (section 4)

## Updates in Version 2 (January 2013)

### Identity and physico-chemical properties

The copper risk assessment evaluated potential risks from the production, use and disposal of copper massive, copper powders and several copper compounds. This CSR is applicable to copper in massive and powder forms, as well as to coated copper flakes, which were not assessed separately in the copper VRA report.

Coated copper flakes, representing < 0.1% of the copper market, are produced by a distinct process (see section 2.1) and are characterised by a high mass-specific surface area (mm<sup>2</sup>/gm). The normal handling and use of copper massives and powders do not produce such flakes. Their hazards are therefore considered separately.

Separate CSRs are also generated for copper compounds. The “effects” data and “regional exposure data” on copper and compounds, as developed in the copper risk assessment, have nevertheless been retained and used in this CSR in order to ensure transparency, consistency and to allow for read-across.

Additional work on physico-chemical characterization (purity, X-Ray Diffraction analysis, melting point....) of copper powders and flakes, as required under REACH, has been carried out and the results included in the CSR.

### **Environmental fate, hazard and risk assessment**

The CLP guidance provides refined guidance on how to deal with data richness. The data-base on aquatic hazards has therefore been re-assessed, whereby geometric mean values were only calculated if more than 4 data-points were available for the same endpoints.

CLP provides new guidance relevant to the chronic environmental classification. Therefore, additional fate studies, relevant to assessing "removal from the water-column" as equivalent to the "biodegradation of organic substances", have been performed and additional transformation/dissolution tests have been carried out and used for the chronic classification in the CSR Version 2.

- The copper risk assessment report identified some industry sectors with poor data-coverage, such as the cable drawing sector. Additional exposure data have been obtained for this sector and are included in the CSR.

- The copper VRA assessed exposure in the EU-15. A comparison of copper uses between EU-15 and EU 27, as well as additional exposure data from Eastern European producers, have been incorporated.

- In-line with REACH requirements, exposure scenarios have been developed and risk management measures documented.

- SCHER provided additional recommendations and the most important ones have been integrated into the CSR:

- \* Refinement of the marine PNEC with data from a marine mesocosm study.

- \* Refinement of the "reasonable worst case PNEC "for soils, including a more extensive assessment of the European soil chemistry.

- an additional discussion relevant to bioaccumulation and secondary poisoning was included section 7.5.3)- CSR – version 2

### **Human Health**

- Additional information on human health effects from coated copper flakes have been obtained and incorporated (CSR version 1 and version 2 (additional information on acute inhalation toxicity).

- As recommended in the VRA report, in vitro-bioaccessibility tests were carried out to allow for a more appropriate read across between copper compounds, copper flakes and copper powders.

- Additional exposure data from Eastern European producers have been incorporated.

- Exposure scenarios have been developed and risk management measures documented.

- The potential of direct, local effects from inhalation was considered as a weak point in the copper VRA. The results of a new 28 days inhalation study have been incorporated in the chemical safety report (version 2).

## Updates in version 3 (January 2017)

### Section 1: Identity of the substance and its physical-chemical properties

#### Changes:

Copper forms defined:

- Copper Massive: defined as copper having a specific surface area below 0.67 mm<sup>2</sup>/mg (value corresponds to a sphere with a diameter of 1 mm)
- Copper powder (specific surface area below 0.67 mm<sup>2</sup>/mg)
  - A note in the text explains that, for environmental classifications, one can distinguish between fine copper powders (copper powder A, specific surface area below 9.11 mm<sup>2</sup>/mg) and coarse copper powders (copper powder B, specific surface area 0.67—9.11 mm<sup>2</sup>/mg).
- Copper Flakes coated with aliphatic acid

### Section 2: Manufacture and Uses

Changes: The life cycle tree includes the following: *Manufacture, Formulation, Uses at industrial sites, Uses by professional workers, Uses by Consumer and Articles Service life*. The nomenclature uses the latest *use descriptors* of ECHA guidance R12, version 2015.

### Section 3: Classification and labelling

Changes: The newly defined copper forms are self-classified as:

- Copper massive: no classification
- Copper powder: Aquatic Acute 1, Aquatic Chronic 3 (M-factor 1)
  - A note in the text explains that, for environmental hazard classification, one can distinguish between copper powder A and copper powder B. Copper powder B does not have Acute 1 classification.
- Copper Flakes coated with aliphatic acid have the following harmonised classification:

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
029-019-01-X	copper flakes (coated with aliphatic acid)	—	—	Acute Tox. 3 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H319 H400 H410	GHS06 GHS09 Dgr	H331 H302 H319 H410		M = 10'

### Section 4: Environmental fate and pathways

This section contains data and argumentations that support the classification of copper for environmental hazards. The part on transformation-dissolution data has been revised and additional data are now included. The argumentation related to “rapid removal from the water column” has been strengthened.

### Section 5: Human Health Hazard Assessment

#### Changes:

Principles and rationale for a read-across approach have been outlined in the introductory part of the Section 5 Human Health Hazard Assessment (i.e. integrating and elaborating here the previously orphan part titled “Comparative bioavailability deleted and integrated”)

5.2.1.2 Acute toxicity: inhalation. RAC 2014 Opinions on coated copper flakes (i.e. retained Wesson 2001 study) and on copper (II) oxide (i.e. no hazard conclusion) have been included

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5.2.3 Summary and discussion of acute toxicity. Further Weight of evidence and read across information (i.e. Table on Predictions of the LD50 values for the various copper materials) have been added.

5.4.2 Eye. (5.4.2.1 Non-human information & 5.4.4 Summary and discussion on irritation). RAC 2014 Opinion on Coated Copper Flakes study Sanders, A (2001d) as criteria to classify coated copper flakes as Eye irritat. Category 2, and copper (II) oxide not classified.

5.13 Derivation of DNEL(s)/DMEL(s) (5.13.1 Overview of typical dose descriptors for all endpoints; 5.13.2. Selection of the DNEL(s) or other hazard conclusion for critical health effects). Acute oral and inhalation information (derived LD50 and LOAEC values) applicable to coated copper flakes were added/updated. Hazard conclusions for workers (i.e. inhalation systemic and local effects) applicable to coated copper flakes were updated in accordance to RAC 2014 opinion.

### Section 7: Environmental Hazard Assessment

Changes: Based on a literature update, including freshwater ecotoxicity tests with standardized test methods and species, updated Ecotoxicity Reference Values have been derived. The “conclusion on classification for environmental hazards” (section 7.6) has been updated to reflect all new information above (ERVs, rapid removal and transformation-dissolution data). The environmental classification is based on surface-dependent release and the concept of “critical surface area” for environmental classification is introduced. The distinction between copper powders A and B for environmental hazard classification is described and substantiated here in detail.

### Section 9: Exposure Assessment

Changes: Inclusion of a map of use description related to the Exposure Scenarios on the Life Cycle Tree described in section 2

Table on *Predicted and measured copper concentrations for the most relevant PROCs* has been updated to include the last data points

Update of the *long-term exposure parameters* of several identified exposure scenarios, particularly: External inhalation exposure, Internal dermal + inhalation systemic (occupational), Risk Characterisation Ratio (combined dermal and inhalation systemic) and Risk Characterisation Ratio (local inhalation).

## Updates in version 3.1 (January 2018)

**Section 4:** New transformation-dissolution study added

**Section 7.1:** New ecotoxicity study added

**Section 7.6:** Ecotoxicity Reference values (ERVs) adjusted as follows:

Acute ERV (in µg Cu/L)			Chronic ERV (in µg Cu/L)			NOTE: ERV if not split by pH band	
pH 6	pH 7	pH 8	pH 6	pH 7	pH 8	Acute	Chronic
12	14	40	13	12	13	28	13