

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

1. 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, Cu₂O, CuSO₄ and Cu₂Cl(OH)₃. 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>.

2. Introductory note to the Chemical Safety Report

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

Version 1	2010	
Version 2	January 2013	Major update – see note below
Version 3	January 2017	Major update – see note below
Version 3.1	January 2018	Minor update – adjustment of ecotoxicity reference values in (section 7) and addition of new transformation-dissolution test data (section 4)
Version 3.2	June 2019	Minor update – addition of new evidence on Rapid Removal, reference to RAC opinion on Granulated copper, assessing the impact of new ecotoxicity studies on PNEC, addition of a read-across assessment report for the human health hazard assessment.
Version 4	June 2020	Major update – see note below.
Version 5	June 2022	Major update – see note below

Updates in Version 2 (January 2013).

Identity and physico-chemistry

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

Environmental

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 (2009 and 2012) 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).

Human Health

- Additional information on human health effects from coated copper flakes have been obtained and incorporated (CSR version 1 and version 2).
- As recommended in the VRA report, in vitro- bioaccessability 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

Copper forms proposed:

Copper Massive: defined as copper having a specific surface area below 0.67 mm²/mg (value corresponds to a sphere with a diameter of 1 mm). Copper powder (specific surface area below 0.67 mm²/mg).

Section 2: Manufacture and Uses

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 4: Environmental fate and pathways

The part on transformation-dissolution data has been revised and additional data are included. The argumentation related to "rapid removal from the water column" has been strengthened.

Section 5: Human Health Hazard Assessment

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")

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

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 irrit. 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

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.

Section 9: Exposure Assessment

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 latest/ 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

Updates in version 3.2 (June 2019)

Section 4: Addition of new evidence on Rapid Removal,

Section 5: Principles and rationale for a read-across approach have been removed from the introductory section and documented in a separate read-across assessment report (in IUCLID)

Section 7: Consideration of RAC opinion on Granulated copper,

Section 7: Assessing the impact of newly identified freshwater ecotoxicity studies on freshwater PNEC.

Updates in version 4 (June 2020)

Entries on copper flakes have been removed from Sections 1 and 3, consistent with its status as a downstream use of copper under REACH and also its identification under CLP Annex VI.

For reasons of transparency on the hazard assessment and the harmonised classification of copper flakes under CLP, several records and references to copper flakes are included in the dossier (Sections 1.3, 5, 6 and 7).

The report „The environmental hazard classification of copper“ (attachment) was updated. New transformation-dissolution data for copper powder were included. This led to a revision of the classification of copper powder as Aquatic Chronic 2.

The report „Read-across approach for copper and copper compounds“ (attachment) was updated to include a section on read-across and counter-ion toxicity in the environment.

Updates in version 5 (June 2022)

Section 7: Environmental Hazard Assessment

The environmental hazard assessment has been updated for the aquatic freshwater compartment (sections 7.1 and 7.6). The following relevant assessment reports have been developed and attached (IUCLID), documenting this update:

1. The Chronic Copper Bioavailability Models for freshwater: This report covers the update of the chronic Cu bioavailability normalization procedure by incorporating the most recent ecotoxicity data and by optimization of the bioavailability models (i.e. gBAMs), while also up-dating the speciation calculations to the most state-of-the-art speciation software (WHAM VII).
2. Environmental Effects Assessment of Copper in the Freshwater Compartment: This report explains the update of chronic Cu toxicity database and chronic Cu bioavailability models by including the most recent science. A generic PNEC has been derived based on the same approach as agreed in the VRAR , i.e. as the most sensitive of 7 European freshwater scenarios (i.e. ecoregions). However, the PNEC derivation methodology has been updated to incorporate the most recent science. In situations where the minimum set of physico-chemistry parameters is not available, the generic PNEC of 6.3 µg dissolved Cu/L may be used.

Sections 9 and 10

In follow-up of the MISA programme¹ priority on exposure assessment, a series of dossier improvements and updates have been made: Via the Self-Assessment Tool (SAT) and a scoping exercise, the copper consortium critically evaluated the existing exposure scenarios in the copper REACH dossier. Several areas of improvement were identified: i) improved description of conditions of use (CoU) with avoiding “if-statements”, ii) exposure data should better reflect similar CoU, iii) Contributing exposure scenarios (ESs) with several process categories (PROCs) is not recommended and is to be simplified where possible, iv) exposure data should be recent (reflect up-to-date situation), v) improved link between CoU and exposure data is recommended and vi) better description of analytical contextual information is to be provided.

To address these improvements, a dedicated data collection was performed to map the data availability level in copper manufacturing and prioritised downstream uses for setting CoU. The current update includes updates to the worker data and scenarios for copper manufacturing and fabricator uses, implementing the

¹ <https://echa.europa.eu/-/echa-and-eurometaux-agree-on-framework-for-cooperation>

outcomes from the data collections and separating non-routine cleaning, maintenance and renovation activities.

Environmental risk assessment and scenarios have been updated with recently collected data, taking into account the revised freshwater PNEC value and including the development of additional (less generic) scenarios for downstream uses. These include service life scenarios with a dedicated road border scenario and incineration and landfill scenario.

Exposure and risk assessment data have been implemented in ECHA's chemical safety assessment and reporting tool, Chesar: The CSR section 9-10 has been generated as a separate report (CSR_Copper_v5_report_Ch 9-10) using Chesar (completing the transition from previous VRA summary reporting), with separate Annexes to cover the following additional information:

Annex 1: Human exposure via the environment

Annex 2: Comments on assessment approach for workers: Data collection sheet

Annex 3: Worker and combined worker and consumer risk characterisation