European Copper Institute
Copper Alliance

Summary of changes of 2017's update of the Copper Dossier by section of the Copper Chemical Safety Report

[The following list summarises the main changes and modifications included in the Copper Dossier submitted by the lead registrant on January 11th, 2017. The changes are described by section of the Copper Chemical Safety Report. This note is for information proposes only.]

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

Rationale*:* The environmental classification of copper depends partly on the specific surface area of individual forms. In 2010, three forms were identified, each meeting different classification criteria: copper massive, copper powder and copper flakes. Copper massive was defined as copper with a particle size above 1 mm; copper powder was particles below 1 mm.

Recently, *Granulated Copper (GC)* has been registered as an active substance under the Biocidal Product Regulation (BPR) and, as such, will automatically get a harmonised classification (CLH). Due to its specific surface area, granulated copper falls across two of the forms defined in CSR dossier (massive and powder).

ECI redefined various copper forms based on the specific surface area approach and, within the copper powders, to define two forms (Powder A, a finer powder and Powder B, a coarser powder) with different classifications for environmental hazards.

Copper powder A has the same classification for environmental hazards as copper powder has today (Acute 1 and Chronic 3). Copper powder B has a less stringent classification for environmental hazards (no Acute, Chronic 3).

Powders A and B are not included formally as separate forms in the IUCLID, to avoid inconsistencies (e.g. related to manufacture & use and exposure sections). Formally, there is only one "copper powder" with the same environmental hazard classification as today. This implies that powder producers can do business as usual if they wish. However, the two powders are described in words in the appropriate sections of the CSR (sections 1, 3, 4 and 7). This means that the producers of coarse powders may wish to use these sections and implement the classification of their coarse powder accordingly in their Safety data Sheets (SDS/e- SDS).

Changes:

Copper forms currently defined in the dossier

- Copper Massive: defined as copper having a specific surface (SSA) area equal or below 0.67 mm^2/mg (value corresponds to a sphere with a diameter of 1 mm)
- Copper powder (specific surface area above 0.67mm_2/mg)
    - A note in the text explains that, for environmental classifications, one can distinguish between fine copper powders (copper powder A, specific surface area above 9.11 mm2/mg) and coarse copper powders (copper powder B, specific surface area 0.67—9.11 mm2/mg).
- Copper Flakes coated with aliphatic acid

Section 2: Manufacture and Uses

Rationale: Section 2 of the CSR and Section 3.5 of IUCLID 6 need to contain the same information. Prior to 2017's update, the life cycle tree of copper described the manufacture and uses of copper, based on a former version of ECHA's R12 guidance, and required updating to be compatible with the requirements of IUCLID 6.

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

Rationale: For copper powder environmental hazards, a distinction is proposed between coarse and fine copper powders (see section 1).

Given that the active substance "*Copper flakes coated with aliphatic acid"* is used as a biocidal product, the European Commission has issued a harmonised classification within the 9th Adaptation to Technical and Scientific Progress (ATP) for implementation by March 2018.

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

- Copper massive: no classification
- Copper powder: Aquatic Chronic 3, Aquatic Acute 1 (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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment 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 the data obtained for granulated copper are now included. The argumentation related to "rapid removal from the water column" has been strengthened.

Section 5: Human Health Hazard Assessment

Rational: In follow up of the OECD 2015 decision on Copper and the RAC 2014 Opinion on Coated Copper flakes, ECI has updated the introductory section to reflect latest REACH Guidance on Read-across Assessment Framework (RAAF).

Changes:

Principles and rational 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

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 iritat. 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

Rationale: Responding to various regulatory pressures (e.g. December 2014 ruling by RAC), ECI has updated the copper Ecotoxicity Reference Values (ERVs) based on the latest scientific literature. Via read across, these form the basis of the environmental hazard assessment of all copper-containing materials.

Acute ERVs for copper (in µg Cu/L)		
pH 6	**pH 7**	**pH 8**
12.1 (25)	14.0 (35)	40.0 (29.8)
Chronic ERVs for copper (in µg Cu/L)		
pH 6	**pH 7**	**pH 8**
11.4 (20)	6.3 (7.4)	12.6 (11.4)

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

Rationale: ECHA's latest recommendations, to promote data exchanges among the value chain and downstream users, suggested the development of a map of use descriptors.

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

Rationale: The long-term exposure scenarios are based on 2008 data collected by ECI for the Copper Voluntary Risk Assessment (VRAR). Several, more recent data collection campaigns have provided new data on human work place and environmental exposure. These are:

- Updated exposure data, consistent with information in the intermediates dossiers (2012-2014)
- Additional information on "powder production", reflecting the closure of one production site
- Additional information on "melting, casting and production of wire rod", obtained from an occupational exposure monitoring campaign at German sites

Changes:

- Table on *Predicted and measured copper concentrations for the most relevant PROCs* has been updated to include the lasts 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).