MeClas

A tiered calculation tool

for hazard classification of copper concentrates

and other complex inorganic materials

Prepared by

Stijn Baken and Alvin Chao, International Copper Association

Frederik Verdonck, ARCHE Consulting / MeClas coordinator

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Description of MeClas

MeClas is a tool to assist users in classifying complex inorganic materials, such as ores and concentrates, complex intermediates, alloys or UVCBs[1] for health and environmental hazards, recognizing the specific properties and assessment techniques for inorganic materials. Physical hazards are not in scope of MeClas.

Regulatory compliance is the core of MeClas. It fully complies with several key classification systems and legal instruments, including:

- United Nations Globally Harmonized System (UN GHS), 10th revised edition
- European Union Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (EU CLP regulation), including its latest Adaptations to Technical Progress
- Marine pollutants as defined by the International Convention for the Prevention of Pollution from Ships (MARPOL), which refers to UN GHS fourth revised edition

[1] UVCBs: substances of Unknown or Variable composition, Complex reaction products or Biological materials.

- Materials hazardous only in bulk - toxic solid (MHB-TX) as defined in the International Maritime Solid Bulk Cargo (IMSBC) Code, including amendments 07-23, which refers to UN GHS ninth revised edition.

Depending on the local regulation, copper concentrates and other complex inorganic materials can be considered as substances or as mixtures. Generally, UN GHS and EU CLP mandate that available hazard data on the complex inorganic material itself, or on a similar material, should primarily be used to determine classification. If such data is lacking, which is usually the case for copper concentrates, **the classification systems mandate that the hazard assessment be based on the hazard data of the individual ingredients (in case of mixtures) or constituents (in case of substances) to classify the material for the relevant hazard, using the so-called "mixture rules"**. Depending on the hazard class, these mixtures rules are based on additivity calculation rules, summation rules, generic cut-offs, concentration limits, or M-factors. Therefore, the calculations by MeClas comply with legal requirements regardless of whether a material is considered a substance or a mixture. The backbone of MeClas consists of the following information:

- The aforementioned mixture rules
- Classification information for individual substances, based on mandatory lists (e.g. CLP Annex VI) and on industry self-classifications, which is kept up-to-date
- Corresponding concentration limits, Toxicity or Ecotoxicity Reference Values, information on rapid degradability, M-factors, etc…

MeClas is widely used by the EU and global metal mining industry, by metal federations, and by metal producers (Figure 1). MeClas has furthermore been acknowledged in regulatory discussions between Eurometaux and the European Chemicals Agency, e.g. in discussions on inorganic UVCB substances (Oct 2020), in a workshop on inorganic UVCB substances as part of the MISA program (Nov 2019), in discussions on UVCB classification (Oct 2013), and in discussions on UVCB chemical safety assessment and reporting (May 2012).

MeClas includes certain approaches which are in line with legal provisions and with the state of the science, but which have not (yet) received formal acceptance in certain jurisdictions. This is the case for bioaccessibility corrections and for rapid environmental transformation assessments. Where applicable, the MeClas output provides a clear note on this.

MeClas is freely available to users, with a restriction on the number of compositions a user can create. Companies and associations can become MeClas sponsors for a modest fee. This entitles you to free support, an unlimited number of compositions, and a seat on the MeClas Steering Committee, which decides on new implementations for the upcoming year. Companies may wish to learn to use MeClas themselves, or they can ask a contractor to work with MeClas on their behalf. Resources available on the MeClas website www.meclas.eu include a manual, a short video and a more extensive video. MeClas has been published in the scientific literature too. More info can be obtained by sending an inquiry to info@meclas.eu.

MeClas applied to copper concentrates

Users of MeClas will need to provide information on the identity and composition of the material they wish to assess. MeClas then applies a tiered approach to classify the material for health and environmental hazards (Figure 2). If only limited information is provided, then the classification is calculated based on worst-case assumptions: the elements are assumed to occur in their most soluble and bioavailable form ("tier 0"). As a result, the material may be classified quite conservatively for many endpoints. Additional information on the constituents (minerals) and on bioavailability and bioaccessibility can help to derive a more accurate classification through higher-tier assessments ("tier 1" or "tier 2").

For copper concentrates, tier 2 assessments are recommended by ICA, because the assessments consider data estimating how much metal is bioavailable rather than how much is present in total in the concentrate. This results in a more correct and generally less severe classification. The information necessary for a tier 2 assessment is shown in Table 1 for a hypothetical copper concentrate. ICA has issued specific guidance on how this information can be sourced and integrated into a classification assessment for copper concentrates [2]. For environmental endpoints, the ICA guidance describes how the hazard classification of copper concentrates can be calculated based on the content of the copper bearing minerals (e.g. chalcopyrite, bornite, chalcocite). For systemic human health endpoints, the ICA guidance proposes worst-case estimates of bioaccessibility based on a set of reference concentrates. The ICA guidance therefore avoids the need to gather bioavailability and bioaccessibility data by testing each individual concentrate with variable composition. Using a Tier 2 assessment, it can be shown that around 85% of copper concentrates globally are not classified as Harmful to the Marine Environment (HME) under the MARPOL Convention.

As an alternative to the approach described in the ICA guidance, it is also possible to measure the bioavailability and bioaccessibility of relevant elements in the copper concentrate. For environmental endpoints, this can be done through an OECD 29 Transformation/Dissolution test. This test has been accepted for environmental endpoints under GHS and CLP since their inception. It can equally be used to classify other complex materials from the copper industry. For systemic human health endpoints, measuring the bioaccessibility can be done using a gastric bioelution test.

[2] ICA guidance on hazard classification of copper concentrates: https://copperalliance.org/resource/transport-regulations-by-the-international-maritime-organization-marpol-annex-v-and-imsbc-code/

Figure 1: MeClas sponsors

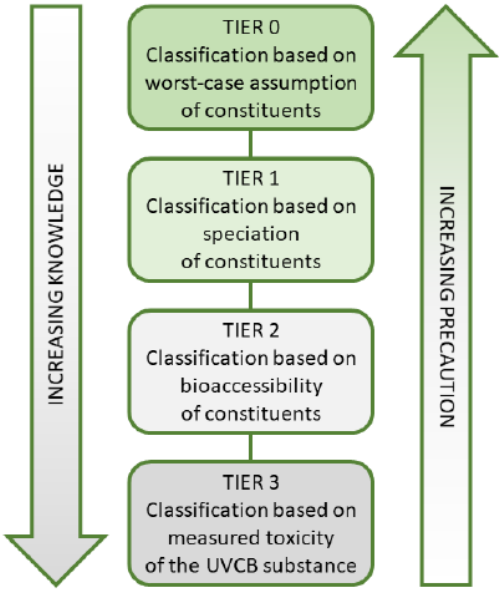

Figure 2: The "tiered approach" behind MeClas

Table 1: Information necessary for a tier 2 assessment of a hypothetical copper concentrate

Elemental composition	**Speciation and mineralogy**	**Bioaccessibility and bioavailability**
As 0.08% Cd 0.004% Cr 0.004% Cu 27% Ni 0.003% Pb 0.25% Zn 0.9%	Copper minerals: 72% chalcopyrite 3% bornite Trace constituents are present as sulfide minerals: galena, sphalerite, pentlandite…	Environmental bioavailability after 7 days: Cu 1.1%, As 5%, Cd 9.8%, Co 12%… Environmental bioavailability after 28 days: Cu 1.4%, As 14%, Cd 10%, Co 30%… Bioaccessibility in gastric media: As 1.8%; Cd 14%; Co 4%,… This information was estimated based on the ICA guidance. As an alternative, it could be measured through testing