Eurometaux
European Association of Metals

Eurometaux comments on the conceptual aspects of the proposal for an Environmental harmonized hazard classification of Copper, Granulated.

17 May, 2017

The Granulated Copper classification proposal raises some relevant and important conceptual and methodological aspects related to the environmental classification of metals and data rich substances. We noted from previous cases that specificities related to the environmental classification of metals and/or to data-richness, have raised some concerns in RAC due to the specificity/complexity of the ruling as outlined in the metals CLP text and guidance.

It is in this respect that Eurometaux provides herewith some supportive comments and suggestions from a conceptual perspective, while directly relevant to the Granulated Copper case.

We have been informed on the Copper sector's specific comments as well as on the additional data and information provided by the Copper sector. We noted that those are in agreement with the conceptual/methodological comments raised here below. Therefore, the remarks made by Eurometaux are supporting the comments from the copper sector.

We would like to state from the start that the environmental section of the data rich Granulated Copper file as prepared by France is well conducted and of high quality. Several of our remarks are therefore supportive in nature, in particular:

- The recognition for the additional ecotoxicity (fish at low pH) data conducted and submitted by the Copper sector in follow-up of the outstanding question of the RAC opinion forming on Copper Flakes
- The way how Transformation-dissolution data (OECD 29) was applied (surface based)
- The way how the ecotoxicity data sets were selected for this data rich file (use of standard species,…)

In the comments hereunder we focused on the conceptual relevance and outstanding issues and made some further suggestions for the Dossier Submitter's consideration.

Recognition of the RAC recommendation to complete a data gap for low pH

In its opinion on Copper flakes, RAC concluded to a data gap on long-term data for the fish species P. promelas at the low pH end. Eurometaux notes that industry completed the data gap and even added an additional standard species. All this new evidence was fully recognised in the environmental classification proposal (pages 147, 154). We appreciate this and would like to know how this would now impact the previously assessed Copper-flakes dossier. Indeed, the results of these 2 new fish tests indicate that there is "no significant relationship between pH and long-term copper toxicity at the

lower pH end". This means that the Copper ion toxicity at low pH was not as low as "assumed" in the classification opinion on Copper flakes. This should in our opinion be corrected.

The appropriate use of Transformation dissolution data to derive the environmental classification

The release/surface is an intrinsic property of a metal or a sparingly soluble metal compound, a recognised property in Environmental hazard assessment Eurometaux notes the use of 7 and 28 days Transformation-Dissolution data with granulated copper as the test substance. The transformation dissolution release rate and levels were compared with the respective acute and chronic ERVs on a comparable pH basis to derive the classification level (p 191). This approach is correctly applied in a substance specific way. It is probably important to reconfirm that the results are applicable to the substance tested, i.e. to the granulated Copper only.

Rapid Removal from the water column for Chronic Environmental hazard ID for metal-ions

The CLP legal text refers -for the environmental long term classification- to the potential to demonstrate degradability and for metals more specifically "rapid removal from the water column". We noted that the proposal for Granulated Copper does not include an assessment of the rapid removal from the water column referring to "the lack of guidance" (p 140). Extensive evidence for Cu ion (as well as for many other metal ions) is available (from the Registration dossiers on Cu) and was also transferred in an integrated package to ECHA in 2012 in follow-up of a workshop aiming at defining potential guidance (held in February 2011). The lack of guidance can in our view not be used as a valid argument to further reject this principle for the metals given the legal text foresees the principle being applicable to metals. We noted that the copper sector has not provided further evidence in their submission. In such case we would like to request RAC to conclude that "*the evidence for such demonstration was not part of the submitted data set*", i.e. not being the consequence of missing guidance. Moreover, we feel that postponing the development of such guidance puts the metals sector in a non-level playing field situation with the organic sector and other jurisdictions.

Data selection for data rich substances

The ecotoxicity data base refers to high-quality data for the copper ion obtained from soluble salt experiments. Copper is widely studied resulting in hundreds of data points on acute and long term (chronic) endpoints, for many standard, non-standard, generic and endemic species. We noted that like for previous metal environmental classification assessments, the rapporteur focussed on standard species to ensure a level playing field for the hazard assessment.

Alternatively, the CLP guidance allows for very large data sets to apply statistical techniques based on grouping and/or Species Sensitivity Distribution and other.

Data grouping and statistics for data rich substances

For large data sets covering multiple experiments for the same biological species for the same endpoint, it is assumed they cover a "range of conditions". The GHS and CLP guidance therefore foresee that for "*larger data sets (four or more values) for the same species, the geometric mean of*

toxicity values may be used as the representative toxicity value for that species." (CLP Guidance, v. 4.1, p. 500-501).

This approach was applied by the submitting country but on a pH band basis, thereby further splitting the data set before applying this data grouping rule. Neither the CLP nor the GHS makes reference to such an additional criterion to split data sets, neither was this done in the past for other data rich metals. The CLP reference referring to "a case-by-case check on the relevance of grouping" was intended to ensure that data sets covered some variability of conditions (not all done in the same laboratory with the same genetic strain, for example).

EUROMETAUX is therefore of the opinion that this additional splitting of the data set before applying the grouping by using the geometric mean, is difficult to justify extension of the GHS and CLP requirements. Moreover, not applying geometric means for extensive data sets would –purely for statistical reasons- result in lower ERVs when the data base becomes larger, which is contrary to the reduced uncertainty.

Assessment methods that make full use of the entire selected data set should be promoted. For metals this includes normalisation techniques (with BLMs) that allows for assessing the impact of relevant factors on toxicity data sets. This prevents using only parts of the data set to assess the impact of pH.

Thank you for considering these comments

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