

Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

Dicopper chloride trihydroxide

EC number: 215-572-9
CAS number: 1332-65-6

CLH-O-0000001412-86-43/F

Adopted
04 December 2014

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON DICOPPER CHLORIDE TRIHYDROXIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All attachments including confidential documents received during the public consultation have been provided in full to the dossier submitter, to RAC members and to the Commission (after adoption of the RAC opinion). Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website.

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Substance name: Dicopper chloride trihydroxide

CAS number: 1332-65-6

EC number: 215-572-9

Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2014	Spain		MemberState	1
Comment received				
The Spanish CA supports the proposal of the French CA for harmonized classification and labelling of copper oxychloride.				
Dossier Submitter's Response				
Ok thank you				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	Germany		MemberState	2
Comment received				
The DE CA supports the FR CA's proposal for changing the classification to Eye Dam 1 – H318 and deletion of Skin Irrit 2 – H315. The DE CA has general problems with some methodologies referring to the environmental classification used in the CLH-proposal. The DE CA supports the proposed acute classification as H400 with M-factor of 10 but suggests using lowest acute data from the DAR. In addition, the DE CA suggests considering classification as Aquatic Chronic 1, H410 with M-factor of 10.				
Dossier Submitter's Response				
Human health hazard: The DE CA comment is confusing. Indeed, based on eye and skin irritation studies available with copper oxychloride, FR CA has proposed in the CLH report, no classification for eye and for skin irritation for this copper form.				
Environmental health : see response to detailed comment below.				
RAC's response				
This comment most likely refers to another copper compound. Response to environmental comments: see below.				

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Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	United Kingdom	Regulatory Compliance Limited	Industry or trade association	3
Comment received				
<p>We acknowledge and appreciate the alignment with the copper risk assessment dossier as well as the incorporation of some post risk assessment data.</p> <p>For most endpoints, the data used and interpretation of the data reflect the hazard profiles agreed in the copper risk assessment report (RAR) and used for the REACH dossiers.</p> <p>For the environmental endpoints, we noted some differences between the copper oxychloride CLH report and the REACH dossier. We have therefore focused the response on these endpoints and in addition propose to revise the human health classification to:</p> <p>Acute Tox. 4 - H302: Harmful if swallowed</p> <p>See non-confidential attachment.</p> <p><i>[ECHA note: Please see attachment no. 3,4,5]</i></p> <p>For the final decision, we would appreciate if the following CAS numbers are included in the decision for this substance - 1332-65-6 and 1332-40-7</p>				
Dossier Submitter's Response				
<p>Human health hazard: the classification for acute toxicity must be based on the lowest acute toxicity estimate value in the most sensitive appropriate species tested. In the case of the acute oral toxicity end-point, the mouse was considered the most sensitive species with an acute oral LD50 sexes combined of 299 mg/kg bw. This value lies within the range (50-300 mg/kg) for classification as Acute Tox. 3 (H301).</p> <p>Environmental hazard: see response to detailed comment below.</p>				
RAC's response				
<p>Human health hazard: See RAC's response to comment no. 5.</p> <p>Environmental hazard: See response to comment no. 11 below.</p>				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2014	Spain		MemberState	4
Comment received				
<p>The Spanish CA regards the available genotoxicity data insufficient to evaluate the genotoxic potential of copper compounds. Therefore, it is not possible to reach a final conclusion on this hazard for copper oxychloride.</p>				
Dossier Submitter's Response				
<p>Human health hazard: As concluded in the CLH report, data indicates that copper compounds do not meet the criteria for classification as a genotoxic however there was insufficient evidence to exclude a local genotoxic potential of copper as some studies by IP route were positive (but with a low reliability). Moreover, during the EFSA peer review of copper substances, the experts have discussed in detail the results of the genotoxicity studies, their relevance in the case of inhalation exposure as concerns operators and bystanders, and the inconclusive epidemiological data on lung tumours. The expert meeting</p>				

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conclusion was that Genotoxicity is not of concern upon oral administration, but there is insufficient evidence to exclude genotoxic potential of copper after non-oral administration and raised a critical area of concern on the genotoxic potential of copper (I) and (II) variants by inhalation (EFSA 2008).

RAC's response

Noted. RAC agrees that in the absence of sufficient data on dicopper chloride trihydroxide no proposal for classification for mutagenicity can be made for this substance.

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	United Kingdom	Regulatory Compliance Limited	Industry or trade association	5

Comment received

We note that the acute oral toxicity classification has been based on a mouse study. However, the results for the acute oral toxicity test in rats will more accurately predict the effects in humans, and it is strongly recommended to utilise this information for the classification of copper oxychloride. Furthermore in accordance with the CLP Guidance document, acute studies conducted on the rat are preferred to studies conducted on other species.

We therefore propose that the classification assigned to dicopper chloride trihydroxide on the basis of acute oral toxicity is Acute Tox. 4 - H302: Harmful if swallowed.

See non-confidential attachment.

ECHA'note: Please see attachment no. 3,4 and 5.

Dossier Submitter's Response

Human health hazard: the classification for acute toxicity must be based on the lowest acute toxicity estimate value in the most sensitive appropriate species tested. In the case of the acute oral toxicity end-point, the mouse was considered the most sensitive species with an acute oral LD50 sexes combined of 299 mg/kg bw. This value lies within the range (50-300 mg/kg) for classification as Acute Tox. 3 (H301)

RAC's response

RAC considers that no clear evidence is presented in the comments that mouse data would not be relevant to humans. RAC therefore supports the dossier submitter proposal to base the classification for acute oral toxicity for dicopper chloride trihydroxide on the mouse data, resulting in Acute Tox. 3 – H301.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	United Kingdom		MemberState	6

Comment received

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It is important to note that our comments reflect the general classification approach used for the range of copper compounds and are not specific to individual substances.

Many of the copper compound CLH Reports refer extensively to biocide CARs or pesticide DARs. Whilst we appreciate the time since the reports were initially prepared, we note that a more recent EFSA opinion and agreed endpoints for pesticidal uses of copper (dated 2013) than the one referred to (2008) is available. The authors may wish to consider the final agreed key endpoints and data gaps identified by EFSA (along with more recent biocide reviews) to see if there are any significant changes or new data.

For all the copper compounds, it would help to be clear throughout the reports whether they are referring to the whole technical substance in question, the pure substance, total copper, or dissociated ionic copper (Cu^{2+}). This is important when it comes to how the exposure and (eco)toxicity units are presented. Wherever units are quoted (e.g. $\mu\text{g/L}$), it should say in what form that copper is expressed.

It is useful to have noted that nano-forms of Cu exist - and we agree with the suggestion that these are considered separately pending further information on representivity/read-across of the existing bulk Cu data. This would be a useful principle to note for all future substances where nano-forms also exist and we feel this distinction should also appear in the final

Environmental fate assessment

Much of the env.fate section attempts to equate removal of dissolved ionic copper from the water phase with the rapid degradation criterion for organic substances of >70% degradation in 28 days. It is noted in the reports that transformation of one metal 'species' to another does not equate with degradation of an organic substance and that (bio)availability of the different forms of copper is a key consideration. The current ECHA CLP Guidance for metals (Annex IV) focuses mainly on exposure to metals and metal compounds dissolved in the water phase and on transformation processes that occur only within the water column. The focus in the guidance is on determining 'rapid environmental transformation'. However, it does suggest that it may be possible to incorporate other processes such as water-column residence times, deposition and subsequent re-mobilisation. Whilst the copper CLH reports clearly attempt to do this, there is currently no standard means of incorporating removal, e.g. to dissolved organic carbon (DOC) or sediment, within the hazard classification system for organic or inorganic substances.

The approach used in the reports to indicate rapid environmental transformation or removal relies on a number of assumptions which are not well supported; for example:

- It assumes that there is sediment present to act as a 'sink' for copper, which may not always be the case.
- It is not always clear what form the initial loading comprised in each case - was it already as dissolved Cu^{2+} and if so, can the model (and fate studies) account for different loading rates and the different forms of copper discussed here (which presumably initially dissociate at different rates)?
- The main scenario discussed is a generalized 3 m deep lake situation. Lakes are usually large, static, permanent and have sediment of some description, however this may not reflect many other EU surface water bodies such as ponds, rivers and streams - where increased water movement, turbidity, less sediment, different depths, etc.. could affect the amount of copper remaining in solution or suspension. We therefore wonder whether a 'realistic worst case' situation has indeed been modelled?
- With various adjustments, e.g. to settling velocity, suspended solids, the TICKET-UWM

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model appears able to reflect the fate of copper in some (not all) of the available field/semi-field tests. However, it is not then used to extrapolate to other water body types with very different characteristics. We think this should be the main point of the modelling, to add value to the existing field data set, rather than to simply interpret it.

- Where there was continuous 'post-loading' in the MELIMEX experiment, this was more difficult to model and indicated that the rapid removal benchmark was not met. In the 'real-world' there may be continuous or repeated exposures, particularly of larger water bodies, from multiple sources. The chronic criteria (+ M-factor) are meant to address hazards over a longer time period than just a few days - so, for hazard classification purposes we would expect rapid transformation/removal to be able to cover the majority of situations, not just one-off exposures.

- The reports considers that most copper reaches the sediment, where much of this is then locked up in different forms (especially with sulphides) and is no longer available. This relies upon the assumption that most sediment, if present, is anaerobic and this process is fairly instantaneous. In reality, the top layers of sediment might well be aerobic - and the transit and mixing time with more anaerobic layers will vary according to the water body and sediment type, as well as temporally and spatially. Is this variability covered? Are the levels of sulphide assumed in the model (based on the Flanders data set) representative of other EU water bodies? Also, what happens if the sediment is already contaminated with metals, is there always enough 'spare' AVS left or will there be cases where it is already saturated so not available for new metal?

Because of these difficulties in describing and modelling all (or even one) relevant/realistic 'worst case' scenario for removal to sediment or to DOC/POC - such mitigating factors are rarely used to refine the hazard classification for organic substances. Most tests for organic substances in fact try to minimise such removal mechanisms to make them as bioavailable as possible, therefore taking account of this for metals would be inconsistent with usual practice. Ready biodegradability tests are difficult to pass, so metal transformation/removal should also face a similarly stringent test. Because of this, we cannot currently support the claim of rapid removal of copper based on the evidence in the dossiers.

On bioaccumulation; we agree this is probably not an issue, provided internal homeostatic excretion, transformation and detoxification mechanisms can always regulate levels within organisms under realistic worst case exposure conditions. Could the bioaccumulation potential of copper be related to the standard CLP triggers in a similar way as attempted for rapid degradation?

Ecotoxicity assessment

It isn't always clear why some ecotoxicological endpoints (e.g. from the DAR) are quoted for some forms of copper but not others. They're not just the worst case values and its not always clear between the various reports why they've been selected and how they're treated. Whilst there may be limitations to what was measured and reported in the studies and DAR, some endpoints appear as both total and dissolved Cu, as nominal or measured. Could these all be adjusted and expressed in the same consistent way? The form in which data from the EU Voluntary Risk Assessment Report (VRAR) are expressed is also unclear in the tables (dissolved copper?).

The separation of the VRAR endpoints into the different pH ranges is potentially useful, although there is no explanation why the particular bands have been chosen and only the lowest values are selected anyway, which makes it unclear why the separation was performed in the first place. There is also no discussion of the impact of other water quality parameters (e.g. hardness) on toxicity. Ultimately, at least for some of the substances, the

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DAR endpoints are preferred anyway - so it is not always clear what role the VRAR data have. As mentioned, these data have never been considered by a 'technical group competent for classification' and there is uncertainty over transformation/dissolution of some of the substances. It might therefore be useful to present more information on data from the VRAR in an Appendix - if their basis and validity were described in more detail, then greater reliance and use might be made of them. All of the DAR and VRAR endpoints might then be considered together instead of separately?

The use of geometric means may be accepted if they cover the same effect end points for the same species, tested under similar enough conditions (the dossiers do not provide any rationale for the derivation of geometric means for individual species). The CLP guidance also indicates that at least four endpoints are preferred for each geomean. This may be important for key values such as the short-term Pimephales promelas data at pH 5.5-6.5, where only two studies are available. In this case, might it be better to select the lowest value of 0.0044 mg/L for this pH range? Ideally 'sensitive' species in acute tests should also be reflected in the chronic data set. As there is no long-term test for P. promelas at this pH range, might this require use of the surrogate approach and affect the acute and chronic reference values that have been selected? For long-term toxicity to fish, it also appears that an Oncorhynchus mykiss ELS NOEC of 0.0017 mg dissolved Cu/L (from DAR data) is missing from the study on 'Copper Hydroxide WP' - this would be equivalent to (and lower than) the dissolved Cu values apparently from the VRAR.

Given the amount of ecotoxicological data on copper, could more use be made of species sensitivity distributions (SSD) and HC5 values (if presented separately for each trophic group and for short and long-term). It appears that there are more ecotox data on copper than those given here, particularly for invertebrates where only Daphnia/Ceriodaphnia are presented in the reports. Data on various other invertebrates are reported in the VRAR but its not clear why these are omitted.

Additional SSDs are presented in the VRAR, are any of these appropriate? Discussion with colleagues working on the Water Framework Directive highlight that they have derived Environmental Quality Standards (EQS) for copper using the whole available data set, including data in the VRAR. These EQS were, in part, determined using SSDs and Biotic Ligand Model (BLM) calculations and a fairly high degree of confidence was expressed in their derivation. Since there are analogies with at least the chronic classification endpoint for copper, we wonder whether use could also be made of this EQS work? The use of SSDs and HC5s for copper would set new precedents for hazard classification however, so it might be questioned whether we should always default to the lowest value when we have such a data-rich substances.

One HC5 is mentioned in the CLH Reports for sediment dwellers. Given the suggested removal to and persistence in sediment, there is relatively little discussion of the exposure and hazard to sediment dwellers - even though it is said that uncertainty here is high. The SSD behind this HC5 is not presented and there is also little information on the chironomid study from the tribasic copper sulphate DAR (included under algal endpoints at 5.5). Presumably this is based on a water spiking study whereas the VRAR HC5 (in mg/kg) is from sediment spiked studies? With further information from the studies, might it be possible to recalculate the endpoints according to sediment pore water concentrations? How the aquatic hazard classification should be determined in the presence of sediment is still unclear however.

Further reference to the studies reported in the copper DARs for algae may allow presentation of their NOEC values for inclusion in the long-term hazard assessment.

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The final 2013 EFSA Conclusion on pesticidal use of copper compounds reports a microcosm 'NOEC' of 0.0048 mg dissolved Cu/L (rather than 0.00312 mg/L at 5.4.4 and 5.5), although it is unclear how this would be used for hazard classification.

In the table at Section 5.5 a 21-day endpoint for *O. mykiss* is reported, but it is not clear how relevant this is for comparison with the classification criteria.

Ideally it would help to have briefly explained the Ecotoxicity Reference Value (ERV) concept, as it is not initially clear why endpoints expressed as either the substance in question, or total Cu, or ionic Cu²⁺ (whichever is considered the most appropriate form) cannot be used at face value. We haven't checked all of the ERV calculations, however, whilst the chronic ERVs from the VRAR can be back-calculated to identifiable endpoints, we could not find the endpoint used to derive the acute VRAR ERV at pH 5.5-6.5 of 0.045 mg/L. Overall, the selection of appropriate short and long-term endpoints for each trophic group and the workings for these ERV calculations, could be presented more clearly for each substance.

Overall, and depending on the response to our comments, we do not currently agree that the substances can be considered rapidly removed, therefore we feel that all of the substances should be classified H400/410 with relevant M factors.

Dossier Submitter's Response

In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).

For bioaccumulation, the question would need further clarification before answering.

All endpoints are expressed in all available forms in the tables for better transparency. For the VRA, as mentioned in the introduction of section 5.4, all endpoints are expressed in dissolved copper.

Concerning VRAR endpoints, a link to the appendix related to classification could be added in the document. For the question on whether or not data from the DAR and VRAR should be considered together, we considered that they shouldn't as data from the VRAR are not specific for Dicopper oxide; copper (I) oxide, when data from the DAR are.

Considering the use of geo mean values, we agree, however in this case there is no impact on classification.

For long term data on fish issued from the DAR, data on specific salts were related to each compound.

Concerning SSD, it is our knowledge that HC5 are not used for classification purposes. Concerning the remark on microcosm study, it is our understanding that these values are neither used for classification purposes.

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In the table at Section 5.5 a 21-day endpoint for *O. mykiss* is reported for information.

For ERV calculations, all endpoints used were expressed in dissolved copper before transformation.

RAC's response

We note that the DS did not respond to the suggestion to check the most recent EFSA opinion for pesticidal uses of copper (dated 2013), which includes microcosm data (a NOEC of 0.0048 mg dissolved Cu/L). Given the amount of data already available, we do not think that significant changes are likely.

In terms of how the test results were reported (i.e. technical substance, pure substance, total copper or dissociated ionic copper), we note the comments of the DS so have assumed that the results are expressed in terms of dissolved copper ions unless otherwise indicated.

We agree with the comments made about the rapid removal concept, and note that the DS does too. This affects the chronic classification. The comment about bioaccumulation potential was not addressed by the DS, but it does not affect the classification given the decision on rapid removal.

The comments suggest that more information should be provided about the data from the vRAR. The DS said that an appendix could be added, but that the data should not be combined with those for the substance because they are not substance-specific (unlike the DAR). We do not think this is correct – classification has to take account of all reliable relevant data on copper ecotoxicity. This has been done in the opinion.

The DS agrees with the comment that the use of geometric means may not be appropriate for the short-term *P. promelas* data at pH 5.5-6.5 (implying that the surrogate approach should be considered), but states that there is no impact on the classification. We think there is an impact, and this is considered in the opinion. The DS prefers data from the DAR for each substance, but as noted above, all relevant data should be considered, including the missing *O. mykiss* ELS NOEC. This is also considered in the opinion.

The DS does not consider that species sensitivity distributions (SSD) or microcosm data are relevant for classification. We think that these could be used with an adequate justification, especially for data rich substances such as copper, provided that they do not mask differences in sensitivity under different abiotic conditions. The DS does not respond to the comment that copper data have been considered for EQS setting by some Member States, but as no references were provided, this cannot be followed up by RAC.

We do not think that toxicity to sediment dwellers is relevant for the proposal.

The DS does not respond to the comment that it is unclear which endpoints were used to derive the ERVs. We have therefore clarified this in the opinion and shown how the ERVs are calculated for each substance.

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	Belgium		MemberState	7
Comment received				
See attachment				

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ECHA's note: The information below was provided in 'Copper oxychloride.docx' [attachment no. 1]

General remark for all copper dossiers. Why was the acute ERV for copper not based on the acute aquatic toxicity results on Pimephalus promelas which are considered of high quality?

We support the proposed classification of $\text{Cu}_2\text{ClH}_3\text{O}_3$ as aquatic acute 1-H400 and aquatic chronic cat 2- H411, however we think that an Macute =100 is more appropriate.

The measured water solubility of Copper oxychloride (pH6.5 = 1.19 mg/l, pH10.1=0.525 mg/l) is greater than the acute ERV of the dissolved metal ion and therefore the metal compound can be considered readily soluble.

In water copper is rapidly bound to material resulting in very low levels of free Cu^{2+} ion in Solution. More than 70% of copper is removed from the water column within 28 days. Copper remobilization from the sediment is considered limited (the pseudo-steady state total and dissolved copper conc. were lower than the conc. corresponding to 70% removal, which is supported by sediment sensitivity analyses). Copper binds to the sediment organic carbon and the anaerobic sulphides with formation of Copper sulfide. The latter has a very low stability constant and thus the remobilization of the anaerobic sediment layer is considered limited.

There is still lack of scientific consensus on the interpretation of rapid removal for classification purposes.

	pH range	Ecotoxicity Reference Value (ERV) $\text{Cu}_2\text{ClH}_3\text{O}_3$	
		L(E)C50 (mg/l)	NOEC (mg/l)
DAR		0.09	
EU RAR	pH 5.5-6.5	0.007	0.034
EU RAR	pH >6.5-7.5	0.079	0.012
EU RAR	pH >7.5-8.5	0.050	0.027

The lowest Acute ERV of Copper oxychloride, based on the results of the metal for Pimephales promales at pH 5.5-6.5 and adjusted for molecular weight of the metal compound is lower than 1 mg/l and therefore Copper oxychloride should be classified as Aquatic acute 1, H400.

If the number of datapoints <4, the lowest value should be taken. The lowest data point (n=2) for Pimephalus promelas = 0.0044mg/l, adjusted for molecular weight, this results in a M-factor of 100 (0.001mg/l < acute ERV ≤ 0.01mg/l).

Based on the geom.mean of the most sensitive species (invertebrate Ceriodaphnia dubia, at pH >6.5-7.5), the lowest Chronic ERV for the metal compound is 0.013 mg/l. If the chronic ERVcompound is > 0.01mg/l and ≤ 0.1 mg/l and there is evidence of rapid environmental transformation, than the compound should be classified as chronic category 2.

[End of attachment no. 1]

Dossier Submitter's Response

In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification

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and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).

For the acute aquatic toxicity for fish, we agree, however in this case there is no impact on classification.

RAC's response

We note that the comment appears to support the approach to rapid removal proposed originally by the DS, but that this is no longer the position of the DS (or several other Member State stakeholders). As explained in the opinion, we do not believe that sufficient evidence has been provided to support the rapid removal concept for copper.

The DS does not respond to the comment that the lowest datapoint (n=2) for *Pimephales promelas* (0.0044 mg/l) has an impact on the proposed M-factor for some substances. This is addressed in the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2014	Denmark		MemberState	8

Comment received

We do not agree that copper oxychloride can be regarded as rapidly "degrading", and therefore the chronic classification should be Chronic 1 with an M-factor of 1 and not Chronic 2 as suggested in the dossier

ECHA's note: The information below was provided in 'Rapid-degradation-copper oxychloride.doc' [attachment no. 2]

In the section on classification for environmental hazards the concept of "rapid removal" has been applied as an analogy to rapid degradation.

However, the "rapid removal" concept is not generally accepted as an applicable tool in classification of metals in neither the CLP nor in the GHS.

Thus in the CLP guidance the paragraphs on "rapid removal" that were introduced in a draft were removed because of "lack of scientific consensus" (Guidance on the Application of the CLP Criteria, Version 4.0, November 2013, Appendix IV, IV.3).

Likewise, EUROMETEAUX and ICMM proposed to introduce the concept of "rapid removal" in the GHS guidance document, Annex A9.7, but the GHS correspondence group in December 2013 decided to leave it out for the same reasons as above in the CLP guidance.

The "rapid removal" concept is risk based, and not adequate for hazard classification purposes.

The outlined procedures and models in the "rapid removal" concept assume completely still-standing water, a situation you will hardly find anywhere in natural waters; certainly that would be rather special localities, and the concept is absolutely inapplicable to running waters. Thus, the suggested procedure not only represents risk assessment, it is not even generic risk assessment, but very, very local risk assessment.

Binding to particles in the water column with a following sedimentation and binding in the sediment has not been accepted for organic substances. The reason for this is that such processes will depend highly on local conditions. Also, the rate of such processes will vary with the depth of the water column, and this was the main argument for not taking volatility into account in the hazard assessment. For the same reasons these processes cannot be applied in the hazard assessment and classification of metals.

The Ticket-Unit-World model has been developed for lakes, so far without currents and turbulence. And the model will not be applicable to running waters. The model also employs binding to organic particles and precipitation of these to the sediment,

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which, as said above, cannot be accepted in the framework of hazard assessment and classification.

The binding in the sediment (e.g. to sulphides) is not really an irreversible process. It requires undisturbed sediment that doesn't get oxygenized, while in natural waters you will normally see a number of processes that can stir the sediment at different times, such as e.g. storms and burrowing animals. And again, it won't apply to running waters.

Thus the "rapid removal" concept is purely a risk assessment tool and not applicable to hazard identification and classification, and has not been accepted for hazard identification under the CLP and GHS.

Further, it is in the dossier suggested that 70% removal of the soluble form of a metal would be analogous to 70% degradation (mineralization) of an organic substance.

However, recall that the 70 % (or 60% depending on test-method) mineralization of organic substances really represents close to 100% degradation, as a substantial part of the last 30 % is built into microbial biomass. A 70% removal of a metal is therefore not at all equivalent with the 70 % mineralization of organics.

Also, looking at the transformation/dissolution protocol results given in the voluntary risk assessment (VRAR) Appendix K1, it is evident that there is a marked *increase* in soluble Cu from day 7 to day 28 (about a factor of 4). If there was a rapid transformation of soluble forms to insoluble forms this would be seen as a marked *decrease* of soluble forms in the T/D protocol tests. The table below is from VRAR:

Table 8: Summary of the transformation/dissolution data obtained for CuO, at different loadings and different pHs.

CuO loading rate (mg/l)	Time (days)	Measured Cu concentration (µg/l)		
		pH6	pH7	pH8
1	7	49	5	0
10	7	221	22	3
100	7	980	64	10
1	28	210	9	1

The implication of this is that the substance cannot be regarded as rapidly "degrading", and therefore the chronic classification should be Chronic 1 with an M-factor of 1.

Danish Environmental Protection Agency,
Strandgade 29, DK-1401 Copenhagen K, Denmark

[End of attachment 2]

Dossier Submitter's Response

In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).

RAC's response

We agree with the comments made about the rapid removal concept, and note that the DS

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON DICOPPER CHLORIDE TRIHYDROXIDE

does too. This affects the chronic classification.

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	Germany		MemberState	9

Comment received

The DE CA has general problems with some methodologies referring to the environmental classification used in the CLH-proposal:

i) Methodology for chronic classification

Regarding the chronic environmental classification and labeling, the proposal is based on the concept of "rapid removal" for assessment of environmental transformation. However, the interpretation of this concept is not yet finally agreed upon (cf. comment by the ECHA on page 503 of the Guidance Document for the application of CLP criteria).

In the view of the German Federal Environment Agency the concept of "rapid degradation" as foreseen by the CLP Regulation for organic substances cannot be compared to the risk based concept of "rapid removal/transformation" of inorganic substances (metals are not degraded but simply relocated from the water column to e.g. the sediment). Hence, the concept of "rapid removal" seems not adequate for the hazard based classification according to CLP. For this reason we cannot support the chronic classification proposed by FR.

As long as the concept of "rapid removal" for inorganic compounds is not finally agreed upon, the aquatic chronic classification should be based on the criteria for not rapidly degradable substances as it was done for all substances including metals before.

ii) Use of geometric mean for classification and labeling

According to the CLP Regulation (section 4.1.2.3) "the lowest of the available toxicity values shall normally be used to define the appropriate hazard category(ies)." In the Guidance Document on the application of the CLP criteria the following is stated: "Where more than one acceptable test is available for the same taxonomic group, the most sensitive (the one with the lowest L(E)C50 or NOEC/EC10) is generally used for classification. [...] When larger data sets (four or more values) are available for the same species, the geometric mean of toxicity values may be used as the representative toxicity value for that species."

Accordingly, the geometric mean may be used for the derivation of the lowest acute and chronic endpoint for data rich substances, if four or more endpoints are available for one species. Please note that this is not always the case for the data used for classification in the CLH reports. We therefore suggest using the lowest effects value as it was proposed and agreed for example within the Competent Authority Assessment Reports (e.g. DAR for pesticides, CAR for biocides).

iii) Data basis for classification

Most of the data available on copper compounds has been submitted under the EU Voluntary risk assessment (VRA) under the Existing Substances Regulation. The adequacy of the data presented in the VRA is questionable with regard to classification and labeling as it has not been discussed by any technical group competent for classification as stated by FR in the CLH Report. Therefore we suggest taking into account the data which has recently been fully evaluated by competent authorities and which has been taken for a classification and labeling proposal (e.g. DAR for pesticides, CAR for biocides, see specific comments on environmental classification).

For these three indicated points, we propose to revise the CLH-Dossier accordingly.

Further points:

pp. 177ff: In general, we would appreciate more background information in section 5.4 on

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why data are presented and how they are being used in the course of environmental classification.

p. 177: "As long as copper compounds dissociate in water, all acute tests were conducted with the salt of concern, when the chronic studies were conducted with other salts but considered relevant. All endpoints are expressed as copper."

It is not quite clear what is meant with this statement. If all acute tests were conducted with the salt of concern this would mean that for the assessment of the acute toxicity only those tox-data were taken into account which were actually conducted with the copper salt of concern i.e the classification and labeling dossiers should contain different effect values for acute toxicity. However mainly all dossiers all contain the same data.

p. 182 Please add the name of the standard test method and in table 2 the test substance, where Reference Value originates, Please clarify whether the given toxicity data refer to the copper ion only or a copper compound.

p. 183: Please state if the solubility is the highest at pH 6.5 and 10.1 therefore the solubility at 5.5 is not mentioned.

p. 183: Conclusion on environmental classification and labelling:

The ERV used for environmental classification should be the one calculated with the toxicity data from the pesticide monograph (DAR). These studies have been peer reviewed and found to be acceptable (see general comment).

We suggest using lowest acute data from the DAR (LC50 *Oncorhynchus mykiss* = 0.052 mg Cu/L) and the acute ERV –Copper Oxychloride of 0.09 mg Copper Oxychloride/L. This will not change the proposed acute classification as H400 with M-factor of 10.

For chronic environmental classification we suggest using lowest chronic data from the DAR the NOEC for *Daphnia magna* obtained in the study by Bellmann (1993). The NOEC = 0.0076 mg Cu/L results in a chronic ERV – Copper Oxychloride = 0.01 mg Copper Oxychloride /L. Since the interpretation of "rapid removal" for assessment of environmental transformation is not finally agreed yet, we suggest considering "no rapid transformation"; hence classification as chronic category 1, H410 with M-factor of 1.

Dossier Submitter's Response

- i) In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).
- ii) We agree, however in this case there is no impact on classification
- iii) The biocide CAR is based on data submitted in the RAR. All data available in the pesticide DAR are also included in this dossier.

RAC's response

- i) We agree with the comments made about the rapid removal concept, and note that the DS does too. This affects the chronic classification.
- ii) We agree with the comments about the use of the geometric mean, provided that the data are all reliable. Contrary to the response of the DS, the way that this is applied to some of the data could have implications for the environmental classification of some of the copper compounds (because of the way that molecular weight and number of copper atoms affects ERVs for individual substances based on the same ecotoxicity data point).
- iii) We are disappointed that the CLH dossier did not in fact include all relevant data available in the REACH CSRs (and voluntary risk assessment report, vRAR), such as for

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invertebrates. These data have been assessed to be reliable for use in REACH registrations, so we believe they should be used for classification purposes too, even if they have not been independently validated by a regulatory authority (we note that there was some oversight of the data assessment process provided by the Italian Competent Authority and the Technical Committee for New and Existing Substances (TC NES) under the former Existing Substances Regulation, and more recently agreement of the data set at the OECD CoCAM; the overall level of scrutiny provided is unclear – in particular the TC NES did not “agree” any of the data). The opinion therefore considers the impact of the additional data on the classification.

The DS has not responded to the additional points that were made, which raise valid concerns about the transparency of the dossier. The opinion discusses the molecular weight of the hydrated and anhydrous forms where appropriate and the number of copper ions per substance.

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	Finland		MemberState	10

Comment received

Comments by the Finnish Competent Authority:

The CLH proposal includes an assumption that copper undergoes rapid removal from the water column, which is proposed to correspond to rapid environmental transformation as defined in the classification criteria. The Finnish CA considers that the provided justification for rapid environmental transformation based on the rapid removal of copper (i.e. more than 70% removal of copper from the water column within 28 days, as indicated by the TICKET-UWM model simulations), is not acceptable.

In the CLH report, it is mentioned that "the processes considered by the model include complexation by aqueous inorganic and organic ligands such as dissolved organic carbon (DOC), adsorption to particulate phases such as particulate organic carbon (POC) and iron/manganese oxides, binding to biological receptors (biotic ligands), dissolution kinetics of metals powders, and cycling of organic matter and sulfide production in lakes"

It is noted that the above-mentioned processes are dependent on site-specific factors and may vary spatially and temporally. Therefore, these factors cannot be used for hazard assessment which should be based on intrinsic properties of the substance and should not be dependent on local conditions.

It is also noted that in the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have been deleted for the time being as explained in the comment by ECHA (p.606 of the guidance).

In the CLH report the lowest recorded geometric mean LC50 value was mentioned to be 0.0081 mg Cu/L for fish *Pimephales promelas* for pH 5.5-6.5. However, this value has not been used as in the table p. 182 the lowest reference value LC50 (mg/l) for pH 5.5-6.5 was claimed to be 0.0292 mg/l. It is unclear where this value comes from. The classification for acute hazard should be based on the lowest reference value of 0.0081 mg/l (acute ERV- $\text{Cu}_2\text{Cl}(\text{OH})_3$ 0.014 mg/l) which, however, would not change the classification in this case.

Considering the proposal for chronic hazard, as there is no reliable evidence of rapid environmental transformation and taking into account the lowest chronic ERV- $\text{Cu}_2\text{Cl}(\text{OH})_3$

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value of 0.012 mg/l (<0.1), the classification for chronic hazard should be Category chronic 1, H410, with an M-factor of 1.

Dossier Submitter's Response

In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).

RAC's response

We agree with the comments made about the rapid removal concept, and note that the DS does too. This affects the chronic classification.

The comments also point out inconsistencies in acute data presentation for fish, and we have clarified the choice of data in the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2014	United Kingdom	Regulatory Compliance Limited	Industry or trade association	11

Comment received

ECHA note: The information below was provided in 'CLH dossier comments Copper Oxychloride ECI Jan 2014.doc' [attachment no. 4]

3) ENVIRONMENTAL HAZARDS

In the CLH and REACH dossier, the following classifications for environmental hazard were derived:

Acute category 1. M factor =10.

Chronic category 2.

Some differences in the assessment were noted as described below.

3.1 ECOTOXICITY DATABASE

In the CLH report, two data-sets are used independently for the classification: the ecotoxicity data from the RAR, based on tests with soluble copper compounds, and the ecotoxicity data from the DAR, based on tests with copper oxychloride.

Only test results expressed as measured dissolved copper concentrations were retained for the CLH report (RAR and DAR data-set) and REACH dossier (RAR data-set). Considering that the ecotoxicity data from the RAR relies on tests with soluble copper compounds while the ecotoxicity data from the DAR relies also on sparingly soluble copper species (Copper oxychloride solubility 1.19 mg/L at pH 6.5 and 0.525 mg/l at pH 10), a comparison between total and dissolved concentrations is therefore relevant to the data-interpretation

- In the RAR total and dissolved concentrations were compared for the chronic toxicity tests, carried

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out with soluble copper species. The data showed dissolved fractions >72-100% of the total fraction and assessment concluded that almost all copper was present in the dissolved form in the toxicity tests (more details - see RAR, aquatic effects -*Extract section 3.2.2.27*).

- When evaluating the ecotoxicity data from the RAR (Table in section 5.5), up to 40 times lower L(E) C50 values expressed as total versus dissolved copper concentrations were recorded. This indicates that some of the less soluble copper compounds (eg copper oxychloride) may have precipitated and reproducibility and dose-response relationship for dissolved copper concentrations therefore needs further elaboration.
- As proposed in the CLP guidance, ecotoxicity data from tests carried out with fully soluble compounds (cf. RAR/REACH data-sets) are therefore preferred.
- The RAR ERVs, retained in the CLH report, are slightly higher than the ones defined in the REACH dossier because in the RAR geometric mean values were derived, also when only 2 and 3 data-points per species were available. In the REACH report, the geometric mean was only applied if 4 or more data-points are available. This refinement slightly lowered some species-specific reference values (more information from Van Sprang and Delbeke, 2010 – Attachment 1).

Table 2 summarises the ERVs retained from the DAR, RAR and REACH, expressed as mg copper oxychloride/L(after molecular weight translation).

Table 2: Summary of the acute and chronic ERVs for copper oxychloride

Source	pH range	Acute ERV CuOCl	Chronic ERV CuOCl
DAR		0.087	
RAR	5.5-6.5	0.049	0.034
	>6.5-7.5	0.079	0.012
	>7.5-8.5	0.050	0.027
REACH	5.5-6.5	0.042	0.034
	>6.5-7.5	0.059	0.012
	>7.5-8.5	0.050	0.019
	across all pHs	0.058	0.025

Note: In the RAR and the REACH dossier, the ecotoxicity data from *P. promelas* at pH 6 (Erickson *et al.*, 1996) were rejected and it may be clarifying to also mention this in the CLH report.

The test was performed with larvae (< 24 h old) in a flow-through with a very short retention time (± 45 min.), using a diluted reconstituted medium (prepared from Lake Superior water through reverse osmosis) with a low hardness (22 mg/l CaCO₃) and DOC concentration (reverse osmosis) This test performed represent worst case conditions explaining therefore this low LC50 value. Moreover the observed pH dependency observed for *P. promelas* at (sensitivity at pH 6 versus pH 7) is unexpected and may be related to insufficient adaptation to low pH conditions (from Van Sprang and Delbeke, 2010 -Attachment 1).

3.2 CLASSIFICATION

The CLH and REACH dossiers consider copper oxychloride as fully soluble (1.19 mg/L at pH 6.5 and 0.525 mg/l at pH 10). No transformation dissolution data are available. However, for comparison purposes, the classification versus solubility for copper compounds and copper flake is presented in Attachment 2 for completeness.

The CLH and REACH dossiers consider copper oxychloride as rapid degradable (with evidence for rapid

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removal of copper from the water column presented).

Classification in both dossiers (CLH and REACH) is therefore based on straight comparison between ERV values (Table 1) and classification cut-off values.

- Table 1 consistently indicated Acute ERV values between <0.1 mg/L and >0.01 mg/L. The assessment therefore confirms the environmental hazard **Acute 1 - H400. M factor = 10**.
- For chronic toxicity, the ERVs are <0.1 mg/L and >0.01 mg/L, confirming the environmental hazard classification entry as **Chronic 2 - H411**.

4) RELEVANT ATTACHMENTS

Attachment 1: Van Sprang and Delbeke, 2010

Attachment 2: Classification versus solubility for copper compounds and copper flake

CONTACTS

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[End of attachment 4]

Dossier Submitter's Response

In the current published version of the CLP guidance (Guidance on the Application of the CLP Criteria Version 4.0 – November 2013) the parts concerning "rapid removal from water column" have indeed been deleted. Moreover, as no consensus was found during the ECHA workshop on the concept of rapid removal on February 8th, 2012, and taking into account comments from several MS (Finland, Germany, Denmark, UK, Belgium) this concept might be not considered in the current assessment. The long-term classification and M factors would therefore need to be updated accordingly (see final proposal for Chronic classification and M factor at the end of this document).

RAC's response

We agree with the DS response about the rapid removal concept, which affects the chronic classification. Our reasons are given in the opinion.

We note that the DS has not responded to any of the other comments that were made. These point out differences in data aggregation between the REACH registration dossiers and the CLH report which result in different ERV values for some substances. We have considered this in the opinion and shown how the ERVs are calculated for each substance.

The comments also highlight some concerns about the ecotoxicity data for *P. promelas* at pH 6 (Erickson et al., 1996), which are used in the CLH report but rejected in the REACH registration dossiers. This study is important as it appears to be the most sensitive for fish, and we have discussed some of the issues in the opinion.

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The comments also refer to transformation/dissolution (T/D) data and relative solubility of the different substances, and state that the most soluble copper compounds would carry the most stringent environmental classification. We note that only some substances have T/D data. We have considered solubility for each substance in the opinions (– except for copper flakes, for which T/D data were used) – in our view, all of the substances can be considered to be readily soluble metal compounds in accordance with the CLP Guidance. The stringency of the classification depends not only on solubility but also molecular weight and the number of copper atoms per substance. This is clarified in each opinion.

Dossier Submitter's New Chronic Classification proposal without rapid removal concept

chronic 1

M = 1

Attachments received: 5

1. Belgian comments (filename: Copper oxychloride.docx), submitted by Belgium on 3.2.2014. The content was copied to comment no. 7.
2. Danish comments on the environmental classification of copper oxychloride (filename: Rapid-degradation-copper oxychloride.doc), submitted by Denmark on 30.01.2014. The content was copied to comment no. 8.
3. ECI comments (filename: Classification versus pH and solubility.doc), submitted by UK on 03.02.2014. Refer to comment no. 3, 5 and 11.
4. ECI comments (filename: CLH dossier comments Copper Oxychloride ECI Jan 2014.doc), submitted by UK on 03.02.2014 was partially copied into the table. Refer to comment no. 3 and 11.
5. ECI comments (filename: Van Sprang and Delbeke_2010.pdf), submitted by UK on 03.02.2014. Refer to comment no. 3, 5 and 11.