

**Committee for Risk Assessment
RAC**

Annex 2
Response to comments document (RCOM)

to the **Opinion**
**on the harmonised classification of lead
(environment)**

Pursuant to Article 77(3)(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

EC Number: 231-100-4
CAS Number: 7439-92-1

A77-O-0000007042-85-01/F

Adopted
16 September 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON LEAD UNDER ART. 77(3)(C)

COMMENTS AND RESPONSE TO COMMENTS ON CLH UNDER ART. 77(3)(C): PROPOSAL AND JUSTIFICATION

Comments provided during 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 comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: lead
EC number: 231-100-4
CAS number: 7439-92-1

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
04.09.2020	United Kingdom	International Lead Association	Industry or trade association	1
Comment received				
<p>Since the original RAC opinion Industry has generated new data through a GLP OECD 243 test on the pond snail <i>Lymnaea stagnalis</i> (Fox, 2020) and a 28 day transformation and dissolution test on lead metal powder (ECTX, 2020). Results of both studies have been submitted to ECHA in a REACH dossier update but are also described in the public attachment included with this submission and the full report of the T/Dp test is included in the confidential section. This new information, together with additional supporting information on the special manufacturing process required to produce lead metal powders (that contrasts with typical smelting processes used to produce lead metal in massive form) and information supporting the conclusion that under normal use conditions it is not likely that powders or dust are formed in relevant quantities from lead metal massive highlights that a review of the original RAC opinion for lead metal in massive ($\geq 1\text{mm}$] is warranted. An audio power point presentation highlighting how this new evidence impacts the original RAC opinion has been prepared but due to its large file size we were unable to submit using this webform. It has been sent directly to ECHA for consideration.</p> <p>ECHA note – Two attachments were submitted with the comment above. Refer to public attachment ILA Comments_lead metal CLH_final.docx and Lead Metal CLH-Sept 2020_Final_audio version.pptx</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment FR X01-323_lead metal powder dissolution test.zip</p>				
RAC's response				
RAC took note of this comment and the three attachments. In general, the availability of new test results which are less sensitive do not override and invalidate existing data and				

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information, which have been evaluated as relevant for the purpose of aquatic hazard classification.

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Germany	Wirtschaftsvereinigung Metalle	Industry or trade association	2

Comment received

WVMetalle would like to raise the aspect of downstream legislation consequences of the pro-posed classification. For example, the SEVESO directive and transport regulations are triggering additional requirements which are increasing administrative burdens, costs and measures which are not justified by the intrinsic properties of lead metal, especially when it comes to massive parts.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-09-07_WVMetalle comment on RAC Pb Env Clas consultation.pdf

RAC's response

RAC took note of this comment and the attachment. In general, downstream legislation consequences of a classification is not taken into account by RAC.

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Denmark	<confidential>	Company-Manufacturer	3

Comment received

Dear members of the RAC committee,

Regarding the request to deliver comments in regards to the following consultation:
 1. whether, based on this new information the current RAC opinion on the environmental classification of this substance as Aquatic Chronic 1, H410; M=10 should be revised;
 2. whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment. Interested parties should also be requested to submit data relevant to the properties of the powder and massive forms in the consultation

We as an international cable manufacturer (producing integrated lead sheets as part of cables) support the re-assessment of the data which lead to the conclusion of Lead being classified as Aquatic Chronic 1, especially in light of the new results provided by the International Lead Association regarding the chronic toxicity of lead in the pond snail *Lymnea stagnalis*. We support the need for further and more standardized testing regarding the effects of massive form lead on the aquatic environment.

Regarding the second point of the consultation we do not see a possibility under normal circumstances that lead from our products could be turned into powder form and therefore we support further analysis on a distinction between powder and massive forms of Lead, especially due to the presented testing data which shows no evidence of rapid environmental transformation and that the malleable structure of lead would not allow "fines" to be created when being drilled or otherwise processed.

RAC's response

RAC took note of this comment.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
04.09.2020	Belgium	Eurometaux	Industry or trade association	4
Comment received				
eurometaux would like to submit some general and specific comments in respect to the environmental hazard classification of lead metal				
<p>General concerns</p> <p>In general, Eurometaux would make a strong plea for 1) using all evidence of good quality provided in the registration dossiers, 2) following the (metal specific) guidance without further interpreting it and 3) ensuring consistency with other metal dossiers previously assessed for their environmental hazard and classification. All these aspects are relevant to the assessment of the environmental aquatic classification review of Lead metal given, we noted that during the previous opinion forming:</p> <ul style="list-style-type: none"> - not all data available in the registration dossier were used. Some were put aside to the benefit of default approaches (e.g. transformation dissolution data on the massive form) - several derivations from the published CLP guidance on metals or extended interpretations (e.g. criteria for a separate classification entry for metals in massive form), some of them further discussed here below under the specific comments - a lack in consistency with how previous comparable data sets on metals were handled (e.g. in respect to separate entries for the massive and powder form or the methodology used to derive the classification). This challenges the robustness, predictability and transparency of the harmonised classification process <p>Eurometaux is therefore pleased that the dossier will be re-evaluated and would therefore call upon the reviewers to use all evidence available by screening it for quality and relevance and ensuring the CLP guidance for metals is applied in full and consistently with previous dossiers.</p>				
<p>Specific comments</p> <p>In line with the announced review of the ERV and environmental classification of Lead in metal form Eurometaux would like to raise specific comments and input on:</p> <ol style="list-style-type: none"> 1. the handling of “new high-quality ecotox data” in respect to the snail data from Fox et al (2020) 2. the conditions of splitting the metal entry in one for the massive metal and one for the powder metal form 3. the application of the metal’s classification scheme in case extensive data sets on Transformation Dissolution (T/D) and ecotoxicity are available for different pH bands 				
<p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Eurometaux contribution to the RAC consultation on the Environmental Classification of Lead metal.zip</p>				
RAC’s response				
RAC took note of this comment and the attachment.				

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Date	Country	Organisation	Type of Organisation	Comment number
04.09.2020	United Kingdom	International Lead Association	Industry or trade association	5
Comment received				
<p>A detailed set of comments and explanations is described in the public attachment included with this submission. However an executive summary of our points is included below:</p> <ul style="list-style-type: none"> • The new standard OECD 243 snail test (Fox, 2020) resulted in a NOEC of > 110 µg/L for dissolved Pb and this should replace the previous non-standard value for the snail used in the original RAC opinion • This new evidence changes the chronic ERV derived by RAC for lead metal and the most sensitive organism now becomes a green algae at pH 8 • The updated chronic ERV should subsequently be evaluated for impacts on the classification and chronic M-factors for Pb metal • A separate CLP entry for the massive form is justified given all 3 criteria described in the CLP guidance to distinguish massive and powder metals are fulfilled • New complementary Transformation Dissolution data (ECTX, 2020) now allows direct comparison of lead dissolution from powder and massive at equivalent loading, pH and time duration. • This illustrates that the dissolution of lead ions from lead in massive and powder forms is hugely different (orders of magnitude); the documented evidence available for transformation & dissolution of massive should be used in the classification decision for the massive form • The highest dissolution of Pb from lead massive occurs at low pH (pH 6) (being >20 times higher than at high pH (pH 8) • In contrast, the highest chronic toxicity occurs at high pH (being 3 times more toxic than at low pH) • As the CLP metals guidance recommends, toxicity and dissolution should be compared at equivalent pH to derive the CLP classification given such information is available for lead. • Normalisation of lead experimental toxicity data using the validated BLM reduces the experimental variability and allow all available toxicity data points to be considered in ERV derivation. However, this does not substantively change the chronic ERV and does not change the classification conclusion • If comparing toxicity and dissolution at an equivalent pH band, at no pH is the dissolved fraction from the 28-day T/Dp at 1 mg/l loading of lead massive HIGHER than the chronic ERV of the most sensitive species. This indicates that chronic ENV classification of lead in massive form is NOT required 				

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<p>ECHA note – Two attachments were submitted with the comment above. Refer to public attachment ILA Comments_lead metal CLH_final.docx and Lead Metal CLH-Sept 2020_Final_audio version.pptx</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment FR X01-323_lead metal powder dissolution test.zip</p>
<p>RAC's response</p>
<p>RAC took note of this comment and the two attachments. In general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.</p>

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Germany	Wirtschaftsvereinigung Metalle	Industry or trade association	6
<p>Comment received</p>				
<p>WVMetalle plea for using all available high-quality information, including the latest update of the lead- and lead compounds registration dossiers. In addition, applying the metal specific guidance as it stands will ensure consistency with other metal dossiers previously assessed for their environmental classification. Taken together, this indicates that a chronic environmental classification of lead metal in massive form is not required</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-09-07_WVMetalle comment on RAC Pb Env Clas consultation.pdf</p>				
<p>RAC's response</p>				
<p>RAC took note of this comment and the attachments.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Denmark	<confidential>	Company-Manufacturer	7
<p>Comment received</p>				
<p>We as an international cable manufacturer (producing integrated lead sheets as part of cables) support the re-assessment of the data which lead to the conclusion of Lead being classified as Aquatic Chronic 1, especially in light of the new results provided by the International Lead Association regarding the chronic toxicity of lead in the pond snail Lymnea stagnalis.</p> <p>We support the need for further and more standardized testing regarding the effects of massive form lead on the aquatic environment.</p> <p>Regarding the second point of the consultation we do not see a possibility under normal circumstances that lead from our products could be turned into powder form and therefore we support further analysis on a distinction between powder and massive forms of Lead, especially due to the presented testing data which shows no evidence of rapid environmental transformation and that the malleable structure of lead would not allow "fines" to be created when being drilled or otherwise processed.</p>				
<p>RAC's response</p>				
<p>RAC took note of this comment.</p>				

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Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	France		MemberState	8
Comment received				
<p>France welcome the generation of new data for characterising the chronic toxicity of lead for snail. The test was performed according to the OECD 243 and GLP. The results provide value of lead nitrate toxicity of NOEC of dissolved Pb of $\geq 110 \mu\text{g/L}$ ($\geq 116 \mu\text{g/L}$ total Pb or $\geq 300 \mu\text{g/L}$ nominal lead nitrate). This value is higher than the previous value available in the CLH report for this species (NOEC of $1.7 \mu\text{g/L}$). Nevertheless, as several chronic toxicity values are available and of good quality (Klimisch 1 and 2) and that they cover various species in different trophic levels, the classification as Acute 1, H400; M=1 and Aquatic Chronic 1, H410; M=10 seems appropriate.</p> <p>The powder and massive forms of lead warrant the same classification for hazards to the aquatic environment as it seems to largely dissolve in this assay (as a nitrate form). The measured dissolved concentrations of Pb did not differ from the total measured Pb levels (95 -97% agreement). This is in accordance to available information in the CLH report.</p>				
RAC's response				
<p>RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Denmark		MemberState	9
Comment received				
<p>The present consultation seeks comments on two questions:</p> <ol style="list-style-type: none"> whether, based on this new information the current RAC opinion on the environmental classification of this substance as Aquatic Chronic 1, H410; M=10 should be revised; whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment. Interested parties should also be requested to submit data relevant to the properties of the powder and massive forms in the consultation <p>Question 1: Manufacturers of the substance have provided new information (Fox, 2020) on the chronic toxicity of lead in the pond snail <i>Lymnea stagnalis</i> (OECD 243). This 28-day study concludes that there are no statistically significant adverse effects on reproduction, growth or survival at any of the exposure concentrations tested (semi-static; 0.0 (control) - 300 $\mu\text{g/L}$ as nominal lead nitrate; <0.5-116 $\mu\text{g/L}$ as measured total Pb; <0.5-110 $\mu\text{g/L}$ as measured dissolved Pb). However, several other studies have found EC10 values of 0.48 $\mu\text{g/l}$ (56 day, reproduction), 4.1 $\mu\text{g/l}$ (14 day, growth), 1.7 $\mu\text{g/l}$ (30 day, growth) and 7.4 $\mu\text{g/l}$ (16 day, growth). They have all been classified as reliable (with restrictions) by industry in the REACH registration dossier. Therefore, considering the vast amount of data showing aquatic toxicity of lead, one new study showing no effects does not change the outcome of the Weight of Evidence-analysis. The conclusion is still that lead is toxic to the aquatic environment and Denmark is not of the opinion that the environmental classification of lead as Aquatic Chronic 1 should be revised.</p> <p>Question 2:</p>				

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To our knowledge, there is no new evidence since the discussion at RAC to challenge having the same classification for powder and massive forms of lead. There is no new evidence showing that the powder form is different from the massive form in terms of toxicity to the aquatic environment. In RAC, it was decided to base the classification on the intrinsic properties of lead not taking the form of the metal into account because there is no difference in the biological impact of the massive form and powder form of lead. Increased solubility of the powder form is not a valid argument for splitting the classification, as smaller particles will always be more soluble. The solubility is a function of the particle size, and you do not classify according to particle size as such. The powder form is produced from the massive form and the two forms can be considered identical in nature.

According to the CLP guidance, a split in classification can be considered when the two forms exhibit different crystalline structures and the manufacture of powder has been produced by a special process. Neither of the two scenarios is the case and the majority of RAC members agreed on one classification. We therefore maintain our view, that the classification should not be split.

As discussed during the classification process at RAC, the DS recommended not splitting the data into pH bands. The values were derived from studies performed under different conditions, not making it possible to split them into pH bands and calculate geometric means. In this case, RAC agreed with this consideration and therefore accepted to use the lowest value instead of the geometric mean for the derivation of ERVs. During the discussion at RAC, the members questioned the need to normalize the data. There was not seen a clear trend in the water quality parameters taking into account in the ecotoxicity tests. The conclusion was that normalization could not be justified.

RAC's response

RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	United Kingdom	HSE	National Authority	10

Comment received

Lead (EC 231-100-4; CAS 7439-92-1)

The L. stagnalis study (Unnamed, 2007) which forms the basis of the current chronic ERV was considered the most sensitive endpoint for this species in the CLH proposal in 2017 and in the RAC opinion. This decision has been agreed by the European Commission and is now included in the C&L Inventory. We agree with the RAC that this study is valid and cannot be excluded, noting that the endpoint is supported by three other long-term toxicity studies included in the online REACH registration dossier on the growth of L. stagnalis larvae showing a similar sensitivity. We also note that a geometric mean of the toxicity values for this species is currently not appropriate due to the different study durations. If it is possible to derive endpoints for a consistent exposure duration by re-examining the data, a geometric mean could be appropriate.

While this key endpoint in the CLH proposal and in the RAC opinion is for the larvae stage, the new L. stagnalis study (Fox, 2020) submitted for the targeted consultation is for the adult life-stage. Results indicate that growth in the larvae stage (measured as

blot-dried wet weight) is more sensitive than in the adult life-stage (measured by shell growth). Nonetheless, we consider that the new study may not be valid according to the OECD TG 243 validity criteria, at least in terms of fecundity, because there appear to be less than 4 egg clutches per individual-day (0.482) in the control. We note the disparity between this number of clutches per individual-day and the average number of clutches per snail which the study author(s) considers to meet the validity criterion for reproduction in the control. Therefore, please could possible differences in calculations and the presentation of data used to determine the validity based on fecundity be clarified? Overall, we suggest that the new 2020 study should not impact the Aquatic Chronic 1 (with Chronic M-factor of 10) classification previously proposed by the RAC given the relatively lower sensitivity of the adult life-stage.

However, we also now note that the online REACH registration dossier includes a more sensitive endpoint for *L. stagnalis* with a 56 d-EC10 of 0.48 and 1.08 µg Pb/L based on reproduction and growth rate, respectively (Munley et al., 2013). These endpoints were not included in the 2017 CLH report, although they could impact the ERV. This study is considered as supporting information by the Registrant and is of longer duration, though it is similar in terms of reliability to many of the other available snail studies. Please could the relevance of this study in comparison with the other snail studies therefore be clarified?

No new information relating to a single or dual classification based on the massive or powder form have been submitted. As the RAC were in favour of a single classification and have presented the reasoning and alternatives in the RAC opinion, and this is also in some ways a policy decision for the EU, we will not comment on this aspect.

RAC's response

RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.

Thanks for indicating that you consider the new *L. stagnalis* study (Fox, 2020) not valid according to the OECD TG 243 validity criteria, at least in terms of fecundity. RAC has examined the validity criteria of OECD TG 243 and has determined that the number of egg clutches per day indicate that the validity criteria is in fact met. RAC therefore finds the study to be valid.

Thanks for indicating that in the online REACH registration dossier a more sensitive endpoint for *L. stagnalis* with a 56 d-EC10 of 0.48 and 1.08 µg Pb/L based on reproduction and growth rate, respectively is included. (Munley et al., 2013). RAC examined this study and considered it valid, reliable and relevant for use under CLP. In RAC's opinion, this value should be used as the chronic ERV for lead.

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Germany		MemberState	11
Comment received				
Reassessment on ERV values for lead, using the existing data set from the original CLH dossier and taking into account the new chronic toxicity study for lead in <i>Lymnaea</i>				

stagnalis (OECD TG 243):

The existing data set – especially the long-term snail toxicity study on *Lymnaea stagnalis* – was considered valid and reliable without restriction by the dossier submitter as well as RAC. With this new chronic study for lead in *Lymnaea stagnalis* there are now new results available with this organism.

The new study was conducted according OECD TG 243 (adult animals were exposed over 28d to concentrations up to 300 µg/L) and showed no significant effects for mortality growth, and reproduction up to the highest test concentration. There was an effect at the highest test concentration for reproduction (no. of egg clutches produced per day) of about 20% which was not statistically significant.

From other data publicly available (e.g. Munley et al., 2013) and also from the VRAR (2008), it seems that the growth of juvenile snails (*Lymnaea stagnalis*) is a very sensitive endpoint concerning the toxicity of lead to this snail species. As the test according to OECD TG 243 is generally conducted with adult snails, the difference in the resulting effects may not be surprising.

Generally, providing a newly generated toxicity study should not devalue or override the existing data.

References:

Munley, K.M.; Brix, K.V.; Panlilio, J.; Deforest, D.K.; Grosell, M. (2013): Growth inhibition in early life-stage tests predicts full life-cycle toxicity effects of lead in the freshwater pulmonated snail, *Lymnaea stagnalis*. *Aquatic Toxicology* 128-129: 60-66

VRAR (2008). European Union Risk Assessment Report - Voluntary Risk Assessment on Lead metal and Lead compounds prepared by the Lead Development Association International (LDA International). Draft of May 2008 available at https://echa.europa.eu/voluntary-risk-assessmentreports-lead-and-lead-compounds?diss=true&search_criteria_ecnumber=231-100-lead-and-lead-compounds?diss=true&search_criteria_ecnumber=231-100-4&search_criteria_casnumber=7439-92-1&search_criteria_name=Lead

RAC's response

RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.

Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Sweden		MemberState	12

Comment received

The Swedish CA has comments on the targeted public consultation of lead (Article 77(3) request). The consultation seeks comments on:

1. whether, based on this new information the current RAC opinion on the environmental classification of this substance as Aquatic Chronic 1, H410; M=10 should be revised;
The Swedish CA: A new study (Scymaris 2020, study number 1077.00101) was submitted. This study evaluates the toxicity of lead nitrate to adult snails (*Lymnaea*

stagnalis) in accordance with OECD TG 243. There were no statistically significant adverse effects ($p < 0.05$) on reproduction, growth, and survival at any of the exposure concentrations tested. Therefore, the overall NOEC of total lead was 116 $\mu\text{g/L}$ (110 $\mu\text{g/L}$ dissolved lead).

In the RAC Opinion the aquatic chronic classification proposal for lead is based on a different study on the same species, i.e. study evaluating the effects of lead in newly hatched snails and the EC10 (growth; 30 d) was found to be 1.7 $\mu\text{g/L}$. RAC agreed with the DS to consider this study as reliable and valid for classification purposes and RAC used the EC10 of 1.7 $\mu\text{g/L}$ for chronic ERV derivation.

In our opinion, both studies are reliable and measure toxic effects of lead on different life stages of the same species. Therefore, both should be considered in the classification of lead. The study indicating effects of lead in larvae should therefore not be disregarded, based on the results from the study performed with adult snails.

2. whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment.

The Swedish CA: It is stated in recital 3 of ATP 15 that "With regard to the substance lead (CAS number 7439-92-1 and index numbers 082-013-00-1 (lead powder; [particle diameter $< 1 \text{ mm}$];) and 082-014-00-7 (lead massive; [particle diameter $\geq 1 \text{ mm}$];)), RAC proposed in its opinion of 30 November 2018 to apply the same environmental classification to the massive and the powder form. However, in view of the lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead."

When RAC now will examine whether there should be a common classification for lead or a split classification between what is called powder and massive it is again important to understand and follow the classification strategy given in Annex IV of the ECHA guidance document of the application of the CLP criteria. As stated in subsection IV.5.5 of:

"Normally, the classification data generated would have used the smallest particle size marketed to determine the extent of transformation. There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (e.g. different crystallographic structure) and/or it has been produced by a special process and is not generally generated from the massive metal, classification of the massive can be based on testing of a more representative particle size or surface area, if such data are available."

Hence, normally there would not be a split entry for the same metal. We understand also from the RAC conclusions that there is no structural difference between the two general forms. And a crucial question becomes whether significant amounts of particles with the larger surface area ($> 5.3 \text{ cm}^2/\text{g}$) will be produced during reasonably expected use, including disposal and accidental exposure (section 1.2 of the ECHA guidance document of the application of the CLP criteria). If so, we see no reason for a split classification between the two general physical forms.

RAC's response

RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.

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Date	Country	Organisation	Type of Organisation	Comment number
07.09.2020	Finland		MemberState	13
Comment received				
<p>FI CA considers that the new freshwater snail study with <i>L. stagnalis</i> is valid and conducted following the OECD Test Guideline 243. No statistically significant effects were observed for reproduction, growth or survival in the study. Thus, the NOEC value of ≥ 110 $\mu\text{g/L}$ was determined for dissolved Pb.</p> <p><i>L. stagnalis</i> is one of the most sensitive species (juvenile growth) in the classification proposal of lead for chronic aquatic toxicity. The available studies for <i>L. stagnalis</i> in the proposal are non-guideline studies with juvenile snails. However, they were considered valid and reliable in the RAC opinion (2018). The new OECD TG 243 study is performed with adult test species following the test guideline. The OECD TG 243 is a 28 day test with endpoints for reproduction, growth, and mortality of adult snails. Compared to juvenile snails, adult snails are not expected to have significant growth during the 28 day test. Thus, the growth parameter cannot be considered as a sensitive endpoint in the OECD TG 243 compared to studies with juvenile test organisms. The growth of juvenile snails was measured from wet weight compared to adult shell length in TG 243. Wet weight could be considered as more sensitive to detect potential inhibitory effects of lead as juvenile snails are expected to grow and develop during the test.</p> <p>Based on the new TG 243 study, no effects on reproduction were observed (NOEC ≥ 110 $\mu\text{g/L}$) for <i>L. stagnalis</i>. In conclusion, juvenile growth, observed in the non-guideline studies, remains the most sensitive endpoint of <i>L. stagnalis</i> for lead. This susceptible time period in the development of snails cannot be discarded when considering the chronic aquatic classification of lead. Thus, FI CA opinion is that the new OECD TG 243 study alone does not warrant a revision of the RAC opinion on the environmental classification of lead as Aquatic Chronic 1, H410 with an M-factor of 10.</p>				
RAC's response				
<p>RAC took note of this comment. RAC agrees that, in general, the availability of new test results which are less sensitive do not override and invalidate existing data and information, which have been evaluated as relevant for the purpose of aquatic hazard classification.</p>				

PUBLIC ATTACHMENTS

1. 2020-09-07_WVMetalle comment on RAC Pb Env Clas consultation.pdf [Please refer to comment No. 2, 6]
2. Eurometaux contribution to the RAC consultation on the Environmental Classification of Lead metal.zip [Please refer to comment No. 4]
3. ILA Comments_lead metal CLH_final.docx [Please refer to comment No. 1, 5]
4. Lead Metal CLH-Sept 2020_Final_audio version.pptx [Please refer to comment No. 1, 5]

CONFIDENTIAL ATTACHMENTS

1. FR X01-323_lead metal powder dissolution test.zip [Please refer to comment No. 1, 5]