

Committee for Risk Assessment
RAC

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

phosphine

EC Number: 232-260-8
CAS Number: 7803-51-2

CLH-O-0000001412-86-251/F

Adopted
30 November 2018

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON PHOSPHINE

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 comments and attachments including confidential information received during the public 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 public 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.

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Substance name: phosphine

EC number: 232-260-8

CAS number: 7803-51-2

Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	1
Comment received				
<p>We agree with the proposed classification in table 4 of the CLH-Report. However, we would like to provide following general comments: The focus of the dossier is on updating the minimum classification for acute toxicity. The current classification includes a minimum classification of Acute Tox. 2*, H330 which is changed to Acute Tox. 1, H330. Due to the broad database the ATE which is the basis for classification as Acute Tox. 1 should also be harmonised. The relevant ATE should be included in column "specific Conc. Limits, M-factors, ATE". Only with a harmonised ATE it is possible to correctly classify a mixture containing phosphine for its inhalative toxicity.</p> <p>Concerning table 6 (summary of physicochemical property) in chapter 7 "Physicochemical Properties" the BVL reference numbers in the column "Reference" are not considered as useful. These numbers have no relevance in a reference list of a CLH report. Additionally the reference for the dissociation constant in this table is unclear: it states "no reference" but in the column "Comment" the chemical textbook is mentioned which is inconsistent.</p>				
Dossier Submitter's Response				
<p>FR: in the template we used, "ATE" is not proposed in the title of the column. However, we agree that it would be relevant.</p> <p>FR: noted. The reference number of each report (as mentioned in the monograph) was added. However, the information (author, year) may be sufficient as reference. Regarding dissociation constant, no reference was added since data were estimated from literature. It should have been read "estimated" in the column "comment".</p>				
RAC's response				
Noted.				

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Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	2
Comment received				
BECA thanks ANSES for the submission of this dossier and welcomes the proposal to adapt the classification of Phosphine.				
Dossier Submitter's Response				
FR: thank you for your comment.				
RAC's response				
Thank you. Noted.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	3
Comment received				
<p>Note on the harmonized ATE value for Annex VI: The overall impression from the studies considering reliability, relevance and completeness indicates a ATE value > 11 ppmV taken from study 6 (e.g. study 1). The result from study 4 also indicates a value > 11 ppmV. It should also be taken into account that the RAC consultation considered in the dossier e.g. for aluminium phosphide referred only to three studies (3, 5, 6) and the classification was based on the dust levels. With regard to the larger selection of studies considered here and the dosage levels not documented in Study 6, Study 6 is therefore of less relevance.</p>				
Dossier Submitter's Response				
<p>FR agrees with the overall impression of Germany about the ATE value. However, as stated in the CLH report, the general quality of the studies available is not really good : most of these studies are old, and none of them is sufficiently robust. Considering that this is the first option proposed in the guidance (<i>"In general, classification is based on the lowest ATE value available i.e. the lowest ATE in the most sensitive appropriate species tested. However, expert judgement may allow another ATE value to be used in preference, provided this can be supported by a robust justification"</i>), and that there is no robust justification for another choice, as a conservative option, FR then made the choice to select the lowest value.</p>				
RAC's response				
Thank you. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	4
Comment received				
<p>BECA agrees with ANSES's proposal to modify the current classification of phosphine as follow: Acute toxicity category 1 for inhalation instead of category 2. 8 studies are available and most of them (5) consistently concluded on LC50 that fall into category 1, according to the Guidance on the Application of the CLP Criteria (< 100 ppmV). Only one study concluded on a LC50 compatible with Category 2. The remaining 2 studies did not derive any LC50. BECA thus supports the proposal to classify phosphine as Acute tox. 1 via the inhalation route. This is further supported by a RAC opinion on aluminium phosphide which recommended to modify the classification of phosphine as it met the Acute Tox. 1 (H330) criteria.</p>				

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Dossier Submitter's Response
FR: Thank you for your comment.
RAC's response
Thank you. Noted.