Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at Community level of

trimagnesium diphosphide

ECHA/RAC/DOC CLH-O-0000002194-79-01/A2

Adopted

2 December 2011

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

[ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.]

Substance name: **Trimagnesium diphosphide**
CAS number: **12057-74-8**
EC number: **235-023-7**

General comments

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comments
20/04/2011	Germany / Sabine Hildenbrand / Detia Freyberg GmbH / Company-Importer	p. 4 P231 the following comments are also comparable to trimagnesium diphosphide because the use of these biocidal products is similar to AlP biocidal products: Comments on the draft Competent Authority Report of Aluminium phosphide releasing phosphine (PT 23) (11.11.2010):Applicant Detia Freyberg GmbH: Phostoxin WM is a biocidal product for outdoor use. The b. p. liberates in contact with moisture or water toxic phosphine gas and the efficacy of the b. p. is based on this toxic property. Therefore, Phostoxin WM needs the moisture to reach the biocidal effect and cannot be handled under inert gas. RMS (DE): We agree to the comments of the applicant and propose to optimize the intended precautionary statements of the b. p., that means, omit P231 + P232 (Handle under inert gas. Protect from moisture.) and add P271 (Use only outdoors or in a well-ventilated area.) as well as P403 (Store in a well-ventilated place.). P403 may be added in form of a new combination (P402 + P403 + P404). Table 2-8 will be amended accordingly. On the other hand it should be stated quite clearly somewhere else on the label and in the SDS that contact with water as well as moisture has to be strictly avoided before the b. p. is finally used as intended.	We disagree to omit/change the precautionary statements, because Detia Freyberg GmbH refers to the use of a biocidal product and not to trimagnesium diphosphide. Phostoxin WM is a preparation with ignition inhibiting additives, therefore it is not comparable with Aluminium phosphide nor with trimagnesium diphosphide.	Since contact with water or acids initiate emission of very toxic gas, it is safer to keep Mg3P2 under inert gas and labelled with P231+P232
06/05/2011	Finland / Hinni Papponen / Member State	We agree with the need to harmonise the classifications of different phosphides and the addition of labeling Mg3P2 also with R32/EUH032 is supported. As it is stated in the report PH3 is liberated from metal phosphides rather more readily by acids than by water and Mg3P2 is labeled with R15/29/EUH029.	Comment supports the classification proposal.	Thank you for support
09/05/2011	United Kingdom / Membe State	Justification	First sentence is not	

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		It is not clear from the present CLH report why this proposal has been put forward. Trimagnesium diphosphide is an active substance in plant protection and biocidal products. Generally, such substances are subject to harmonised classification for all endpoints. In this case, only certain hazard classes (Acute oral and dermal toxicity and the addition of EUH032) have been addressed, but it has not been made clear why the other hazard classes have not been included. It just states that the other endpoints are not covered. In addition, the dossier does not propose to amend the physico-chemical classification of this substance, but a section on the physico-chemical hazards has been included Table 2 – VII.7.1 the text in column under value could be amended to say "Gaseous with a fishy or garlic-like odour" P13 Section 5 – Human Health Hazard Assessment The introductory paragraph is a bit confusing at present and does not add any real value to the document. It might be better to clearly indicate that, as a group, alkali and alkaline earth metal phosphides react with water and acids to liberate phosphine gas. Therefore, taking account of the similarities in reactivity between magnesium and aluminium phosphide, the acute dermal toxicity information on aluminium phosphide can be used to read across to magnesium phosphide. However, please refer to our comments on the acute toxicity. Toxicokinetics This section does not appear to add any useful information relevant for classification of magnesium phosphide, and could be deleted or significantly reduced.	comprehensible. According to current practice in the CLH-procedure only those endpoints for which harmonised classification and labelling is sought were addressed. It was not intended to deliver a survey on all available knowledge for all endpoints where consensus has already been achieved in the scientific discussion under the BPD, resulting in the current C&L.	It would be good to have classification in all endpoints harmonized, but DS has submitted only data for some of them. We have added justification of read across approach at the beginning of section Human Health Hazard Assessment

Carcinogenicity

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		No comments received.		

Mutagenicity

Date	Country/ Person/ Organisation/ MSCA	Comment	Response of the dossier submitter	RAC comments
		No comments received.		

Toxicity to reproduction

/Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comments
		No comments received.		

Respiratory sensitisation

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comments
		No comments received.		

Other hazards and endpoints

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comments
20/04/2011	Germany / Sabine Hildenbrand / Detia Freyberg GmbH / Company-Importer	p. 8 Explosive properties Please correct guideline: Guideline 92/69/EEC, A.14 p. 8 Relative Self-ignition temperature for solids Please correct guideline: Guideline 92/69/EEC, A.16 p. 11 Manufacture and uses please add the following text to point 2.1, 2.2 and 2.3: Not relevant for this type of dossier. p.22 References Please add Reference BAM II.2 (2010)and BAM II.21	Correction on p. 8 Explosive properties: To delete: OECD Test No.113 (DSC): $\Delta H <$ 500J/g (exothermic decomposition energy) explosive properties can be excluded. To insert: Trimagnesium diphosphide has no explosive properties in the sense of Guideline 92/69/EEC, A.14. Typo on p. 8 Relative Self-ignition temperature for solids: To delete: Guideline 96/69/EEC, A.16:	DS submitter have included these suggestions into background document

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			To insert: Guideline 92/69/EEC, A.16 We add text on p. 11: Not relevant for this type of dossier. Correction on p. 21: Add reference: BAM II.2 – 2010 - Expert judgement by BAM Federal Institute for Materials Research and Testing, Division II.2, Berlin, Germany.	
05/05/2011	France / Member State	Acute toxicity: dermal (p.15) The dermal DL50 for MG3P2 calculated from the acute dermal toxicity study on Aluminium phosphide is 1 047 mg/kg that leads to propose a classification as Acute Tox. 4 – H312 (not Acute tox.3 – H311) according to Annex I of Regulation 1272/2008/CE. Please correct.	As already mentioned in the CLH-Report, for Mg_3P_2 classification as Acute Tox. 3 – H311 is proposed. This proposal is based on the fact that only a dermal toxicity study performed with AlP is available: The LD_{50}-value in this study of 900 mg/kg bw AlP indicated category 3 – H311, but expressed as Mg_3P_2 (1047 mg/kg bw) the range for category 3 is slightly exceeded. However, since the proposal for Mg_3P_2 is based on read across from AlP the same proposal for both metal phosphides on	We agree with that proposal and considered it in draft opinion. The results of other relevant studies have been taken into account in the final opinion.

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			dermal toxicity seems to be appropriate.	
06/05/2011	Finland / Hinni Papponen / Member State	Acute Oral toxicity We agree that the classification of AlP as Acute Tox. 2, H300 is confirmed, since the LD50 values for oral toxicity were within the ATE limits of category 2. Acute dermal toxicity In the CLH report one dermal study done with aluminium phosphide is introduced. Based on this study aluminium phosphide is proposed to be classified Acute Tox 3, H311/ Xn, R21 and the same classification is also proposed to Mg3P2 using read across method. Document attached in IUCLID file contains information of edema or hemorrhagic infiltrations development to the treated skin in the study for acute dermal toxicity used in CLH report. However, the possible influence of these skin reactions to the dermal absorption is not considered. In skin irritation studies only slight edema has been reported after removal of the test substance, and the substance is not classified for skin or eye irritation. The explanation for differing skin effects may be related to used vehicles or animal species. With some other weaknesses of this study that are considered in IUCLID file, this raises the question of the usability of this study. Metalphosphides have been evaluated as active substances in Plant Protection and Biocidal Products. It seems that during that evaluation process also other studies have been available, such as acute dermal toxicity studies for aluminium phosphide and zinc phosphide and these should also be assessed in the CLH report. When using read across among metal phosphides all available information should be used, or justify why selected studies are the most appropriate. (In public available documents: EFSA: Conclusion regarding the peer review of the pesticide risk assessment of the active substance aluminium phosphide, EFSA: Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide, Draft Assessment Report (DAR): Zinc phosphide.)	Thank You. First of all, the available dermal toxicity studies were considered to be supplementary only due to limitations in the study designs. However, taken into account that the LD_{50}-values in all dermal toxicity studies were within the same range, the observed skin effects in the study by Dickhaus & Heisler, (1987) were considered not to have any influence on the dermal toxicity of AlP. Due to the decomposition by moisture other phosphides than magnesium phosphide are regarded as adequate model compounds in acute toxicity studies. However, it was agreed to refer only to those	Thank you Since DS did not submitted any proposal of classification on skin irritation, RAC cannot initiate this process.

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			studies in the CLH-Report on which the proposal for C&L is based on.	
09/05/2011	United Kingdom / Member State	Acute Oral Toxicity: We support the proposal for acute oral toxicity classification. To assist the reader, it would help if the criteria for Acute Tox 2 were stated (i.e., 5 < ATE ≤ 50 mg/kg bw) in the brief discussion following Table 4. Also, as it is mentioned in the table, it would be beneficial to state the criteria for R28 (i.e., LD50 ≤ 25 mg/kg bw). Acute Dermal Toxicity Is it possible that the mortalities in this study were due to phosphine being liberated as the aluminium phosphide reacts with the moisture in the air and in sweat? If so, it is quite likely that classification for acute dermal toxicity is not necessary, as the observed mortalities are secondary to phosphine gas toxicity. In the toxicokinetics section (section 5.1), it states that dermal absorption is 'negligible' and that contact with the humid skin surface is expected to initiate the liberation of PH3 gas. We would suggest that, in light of our comments above this is considered further. In addition, it is not clear what is meant by the final paragraph "As it is believed that PH3 is liberated from metal phosphides rather more readily by acids than by water, this appears to be accidental." Is this referring to the omission of EUH032 from the classification of trimagnesium phosphide? If so, it would be useful if this was stated more clearly.	Noted It seems unlikely that the mortalities occurred in the dermal toxicity study were due to inhaled phosphine (liberated from AlP): In acute inhalation studies mortality occurs normally within one day (1-4 hr, during exposure), in contrast to the acute dermal toxicity study, where lethality was observed within one and 7 days after administration of significant higher doses. Additional proposal: R32 based on Annex VI of Council Directive 67/548/EEC and EUH032 (Contact with acid liberates very toxic	Thank you. Included in comparison with classification criteria Having in mind large doses applied on skin: 500, 1000 and 2000mg/kg it is unlikely that inhalation exposure was probably a cause of death. The lethal doses would be much smaller – compare with oral LD50 equal 11.2 mg/kg, thus 100 times lower than dermal LD50. Thus dermal absorption is significantly

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			gas) based on Annex I of Regulation (EC) No. 1272/2008	lower than absorption in gastrointestinal tract. .