Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

aluminium phosphide

ECHA/RAC/CLH-O-0000002201-92-01/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: **aluminium phosphide**
CAS number: **20859-73-8**
EC number: **244-088-0**

General comments

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
20/04/2011	Germany / Sabine Hildenbrand / Detia Freyberg GmbH / Company Manufacturer	p. 4 P231 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 Aluminium phosphide. Phostoxin WM is a preparation with ignition inhibiting additives, therefore it is not comparable with Aluminium phosphide.	Agree with DS
04/05/2011	Spain / Member State	The proposed Classification and Labelling fulfils the criteria established both in CLP Regulation and 67/548/EEC Directive. In general terms, the Spanish CA supports the German proposal to establish a harmonised classification & labelling for aluminum phosphide. Additionally we propose its classification as Acute Tox. 1 (inhalation) H330: Fatal if inhaled according to Regulation EC 1272/2008 and as T+; R26 Very toxic by inhalation according to Directive 67/548/EC	This should be discussed by RAC	Agree with DS
06/05/2011	France / Member State	France has no specific comment and agrees with the RMS proposal	Thank you	noted
09/05/2011	United Kingdom	Justification	According to	Agree with DS

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
	/ Member State	Aluminium phosphide is an active substance in plant protection and biocidal products. Generally, such substances are subject to harmonised classification for all hazard classes. In this case, only certain hazard classes (acute oral and dermal toxicity) have been addressed, but it has not been made clear why the other hazard classes have not been included. The dossier only 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.	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.	
		P13. Section 5.1. This section does not add any real value to the document, and we suggest it could be reduced in size. The key point is that the toxicity of metal phosphides is related to the liberation of hydrogen phosphide (PH3) gas when such substances hydrolyse with water or acids. Toxicokinetics This section does not appear to add any useful information relevant for the classification of aluminium phosphide, and could be deleted or significantly reduced.	Additional proposal: R32 based on Annex VI of Council Directive 67/548/EEC and EUH032 (Contact with acid liberates very toxic gas) based on Annex I of Regulation (EC) No. 1272/2008	

Carcinogenicity

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

Mutagenicity

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

Toxicity to reproduction

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

Respiratory sensitisation

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

Other hazards and endpoints

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
20/04/2011	Germany / Sabine Hildenbrand / Company Manufacturer	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.21 References Please add Reference BAM II.2 (2010	Correction on p. 8 Explosive properties: To delete: OECD Test No.113 (DSC): ΔH< 500J/g (exothermic decomposition energy) explosive properties can be excluded. To insert: Aluminium	Noted

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
			phosphide 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: To insert: Guideline 92/69/EEC, A.16 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.	
04/05/2011	Spain / Member State	p. 7-10 and p.17 Summary of discussion of human health of Physico-chemical properties Flammability The Spanish CA supports the proposed classification of aluminium phosphide as Water-react. 1 H260: In contact with water releases flammable gases which may ignite spontaneously and EUH029 Contact with water liberates toxic gas according to Regulation EC 1272/2008 and as F; R15/29 Contact with water liberates toxic extremely flammable gases according to Directive 67/548/EC. The classification is based on the well known chemical properties of aluminium phosphide to generate toxic gas phosphine in contact with water and the results obtained in flammability studies (Smeykal, 2002). Contact with acids liberates very toxic gases The Spanish CA supports the proposed classification of aluminium phosphide as EUH032 Contact with acids	No further comment; see above.	Noted

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
		liberates very toxic gas according to Regulation EC 1272/2008 and as R32 Contact with acids liberates very toxic gases according to Directive 67/548/EC. The classification is based on the well known chemical properties of aluminium phosphide to generate toxic gas phosphine in contact with acids. p. 14 Summary and discussion of acute toxicity Acute oral toxicity The Spanish CA supports the proposed classification of aluminium phosphide as Acute Tox. 2 (oral) (H300: Fatal if swallowed) (limits LD50 = 5-50 mg/kg bw) according to Regulation EC 1272/2008 and as T+; R28: Very toxic if swallowed (limits LD50 ≤ 25 mg/kg bw) according to Directive 67/548/EC. This classification is due to the LD50 values obtained in two acute oral toxicity studies in rats: LD50 = 8,7 mg/kg bw (Sterner, 1977) and LD50 = 14,8 mg/kg bw (Leuschner, 1992). Acute dermal toxicity The Spanish CA supports the proposed classification of aluminium phosphide as Acute Tox. 3 (dermal) H311: Toxic in contact with skin (limits LD50 = 200-1000 mg/kg bw) according to Regulation EC 1272/2008 and as Xn; R21 Harmful in contact with skin (limits LD50 = 400-2000 mg/kg bw) according to Directive 67/548/EC. This classification is due to the LD50 values obtained in three acute dermal toxicity studies in rats: LD50 = 900 mg/kg bw (Dickhaus, 1987), LD50 = 461,2 mg/kg bw (Stephen, 2000), LD50 = 901 mg/kg bw (Joshi, 1998). Acute inhalation toxicity The acute inhalation toxicity is not covered by the German Proposal. However the Spanish CA supports the classification of aluminium phosphide as Acute Tox. 1 (inhalation) H330: Fatal if inhaled according to Regulation EC 1272/2008 and as T+; R26 Very toxic by inhalation according to Directive 67/548/EC. This classification is due to the obtained value (Roy, 1998) LC50 = 0,048 mg/l (phosphine levels liberated from aluminium phosphide dust). Moreover,it is reported that phospine gas is released from inhaled aluminium phosphide dust in the moist air sacs of the lung(1,2). Phosphine is classified as T+; R26 Very toxic by inhalation according to Directive 67/548/EC and as Acute Tox. 1 (inhalation) H330: Fatal if inhaled according to CLP Regulation. The draft EFSA Scientific Report (2008) proposed, as well, classifies aluminium phosphide with T+; R26. References 1. Gehring, P.J., Nolan, R.J., Watanabe, P.G. and Schumann, A.M. 1991. Chapter 14: Solvent, Fumigants and Related Compounds, In Hayes, W.J. and Laws, E.R., Jr. (Eds.) Handbook of Pesticide Toxicology, Academic Press, New York, NY. 2. U.S. Department of Health and Human Services. 1994. File: Aluminum Phosphide Hazardous Substance Data Base (HSDB). HHS. Washington, DC.		
06/05/2011	Finland / Hinni Papponen /	Acute Oral toxicity: We agree that the classification of AlP as Acute Tox. 2, H300 is confirmed, since the LD50 values for oral	First of all, the available dermal	Agree with DS

Date	Country / Person / Organisation / MSCA	Comment	Response of the dossier submitter	RAC comment
	Member State	toxicity were within the ATE limits of category 2. Acute dermal toxicity: 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. Since we don't have access to the original study report, we request a careful consideration of validity of this study. If this study is considered to be valid and adequate, we agree the proposed classification for acute dermal toxicity (R21 according to Annex VI of Council Directive 67/548/EEC; Acute Tox 3 H311 according to Annex I of Regulation (EC) No. 1272/2008). 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 another acute dermal toxicity study for aluminium phosphide and these should also be assessed in the CLH report. (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.)	toxicity studies were considered to be supplementary only due to limitations in the study designs. However, taken into account that the LD50-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 aluminium phosphide are regarded as adequate model compounds in acute toxicity studies. However, it was agreed to refer only to those studies in the CLH-Report on which the proposal for C&L is based on.	
09/05/2011	United Kingdom / Member State	P14. Section 5.2.1 Acute toxicity (oral). We agree that the data presented confirm the minimum classification of Acute Tox 2, H300. To assist the reader, it would help if the criteria for Acute Tox 2 were stated (i.e., $5 < ATE \leq 50$ 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).	noted	noted

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		P15. Section 5.2.3 Acute toxicity (dermal). 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.	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.	