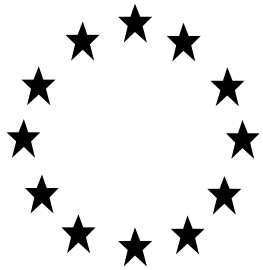
Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Aluminium phosphide releasing phosphine

Product-type 18 (Insecticides, Acaricides and Products to control other Arthropods)

17th September 2009

Annex I - Germany

Aluminium phosphide releasing phosphine (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 17 September 2009 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of aluminium phosphide releasing phosphine as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Aluminium phosphide (CAS No. 20859-73-8) was notified as an existing active substance, by Detia Freyberg GmbH, Germany, hereafter referred to as the applicant, in product-type 18.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for aluminium phosphide as an active substance in product-type 18 was 30 April 2006, in accordance with Article 9 of Regulation (EC) No 1451/2007.

On 27 April 2006, the German competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 26 October 2006.

On 26 October 2007, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 12 November 2007. The competent authority report included a recommendation for the inclusion of aluminium phosphide in Annex I to the Directive for product-type 18.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 29 February 2008. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of aluminium phosphide releasing phosphine in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 17 September 2009. As aluminium phosphide releases phosphine gas, which is acting as the biocidal active substance under use conditions, aluminium phosphide is included in Annex I to Directive 98/8/EC as "aluminium phosphide releasing phosphine".

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 17 September 2009.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include aluminium phosphide in Annex I to Directive 98/8/EC for product-type 18. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 18 that contain aluminium phosphide. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing aluminium phosphide for the product-type 18, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern

3 http://ec.europa.eu/comm/environment/biocides/index.htm

beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity, Physico-chemical Properties and Method of Analysis of Aluminium phosphide

The identity of aluminium phosphide (CAS-No. 20859-73-8) is given in detail in the confidential part of the dossier. The evaluation has established that for the active substance notified by Detia Freyberg GmbH, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Aluminium phosphide is a grey powder with a foul fishy, garlic-like odour that releases highly toxic, extremely flammable and pyrophoric phosphine gas when exposed to moisture. Its vapour pressure (< 10^{-5} Pa at 25 °C) is low. Due to hydrolysis, the log P_{ow} of aluminium phosphide is not experimentally determinable.

Aluminium phosphide is thermally stable and does not form breakdown products while heating up to 500 °C. The substance evolves highly flammable gases in contact with water or humid air, is not explosive nor has oxidising properties and has no relative self-ignition up to 400 °C.

Residue analytical methods are available for residues of aluminium phosphide (determined as phosphine (PH_3)) in air, in water, in animal tissues and in plant material. Analytical methods are not required for soil (none) and water (confirmatory method).

Identity, Physico-chemical Properties and Method of Analysis of Phostoxin and DETIA-GAS-EX B

The identity of the rodenticide insecticides Phostoxin, which contains 56 % of the active substance aluminium phosphide, and DETIA-GAS-EX B, which contains 57% of the active substance aluminium phosphide, are given in detail in the confidential part of the dossier. Due to the nature of the biocidal products, Phostoxin and DETIA-GAS-EX B are not expected to exhibit any hazardous physico-chemical properties.

Aluminium phosphide (determined as PH_3) is the only substance of concern and adequate methods are provided for drinking and surface water, air, animal tissues and in plant material. Therefore, additional analytical methods to determine residues of aluminium phosphide from the biocidal products DETIA-GAS-EX B and Phostoxin in food and feedingstuffs, are not considered necessary. Likewise, analytical methods are not required for soil (none) and water (confirmatory method, Independent Laboratory Validation).

2.1.2. Intended Uses and Efficacy

The products Phostoxin and DETIA-GAS-EX B containing the active substance aluminium phosphide are intended to be used against insects to protect storage goods like animal feed and feed ingredients, food and food ingredients (for example: corn flakes, potato products, cured, dried and processed meat and fish products, dairy products or chocolate and chocolate products) and non-food items (for example: processed natural fibres (e.g. wool, cotton, cloths, etc.), leather, paper and paper products or packing material (e.g. cardboard boxes, paper and

jute bags)). The products can be applied successfully under almost all storage conditions, provided that the structure is tightly sealed (silos, flat storage, stacks). The products are effective fumigants against all kinds of storage pests (moths, beetles, etc.) including all stages of development.

Based on the available information, it is expected that a high risk may exist for development of resistance to phosphine by stored product insects. Precautions have to be taken to reduce the possibility of insects developing resistance to fumigants. Therefore, a management strategy is proposed for the application of the products Phostoxin and DETIA-GAS-EX B, for the timing of their applications and for monitoring of populations in key areas in order to detect any significant changes in susceptibility. The products have to be applied only by trained and certified personnel / users.

2.1.3. Classification and Labelling

Classification and labelling of the active substance

Evaluation of the submitted data under Directive 98/8/EC resulted in the following proposal for classification and labelling:

Table 2-1 Proposed classification for aluminium phosphide

Class of danger	F	Highly flammable
	T+	Very toxic
	(Xn)	Harmful
	N	Dangerous to the environment
R phrases	R 15/29	Contact with water liberates toxic extremely flammable gas
	R 21	Harmful in contact with skin
	R 28	Very toxic if swallowed
	R 32	Contact with acids liberates very toxic gas
	R 50	Very toxic to aquatic organisms
S phrases	S (1/2)	Keep locked up and out of the reach of children.
	S 8	Keep container dry
	S 3/9/14/49	Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer)
	S 30	Never add water to this product.
	S 36/37	Wear suitable protective clothing and gloves.

	S 45	In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.)
	S 60	This material and/or its container must be disposed of as hazardous waste
	S 61	Avoid release to the environment. Refer to special instructions/ material safety data sheet

Note:

Phosphine which develops after contact of aluminium phosphide with water by spontaneous hydrolysis of the phosphide is very toxic by inhalation. According to Annex I to Directive 67/548/EEC, classification and labelling of the gas is appropriate (T+; R 26) but aluminium phosphide itself is not classified with regard to inhalation toxicity.

In deviation to the applicant's classification and existing legal classification/labelling of aluminium phosphide, a classification and labelling as '**harmful in contact with skin' (Xn; R 21)** is proposed in addition to the already existing legal classification/labelling, because aluminium phosphide is of moderate acute dermal toxicity.

S 49 is considered necessary for aluminium phosphide. Furthermore, labelling with S 60 'This material and/or its container must be disposed of as hazardous waste' is proposed.

Concerning labelling of S28 (which normally is obligatory for very toxic substances according to Dir. 67/548/EEC), it is accepted that brushing or wiping off of aluminium-phosphide-dust is more reasonable than washing it from skin or cloth, but this wording is not possible within S28. Instead, it is recommended to label the GHS-P335 "Brush off loose particles from skin" and hair (or similar: skin and hair must be brushed free of residues in a well-ventilated place after contact and always after work and before washing, eating, drinking or going out in the rain), voluntarily.

Classification and labelling of the biocidal products

Table 2-2 Proposed classification Phostoxin" and "DETIA-GAS-EX B"

Class of danger	F	Highly flammable
	T+	Very toxic
	(Xn)	(Harmful)
	N	Dangerous to the environment
R phrases	R 15/29	Contact with water liberates toxic extremely flammable gas
	R 21	Harmful in contact with skin
	R 28	Very toxic if swallowed
	R 32	Contact with acids liberates very toxic gas
	R 36	Irritating to eyes
	R 50	Very toxic to aquatic organisms
S phrases	S (1/2)	Keep locked up and out of the reach of children.
	S 3/9/14/49	Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer)
	S 7/8	Keep container tightly closed and dry.
	S 30	Never add water to this product.
	S 36/37	Wear suitable protective clothing and gloves.
	S 45	In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.)
	S 60	This material and/or its container must be disposed of as hazardous waste
	S 61	Avoid release to the environment. Refer to special instructions/ material safety data sheet

Remark:

In addition to the current legal classification and labelling, Xn, R 21 is considered necessary for aluminium phosphide, which has to be adopted for Phostoxin and DETIA-GAS-EX-B since the limit concentration of 25 % (w/w) (Directive 1999/45/EC) is exceeded in the biocidal products.

No studies with respect to skin and eye irritation were submitted. However, eye irritation properties of metal phosphide products are known from similar plant protection products and are additionally based on mechanistic considerations. Since the compositions of the products are almost identical to Phostoxin and DETIA-GAS-EX-B, the classification with R 36 (Irritating to eyes) is also adopted for the biocidal products. Thus, Phostoxin and DETIA-GAS-EX-B have to be classified and labelled as R 36 (Irritating to eyes).

Additionally, one of the stabilisers used in the formulation Phostoxin, representing 21 % w/w of the total amount, has been proposed to be classified "Irritating to eyes" (R 36) by its manufacturer. Since the concentration in the product is beyond the threshold value for classification, R 36 is allocated for Phostoxin according to the Conventional Method of Directive 1999/45/EC.

At present, the biocidal product Phostoxin is placed on the market as a plant protection product with the identical composition to the biocidal product in Germany. The current S-phrases of the products Phostoxin and DETIA-GAS-EX-B are based on the evaluation in the frame of self classification of the applicant. On the other hand, the allocation of S-phrases on basis of the Directive 1999/45/EC leads to differing results (see table 2-2).

Proposed packaging and labelling

The applicant refers to the resistance of tightly closed Aluminium bottles that were tested by Detia Freyberg GmbH itself.

Additionally, it is suggested to use containers made of austenitic Cr-Ni or Cr-Ni-Mo-steels and plastics. In any case, moisture has to be excluded, which can be managed by closing the containers tightly and adding a small bag of silica gel.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, distribution, excretion, and metabolism

Metal phosphides in contact with moisture (GI tract) readily decompose to metal or e.g. aluminium hydroxide and phosphine, the toxicological principle. Due to the decomposition by moisture, other phosphides are regarded as adequate model compounds. Studies with zinc phosphide and phosphine are available. Once formed from the metal phosphide, phosphine is rapidly and completely excreted by exhalation or via urine after oxidation to hypophosphite or phosphite. The phosphine metabolites, hypophosphite or phosphite, are regarded as less toxic than phosphine itself.

Following oral administration of zinc phosphide, ^{32}P was rapidly absorbed from the gastrointestinal tract. Inhaled PH_3 is considered to be rapidly and quantitatively absorbed through the lungs. ^{32}P was detectable in all organs and tissues, with temporary higher levels in liver and medulla oblongata. PH_3 is excreted as such with the expired air or, after metabolic oxidation, with the urine in the form of hypophosphite and phosphite.

In the absence of experimental data, for dermal absorption of both aluminium phosphide and PH_3 a default value of a maximum of 10 %, based on expert judgement, is assumed.

- Due to the nature of the formulated product (pellets or tablets), only a minor part of the active substance, if any, is expected to come into contact with the skin.
- Contact with the (humid) skin surface would be expected to initiate liberation of PH_3 gas making systemic absorption highly unlikely.
- In previous evaluations by both the WHO (Environmental Health Criteria 73 of 1988) and the German 'MAK-Kommission' for aluminium phosphide/PH_3 dermal absorption was stated to be negligible.
- In decades of approved use, no casualties or serious intoxications have been reported for operators dermally exposed to aluminium phosphide.

Acute toxicity

Aluminium phosphide is of high toxicity when administered orally to rats and mice. Therefore, classification as 'very toxic if swallowed' (T+; R 28) is required. PH_3, which is developed after contact of aluminium phosphide with water by spontaneous hydrolysis of the phosphide, is very toxic by inhalation. According to Annex I to Directive 67/548/EEC, classification and labelling of the gas is appropriate (T+; R 26), but aluminium phosphide itself is not classified with regard to inhalation toxicity.

In addition to T+; R 28, aluminium phosphide has also been classified and labelled with F; R 15/29 ('contact with water liberates toxic extremely flammable gas') and R 32 ('contact with acids liberates very toxic gas') according to Annex I to Directive 67/548/EEC. Furthermore, aluminium phosphide is of moderate acute dermal toxicity. Therefore, classification as 'harmful in contact with skin' (Xn; R 21) is proposed in addition to the already existing legal classification/labelling.

No eye irritation and only slight (below threshold for classification) and rapidly reversible signs of dermal irritation were noted after application of aluminium phosphide to the eye and skin of rabbits. Aluminium phosphide is not considered to be irritating/corrosive to skin and/or eyes.

No sensitisation study has been presented using aluminium phosphide but a Buehler-test (three induction applications) performed with the biocidal product was submitted. The findings of this experiment can be applied to the active substance since the product contains 56 % active substance. Thus, aluminium phosphide is considered not sensitising via the skin. The Buehler-test was accepted in this particular case instead of the usually preferred guinea pig maximisation test for reasons of animal welfare based on the consideration that no evidence of any sensitising potential of the active substance has been noted in humans although it has already been on the market for 40 years.

Medium-term toxicity

In an oral 90-day gavage test, mortality was increased at 2 mg aluminium phosphide/kg bw/d (corresponding to 1.18 mg PH_3/kg bw/d) in both sexes, the NOAEL being 1 mg aluminium phosphide/kg bw/d, equivalent to 0.59 mg PH_3/kg bw/d, respectively. However, these values

are considered to be of limited reliability due to methodological deficiencies of the respective study report. As the oral route is not seen as being relevant with regard to the intended use of aluminium phosphide as an insecticide and based on other data sources claiming that non-rodents are not more sensitive to aluminium phosphide/PH_3 toxicity than rodents, the applicant's justification for non-submission of an oral subchronic study in a non-rodent species was accepted.

After inhalative administration of up to 3 ppm PH_3 gas (equivalent to ca. 1.1 mg/kg bw/d) to rats over a period of 90 days, no substance-related adverse effects were observed. Two satellite groups at 5 and 10 ppm, respectively, were introduced during the course of the study. In the 5 ppm satellite group, which received the test item for only 2 weeks, no relevant effects were observed (which is in accordance with the NOAEL of 4.9 ppm in the inhalative developmental study in rats, cf. below). Inhalative administration of 10 ppm PH_3 (3.8 mg PH_3/kg bw/d) was terminated after 3 days, when already 4/10 females had died.

A subchronic inhalation study in a second, non-rodent species was not submitted. The applicant provided an expert statement that the toxicological profile of aluminium phosphide/PH_3 does not differ significantly between rodents and non-rodents and thereby justified non-submission of such data.

In summary, a medium-term NOAEL of 1.1 mg PH_3/kg bw/d, equivalent to 1.9 mg aluminium phosphide/kg bw/d, was established.

Genotoxicity

The submitted in vitro and in vivo studies showed negative results. Overall, the submitted data base on genotoxicity was seen as sufficient and aluminium phosphide/PH_3 is not likely to be genotoxic in humans.

Chronic toxicity/ Carcinogenicity

Following inhalative administration of up to 3 ppm PH_3 gas (equivalent to ca. 1.1 mg PH_3/kg bw/d and 1.9 mg aluminium phosphide/kg bw/d; the highest concentration tested) to Fischer rats over a period of 104 weeks, no significant substance-related adverse effects were observed. There was no evidence of a carcinogenic effect.

No long-term study in a second species was submitted. Waiving was accepted based on the considerations that species-specific differences do not seem likely as well as taking into account the absence of genotoxic concern.

Reproduction toxicity

In an inhalative developmental study in rats, no treatment-related effects were observed up to 4.9 ppm PH_3 (equivalent to 1.9 mg PH_3/kg bw/d). However, at 7.0 ppm (2.7 mg PH_3/kg bw/d), the first 14 mated females died after 3-10 days of exposure. There was no evidence of reproductive disturbing effects at dose levels below maternal toxicity.

No multi-generation study and no developmental toxicity study in a non-rodent species were submitted. Waiving was accepted based on the steep dose response curve of aluminium phosphide/PH_3 toxicity from which it can be assumed that maternal mortality would dominate over reproductive effects. Furthermore, no developmental or reproductive effects were

observed in the teratogenicity study in rats. Subchronic or chronic toxicity studies did not reveal that tissue associated with reproduction are targets for PH_3 mediated toxicity.

Neurotoxicity

The neurotoxicity of phosphine has been assessed in rats in an acute and a 90-day inhalation study. In the acute neurotoxicity study, the NOAEL of phosphine in rats was 38 ppm with regard to neuropathology and the behavioural and neurological status observed in the functional observational battery and less than 21 ppm with regard to changes in motor activity on day one. The latter effect was not considered as a specifically neurotoxic finding but was seen as a clinical sign related to high dose levels at or exceeding those fatal in the acute lethality studies.

In the subchronic neurotoxicity study, the NOAEL of phosphine for systemic (including motor activity)/ neurotoxic effects in rats was 3 ppm, the highest dose tested in this study.

Thus, no specific substance-related neurotoxicity was observed in the toxicological database.

Mechanistic studies

It was demonstrated that phosphine or other phosphide- derived reaction products induced Heinz body formation in relatively low concentrations (1.25 ppm) in normal human erythrocytes. The time course for the induction of Heinz bodies is relatively slow (4 h). The formation of Heinz bodies by phosphine is oxygen-dependent, consistent with earlier work regarding the insecticidal properties of the chemical. Finally, these in vitro data lead to the speculation that prolonged in vivo exposure to phosphine in concentrations exceeding the permissible exposure limit (PEL) might have an adverse effect on haemoglobin in susceptible segments of the worker population exposed to the chemical.

The results of another study show that after acute poisoning of rats by phosphine the respiration of the isolated liver-mitochondria is diminished. The oxidation of α-ketoglutarat turned out to the most sensitive. The oxidative phosphorylation, however, remains on a normal level. In general, the disturbance equals that of phosphine action on isolated mitochondria in vitro. Similar effects have been observed on the isolated sarcosomes of heart muscle of poisoned animals on an early state of intoxication. But in the sarcosome, respiration and phosphorylation is uncoupled at the same time. Since the respiration of *Neurospora crassa* is also decreased by phosphine, it is to assume that this agent acts by this mechanism on living cells in general. The same kind of disturbance can be demonstrated in the mitochondria after chronic administration of doses which are far below the toxic ones of phosphine and by which animals don't show any sign of damage. There is a small but considerable fall of CoA in the liver of acute poisoned animals.

Medical data

No significant effects caused by PH_3 in personnel with occupational exposure have been observed except for one study report (Garry et al.), in which chromosome aberrations were reported in fumigators stated to have been exposed exclusively to PH_3 gas. However, it was not possible to assess exact exposure conditions from this publication. Also, it was not clear, whether other possible confounding factors (e.g. smoking, age) were adequately considered in this study. The case reports submitted by the applicant are considered to be representative of the numerous records of poisoning cases which are available from the literature, in connection

with suicide, but also with accidental poisoning among others of children in developing countries.

Diagnosis is mainly based on the history of intake, gastrointestinal symptoms, shock symptoms and silver nitrate impregnated paper test. Main symptoms are severe circulatory, cardiac, and renal failure, uraemia, hepatic damage, changes in ECG, and respiratory distress connected with a high mortality rate. Histopathological changes have mainly been observed in lungs, liver, heart and kidney. Since an antidote is not available, therapy relies on treatment of the clinical symptoms and administration of high doses of corticoids.

Biocidal Products Phostoxin and DETIA-GAS-EX-B

The insecticides Phostoxin and DETIA-GAS-EX-B containing 56% to 57% (w/w) aluminium phosphide, respectively, are very toxic if swallowed (T+; R 28). An acute oral toxicity study was performed with a biocidal product that is considered identical to Phostoxin. The results of this study are also adopted for DETIA-GAS-EX-B since the content of the active substance, which is also the most acute toxic ingredient of the biocidal product, is almost the same. No acute dermal and no inhalation study were performed using Phostoxin or DETIA-GAS-EX-B.

Phostoxin and DETIA-GAS-EX-B are not irritating to the skin but are considered as irritating to eyes. This classification was deduced from information of similar plant protection products as well as mechanistic considerations. Since the mode of action of metal phosphides (hydrolysis) is comparable and since the compositions of these products are almost identical to Phostoxin and DETIA-GAS-EX-B this classification is also adopted for the biocidal products.

A Buehler-test using a biocidal product identical to Phostoxin was submitted yielding no signs of sensitisation. In consequence, Phostoxin and DETIA-GAS-EX-B are regarded as non-sensitising.

2.2.1.2. Effects assessment

Metal phosphides in contact with moisture (GI tract) readily decompose to metal or e.g. aluminium hydroxide and phosphine, the toxicological principle. Due to the decomposition by moisture, other phosphides are regarded as adequate model compounds. Once formed from the metal phosphide, phosphine is rapidly and completely excreted by exhalation or via urine after oxidation to hypophosphite or phosphite.

Following oral administration of zinc phosphide, ^{32}P was rapidly absorbed from the gastrointestinal tract. Inhaled PH_3 is considered to be rapidly and quantitatively absorbed through the lungs. ^{32}P was detectable in all organs and tissues, with temporary higher levels in liver and medulla oblongata. PH_3 is excreted as such with the expired air or, after metabolic oxidation, with the urine in the form of hypophosphite and phosphite.

In the absence of experimental data, for dermal absorption of both aluminium phosphide and PH_3 a default value of a maximum of 10 %, based on expert judgement, was assumed.

Aluminium phosphide and phosphine gas, which is liberated from the former by contact with moisture, are of high toxicity when ingested or inhaled, respectively. Aluminium phosphide is harmful upon skin contact. With regard to local toxicity, aluminium phosphide was found to be neither irritating to skin nor to the eyes, and it was not sensitising via the dermal route.

Based on the available data, a genotoxic or carcinogenic potential of aluminium phosphide or PH_3 can be considered as unlikely. The same holds true for effects on fertility or the development of offspring after treatment of parental animals, where mortality is regarded as the pre-dominant effect. Furthermore, no specific substance-related neurotoxicity was observed in the toxicological database.

From the NOAELs obtained in the 90-day and 2-year inhalation studies performed with PH_3 in rats, a Systemic Acceptable Exposure Level (AEL) of 0.011 mg PH_3/kg bw/d (corresponding to 0.019 mg aluminium phosphide/kg bw/d) was derived for medium and long-term exposure applying a default assessment factor of 100.

An AEL for acute exposure of 0.019 mg/kg PH_3/kg bw/d (equivalent to 0.032 mg aluminium phosphide/kg bw/d) was set based on the NOAEL from the developmental inhalation study in rats applying a default assessment factor of 100.

Taking into account the proposed use of the products as insecticide for fumigation of stored goods in closed/sealed rooms and fumigation of empty rooms for all types of non-agricultural purposes, it is not expected that residues of aluminium phosphide in food or feeding stuffs will occur in relevant amounts. Anyhow, they cannot be excluded with certainty and therefore, based on the 2-year inhalation study and the developmental study in rats, an Acceptable Daily Intake (ADI) of 0.011 mg PH_3/kg bw (0.019 mg aluminium phosphide/kg bw) and an Acute Reference Dose (ARfD) of 0.019 mg PH_3/kg bw (0.032 mg aluminium phosphide/kg bw) are proposed.

2.2.1.3. Exposure assessment

Exposure of Professionals

Aluminium phosphide and the biocidal products are produced within the EU. The biocidal products Phostoxin (pellets/tablets, 56 % active substance) and DETIA-GAS-EX-B (bag chain, 57 % active substance) are intended for the use in fumigation of stored goods in closed/sealed rooms and empty rooms, to control insects. In case of inhalation exposure, the exposure to phosphine and dust of aluminium phosphide is estimated whereas the dermal exposure is assessed for the contact to aluminium phosphide dust.

The following scenarios are covered by this exposure assessment:

- Application of pellets/tablets using an applicator in storage flat rooms (scenario 1)
- Application of bag chain in storage flat rooms (scenario 2)
- Secondary exposure during fumigation period (scenario 3)

The biocidal product can be used in form of pellets (0.6 g) tablets (3 g) or bag chain (340 g) for grain fumigation. Due to the gap of information considering the application in ships, containers, silo etc., it is decided to assess the use of pellets/tablets and bag chains only in flat storage rooms. The assessment is based on a study report determining the inhalation exposure to phosphine during the application of pellets in a flat storage room by an applicator (scenario 1). Due to the limitations of the provided measurement results in the study it is decided to use the highest determined values and to add in an error metering precision. The potential inhalation exposure is assessed for all phases of application: opening of flasks with pellets/tablets or package of bag chain; application by applicator pellets/tablets or bag chain into grain; sheeting of grain; ventilation of site and de-sheeting of plastic sheeting and removal of product residues from grain. The highest exposure values were observed during the opening of the flasks, during the application and de-sheeting procedure. The shift averages for potential inhalation exposure is > 2 mg/m^3 and above the occupational exposure level of 0.14 mg/m^3 (SCOL-recommendation). However the operators wear respiratory protective equipment during all phases of handling the biocidal products (for details please see Table 2-3 below).

It is assessed that the level of exposure to phosphine estimated for the application of pellets/tablets is also valid for the application of bag chains (scenario 2) since the degassing behaviour is nearly equivalent for pellets, tablets and bag chains.

In addition to the potential inhalation exposure a potential dermal exposure due to the application of pellets/tablets is expected and assessed by expert judgement (layer of product on the skin). The potential dermal exposure is estimated to be 1.9 mg/person/day for tablets and 3.0 mg/person/day for pellets (scenario 1). The potential dermal exposure is significantly reduced using a bag chain since the active substance is sealed in bags (scenario 2).

For the secondary exposure during the fumigation period (scenario 3) it is expected that nobody enters incidental the fumigated flat storage room, since the flat storage room is sealed and marked as restricted area. This restricted area is within a larger ‘danger area’ and access to this is also restricted. This assessment is valid for the use of pellets/tablets and bag chains.

For the application of aluminium phosphide products in ships, containers, silo etc. it is expected that workers handling pellets/tablets and/or bag chain are exposed to high levels of phosphine. A detailed exposure assessment is only possible on the basis of information provided by the participant. Detailed information should be provided by the participant for future authorisation processes based on product details and information from literature.

Exposure of Non-Professionals

Aluminium phosphide and its biocidal products Phostoxin and DETIA-GAS-EX-B are produced, formulated and applied by professionals only. Primary exposure of non-professionals can be excluded.

No significant secondary non-professional exposure to aluminium phosphide and phosphine is expected if professional application of the biocidal product is performed appropriately and professionally, i. e. if treated buildings are in adequate distance to inhabited houses (at least 10 meters according to TNsG) and are sealed. The exposure estimates are in all cases below the medium-term AEL (in maximum 42% of $AEL_{medium\text{-}term}$). All MOEs were above 195. Thus

it is concluded that secondary exposure of non-professionals to phosphine from the use of Phostoxin or DETIA-GAS-EX-B is acceptable in relation to human health.

Dietary exposure

The intended uses of Phostoxin and DETIA-GAS-EX B containing the active substance aluminium phosphide are comparable to existing pesticide uses apart from the fact that the biocide uses have higher application concentrations. As a result of the pesticide uses, maximum residue levels (MRLs) have been established on EU level by Regulation (EC) No. 396/2005 and also on WHO/FAO level. To comply with these existing MRLs, aluminium phosphide containing pesticides are applied under adherence to waiting period recommendations (which may differ for various storage goods). It should be noted that for national biocide product authorisation of Phostoxin and DETIA-GAS-EX B, the storage goods which might be present in treated storage facilities will have to be detailed. Adequate residue trials are required to allow consumer risk assessment and to decide if waiting period recommendations will be needed. Data requirements will be similar to those described for pesticides in „*Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market“*, Appendix B and D.

Conclusion

Primary non-occupational exposure is not expected. Secondary exposure of non-professionals and consumers to phosphine from the use of Phostoxin or DETIA-GAS-EX-B is acceptable in relation to human health.

An acute or chronic risk arising from phosphide - residues within the existing MRLs can be excluded.

2.2.1.4. Risk characterisation

Risk Assessment at the workplace

The occupational risk assessment for the active substance aluminium phosphide in the biocidal products specified is based upon the long-term AEL of 0.66 mg/person/day and the estimate of actual occupational exposure. The long-term AEL is based on a 2-year inhalation study with phosphine and the assumption of a 100% absorption by inhalation. The actual exposure accounts for personal protective equipment to reduce dermal exposure and for respiratory protection equipment to reduce exposure by inhalation (table 2-3).

Table 2-3: Actual exposure (professionals, aluminium phosphide (AlP), phosphine)

Exposure scenario		Inhalation Shift average (mg/m^3) (1)	Dermal exposure (2) (mg/person/day)	Internal body burden phosphine (mg/person/day)		
				Inhalation (3)	Dermal (4)	Total
Application of tablets by applicator	potential	2.7	1.9 AlP 1.1 PH_3	27	0.1	27.1
	actual	0.068	0.1 AlP 0.06 PH_3	0.68	0.006	0.69
Application of pellets by applicator	potential	2.7	3.0 AlP 1.8 PH_3	27	0.18	27.18
	actual	0.068	0.15 AlP 0.09 PH_3	0.68	0.009	0.69
Application of bag chains by hand	potential	2.7	(5)	27	-	27
	actual	0.068	(5)	0.68	-	0.68
Post-application (de-sheeting) of pellets/tablets or bag chains	potential	2.1	(5)	21	-	21
	actual	0.053	(5)	0.53	-	0.53

(1) short-term values decided to be also valid for a shift (see chapter IIB 8.2.2)

(2) Molecular mass ratio phosphine/aluminium phosphide is 0.59; it is assumed that aluminium phosphide releases 100% PH_3

(3) Based on the assumption of 100 % inhalative absorption; breathing volume of 10 m^3 per shift.

(4) Based on the assumption of 10 % systemic availability after dermal contact

(5) Dermal exposure not expected

In addition to the AEL approach, air-borne concentrations of phosphine are compared to the corresponding OEL of 0.14 mg/m³ and to the STEL (15 min) of 0.28 mg/m³ derived by SCOEL. The TWA value 0.14 mg/m³ relates to systemic effects of phosphine; the STEL of 0.28 mg/m³ is established in order to avoid respiratory tract irritation.

Table 2-4: Risk characterisation /AEL (professionals, phosphine, actual exposure)

Exposure scenario	Total internal body burden (mg/person/day)	Long-term AEL [1] (mg/person/day)	Total internal body burden divided by AEL	Concern	
				Yes	No
Application of tablets by applicator	0.69	0.66	1	?	
Application of pellets by applicator	0.69	0.66	1	?	
Application of bag chains by hand	0.68	0.66	1	?	
Post-application (de-sheeting) of pellets/tablets or bag chains	0.53	0.66	0.8		X

(1) AEL: 0.011 mg/kg/day (for phosphine) x 60 kg

So far the risk calculated is expressed as total internal body burden divided by the AEL. This risk characterisation may be additionally presented as "margin of exposure". In the MOE approach the scenario-specific MOE (the relationship between the internal NOAEL and the scenario-specific total internal body burden) is compared with a reference MOE (the product of assessment factors). Both approaches only differ in form, not in content.

Table 2-5: Risk characterisation / MOE (professionals, phosphine, actual exposure)

Exposure scenario	Reference MOE [1]	Scenario-specific MOE [2]	Reference MOE divided by scen.-spec. MOE	Concern	
				Yes	No
Application of tablets by applicator	100	96	1	?	
Application of pellets by applicator	100	96	1	?	
Application of bag chains by hand	100	97	1	?	
Post-application (de-sheeting) of pellets/tablets or bag chains	100	125	0.8		X

(1) Product of assessment factors used (10 x 10)

(2) Internal NOEL of 1.1 mg/kg/d x 60 kg/sc.-sp. total internal body burden

The risk characterisation for the specified uses of the biocidal product is mainly triggered by exposure to air-borne concentrations of phosphine. Respiratory protection equipment results in air-borne exposure levels of phosphine which are 1 for the AEL approach and lower than the corresponding health-based reference OEL value.

This risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of annex I inclusion of aluminium phosphide. It is essential to indicate, that the conclusions only apply to the active substance in the biocidal product (and not to other ingredients).

Despite the fact that the AEL approach resulted in a value of exactly 1, the exposure-to-OEL-ratios (between 0.36 and 0.5) supports a risk characterisation of no concern. Proper functioning and professional use of respiratory protection equipment is a precondition for this conclusion. Based on the toxicological knowledge of a very steep dose-response relationship for phosphine, namely in order to prevent poisoning and fatalities, phosphine exposure by inhalation strictly has to adhere to the TWA value of 0.14 mg/m³.

Safety Measures for professionals

Respiratory protection equipment (RPE) is required mandatorily to be worn by fumigators for elimination of danger caused by the acute toxicity of phosphine. Necessary is a power-assisted filtering device incorporating full-face gas mask (TM3, protection factor 40) with B1-filter (or special phosphine filter).

Routinely high exposure - like peak loads of phosphine detected during opening of the flasks (46 ppm) - should be avoided by technical means (according to the Chemical Agent Directive 98/24/EC, article 6, paragraph 2).

Wearing of protective gloves (according to EN 374) is required for reduction of exposure. Gloves are considered to provide a reduction of exposure of 95% towards solids (according to Gerritsen-Ebben et al.).

Conclusion:

The inclusion of Aluminium Phosphide (CAS-No. 20859-73-8) in Annex I of the Directive 98/8/EC as active substance in insecticides (product type 18) should be restricted to professional pest controllers, due to the high exposure to the acute toxic substance phosphine which indispensably demands the correct use of respiratory protection equipment (RPE).

2.2.2. Environmental Risk Assessment

Aluminium phosphide is unstable in water/moisture and reacts to gaseous PH_3 and $Al(OH)_3$ x 3 H_2O. The performance of studies with aluminium phosphide is in the most cases technically and scientifically unfeasible.

Due to the fact that aluminium phosphide in contact with humidity is rapidly decomposed to the actual in-situ generated active substance phosphine (PH_3), the risk assessment and characterisation is based on the data of phosphine, primarily.

For the environmental assessment also the effects of the second reaction product $Al(OH)_3$ on environmental organisms have to be considered. However, as $Al(OH)_3$ is ubiquitous in the environment and it can be assumed that the release of this reaction product from the use of aluminium phosphide as insecticide in closed/sealed rooms will not significantly increase the environmental concentration of this compound or of freely available Al^{3+}, the second reaction product is not further regarded for the environmental risk assessment.

2.2.2.1. Fate and distribution in the environment

Biodegradation

Both, solid aluminium phosphide and the in-situ generated gaseous PH_3, as well as the aluminium entity are inorganic compounds and thus not susceptible to biological degradation in the environment. Further, due to the intrinsic properties of aluminium phosphide, PH_3 and aluminium hydroxide, biodegradability studies are technically not feasible.

Phosphine released into the aquatic compartment is poorly soluble in water (24 ml/100 ml water at 24° C); the main rest will bubble up and be released into the air. Phosphine released into the terrestrial compartment will (depending on the oxidising efficiency of different soils) be subject to further oxidative degradation. Via intermediate products (e.g. orthophosphate), the ultimate fate of PH_3 is oxidation to phosphoric acid and subsequent integration into the natural phosphorous-cycle.

Aluminium hydroxide is not biodegradable and belongs to the natural constituents of surface water, sediment and soil. Due to the intended use of aluminium phosphide as fumigant in closed/sealed rooms a quantitatively relevant aquatic contamination is not expected.

Abiotic degradation

In water, aluminium phosphide is decomposed into phosphine (PH_3). PH_3 is not stable in water for more than one week independent of the pH of the test solutions. The DT_{50} water values are approximately 4-5 days at each pH. Due to the nature of phosphine, it is justified that the abiotic degradation reaction is not a hydrolysis reaction, but must be an oxidation with the possible reaction products phosphite and phosphate. Therefore, it does not appear to be reasonable to derive hydrolytic half life from the degradation curve.

A test on the direct photo-transformation of aluminium phosphide is not considered to be required, since the substance does not absorb light at relevant wavelengths to any significant degree. A study on the photo-transformation of aluminium phosphide in water is furthermore not feasible due to the rapid reaction of aluminium phosphide with water resulting in the volatile degradation product phosphine.

Aluminium phosphide has a negligible vapour pressure ($<<10^{-5}$ Pa at 25°C). No direct emission into air of aluminium phosphide is to be expected. In contact with humidity, aluminium phosphide will be degraded rapidly. The degradation product phosphine is volatile and is decomposed rapidly in air. According to the references, the maximum half life of phosphine in air is estimated to be 28 hours using a 24-hours-day with an OH radical concentration of $5.0x10^5$ radicals cm^{-3} which is regarded as the global 24-hours-mean concentration. Based on this half life, an accumulation of phosphine in the air is not to be expected.

Distribution

The performance of adsorption and desorption studies are technically and scientifically unfeasible. The preparation of a solution in water for the subsequent adsorption/desorption experiments is not possible.

The horizontal spreading of PH_3 in soil is relatively fast (faster in dry soils). Phosphine disappeared within 168 hours.

The vertical spreading rate of PH_3 in soil is very low. During the whole experiment, the highest concentration was found near the buried pellet. In a distance of 40 cm to the buried

pellet only 3 – 15 % of the values detected at 10 cm to the buried pellet were measured. After 24 hours, phosphine has almost disappeared.

Mobility

The use pattern of the biocidal products (Phostoxin, DETIA-GAS-EX-B) as fumigant in closed/sealed rooms and the spontaneous reaction with water precludes the active substance itself from leaching. Phosphine is poorly water soluble (24 ml/100 ml water at 24 °C) and has a very high vapour pressure (3295 kPa at 22 °C). The Henry's law constant is estimated to be > 320000 Pa m^3 mol^{-1}. Thus, considerable transport of dissolved phosphine in the pore water of soil is most unlikely. In addition, phosphine is oxidised to phosphoric acid by atmospheric O_2 already in the air phase. This fact further reduces the amount of phosphine that can potentially leach. Therefore, contamination of groundwater by phosphine can be excluded.

Bioaccumulation

The low log P_{ow} = 0.9 of PH_3 indicates that PH_3 has a low potential to bioaccumulate in organisms. The calculated bioconcentration factor (BCF) of PH_3 as a function of log P_{ow} for aquatic organisms (BCF_{fish}= 1.16) and for terrestrial organisms ($BCF_{earthworm}$ = 0.94) can be classified as low.

2.2.2.2. Effects assessment

Aquatic compartment

Acute tests with fish and daphnids and a growth inhibition test with green algae show a high toxicity to aquatic organisms. Although the studies available for daphnids and green algae are not valid, it was decided not to ask for further studies with these organisms as no relevant exposure of the aquatic compartment is expected from the intended use of aluminium phosphide as fumigant in closed/sealed rooms. The lowest effect value of 7.98 µg/l was obtained for a valid study with *Oncorhynchus mykiss*. According to the TGD an assessment factor of 1000 has to be applied to this effect value resulting in: $PNEC_{aqua}$ = 7.98 µg/l / 1000 = 7.98 ng/l. Related to the reaction product phosphine PH_3 the $PNEC_{aqua}$ is 4.68 ng/l. This study triggers the classification as N, R50.

Sediment

No tests with sediment organisms are available. Neither aluminium phosphide nor the reaction product phosphine is expected to accumulate in sediments. In addition, no relevant exposure of the aquatic compartment (incl. sediment) occurs from the intended use of aluminium phosphide as fumigant in closed/sealed rooms. Therefore, it is not necessary to derive a $PNEC_{sediment}$.

Terrestrial compartment

Soil inhabiting organisms

There is only one test with soil organisms available. In a soil micro-organism study at the only tested concentration temporary adverse effects on dehydrogenase activity were found. Although the effects observed were < 50 % (max. 37.8%), in a first approach the test concentration of 8.9 mg/kg dw related to the active substance aluminium phosphide is used as an EC_{50} for the PNEC derivation. With an assessment factor of 1000, a $PNEC_{soil}$ of 8.9 µg/kg dw can be derived. Although this is a very rough estimation, this is the only possible approach to derive a $PNEC_{soil}$ with the available data. The $PNEC_{soil}$ of 8.9 µg/kg dw corresponds to 7.9 µg/kg ww. Related to the reaction product phosphine PH_3 the PNEC soil is 5.2 µg/kg dw.

Toxicity test results with further terrestrial organisms are not available. Acute toxicity tests with earthworms and plants belong to the additional data requirements for active substances of product type 18 (insecticide) for products used outside of buildings as well as products to be used by gassing, fogging or fumigation. Because of aluminium phosphide used as fumigant is only applied in closed/sealed rooms exposure of the terrestrial compartment is only negligible. Therefore, the submission of data on toxicity of aluminium phosphide to earthworms and plants is not necessary.

Effects on Birds

Data on the toxicity to birds belong to the additional data requirements for biocides of PT 18 (insecticides) for products used outside of buildings in the form of bait, granules or powder. As this is not the case for aluminium phosphide (application in closed/sealed rooms), the submission of data on toxicity to birds is not required. A direct exposure of birds in the case of the intended use in closed/sealed rooms and around the fumigated buildings is negligible.

Effects on mammals

No data in addition to that already discussed (chapter 2.2) are available. But all non-target vertebrates which are staying in the fumigated room should be highly endangered by inhalation of the arising PH_3.

2.2.2.3. PBT assessment

Even though the T criterion is fulfilled, aluminium phosphide respectively phosphine is neither PBT- nor vPvB – candidate as the P and B criteria are not fulfilled.

2.2.2.4. Exposure assessment

The environmental exposure assessment is based on the concept of releases to the environment occurring at all relevant life cycle stages of the aluminium phosphide and phosphine (PH_3) as its degradation product and actual active substance, respectively.

With consideration of the physico-chemical properties and rapid decomposition of the active substance to phosphine, as well as the pattern of use in closed/sealed rooms where phosphine is released from the active substance on purpose, the estimation of the predicted environmental concentrations (PECs) at the local scale is performed for phosphine only for the release from production, formulation and professional use, not for the active substance aluminium phosphide. For the life cycle stages **production and formulation** PEC calculations are performed by C.A. with generic and/or specific scenarios using the EU Technical Guidance Document on Risk Assessment (TGD, 2003) and legal regulations.

The considerations for **intended use** (fumigation of stored goods in closed/sealed rooms and empty rooms) are based on a realistic worst-case assumption for the release of phosphine after fumigation of stored goods in storage buildings, containers, etc. For the exposure assessment the local PECs for the environmental compartments are estimated according to the TGD (2003) and legal regulations.

An environmental exposure assessment is not performed for "private use" because the biocidal products must not be used by general public but only by professionals.

Release from disposal is not to be expected. Because of formation of phosphine in contact with water the biocidal products must not be disposed of. Under normal circumstances practically no residues for disposal will occur during intended use.

The biocidal products and/or its container must be disposed of as hazardous waste (waste code according to Guideline 2001/118/EC).

The intended use of the biocidal products can lead to a direct release of phosphine into air, as well as via deposition to soil and surface water.

Release from life cycle stage production of active substance and formulation of the biocidal product

For life cycle stages production and formulation it is stated by the applicant, that a release of active substance into water and soil is excluded and that no waste disposal will occur. With respect to a release of phosphine into air the applicant refers to national German regulation for the subject to approval of facilities (TA Luft) and to monitoring measurements during maintenance work at the mixing equipment. In this regulation is laid down that a release via the exhausted air of 2.5 g/h (which is equivalent to 0.06 kg/d) and a concentration of 0.5 mg/m^3 phosphine must not exceeded.

This value is used by the C.A. as the worst case value for the calculation of

- PEC local air. = 1.668 x 10-5 mg/m^3

A direct release of the active substance into water and soil during the life stage cycle stage "production" and "formulation" is not relevant, but the indirect exposure of these environmental compartments via deposition is taken into account for the PEC calculation of

- PEC local surface water = 0.06 ng/l/d

- PEC local soil = 18 ng /m^2 /d mg/kg ww

Release from professional use

Aluminium phosphide is used in the biocidal products (Phostoxin, 56 % active substance; DETIA–GAS-EX-B, 57 % active substance) for fumigation of insects in stored goods or empty rooms. The biocidal products can be used in form of pellets or tablets placed on sheets of paper or other suitable materials or in bags, bag chains and blankets which are distributed evenly in closed/sealed rooms.

The applicant provides data on the application rate of 5 g PH_3/m^3 in empty rooms and of 6-12 g/m^3 PH_3 for stored goods.

As there is no specific scenario for the fumigation of stored goods in the second draft of the ESD on PT 18 for professional use of insecticides, neither in storage buildings, mills, containers nor in ships, and an average size of such buildings or spaces will depend on many different criterions according to the ESD, the risk assessment is based on the maximum release as stated in the regulations for aeration after fumigation in the German technical rules for hazardous substances on fumigations (TRGS 512). Following these regulations, the release of phosphine to air during aeration is limited to a maximum concentration in air of 0.5 mg/m^3 or 2.5 g PH_3 /h respectively. Ventilation of store rooms, silos, and containers fumigated with PH_3 must be conducted in such a way that these concentrations will not be exceeded in the flue gas stream. If national regulations in the MS exceed these limits, a refined calculation has to be performed for product authorisation.

Applying this concentration value:

PEC local air of 1.668×10^{-5} mg/m^3

has been calculated.

A direct release of the active substance into water and soil during the intended use is not relevant, but the indirect exposure of these environmental compartments via deposition is taken into account for the PEC calculation of

$PEC_{local\ surface\ water}$ of 0.06 ng/l/d

$PEC_{local\ soil}$ of 18 $ng/m^2/d$

If national regulations in the MS exceed the limits given in the German TRGS for aeration after fumigation, a refined calculation based on the respective values has to be performed for product authorisation.

2.2.2.5. Risk characterisation

Atmosphere

Aluminium phosphide has a negligible vapour pressure ($<<10^{-5}$ Pa at 25 °C). No emission into air of aluminium phosphide is to be expected. In contact with humidity, aluminium phosphide will be degraded rapidly. The degradation product phosphine is volatile and is decomposed rapidly in air. According to the references, the maximum half life of phosphine in air is estimated to be 28 hours using a 24-hours-day with an OH radical concentration of

5.0×10^5 radicals cm^{-3} which is regarded as the global 24-hours-mean concentration. Based on this half life, an accumulation of phosphine in air is not to be expected.

Direct reactions of phosphine with ozone are not expected to be quantitatively important, since the degradation via reaction with OH-radicals will degrade the phosphine before it will reach the ozone-rich upper atmosphere layer.

Therefore, phosphine has no potential to deplete stratospheric ozone, as well as it does not contain any chlorine, bromine, or iodine atoms.

A local PEC of 1.668×10^{-5} mg/m^3 phosphine for the atmospheric compartment is estimated.

In view of the spatially and temporally restricted application of the biocidal product (Phostoxin, 56 % active substance, DETIA-GAS-EX-B; 57 % active substance) for fumigation of stored goods in closed/sealed rooms and fumigation of empty rooms for all types of non-agricultural purposes and the results mentioned above no risk for the atmosphere can be indicated.

Aquatic compartment including sediment

No direct exposure of the aquatic compartment (surface water incl. sediment and sewage treatment plant) occurs from the intended use of aluminium phosphide /phosphine as fumigant in closed/sealed rooms. In addition exposure via deposition of PH_3 to surface water is negligible, if aluminium phosphide / phosphine is used as intended as an insecticide for fumigation of stored goods in closed / sealed rooms and fumigation of empty rooms for all types of non-agricultural purposes. The PEC/PNEC-ratio is < 1. Therefore there is no risk for the aquatic compartment expected.

Terrestrial compartment including groundwater

There is no direct release to the terrestrial compartment during the application of the biocidal products. The exposure is restricted to the deposition of phosphine during aeration. The vertical spreading rate of PH_3 in soil is very low. Therefore a permeation of the soil volume can be neglected. Exposure of the terrestrial compartment (including groundwater) is negligible. The PEC/PNEC ratio is << 1. Therefore, no risk for the terrestrial compartment can be indicated.

Groundwater:

The use pattern of biocidal products (Phostoxin, DETIA-GAS-EX-B) for fumigation in closed / sealed rooms and the spontaneous reaction with humidity, preclude the active substance itself from leaching. A considerable transport of dissolved phosphine in the pore water of soil is most unlikely. In addition, phosphine is oxidised to phosphoric acid by atmospheric O_2 already in the air phase. This fact further reduces the amount of phosphine that can potentially leach. Therefore no relevant exposure and risk of groundwater can occur.

Non compartment specific effects relevant to the food chain (secondary poisoning)

Primary Poisoning

No risk for non-target organisms living and staying outside the fumigated rooms / buildings can be expected. There is a potential risk for primary poisoning for all non-target organisms if

they are staying in the fumigated rooms or buildings by inhalation of the arising PH_3. This includes the risk to all non-target mammals. For mammals no quantitative risk assessment can be performed for this scenario as there is no guidance for the derivation of a $PNEC_{mammal}$ for inhalative exposure. However, it can be assumed that the concentration of PH_3 that kill the target organism will also be lethal for non-target mammals.

To mitigate this potential risk and prevent exposure, it has to be assured that animals are not staying in these rooms and buildings during the fumigation takes place and the fumigated rooms are safely closed and sealed.

For the aeration period it can be stated that no significant exposure to non-target organisms staying outside the fumigated rooms can be assumed as well if professional application of the biocidal product is performed appropriately.

As aeration of fumigated rooms must not be performed during atmospheric inversion, a fast dilution of phosphine in the surrounding fresh air is assured.

Secondary Poisoning

Aluminium phosphide and its reaction product phosphine may theoretically pose a risk for carnivorous and scavenging terrestrial vertebrates that feed on intoxicated animals. However, according to the intended use of the substance in closed/ sealed rooms, the presence of intoxicated animals is not relevant resp. negligible. In addition, in organisms phosphine is metabolised to non-toxic phosphates. Thus a relevant exposure of these non-target organisms via the food chain can be excluded and there seems to be no risk of secondary poisoning.

2.2.2.6. Overall conclusions of the evaluation

There is no risk for the aquatic compartment (incl. sediment) from the professional use according to the intended application expected. But due to the high aquatic toxicity in general there exists a possible potential risk for the aquatic environment compartment and therefore special care should be taken in handling and applying these products. The fumigant causes also no risk to the atmosphere.

There is no a risk for the terrestrial compartment (incl. groundwater).

There is a potential risk for primary poisoning of all non-target organisms by inhalation of the arising PH_3 if they are staying in the fumigated rooms and buildings. To mitigate these potential risks, the instructions for use must strictly be followed (e.g. safely close and seal of the fumigated rooms and buildings). There is no risk for secondary poisoning.

The effect value for aquatic toxicity is the 96h-LC_{50} for the fish *Oncorhynchus mykiss* of 7.98 µg/l triggers the classification as N, R50.

Classification/labeling for environmental toxicity according to Directive 67/548/EEC:

Based on the available ecotoxicity test with fish, aluminium phosphide has to be classified as:

Hazard Symbol: N

Indication of danger: dangerous to the environment

R 50 very toxic to aquatic organisms

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

Article 10 of the Biocides Directive 98/8/EC addresses the inclusion of an active substance in the Annexes I, IA or IB. For the decision of inclusion or non-inclusion, it has to be examined if the criteria of article 10 (1) are fulfilled.

Evaluation of the active substance aluminium phosphide showed the following results: The physico-chemical properties of aluminium phosphide are deemed acceptable for the appropriate use, storage and transportation of the active substance.

The available data on analytical methods for determination of residues of aluminium phosphide (determined as PH_3) are considered sufficient to support an Annex I inclusion of aluminium phosphide.

To comply with MRLs established on EU level by Regulation (EC) No. 396/2005 and also on WHO/FAO level, aluminium phosphide containing pesticides are applied under adherence to waiting period recommendations. For national biocide product authorisation of Phostoxin and DETIA-GAS-EX B, adequate residue trials are required to allow consumer risk assessment and to decide if waiting period recommendations will be needed. An acute or chronic risk arising from phosphide-residues within the existing MRLs can be excluded.

The effects on human health have been assessed in accordance with the provisions of Article 10(1) of Directive 98/8/EC, for the uses proposed by the applicant. Aluminium phosphide and phosphine gas are of high toxicity when ingested or inhaled, respectively. Aluminium phosphide is harmful upon skin contact but not irritating to skin and eyes and not sensitising. Based on the available data, a genotoxic or carcinogenic potential of aluminium phosphide or PH_3 can be excluded. No effects on fertility or development and no specific substance-related neurotoxicity were observed in the toxicological database.

Acceptable exposure levels for acute, medium- and long-term exposure could be derived for aluminium phosphide and phosphine.

Primary exposure of non-professionals is not expected. Secondary exposure of non-professionals and consumers to phosphine from the use of Phostoxin or DETIA-GAS-EX-B is acceptable in relation to human health. Therefore, no risk to non-professionals concerning human health could be anticipated for the active substance and phosphine residues. All studies required by Directive 98/8/EC are available or statements for non submission have been accepted.

The main risks of aluminium phosphide containing products for professionals are caused by inhalation of phosphine, which is highly toxic. For dermal contact, however, aluminium phosphide dust is in the focus of interest. Since phosphine is formed by reaction of aluminium phosphide with water, aluminium phosphide dusts are a source of inhalation concern, too.

Occupational safety measures to mitigate the concern during use of aluminium phosphide containing products are addressed in the following proposal for Annex I inclusion.

The biocidal products Phostoxin and DETIA-GAS-EX B contain 56% to 57% (w/w) aluminium phosphide, respectively and beside the proposal for classification of aluminium phosphide with F; T^+; R 15/29, R 28, R32, R 21, further classification and labelling of the products according to Directive 1999/45/EC with R 36 (Irritating to eyes) is required with regard to toxicity data of other metal phosphide products and one stabiliser in the formulation Phostoxin.

The products Phostoxin and DETIA-GAS-EX B containing the active substance aluminium phosphide are intended to be used against insects to protect storage goods like animal feed and feed ingredients, food and food ingredients (for example: corn flakes, potato products, cured, dried and processed meat and fish products, dairy products or chocolate and chocolate products) and non-food items (for example: processed natural fibres (e.g. wool, cotton, cloths, etc.), leather, paper and paper products or packing material (e.g. cardboard boxes, paper and jute bags). The products can be applied successfully under almost all storage conditions, provided that the structure is tightly sealed (silos, flat storage, stacks). The products are effective fumigants against all kinds of storage pests (moths, beetles, etc.) including all stages of development.

The estimation of hazards and the exposure assessment for the environment for Phostoxin and DETIA-GAS-EX-B showed the following results: The intended use of aluminium phosphide / PH_3 poses a potential risk to all organisms; animals (like birds, cats) which are staying in the fumigated rooms /buildings are highly endangered by inhalation of the arising PH_3.

Therefore appropriate risk mitigation measures concerning the conditions of proper use and handling of the biocidal products must be applied: The instructions for use must strictly be followed (e.g. fumigated rooms and buildings are safely closed and sealed). Only use by specialised professionals familiar with the precautionary measures and who are experienced in assessment of the sites to be treated should be allowed.

Due to the special conditions of use, there is no risk for the aquatic and terrestrial compartment and the atmosphere, therefore, no additional specific measures and precautions are necessary. However, because of the high aquatic toxicity of the active substance and biocidal products, in general, there exists a possible potential risk for the aquatic environment compartment and therefore special care should be taken in handling and applying these products. Taking into account the measured log Pow of 0.9 there is a low potential to bioaccumulate. The estimated BCF_{fish} (=1.16) and the $BCF_{earthworm}$ (=0.94) for the aquatic and terrestrial environment are low and confirm this conclusion.

Overall, it may be expected, that the use of aluminium phosphide in insecticides will fulfill the conditions laid down in Article 10 (1) of Directive 98/8/EC and therefore the inclusion into Annex I of Directive 98/8/EC can be recommended.

3.2. Decision regarding Inclusion in Annex I

The active substance aluminium phosphide releasing phosphine shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 18 (insecticides, acaricides and products to control other arthropods), subject to the following specific provisions:

The active substance aluminium phosphide, as manufactured, shall have a minimum purity of 830 g/kg.

When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Community level risk assessment. In particular, where relevant, Member States shall assess outdoor use.

When granting product authorisation, Member States shall ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.

Member States shall ensure that authorisations are subject to the following conditions:

(1) Products shall only be sold to and used by specifically trained professionals in the form of ready-for-use products.

(2) In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.

(3) For products containing aluminium phosphide that may lead to residues in food, labels and/or safety data sheets for authorised products must contain instructions for use which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No. 396/2005 of the European Parliament and of the Council (*).

3.3. Elements to be taken into account by Member States when authorising products

The occupational exposure limit for phosphine of 0.14 mg/m³ (0.1 ppm), also derived by SCOEL shall be taken into account for authorisation of insecticides, acaricides and products to control other arthropods containing aluminium phosphide.

In the view of the physico-chemical properties of aluminium phosphide, biocidal products must be packaged in appropriate containers and appropriately stored in a way to avoid the release of phosphine.

* OJ L 70, 16.3.2005, p.1

The requested intended use of aluminium phosphide / phosphine poses a potential risk to all organisms which are staying in the fumigated rooms and buildings. Due to the high aquatic toxicity of the biocidal products/ active substance in general there exists a possible potential risk for the aquatic environmental compartment.

Therefore, special care should be taken and appropriate risk mitigation measures concerning the conditions of proper use and handling of the biocidal products must be applied.

Where necessary, also additional appropriate technical precaution measures or special advices for the controlled aeration/ventilation of the fumigated rooms after fumigation have to be taken into account at the national biocidal products authorisation procedure (like filter installation, exhauster).

For scenarios not submitted by the participant and not assessed in this report adapted safety measures are necessary according to the situation (e.g. indoor vs. outdoor) and the fumigation object (e.g. container, storage silo etc.). The risks for different scenarios have to be assessed thoroughly before granting an authorisation and/or performing a fumigation.

As the risk assessment is based on the maximum release as stated in the regulations for aeration after fumigation in the German technical rules for hazardous substances on fumigations (TRGS 512), member state should consider if the respective national regulation for aeration differs from the given maximum concentrations in air of 0.5 mg/m³ or 2.5 g PH3 /h respectively. If so, an adapted exposure assessment should be performed accordingly.

Where necessary, Member States should have a special care on the borderline with the plant protection product regulation, and ensure that the product is indeed a biocidal product and not a plant protection product.

Adequate residue trials are required to allow consumer risk assessment and to decide if waiting period recommendations would be needed. Data requirements will be similar to those described for pesticides in „Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market“, Appendix B and D.

Occupational Safety Measures

Beyond the measures proposed for Annex-I inclusion, it is desirable for harmonisation of the quality of safety measures on community level to develop a code of good practice (conditions which are necessarily fulfilled by a specialised professional to obtain an exposure below the OEL) for pest control measures or special aspects of pest control like fumigation. It is proposed that member state experts should harmonise an according document on community level which should specify regulations on safety and health at work (instruction, training, exposure control, PPE) for the user and give guidance for authorisation of biocidal products for the competent authorities.

Technical risk reduction measures are to be considered when authorizing biocidal products. One idea is to reduce the peak during opening of the package (flasks) by bottling the biocidal tablets/pellets in inert gas (e.g. nitrogen) and adding small bags of silica gel into the flask.

Non-professional / General Public Safety Measures

No further measures for the general public are required since use of the biocidal products is restricted to professionals and secondary exposure is usually not expected under the conditions and intended uses described and if professional application of the biocidal product is performed appropriately and professionally. However due to the physical, chemical, irritating properties and the oral, inhalative, dermal toxicity, for preventive health care the following S phrases for the biocidal products are proposed:

(S 1/2) Keep locked up and out of the reach of children.

S 7/8 Keep container tightly closed and dry.

S 3/9/14/49 Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer).

S 30 Never add water to this product.

S 36/37 Wear suitable protective clothing and gloves.

S 45 In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.)

S 60 This material and/or its container must be disposed of as hazardous waste

S 61 Avoid release to the environment. Refer to special instructions/ material safety data sheet

Environmental Protection Measures

Due to the special properties of the product and the conditions of use, there is no risk for the aquatic and terrestrial environment and the atmosphere.

Nevertheless, both active substance and biocidal products are classified as very toxic to aquatic organisms. The half-life of abiotic decomposition of phosphine in water amounts approx. 4-5 days.

Uncontrolled (or accidental) releases to surface waters have to be avoided.

Aluminium phosphide / PH_3 is very toxic to animals. There is a potential risk to all animals (e.g. birds, cats) which are staying in the room during the fumigation takes place. Therefore appropriate risk reduction measures and precautions concerning the special conditions of proper use and handling of the biocidal products must be applied:

- Safe use and handling only by trained and certified specialised professional users familiar with the precautionary measures and who are experienced in assessment of the objects /areas to be treated:

- the instruction for use are strictly followed

- it has to be assured that animals are not staying in these rooms during the fumigation takes place

- safely close and seal the rooms in which the fumigant is applied.

The maximum release into air is stated in the regulations for aeration after fumigation in the German technical rules for hazardous substances on fumigations (TRGS 512). Following these regulations, the release of phosphine to air during aeration after fumigation is limited to a maximum concentration in air of 0.5 mg/m³ or 2.5 g PH_3 /h respectively. Ventilation of store rooms, silos, and containers fumigated with PH3 must be conducted in such a way that these concentrations will not be exceeded in the flue gas stream. In addition, aeration of fumigated rooms must not be performed during atmospheric inversion.

Where necessary, additional appropriate technical precaution measures or special advices for the controlled aeration/ventilation of the fumigated rooms after fumigation have to be taken into account at the national biocidal products authorisation procedure (like filter installation, exhauster).

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of aluminium phosphide in Annex I to Directive 98/8/EC.

When Member States are authorising products, the source and nature of the non-active components within the product must be considered, since their classifications could affect the classification of the product overall. Thus, the potential for the product(s) to require classification as eye irritant needs to be considered as no studies were submitted for the products Phostoxin and Detia-Gas-Ex-B.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of aluminium phosphide releasing phosphine in Annex I to the Directive.

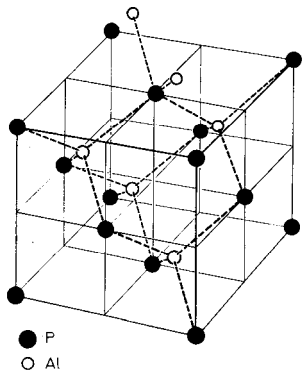
APPENDIX I: LIST OF ENDPOINTS

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Aluminium phosphide
Function (*e.g.* fungicide)	insecticide

Rapporteur Member State	Germany

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	Aluminium phosphide
Chemical name (CA)	Aluminium phosphide
CAS No	20859-73-8
EC No	244-088-0
Other substance No.	
Minimum purity of the active substance as manufactured (g/kg or g/l)	830 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	impurities are given in the confidential part of the dossier
Molecular formula	AlP
Molecular mass	57.96 g/mol
Structural formula	

Physical and chemical properties of aluminium phosphide (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	no melting point up to 500 °C (purity 86.5 %)
Boiling point (state purity)	no boiling point up to 500 °C at 1013.3 hPa (purity 86.5 %)

Temperature of decomposition	no decomposition up 500 °C
Appearance (state purity)	grey powder (purity 86.5 %)
Relative density (state purity)	2.32 at 23.5 °C (purity 86.5 %)
Surface tension	technically not feasible (hydrolysis)
Vapour pressure (in Pa, state temperature)	<< 10^{-5} Pa at 25 °C (purity 86.5 %)
Henry's law constant (Pa m^3 mol^{-1})	not calculated (negligible vapour pressure and violent reaction in water)
Solubility in water (g/l or mg/l, state temperature)	technically not feasible (hydrolysis)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Test was not conducted (technically not feasible). For structural reasons it could be concluded that aluminium phosphide is insoluble in organic solvents.
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	technically not feasible (insolubility)
Partition coefficient (log P_{OW}) (state temperature)	technically not feasible (hydrolysis)
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH_____:
	pH_____:
	pH_____:
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	technically not feasible
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Absorption spectra are technically not feasible
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	
Flammability	Not highly flammable in the sense of EEC A.10. The substance does evolve any flammable gases in contact with water or humid air and is therefore highly flammable in the sense of EEC A.12 (purity 86.5 %)
Explosive properties	Not explosive (purity 86.5 %)

Physical and chemical properties of phosphine (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	- 133 °C (purity unknown)
Boiling point (state purity)	- 87 °C (purity unknown)
Temperature of decomposition	thermal decomposition at 550 °C
Appearance (state purity)	colourless gas (purity unknown)
Relative density (state purity)	1.529 at 20 °C (purity unknown)
Surface tension	test not conducted as a surface tension of > 60 mN/m at 20°C is expected due to the chemical structure of the substance
Vapour pressure (in Pa, state temperature)	3295 kPa at 22 °C

Henry's law constant (Pa m^3 mol^{-1})	320480 Pa x m^3 x mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	24 ml/100 ml water at 24 °C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	319 ml/100 ml acetic acid at 20 °C 445 ml/100 ml acetone at 22.4 °C 715 ml/100 ml toluene at 22.5 °C
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	.
Partition coefficient (log P_{OW}) (state temperature)	log P_{OW} 0.9 at 21 °C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH_____: pH_____: pH_____:
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	pK (B) = 27.4 at 27 °C pK (S) = 28.8 at 27 °C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Absorption spectra are technically not feasible
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	
Flammability	Extremely flammable and pyrophoric
Explosive properties	Not explosive

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	**F; R 15/29** (Contact with water liberates toxic, extremely flammable gas)
with regard to toxicological data	**T+; R 28** (Very toxic if swallowed)* **Xn; R 21** (Harmful in contact with skin)** **R 32** (Contact with acids liberates very toxic gas) **(F; R 15/29)** (Contact with water liberates toxic, extremely flammable gas) ---------- **(F); T+; R (15/29-) 21-28-32**
with regard to fate and behaviour data	
with regard to ecotoxicological data	**N; R 50** (Very toxic to aquatic organisms)

* Since aluminium phosphide is the active substance dealt with in this assessment report it is not classified for inhalation toxicity. PH_3 was inserted into Annex I to Directive 67/548/EEC with appropriate classification and labelling (R 26).

** Proposal

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Hydrolysis with sulphuric acid followed by precipitation with mercuric chloride solution. The resulting hydrogen chloride is determined by titration with potassium hydroxide solution.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Standardless x-ray measurement based on an advanced fundamental parameters algorithm. Titration for aluminium nitride.

Residue definitions for monitoring purposes

Food of plant origin		Indoor use: phosphine and residual aluminium phosphide, expressed as phosphine
Food of animal origin		Not relevant, no MRL proposed, no residue definition for monitoring
Soil		Not relevant, DT_{90} < 3 days
Water	surface	Not relevant
	drinking/ground	Not relevant
Air		Phosphine
Body fluids and tissues		Not applicable

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	not required, DT_{90} < 3 days
Air (principle of method and LOQ) (Annex IIA, point 4.2)	phosphine photometric determination at 625 nm LOQ =25 µg/m^3 (for enforcement of the occupational exposure limit)
Water (principle of method and LOQ) (Annex IIA, point 4.2)	phosphine GC-NPD headspace LOQ = 0.1 µg/L
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	zinc phosphide GC-NPD LOQ = 0.0025 mg/kg (muscle, liver)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	phosphine GC-NPD headspace LOQ = 0.01 mg/kg
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not required, no residue definition

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)*

Rate and extent of oral absorption:	Ready absorption of phosphine through the lungs and after oral exposure
Rate and extent of dermal absorption:	Default value of maximum 10 % for aluminium phosphide and PH_3 (based on expert judgement)
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapid excretion with urine as hypophosphite and phosphite and via lungs as phosphine
Toxicologically significant metabolite	Phosphine

* Studies performed with zinc phosphide

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	8.7 mg/kg bw
Mouse LD_{50} oral	14.8 mg/kg bw
Rat LD_{50} dermal	900 mg/kg bw
Rat LC_{50} inhalation (PH_3)	Males: 11 ppm PH_3 (equivalent to 0.015 mg PH_3/L air or 2.8 mg/kg bw) (4 h exposure, whole body)
Skin irritation	Not irritant
Eye irritation	Not irritant
Skin sensitization (test method used and result)	No indication of skin sensitisation (Buehler test, 3 inductions using the biocidal product containing 56 % w/w aluminium phosphide)

Repeated dose toxicity (Annex IIA, point 6.3/6.4)

Species/ target / critical effect	Mortality
Lowest relevant oral NOAEL	No reliable data, no study required
Lowest relevant dermal NOAEL	No data, no study required
Lowest relevant inhalation NOAEL	NOAEL 3 ppm PH_3 (equivalent to 1.1 mg/kg bw/d), rat 90-d and 2-yr, the highest dose tested

Genotoxicity (Annex IIA, point 6.6)	No evidence of a genotoxic potential

Chronic toxicity/Carcinogenicity (Annex IIA, point 6.5/6.7)

Target / critical effect	None
Lowest relevant NOAEL	NOAEL 3 ppm PH_3, equivalent to 1.1 mg/kg bw/d (rat 2-yr inhalation)

Carcinogenicity	Not carcinogenic in the rat No data on mice, justification given

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	No data, justification given
Lowest relevant reproductive NOAEL	No data, justification given
Species/Developmental target / critical effect	Rat: Mortality of dams
Lowest relevant developmental NOAEL	Rat, developmental study: NOAEL 4.9 ppm PH_3 (equivalent to 1.9 mg/kg bw/d) No data on rabbits, justification given

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	No neurotoxic potential
Lowest relevant NOAEL	NOAEL (acute study): 40 ppm PH_3 (analytical conc. 38 ppm) (with regard to anatomic pathology, behavioural and neurological status) < 20 ppm PH_3 (with regard to changes in motor activity) NOAEL (subchronic study): 3 ppm PH_3 equivalent to 1.1 mg/kg bw/d

Other toxicological studies (Annex IIIA, VI/XI)

.....	Mechanistic study with mouse Hepa c1c7 liver cancer cells demonstrating a possible mechanism for DNA damage by PH_3 via generation of reactive oxygen species.
Study on Heinz body formation	Phosphine induced Heinz bodies in human erythrocytes.
Influence on respiration and oxidative phosphorylation	The respiration of liver mitochondria is diminished by phosphine. The oxidative phosphorylation remains on normal level.

Medical data (Annex IIA, point 6.9)

.....	No compelling evidence of negative health effects from examinations of personnel with occupational exposure. Records of poisoning cases, mainly in connection with suicide are available. Accidental poisoning cases mainly in developing countries.

Summary aluminium phosphide (Annex IIA, point 6.10)	Value	Study	Assessment factor
AEL_{acute}	0.032 mg/kg bw*	Developmental inhalation, rat	100
$AEL_{medium\text{-}term}$	0.019 mg/kg bw/d*	90-d inhalation, rat	100
$AEL_{long\text{-}term}$	0.019 mg/kg bw/d*	2-yr inhalation, rat	100

ADI	0.019 mg/kg bw*	2-yr inhalation, rat	100
ARfD	0.032 mg/kg bw*	Developmental inhalation, rat	100

* Based on a maximum liberation of gas of 0.59 g PH_3 /g aluminium phosphide

Summary PH_3 (Annex IIA, point 6.10)	Value	Study	Assessment factor
AEL_{acute}	0.049 ppm or 0.070 µg/L air or 0.019 mg/kg bw/d	Developmental inhalation, rat	100
$AEL_{medium-term}$	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	90-d inhalation, rat	100
$AEL_{long-term}$	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	2-yr inhalation, rat	100
ADI	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	2-yr inhalation, rat	100
ARfD	0.049 ppm or 0.070 µg/L air or 0.019 mg/kg bw/d	Developmental inhalation, rat	100

professional user

Reference value for inhalation (proposed OEL)	0.14 mg/m³ 0.28 mg/m³	TWA (SCOEL) STEL (SCOEL)	
Reference value for dermal absorption	not necessary		

Acceptable exposure scenarios (including method of calculation)

Professional users	**Intended uses**
Production of active substance:	The production of active substance is not assessed for risk characterisation purposes under the requirements of the BPD.
Formulation of biocidal product	The formulation of the biocidal product is not assessed for risk characterisation purposes under the requirements of the BPD.
Intended uses: Application of pellets/tablets by applicator (scenario 1)	Ready for use tablets/pellets with 56 % aluminium phosphide

Mixing & loading: No mixing & loading, ready for use product **Application:** Opening of flasks, filling of applicator, placing pellets/tablets, pulling sheeting over grain Form of exposure: released phosphine (inhalation), solid aluminium phosphide (dermal) Duration: 60 min Frequency: 1-4 flat storage rooms per day Inhalation exposure assessment is based on study report Old et. al. (2003). Dermal exposure assessment is based on expert judgement. Control measures: Full face mask TM3, B1, suitable gloves **Post-application:** Ventilation of site, de-sheeting and removal of product Form of exposure: released phosphine Duration: 60 min. Frequency: 1-4 flat storage rooms per day Inhalation exposure assessment is based on study report Old et. al. (2003). Control measures: : Full face mask TM3, B1, suitable gloves	Actual Inhalation exposure (application) Actual dermal exposure (application) Actual inhalation exposure (post-application)	0.068 mg/m^3 (shift-average) 0.131 mg/m^3 (Peak-value) Tablet: 0.10 mg/person/day AlP Pellet: 0.15 mg/ person/day AlP 0.053 mg/m3 (shift-average) 0.055 mg/m3 (Peak-value)
Intended uses: Application of bag chains by hand (scenario 2)	Bag chains with 57 % aluminium phosphide, ready for use product	

Mixing & loading: No mixing & loading, ready for use product **Application:** Opening of packages, placing bag chains and covering with grain, pulling sheeting over grain Form of exposure: released phosphine Duration: 60 min Frequency: 1-4 flat storage rooms per day Inhalation exposure assessment is based on study report Old et. al. (2003). Dermal exposure assessment is based on expert judgement. Control measures: Full face mask TM3, B1, suitable gloves **Post-application:** Ventilation of site, de-sheeting and removal of product Form of exposure: released phosphine Duration: 60 min. Frequency: 1-4 flat storage rooms per day Inhalation exposure assessment is based on study report Old et. al. (2003). Control measures: : Full face mask TM3, B1, suitable gloves	Actual inhalation exposure (application) Actual inhalation exposure (post-application)	0.068 mg/m3 (shift-average) 0.131 mg/m3 (Peak-value) 0.053 mg/m3 (shift-average) 0.055 mg/m3 (Peak-value)
Secondary exposure	It is expected that nobody enters incidental the fumigated flat storage rooms, since the flat storage room is sealed and marked as restricted area.	
Non-professional users	Non-professional use is not intended.	
Indirect exposure as a result of use	No indirect exposure expected, uses acceptable: Bystander, adult: 42% of $AEL_{medium-term}$ Bystander, infant: 51% of $AEL_{medium-term}$ Re-entry, adult: 0.7% of $AEL_{medium-term}$ Re-entry; infant: 0.8% of $AEL_{medium-term}$	

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	In water, aluminium phosphide is decomposed into phosphine and aluminium hydroxide.
The study is conducted with hydrogen phosphide (phosphine).	PH_3 is stable in water for less than one week. The stability of PH_3 in water does not depend on the pH of the buffer solution. DT_{50} for decomposition of PH_3: approx. 4 – 5 days
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	not applicable.
Readily biodegradable (yes/no)	not applicable
Biodegradation in seawater	not applicable
Non-extractable residues	not applicable
Distribution in water / sediment systems (active substance)	not applicable
Distribution in water / sediment systems (metabolites)	not applicable

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	not applicable.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic)
	DT_{90lab} (20°C, aerobic):
	DT_{50lab} (10°C, aerobic):
	DT_{50lab} (20°C, anaerobic):
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}: not applicable
	DT_{90f}: not applicable
Anaerobic degradation	not applicable
Soil photolysis	not applicable
Non-extractable residues	not applicable
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	not applicable
Soil accumulation and plateau concentration	not applicable

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	not applicable.

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	not applicable.
Quantum yield of direct photolysis	not applicable
Photo-oxidative degradation in air	Active substance: not applicable. Phosphine: Half life: approx. 28 hours (24-hour-day, 5.0 10^5 OH/cm^3)
Volatilization	Active substance: not expected in regards of the low vapour pressure.

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	LC50	7.98 µg/l
Invertebrates			
*Daphnia magna**	24 h	EC50	0.18 mg/l
Algae			
*Selenastrum capricornutum**	48 h	ErC50	1.44 mg/l
Microorganisms			
		PH_3: Toxicity towards aquatic micro-organism free available Al^{3+} biocidally active in water	No data submitted

* Reliability 3

Effects on earthworms or other soil non-target organisms

Acute toxicity to …….. (Annex IIIA, point XIII.3.2)	not tested
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	not tested

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	< 25% effects at 8.9mg a.i./kg dw soil
Carbon mineralization	> 25% effects at 8.9mg a.i /kg dw soil (max. 37.8% (56d)) EC50 = 8.9 mg a.i./kg dw soil (7.9 mg a.i./kg w/w soil)

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	See chapter 3 Impact on Human Health
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	not tested.
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	not tested
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	not tested

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	not tested
Acute contact toxicity	not tested

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	not tested
Acute contact toxicity	not tested
Acute toxicity to ……..	

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	BCF phosphine (calculated on the basis of log P_{OW} = 0.9 according to TGD): aquatic: BCF_{fish} = 1.16 terrestrial: $BCF_{earthworm}$ = 0.94
Depration time (DT_{50}) (DT_{90})	not tested
Level of metabolites (%) in organisms accounting for > 10 % of residues	not tested

Chapter 6: Other End Points

Appendix II: List of Intended Uses

The intended uses of the representative insecticide (PT 18) are only for professional application. Gas-generating formulations containing 57% or 56 % aluminium phosphide, respectively, are proposed for fumigation against insects to protect storage goods like animal feed and feed ingredients, food and food ingredients (for example: corn flakes, potato products, cured, dried and processed meat and fish products, dairy products or chocolate and chocolate products) and non-food items (for example: processed natural fibres (e.g. wool, cotton, cloths, etc.), leather, paper and paper products or packing material (e.g. cardboard boxes, paper and jute bags)). The products can be applied successfully under almost all storage conditions, provided that the structure is tightly sealed (silos, flat storage, stacks). The products are effective fumigants against all kinds of storage pests (moths, beetles, etc.) including all stages of development.

Summary of intended uses

Object and/or situation	**Member State or Country**	**Product name**	**Organisms controlled**	**Formulation**		**Application**			**Applied amount per treatment**			**Remarks:**
				Type	**Conc. of as**	**method kind**	**number**	**interval between applications (min)**	**g as/L**	**water L/m²**	**g as/m²**	
Insecticide: Fumigation of stored goods in closed / sealed rooms; fumigation of empty rooms.	Germany	Detia-Gas-Ex B/ Phostoxin	Insecrts	Gas generating product (GE)	57% (Detia-Gas-Ex B) 56% (Phos-toxin)	Fumigation: the required amount is placed onto sheets of paper or other suitable material which are distributed evenly.	One or repeated if new infestation	Not specified	Empty rooms: 5g PH_3/m^3 Stored goods: 6-12 g PH_3/m^3			

Appendix III: List of studies

The references/studies listed below are those included in the German Competent authority report for aluminium phosphide in insecticides, acaricides and products to control other arthropods (PT 18).

Data protection is claimed by Detia Freyberg GmbH, Germany, in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "yes" in the "Data Protection Claimed" column of the table below. For studies marked "yes" data protection is claimed under Article 12.1(c)(ii). Since there has not been a national legislation on biocides in Germany, no studies have been seen before by the Rapporteur Member State. Therefore, these claims are based entirely on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It is not possible for the Rapporteur Member State to confirm the accuracy of this information.

References which have been marked (*) in the tables are considered to be KEY STUDIES.

Section No / Reference No	**Author(s)**	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
Doc. II A 3, Doc. II A 5 Doc. II B 9		2003	Emission Scenario Document for Biocides used as Rodentizides. J.Larsen. Danish EPA: EUBEES	No	Public
Doc. II A 3, Doc. II A 5 Doc. II B 9		2003	Technical Guidance Document on Risk Assessment for new, extisting and biocidal substances. European Chemicals Bureau	No	Public
Doc II-A 4	Cleveland L., Buckler D.R. & Brumbaugh W.G.	1991	Residue dynamics and effects of aluminium on growth and mortality in brook trout, Environ . Toxicol. Chem., 10, 2, 243-248	No	Public
Doc II-A 4	Scheffer F. & Schachtschabel P.	1991	Lehrbuch der Bodenkunde, 491 pages, Enke Verlag; Stuttgart	No	Public
Doc II-A 4	United Nations Environment Programme (UNEP), WHO, International Programme on Chemical Safety	1997	Environmental Health Criteria 194 Aluminium	No	Public
Doc II-A 4, Doc II-B 7, Doc II-B 10		1999	Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.	No	Public

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc. II-A 5 Doc. II-C 14	Salminen R. et.al.	2005	Geochemical Atlas of Europe. Part 1 - Background Information, Methodology and Maps. http://www.gtk fi/publ/foregsatlas	No	Public
Doc II-B 8		2002	EU (June 2002): Technical Notes for Guidance: Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002“ http://ecb.jrc.it/biocides].	No	Public
Doc II B8	Old, J.	2003	Measurement of Potential exposure to Phosphine During Grain Fumigation, Inveresk Research, Tranent, Scotland, Report Number 21517		public
Doc II B8	Reed, C.	2001	Influence of environmental, structural, and behaviour factors on the presence of phosphine in worker are during fumigants in grain elevators, Journal of Agricultural Safety and Health, Vol. 7 (1): 21 - 34		public
Doc II-C 12	Banasiak U, Heseker H, Sieke C, Sommerfeld C, Vohmann C	2005	German VELS-Model (Model for the assessment of the long and short risk of pesticide residues in food), Bundesgesundheitsblatt – Gesundheitsforsch – Gesundheitsschutz 2005 48:84-98	No	Public
Doc II-C 12			TNsG Human Exposure to Biocidal Products, Part 1, p. 5-6, June 2002	No	public
Doc II-C 12		1998	SCOEL(1998): European Commission, Report EUR 18216, Recommendation of the Scientific Committee for Occupational Exposure Limits for phosphine, SCOEL/SUM/58 final, 1998	No	Public
Doc II C12 Doc II C15	BAuA - Federal Institution for occupational safety and health, Germany (Dortmund)	Oct. 2005	Job-site inspection of manufacturing plant of Detia Freyberg in Laudenbach, Germany (19.10.2005, 11 – 14 o’clock)	Yes	BAuA
Doc II C12 Doc II C15	Editor: german AGS – Committee of hazardous substances, at the Federal Institution for occupational safety and health (BAuA)	Jan. 2007	TRGS 512 – german Technical Rule for hazardous substances: Fumigation	No	public
Doc II C15	EU	April 2007	Draft final report of TNsG (project ‘Development of worked examples for exposure scenarios of biocidal products to		

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			humans', CCR.IHCP.C431564.XO), version 2		
Doc II C15	Gerritsen-Ebben, R.; Brouwer, D.H.; van Hemmen J.J.	Nov. 2006	Effective Personal Protective Equipment (PPE) – Discussion document on the use of PPE in registration purposes for handling of agrochemical, microbiological and biocidal pesticides	No	public
Doc II C15	Editor: german HVBG – Federation of Institutions of Statutory Accident Insurance and Prevention	Apr. 2004	BGR 190 – Rules for safety and health at work by german Employer's Liability Insurance Association: Use of respirators	No	HVBG
Doc II C15	Editor: german AGS – Committee of hazardous substances, at the Federal Institution for occupational safety and health (BAuA)	Jan. 2005 Revised Mar. 2007	TRGS 900 – german Technical Rule for hazardous substances: Occupational threshold limit values	No	public
Doc. IIIA					
A 2.6	Schmitt, S; Stammler, B	2004	Manufacturing Method of Aluminium Phosphide	No	Detia Freyberg GmbH
A 2.7	Schmitt, S; Dierks-Lange, H	2003	Quality Control Certificate	Yes	Detia Freyberg GmbH
A 2.8	Schmitt, S; Stammler, B	2004	Content of Impurities	Yes	Detia Freyberg GmbH
A 3.1.1.01	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH
A 3.1.1.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag
A 3.1.1.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.1.2.01	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 3.1.2.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag
A 3.1.2.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.1.3.01	Smeykal, H	2002	Aluminium phosphide technical: Relative Density Report-No. 20020427.02	No	Detia Freyberg GmbH
A 3.1.3.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag
A 3.1.3.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.2.01	Drägerwerk AG	1993	Dräger-Röhrchen Handbuch	No	Public
A 3.2.02	Lide, David R.	1991	Vapour pressure of fluids at temperature below 300 K Handbook of Chemistry and Physics. 82nd Edition 1991-1992, page 6-91	No	Public
A 3.2.02	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH
A 3.2.1	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH
A 3.3.1	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.3.2	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.3.3	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 3.4.01	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.4.02		1965	Gmelins Handbuch Phosphor Verlag Chemie GmbH	No	Public
A 3.4.03	Fluck, E	1973	Chemistry of Phosphine Springer Verlag	No	Public
A 3.4.1	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH
A 3.4.2	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH
A 3.4.3	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH
A 3.4.4	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH
A 3.5.01	Fluck, E	1973	Chemistry of Phosphine Springer Verlag	No	Springer Verlag
A 3.5.02	WHO	1988	Phosphine and Selected Metal Phosphides Phosphine and Selected Metal Phosphides. Geneva, 1988, p. 17 - 19	No	Public
A 3.5.02	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH
A 3.6.01	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH
A 3.6.02	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH
A 3.7.01	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.7.02	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 3.8	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH
A 3.9	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH
A 3.9	Schlösser W	1989	Untersuchungsbericht: Octanol-Wasser-Verteilungskoeffizient von PH3 Report-No. 05011	No	Chemische Fabrik Wülfel
A 3.10.01	Smeykal H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH
A 3.10.02	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH
A 3.10.03	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH
A 3.11.01	Smeykal, H	2002	Aluminium technical: Flammability Report-No. 20020427.03	No	Detia Freyberg GmbH
A 3.11.02	Smeykal, H	2002	Aluminium phosphide technical: Explosive properties, auto-flammability Report-No. 20020427.04	No	Detia Freyberg GmbH
A 3.11.03	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisation
A 3.13	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH
A 3.14	Steinleitner, Hans-Dieter	1979	Anorganische Stoffe. Stoffzusammenstellung und sicherheitstechnische Kennwerte; Tabellenbuch brennbarer und gefährlicher Stoffe. Staatsverlag der Deutschen Demokratischen Republik, Berlin 1979, page 113	No	Public
A 3.15.01	Smeykal, H	2002	Aluminium phosphide technical: Explosive properties, auto-flammability Report-No. 20020427.04	No	Detia Freyberg GmbH

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 3.15.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion
A 3.16	Voigt, M; Schmitt S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH
A 3.17	F & E loboratory	2003	Determination of the Storage Stability of Phostoxin	No	Detia Freyberg GmbH
A 4.1	F & E laboratory	2004	Determination of Hydrogen phosphide and aluminium phosphide	No	Detia Freyberg GmbH
A 4.1.01	Kiefer, R.	2006	Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, GAB Biotechnologie GmbH & GAB Analytik GmbH, 20051467/01-U5B ,GLP, unpublished	Yes	Detia Freyberg GmbH
A 4.1.2 .01*	R & D Laboratory	2003-	Determination of aluminium nitride, , ,not GLP, unpublished	No	Detia Freyberg GmbH
A 4.1.2 .01a	Kiefer, R.	2006	Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, eurofins-GAB GmbH, 20051467/02-U5B ,GLP, unpublished	Yes	Detia Freyberg GmbH
A 4.1.2.01.b	Kiefer, R.	2006	Report Amendment No. 1 to Study 20051467/02-U5B: Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, eurofins-GAB GmbH, 20051467/02-U5B ,GLP, unpublished	Yes	Detia Freyberg GmbH
A 4.1.2 .02*	R & D Laboratory	2003	Determination of aluminium oxide, , ,not GLP, unpublished	No	Detia Freyberg GmbH
A 4.1.2 .03*	R & D Laboratory	2004	Determination of metals in technical aluminium phosphide, , ,not GLP, unpublished	No	Detia Freyberg GmbH
A 4.1.2 .03	R & D Laboratory	2004	Determination of metals in technical aluminium phosphide	No	Detia Freyberg GmbH

A 4.1.2.04	Kiefer, R.	2006	Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, GAB Biotechnologie GmbH & GAB Analytik GmbH, 20051467/01-U5B ,GLP, unpublished	Yes	Detia Freyberg GmbH
A 4.1.2 .05	Kiefer, R.	2006	Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, eurofins-GAB GmbH, 20051467/02-U5B ,GLP, unpublished	Yes	Detia Freyberg GmbH
A 4.2 b	Kettrup, A, Angerer, J	1994	Luftanalysen, Sonderdruck aus DFG – Deutsche Forschungsgemeinschaft. Band 1, Ed. Greim, H., published	No	public
A 4.2 c	Werle, H	1999	Determination of Residues in Surface Water and potable Water; report no.: 995040303, GLP, unpublished	Yes	Scotts Celaflor GmbH & Co. KG
A 4.2d	Witte, A.	2001	Residue analysis of Zinc Phosphide in Animal Tissues, Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, report no.: 20001426/01-RVAT, August 17,2001, GLP, unpublished	Yes	Arbeitsgem ein-schaft GAB Biotechnolo gie GmbH & IFU Umweltanal ytik GmbH
A 4.2d	Heintze, A.	2001	Residue analysis of Zinc Phosphide in human blood, Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, 20001426/01-RVAT, October 9, 2001	Yes	Arbeitsgem ein-schaft GAB Biotechnolo gie GmbH & IFU Umweltanal ytik GmbH
A 4.3*	Mende, P.	1999	Determination of Residues in Different Storage Goods. Detia Freyberg GmbH, 1999-12-08 GLP, unpublished	Yes	Detia Freyberg GmbH
A 5.4*	Price, N. R.	1980	A review of the mode of action of phosphine, Pesticide Science	No	Public
A 5.4*	Chin, K.L. et al.	1992	The interaction of phosphine with haemoglobin and erythrocytes, Xenobiotica, Vol. 22, No. 5, 599-607	No	Public
A 5.4*	Chaudry, M.Q. and Price, N.R.	1990	A spectral study of the biochemical reactions of phosphine with various haemproteins, Pesticide Biochemistry and Physiology 36, 14-21	No	Public
A 5.4*	Hsu, C.-H., et al.	1998	Phosphine-induced stress in hepa 1c1c7 cells, Toxicological Sciences 46, 204-210	No	Public

A 5.7.1/01	Rajendran, S.	2001	Insect resistance to phosphine - challenges and strategies.,International Pest Control International Pest Control, ,not GLP, published	No	
A 5.7.1/02	Reichmuth Ch	1992	Schnelltest zur Resistenzbestimmung gegenüber Phosphorwasserstoff bei vorratsschädlichen Insekten.,Mitt. Dtsch. Ges. Allg. Angew. Ent., Bd. 8, S. 245-247 Mitt. Dtsch. Ges. Allg. Angew. Ent., Bd. 8, S. 245-247, ,not GLP, published	No	
A 5.7.1/03	Tyler, P. S.; Taylor, W.R.; Rees, D.P.	1983	Insect resistance to phosphine fumigation in food warehouses in Bangladesh,International Pest Control, 25: 10-13 International Pest Control, 25: 10-13, ,not GLP, published	No	
A 6.1.1.01*	Leuschner, J.	1992	Acute toxicity study of AlP by oral administration to nmri mice, report no. 7129/92, Laboratory of Pharmacology and Toxicology, Detia Freyberg GmbH, 1992-06-15, GLP, unpublished	No	Detia Freyberg GmbH
A 6.1.1.02*	Sterner, W; Stiglic, A	1977	Acute oral toxicity of AlP in Rats, report no. 0-0-51-77, International Bio-Research Inc., Detia Freyberg GmbH, 1977-01, non-GLP unpublished	No	Detia Freyberg GmbH
A 6.1.2*	Heisler, E; Dickhaus, S	1987	Acute percutaneous toxicity, report no. 1-4-142-87, PHARMAROX Beratung und Forschung GmbH, Detia Freyberg GmbH, 1987-09, GLP, unpublished	No	Detia Freyberg GmbH
A 6.1.3*	Shimizu, Y; Ogawa, Y; Tokiwa K	1982	Acute inhalation toxicity testing of hydrogen phosphide in rats, NRI 82-7489, NOMURA RESEARCH INSTITUTE, Degesch Japan Co., 1982-05, non-GLP, unpublished	No	Detia Freyberg GmbH
A 6.1.3*	Waritz, RS; Brown, RM	1975	Acute and Subacute Inhalation Toxicities of Phosphine..., published, American Industrial Hygiene Association Journal, Haskell Laboratory, 1975-06	No	Public
A 6.1.4.01*	Heisler, E; Dickhaus, S	1987	Skin irritation, 1-3-183-87, Pharmatox Beratung und Forschung GmbH, Degesch GmbH, GLP, unpublished	No	Detia Freyberg GmbH
A 6.1.4.02*	Heisler, E; Dickhaus, S	1987	Eye Irritation, 1-3-184-87, Phamatox Beratung und Forschung GmbH, GLP, unpublished	No	Detia Freyberg GmbH
A 6.1.5	Corea Costa, K	2002	Evaluation of Skin Sensitization, R.E.428.192.02, Bioagri Laboratorios Ltda., Degesch do Brasil Industria e comercio Ltda., non-GLP, unpublished	Yes	Detia Freyberg GmbH
A 6.2.01*	Curry, AS et al.	1959	Absorption of Zinc phosphide particles, Nature, non-GLP, published	No	Public

A 6.2.02*	Andreev, SB et al.	1959	Use of Tracer Techniques in the Study of Plant Protection, 2nd Int. Conf. Peaceful Uses Atomic Energy, non-GLP, published	No	Public
A 6.2.03*	WHO	1988	Environmental Health Criteria 73, pp. 48-51, WHO, non-GLP, unpublished	No	Public
A 6.3.1			please refer to Sec. IIIA 6.3.3		
A 6.3.2			please refer to Sec. IIIA 6.3.3		
A 6.3.3	Omae, K et al.	1996	Acute and subacute inhalation toxicity, J. Occup Health, non-GLP, published	No	Public
A 6.4.1	Schnellhardt, M	1985	Study on the subchronical toxicity of AlP, Forschungszentrum für Tierproduktion, Dummerstorf-Rostock, Delicia Freyberg GmbH, non-GLP, unpublished	No	Detia Freyberg GmbH
A 6.4.1			please refer to Sec. IIIA 5.4		
A 6.4.2			please refer to Sec. IIIA 6.4.3		
A 6.4.3*	Newton, PE	1990	13 week inhalation toxicity study of phosphine in the rat, 87-8030, Bio/dynamics Inc., Degesch America Inc., GLP, unpublished	Yes	Detia Freyberg GmbH
A 6.4.3			please refer to Sec. IIIA 5.4, 6.8.1		
A 6.5.01*	Newton, PE	1998	2-Year combined Inhalation Chronic Toxicity and Oncogenicity Study Rat, 750-001, MPI Research, Degesch America Inc., GLP, unpublished	Yes	Detia Freyberg GmbH
A 6.5.02	Telle, C et al.	1985	Nutritional / toxicological effects of long-term ingestion in the rat, Ed. Chem. Toxic., non-GLP, published	No	Pulbic
A 6.5.03	Hackenberg, U	1969	2 years toxicity studies with Phostoxin treated food on rats, A0187/012, Institut für Insurtrielle und Biologische Forschung, Degesch GmbH Frankfurt, non-GLP, unpublished	No	Detia Freyberg GmbH
A 6.5			please refer to Sec. IIIA 6.12.3, 6.7, 6.4.1, 6.4.3		
A 6.6.1.01	Sutou, S; Yamamoto, K; Shirkawa, H	1982	In vitro microbial mutagenicity testing of hydrogen phosphide, 82-7492, NOMURA RESEARCH INSTITUTE, Degesch Japan Co., non-GLP, unpublished	No	Detia Freyberg GmbH
A 6.6.1.02	Stankowski, LF	1990	Ames/Salmonella Plate Incorporation Assay on PH3, PH 301-DA-001-89, Pharmakon Research International Inc., Degesch America Inc., GLP, unpublished	No	Detia Freyberg GmbH
A 6.6.2	San Sebastian JR	1990	Structural Chromosome Aberration CHO cell induced by PH3, PH 320-DA-001-89, Pharmakon Research International Inc., Degesch America Inc. GLP, unpublished	No	Detia Freyberg GmbH

A 6.6.3	Leuschner F	1992	Phosphine. Mutagenicity study in Mammalian cells (V79) in vitro, 6990/91, Laboratory of Pharmacology and Toxicology, Detia Freyberg GmbH, GLP, unpublished	No	Detia Freyberg GmbH
A 6.6.4.01*	Kligerman, AD et al.	1994	Cytogenetic Effect of Phosphine Inhalation by Rodents, Environ. Mol.Mutagen., GLP status uncertain, published	No	Public
A 6.6.4.02*	Kligerman, AD et al	1994	Cytogenetic and Germ Cell Effects of Phosphine Inhalation by Rodents, Environ.Mol.Mutagen., GLP status uncertain, published	No	Public
A 6.6.5*	McKeon, ME	1993	In vivo/in vitro assay for unscheduled DNA synthesis in rat, A0040-0-494, Hazleton Laboratories America, Inc., Degesch America Inc, GLP, unpublished	No	Detia Freyberg GmbH
A 6.7*	Newton, PE	1998	2-Year combined Inhalation Chronic Toxicity and Oncogenicity Study Rat, 750-001, MPI Research, Degesch America Inc., GLP, unpublished	Yes	Detia Freyberg GmbH
A 6.7			please refer to Sec. IIIA 6.12.3, 6.7, 6.4.1, 6.4.3		
A 6.8.1	Newton, E.P.	1993	Inhalation toxicity of Phosphin in the rat:, Inhal. Tox., Bio/dynamics Inc.	No	Detia Freyberg GmbH
A 6.8.1	Klimmer, OR	1969	Beirat zur Wirkung des Phosphorwasserstoffes,published, Archiv für Toxikologie, Pharmaklogisches Institut der Universität Bonn	No	Public
A 6.8.1	Müller, W	1940	Über Phosphorwasserstoffvergiftung, published, Archiv für experimentelle Pathologie und Pharmakologie	No	Public
A 6.8.1	World Health Organisation	1988	Phosphine and Selected Metal Phosphides, World Health Organisation, non-GLP, published	No	World Health Organisa-tion
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* key study