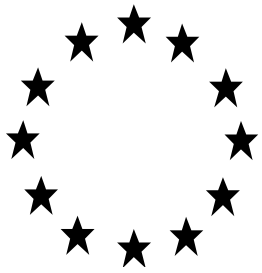
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Aluminium phosphide releasing phosphine

Product-type 20
(Control of other vertebrates)

September 2013

Germany

Aluminium phosphide releasing phosphine (PT 20)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 27 September 2013

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of aluminium phosphide releasing phosphine as product-type 23 (Products for the control of other vertebrates), 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 market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 23 containing aluminium phosphide that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive. Product type 23 as defined in Annex V of directive 98/8/EC corresponds to product-type 20 as defined in Annex V to Regulation (EU) No 528/2012.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of aluminium phosphide releasing phosphine for product-type 20, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 20 that contain aluminium phosphide. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern 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 Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

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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

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of aluminium phosphide releasing phosphine as product-type 23 (Products for the control of other vertebrates), 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[2], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Aluminium phosphide releasing phosphine (CAS no. 20859-73-8) was notified as an existing active substance, by Detia Freyberg GmbH, hereafter referred to as the applicant, in product-type 23.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[3] 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 releasing phosphine as an active substance in Product Type 23 was 31.10.2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 08.09.2008, 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 08.12.2008.

On 23.07.2010, 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 29.07.2010. The competent authority report included a recommendation for the inclusion of aluminium phosphide releasing phosphine in Annex I to the Directive for product-type 23.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 29.07.2010. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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2 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

3 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

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

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 27 September 2013.

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 and the physico-chemical properties of aluminium phosphide (CAS-No. 20859-73-8) are given in detail in the confidential part of the CA-report. 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 Pow 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 WM

The identity and the physico-chemical properties of Phostoxin WM, which contains 56 % of the active substance aluminium phosphide, are given in detail in the confidential part of the dossier. Due to the content of Aluminium phosphide, Phostoxin WM is classified as highly flammable as it evolves highly flammable gases (PH_3) in contact with water or humid air.

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 product Phostoxin WM in food and feedingstuffs, are not considered necessary. Likewise, analytical methods are not required for soil (none) and water (confirmatory method, Independent Laboratory Validation).

The determination of relevant residues of aluminium phosphide (determined as PH_3) in air, water, in animal tissues and plant material is covered by the data set for the active substance.

Analytical methods are not required for soil. No methods for the determination of non-active ingredients were submitted. They were not considered necessary as no relevant residues of non-active ingredients are expected.

2.1.2. Intended Uses and Efficacy

Aluminium phosphide has been evaluated for its use as a product for the control of other vertebrates belonging to product type 23 according to Annex V of the Directive 98/8/EC.

Target organisms are moles (Talpa europaea) and rabbits (Oryctolagus cuniculus).

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious. Efficacy has only been proven for moles and rabbits. For all other uses against other vertebrates information should be provided at product authorisation phase.

The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The product containing the active ingredient aluminium phosphide releasing phosphine is intended to be used for outdoor control of other vertebrates for all types of non-agricultural purposes, including embankments and dikes. Aluminium phosphide products are laid out in burrow systems only by trained professional users familiar with the precautionary measures to be applied.

The active ingredient aluminium phosphide reacts with moisture in soil and air and releases the toxic gas, phosphine. Phosphine induces oxidative stress in mammalian cells and administration of high doses causes methaemoglobinemia in the mammal.

The effectiveness of the product Phostoxin WM containing the active substance aluminium phosphide releasing phosphine was sufficient when used to control the populations of moles and rabbits by using one tablet (3g releasing 1g phosphine) per hole and one additional tablet per treatment if upon inspection the hole was reopened. 100 % effectiveness was achieved against moles (Talpa europaea) using one 3 g tablet per hole and treatment; retreatment was necessary one to three times during a test period of 14 to 28 days. 100 % effectiveness was also achieved against rabbits (Oryctolagus cuniculus) using one 3 g tablet per hole and treatment; in one case retreatment was not necessary during the test period of 6 days; in the other study, retreatment was necessary three times during a test period of 21 days.

Aluminium phosphide products should be applied only by trained professional users familiar with the precautionary measures and who are experienced in assessment of the sites to be treated.

Resistance against aluminium phosphide did not occur in relevant susceptible pests. This lack of development of resistance in the target organisms to this biocidal product is assumed to be related to the inorganic nature of the active ingredient. However, ineffective sealing of treated burrows and other inaccurate applications may reduce the effectiveness of the treatment and therefore the use instructions should strictly be followed to obtain satisfying results.

To maximise the effectiveness and humaneness of fumigation, the gas must be widely distributed throughout a burrow system and maintained at a high enough concentration to cause rapid death. The latter is dependent on the porosity and dampness of soil.

2.1.3. Classification and Labelling

Classification and Labelling of aluminium phosphide

Evaluation of the submitted data under Directive 98/8/EC resulted in following proposal for classification and labelling which is in accordance with classification and labelling guidance under Directive 67/548/EEC (i.e. in the 29th ATP published as Directive 2004/73/EC) and Regulation (EC) No 1272/2008:

Table 1 Proposed classification of aluminium phosphide based on Directive 67/548/EEC

	Classification	Wording
Hazard Symbols, Indications of danger	F T^+ Xn N	Highly flammable Very toxic Harmful Dangerous to the environment
R-phrases	R15 R26*/28 R21 R29 R32 R50	Contact with water liberates extremely flammable gases Very toxic by inhalation* and if swallowed Harmful in contact with skin Contact with water liberates toxic gas Contact with acids liberates very toxic gas Very toxic to aquatic organisms

* According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS

Remark:

Phosphine, which develops after contact of aluminium phosphide with water by spontaneous hydrolysis of the phosphide, is very toxic by inhalation. According to former Annex I to Directive 67/548/EEC, classification and labelling of the gas is appropriate (T+; R 26), but aluminium phosphide itself has not been classified with regard to inhalation toxicity. Because phophine is released from aluminium phosphide, the RAC proposed an additional classification of aluminium phosphide with T+; R26 (RAC Opinion of 2nd December 2011).

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

The proposed classification in this table corresponds to the proposal in the CLH-Report (Annex VI Dossier) of aluminium phosphide, except for R26, which is proposed in the RAC Opinion of 2nd December 2011.

Table 2 Proposed classification of aluminium phosphide based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Water-react. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 1* Aquatic Acute 1	
Hazard statements	H260 H300 H311 H330* H400	In contact with water releases flammable gases which may ignite spontaneously Fatal if swallowed Toxic in contact with skin Fatal if inhaled Very toxic to aquatic life

* According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS

Remark:

The content of this table is mainly based on table 3.1 of Annex VI of Regulation (EC) No 1272/2008 and the results of the acute dermal toxicity study.

The proposed classification in this table corresponds to the proposal in the CLH-Report (Annex VI Dossier) of aluminium phosphide, except for Acute Tox. 1; H330, which is proposed in the RAC Opinion of 2nd December 2011.

Table 3 Proposed labelling of aluminium phosphide based on Directive 67/548/EEC (30th ATP)

	Labelling	Wording
Hazard Symbols, Indications of danger	F T^+ N	Highly flammable Very toxic Dangerous to the environment
R-phrases	R15/29 R21 R26*/28 R32 R50	Contact with water liberates toxic, extremely flammable gas Harmful in contact with skin Very toxic by inhalation* and if swallowed Contact with acids liberates very toxic gas Very toxic to aquatic organisms
S-phrases	(S1/2) S3/9/14/49 S8 S22 S30 S36/37 S43 S45 S60 S61	Keep locked up and out of the reach of children Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer) Keep container dry Do not breathe dust Never add water to this product Wear suitable protective clothing and gloves In case of fire use … Never use water In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheet.

* According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS

Remark:

Concerning S-phrases, S 8 “Keep container dry” and S 49 “Keep only in the original container” are considered necessary for aluminium phosphide and should be added. As it is the case with Mg3P2 the S-phrase 22 should be added here too. Both substances are powders and have about the same toxicity.

Concerning labelling with S 28 (which is obligatory for very toxic substances according to Dir. 67/548/EEC), it is accepted that brushing or wiping off of aluminium phosphide-dust/ -particles is more reasonable than washing it from skin or cloth; but this wording is not possible within S 28 (cf. P335 “Brush off loose particles from skin”). So this S-phrase should be omitted.

The proposed labelling in this table corresponds to the proposal in the CLH-Report (Annex VI Dossier) of aluminium phosphide, except for R26, which is proposed in the RAC Opinion of 2nd December 2011.

Table 4 Proposed labelling of aluminium phosphide based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS02 GHS06 GHS09	
Signal Word	Danger	
Hazard statements	H260 H300 H311 H330* H400	In contact with water releases flammable gases which may ignite spontaneously Fatal if swallowed Toxic in contact with skin Fatal if inhaled Very toxic to aquatic life
Suppl. Hazard statements	EUH029 EUH032	Contact with water liberates toxic gas Contact with acids liberates very toxic gas
Precautionary statements	P223 P231 + P232 P234 P260 P273 P280 P301 + P310 P321 P335 P370 + P378 P402 + P404 P405 P501	Keep away from any possible contact with water, because of violent reaction and possible flash fire Handle under inert gas. Protect from moisture Keep only in original container Do not breathe dust/fume Avoid release to the environment Wear protective gloves/ protective clothing/ eye protection/ face protection IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician Specific treatment (see … on this label) Brush off loose particles from skin In case of fire: Use … for extinction Store in a dry place. Store in a closed container Store locked up Dispose of contents/container to …

*According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS

Remark:

The content of this table is mainly based on table 3.1 of Annex VI of Regulation (EC) No 1272/2008.

The number of the Precautionary statements is quite big but they were all recommended in Annex I of Regulation (EC) No 1272/2008 based on the given Hazard statements.

The proposed labelling in this table corresponds to the proposal in the CLH-Report (Annex VI Dossier) of aluminium phosphide, except for H330, which is proposed in the RAC Opinion of 2nd December 2011.

Classification and Labelling of Phostoxin WM

Table 5 Proposed classification of Phostoxin WM based on Directive 1999/45/EC

	Classification	Wording
Hazard Symbols, Indications of danger	F T^+ Xn Xi N	Highly flammable Very toxic Harmful Irritant Dangerous to the environment
R-phrases	R15 R26*/28 R21 R36 R29 R32 R50	Contact with water liberates extremely flammable gases Very toxic by inhalation* and if swallowed Harmful in contact with skin Irritating to eyes Contact with water liberates toxic gas Contact with acids liberates very toxic gas Very toxic to aquatic organisms

* Applies if RAC Opinion of 2nd December 2011 is implemented in a corresponding ATP of Regulation (EC) 1272/2008

Remark:

In addition to current legal classification (and labelling), "**Xn; R 21**" which is considered necessary for aluminium phosphide has to be adopted for the biocidal product since the limit concentration of 25 % (w/w) (Directive 1999/45/EC) is exceeded.

Eye irritation properties of metal phosphides are known from other relevant sources and additionally based on mechanistic considerations. Since the compositions of the products are almost identical, classification as "**Xi; R36**" is also adopted for the biocidal product. Moreover, one of the stabilisers used in the formulation, representing 21 % w/w of the total amount, has been proposed to be classified as "Irritating to eyes" (Xi; R 36) by its manufacturer. Since the concentration in the product is beyond the threshold value for classification, R 36 is allocated for the biocidal product according to the Conventional Method of Directive 1999/45/EC.

At present, the biocidal product is placed on the market for plant protection with identical composition to the biocidal product in Germany. The proposed classification here corresponds to that of the plant protection product. The current S-phrases are based on the evaluation in the frame of self classification of the applicant.

Table 6 Proposed classification of Phostoxin WM based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Water-react. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox 1 Eye Irrit. 2 Aquatic Acute 1	
Hazard statements	H260 H300 H311 H330* H319 H400	In contact with water releases flammable gases which may ignite spontaneously Fatal if swallowed Toxic in contact with skin Fatal if inhaled Causes serious eye irritation Very toxic to aquatic life

* Applies if RAC Opinion of 2nd December 2011 is implemented in a corresponding ATP of Regulation (EC) 1272/2008

Remark:

The classification of the biocidal Product is transformed mainly based on the rules of the Regulation (EC) No 1272/2008 (cf. Table 2).

Table 7 Proposed labelling of Phostoxin WM based on Directive 1999/45/EC

	Labelling	Wording
Hazard Symbols, Indications of danger	F T^+ N	Highly flammable Very toxic Dangerous to the environment
R-phrases	R15/29 (R21) R26*/28 R32 R36 R 50	Contact with water liberates toxic, extremely flammable gas (Harmful in contact with skin) Very toxic by inhalation and if swallowed Contact with acids liberates very toxic gas Irritating to eyes Very toxic to aquatic organisms
S-phrases	(S1/2) S3/9/14/49 S7/8 S30 S36/37/39 S43 S45 S60 S 61	Keep locked up and out of the reach of children Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer) Keep container tightly closed and dry Never add water to this product Wear suitable protective clothing, gloves and eye/face protection In case of fire … Never use water In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.) This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheet

* Applies if RAC Opinion of 2nd December 2011 is implemented in a corresponding ATP of Regulation (EC) 1272/2008

Remark:

Concerning the S-phrases, **S39** is added because of R36 and possible toxic effects by contact with the eyes. **S43** is taken over from the active substance (30th ATP).

In the RAC Opinion of 2nd December 2011, a classification of the active substance with T+;R26 was proposed. If this proposal is implemented in a corresponding ATP of Regulation (EC) No 1272/2008 at the time of product authorisation, the same classification applies to the representative product. In this case, the S-phrases may have to be revised.

Table 8 Proposed labelling of Phostoxin WM based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS02 GHS06 GHS09	
Signal Word	Danger	
Hazard statements	H260 H300 H311 H330* H319 H400	In contact with water releases flammable gases which may ignite spontaneously Fatal if swallowed (Toxic in contact with skin) Fatal if inhaled Causes serious eye irritation Very toxic to aquatic life
Suppl. Hazard statements	EUH029 EUH032	Contact with water liberates toxic gas Contact with acids liberates very toxic gas
Precautionary statements	P223 P232 P234 P260 P273 P280 P301 + P310 P321 P335 P370 + P378 P402+P403+P404 P405 P501	Keep away from any possible contact with water, because of violent reaction and possible flash fire Protect from moisture Keep only in original container Do not breathe dust/fume/gas/ Avoid release to the environment Wear protective gloves/ protective clothing/ eye protection/ face protection IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician Specific treatment (see … on this label) Brush off loose particles from skin In case of fire: Use … for extinction Store in a dry place. Store in a well-ventilated place. Store in a closed container Store locked up Dispose of contents/container to …

* Applies if RAC Opinion of 2nd December 2011 is implemented in a corresponding ATP of Regulation (EC) 1272/2008

Remark:

The labelling of the biocidal Product is transformed mainly based on the rules of the Regulation (EC) No 1272/2008 (cf. Table 4). The number of the Precautionary statements is quite big but they were all recommended in Annex I of Regulation (EC) No 1272/2008 based on the given Hazard statements.

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.

According to Article 20(3) of Directive 98/8/EC it should be stated quite clearly somewhere else on the label and in the SDS that contact with water as well as moisture has to be strictly avoided before the b. p. is finally used as intended.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Effects assessment

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, 32P was rapidly absorbed from the gastrointestinal tract. Inhaled PH_3 is considered to be rapidly and quantitatively absorbed through the lungs. 32P 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 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 a.s., 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+; R28) 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. Because phophine is released from aluminium phosphide, the RAC proposed an additional classification of aluminium phosphide with T+; R26 (RAC Opinion of 2nd December 2011). In addition to T+; R28, aluminium phosphide has also been classified and labelled with R 29 ('contact with water liberates toxic gas') and R32 ('contact with acids liberates very toxic gas') according to former 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; R21) 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. The test compound did not demonstrate a potential for sensitisation (the concentration of the test substance in the product caused signs of mild irritation at 24 and 48 hours after administration, skin reactions in the animals such as oedema and erythema were observed). 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. The study has some deviations from the OECD protocol, which results in a reliability factor of 3. However, it was decided to accept it for Annex I inclusion.

Overall, aluminium phosphide is considered not sensitising via the skin.

Medium-term Toxicity

In an oral 90-day gavage test in Wistar rats, 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 and based on other data sources claiming that non-rodents are not more sensitive to AlP/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 phoshide / PH_3 toxicity from which it can be expected 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 phosphine 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 and 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 a.o. 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 ProductPhostoxin WM

The biocidal product Phostoxin WM containing 56 % (w/w) aluminium phosphide is very toxic if swallowed (T+; R28). In addition, "Xn; R21" which is considered necessary for aluminium phosphide has to be adopted for the biocidal product since the limit concentration of 25 % (w/w) (Directive 1999/45/EC) is exceeded. Eye irritation properties of metal phosphides are known from other relevant sources and additionally based on mechanistic considerations. Since the compositions of the products are almost identical, classification as "Xi; R36" is also adopted for the biocidal product. Moreover, one of the stabilisers used in the formulation, representing 21 % w/w of the total amount, has been proposed to be classified as "Irritating to eyes" (Xi; R36) by its manufacturer. Since the concentration in the product is beyond the threshold value for classification, R36 is allocated for the biocidal product according to the Conventional Method of Directive 1999/45/EC. Because phophine gas is released from aluminium phosphide, the RAC proposed an additional classification of aluminium phosphide with T+; R26 (RAC Opinion of 2nd December 2011). If this proposal is implemented in a corresponding ATP of Regulation (EC) No 1272/2008, the same classification also applies for the representative product.

Summary & Conclusion

Aluminium phosphide and phoshine 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, AlP 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 AlP 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 AlP/kg bw/d) was derived for medium and long-term exposure. An AEL for acute exposure of 0.019 mg/kg PH_3/kg bw/d (equivalent to 0.032 mg AlP/kg bw/d) was set based on the NOAEL from the developmental inhalation study in rats.

Although no exposure towards aluminium phosphide/PH_3 residues via food is expected from use in PT 20 (former PT 23) products, it is noted that during the risk assessment for other PT, an Acute Reference Dose of 0.019 mg PH_3/kg bw (0.032 mg AlP/kg bw) as well as an Acceptable Daily Intake value of 0.011 mg PH_3/kg bw (0.019 mg AlP/kg bw) have been deduced from the database.

Summarising the study results and all considerations above aluminium phosphide requires classification(and labelling) for human health according to Directive 67/548/EEC as follows:
T+; R 28 (proposed by the RMS)
T+; R26 (according to RAC Opinion)
Xn; R 21, R 29, R 32 (proposed by the RMS)

According to Regulation (EC) No 1272/2008 aluminium phosphide requires classification (and labelling) as follows:
Acute Tox 1 / H330 (according to RAC Opinion)
Acute Tox 2 / H300 (proposed by the RMS)
Acute Tox 3 / H311 (proposed by the RMS)
(EUH029, EUH032) (proposed by the RMS)

2.2.1.2. Exposure assessment

Exposure of Professionals

The active substance aluminium phosphide is produced in the EU.

According to the participant the product Phostoxin WM (pellets/tablets, 56 % active substance) is used for outdoor control of other vertebrate species like rabbits and moles for all types of non-agricultural purposes, i.e along railway embankments. Aluminium phosphide releases phosphine gas upon contact with moisture from e.g. soil or air. The biocidal product is placed in two different forms on the market: a 3 g tablet and a 0.6 g pellet, both with 56 % a.s.. The biocidal product is inserted into burrows by an applicator. The applicator is a simple device for gravity placement of tablets/pellets.

In case of inhalation exposure, the exposure to phosphine is estimated whereas the dermal exposure is assessed for the contact to the solid aluminium phosphide.

Inhalation exposure

The assessment of inhalation exposure to phosphine is based on measurement results of the company Rentokil (Barnett, 1999). The sampling of phosphine in air includes all aspects of the treatment: can open, transfer of the biocidal product into the applicator, application of the tablets and cleaning of the applicator. All personal and static samples are under the limit of detection of 1 mg/m3. To estimate the inhalation exposure the half of the limit of detection is used. The resulting inhalation exposure is estimated to be 0.05 mg/m3. The extent of inhalation exposure to phosphine during inspection is unclear since the participant provided no information concerning the release rate of phosphine (from the b.p.). After 5-6 days it is assumed that degradation of the b.p. as well as the resulting phosphine is complete. Inhalation exposure to aluminium phosphide or phosphine is expected no more.

Dermal exposure

During the transfer of the biocidal product into the applicator no dermal exposure is expected.

During handling the applicator, the direct contact with the biocidal product is incidental. If one tablet is in the tube it is reasonable that the dermal contact could occur. The assessment of the dermal exposure based on expert judgment. For the application of the tablets/pellets the thickness of the substance layer on the skin is assessed to be 0.0001 cm. This assessment is based on the low abrasion characteristics of the tablets/pellets with is expected to be a factor of 100 lower than the assessment of Vermeire et al. (1993) of 0.01 cm. The resulting potential

dermal exposure is 1.9 mg a.s./person/day for tablets and 3.0 mg a.s./person/day for pellets. It is expected that the palm of one hand (210 cm2) is contaminated. The duration for professional use of pellets is assessed to be a worst case situation 8 hours for 110 days per year. Dermal exposure to aluminium phosphide during inspection of the holes is not expected.

Secondary exposure is not expected.

Exposure of Non-Professionals

Non-professional use

Non-professional use of Phostoxin WM is not allowed. Application of the biocidal product is restricted to professional operators. Primary exposure of non-professionals can be excluded.

General public

No significant secondary exposure of the general public to aluminium phosphide and phosphine is expected if professional application of the biocidal product Phostoxin WM is performed appropriately and professionally, i.e. if access to outdoor areas, in which treatments have been carried out, is safely prevented and if it is performed in adequate distance to inhabited houses (at least 10 metres according to TNsG on Human Exposure 2002 Part 2, pp. 106 and 127).

In general it is assumed that only risks from acute exposure to phosphine are relevant for the general public. However, the medium-term exposure cannot be absolutely excluded since treatments last up to 14 days. Chronic (long-term) secondary exposure of the general public to aluminium phosphide or phosphine is considered not relevant.

Re-entry for other persons than the operator to treated areas should only be allowed if the concentration of phosphine is below 0.01 ppm (corresponding to 0.014 mg/m3). This concentration is recommended by the Scientific Committee on Occupational Exposure Limits (SCOEL) and is also given in the German TRGS 512, which regulates among others the gassing with phosphine and phosphine-releasing preparations. If a person stays for 24 h in an area which has been cleared for re-entry by the operator (i.e. phosphine concentration is below the limit) after treatment and it is assumed that the concentration remains stable over this time period (worst case, no degradation, no ventilation) the person would be exposed to 0.28 mg/d (adults) or 0.056 mg/d (infants) assuming a respiration rate of 20 m3/d (adults) or 4 m3/d (infants). If a body weight of 60 kg and 10 kg, respectively, and an inhalation absorption of 100 % is expected this results in an internal dose of 0.00467 mg/kg bw(/d) for adults and 0.00560 mg/kg bw(/d) for infants.

According to a study provided by the applicant (Old, 2003) no phosphine gas is detectable outside of buildings if biocidal products containing aluminium phosphide are applied appropriately. In this study phosphine gas was detected only for approximately 1 min during one (of 6) fumigation (each fumigation lasted 7 to 14 days). Thus, it can be concluded that concentration of phosphine gas is in general under the detection limit. The most sensitive sensors in this study had a detection limit of 0.5 ppb (corresponding to 0.0007 mg/m3). Although also less sensitive detectors were used the detection limit of the most sensitive detector is used for the following calculations. If it is assumed that a bystander is exposed for 8

h to this concentration (inhalation absorption 100 %; body weight 60 kg for adults and 10 kg for infants; respiration rate 20 m3/d for adults and 4 m3/d for infants) this would result in internal doses of 0.0000778 mg/kg bw(/d) and 0.0000933 mg/kg bw(/d) for adults and infants, respectively.

The cited study was performed in buildings. Nevertheless, it is assumed, that the results are also valid for outdoor use. The phosphine concentration has always to be controlled independently whether the biocidal product is used out- or indoors. Therefore, it is expected that the concentration will not exceed the limit values if measurements are performed appropriately and treated areas burrows are safely blocked off. Furthermore, it can be assumed that the aerial concentration during outdoor treatment is generally lower, due to the stronger ventilation and the bigger volumes, in which the gas is dispersed.

Dietary exposure

Aluminium phosphide is intended to be used in a gas-generating product against vertebrates (PT 20 (former PT 23)). The application takes place exclusively in the burrows of such animals. As no contact with food, feed or livestock occurs, residues in food or feed are not expected as a result of this use. Therefore, dietary exposure of humans from the use of aluminium phosphide as a biocide of PT 20 (former PT 23) can be excluded.

2.2.1.3. Risk characterisation

Risk Assessment for Professionals

The product Phostoxin WM (pellets/tables) with 56 % active substance is used for outdoor control of rabbits and moles for all types of non-agricultural purposes, i.e along railway embankments. The biocidal product is applied using an applicator, which is a simple device for gravity placement of tables/pellets in the rodent burrows. The biocidal product is assumed to be for a worst case scenario in use 110 days per year, 8 hours per day.

For risk characterisation, external exposure values are translated into internal body burden. Exposure by inhalation directly refers to air-borne concentrations of phosphine. For calculation of the internal body burden, for phosphine a 100 % absorption by inhalation is assumed. During transfer of the biocidal product into the applicator no dermal contact is expected, but during handling of the applicator, the direct contact with the biocidal product is incidental. It is assumed that 10 % of dermally exposed aluminium phosphide is available internally as phosphine

When using these absorption percentages the total internal body burden is with a maximum potential exposure of 80 % triggered by inhalation, the contribution of dermal contact is close to 30 %.

For risk characterisation the total internal body burden is compared to the AEL long-term (as internal reference value).

The AEL is based upon a 90-day and 2-year inhalation toxicity study in rats. The determined NOAEL of both studies is 1.1 mg PH_3/kg bw/d equivalent to 4.2 mg PH_3/m3. Application of an

10 x 10 assessment factor for inter- and intraspecies differences and the assumption of 100 % absorption by inhalation results in an AEL for medium and long-term exposure of 0.011 mg PH_3/kg bw/d (corresponding to 0.019 mg AlP/ kg bw/d).

Against the background of a decision criterion of 1 for the exposure-to-AEL ratio there is a borderline situation for the application of tables/pellets without PPE and a refinement of exposure is considered necessary.

Since potential air-borne concentrations of 0.05 mg/m3 phosphine are lower as the corresponding OEL (Occupational exposure level) of 0.14 mg/m³ derived by SCOEL the exposure is refined only for the dermal route. The reduction of dermal exposure as a result of PPE lead to exposure-to-AEL ratios of 0.7 for both applications, systemic health effects are not anticipated to occur.

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):

For the conditions specified, there is no concern for the application of tablets/pellets by applicator.

Safety Measures for Professionals

Since the OEL is kept but the ratio of the 'total internal body burden' towards AEL is exactly 1, it is permissible to reduce exposure by dermal protection measures, only. Technical and / or organisational measures have to be considered, preferentially, according to the Chemical Agent Directive 98/24/EC, article 6, paragraph 2. As last resort, adequate personal protective equipment (PPE) has to be recommended. This should apply to pellets as well as to tablets for hygienic reasons (to avoid carry-over from hand to mouth or to another person's skin) because - in praxis - users are not supposed to distinguish between tablets and pellets.

As dermal exposure is limited to hands and forearms of the user, it can be controlled by approved chemical protection gloves with gauntlets. A protection factor of 90 % is applied to the area of the hands towards aluminium phosphide-dust (according to TNsG on Human Exposure) for specialized professionals (e.g. pest controllers) using the applicator if label and safety data sheet inform about

- material,
- thickness,
- break through time (level),
- fulfilled European Standards (e.g. EN 374), and give
- an exemplary gloves-product.

Towards gases, protection cannot be granted nor quantified as phosphine may also enter the glove along the wrist.

Risk Assessment for Non-Professionals (primary exposure)

No risk assessment for non-professional use has been conducted since products may only be applied by [specially trained] professionals.

Risk assessment for the general public (secondary exposure)

In all scenarios risks from secondary exposure of the general public to phosphine from the use of Phostoxin WM were acceptable in relation to human health assuming that safety measures are applied correctly.

*Safety Measures for Non-Professionals*Bystanders including the general public will not be exposed to Phostoxin WM or its active substance aluminium phosphide in its normal use in PT 20 (former PT 23) provided that access to the treated area during application is restricted to the professional user only. The professional user has to ensure this by applying appropriate measures on site. No additional protection measures are necessary if it is presumed that the application of the biocidal product is performed appropriately, professionally and in accordance to the instructions for use.

2.2.2. Environmental Risk Assessment

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

Due to the fact that AlP in contact with humidity is rapidly decomposed to the actual a.s. phosphine (PH_3) generated in-situ, 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, $Al(OH)_3$ is ubiquitous in the environment and it can be assumed that the release of this reaction product from the use of aluminium phosphide as fumigant in underground tunnel systems will not significantly increase the environmental concentration of this compound or of freely available Al^{3+}. A comparison of the calculated aluminium concentration in soil after application with available literature data of natural aluminium occurrence confirms this statement. Therefore the second reaction product is not further regarded for the environmental risk assessment with some exceptions.

2.2.2.1. Fate and distribution in the environment

Biodegradation

Both, solid AlP 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 AlP, PH_3 and aluminium hydroxide, biodegradability studies are technically not feasible.

Phosphine released into the aquatic compartment is poorly soluble in water (24 ml/100ml 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 phosphorus cycle.

Aluminium hydroxide is not biodegradable and belongs to the natural constituents of surface water, sediment and soil.

Abiotic Degradation

In water, aluminium phosphide is decomposed into hydrogen 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 AlP is not feasible due to the rapid reaction of AlP with water resulting in the volatile reaction product phosphine. A study on photo-transformation of PH_3 is also not considered to be required, since the substance does not absorb light at relevant wavelengths to any significant degree.

AlP has a negligible vapour pressure (<<10-5 Pa at 25 °C). No direct emission into air of AlP is to be expected. In contact with humidity AlP 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 the air is not to be expected.

Distribution

The performance of adsorption and desorption studies is 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.

The use pattern of b.p. (Phostoxin WM,) as fumigant in underground tunnel systems 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 m³ 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 Pow for aquatic organisms (BCF_{fish} = 1.16 L/kg) and for terrestrial organisms ($BCF_{earthworm}$ = 0.94 L/kg) can be classified as low.

2.2.2.2. 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 underground tunnel systems. The lowest effect value of 7.98 µg/L was obtained from 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 underground tunnel systems. 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 AlP 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 (corresponding to 4.6 µg/kg/ww).

Toxicity test results with further terrestrial organisms (plants, earthworms etc.) are not available. Such data do not belong to the core data or the additional data requirements for active substances of product type 20 (former PT 23). However, the intended use of aluminium phosphide as a fumigant in underground burrow systems (railway embarkments, dikes etc.) causes an exposure of the terrestrial compartment. As stated by the applicant, any terrestrial organisms (vertebrates, soil insects, earthworms…) inhabiting the soil compartment in the target area will be killed by the arising PH_3 concentrations. For plants, a direct exposure may only occur via the roots, but this can be assumed to be minimal.

The performance of tests with terrestrial organisms like earthworms and insects is not deemed necessary as these tests will only show what is already known (mortality of the soil organisms at the PH_3 concentrations arising from the intended use of AlP). As the exposure is only limited to a small area and the PH_3 concentrations will decrease relatively fast, it can be assumed that the non-target organisms will resettle the exposed area within a short time after use of AlP-containing products.

Honeybees and other beneficial arthropods

Acute toxicity to honeybees is neither a core data nor a product type specific additional data requirement for the intended use (product type 20 (former PT 23)). No such data have been submitted. However, due the application of aluminium phosphide in underground burrow systems, direct exposure to honey bees is unlikely and therefore such information is not regarded necessary.

Effects on Birds

Data on the toxicity to birds belong to the additional data requirements for biocides of PT 20 (former PT 23) (control of other vertebrates) for products used outside of buildings in the form of bait, granules or powder. No data have been provided by the applicant with the justification that the special conditions of use exclude the possibility that birds come into contact with aluminium phosphide or phosphine gas. It was agreed that the submission of data on toxicity of aluminium phosphide to birds is not considered to be required as the intended use in underground tunnel systems makes a direct exposure of birds negligible.

Effects on mammals

No data in addition to that already discussed are available. As stated by the applicant, all non-target vertebrates which are using the tunnels of the target organisms as a part of their habitat or living in similar holes in the same habitat are highly endangered by the arising PH_3.

2.2.2.3. PBT assessment

Even though the T criterion is fulfilled, aluminium phosphide resp. phosphine is neither PBT- nor vPvB – candidate as the P and B criteria are not fulfilled. In general the PBT criteria do not apply to inorganic substances.

Equally the POP criteria are not fulfilled. There is no potential for long-range transport because of the half-life time in air of phosphine is lower than 48 hours. There are no indications for endocrine disrupting effects.

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 (AlP) and phosphine (PH_3) as its degradation product and actual a.s., respectively.

The estimation of the predicted environmental concentrations (PECs) at the local scale for the life cycle stages production and formulation and professional use and for the relevant environmental compartments are performed for phosphine only according to the EU Technical Guidance Document on Risk Assessment (TGD, 2003) and according to the Emission Scenario Document for biocides used as rodenticides (EUBEES, May 2003). For the PEC calculation for the life cycle stages production and formulation, also legal regulations are taken into account.

The PEC calculation for intended use (gassing of underground tunnel systems/burrows, e.g. railway embankments, dikes etc.) is provided by the applicant according to the "Emission Scenario Document for biocides used as rodenticides (EUBEES, May 2003)".

The considerations for intended use (fumigation of underground tunnel systems) are based on a realistic worst-case assumption for the release of phosphine after fumigation.

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

Release to water is not a relevant exposure pathway for all life cycle stages. Therefore, no PEC for the aquatic compartment is calculated.

Release from disposal is not to be expected. Because of formation of phosphine in contact with water the b.p. must not be disposed of unregulated in water. Under normal circumstances practically no residues for disposal will occur during intended use. For the cleaning of the applicator in the post application phase the participant recommends to use a bowl of soapy water. In this way possibly solid $Al(OH)_3$ generated after release of phosphine will be disposed of appropriately.

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

Release from life cycle stage production a.s. and formulation b.p.

For life cycle stages production and formulation it is stated by the applicant, that a release of a.s. 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. According to the restriction in this regulation, a maximum concentration

of 0.5 mg/m3 in the exhaust stream and an amount of 2.5 g PH_3/h (which is equivalent to 0.06 kg/d) must not be exceeded.

This value is used as the worst case input value.

A direct release of the a.s. 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.

Release from professional use

Aluminium phosphide is used in the biocidal product (Phostoxin WM, 56 % of active substance) as fumigant in underground tunnel systems (burrows). The biocidal product can be used in form of pellets or tablets and is inserted into underground tunnel systems by an applicator.

Based on the worst case scenario recommendation to apply 5 pellets (à 0.6 g) every 3 m of the burrow, maximal 833 pellets will be applied per ha, corresponding to 500 g b.p. (Phostoxin WM) / ha. According to the position paper of the applicant the number of pellets will be reduced to 555 this is equivalent to 333 g b.p. (Phostoxin WM) /ha and 186 g AlP/ ha = 109 g PH_3/ha.

Using these data, PEC $local_{soil}$ of 3.4 mg/kg w/w and PEC $local_{air}$ of 0.075 mg/m3 have been calculated.

In addition, the soil concentration of the second reaction product $Al(OH)_3$ resp. aluminium (Al) have been calculated

- realistic case scenario: $C_{local\ soil\_Al}$ = 0.543 mg Al /kg w/w
- worst case scenario: $C_{local\ soil\_Al}$ = 1.357 mg Al /kg w/w.

2.2.2.5. Risk characterisation

Atmosphere

Aluminium phosphide (AlP) has a negligible vapour pressure (<<10-5 Pa at 25 °C). No emission into air of AlP is to be expected. In contact with soil and air humidity, AlP 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 x 105 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 phosphine before it will reach the ozone-rich upper atmosphere layer.

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

A local PEC of 0.075 mg/m3 phosphine for the atmospheric compartment is estimated.

In view of the spatially and temporarily restricted application of the biocidal product (Phostoxin WM 56 % of active substance) for the intended use as fumigant in underground tunnel systems (burrows) and the results mentioned above, no risk for the atmosphere can be indicated.

Aquatic Compartment (incl. 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 underground tunnel systems. However, because of the high aquatic toxicity of the active substance and biocidal product in general there exists a potential risk for the aquatic environment compartment and therefore special care should be taken in handling and applying these products. Nevertheless, the risk for the aquatic environment compartment is negligible if the pellets are properly handled by trained professionals and precaution measures will be carefully attended. Therefore, no risk characterisation is performed for this environmental compartment.

Terrestrial Compartment including Groundwater

The terrestrial compartment is the most relevant compartment on risk because of the direct release during the application of the biocidal product. A PEC/PNEC ratio of 739 (refined PEC/PNEC ratio of 489 according to the position paper of the applicant) is calculated for this environmental compartment indicating a clear risk to the terrestrial compartment from the use of aluminium phosphide as fumigant in underground tunnel systems. Data improvement may theoretically be possible on the effects side, as the $PNEC_{soil}$ is based on only one study with soil micro-organisms, in which no real EC_{50} could be derived. However, from the high acute toxicity of PH_3 it can be concluded that all soil organisms inhabiting the soil compartment in the target area (e.g. earthworms, arthropods …) will be killed by the arising PH_3 concentrations. Therefore, the performance of further tests with such soil organisms is not deemed necessary as these tests will only show what is already known. Improvement of the $PNEC_{soil}$ resulting in a PEC/PNEC ratio < 1 by performing further tests seems not possible. As the exposure is limited both spatially and temporarily and no residue formation can be expected, it can be assumed that the non-target organisms will resettle the exposed area within a short time after use of aluminium phosphide-containing products. This assumption is supported by position papers from the applicant concerning the refinement of the exposure scenarios for the different target organisms, the emission estimation and the recovery of soil organisms and potential for re-colonisation.

This statement, however, has to be substantiated in the frame of product authorisation.

After application to underground tunnel systems also the second reaction product $Al(OH)_3$ resp. aluminium will remain in the soil. The soluble and toxic forms of aluminium (Al^{3+}) are only present in soil under soil pH values of less than 4.5. Nevertheless, the amount of aluminium added by use of AlP is negligible compared to the natural background level and also spatially

and temporally restricted. Aluminium is the most commonly occurring metallic element in the earth crust. From literature it is known that the typical range of aluminium in European soils is from 1 % to 30 % (10,000 to 300,000 mg Al/kg), with naturally occurring concentrations varying over several orders of magnitude. The median Al_2O_3 content is 11.7 % in subsoil and 11.0 % in topsoil, the average total concentration of aluminium in global soil is reported as 80,000 mg Al/kg. The comparison of the calculated aluminium concentration in soil after application with the available literature data of natural aluminium occurrence has been shown that the release of this reaction product from the use of aluminium phosphide as fumigant in underground tunnel systems will not significantly increase the environmental concentration of this compound or of freely available aluminium (Al^{3+}).

Groundwater

The use pattern of the biocidal product Phostoxin WM inside of underground tunnel systems/burrows and the spontaneous reaction with humidity precludes 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 of the treated underground tunnel systems/burrows. This fact further reduces the amount of phosphine that can potentially leach. Therefore, no relevant exposure and risk of groundwater will occur.

In the case of the second reaction product $Al(OH)_3$ resp. aluminium, it can be assumed that use of aluminium phosphide as requested will not lead to a significant groundwater contamination. From literature, it is known that aluminium has a low mobility under most environmental conditions. The mobility of aluminium in soil is very much depended on soil pH. Aluminium hydroxide will further react to produce mineral phases. Aluminium minerals occur naturally in the environment. The natural back ground level in groundwater in Germany normally varies from < 0.01 – 0.1 mg Al/L depending on the geogenic nature of the area. According to Directive 98/83/EC, the drinking-water indicator parametric level for aluminium is fixed to 0.2 mg Al/L.

The mobility of aluminium is difficult to calculate and very much dependent on geogenic aspects. Therefore, not the total values of anthropogenically added aluminium by the intended use of AlP is important for ground-water aluminium concentration but the pH of the receiving soil compartment which is decisive for the aluminium groundwater concentration. However, the very small aluminium input to soil is not judged as a decisive input to groundwater aluminium concentration, as the difference to natural occurring aluminium soil concentration is four - five orders of magnitude with respect to the average total concentration of aluminium up to 80.000 mg Al /kg in the earth crust.

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

Primary Poisoning

There is a potential risk for primary poisoning for non-target organisms if they dig out a pellet and swallow it.

To mitigate this potential risk, it has to be assured that the holes in which the pellets are applied are safely closed to avoid easy access of non-target organisms like dogs.

Nevertheless, the formulation is not an attractive bait for ingestion/feeding but a supporter for the fumigant, and the generated phosphine has a strong smell of garlic, ammonia and carbide and is likely to act as a repellent.

In addition to the risk through primary poisoning, there is a risk to all non-target mammals which are using the tunnels of the target organisms as a part of their habitat or living in similar holes in the same habitat by inhalation of the arising PH_3. 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 kills the target organism will also be lethal for non-target mammals.

To prevent exposure of non-target organisms on risk by inhalation of PH_3, it has to be assured that only the underground tunnel systems / burrows of the target organisms are treated and that areas, where non-target organisms, which are using the tunnels of the target organisms as a part of their habitat or living in similar holes in the same habitat, can be expected, must not be treated.

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 underground tunnel systems, 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

Despite of the high aquatic toxicity, there is no risk for the aquatic compartment (incl. sediment) from the professional use according to the intended application. The fumigant causes also no risk to the atmosphere.

There is a risk for the terrestrial compartment, because of the direct release into soil according to the intended use. However, as the exposure is spatially and temporarily restricted and no residue formation can be expected, it can be assumed that the affected non-target organisms will resettle the exposed area within a short time after use of aluminium phosphide-containing products. This statement, however, has to be substantiated in the frame of product authorisation.

There is a potential risk for primary poisoning of non-target organisms like dogs if they dig out a pellet and swallow it. In addition, there is a risk to all non-target mammals which are using the tunnels of the target organisms as a part of their habitat or living in similar holes in the same habitat by inhalation of the arising PH_3. To mitigate these potential risks, the instructions for use must strictly be followed (e.g. safely close the holes in which the pellets are applied to

avoid easy access of non-target organisms, areas where other burrowing mammals can be expected must not be treated).

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, R 50.

Classification/labelling 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

Classification and labelling for environmental toxicity according to Regulation (EC) No 1272/2008:

H 400 very toxic to aquatic life (M-factor 100)

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. PROPOSED DECISION

3.1. Background to the proposed decision

The physico-chemical properties of the aluminium phosphide containing product Phostoxin WM are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

The effect on target organisms is respiratory toxic due to the release of phosphine gas.

100 % effectiveness was achieved against moles (Talpa europaea); retreatment was necessary one to three times during a test period of 14 to 28 days. 100 % effectiveness was also achieved against rabbits (Oryctolagus cuniculus); in one case retreatment was not necessary during the test period of 6 days; in the other study, retreatment was necessary three times during a test period of 21 days.

Overall, it could be demonstrated, that aluminium phosphide and an aluminium phosphide containing formulation have a sufficient efficacy against moles and rabbits. Efficacy has only been proven for moles and rabbits. For all other uses against other vertebrates information should be provided at product authorisation phase.

The estimation of hazards and the exposure assessment for human health of Phostoxin WM showed the following results: The product Phostoxin WM containing 56 % (w/w) aluminium phosphide is very toxic if swallowed. No acute dermal and no inhalation studies were performed using Phostoxin WM. Phostoxin WM is not irritating to the skin but is due to one co-formulant irritating to eyes as was derived using the conventional method (Annex II, Part B) of Directive 1999/45/EC. Studies with the biocidal product in the detailed composition given in the dossier for inclusion into Annex I of Directive 98/8/EC have not been submitted.

Phostoxin WM is regarded as non-sensitising.

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.

From the occupational risk assessment, certain scenarios have been identified which lead to concern even on the background of safety measures already applied. 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 available data on analytical methods for determination of residues of aluminium phosphide (determined as PH_3) are considered sufficient.

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. Primary exposure of non-professionals is not expected. Secondary exposure of non-professionals to phosphine from the use of Phostoxin WM is acceptable in relation to human health. Therefore, no risk to non-professionals/general public via primary or secondary exposure 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 biocidal product Phostoxin WM contains 56% (w/w) aluminium phosphide. Based on the proposal for classification of aluminium phosphide, the biocidal product is classified and labelled with F; R15, T+; R26*/28, Xn; R21, R29, R32, N; R50. Further classification and labelling of the biocidal product according to Directive 1999/45/EC with Xi; R 36 (Irritating to eyes) is required when taking into consideration toxicity data of other metal phosphide products and a stabiliser in the formulation Phostoxin WM.

The estimation of hazards and the exposure assessment for the environment for Phostoxin WM showed the following results: The requested intended use of aluminium phosphide / PH_3 poses a risk to terrestrial non-target organisms. Therefore, appropriate risk mitigation measures concerning the conditions of proper use and handling of the biocidal product must be applied: The instructions for use must strictly be followed (e.g. areas where other burrowing mammals can be expected must not be treated, holes in which the pellets are applied must be closed safely to avoid easy access of non-target organisms). Only use by trained 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 compartment and the atmosphere, therefore, no additional specific measures and precautions are necessary. However, because of the high aquatic toxicity of the a.s. and b.p., 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 for PH_3 there is a low potential to bioaccumulate. The estimated BCF_{fish} (=1.16 L/kg) and the $BCF_{earthworm}$ (=0.94 L/kg) for the aquatic and terrestrial environment are low and confirm this conclusion.

3.2. Proposed decision

The overall conclusion from the evaluation of aluminium phosphide releasing phosphine for use in product-type 23 (products for the control of other vertebrates), is that it may be possible to issue authorisations of products containing aluminium phosphide in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

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* According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS

Product type 23 as defined in Annex V of directive 98/8/EC corresponds to product-type 20 as defined in Annex V to Regulation (EU) No 528/2012.

It is therefore proposed to approve aluminium phosphide releasing phosphine as an active substance for use in product-type 20 (control of other vertebrates), subject to the following specific conditions:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following conditions:

1) Products shall only be sold to and used by specifically trained professionals.

2) In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level.

3) In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others, the non-treatment of areas where other burrowing mammals than the target species are present.

3.3. Elements to be taken into account 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 products to control other vertebrates containing aluminium phosphide releasing phosphine.

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.

It has to be guarantied that treated burrows are in adequate distance of inhabited houses (at least 10 meters) or that treated burrows do not meet cellars. The concentration of phosphine outside this zone has to be below 0.01 ppm. Re-entry for other persons than the operator should only be allowed if the clearance is granted and the concentration of phosphine is below 0.01 ppm (corresponding to 0.014 mg/m^3).

The statement has to be substantiated that the exposure is spatially and temporarily restricted and no residue formation can be expected and that it can therefore be assumed that the affected non-target organisms will resettle the exposed area within a short time after use of aluminium phosphide-containing products.

At the product authorisation stage, due to the characteristics and risks linked to the use of aluminium phosphide, the benefit of using the product should be considered. For instance, it should be considered if products should only be applied to soils that can be considered as 'technosphere' where hole-digging organisms have to be controlled to guarantee safety (i.e. underneath railroad and in dikes)

The assessed use of aluminium phosphide releasing phosphine was the outdoor use against vertebrates like rabbits and moles in embankments and dykes. To maximise the effectiveness and humaneness of fumigation, the gas must be widely distributed throughout a burrow system and maintained at a high enough concentration to cause rapid death. The latter is dependent on the porosity and dampness of soil.

Aluminium phosphide is a very toxic substance and develops very toxic gases in contact with water. Even very low concentrations result in lethal risks for the operator. For scenarios not submitted by the applicant 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. burrows, mole hills etc.). The risks for different scenarios have to be assessed thoroughly before granting an authorisation and/or performing a fumigation. The use of an applicator shall be mandatory for outdoor application of a phosphine-generating product which is intended to be applied as a product to control other vertebrates against rabbits and moles in burrows because:

- manual application results in concern for inhalation.
- with applicator potential inhalation risks do not lead to concern,

Substitution of a process or technical safety measures have to be favoured for risk mitigation according to article 6(2) of Directive 98/24/EC.

The requested intended use of aluminium phosphide releasing phosphine poses a risk to terrestrial non-target organisms. Therefore, appropriate risk mitigation measures concerning the conditions of proper use and handling of the biocidal product must be applied.

Aluminium phosphide / phosphine show high potential risks for operators if not applied skilfully and according to the described conditions. The necessary expertise is guaranteed by trained professionals only:

Technical and organisational protective measures are only known by trained professionals, e.g. pest control operators or fumigators. This knowledge is not acquired by reading instructions only but by thorough education and experiences.

For all possible scenarios of fumigation with phosphine, different/combined safety measures may be necessary according to the situation (e.g. indoor vs. outdoor) and the fumigation object (e.g. burrows, mole hills etc.). For the situational application of these measures, a thorough education and experiences are necessary.

Only for trained professionals, the high protection factors of personnel protective equipment (PPE) can be achieved. Trained professionals will be able to decide on the necessity of PPE which is dependent on the situation (e.g. type of filter, wearing time) and know about routine of good practice (e.g. maintenance of equipment). Respiratory protective equipment should be

effective against gaseous phosphine, since hydrolysis of dust in the filter of a dust mask or respirator may give rise to high phosphine exposure. The means to measure concentrations of phosphine in air should always be available and used to check atmospheric concentrations.

Both the active substance and the biocidal product are very toxic to aquatic organisms. The half-life of decomposition of phosphine in water amounts approx. 4-5 days. Therefore, additional precaution measures to prevent exposure of the aquatic environment have to be taken into account when authorising products (like special advices for an appropriate safety distance to surface waters) to avoid uncontrolled release of the pellets in waters during the period of usage.

Specific national conditions concerning nature conservation regulations have to be taken into account in the frame of national product authorisation.

Occupational Safety Measures

Concern was assessed for professional application of pellets by a ratio of the '*total* internal body burden' towards AEL of exactly 1 (table 12-5 of document II). Since the OEL is kept (see chapter 15.1.2 of document II), it is permissible to reduce exposure by *dermal* protection measures, only.

Technical and / or organisational measures have to be considered, preferentially, according to the Chemical Agent Directive 98/24/EC, article 6, paragraph 2. As last resort, adequate personal protection equipment (PPE) has to be recommended. This should apply to pellets as well as to tablets for hygienic reasons (to avoid carry-over from hand to mouth or to another person's skin) because - in praxis - users are not supposed to distinguish between tablets and pellets.

As dermal exposure is limited to hands and forearms of the user, it can be controlled by approved chemical protection gloves with gauntlets. A protection factor of 90 % is applied to the area of the hands towards aluminium phosphide-*dust* (according to TNsG on Human Exposure) for specialized professionals (e.g. pest controllers) using the applicator if label and safety data sheet inform about

- material,
- thickness,
- break through time (level),
- fulfilled European Standards (e.g. EN 374), and give
- an exemplary product.

Towards gases, protection cannot be granted nor quantified as phosphine may also enter the glove along the wrist. For detailed information, see chapter 15 of document II.

Non-professional / General Public Safety Measures

No further measures for the general public are required since there is no risk to non-professionals via primary and secondary exposure. The 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 biocidal product is proposed to be labelled with the following S-phrases:

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 36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S 43	In case of fire … Never use water
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 its container must be disposed of as hazardous waste
S 61	Avoid release to the environment. Refer to special instructions/Safety data sheet

In the RAC Opinion of 2nd December 2011, a classification of the active substance with T+;R26 was proposed. If this proposal is implemented in a corresponding ATP of Regulation (EC) No 1272/2008 at the time of product authorisation, the same classification applies to the representative product. In this case, the S-phrases may have to be revised.

Environmental Protection Measures

As a result of the risk assessment, the intended use of aluminium phosphide releasing phosphine poses a risk to terrestrial non-target organisms. Therefore, appropriate risk reduction measures and precautions concerning the special conditions of proper use and handling of the biocidal product (according to the “principle of best practice code”) must be applied.

- Safe use and handling only by trained and certified professional users familiar with the precautionary measures and who are experienced in assessment of the sites to be treated
- Use of an appropriate applicator/specialist spiked instrument.

- The instruction for use must strictly be followed.

- Areas where other burrowing mammals can be expected must not be treated

- Safely close the holes/burrow in which the pellets are applied with a plug (of natural occurring materials which are available in the vicinity like earth, stones or turf plugs).

- Access to treated areas has to be prevented and those areas have to be marked by warning signs to keep away people and animals, non-target organisms from these areas to exclude exposure to phosphine.

- The treated area has to inspected at appropriate intervals to ensure that all burrows have remained blocked and not re-opened by any target-organisms.

- Do not use in case of bad weather conditions (like intense fog, rain, heavy moisture penetration of soil).

- The concentration of phosphine has to be monitored in the treated area and in the vicinity. The means to measure concentrations of phosphine in air should always be available and used to check atmospheric concentrations

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

Nevertheless both a.s. and b.p. are classified as very toxic to aquatic organisms. The half-life of abiotic decomposition of phosphine in water amounts approx. 4-5 days.

Therefore additional precaution measures for the protection of surface waters have to be taken into account at the national b.p. authorisation procedure (like special advises for an appropriate safety distance to surface waters) to avoid uncontrolled release of the pellets to waters during the period of usage (e.g. in case of intense rain). Such a measure could be: “no use in Water Protection Areas and in surrounding of surface waters (safety distance not less than 10 m)”.

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

Specific national conditions concerning nature conservation regulations have to be taken into account.

Special Consideration: According to Article 37 paragraph 4 of Regulation (EU) 528/2012, Member States may refuse mutual recognition of authorisations granted for product type 15, 17 and 20, provided that such a limitation can be justified. In some Member States, the protection of vertebrates is of high importance (for example the German Act on Animal Welfare generally prohibits the killing of vertebrates).

In the frame of national product authorisation especially national nature conservation regulations have to be taken into account. In some Member States national authorisation of biocidal products for product-type 20 as well as for product-type 15 or 17 is not permitted.

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.

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 to require classification as eye irritant needs to be considered as no studies were submitted for the product Phostoxin WM.

3.5. Updating this Assessment Report

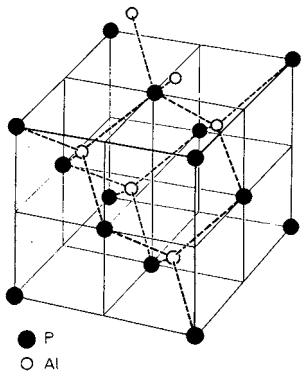
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of aluminium phosphide releasing phosphine.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Aluminium phosphide
Product-type	Control of other vertebrates

Identity

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)	Arsenic (Cas No. 7440-38-2) 0.065 g/kg
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 solid (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})	no melting point up to 500 °C (purity 86.5 %)
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)	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	technically not feasible (insoluble)
Partition coefficient (log P_{OW}) (state temperature)	technically not feasible (hydrolysis)
Hydrolytic stability (DT_{50}) (state pH and temperature)	Water and acids cause aluminium phosphide to decompose in a violent reaction into highly inflammable hydrogen phosphide. (technically not feasible)
Dissociation constant	technically not feasible (hydrolysis)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	technically not feasible (ionic compound)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	n.a.
Quantum yield of direct phototransformation in water at Σ > 290 nm	n.a.
Flammability	The test substance is not a readily combustible solid in the sense of Guideline 92/69/EEC, A.10 The test substance is hazardous in the sense of Guideline 92/69/EEC, method A.12. In contact with water the test substance evolves highly flammable gases in dangerous quantities. The gas ignites spontaneously.
Explosive properties	The test substance has no danger of explosion according to the explosive properties in the sense of Guideline 96/69/EEC, A. 14.

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 m3 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)	logPow 0.9 at 21 °C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	
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 of the active substance based on Directive 67/548/EEC

with regard to physical/chemical data	F R15 (S2), S3/9/14/49, S8, S30, S43
with regard to toxicological data	T^+, Xn R21, R26*/28, R29, R32 (S1/2), S22, S36/37, S45
with regard to fate and behaviour data	No classification is required
with regard to ecotoxicological data	N R50 S60, S61

* According to RAC Opinion of 2nd December 2011, in addition to the proposal by the RMS.

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	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)	Standardless x-ray measurement based on an advanced fundamental parameters algorithm. Titration for aluminium nitride. Atomic absorption spectrometry with flowing injection hydride system (FIAS-AAS) for arsenic.

Analytical methods for residues

Soil (principle of method and LOQ)	not required, DT90 < 3 days
Air (principle of method and LOQ)	phosphine Photometric determination at 625 nm LOQ = 25 µg/m³ (for enforcement of the occupational exposure limit)
Water (principle of method and LOQ)	phosphine GC-NPD headspace LOQ = 0.1 µg/L (surface water) GC-FPD LOQ = 0.05 µg/L (drinking and surface water)
Body fluids (principle of method and LOQ) (Annex IIA, point 4.2)	not required Aluminium phosphide is not volatile and hydrolyses rapidly to phosphine (PH_3). Phosphine is unstable in human blood (Heintze, 2001)
Body tissues (principle of method and LOQ) (Annex IIA, point 4.2)	zinc phosphide GC-NPD headspace LOQ = 0.0025 mg/kg (muscle, liver)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	not required Based on the intended uses exposure to food and feeding

	stuffs will not occur. Nevertheless, acceptable analytical methods were submitted for phosphine: GC-NPD headspace LOQ = 0.01 mg/kg (meal, shell fruit, tea) LOQ = 0.005 mg/kg (maize grain, sunflower seed)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	not required, no residues expected

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Ready absorption of phosphine through the lungs and after oral exposure
Rate and extent of dermal absorption for the active substance:	Not applicable
Rate and extent of dermal absorption for the representative product(s)[4]:	Default value of a maximum of 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

Acute toxicity

Rat LD_{50} oral	8.7 mg/kg bw
Mouse LD50 oral	14.8 mg/kg bw
Rat LD_{50} dermal	900 mg/kg bw
Rat LC_{50} inhalation	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 sensitisation (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

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

Genotoxicity	No evidence of a genotoxic potential

4 Please consider Q5 on *Derivation of dermal absorption values* of section 4.1.1 of the Manual of Technical Agreements (MOTA) version 5.

Carcinogenicity

Species/type of tumour	Rat: No treatment-related tumours. Mice: No data, justification is given
lowest dose with tumours	NOAEL 3 ppm PH_3, equivalent to 1.1 mg/kg PH_3 bw/d and 1.9 mg aluminium phosphide/kg bw/d (rat 2-yr inhalation highest concentration tested)

Reproductive toxicity

Species/ Reproduction target / critical effect	No data, justification given
Lowest relevant reproductive NOAEL / LOAEL	No data, justification given
Species/Developmental target / critical effect	Rat: Mortality of dams

Developmental toxicity

Lowest relevant developmental NOAEL / LOAEL	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

Species/ target/critical effect	No neurotoxic potential
Lowest relevant developmental NOAEL / LOAEL	Acute study: 40 ppm PH_3 (analytical conc. 38 ppm) (with regard to neuropathology, behavioural and neurological status); < 21 ppm PH_3 (with regard to changes in motor activity) Subchronic study: 3 ppm PH_3 equivalent to 1.1 mg/kg bw/d (highest dose tested; with regard to systemic/neurotoxic effects)

Other toxicological studies

.....	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

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

Summary aluminium phosphide	Value	Study	Safety factor
Non-professional user			
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 (acceptable daily intake, external long-term reference dose)	0.019 mg/kg bw*	2-yr inhalation, rat	100
ARfD (acute reference dose)	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	Value	Study	Safety factor
Non-professional user			
AEL_{acute}	0.049 ppm or 0.070 µg/L air or 0.019 mg/kg bw/d	Developmental inhalation, rat	100
$AEL_{medium\text{-}term}$	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	90-d inhalation, rat	100
$AEL_{long\text{-}term}$	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	2-yr inhalation, rat	100
ADI (acceptable daily intake, external long-term reference dose)	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	2-yr inhalation, rat	100
ARfD (acute reference dose)	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 concerning the active substance:	not determined		
Reference value for dermal absorption concerning the representative product(s)[4]:	not determined		

Acceptable exposure scenarios (including method of calculation)

Professional users

Production of active substance:	Not assessed
Formulation of biocidal product	Not assessed
Intended uses No mixing&loading , ready-for-use product **Application:** Outdoor use of ready-for-use product (56 % a. s.) in form of tablets or pellets using an applicator. **Post-application:** No post-application, the ready-for-use product itself is used up during the application process. Control: chemical protection gloves with gauntlets (protection factor of 90 %)	Using an applicator (tablets/pellets) Potential inhalation exposure (all phases): 0.05 mg/m3 (phosphine) Actual dermal exposure (all phases): 0.2 mg a.s./person/day (placing tablets) 0.3 mg a.s./person/day (placing pellets)
Secondary exposure	Not expected
Non-professional users	Non-professional use is not intended.
Indirect exposure as a result of use (eg via food or feed)	Bystander, adult: 4.67 x 10-3 mg PH_3/kg bw (= 42 % of AELmedium-term) Bystander, infant: 5.60 x 10-3 mg PH_3/kg bw (= 51 % of AELmedium-term) Re-entry, adult: 7.78 x 10-5 mg PH_3/kg bw (= 0.7 % of AELmedium-term) Re-entry; infant: 9.33 x 10-5 mg PH_3/kg bw (= 0.8 % of AELmedium-term)

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

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

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 active ingredient (range and maximum)	not applicable
Soil accumulation and plateau concentration	not applicable

Adsorption/desorption

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

Fate and behaviour in air

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

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)

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

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	not tested
Reproductive toxicity to ……	not tested

Effects on soil micro-organisms

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

Effects on terrestrial vertebrates

Acute toxicity to mammals	See Chapter 3 Impact on Human Health
Acute toxicity to birds	not tested
Dietary toxicity to birds	not tested
Reproductive toxicity to birds	not tested

Effects on honeybees

Acute oral toxicity	not tested
Acute contact toxicity	not tested

Effects on other beneficial arthropods

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

Bioconcentration

Bioconcentration factor (BCF)	BCF phosphine (calculated on the basis of log Pow = 0.9 according to TGD): aquatic: 1.16 L/kg (terrestrial: 0.94 L/kg)

Depuration time(DT_{50}) (DT_{90})	not tested
Level of metabolites (%) in organisms accounting for > 10 % of residues	not tested

Chapter 6: Other End Points

The active substance does not come into contact with food, feed or livestock. Residues in food or feed are not expected as a result of the proposed use as PT 20 (former PT 23).

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Re marks:
(a)			(c)	Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	number min max	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	
Outdoor Control of other vertebrates for all types of non-agricultural purposes	Germany	PHOSTOXIN WM or Detia Wühlmaus-killer	Moles (Talpa europaea) and rabbits (Oryctolagus cuniculus).	Gas-genera-ting product (GE)	56 %	*)	One or repeated if new infestation	n.a.	Rabbits: 1-5 pellets depending on size of burrows, humidity and kind of soil or one tablet per hole; additional tablet if upon inspection treated hole was re-opened Moles: 2-5 pellets per tunnel or molehill depending on length of tunnel, humidity and kind of soil or one tablet per hole; additional tablet if upon inspection treated hole was re-opened			In the efficacy studies provided by the applicant, one tablet of 3 g releasing 1 g of phosphine per hole is used and one additional tablet per hole if upon inspection the treated hole was re-opened. This application rate corresponds to 5 pellets of 0.6 g per hole.

*) gassing of target animals in their burrows; laying out gas-generating pellets using applicator or by hand

(a) e.g. biting and suckling insects, fungi, molds; (b) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained

(e) g/kg or g/l;(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench;

(g) Kind, e.g. overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;

(h) Indicate the minimum and maximum number of application possible under practical conditions of use;

(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based 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 was however not possible to confirm the accuracy of this information.

Reference list of studies on the active substance

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
A 2.6	Schmitt, S; Stammler, B	2004	Manufacturing Method of Aluminium Phosphide	No	Detia Freyberg GmbH	Yes	Yes
A 2.7	Schmitt, S; Dierks-Lange, H	2003	Quality Control Certificate	Yes	Detia Freyberg GmbH	Yes	Yes
A-2.7a	Schmitt, S; Dierks-Lange, H	2006	Minimum and nominal content (g/kg) of technical active substance aluminium phosphide and relevant impurities	Yes	Detia Freyberg GmbH	No	No
A 2.8	Schmitt, S; Stammler, B	2004	Content of Impurities	Yes	Detia Freyberg GmbH	Yes	Yes
A-2.8a	Schmitt, S; Dierks-Lange, H	2006	Minimum and nominal content (g/kg) of technical active substance aluminium phosphide and relevant impurities	Yes	Detia Freyberg GmbH	No	No
A 3.1.1.01	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH	Yes	Yes
A 3.1.1.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag	Yes	Yes
A 3.1.1.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
A 3.1.2.01	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH	Yes	Yes
A 3.1.2.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag	Yes	Yes
A 3.1.2.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.1.3.01	Smeykal, H	2002	Aluminium phosphide technical: Relative Density Report-No. 20020427.02	No	Detia Freyberg GmbH	Yes	Yes
A 3.1.3.02	Römpp	2006	Phosphine Römpp online. Version 2.10. 2006	No	Georg Thieme Verlag	Yes	Yes
A 3.1.3.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.2.01	Drägerwerk AG	1993	Dräger-Röhrchen Handbuch	No	Public	Yes	Yes
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	Yes	Yes
A 3.2.02	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH	Yes	Yes
A 3.2.1	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH	Yes	Yes
A 3.3.1	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.3.2	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
A 3.3.3	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.4.01	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.4.02		1965	Gmelins Handbuch Phosphor Verlag Chemie GmbH	No	Public	Yes	Yes
A 3.4.03	Fluck, E	1973	Chemistry of Phosphine Springer Verlag	No	Public	Yes	Yes
A 3.4.1	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH	Yes	Yes
A 3.4.2	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH	Yes	Yes
A 3.4.3	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH	Yes	Yes
A 3.4.4	Voigt, M; Schmitt, S	2002	Statement	No	Detia Freyberg GmbH	Yes	Yes
A 3.5.01	Fluck, E	1973	Chemistry of Phosphine Springer Verlag	No	Springer Verlag	Yes	Yes
A 3.5.02	WHO	1988	Phosphine and Selected Metal Phosphides Phosphine and Selected Metal Phosphides. Geneva, 1988, p. 17 - 19	No	Public	Yes	Yes
A 3.5.02	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH	Yes	Yes
A 3.6.01	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH	Yes	Yes
A 3.6.02	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH	Yes	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
A 3.7.01	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.7.02	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH	Yes	Yes
A 3.8	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH	Yes	Yes
A 3.9	Voigt, M; Schmitt, S	2003	Statement - Solubility in organic solvents	No	Detia Freyberg GmbH	Yes	Yes
A 3.9	Schlösser W	1989	Untersuchungsbericht: Octanol-Wasser-Verteilungskoeffizient von PH_3 Report-No. 05011	No	Chemi-sche Fabrik Wülfel	Yes	Yes
A 3.10.01	Smeykal H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH	Yes	Yes
A 3.10.02	Smeykal, H	2002	Melting and Boiling Point, Vapour Pressure Report-No. 20020427.01	No	Detia Freyberg GmbH	Yes	Yes
A 3.10.03	Detia Freyberg GmbH	1994	Phosphorwasserstoff	No	Detia Freyberg GmbH	Yes	Yes
A 3.11.01	Smeykal, H	2002	Aluminium technical: Flammability Report-No. 20020427.03	No	Detia Freyberg GmbH	Yes	Yes
A 3.11.02	Smeykal, H	2002	Aluminium phosphide technical: Explosive properties, auto-flammability Report-No. 20020427.04	No	Detia Freyberg GmbH	Yes	Yes
A 3.11.03	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.13	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH	Yes	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
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	Yes	Yes
A 3.15.01	Smeykal, H	2002	Aluminium phosphide technical: Explosive properties, auto-flammability Report-No. 20020427.04	No	Detia Freyberg GmbH	Yes	Yes
A 3.15.02	World Health Organisation	1988	Phosphine and Selected Metal Phosphides	No	World Health Organisa-tion	Yes	Yes
A 3.16	Voigt, M; Schmitt S	2002	Statement of performance: A6, A8, A17, C7	No	Detia Freyberg GmbH	Yes	Yes
A 3.17	F & E loboratory	2003	Determination of the Storage Stability of Phostoxin	No	Detia Freyberg GmbH	Yes	Yes
A 4.1	F & E laboratory	2004	Determination of Hydrogen phosphide and aluminium phosphide	No	Detia Freyberg GmbH	Yes	Yes
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	No	Yes
A 4.1.2 .01*	R & D Laboratory	2003	Determination of aluminium nitride, not GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
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	No	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
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	No	Yes
A 4.1.2 .02*	R & D Laboratory	2003	Determination of aluminium oxide, not GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 4.1.2 .03*	R & D Laboratory	2004	Determination of metals in technical aluminium phosphide, not GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 4.1.2 .03	R & D Laboratory	2004	Determination of metals in technical aluminium phosphide	No	Detia Freyberg GmbH	Yes	Yes
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	No	Yes
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	No	Yes
A-4.2a	Analytisches Labor	1983	Decomposition Behaviour of Hydrogen Phosphide in Standard Soils,not GLP, unpublished	No	Detia Freyberg GmbH	No	Yes
A 4.2 b	Kettrup, A, Angerer, J	1994	Luftanalysen, Sonderdruck aus DFG – Deutsche Forschungsgemeinschaft. Band 1, Ed. Greim, H., published	No	public	Yes	Yes
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	Yes	Yes

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	Already submitted for PT14 (Yes/No)	Already submitted for PT18 (Yes/No)
A 4.2d	Chan LTF et al.	1983	Phosphine Analysis in Post Mortem Specimens,Journal of Analytical Toxicology , Journal of Analytical Toxicology, ,not GLP , published	No		No	No
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 Biotechnol ogie GmbH & IFU Umweltana lytik GmbH	Yes	Yes
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 Biotechnol ogie GmbH & IFU Umweltana lytik GmbH	Yes	Yes
A-4.2e	Shrimali, A.	2007	Validation of a confirmatory method for determination of aluminium phosphide (releasing phosphine) in water, JAI Research Foundation, , 6710 ,GLP, , unpublished	Yes	Detia Freyberg GmbH	No	No
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	Yes	Yes
A-4.3a	Maccaferri, L.	2005	Independent Laboratory Validation, GAB Analisi S r.l., , 20055054/01-RVP ,GLP, , unpublished	Yes	Detia Freyberg GmbH	No	No
A 5.4*	Price, N. R.	1980	A review of the mode of action of phosphine, Pesticide Science	No	Public	Yes	Yes
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	Yes	Yes

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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	Yes	Yes
A 5.4*	Hsu, C.-H., et al.	1998	Phosphine-induced stress in hepa 1c1c7 cells, Toxicological Sciences 46, 204-210	No	Public	Yes	Yes
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		No	Yes
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		No	Yes
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		No	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes

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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	Yes	Yes
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	Yes	Yes
A 6.1.3	ECHA Committee for Risk Assessment	2011	Opinion proposing harmonised classification and labelling at Community level of aluminium phosphide	No	Public	No	No
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
A 6.2.01*	Curry, AS et al.	1959	Absorption of Zinc phosphide particles, Nature, non-GLP, published	No	Public	Yes	Yes
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	Yes	Yes
A 6.2.03*	WHO	1988	Environmental Health Criteria 73, pp. 48-51, WHO, non-GLP, unpublished	No	Public	Yes	Yes
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	Yes	Yes

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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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
A 6.6.1.02	Stankowski, LF	1990	Ames/Salmonella Plate Incorporation Assay on PH_3, PH 301-DA-001-89, Pharmakon Research International Inc., Degesch America Inc., GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes

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A 6.6.2	San Sebastian JR	1990	Structural Chromosome Aberration CHO cell induced by PH_3, PH 320-DA-001-89, Pharmakon Research International Inc., Degesch America Inc. GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
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	Yes	Yes
A 6.8.1	Klimmer, OR	1969	Beirat zur Wirkung des Phosphorwasserstoffes,published , Archiv für Toxikologie, Pharmaklogisches Institut der Universität Bonn	No	Public	Yes	Yes

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A 6.8.1	Müller, W	1940	Über Phosphorwasserstoffvergiftung, published, Archiv für experimentelle Pathologie und Pharmakologie	No	Public	Yes	Yes
A 6.8.1	World Health Organisation	1988	Phosphine and Selected Metal Phosphides, World Health Organisation, non-GLP, published	No	World Health Organisa-tion	Yes	Yes
A 6.8.1	Potter WT, Rong S, Griffith J, White J, Garry VF.	1991	Phosphine-mediated Heinz body formation and hemoglobin oxidation in human erythrocytes. Toxicol Lett. 57(1):37-45.	No	Public	Yes	Yes
A 6.8.1	Okolie NP, Aligbe JU, Osakue EE.	2004	Phostoxin-induced biochemical and pathomorphological changes in rabbits. Indian J Exp Biol. 42(11):1096-9.	No	Public	Yes	Yes
A 6.8.1	Jakote CH	1904	Experimentelle Studien über den Einfluß technisch und hygienisch wichtiger Gase und Dämpfe auf den Organismus. Teil XI. Studien über Phosphorwasserstoff. Arch. für Hyg. 49/50: 275-306.	No	Public	Yes	Yes
A 6.8.1		1997	IPCS International Programme on Chemical Safety. Poisons Information Monograph 865. Phosphine.	No	Public	Yes	Yes
A 6.8.1*	Schroeder, RE	1989	Teratogenicity test, 89-3413, Bio/dynamics Inc., Degesch America Inc., GLP, unpublished	Yes	Detia Freyberg GmbH	Yes	Yes
A 6.8.2	Neurath, G.	2004	Statement on the requiement of a 2 Generation reproduction study with aluminium phosphide, GAB-Consult-ing GmBH, non-GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 6.8.2	Domingo, J.L.	1994	Metal-Included developmental toxicity in mammals: a review, J. of Tox. & Env. H., non-GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 6.8.2			please refer to Sec. IIIA 6.8.1				
A 6.9*	Schaefer, G.J	1996	Acute neurotoxicity study in rats, 750-002, MPI Research, Degesch America Inc., GLP, unpublished	Yes	Detia Freyberg GmbH	Yes	Yes

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A 6.9*	Schaefer, G.J. et al.	1998	Acute and subchronic inhalation neurotoxicity of phosphine in the rat. Inhalation toxicology, 10, pp. 293-320.	No	Public	Yes	Yes
A 6.10*	Hsu, C.-H., et al.	1998	Phosphine-induced stress in hepa 1c1c7 cells, Toxicological Sciences 46, 204-210	No	Public	Yes	Yes
A 6.12.1	Guth, E	2003	Occupational Health Care for Employees under PH_3 Exposition, IAS, Detia Freyberg GmbH, non-GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 6.12.2	Zipf, KE et al	1967	Clinical Observation of a Case of Phostoxin Poisoning, 1st Medical University Clinic, Frankfurt/Main, Springer Verlag, non-GLP, published	No	Springer Verlag	Yes	Yes
A 6.12.3	Barbosa, A; Bonin, AM	1994	Evaluation of phosphine genotoxicity, Occupational and Environmental Medicine, non-GLP, published	No	Public	Yes	Yes
A 6.12.3	Garry, V. F. et al.	1989	Human genotoxicity: pesticide applicators and phosphine. Science, 246, pp. 251-255	No	Public	Yes	Yes
A 6.12.3	Garry, VF et al.	2002	Environmental Health Perspectives 110 (Suppl. 3), 441-449	No	Public	Yes	Yes
A 6.12.5	Chugh, SN et al.	1991	Incidence & outcome of AlP poisoning in a hospital study, Indian J Med Res, non-GLP, published	No	Public	Yes	Yes
A 6.12.7	Benzing, L	1992	Erste Hilfe und Therapiemaßnahmen, Verlag Alfred Strothe, non-GLP, published	No	Verlag Alfred Strothe	Yes	Yes
A 6.12.7	Weller, D	1982	Toxicology of Hydrogen Phosphide, Degesch GmbH Frankfurt, non-GLP, published	No	Degesch GmbH Frankfurt	Yes	Yes
A 6.12.7		2003	EC-Safety Data Sheet, Laudenbach, Germany	Yes	Detia-Degesch GmbH	Yes	Yes
A 6.12.8	Misra, UK et al.	1988	Acute Phosphine poisoning following Ingestion of AlP, Human Toxicol., non-GLP, published	No	Public	Yes	Yes

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A 6.15.1	Pollmann B	1999-12-09	Determination of Residues of Detia Gas-Ex-B, Degesch Magtoxin und Phostoxin Tablets after Fumigation of Different Storage Goods, GAB Biotechnologie GmbH, 99322/01-SRPH ,GLP, unpublished	Yes	Detia Freyberg GmbH	No	Yes
A 6.15.3.01	Köhl, W; Hofer, M	2003	First Chapter on new Level, 150-002, SCC Scientific Consulting Company, Detia Freyberg GmbH, non-GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 6.15.3.02	Heller G	2003	Products generating hydrogen phosphide, Büro für praktische Biologie, Detia Freyberg GmbH, non-GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
A 6.15.4			see 6.15.1 / 6.15.2				
A 7.1.1.1.1*	Friemel, W. , Ehret, R:	1983	Examination of the behaviour of phosphine in water. Detia Freyberg GmbH, Laudenbach; report no.: not available, unpublished report, 1983	No	Detia Freyberg GmbH	Yes	Yes
A 7.2.3.2*	Friemel, W. , Ehret, R:	1983	Distribution of PH_3 in soil-horizontal and vertical spreading. Detia Freyberg GmbH, Laudenbach; report no.: not available, unpublished report, 1983	No	Detia Freyberg GmbH	Yes	Yes
A 7.3.1	Becker, K.H. et al.	1984	Phosphine. In: Methods of the Ecotoxicological Evaluation of Chemicals: Photochemical Degradation in the Gas Phase, Vol. 6, 109	No	Public	Yes	Yes
A 7.3.1	Frank, R. & Rippen, G.	1987	Fate of Phosphine in the Atmosphere, BATELLE INSTITUT E.V., Frankfurt, Germany, report no.: not available	No	Detia Freyberg GmbH	Yes	Yes
A 7.3.1	Fritz,B. et al.	1982	Laboratory kinetic investigations of the tropospheric oxidation of selected industrial emissions; In: Versino, B.; Ott, H. (Eds.): Physico-Chemical Behaviour of Atmospheric Pollutants, 192-202	No	D. Reidel Publi-shing Company	Yes	Yes

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A 7.4.1.1*	Leuschner, F.	1984	EXAMINATION OF THE ACUTE TOXICITY OF ALUMINIUM PHOSPHIDE ON RAINBOW TROUT, LPT, Hamburg, Germany; Report-No. not available, 22.11.1984, dates of experimental work: 05.10.1984 until 08.11.1984	No	Freyberg GmbH Degesch GmbH	Yes	Yes
A 7.4.1.2*	von Holt, H.	1986	Toxicity test on daphnia magna, Ökolimna, Burgwedel, Germany; unpublished Report-No. DM-FRE-08/86-034, 29.10.1986, dates of experimental work: 12.08.86 until 05.09.86	No	Detia Freyberg GmbH	Yes	Yes
A 7.4.1.3*	K. Kasthuri Raman	2000	ALGA (Selenastrum capricornutum), GROWTH INHIBITION TEST WITH ALUMINIUM PHOSPHIDE PELLET, JAI RESEARCH FOUNDATION, Gujarat, India, unpublished report number 2503,10.03.2000 GLP	Yes	Prosanitas GmbH	Yes	Yes
A 7.5.1.1	Schönborn, W.	1989	Studies on the effects of Phostoxin on the activity of the soil microflora (translation), BATELLE-INSTITUTE e.V., Frankfurt, Germany; Report-No. V-67.097, 20.06.1989, dates of experimental work: 21.12.1988 until 10.05.1989 Studies on effects of Phostoxin on activity of soil microflora GLP	No	Degesch GmbH Detia Freyberg GmbH	Yes	Yes

* key study

Reference list of studies on the biocidal product

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B2.2/01	Schmitt, S; Stammler, B	2004	Certifikate of Composition: Phostoxin, not GLP, unpublished	Yes	Detia Freyberg GmbH	Yes	Yes
B2.2/01a	Voigt, M.; Hildenbrand, S.	2008	Update certificate of composition: PHOSTOXIN, Detia Freyberg GmbH, , ,not GLP, , unpublished	Yes	Detia Freyberg GmbH	No	No
B2.10.1	Barnett,DJ	1999	Respiratory Exposure to Phosphine, Rentokil Initial plc, 264/3 ,GLP, unpublished	Yes	Rentokil Initial plc	Yes	Yes
B3.2	Smeykal, H	2002	Explosive properties, Siemens Axiva GmbH & Co. KG, 20011378.01 ,GLP, unpublished	No	Delicia Freyberg GmbH	Yes	Yes
B3.3	Voigt, M; Schmitt, S	2002	Statement of performance: A6, A8, A17, C7, not GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
B3.4.01	Michael, H	2001	Determination of inflammability of Phostoxin Pellets, Kesla BioLab, KBL/2001/1216EZF ,GLP, unpublished	No	Delicia Freyberg GmbH	Yes	Yes
B3.4.02	Smeykal, H	2002	Phostoxin Pellets: Auto-flammability, Siemens Axiva GmbH & Co. KG, 20011378.02 ,GLP, unpublished	No	Delicia Freyberg GmbH	Yes	Yes
B3.7	Michael, H	2002	Storage stability - stability and shelf-life, Kesla BioLab, KBL/2002/1373ASTH ,GLP, unpublished	No	Delicia Freyberg GmbH	Yes	Yes
B4.1	Anonymus	2006	Determination of Hydrogen Phosphide and Metal Phosphide respectively, Detia Freyberg GmbH, 0001 A ,not GLP, unpublished	No	Detia Freyberg GmbH	No	Yes

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B4.1.01	Kiefer, R.	2006	Validation of an Analytical Method for Determination of Aluminium Phosphide and Arsenic in Phostoxin, eurofins-GAB GmbH, , 20061336/01-UVX ,GLP, unpublished	Yes	Detia Freyberg GmbH	No	No
B4.2.01	Kiefer, R.	2006	Validation of an Analytical Method for Determination of Aluminium Phosphide and Arsenic in Phostoxin, eurofins-GAB GmbH, , 20061336/01-UVX ,GLP, unpublished	Yes	Detia Freyberg GmbH	No	No
B5.10/01*	Steuerwald, R	2004	Versuchsbericht zur Wirksamkeit von Phostoxin Pellets gegen Vorratsschädlinge in einem Flachlager mit Weizen, Detia Freyberg GmbH, PH_3 04 008 ,not GLP, unpublished	Yes	Detia Freyberg GmbH	No	Yes
B5.10.2/03 *	Kabuth	2002	Versuchsbericht zur Prüfung von Detia Wühlmauskiller gegen Schermäuse, N. F. V. Göttingen, not GLP, unpublished	Yes	Detia Freyberg GmbH	Yes	No
B5.10.2/04 *	Klemann N	2005	Field study Rat, Klemann N, KLN/DD/2005-1 ,not GLP, unpublished	Yes	Detia Freyberg GmbH	Yes	No
B5.10./06	Clarke, F. M.	1993	Field trial of Phostoxin against rabbits in warrens on a farm in West Sussex, Rentokil Limited R & D Division, , 246A/12e ,GLP, unpublished	Yes	Rentokil Limited R & D Division	No	No
B5.10./07	Clarke, F. M.	1993	Field trial of Phostoxin against rabbits in warrens on a golf course in Sussex, Rentokil Limited R & D Division, , 246A/21d ,GLP, , unpublished	Yes	Rentokil Limited R & D Division	No	No
B5.10/08	Clarke, F. M.	1993	Field trial of Phostoxin against moles in a garden at Pembury, Kent, Rentokil Limited R & D Division, , 246A/6c ,GLP, unpublished	Yes	Rentokil Limited R & D Division	No	No

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B5.10./09	Clarke, F. M.	1993	Field trial of Phostoxin against moles in a garden in East Sussex, Rentokil Limited R & D Division, , 246A/6d ,GLP, unpublished	Yes	Rentokil Limited R & D Division	No	No
B5.10./10	Clarke, F. M.	1993	Field trial of Phostoxin against moles in the quarantine area of a veterinary surgery in Oxted, Rentokil Limited R & D Division, , 246A/12c ,GLP, unpublished	Yes	Rentokil Limited R & D Division	No	No
B5.10./10. 1	Pepper, I. P.	2007	Pre-Annex I Letter of Access, Rentokil Limited R & D Division, not GLP, unpublished	Yes	Rentokil Limited R & D Division	No	No
5.10./10.2	Moore, D. F.	1992	Good Laboratory Practice, Statement of Compliance in accordance with Directive 88/320 EEC, Department of Health of the Government of the United Kingdom, not GLP, unpublished	Yes	Rentokil Group Plc, R & D Division	No	No
B5.10.2*	Müller, H	1959	Efficacy data, Biologische Bundesanstalt für Land- und Forstwirtschaft, not GLP, unpublished	No	Degesch GmbH Frankfurt/ Main	Yes	No
B5.11.1/01	Rajendran, S.	2001	Insect resistance to phosphine - challenges and strategies.,International Pest Control International Pest Control, ,not GLP, published	No		No	Yes
B5.11.1/02	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		No	Yes

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B5.11.1/03	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		No	Yes
B6.1.1*	Gargus, JL et al.	1983	Acute Oral Toxicity Study in Rats: DEGESCH PHOSTOXIN Formulation, Hazleton Laboratories, 2038-103 ,not GLP, unpublished	No	Degesch America Inc	Yes	Yes
B6.1.2*	Heisler, E; Dickhaus, S	1987	Acute percutaneous toxicity, PHARMAROX Beratung und Forschung GmbH, 1-4-142-87 ,GLP, unpublished	No	Detia Freyberg GmbH	Yes	Yes
B6.1.3	Shimizu, Y; Ogawa, Y; Tokiwa K	1982	Acute inhalation toxicity testing of hydrogen phosphide in rats, NOMURA RESEARCH INSTITUTE, NRI 82-7489 ,not GLP, unpublished	No	Degesch Japan Co.	Yes	Yes
B6.2.01	Dickhaus, S; Heisler, E	1987	Irritant effects of aluminiumphosphid on intact skin of rabbits (OECD-Guidelines No. 406), Pharmatox Beratung und Forschung GmbH, , 1-3-183-87 ,GLP, , unpublished	No	Degesch GmbH	Yes	Yes
B6.2.02	Dickhaus, S; Heisler, E	1987	Irritant effects of aluminiumphosphid on rabbit eye Acc. to OECD No. 405, Phamatox Beratung und Forschung GmbH, , 1-3-184-87 ,GLP, , unpublished	No	Detia Freyberg GmbH	Yes	Yes
B6.3*	Corea Costa, K	2002	Evaluation of Skin Sensitization, Bioagri Laboratorios Ltda., R.E.428.192.02 ,not GLP, unpublished	Yes	Degesch do Brasil Industria e comercio Ltda.	Yes	Yes

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B6.6	Old J, Foster A	2003	Measurement of Potential Exposure to Phosphine during Grain Fumigation, Inveresk Research, 21517 ,not GLP, unpublished	Yes	Detia Degesch GmbH	No	Yes
B6.6a	Anonymus	2006	Detia Degesch Manual for safe practices in handling and use of phosphine fumigants ,not GLP, published	No	Detia Degesch GmbH	No	No
B6.6b	Schmitt S	2006	Degassing Behaviour of Detia Degesch Fumigation Products, Detia Freyberg GmbH ,not GLP, unpublished	No	Detia Freyberg GmbH	No	No
B8.3	Detia Garda GmbH	2009	TOPEX Applicator Manual ,not GLP, published	No	Detia Freyberg GmbH	No	No

* key study