# CONCLUSION ON PESTICIDE PEER REVIEW

## Conclusion regarding the peer review of the pesticide risk assessment of the active substance magnesium phosphide

## Issued on 30 September 2008

## SUMMARY

Magnesium phosphide is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on magnesium phosphide in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 19 June 2007. The peer review was initiated on 29 October 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Detia Freyberg GmbH. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in June - July 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, rodenticide, talpicide and leporicide as proposed by the notifier. Full details of the GAP can be found in the attached list of endpoints.

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

The representative formulated product for the evaluation was "Degesch Magtoxin", a gas generating product (GE). The gas phosphine that is produced is the true active ingredient.

A method of analysis for phosphine in products of plant origin is available however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the $DT_{90}$ in soil is < 3 days for phosphine. A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the aluminium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. The case where the spent material is not removed has not been considered in the peer review process.

The mammalian toxicology of magnesium phosphide was assessed in a series of tests.
When coming into contact with moisture magnesium phosphide decomposes to magnesium hydroxide and phosphine which is the toxicologically active and relevant component for the assessment of mammalian toxicology of magnesium phosphide. Magnesium phosphide is classified as **R29 "Contact with water liberates toxic gas".** In addition a classification as **R32 "Contact with acids liberates very toxic gas"** has been proposed by the experts. Phosphine is rapidly absorbed from the gastrointestinal tract and the lungs. It is widely and evenly distributed in the body and has no potential for accumulation. Phosphine is excreted as such via expired air or with the urine in form of hypophosphite or phosphite. Magnesium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is neither a skin nor an eye irritant nor a skin sensitizer. Based on data on acute toxicity a classification as **T+; R28 "Very toxic if swallowed", Xn; R21 "Harmful in contact with skin"** and **T+; R26 "Very toxic by inhalation"** is proposed. A short term NOAEL of 1.1 mg/kg bw/d for phosphine (the highest dose tested, no adverse effects observed) was derived from a 90-day inhalation rat study. Magnesium phosphide is not genotoxic. A NOAEL of 1.1 mg/kg bw/d, which was the highest dose tested since no adverse effects were observed, was established for phosphine in a 2-year inhalation study with rats. A mouse carcinogenicity study was not carried out and not considered necessary based on the toxicity profile of the substance (lethality anticipated at low doses). In an inhalation developmental study with rats (a rabbit study was not provided) no specific developmental effects were observed and an overall NOAEL of 1.9 mg/kg bw/d was set based on mortality occurring in dams. Effects on reproduction have not been assessed, but are based on the toxicity profile of the substance not anticipated.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.022 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.038 mg/kg bw. The corresponding values for phosphine are 0.011 mg/kg bw/d (ADI and AOEL) and 0.019 mg/kg bw (ARfD).When applying magnesium phosphide in rodent burrows without the use of respiratory protective equipment (RPE) maximum exposure levels amounted to a maximum of 93% of the AOEL for operators. For workers and bystanders, however, actual exposure levels will be considerably lower.

Application of magnesium phosphide in storage rooms when no respiratory protective equipment is used amounted for operators to 30% and 120% of the AOEL considering low and high use respectively. When respiratory protective is used the value for high use application is reduced to 10% of the AOEL. **EFSA disagrees with the operator exposure assessment for the use of magnesium phosphide in storage rooms.** Exposures of workers and bystanders after application in storage rooms account for a maximum of 25% and 33% of the systemic AOEL respectively.

Two main uses of magnesium phosphide were evaluated, 1) as rodenticide, talpicide, leporicide to control rodent and non-rodent species by fumigation of underground tunnels and burrows in cropland and non-cropland situations, 2) as fumigant to control insects in various harvested plant products and in empty warehouses or transportation facilities. Due to its physico-chemical properties, no specific studies to evaluate metabolism and distribution of magnesium phosphide in treated commodities were submitted. In contact with soil or atmospheric moisture, magnesium phosphide is rapidly hydrolysed to produce phosphine ($PH_3$) and magnesium hydroxide $Mg(OH)_2$. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine and residual metal phosphide, the residue definition for monitoring and risk assessment was set as “phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine”.

No residue trials were submitted to support the uses of magnesium phosphide as rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plants and therefore, the possible residues in plants. For post harvest applications, in addition to the aeration period, the RMS proposed for each commodity or group of commodities a withholding period. Thus, during the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of these additional withholding periods of 7 to 35 days, depending on the commodities. Consequently and after the meeting, EFSA was of the opinion that the fumigation practices have not been sufficiently defined to allow the MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap.

No storage stability study was provided considering that the inherent properties of phosphine lead to a low stability in stored products. No processing studies and no livestock metabolism and feeding studies were provided, considering that no significant residues of magnesium phosphide and

phosphine are expected in post harvested plant commodities. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and non-rodent species. No unacceptable chronic or acute risks to consumers were identified, taking into account that the proposed MRL values do not reflect the critical GAPs as initially defined by the applicants.

When placed in animal burrows (i.e. the soil environment) magnesium phosphide will rapidly hydrolyse producing phosphine gas and magnesium salts. The phosphine gas produced which was shown to exhibit very low persistence will volatilise to the atmosphere or adsorb to soil and be converted to phosphate anions. Any phosphine gas that reaches the upper atmosphere will be subject to indirect photooxidation to phosphonic acid and phosphoric acid that would be removed from the atmosphere by wet deposition. The rate of indirect photooxidation of phosphine measured was rapid enough to indicate that phosphine will not be subject to long range atmospheric transport. The potential for groundwater exposure of magnesium phosphide and phosphine was assessed as low from the applied for intended uses. There is a potential for surface water exposure by phosphine gas when treated target organism burrows are adjacent to surface water (via movement in the gas phase). A data gap was identified to better characterise this exposure potential.

Due to the representative uses (applied outdoor directly into the burrow systems or indoor in food storage rooms), the exposure to non-target species was considered to be only local or negligible. On the basis of potential exposure of surface water to phosphine, in case that target organism burrows are adjacent to water bodies, the risk from the outdoor use to aquatic organisms needs to be addressed and therefore valid studies on invertebrates and algae should be provided.
The risk to birds, mammals, bees, non-target arthropods, earthworms, soil non target macro- and micro- organisms, non-target plants and biological methods of sewage treatment was expected to be low for the representative use evaluated.

**Key words: magnesium phosphide, peer review, risk assessment, pesticide, insecticide, rodenticide, talpicide and leporicide.**

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## BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Magnesium phosphide is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on magnesium phosphide, hereafter referred to as the draft assessment report, received by EFSA on 19 June 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1095/2007 on 29 October 2007 to the Member States and the main applicant Detia Freyberg GmbH as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in June – July 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (rev 1-1 of 14 March 2008)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (rev 2-1 of 26 September 2008).

Given the importance of the draft assessment report including its addendum (compiled version of August 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can be found in the original draft assessment report together with the peer review report, both of which are publicly available.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Magnesium phosphide is the (IUPAC) name for this compound. There is no ISO common name.

Magnesium phosphide is a phosphine generator. Other examples of phosphine (IUPAC name phosphane) generators are calcium and aluminium phosphide. The mode of action is by inhibition of cellular respiration.

The representative formulated product for the evaluation was "Degesch Magtoxin" a gas generating product (GE).

The evaluated representative uses are as an insecticide, rodenticide, talpicide and leporicide. Full details of the GAP can be found in the attached list of endpoints.

## SPECIFIC CONCLUSIONS OF THE EVALUATION

## 1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of magnesium phosphide as manufactured should not be less than 880 g/kg. At the moment no FAO specification exists. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. A data gap for a new specification where arsenic is removed was set. Therefore the case where the spent material is not removed has not been considered in the peer review process.

The content of magnesium phosphide in the representative formulation is 66 % w/w (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of magnesium phosphide or the respective formulation.

The main data regarding the identity of magnesium phosphide and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of magnesium phosphide in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

A method of analysis for phosphine in products of plant origin is available however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the $DT_{90}$ in soil is < 3 days for phosphine. A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the aluminium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified. A method of analysis for body fluids and tissues is not necessary, since phosphine will be quickly exhaled or metabolised to phosphates, even though the active substance is classified as very toxic.

The method of analysis in products of plant origin is GC-NPD with a LOQ of 0.01-0.0024 mg/kg depending on the commodity. The method of analysis for water is GC-NPD with an LOQ of 0.1 µg/L.

## 2. Mammalian toxicology

Magnesium phosphide is an existing active substance (List 3 B) and was discussed at the meeting of experts in July 2008 (PRAPeR 54, round 11, subgroup 2).

Phosphides in contact with moisture readily decompose to metal hydroxides and phosphine. At the meeting of experts it was agreed that due to the decomposition by moisture other metal phosphides can be regarded as adequate model compounds for the evaluation of magnesium phosphide because phosphine is the toxicologically active component. Inhalation is the most relevant route of exposure based on the use of the substance as a fumigant. Classification of the substance as **R29 "Contact with water liberates toxic gas"** (current ECB classification) has been confirmed and classification as **R32 "Contact with acids liberates very toxic gas"** has been additionally proposed by the experts. The experts agreed to propose additionally the Safety Phrase **SPo1: "After contact with skin first remove product with a dry cloth and then wash the skin with plenty of water"**.

### 2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

The experts agreed that, although formally the data requirements as laid down in Directive 91/414/EC were not fulfilled for this section, the information provided in the DAR was sufficient for an adequate evaluation of the active substance. Based on data obtained in experiments with zinc phosphide it is evident that phosphine is rapidly absorbed from the gastrointestinal tract and rapidly and quantitatively absorbed through the lungs. Phosphine is widely and evenly distributed in the body (temporarily higher levels have been detected in liver and medulla oblongata). It has no potential for accumulation. Phosphine is either excreted as such via the expired air or, after metabolic oxidation, with the urine in form of hypophosphite or phosphite.

### 2.2. ACUTE TOXICITY

Magnesium phosphide is very toxic by the oral ($LD_{50}$ = 10.4 mg/kg bw), harmful by the dermal route (based on read-across from data obtained with aluminium phosphide where an $LD_{50}$ between 460 and 900 mg/kg bw was obtained) and very toxic by the inhalation route ($LC_{50}$ = 0.072 mg/L phosphine generated from magnesium phosphide). Based on data obtained with aluminium phosphide the experts concluded that magnesium phosphide was neither a skin nor an eye irritant. The experts agreed that, based on the negative results obtained in guinea pigs with zinc phosphide in a Magnusson & Kligman test, magnesium phosphide should be considered as not skin sensitising.

Based on the available data on acute effects classification of magnesium phosphide as **T+; R28 "Very toxic; Very toxic if swallowed"** (also the current ECB classification) and additionally **Xn; R21 "Harmful; Harmful in contact with skin"** and **T+; R26 "Very toxic; Very toxic by inhalation"** should be proposed.

### 2.3. SHORT TERM TOXICITY

Short term investigations with oral or dermal application of magnesium phosphide are not presented in the DAR. However, the experts agreed that, based on the mechanism of phosphine mediated toxicity (inhibition of mitochondrial respiration) and since the relevant route of exposure was by the inhalation route, no species specific toxicity was anticipated. The available information (a short term inhalation study with phosphine in rats) was sufficient for the assessment of short term effects of the compound. The NOAEL obtained in the 90-day inhalation study was 1.1 mg/kg bw/d of phosphine which was the highest dose tested (no adverse effects have been observed).

### 2.4. GENOTOXICITY

In a series of standard genotoxicity assays with magnesium phosphide, aluminium phosphide, zinc phosphide and phosphine (six *in vitro* and eight *in vivo* tests are presented in the DAR) consistently negative results were obtained. However, in section B.6.9 of the DAR (Medical Data and Information) increased rates of chromosomal aberrations have been reported after exposure to phosphine in humans. The experts agreed, though the human evidence presented was contradictive and inconclusive, and concluded that the overall weight of evidence suggested clearly that magnesium phosphide had no genotoxic potential.

### 2.5. LONG TERM TOXICITY

A 2-year combined chronic/carcinogenicity study with inhalation exposure (whole body) of rats to phosphine was presented in this section. As no adverse effects (and also no tumours) were observed in this study the NOAEL (for phosphine) was set at a dose of 1.1 mg/kg bw/d (the highest dose tested). A carcinogenicity study with mice was not presented in the DAR. Considering the lack of genotoxic potential, the known mechanism of phosphine mediated toxicity (no species specific toxicity anticipated) and the very steep dose response curve (lethality expected to be the main endpoint) the experts agreed that a carcinogenicity study with mice was not necessary for the evaluation of the compound.

### 2.6. REPRODUCTIVE TOXICITY

In this section a developmental study with inhalation exposure (whole body) of rats to phosphine is presented. A NOAEL for maternal and developmental effects of 5 ppm or 1.9 mg/kg bw/d of phosphine was set based on mortalities of the dams observed at the next higher (= highest dose) of 10 ppm. No effects indicative of developmental toxicity were observed in this study.

Neither a two-generation study nor a developmental study with rabbits is reported in the DAR. Based on the assumptions that lethality would be the main endpoint, that maternal toxicity would dominate over any specific effects and that no species specific differences were anticipated, the experts agreed that neither a two- generation study nor a developmental study with rabbits was necessary for a satisfactory evaluation of the active substance.

### 2.7. NEUROTOXICITY

An acute and a repeated dose neurotoxicity study with rats using phosphine are reported in this section of the DAR.

From the acute study a NOAEL of 40 ppm phosphine was set based on anatomic pathology, behavioural and neurological changes while a lower NOAEL of 21 ppm of phosphine was derived from observations of changes in motor activity.

The NOAEL for neurotoxicity in the 90-day study was set at the highest dose tested which was 3 ppm or 1.1 mg/kg bw/d phosphine. At that dose, effects on palpebral closure and body temperature occurred which were dismissed by the experts as not clearly substance related since they were in the range of the normal fluctuations.

### 2.8. MEDICAL DATA

Several studies on cytogenetic effects in humans by exposure to phosphine are reported in this part of the DAR. These studies have been evaluated by the experts (see section 2.4. Genotoxicity). Furthermore a series of epidemiological studies and reports of clinical cases and poisoning incidents with phosphine, aluminium phosphide and zinc phosphide are described in this section of the DAR, overall, confirming the steep dose response curve of phosphine. Exposure of a human being up to one hour to a concentration of up to 0.26 mg phosphine/L air could still result in no serious health effects while a concentration of 2.8 mg phosphine/L air is immediately fatal.

### 2.9. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

Values have been transferred from phosphine to magnesium phosphide assuming a maximum liberation of gas of 0.50 g phosphine per g magnesium phosphide.

**The ADI for was set at 0.022 mg/kg bw/d** based on the NOAEL of 1.1 mg/kg bw/d for phosphine obtained in the two year rat inhalation study with phosphine applying a safety factor of 100.

**The corresponding ADI for phosphine is 0.011 mg/kg bw/d.**

**The AOEL was set at 0.022 mg/kg bw/d** based on the NOAEL of 1.1 mg/kg bw/d obtained in the 90-day rat inhalation study with phosphine applying a safety factor of 100.
**The corresponding AOEL for phosphine is 0.011 mg/kg bw/d.**

**The ARfD was set at 0.038 mg/kg bw** based on the NOAEL of 1.9 mg/kg bw/d obtained in the rat developmental inhalation study with phosphine applying a safety factor of 100.
**The corresponding ARfD for phosphine is 0.019 mg/kg bw.**

### 2.10. DERMAL ABSORPTION

No measured data for dermal absorption of aluminium phosphide are available. The experts agreed, considering the evaluations of dermal absorption of phosphine and metal phosphides by the WHO[2] and the dermal absorption value already set for aluminium phosphide under the scope of Directive 98/8/EC (biocides directive), to set an overall dermal absorption value of 10 % for magnesium phosphide (phosphine) also.

### 2.11. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The formulation **Degesch Magtoxin** is manufactured in form of pellets and tablets (weight of the pellet is 0.6 g) containing 660 g/kg of magnesium phosphide. Degesch Magtoxin is used for the control of rodents and other non-rodent vertebrates in burrows by placing the product into the burrow. Degesch Magtoxin is applied once at a maximum rate of 10 pellets per meter burrow length or per hole. It is also used for the control of insect pests in empty or full storage rooms for fumigation of a series of different commodities such as for example grain, oil seeds, beans, spices, dried fruits or tobacco by placing it directly in the storage facility. For fumigation Degesch Magtoxin is applied once at a maximum amount of 5 tablets or 15 pellets per $m^3$ (corresponding to 6 g magnesium phosphide) or 30 pellets per tonne (corresponding to 12 g magnesium phosphide).

No operator exposure data for magnesium phosphide are available. Since the product characteristics of the **magnesium phosphide** containing **Degesch Magtoxin** and the **aluminium phosphide** containing **Phostoxin** are similar, exposure studies conducted with **Phostoxin** have been used for the exposure assessment of the **magnesium phosphide** containing **Degesch Magtoxin.**

The experts agreed that for the calculations a lower breathing rate (in the calculations in the original DAR a breathing rate of 3.6 $m^3$/h was used) and an inhalation absorption value of 100% should be used (in the original DAR an inhalation absorption value of 3% was employed) for the assessment of exposures. The revised assessments using a breathing rate of 1.75 $m^3$/h and a value for inhalation absorption of 100% have been provided with an addendum to the DAR (Addendum 4, August 2008).

[2]Phosphine and Selected Metal Phosphides, Environmental Health Criteria 73, International Programme on Chemical Safety, World Health Orgnization, Geneva, 1988.

**EFSA Note:** In several of the new calculations provided in the addendum 4 to the DAR also the work rate was altered. This was not discussed/agreed upon at the meeting of experts.

**EFSA Note**: In the Addendum 4 to the DAR further information on the use of the substance is presented where it is reported that fumigation of storage rooms is restricted to well trained authorised personnel only, possessing a certificate of competence and fumigation licences. Appropriate personal protective equipment has to be used. Regular measurements of phosphine concentration outside the building under fumigation are carried out. If limit values are exceeded fumigation is interrupted. A safety zone restricted to authorised fumigation personnel is established. Following the fumigation, ventilation and phosphine concentration measurements are carried out. Final release of the area is given and re-entry for workers is only permitted when phosphine levels are below the limit of detection. Buildings under fumigation are not entered until residual phosphine is removed.

**EFSA Note:** There are no agreed models for the assessment of gaseous exposures. However, no in depth explanations on how the input parameters have been chosen for the calculations are provided. In addition to that no in depth explanations on which considerations the formulas used for the exposure calculations have been based are provided either.

**Operator exposure**

*Application in rodent burrows*

Based on an assumed average airborne concentration of phosphine of 0.05 mg/kg[3] (default assumption based on the OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application OECD/GD (97) 148) it was calculated that phosphine levels (8 h time weighted average) when using Phostoxin in rodent burrows when no PPE is used make up 93% for “high use” of Phostoxin (treatment of rodents along railway embankment, exposure duration 6.25 hours) and 55% for “typical use” (treatment by a farmer, exposure duration 3.75 hours) of the systemic AOEL of 0.03 ppm or 0.011 mg/kg bw/d phosphine. Identical levels are used for Degesch Magtoxin.

*Application in storage rooms*

Calculations based on input parameters from a monitoring study resulted in phosphine levels (8 h time weighted average) in storage rooms that make up 30% of the AOEL when only 1 fumigation procedure is applied and without the use of respiratory protective equipment. The respective values amount to 120% and 10% of the AOEL when 4 fumigation procedures are carried out without and with the use of respiratory protective equipment respectively when Degesch Magtoxin (Phostoxin) is used.

**EFSA Note:** Taking into account the results from of a series of exposure calculations and field studies with similar products and similar uses (i.e. Gastoxin and Quickphos) where exposures below the AOEL could only be achieved with the use of full respiratory protective equipment and taking also into account the uncertainties/unclarities remaining in regard to the way the exposures have been calculated in this particular case, EFSA disagrees with the operator exposure assessment for the use of Degesch Magtoxin (Phostoxin) in storage rooms.

**Worker exposure**

*Application in rodent burrows*

No specific calculations have been carried out but based on the assumption that the levels detected for operators will be diluted further with unlimited potential since the operation is performed in the open air and phosphine is rapidly degraded in ambient air (half life of phosphine is 5-28 hrs) it is assumed that the worker exposure will not exceed this value of 93% of the AOEL calculated for the exposure of operators.

*Application in storage rooms*

No specific calculations for Degesch Magtoxin (Phostoxin) have been carried out but based on the calculated worker exposure to phosphine when using Gastoxin (see conclusion Aluminium phosphide), namely 25% of the AOEL when RPE is used, it can be reasonably assumed that when Degesch Magtoxin is used in the same manner the AOEL will not be exceeded neither.

**Bystander exposure**

*Application in rodent burrows*

No specific calculations have been presented but measurements of operator exposures resulted in an exposure of maximally 93% of the AOEL. Based on the assumptions that bystanders will be at a greater distance from the burrow and that the phosphine concentration will be further diluted with unlimited potential since the operation is performed in the open air it can be expected that exposure of bystanders will be considerably lower than those of the operator.

*Application in storage rooms*

Based on the assumption that, when fumigation work is carried out, inside the safety zone only authorised personnel is permitted and that the concentrations of phosphine outside the safety zone do not exceed 0.01 ppm (based on monitoring) which is 33% of the AOEL of 0.03 ppm of phosphine and the presence of bystanders is only allowed outside the safety zone it is expected that exposure values of bystanders will not exceed the AOEL.

# 3. Residues

Magnesium phosphide was discussed at the PRAPeR experts' meeting for residues (PRAPeR 55, round 11) in July 2008.

The applicant, Detia Freyberg GmbH, submitted data in order to support two main uses of magnesium phosphide:

1 - as rodenticide, talpicide, leporicide to control rodent and non-rodent vertebrates (rat, voles, rabbits, moles, …) by fumigation of underground tunnels and burrows in cropland and non-cropland situations.

2 - as fumigant to control insects in various harvested plant products (cereals, tree nuts, spices, …), processed food commodities (cereal flour, …) in storage premises (mill, silo, …) and to control insects in empty warehouses or transportation facilities. The fumigation practices on stored commodities were defined as a treatment at a rate of 1 to 6 g $PH_3/m^3$ (tonne) with a length of fumigation of 4 to 7 days depending on the temperature. The length of the aeration period following fumigation and after which the treated products may be safely handled by the workers was not reported. This point has to be clarified. During the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of an additional withholding period that was proposed by the RMS for each commodity or group of commodities. Consequently and after the meeting, EFSA was of the opinion that the fumigation practices have not been sufficiently defined in the GAP to allow the MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap. Finally, the applicant was also asked to clarify the list of commodities intended to be fumigated and especially if the use of magnesium phosphide is restricted to dry stored products only (cereals, tree nuts, spices, …) or if uses are also envisaged on some fresh products (fresh fruit or fresh vegetables).

## 3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

Due to its physico-chemical properties no specific studies to evaluate metabolism and distribution of magnesium phosphide in treated commodities have been submitted but some information from public literature was reported to support the fate of the active substance after application. In contact with soil or atmospheric moisture, magnesium phosphide is rapidly hydrolysed to produce phosphine ($PH_3$) and magnesium hydroxide $Mg(OH)_2$, this decomposition depending on temperature and soil/air humidity. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids (hypophosphite, phosphite, phosphate, …), these oxidation products being widespread in nature and considered of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine (adsorbed and interstitial) and residual metal phosphine when reaction with atmospheric moisture is incomplete, the residue definition for

monitoring and risk assessment was proposed as "phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine".

No residue trials were submitted to support the uses of magnesium phosphide as rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plant and therefore, the possible residues in plants. This statement was supported by information from public literature[3]. Three days after soil application of calcium or aluminium phosphide to control voles, residues of phosphine were below 0.01 mg/kg in carrots and radish roots collected in the treated plots.

Fumigation trials were submitted to propose MRLs on stored commodities following post harvest applications. Trials were performed using aluminium phosphide or magnesium phosphide at dose rates of 4.5 to 10 g/m$^3$ during a fumigation period of 5 to 14 days. The commodities were fumigated in gastight containers where relative humidity and temperature were recorded. All information concerning the experimental designs was detailed in the addendum of June 2008 provided by the RMS. After fumigation the containers were aerated for approximately 1 or 2 days until the phosphine concentration in air reached a value below 0.01 ppm. Samples were then collected (day 0) at predetermined intervals of 7, 14, 21 days after the end of aeration. Samples were shipped to the laboratory and analysed for residues on the day of sampling using a LOQ of 0.005 or 0.010 mg/kg. When analyses could not take place on the same day, samples were stored in liquid nitrogen and analysed at least within two days. However, the applicant was asked to precise the way the samples were handled between sampling and analyses in the study referenced RIP2002-148, since this information was missing in the report.

In addition to the aeration period following the completion of the fumigation, a specific withholding period was proposed by the RMS for each commodity or group of commodities, this withholding period being an additional storage period after fumigation and aeration necessary to reach phosphine residue levels below or at the MRL value. Thus, the MRLs proposed for cereals grains, cereals processed products, tree nuts, cocoa beans, coffee beans and pulses were not calculated taking into account the residue levels observed just after the aeration period (day 0), but after a withholding period of 7 to 35 days, depending on the commodities. Therefore, EFSA was of the opinion that MRLs were not defined following practices as stated in the critical GAPs where only an aeration period is recommended. Moreover, the meeting asked the RMS for clarification regarding the setting of these withholding periods since some of them were set for a long period (up to 35 days) and to reconsider, as an alternative, if higher MRLs with shorter withholding period could be proposed.

[3] Martens-Menzel, R. et al, 1994 ; Rückstandsverhalten von Phosphorwasserstoff in Rettichen und Möhren nach Begasung zur Bekämpfung der Wühlmaus. Translation: Residue behaviour of phosphor-hydrogen in radish and carrot following gassing in vole control. Mitt. a. d. Biol. Bundesanst., 1994, 197

No storage stability study was provided considering that the inherent properties of phosphine (melting point -133.5°c, boiling point -87.4°C, oxidation to phosphorous compounds) lead to a low stability in stored products. Information from public literature confirmed that at -18°C phosphine residues in soya beans and wheat grain were stable up to 33 days only. However, the fumigation conditions may also act upon stability and at equal storage temperature; residues are more persistent in crops that have been fumigated for a longer period than equal residues in crops that have been fumigated for a shorter period. In addition a study performed with tea, meal and shell fruit stores under deep frozen condition in liquid nitrogen showed that phosphine residues were stable for at least two days. Based on this information, the results of fumigation trials used to derive the LMR values were considered as reliable, since samples were analysed immediately or stored in liquid nitrogen and analysed within two days. No processing studies were provided, considering that no significant residues of magnesium phosphide and phosphine are expected in plant commodities following the GAP and the proposed withholding periods. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and no-rodent species.

### 3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Since no significant residues resulting of the use of magnesium phosphide as post harvest fumigant are expected in livestock feed, no metabolism and feeding studies were provided and no MRLs were proposed for products of animal origin.

### 3.3. CONSUMER RISK ASSESSMENT

The chronic and acute consumer risk assessment was performed using the EFSA and the German models and the MRL values listed below, taking into account that EFSA considers that these values do not reflect the GAP as initially defined by the applicants. The calculated Theoretical Maximum Daily Intake (TMDI) was in the range of <0.1% to 12% of the ADI (0.011 mg phosphine/kg bw/d) with the EFSA model and approximately 5% of the ADI using the German consumption data. The acute consumer risk assessments show a maximum NESTI/IESTI in a range of 3 % to 8 % of the ARfD (0.019 mg phosphine/kg bw) for stored goods. Therefore, no chronic or acute concerns are expected after fumigation on stored commodities with magnesium phosphide **if a withholding period is taken into account in the GAP as given in the point 3.4 below**.

### 3.4. PROPOSED MRLS

As mentioned previously, EFSA is of the opinion that MRLs could not be defined in regard to the proposed GAPs where only an aeration period was considered.
Considering the modified GAPs proposed by the RMS and including withholding periods in addition to aeration period, the following MRLs for phosphine were discussed:

| | | | |
|---|---|---|---|
| 0.10 | mg/kg | unprocessed grains of cereals | (withholding period: 7 days) |
| 0.10 | mg/kg | tree nuts | (withholding period: 21 days) |
| 0.10 | mg/kg | pistachio | (withholding period: 35 days) |
| 0.10 | mg/kg | coffee beans | (withholding period: 7 days) |
| 0.05 | mg/kg | cacao beans | (withholding period: 7 days) |
| 0.05 | mg/kg | spices, roots of medicinal plants | (withholding period: 7 days) |
| 0.02 | mg/kg | processed cereal products | (withholding period: 14 days) |
| 0.01* | mg/kg | dried vegetables, fruits and mushrooms | (withholding period: 7 days) |
| 0.01* | mg/kg | pulses | (withholding period: 7 days) |
| 0.01* | mg/kg | other products of plant origin | |

No MRLs were proposed for products of animal origin.

# 4. Environmental fate and behaviour

Magnesium phosphide was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 in June/July 2008.

## 4.1. FATE AND BEHAVIOUR IN SOIL

### 4.1.1. ROUTE OF DEGRADATION IN SOIL

In moist soil under field conditions magnesium phosphide will undergo relatively rapid chemical hydrolysis producing phosphine gas (the efficacious rodenticide substance, note phosphine is denser than air) and magnesium salts (for example magnesium hydroxide). The proportion of phosphine produced that readsorbs to soil will oxidise to form phosphate anions.

The Member State experts compared the quantity of phosphate anions that may originate from the use of magnesium phosphide as a rodenticide with agricultural land phosphate fertiliser recommendations (see addendum 3 to the DAR dated May 2008 where the RMS provided some calculations). Phosphorous levels from the rodenticide use gave a maximum estimate of 0.2 kg/ha. Fertiliser recommendations are ca. 40 kg phosphorous/ha. The Member State experts considered that the contribution from magnesium phosphide as a rodenticide was low compared to the phosphate fertiliser anthropogenic source of phosphate to agricultural soils.

### 4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

In a laboratory soil incubation test carried out at 22°C in two different sand soils phosphine gas (which was applied directly as the test substance mixed with nitrogen) was shown to have a $DT_{50}$ of 5.4 to 5.7 hours. In further laboratory soil incubations (again the test substance applied was

phosphine gas mixed with nitrogen) carried out on 7 different soils at 25°C $DT_{50}$ estimates were reported to be 8 to 60 minutes.

In a field study carried out using aluminium phosphide as the generator of phosphine gas it was demonstrated that vertical spreading of phosphine in soil was low but horizontal spreading was relatively fast with maximum concentrations being measured at 30-90cm from buried pellets 4 hours after burying pellets. Phosphine was not detected after 28 to 48 hours when 1 pellet was buried but it took 168 hours for phosphine not to be detected when 2 pellets were buried.

The Member State experts agreed the soil PEC in appendix 1 for phosphine as appropriate for the applied for intended use outdoors that used a biocides emission scenario[4]. They also agreed that soil exposure from phosphine from the applied for intended uses indoors in the vicinity of treated structures might be expected to be negligible based on the arguments that the applicants for aluminium phosphide put forward as evaluated by the RMS in addendum 3 to the aluminium phosphide DAR dated May 2008 regarding the low potential for wet deposition consequent to the low air concentrations expected (<0.11 ppm monitored at distances greater than 5m in one trial) that must be achieved with respect to worker safety when treated structure are vented in accordance with good practice.

#### 4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Due to the expected rapid transformation of both magnesium phosphide and phosphine gas, leaching in soil for these two compounds can be precluded as a concern for the applied for intended uses outdoors. The transformation product of phosphate anions was considered further. The Member State comments on the DAR did not identify any concerns regarding the magnesium salts that are formed.

As discussed in section 4.1.1 above the Member State experts considered that the contribution of phosphate from magnesium phosphide as a rodenticide was low compared to the phosphate fertiliser anthropogenic source of phosphate to agricultural soils. There is also the legal issue that there is no parametric drinking water limit set for phosphates in the EU drinking water directive[5] so there is no legal limit against which to assess potential groundwater contamination of phosphate.

There is no parametric drinking water limit set for magnesium or its salts in the EU drinking water directive so there is no legal limit against which it is necessary to assess potential groundwater contamination of magnesium or its salts.

[4] Supplement to the methodology for risk assessment of biocides; Emission scenario document for biocides used as rodenticides; May 2003; Danish EPA; J. Larsen; CA-Jun03-Doc.8.2-PT14
[5] Council Directive 98/83/EC on the quality of water intended for human consumption

## 4.2. FATE AND BEHAVIOUR IN WATER

### 4.2.1. SURFACE WATER AND SEDIMENT

Data on the sterile hydrolysis of magnesium phosphide were not available. The estimated half life of phosphine at 20°C was estimated to be 39, 36 and 23 hours at pH 4, 7 and 9 respectively. In a second study where the rate of aqueous hydrolytic transformation of phosphine gas was investigated at pH 5, 7 and 9 at 22 °C at a significantly higher concentration (1090 mg/L) a half life of approximately 2 days could be estimated, being roughly the same at all pH.

The Member State experts considered that the potential for surface water exposure by phosphate anions that would be formed in soil was expected to be low compared to levels that would occur from phosphate fertiliser uses (as already discussed at sections 4.1.1 and 4.1.3).

The Member State experts had an extensive discussion regarding the potential for surface water exposure resulting from phosphine consequent to the applied for intended use outdoors. The applicant had been asked to address this. The statement provided by the applicant in addendum 3 of May 2008 did not address the potential concern that where treated burrows were immediately adjacent to surface water that phosphine in the gas phase in the burrow, may exit the burrow entrance, then being denser than air reach surface water and potentially partition between the air and water. (This potential concern was the comment made by a Member State that had resulted in the applicant being asked to address the potential for surface water exposure by phosphine). The experts at the meeting carried out a very worst case calculation that took a measured burrow air concentration of 0.331 mg/L (from a field study that can be found described in section 4.1.2 of the EFSA conclusion for aluminium phosphide and section B.8.1.1 of the aluminium phosphide DAR, measurement taken 6 hours after 4 pellets were placed in the burrow at 3 m distance from the 4 pellets) and the Henry's law constant for phosphine of 33269 Pa $m^3$/mol. The phosphine concentration calculated was 25 µg/L. This is a low concentration but cannot be considered negligible as phosphine is very hazardous to aquatic organisms and with this concentration a risk cannot be excluded using 1$^{st}$ tier annex VI criteria (The uniform principles for decision making under directive 91/414/EEC). The experts noted that this calculation assumes equilibrium and does not include any dilution in air 3 metres away from pellets in the burrow, dilution in air outside the burrow, resistance to transfer across the air/water interface, any dilution in the water body (mixing with water that is not adjacent to a treated burrow) and has no temporal element (break down processes in water). With further information it would probably be possible to demonstrate that concentrations would respect tier 1 annex VI criteria, but the applicant had not provided any additional calculations that enabled the experts to confirm that this was the case. The experts agreed that it was necessary to identify a data gap as the exposure of surface water by phosphine from the requested outdoor applications of magnesium phosphide needs to be addressed. It was suggested that if filling this data gap in the future, the applicant should

provide consideration of the impact of one or more of the following processes: dilution in air in the burrow, dilution in air outside the burrow, resistance to transfer across the air water interface and any dilution in the water body, on phosphine surface water concentrations. In addition, temporal elements could be included (e.g. break down processes in water). The opinion of the Member State experts was that the information provided to fill this data gap could be assessed nationally when assessing applications for product authorisations.

The Member State experts considered that the potential for surface water exposure by phosphine would be expected to be negligible from the applied for intended uses indoors as vented concentrations in the vicinity of the treated structures would be expected to be low, so wet deposition to surface water would also be low (following the same considerations already discussed above relating to soil exposure from the indoor uses at section 4.1.2).

#### 4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

See section 4.1.3

### 4.3. FATE AND BEHAVIOUR IN AIR

Magnesium phosphide itself has a low vapour pressure ($1x10^{-8}$ Pa calculated for 25°C) so is not volatile. However the phosphine produced by hydrolysis is a dense gas (vapour pressure $3.44x10^{6}$ Pa at 20°C) which will enter the atmosphere. The experimentally derived reaction rate constant for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals for phosphine ($1.6x10^{-11}$ $cm^3$/mol.sec) resulted in an atmospheric half life estimated at 24 hours (assuming an atmospheric hydroxyl radical concentration of $5x10^5$ radicals $cm^{-3}$) indicating that phosphine would be unlikely to be subject to long range atmospheric transport when it reaches the upper atmosphere.
The atmospheric reaction products expected where oxygen is present are phosphonic acid and phosphoric acid that would be removed from the atmosphere by wet deposition.

## 5. Ecotoxicology

Magnesium phosphide was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 53 – sub-group 2) in July 2008 on the basis of Draft Assessment Report (DAR) and the Addendum 3 (May 2008).
The relevant supported uses evaluated were: a) control of rodent and non rodent species in underground burrows (outdoor); b) control of insects in food storage rooms (indoor). The representative product name was Degesch Magtoxin, a gas generating product (GE) formulated as pellets or tablets with a concentration of the active substances of 66%.

No studies on magnesium phosphide were provided, but the effects were addressed by studies conducted with aluminium phosphide. Since metal phosphides react with moisture to evolve phosphine gas, which is responsible for the toxicity, tests with aluminium phosphide could be used to assess the toxicity of magnesium phosphide.
Magnesium phosphide containing products for outdoor use are applied directly into the burrow systems. Therefore, the exposure of non target species was considered as only local for the field use or considered as negligible for the indoor use. No standard risk assessment was conducted.

### 5.1. RISK TO TERRESTRIAL VERTEBRATES

Two acute oral toxicity studies with aluminium phosphide were provided for Japanese quail (*Coturnix japonica*) and pigeon (*Columba livia*) with $LD_{50}$ values of 49 mg/kg bw/day and between 45 and 90 mg/kg bw/day, respectively. No short term or reproductive studies were presented.
On the basis of the mammalian toxicity data on aluminium phosphide, the acute oral $LD_{50}$ (rat) was 8.7 mg /kg bw/day; the acute inhalation $LD_{50}$ was 179 ppm in air ($PH_3$). Also a rat acute oral toxicity study with magnesium phosphide was available ($LD_{50}$ = 11.2 mg /kg bw/day). No data on the long term reproduction effects weres available, while a NOAEL of 1.1 mg $PH_3$/kg bw/day (=3 ppm in air equivalent to 0.0042 mg/L) was observed in a long term 90-day inhalation study and a NOE(A)L of 5 ppm in air ($PH_3$) was observed in an embryo toxicity and teratogenicity inhalation study.

The Member State experts discussed the possibility of secondary poisoning via bioaccumulation in the food chain. A clarification on the need to address the risk to predatory birds and mammals had been asked to the applicant and it was presented by the RMS in addendum 3 (May 2008).
The argumentations were related to the mode of action of phosphide and the metabolism of inhaled phosphine. The main route of phosphide exposure is by inhalation. Studies concerning adsorption, distribution, metabolism and excretion of ingested zinc phosphide in rats indicated that the evolved phosphine was rapidly and completely excreted by exhalation or via urine after oxidation to hypophosphite or phosphite. These phosphine metabolites were less toxic than phosphine itself. The log $P_{OW}$ of phosphine is 1.05. Moreover, intoxicated target animals do not escape from the treated burrows. The Member State experts agreed that it is reasonable to assume that no bioaccumulation in the food chain is expected.
Overall, the experts concluded that for the indoor application the exposure of vertebrates to magnesium phosphide and evolving phosphine gas could be excluded. For the outdoor use no relevant exposure was expected. Therefore, further testing of the effects on terrestrial vertebrates was unnecessary as well as no relevant risk was expected.
However, it was recommended to include in the label a sentence to make sure for outdoor use that burrows are closed and that no pellets remain on the surface.

### 5.2. RISK TO AQUATIC ORGANISMS

An acute toxicity study was provided with aluminium phosphide to rainbow trout (*Oncorhynchus mykiss*, static test, 96h-$LC_{50}$ = 9.65 µg Aluminium Phosphide/L, equivalent to 4.68 µg $PH_3$/L). The RMS recalculated a $LC_{50}$ of 9.3 µg Magnesium Phosphide/L from the $PH_3$ with a factor of 1.98 ($PH_3$ 33.975 g/mol, $Mg_3P_2$ 134.9 g/mol). Studies conducted on invertebrates (acute) and algae were considered not valid by the Member State experts. No chronic studies were provided.

The fate expert meeting agreed that the potential exposure of surface water to phosphine for the outdoor use should be further addressed. In a very worst case calculation a phosphide concentration of 25 µg/L was estimated by the e-fate experts (see point 4.2.1) for the situation where an entrance to treated organism burrow are adjacent to surface water (via movement in the gas phase). Due to the potential high toxicity of the compound a risk to aquatic organisms could not be excluded on the basis of the available data. Therefore, a data gap was identified to further address the risk and consequently to provide valid studies on aquatic organisms.

For the indoor use, the potential atmospheric deposition of aluminium phosphide on surface water that might occur when enclosed spaces were aerated after fumigation, was considered negligible. No risk was expected.

### 5.3. RISK TO BEES

No studies on bees were provided. Under the recommended uses, exposure was not expected, therefore no data were required.

### 5.4. RISK TO OTHER ARTHROPOD SPECIES

No studies on non target organisms were performed with magnesium phosphide. Under the recommended uses, exposure was not expected, therefore no data were required.

### 5.5. RISK TO EARTHWORMS

On the basis of toxicity data on aluminium phosphide, a 14 day-$LC_{50}$ of 663.5 mg Aluminium Phosphide/kg soil was observed (*Eisenia foetida*). No relevant exposure of earthworms was expected for both the indoor and outdoor use. To take into account the potential risk due to the exposure in the burrows a TER value was calculated for the phosphine metabolite. The calculation was based on the acute toxicity end point (14 day-$LC_{50}$ of 663.5 mg Aluminium Phosphide/kg soil, equivalent to 389 mg $PH_3$/kg soil) and the estimated PEC in the burrows of 3.426 mg $PH_3$/kg soil (as agreed by the fate meeting, see point 4.1.2 and appendix 1). The resulting TER of 114 was well above the annex VI trigger of 10, indicating a low risk to earthworms.

### 5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

No studies on other soil non-target macro-organisms were provided. Under the recommended uses, exposure was not expected, therefore no further data were required.

### 5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

A study on the effects of Phostoxin on the activity of the soil microflora was provided. Phostoxin is a formulated product containing 56% of aluminium phosphide. The study was accepted by the RMS. The nitrification activity was inhibited for a fortnight and the dehydrogenasis activity was reduced by approx 29% in one of the tested soil. Both effects were reversible. Overall, it was concluded that no risk was expected for non target micro-organisms.

### 5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

No relevant exposure for non-target organisms (flora and fauna), including these organisms that co-inhabit the tunnel systems, was expected from the proposed uses.

### 5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No relevant exposure of biological waste water treatment organisms was expected from the proposed use.

## 6. Residue definitions

**Soil**

| | |
|---|---|
| Definition for risk assessment: | phosphine |
| Definition for monitoring: | none |

**Water**

**Ground water**

| | |
|---|---|
| Definition for exposure assessment: | phosphine |
| Definition for monitoring: | none |

**Surface water**

| | |
|---|---|
| Definition for risk assessment: | phosphine |
| Definition for monitoring: | phosphine |

**Air**

| | |
|---|---|
| Definition for risk assessment: | phosphine |
| Definitions for monitoring: | phosphine |

**Food of plant origin**

| | |
|---|---|
| Definition for risk assessment: | phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine |

| | |
|---|---|
| Definition for monitoring: | phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine |

**Food of animal origin**

| | |
|---|---|
| Definition for risk assessment: | not proposed |
| Definition for monitoring: | not proposed |

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

**Soil**

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| phosphine | Very low persistence $DT_{50}$ 8 minutes to 6 hours at 22-25°C | The risk was assessed as low |

**Ground water**

| Compound (name and/or code) | Mobility in soil | > 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| phosphine | | No | Yes | Yes | Yes |

**Surface water and sediment**

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| phosphine | Data gap (in case that target organism burrows are adjacent to surface water) |

**Air**

| Compound (name and/or code) | Toxicology |
|---|---|
| Phosphine | Very high inhalation toxicity ($LC_{50}$ = 0.072 mg phosphine/L air phosphine generated from magnesium phosphide)<br>Classification as **T+; R26 "Very toxic; Very toxic by inhalation"** is proposed. |

## LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- New specification where the arsenic has been removed (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- For the products of plant origin: ILV and a confirmatory method (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- Confirmatory method of analysis for water (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- Method of analysis for air with an appropriate LOQ (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- To precise in the GAP the length of the minimum aeration period needed after fumigation to make the handling of the commodities safe for workers (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3)
- To precise the way the samples were handled between sampling and analyses in the study referenced RIP2002-148 (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3.1).
- To clearly define GAPs that include a withholding period in addition to the minimum aeration period (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3.1)
- The potential for exposure of surface water to phosphine moving in the gas phase from the requested outdoor applications of magnesium phosphide has yet to be adequately addressed (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; submission date proposed by the notifier: unknown; refer to point 4.2.1)
- Studies for aquatic invertebrates and algae with phosphine as test substance (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; data gap confirmed by EFSA after the PRAPeR 53 meeting in July 2008; refer to point 5.2).
- Risk assessment on aquatic organisms from exposure to phosphine (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; data gap confirmed by EFSA after the PRAPeR 53 meeting in July 2008; refer to point 5.2).

## CONCLUSIONS AND RECOMMENDATIONS

**Overall conclusions**

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, rodenticide, talpicide and leporicide. Full details of the GAP can be found in the attached list of endpoints.

The representative formulated product for the evaluation was "Degesch Magtoxin", a gas generating product (GE). The gas phosphine that is produced is the true active ingredient.

A method of analysis for phosphine in products of plant origin is available however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the $DT_{90}$ in soil is < 3 days for phosphine. A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the aluminium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. The case where the spent material is not removed has not been considered in the peer review process.

When coming into contact with moisture magnesium phosphide decomposes to magnesium hydroxide and phosphine which is the toxicologically active and relevant component for the assessment of mammalian toxicology of magnesium phosphide. Magnesium phosphide is classified as **R29 "Contact with water liberates toxic gas".** In addition a classification as **R32 "Contact with acids liberates very toxic gas"** has been proposed by the experts. Phosphine is rapidly absorbed from the gastrointestinal tract and the lungs. It is widely and evenly distributed in the body and has no potential for accumulation. Phosphine is excreted as such via expired air or with the urine in form of hypophosphite or phosphite. Magnesium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is neither a skin nor an eye irritant nor a skin sensitizer. Based on data on acute toxicity a classification as **T+; R28 "Very toxic if swallowed", Xn; R21 "Harmful in contact with skin"** and **T+; R26 "Very toxic by inhalation"** is proposed. A short term NOAEL of 1.1 mg/kg bw/d for phosphine (the highest dose tested, no adverse effects observed) was derived from a 90-day inhalation rat study. Magnesium phosphide is not genotoxic. A NOAEL of 1.1 mg/kg bw/d, which was the highest dose tested since no adverse effects were observed, was established for phosphine in a 2-year inhalation study with rats. A mouse carcinogenicity study was not carried out and not considered necessary based on the toxicity profile of the substance (lethality anticipated at low

doses). In an inhalation developmental study with rats (a rabbit study was not provided) no specific developmental effects were observed and an overall NOAEL of 1.9 mg/kg bw/d was set based on mortality occurring in dams. Effects on reproduction have not been assessed but are, based on the toxicity profile of the substance, not anticipated. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.022 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.038 mg/kg bw. The corresponding values for phosphine are 0.011 mg/kg bw/d (ADI and AOEL) and 0.019 mg/kg bw (ARfD).When applying magnesium phosphide in rodent burrows without the use of respiratory protective equipment (RPE) maximum exposure levels amounted to a maximum of 93% of the AOEL for operators. For workers and bystanders, however, actual exposure levels will be considerably lower. Application of magnesium phosphide in storage rooms when no respiratory protective equipment is used amounted for operators to 30% and 120% of the AOEL considering low and high use respectively. When respiratory protective is used the value for high use application is reduced to 10% of the AOEL. **EFSA disagrees with the operator exposure assessment for the use of magnesium phosphide in storage rooms**. Exposures of workers and bystanders after application in storage rooms account for a maximum of 25% and 33% of the systemic AOEL respectively.

Two main uses of magnesium phosphide were evaluated, 1) as rodenticide, talpicide, leporicide to control rodent and non-rodent species by fumigation of underground tunnels and burrows in cropland and non-cropland situations, 2) as fumigant to control insects in various harvested plant products and in empty warehouses or transportation facilities. Due to its physico-chemical properties, no specific studies to evaluate metabolism and distribution of magnesium phosphide in treated commodities were submitted. In contact with soil or atmospheric moisture, magnesium phosphide is rapidly hydrolysed to produce phosphine ($PH_3$) and magnesium hydroxide $Mg(OH)_2$. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine and residual metal phosphide, the residue definition for monitoring and risk assessment was set as “phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine”.
No residue trials were submitted to support the uses of magnesium phosphide as rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plants and therefore, the possible residues in plants. For post harvest applications, in addition to the aeration period, the RMS proposed for each commodity or group of commodities a withholding period. Thus, during the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of these additional withholding periods of 7 to 35 days, depending on the commodities. Consequently and after the meeting, EFSA was of the opinion that the

fumigation practices have not been sufficiently defined to allow the MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap.
No storage stability study was provided considering that the inherent properties of phosphine lead to a low stability in stored products. No processing studies and no livestock metabolism and feeding studies were provided, considering that no significant residues of magnesium phosphide and phosphine are expected in post harvested plant commodities. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and non-rodent species. No unacceptable chronic or acute risks to consumers were identified, taking into account that the proposed MRL values do not reflect the critical GAPs as initially defined by the applicants.

The Member State experts concluded that in relation to the applied for intended uses, the information available on the fate and behaviour of magnesium phosphide, phosphine gas, phosphate and magnesium salts in the environment was sufficient to complete an adequate environmental exposure characterisation with one exception. This exception was that for the use outdoors in animal burrows, where these burrows had openings directly adjacent to surface water, further data were necessary to enable a more realistic exposure estimate for potential concentrations of phosphine gas in surface water and if necessary, demonstrate the effectiveness of potential exposure mitigation measures that might need to be proposed. The potential for groundwater exposure by phosphine and magnesium phosphide from the applied for intended uses was assessed as low and there are no relevant parametric drinking water limits set out in the relevant EU legislation for magnesium salts and phosphate.

Due to the intended uses (applied outdoor directly into the burrow systems or indoor in food storage rooms), the exposure to non-target species was considered to be only local or negligible. On the basis of potential exposure of surface water to phosphine (data gap from fate), in case that target organism burrows are adjacent to water bodies, the risk from the outdoor use to aquatic organisms needs to be addressed (data gap) and therefore valid studies on invertebrates and algae should be provided (data gap).
The risk to birds, mammals, bees, non-target arthropods, earthworms, soil non target macro- and micro- organisms, non-target plants and biological methods of sewage treatment was expected to be low for the representative use evaluated.

**Particular conditions proposed to be taken into account to manage the risk(s) identified**

- For operators the use of respiratory protective equipment is needed.
- To protect birds and mammals, include on the label, a phrase to make sure that burrows are closed and no granules remain on the surface.

## Critical areas of concern

- The peer review has only considered the situation where the spent pellets are removed from the food commodity. The situation where the material remains in the food after the release of phosphine has not been considered in the peer review. If this situation is to be covered then a different technical specification would be required and a risk assessment for the material remaining in the food commodity would have to be conducted.
- EFSA disagrees with the exposure assessment for the use of magnesium phosphide in storage rooms.

*EFSA Scientific Report* **(2008) 190, 1-73**
**Conclusion on the peer review of magnesium phosphide**

**Appendix 1 – list of endpoints**

## APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, physical and chemical properties, details of uses, further information,

| | |
|---|---|
| Active substance (ISO Common Name) ‡ | Magnesium phosphide |
| Function (*e.g.* fungicide) | Insecticide, rodenticide, talpicide and leporicide |
| Rapporteur Member State | Federal Republic of Germany |

**Identity** (Annex IIA, point 1)

| | |
|---|---|
| Chemical name (IUPAC) ‡ | Magnesium phosphide |
| Chemical name (CA) ‡ | Magnesium phosphide |
| CIPAC No ‡ | 228 |
| CAS No ‡ | 12057-74-8 |
| EEC No (EINECS or ELINCS) ‡ | EINECS 235-023-7 |
| FAO Specification (including year of publication)‡ | none |
| Minimum purity of the active substance as manufactured ‡ | 880 g/kg |
| Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured | none |
| Molecular formula ‡ | $Mg_3P_2$ |
| Molecular mass ‡ | 134.9 g/mol |
| Structural formula ‡ | Mg-P-lattice (of type anti-fluorite) |

**Appendix 1 – list of endpoints**

**Physical-chemical properties** (Annex IIA, point 2)

| | |
|---|---|
| Melting point (state purity) ‡ | > 500 °C (90.5 % ± 1.5 %) |
| Boiling point (state purity) ‡ | > 500 °C (90.5 % ± 1.5 %) |
| Temperature of decomposition (state purity) | > 500 °C |
| Appearance (state purity) ‡ | grey solid (techn.) |
| Vapour pressure (state temperature, state purity) ‡ | < $10^{-3}$ Pa (measurement at 32 °C – 151 °C)( 90.5 % ± 1.5 %)<br>1x$10^{-8}$ Pa (calculated for 25 °C, Antoine equation)<br>[$PH_3$: 3.44 x $10^{6}$ Pa (20 °C); 3.90 x $10^{6}$ Pa (25 °C)][6] |
| Henry's law constant ‡ | not determined, rapid hydrolysis |
| Solubility in water (state temperature, state purity and pH) ‡ | not determined, rapid hydrolysis |
| Solubility in organic solvents (state temperature, state purity) ‡ | not soluble, due to ionic structure (not determined) |
| Surface tension ‡<br>(state concentration and temperature, state purity) | not determined, rapid hydrolysis |
| Partition co-efficient (log $P_{OW}$) (state temperature, pH and purity) ‡ | not determined, rapid hydrolysis |
| Dissociation constant (state purity) ‡ | not determined, rapid hydrolysis |
| UV/VIS absorption (max.) incl. ε<br>(state purity, pH) ‡ | not applicable |
| Flammability ‡ (state purity) | The submitted test shows that magnesium phosphide is not highly flammable under the test conditions (EEC A10), but will evolve extremely flammable phosphine at contact with water (EEC A12).<br>However, the ECB has classified aluminium phosphide as F (highly flammable). With respect to the similarity of all the phosphine generating formulations in discussion, the RMS proposes the above listed classification/ labelling also for magnesium phosphide.<br>[$PH_3$: $F^+$, extremely flammable] |

[6] This endpoint originate from the dossier / DAR for aluminium phosphide and is not included in the DAR for magnesium phosphide.

**Appendix 1 – list of endpoints**

| | |
|---|---|
| Explosive properties ‡(state purity) | no explosive properties (according to structure)<br>Heat of decomposition < 500 J/g (86.5 % ± 2 % ) |
| Oxidising properties ‡(state purity) | No oxidising properties under the test conditions (statement) |

## Appendix 1 – list of endpoints

### Summary of representative uses evaluated (Magnesium phosphide)*

| Crop and/or situation (a) | MS or Country | Product name | F/G /I (b) | Pests or Group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as (i) | Method kind (f-h) | Growth stage & season (j) | Number min & max (k) | Interval between applications (min) | kg as/hL min & max | Water L/ha min & max | kg as/ha min & max | Days (l) | (m) |
| Out-door control of rodent and non-rodent species in underground burrows, e.g. in fields and meadows, orchards, forests: | Europe | DEGESCH Magtoxin* | F | Moles<br>Rabbits<br>Rodents | GE | 66 % | gassing | n.a. | 1 | n.a. | n.a. | n.a. | 5 pellets / 3-5 meters borrow length (light soil)/ or<br>5 pellets/ 8-10 meters burrow lenght (all other soils<br>1-10 pellets / hole | n.a. | [1] |

*) same formulation as Magtoxin Pellets, Magtoxin N WM, DEGESCH MAGTOXIN RT, Magtoxin B Pellets, Magtoxin N Pellets, Phostoxin MG bolas

[1] The environmental exposure and risk assessment presented in the DAR it's addenda and this conclusion does not cover the use of 10 tablets. Only the use of up to 5 pellets was assessed.

## Appendix 1 – list of endpoints

| Crop and/or situation | MS or Country | Product name | F/G/I | Pests or Group of pests controlled | Formulation | | Application | | | | Application rate per treatment | | | PHI | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type | Conc. of as | Method kind | Growth stage & season | Number min & max | Interval between applications (min) | kg as/hL min & max | Water L/ha min & max | kg as/ha min & max | Days | |
| (a) | | | (b) | ( c ) | (d-f) | (i) | (f-h) | (j) | (k) | | | | | (l) | (m) |
| In-door control of insects mainly in food storage practice: | | | | | | | | | | | | | | | |
| grain in silos, food and feet in storage rooms | Europe | Degesch Magtoxin*) | I | Storage pests | GE | 66 % | gassing | n.a. | 1 | n.a. | n.a. | n.a. | 3-5 tablets /m³ | | [1], [2] |
| quarantine treatment, grain (also in silo compartments without recirculation fumigation) and other commodities, e. g. oil seeds, cocoa beans, spices, tobacco | Europe | Degesch Magtoxin*) | I<br>I | Storage pests | GE | 66 % | gassing | n.a. | 1 | n.a. | n.a. | n.a. | 3-5 tablets /t | | [1], [2] |

## Appendix 1 – list of endpoints

| Crop and/or situation | MS or Country | Product name | F/G/I | Pests or Group of pests controlled | Formulation | | Application | | | | Application rate per treatment | | | PHI | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type | Conc. of as | Method kind | Growth stage & season | Number min & max | Interval between applications (min) | kg as/hL min & max | Water L/ha min & max | kg as/ha min & max | Days | |
| (a) | | | (b) | ( c ) | (d-f) | (i) | (f-h) | (j) | (k) | | | | | (l) | (m) |
| empty rooms and buildings, transport vehicles, cereal grains and bulk stored expeller in silo compartment (with and without recirculation fumigation), loose commodities and other storage goods, e. g. pulses, nuts, dried fruits, herbs and spices | Europe | Degesch Magtoxin*) | I<br>I | Storage pests | GE | 66 % | gassing | n.a. | 1 | n.a. | n.a. | n.a. | 10-30 pellets/t | | [1], [2] |
| empty rooms and buildings, transport vehicles, sacked and stacked goods (space fumigation), loose and packed commodities, e. g. grain, cocoa, coffee, peanuts, oil seed, soy, dried fruits, dried mushrooms, tea, tobacco | Europe | Degesch Magtoxin*) | I | Storage pests | GE | 66 % | gassing | n.a. | 1 | n.a. | n.a. | n.a. | 3-15 pellets/m³ | | [1], [2] |

*) same formulation as Magtoxin Pellets, Magtoxin N WM, DEGESCH MAGTOXIN RT, Magtoxin B Pellets, Magtoxin N Pellets, Phostoxin MG bolas

1) EFSA disagrees with the exposure assessment when magnesium phosphide (Magtoxin) is used in storage rooms.

2) Solid residues from the formulation have to be removed from the food commodities

## Appendix 1 – list of endpoints

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

## Appendix 1 – list of endpoints

Methods of analysis

**Analytical methods for the active substance** (Annex IIA, point 4.1)

| | |
|---|---|
| Technical as (principle of method) | titration after hydrolysis |
| Impurities in technical as (principle of method) | titration, gravimetrically, ICP-AES, FIAS-AAS |
| Plant protection product (principle of method) | titration after hydrolysis |

**Analytical methods for residues** (Annex IIA, point 4.2)

**Residue definitions for monitoring purposes**

| | | |
|---|---|---|
| Food of plant origin | | Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as as phosphine |
| Food of animal origin | | Not relevant |
| Soil | | Not relevant, $DT_{90}$ < 3 days |
| Water | surface | Phosphine |
| | drinking/ground | None |
| Air | | Phosphine |

**Appendix 1 – list of endpoints**

**Monitoring/Enforcement methods**

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | GC-NPD 0.01 mg/kg (meal, shell fruit, tea)<br><br>ILV and confirmatory method are missing |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not relevant, no MRL, no residue definition for monitoring |
| Soil (analytical technique and LOQ) | Not relevant, $DT_{90}$ < 3 days |
| Water (analytical technique and LOQ) | GC-NPD 0.1 µg/L (surface water) |
| Air (analytical technique and LOQ) | open |
| Body fluids and tissues (analytical technique and LOQ) | not necessary, since phosphine will be quickly exhaled or metabolised to phosphates, even though the active substance is classified as very toxic |

**Classification and proposed labelling** (Annex IIA, point 10)

| | |
|---|---|
| with regard to physical/chemical data | F |

## Appendix 1 – list of endpoints

Impact on human and animal health

### Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

| | |
|---|---|
| Rate and extent of oral absorption ‡ | Ready absorption of phosphine through the lungs and after oral exposure to zinc phosphide |
| Distribution ‡ | Widely distributed |
| Potential for accumulation ‡ | No potential for accumulation |
| Rate and extent of excretion ‡ | Excretion with urine as hypophosphite and phosphite and via lungs as phosphine |
| Metabolism in animals ‡ | Hydrolysis to phosphine, oxidation to hypophosphite and phosphite |
| Toxicologically relevant compounds ‡ (animals and plants) | Phosphine |
| Toxicologically relevant compounds ‡ (environment) | Phosphine |

### Acute toxicity (Annex IIA, point 5.2)

| | | |
|---|---|---|
| Rat $LD_{50}$ oral ‡ | 10.4 mg/kg bw (magnesium phosphide) | T+, R28 |
| Rat $LD_{50}$ dermal ‡ | Ca. 460-900 mg/kg bw (Aluminium phosphide) | Xn, R21 |
| Rat $LC_{50}$ inhalation ‡ | >11 ppm (>0.015 mg $PH_3$/L air or >2.8 mg/kg bw) – 51 ppm (0.072 mg $PH_3$/L air) (4 h exposure, whole body) (Phosphine) | T+; R26 |
| Skin irritation ‡ | Not irritant (aluminium phosphide) | |
| Eye irritation ‡ | Not irritant (aluminium phosphide) | |
| Skin sensitisation ‡ | • No indication of skin sensitisation (Buehler-test, 3 inductions using a product containing 66 % w/w magnesium phosphide and 56 % w/w aluminium phosphide; M&K-test using zinc phosphide) | • |

### Short term toxicity (Annex IIA, point 5.3)

| | | |
|---|---|---|
| Target / critical effect ‡ | Mortality | |
| Relevant oral NOAEL ‡ | No reliable data, no study required | |
| Relevant dermal NOAEL ‡ | No data, no study required | |

**Appendix 1 – list of endpoints**

| | | |
|---|---|---|
| Relevant inhalation NOAEL ‡ | NOAEL 3 ppm phosphine (equivalent to 1.1 mg/kg bw/d), rat 90-d, the highest dose tested | |

**Genotoxicity ‡ (Annex IIA, point 5.4)**

| | |
|---|---|
| No genotoxic potential at realistic exposure levels | |

**Long term toxicity and carcinogenicity (Annex IIA, point 5.5)**

| | | |
|---|---|---|
| Target/critical effect ‡ | None | |
| Relevant NOAEL ‡ | 3 ppm equivalent to 1.1 mg/kg bw/d (rat 2-yr inhalation) | |
| Carcinogenicity ‡ | Not carcinogenic in the rat<br>No data on mice, justification given | |

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

| | | |
|---|---|---|
| Reproduction target / critical effect ‡ | No data, not necessary | |
| Relevant parental NOAEL ‡ | No data, not necessary | |
| Relevant reproductive NOAEL ‡ | • No data, not necessary | |
| Relevant offspring NOAEL ‡ | • No data, not necessary | |

**Developmental toxicity**

| | | |
|---|---|---|
| Developmental target / critical effect ‡ | Rat: Mortality of dams | |
| Relevant maternal NOAEL ‡ | Rat, developmental study, inhalation: 4.9 ppm phosphine (equivalent to 1.9 mg/kg bw/d)<br>No data on rabbits, not necessary, | |
| Relevant developmental NOAEL ‡ | Rat, developmental study, inhalation: 4.9 ppm phosphine (equivalent to 1.9 mg/kg bw/d)<br>• ~~No~~ No data on rabbits, not necessary. | |

## Appendix 1 – list of endpoints

### Neurotoxicity (Annex IIA, point 5.7)

| | | |
|---|---|---|
| Acute neurotoxicity ‡ | NOAEL (acute study, inhalation): 40 ppm $PH_3$ (analytical conc. 38 ppm) (with regard to anatomic pathology, behavioural and neurological status); < 21 ppm (with regard to changes in motor activity) | |
| Repeated neurotoxicity ‡ | NOAEL (subchronic study 90 days): 3 ppm phosphine equivalent to 1.1 mg/kg bw/d | |
| Delayed neurotoxicity ‡ | No study required. | |

### Other toxicological studies (Annex IIA, point 5.8)

| | |
|---|---|
| Mechanism studies | No additional studies required. The relevant metabolite phosphine was generated in the submitted studies |

### Medical data ‡ (Annex IIA, point 5.9)

| |
|---|
| No compelling evidence of negative health effects from examinations of personnel with occupational exposure. Records of poisoning cases, mainly in connection with suicide and accidents (particularly with children) are available. |

## Appendix 1 – list of endpoints

### Summary (Annex IIA, point 5.10)

| **Magnesium phosphide** | Value | Study | Safety factor |
|---|---|---|---|
| ADI ‡ | 0.022 mg/kg bw/d* | 2-yr inhalation, rat | 100 |
| AOEL systemic ‡ | 0.022 mg/kg bw/d* | 90-d inhalation, rat | 100 |
| ARfD ‡ | 0.038 mg/kg bw | Developmental study (inhalation), rat | 100 |
| **Phosphine** | | | |
| ADI | 0.03 ppm or<br>0.042 µg/L air or<br>0.011 mg/kg bw/d | 2-yr inhalation, rat | 100 |
| AOEL systemic ‡ | 0.03 ppm or<br>0.042 µg/L air or<br>0.011 mg/kg bw/d | 90-d inhalation, rat | 100 |
| ARfD | 0.049 ppm or<br>0.069 µg/L air or<br>0.019 mg/kg bw | Developmental study (inhalation), rat | 100 |

* Based on a maximum liberation of gas of 0.50 g $PH_3$ /g magnesium phosphide

### Dermal absorption ‡ (Annex IIIA, point 7.3)

| |
|---|
| Default value 10 % for magnesium phosphide and $PH_3$ (based on expert judgement) |

## Appendix 1 – list of endpoints

**Acceptable exposure scenarios** (including method of calculation)

| | |
|---|---|
| Operator | Exposure assessments considering results of field studies and publications.<br>Use for the control of rodents in burrows: acceptable without the use of personal protective equipment. (high use: treatment along railway embankment 93 % of AOEL). Nevertheless, because temporary exposure concentrations exceeding the AOEL cannot be excluded, PPE/RPE should be recommended.<br><br>Use for the control of insect pests in storage buildings: 30% of the AOEL when 1 fumigation procedure is applied and no RPE is used. **EFSA disagrees with this assessment.**<br>When 4 fumigation procedures are applied: 120 % of AOEL during application without PPE, 10 % of AOEL using RPE, |
| Workers | < 93% of systemic AOEL when used in rodent burrows (no RPE used).<br>≤ 25 % of systemic AOEL when used in storage rooms (RPE used). |
| Bystanders | < 93% of systemic AOEL when used in rodent burrows.<br>≤ 33 % of systemic AOEL when used in storage rooms<br>• |

**Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)**

| | |
|---|---|
| **Magnesium phosphide** | T+; R 15/29-28 (29th ATP)<br>• Additionally proposed by PRAPeR: Xn; R 21, T+; R26, R32<br>• Add Safety phrase SPo1: After contact with skin first remove product with a dry cloth and then wash the skin with plenty of water |
| **Phosphine** | T+; R 26-34 (up to 29th ATP) |

## Appendix 1 – list of endpoints

### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

| | |
|---|---|
| Plant groups covered | Outdoor use: Not required<br>Indoor use:<br>Not required, since no relevant residues apart from phosphine and magnesium phosphide in plants and agricultural products derived thereof are expected. |
| Rotational crops | Not required – Phosphine and magnesium phosphide residues will not be bioavailable to rotational crops. |
| Metabolism in rotational crops similar to metabolism in primary crops? | Not applicable |
| Processed commodities | Not required, since no relevant residues of phosphine and magnesium phosphide in plants and agricultural products derived thereof are expected. |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable |
| Plant residue definition for monitoring | Outdoor use: Not required<br>Indoor use:<br>Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine |
| Plant residue definition for risk assessment | Outdoor use: Not required<br>Indoor use:<br>Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine |
| Conversion factor (monitoring to risk assessment) | none |

### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

| | |
|---|---|
| Animals covered | Not applicable – feeding studies not triggered |
| Time needed to reach a plateau concentration in milk and eggs | Not required for reasons given above |
| Animal residue definition for monitoring | Not required, since no residues of phosphine and magnesium phosphide in plants or feed of plant origin are expected. |
| Animal residue definition for risk assessment | Not required, since no residues of phosphine and magnesium phosphide in plants or feed of plant origin are to be expected. |

## Appendix 1 – list of endpoints

| | |
|---|---|
| Conversion factor (monitoring to risk assessment) | None |
| Metabolism in rat and ruminant similar (yes/no) | Not applicable |
| Fat soluble residue: (yes/no) | not applicable |

**Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)**

| |
|---|
| Not required – Phosphine and magnesium phosphide residues will not be bioavailable to succeeding crops. |

**Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)**

| |
|---|
| Outdoor use: Not required<br>Indoor use:<br>Guideline studies of the stability of magnesium phosphide and phosphine during storage of samples are not available. The active substance is volatile. Therefore, samples should be stored at approximately ≤ - 20 °C and analysed as soon as possible (≤ 2 days). |

## Appendix 1 – list of endpoints

### Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

| | Ruminant: | Poultry: | Pig: |
|---|---|---|---|
| | Conditions of requirement of feeding studies - not applicable (feeding studies not triggered) | | |
| Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level) | no | no | no |
| Potential for accumulation (yes/no): | no | no | no |
| Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no) | not required | not required | not required |
| | Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) - not applicable (feeding studies not triggered)<br>Residue levels in matrices : Mean (max) mg/kg | | |
| Muscle | no | no | no |
| Liver | no | no | no |
| Kidney | no | no | no |
| Fat | no | no | no |
| Milk | no | | |
| Eggs | | no | |

## Appendix 1 – list of endpoints

**Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)**

| Crop | Northern or Mediterranean Region, field or glasshouse and any other useful information | Trials results relevant to the representative uses (mg/kg) (a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR (mg/kg) (c) | STMR (mg/kg) (b) |
|---|---|---|---|---|---|---|
| **No MRLs could be defined according the critical GAPs as defined by the applicants where only an aeration period is considered.** However, MRL proposals were discussed during the meeting of experts taking into account the additional withholding periods proposed by the RMS (see conclusion report). | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

## Appendix 1 – list of endpoints

### Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

| | |
|---|---|
| ADI | 0.011 mg phosphine/kg bw/d |
| TMDI (% ADI) according to WHO European diet<br>TMDI (% ADI) according to national (to be specified) diets | No MRLs could be defined according the critical GAPs<br>However, the MRL proposals discussed during the meeting and based on the residue levels observed after an additional withholding period, lead to TMDI calculations that are below the ADI (see conclusion report). |
| IEDI (WHO European Diet) (% ADI) | Not required |
| NEDI (specify diet) (% ADI) | Not required |
| Factors included in IEDI and NEDI | Not required |
| ARfD | 0.019 mg phosphine/kg bw |
| IESTI (% ARfD)<br>NESTI (% ARfD) according to national (to be specified) large portion consumption data | No MRLs could be defined according the critical GAPs<br>However, the MRL proposals discussed during the meeting and based on the residue levels observed after an additional withholding period, lead to IESTI calculations that are below the ARfD (see conclusion report). |
| Factors included in IESTI and NESTI | Not required |

### Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

| Crop/ process/ processed product | Number of studies | Processing factors | | Amount transferred (%) (Optional) |
|---|---|---|---|---|
| | | Transfer factor | Yield factor | |
| Not applicable | | | | |

Residue levels of phosphine and magnesium phosphide were < 0.1mg/kg in all commodities at the end of the withholding periods and the TMDI generally < 10 % of the ADI value. Therefore, no studies on the effects on residue levels due to processing are necessary.

## Appendix 1 – list of endpoints

**Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)**

| | |
|---|---|
| **Outdoor use** | Not required |
| **Indoor use** | **No MRLs could be defined according to critical GAPs as defined by the applicants where only an aeration period is considered** |
| | However, MRL proposals were discussed during the meeting of experts taking into account additional withholding periods proposed by the RMS (see conclusion report). |

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

## Appendix 1 – list of endpoints

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

| | |
|---|---|
| Mineralisation after 100 days ‡ | not relevant* |
| Non-extractable residues after 100 days ‡ | not relevant |
| Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum) | not relevant |

* Recent, ”state-of-the-art” investigations according to current guidelines for the elucidation of the degradation pathway of magnesium phosphide in soil do not exist. Magnesium phosphide is an inorganic compound. The rate of chemical hydrolysis, which occurs very rapidly and leads to the evolution of phosphine and residual magnesium salts, would be expected to be the predominant mechanism for loss of magnesium phosphide when placed in the soil environment. Phosphine is expected to either partition to the atmosphere due to it’s volatility, or become re-adsorbed onto soil. In both cases, oxidative processes are effective in finally transforming phosphine to phosphate anions.

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

| | |
|---|---|
| Anaerobic degradation ‡ | Indoor applications:<br>Due to the application in closed/sealed rooms (storage protection) contact with soil is excluded.<br>Outdoor applications:<br>Not required since product is applied in underground tunnel systems and in this open field environment anaerobic conditions are not expected to be relevant |
| Soil photolysis ‡ | Not required since product is applied in underground tunnel systems where light is excluded. |

## Appendix 1 – list of endpoints

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

| Metabolite $PH_3$ | Aerobic conditions | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | X[7] | pH | t °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20 °C pF2/10kPa | St. ($r^2$) | Method of calculation |
| sand | | 6 | 22 °C / 40 % | 0.22 / 0.66* | - | - | |
| sand | | 6 | 22 °C / 40 % | 0.24 / 0.72* | - | - | |
| Geometric mean/median | | | | 0.23 / 0.23 | - | | |

* estimated

Laboratory studies ‡

| | |
|---|---|
| $PH_3$ | Aerobic conditions<br>Magnesium phosphide is degraded in soil to yield phosphine gas as an intermediate, and magnesium salts. Theoretically, any phosphine generated during hydrolysis will either be volatilised and subsequently subject to oxidative degradation by reaction with OH-radicals, or it will become re-adsorbed onto soil and subsequently be degraded.<br>After 6 hours only 50 % of the $PH_3$ amount used is found. Therefore a fast primary degradation of $PH_3$ can be concluded. |

| | |
|---|---|
| Field studies ‡ | Field studies were not performed as the laboratory $DT_{50}$ were extremely short. |

| | |
|---|---|
| pH dependence ‡<br>(yes / no) (if yes type of dependence) | Not relevant |
| Soil accumulation and plateau concentration ‡ | Not relevant. |

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

The performance of "state-of-the-art" adsorption/desorption experiments with magnesium phosphide is not considered to be required for the following reasons: (i) All high-resolution analytical methods for magnesium phosphide are based on the principle of liberating phosphine gas, with subsequent head space gas chromatography. Thus, a discrimination between the parent compound magnesium phosphide and any phosphine already present would not be possible in experimental settings. (ii) The preparation of a solution in water for the subsequent adsorption/desorption experiments is not possible. As a result, this renders the performance of such studies as technically and scientifically unfeasible.

## Appendix 1 – list of endpoints

### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

| | |
|---|---|
| Column leaching ‡<br>Aged residues column leaching | For this type of application and this type of pesticide no guideline exists, that can be followed.<br>A study has been performed showing that after 24 hours $PH_3$ has almost disappeared. The study is plausible. |
| Lysimeter/ field leaching studies ‡ | no lysimeter studies performed |

### PEC (soil) (Annex IIIA, point 9.1.3)

| | |
|---|---|
| Parent | not relevant |
| $PH_3$ | $DT_{50}$: 5.7 h |
| Method of calculation | Kinetics: SFO<br>Field or Lab: from laboratory studies |
| Application data | 5 pellets à 0.6 g per 3 – 5 m burrow length (light soils)<br>5 pellets à 0.6 g per 8 – 10 m burrow length (all other soils) |

| **$PEC_{(s)}$** (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---|---|---|---|---|
| Initial | not applicable* | | not applicable | |
| Short term 24h | not applicable | not applicable | not applicable | not applicable |
| 2d | not applicable | not applicable | not applicable | not applicable |
| 4d | not applicable | not applicable | not applicable | not applicable |
| Long term 7d | not applicable | not applicable | not applicable | not applicable |
| 28d | not applicable | not applicable | not applicable | not applicable |
| 50d | not applicable | not applicable | not applicable | not applicable |
| 100d | not applicable | not applicable | not applicable | not applicable |
| Plateau concentration | not applicable | | | |

* Unlike conventional crop protection products, which must be applied over relatively large crop areas, magnesium phosphide products are predominantly applied to discrete sites in form of pellets for fumigation. Therefore a standard estimation of predicted environmental concentrations in soil ($PEC_{soil}$) as for conventional plant protection products can not be calculated

**Appendix 1 – list of endpoints**

Based on estimations using an emission scenario document for biocides used as rodenticides[8] the following $PH_3$-concentrations can be estimated for applications of 5 pellets à 0.6 g = 3 g

| burrow length (application: 3 g product) | Amount of product per treated area (= 2000 m length of exposed hole) | $PH_3$ $PEC_{soil}$ (mg/kg) |
|---|---|---|
| 3 m | 2000 g | 3.426 |
| 5 m | 1200 g | 2.055 |
| 8 m | 750 g | 1.285 |
| 10 m | 600 g | 1.028 |

An additional field experiment showed that the horizontal spreading of $PH_3$ in soil was relatively fast whereas vertical spreading rate of $PH_3$ in soil was low. The highest concentration was found near the buried pellet in a distance of 40 cm (60 cm depth) to the buried pellet (1 m depth), only 3 – 15 % of the values detected at 10 cm (90 cm depth) to the buried pellet were measured. After 24 hours phosphine has almost disappeared.

Though the results are plausible the study can only be taken as supplemental information as no guideline currently exists for this special type of application.

**Route and rate of degradation in water (Annex IIA, point 7.2.1)**

| | |
|---|---|
| Hydrolytic degradation of the active substance and metabolites > 10 % ‡ | Too rapid to estimate.<br>[9]Metabolite $PH_3$ (gas): 1 - 1 ½ d (23 – 39 h at pH 4,7 and 9 20°C) |
| Photolytic degradation of active substance and metabolites above 10 % ‡ | not relevant |
| Quantum yield of direct phototransformation in water at λ > 290 nm | not relevant |
| Readily biodegradable ‡ (yes/no) | not relevant |

| | |
|---|---|
| Degradation in water / sediment: | not relevant |

| | |
|---|---|
| Mineralisation and non extractable residues: | not relevant |

[8] Supplement to the methodology for risk assessment of biocides; Emission scenario document for biocides used as rodenticides; May 2003; Danish EPA; J. Larsen; CA-Jun03-Doc.8.2-PT14

[9] These endpoints originate from the dossier / DAR for aluminium phosphide and are not included in the DAR for magnesium phosphide.

## Appendix 1 – list of endpoints

### PEC surface water and PEC sediment (Annex IIIA, point 9.2.3)

| | |
|---|---|
| Outdoor uses | The calculation of predicted environmental concentrations in surface waters (PECsw) for magnesium phosphide following the GAP use of the product is not considered to be required, since the use of the plant protection product involves laying out of ready-to-use magnesium phosphide-containing product in underground burrows. Thus, any contamination of surface waters by events related in general to pesticides, such as over-spray, drift, run-off, atmospheric deposition etc. is not to be expected. Contamination of surface waters is excluded by the specific conditions of use. Therefore, an estimation of predicted environmental concentrations in surface waters and consequently in sediments for magnesium phosphide is not required. For $PH_3$ (gas) surface water exposure from movement in the gas phase where burrow entrances are adjacent to surface water cannot be completely excluded. A data gap was identified to address this. |
| Indoor uses | Negligible both for magnesium phosphide and $PH_3$ (gas). |

### PEC (ground water) (Annex IIIA, point 9.2.1)

| | |
|---|---|
| Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter), Application rate | It is concluded that there is no risk of contamination of ground water by magnesium phosphide or $PH_3$ and that phosphate would not contaminate groundwater to any relevant degree (for phosphate exposure levels would be lower than from the use of phosphate as fertiliser) |

## Appendix 1 – list of endpoints

### Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

| | |
|---|---|
| Direct photolysis in air ‡ | not relevant for the parent and for $PH_3$ |
| Quantum yield of direct phototransformation | not relevant |
| Photochemical oxidative degradation in air ‡ | not relevant for the parent |
| Volatilisation ‡ | not relevant (vapour pressure << $10^{-7}$ hPa) |
| Metabolites | $PH_3$ (gas, vapour pressure $3.44x10^6$ Pa, 20 °C) :<br>$DT_{50}$ of approximately 24 hours<br>(reaction rate constant, determined experimentally = $1.6 x \cdot 10^{-11}$ $cm^3$ / mol·sec, assumed an average OH radical concentration of $5.0 x 10^5$ OH/cm3 for a 24 h-day) |

**$PEC_{air}$**

**$PEC_{(a)}$**

| | |
|---|---|
| Maximum concentration | Due to the high vapour pressure of $PH_3$ discharge into the air caused by aeration after application is possible. However, $PH_3$ degrades rapidly in the upper atmosphere ($DT_{50}$ air 24 h) and contamination of the environment is expected to be negligible. |

### Residues requiring further assessment

| | | |
|---|---|---|
| Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) | Soil: | $PH_3$ |
| | Surface Water: | $PH_3$ |
| | Sediment: | $PH_3$ |
| | Ground water: | $PH_3$ |
| | Air: | $PH_3$ |

### Monitoring data, if available (Annex IIA, point 7.4)

| | |
|---|---|
| Soil (indicate location and type of study) | not available |
| Surface water (indicate location and type of study) | not available |
| Ground water (indicate location and type of study) | not available |
| Air (indicate location and type of study) | not available |

## Appendix 1 – list of endpoints

### Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

| |
|---|
| No labelling |

## Appendix 1 – list of endpoints

### Effects on Non-target Species

Some of the studies referenced and/or summarised below are conducted with aluminium phosphide or aluminium phosphide containing products. Since both magnesium and aluminium phosphides react with moisture to evolve phosphine gas, which is the substance responsible for the toxicity of the product, tests with aluminium phosphide can be used to assess the toxicity of magnesium phosphide.

**Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)**

| Species | Test substance | Time scale | Endpoint (mg/kg bw/d) | Endpoint (mg/kg feed) |
|---|---|---|---|---|
| Birds ‡ | | | | |
| *Coturnix coturnix japonica* (Japanese quail) | Aluminium phosphide | Acute oral, 21-d | $LD_{50}$ 49 | |
| *Columba livia* (pigeon) | Aluminium phosphide | Acute oral, 21-d | $LD_{50}$ 45 – 90 | |
| Not relevant: Due to the special application method exposure of birds is not expected | | | | |
| Mammals ‡ | | | | |
| Rat | Magnesium phosphide | Acute oral | $LD_{50}$ 11.2 | Not relevant |
| Rat | Phosphine $PH_3$ | Acute inhalation 1 h, female | | 179 ppm |
| Rat | | Long-term, 2-generation reproduction study | No data submitted, justification accepted | |
| Rat | $PH_3$ | Inhalation, long-term, 90-day inhalation | NOAEL 1.1 mg/kg bw | 3 ppm in air = 0.0042 mg/L |
| Rat | $PH_3$ | Inhalation, embryo toxicity and teratogenicity, exposure day 6-15 p.c. | | NO(A)EL 5 ppm in air |
| Additional higher tier studies ‡<br>Not required | | | | |

## Appendix 1 – list of endpoints

### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Indoor: For storage protection magnesium phosphide is exclusively used in enclosed spaces
Outdoor: DEGESCH MAGTOXIN pellets are laid out in underground burrows

| Indicator species/Category | Time scale | ETE | TER | Annex VI Trigger |
|---|---|---|---|---|
| Tier 1 (Birds) | | | | not relevant (no exposure) |
| Higher tier refinement (Birds) | | | | not relevant (no exposure) |
| Tier 1 (Mammals) | | | | not relevant (no exposure) |
| Higher tier refinement (Mammals) | | | | not relevant (no exposure) |

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

| Group | Test substance | Time-scale (Test type) | Endpoint | Toxicity[1] (µg/L) |
|---|---|---|---|---|
| Laboratory tests ‡ | | | | |
| Fish | | | | |
| *Oncorhynchus mykiss* | $PH_3$ (tested as AlP)<br>$Mg_3P_2$ (recalculated from $PH_3$) [2] | 96 hr acute (static) | Mortality, $LC_{50}$ | 4.68 $_{nom}$<br>9.3 |
| Fish | Magnesium phosphide | Chronic | No data submitted, justification accepted | |
| Aquatic invertebrate | | | | |
| *Daphnia magna* | | chronic | No data submitted, justification accepted | |
| Sediment dwelling organisms | | | | |
| No data submitted - not relevant | | | | |
| Algae | | | | |
| Green alga | $Mg_3P_2$ | No data submitted, justification excepted | | |
| Higher plant | | | | |
| No data submitted - not relevant (no exposure expected) | | | | |
| Microcosm or mesocosm tests | | | | |
| Not performed, not relevant | | | | |

[1] Indicate whether based on nominal ($_{nom}$ = analytically confirmed) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".

**Appendix 1 – list of endpoints**

[2] Recalculated from $PH_3$ concentration by RMS with factor 1.98 (MM $PH_3$ 33.975, MM $Mg_3P_2$ 134.9).

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)**

**FOCUS Step1**

Indoor: For storage protection magnesium phosphide is exclusively used in enclosed spaces
Outdoor: DEGESCH MAGTOXIN pellets are laid out in underground burrows

| Test substance | Organism | Toxicity endpoint (mg as/L) | Time scale | $PEC_{sw}$i µg/L | $PEC_{tw}$ a | TER | Annex VI Trigger[1] |
|---|---|---|---|---|---|---|---|
| | not relevant, justification accepted (no exposure) | | | | | | 100 |

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

| **Bioconcentration** | | | |
|---|---|---|---|
| | Active substance | Metabolite $PH_3$ | Metabolite |
| log Pow | Not applicable $Mg_3P_2$ decomposes in water to $PH_3$ + $Mg(OH)_2$ | not applicable, gas | |
| Bioconcentration factor (BCF)[1] ‡ | - | | |
| Annex VI Trigger for the bioconcentration factor | 100 | | |
| Clearance time (days) ($CT_{50}$) | - | | |
| ($CT_{90}$) | - | | |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | - | | |

[1] Only required if log Pow > 3.

## Appendix 1 – list of endpoints

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

| Test substance | Acute oral toxicity ($LD_{50}$ µg/bee) | Acute contact toxicity ($LD_{50}$ µg/bee) |
|---|---|---|
| Magnesium phosphide ‡<br>Preparation[1]<br>Metabolite 1 | No studies were performed:<br>Bees will not be exposed when formulated magnesium phosphide is used in tablets or pellets for out-door control of rodent and non-rodent species in underground burrows or when it is used for indoor application. Therefore no data are required. | |
| Field or semi-field tests | | |
| not required | | |

[1] For preparations indicate whether endpoint is expressed in units of as or preparation

Hazard quotients for honey bees (Annex IIIA, point 10.4)
Crop and application rate

| Test substance | Route | Hazard quotient | Annex VI Trigger |
|---|---|---|---|
| Magnesium phosphide | Contact | - | 50 |
| Magnesium phosphide | oral | - | 50 |
| Preparation | Contact | - | 50 |
| Preparation | oral | - | 50 |

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

| Species | Test Substance | Endpoint | Effect ($LR_{50}$ g/ha[1]) |
|---|---|---|---|
| *Typhlodromus pyri* ‡ | --- | Mortality | No studies were performed:<br>Due to the special application method no undue risk to soil dwelling arthropods is expected. |
| *Aphidius rhopalosiphi* ‡ | --- | Mortality | |

[1] For preparations indicate whether endpoint is expressed in units of as or preparation

## Appendix 1 – list of endpoints

Indoor: For storage protection magnesium phosphide is exclusively used in enclosed spaces
Outdoor: DEGESCH MAGTOXIN pellets are laid out in underground burrows

| Test substance | Species | Effect (LR50 g/ha) | HQ in-field | HQ off-field | Trigger |
|---|---|---|---|---|---|
| -- see above | *Typhlodromus pyri* | -- see above | -- | -- | 2 |
| -- see above | *Aphidius rhopalosiphi* | -- see above | -- | -- | 2 |
| Test substance | Species | Effect ($LR_{50}$ g /ha) | TER off-field [1] | | Trigger |
| -- see above | | -- see above | not relevant | | 10 |

[1] TER approach used by the German Federal Environmental Agency (Schulte et al., 1999: UWSF 11(5) 261-266).
PEC off-crop = Single application rate × drift factor/VDF(5). Without VDF if product is sprayed on plants

Further laboratory and extended laboratory studies ‡

| Species | Life stage | Test substance, substrate and duration | Dose (g/ha)[1,2] | Endpoint | % adverse effect[3] | Trigger value |
|---|---|---|---|---|---|---|
| No laboratory studies were performed:<br>Due to the special application method no undue risk to soil dwelling arthropods is expected. | | | | | | 50 % |

[1] Indicate whether initial or aged residues
[2] For preparations indicate whether dose is expressed in units of as or preparation
[3] Indicate if positive percentages relate to adverse effects or not

| Field or semi-field tests |
|---|
| No field or semi-field tests were performed:<br>Due to the special application method no undue risk to soil dwelling arthropods is expected. |

## Appendix 1 – list of endpoints

**Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA, points 8.4 and 8.5, Annex IIIA, points 10.6 and 10.7)**

| Test organism | Test substance | Time scale | Endpoint[1] |
|---|---|---|---|
| Earthworms | | | |
| *Eisenia foetida* | Aluminium phosphide | Acute 14 days | $LC_{50}$ = 663.5 mg as/kg d.w.soil |
| | Aluminium phosphide | Chronic 8 weeks | Not required, no exposure |
| Other soil macro-organisms | | | |
| | Not relevant | | |
| Soil micro-organisms | | | |
| Nitrogen mineralisation | 15.9 mg Phostoxin (56 % AlP) /kg soil acccording to 3 g product per 8 m burrow length with 5 cm radial extension (333 (=220 mL) mg $PH_3$ evolution per g pellet) | 28 days | < 25 % deviation from control. |
| Carbon mineralisation | 15.9 mg Phostoxin (56 % AlP) /kg soil ) according to 3 g product per 8 m burrow length with 5 cm radial extension (333 (=220 mL) mg $PH_3$ evolution per g pellet) | 28 days | < 25 % deviation from control. |
| Field studies[2] | | | |
| not required | | | |

[1] indicate where endpoint has been corrected due to log $P_{o/w}$ > 2.0 (e.g. $LC_{50corr}$)

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

## Appendix 1 – list of endpoints

### Toxicity/exposure ratios for soil organisms

Crop and application rate
Indoor: For storage protection magnesium phosphide is exclusively used in enclosed spaces
Outdoor: DEGESCH MAGTOXIN is laid out in underground burrows

| Test organism | Test substance | Time scale | Soil PEC[1] | TER | Trigger |
|---|---|---|---|---|---|
| Earthworms (acute, chronic): Based on a $LD_{50}$ (24 d) of 389 mg $PH_3$/kg soil for earthworms and an estimated PECsoil [2] of 3.426 mg $PH_3$/kg in the burrows a corresponding TER value of 114 was estimated. | | | | | |

1 indicate which PEC soil was used (e.g. plateau PEC)
2 $PEC_{soil}$ is based on estimations using an emission scenario document for biocides

### Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

| No data submitted, justification accepted (no exposure expected) |
|---|

Laboratory dose response tests

| Most sensitive species | Test substance | $ER_{50}$ (g/ha)[2] vegetative vigour | $ER_{50}$ (g/ha)[2] emergence | Exposure[1] (g/ha)2 | TER | Trigger |
|---|---|---|---|---|---|---|
| | as ‡ and preparation | not relevant | not relevant | | | |

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of as or preparation

Additional studies (e.g. semi-field or field studies)

| Not relevant |
|---|

### Effects on biological methods for sewage treatment (Annex IIA, point 8.7)

| Test type/organism | Endpoint |
|---|---|
| No data submitted, justification accepted | (no exposure expected) |

## Appendix 1 – list of endpoints

**Ecotoxicologically relevant compounds** (consider parent and all relevant metabolites requiring further assessment from the fate section)

| Compartment | |
|---|---|
| soil | $PH_3$ |
| water | $PH_3$ |
| sediment | $PH_3$ |
| air | $PH_3$ |
| groundwater | $PH_3$ |

**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

| | RMS/peer review proposal |
|---|---|
| Active substance | N, R50<br>dangerous for the environment<br>very toxic to aquatic organisms |
| Phosphine, metabolite | N, R50<br>dangerous for the environment<br>very toxic to aquatic organisms |
| Preparation | N, R50<br>dangerous for the environment<br>very toxic to aquatic organisms |

**Appendix 2 – abbreviations**

## APPENDIX 2 – ABBREVIATIONS

| | |
|---|---|
| ADI | acceptable daily intake |
| AOEL | acceptable operator exposure level |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| a.s. | active substance |
| BCF | bioconcentration factor |
| bp | boiling point |
| bw | body weight |
| c | centi- (x $10^{-2}$) |
| °C | degree Celsius (centigrade) |
| CA | Chemical Abstract |
| CAS | Chemical Abstract Service |
| CIPAC | Collaborative International Pesticide Analytical Council Limited |
| cm | centimetre |
| d | day |
| DAR | draft assessment report |
| DM | dry matter |
| $DT_{50}$ | period required for 50 percent dissipation (define method of estimation) |
| $DT_{90}$ | period required for 90 percent dissipation (define method of estimation) |
| ε | decadic molar extinction coefficient |
| $EC_{50}$ | effective concentration |
| EDI | estimated daily intake |
| EEC | European Economic Community |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINKS | European List of New Chemical Substances |
| EMDI | estimated maximum daily intake |
| ER50 | emergence rate, median |
| EU | European Union |
| F | field |
| FAO | Food and Agriculture Organisation of the United Nations |
| FIA | fluorescence immuno assay |
| FID | flame ionisation detector |
| FIR | food intake rate |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| f(twa) | time weighted average factor |
| g | gram |

## Appendix 2 – abbreviations

| | |
|---|---|
| G | glasshouse |
| GAP | good agricultural practice |
| GC | gas chromatography |
| GC-EC | gas chromatography with electron capture detector |
| GC-FID | gas chromatography with flame ionisation detector |
| GC-MS | gas chromatography-mass spectrometry |
| GC-MSD | gas chromatography with mass-selective detection |
| GCPF | Global Crop Protection Federation (formerly known as GIFAP) |
| GE | Gas generating product |
| GL | guideline level |
| GLP | good laboratory practice |
| GS | growth stage |
| h | hour(s) |
| H | Henry's Law constant (calculated as a unitless value) (see also K) |
| ha | hectare |
| hL | hectolitre |
| HID | helium ionisation detector |
| HPLC | high pressure liquid chromatography |
| | or high performance liquid chromatography |
| I | indoor |
| $I_{50}$ | inhibitory dose, 50 % |
| $IC_{50}$ | median immobilisation concentration |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| K | Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) |
| | (see also H)13 |
| $K_{ads}$ | adsorption constant |
| $K_{des}$ | apparent desorption coefficient |
| $K_{oc}$ | organic carbon adsorption coefficient |
| $K_{om}$ | organic matter adsorption coefficient |
| kg | kilogram |
| L | litre |
| LC | liquid chromatography |
| LC-MS | liquid chromatography-mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| $LC_{50}$ | lethal concentration, median |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LOAEL | lowest observable adverse effect level |

## Appendix 2 – abbreviations

| | |
|---|---|
| LOD | limit of detection |
| LOQ | limit of quantification (determination) |
| LT | lethal threshold |
| m | metre |
| M | molar |
| MAF | multiple application factor |
| µm | micrometer (micron) |
| µg | microgram |
| mg | milligram |
| MHC | moisture holding capacity |
| min | minute(s) |
| mL | millilitre |
| mm | millimetre |
| mN | milli-Newton |
| mo | month(s) |
| mol | Mol |
| MOS | margin of safety |
| mp | melting point |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| n | normal (defining isomeric configuration) |
| nd | not detected |
| NESTI | national estimated short term intake |
| ng | nanogram |
| NIR | near-infrared-(spectroscopy) |
| nm | nanometer |
| no | number |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| NPD | nitrogen-phosphorus detector or detection |
| OC | organic carbon content |
| OM | organic matter content |
| Pa | Pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_A$ | predicted environmental concentration in air |

## Appendix 2 – abbreviations

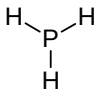
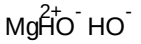
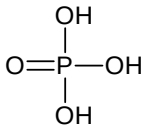
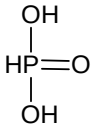
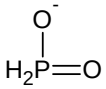
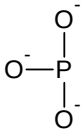
| | |
|---|---|
| $PEC_S$ | predicted environmental concentration in soil |
| $PEC_{SW}$ | predicted environmental concentration in surface water |
| $PEC_{GW}$ | predicted environmental concentration in ground water |
| pH | pH-value |
| PHI | pre-harvest interval |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| PNEC | predicted no effect concentration |
| $P_{ow}$ | partition coefficient between n-octanol and water |
| PPE | personal protective equipment |
| ppm | parts per million ($10^{-6}$) |
| ppp | plant protection product |
| PT | proportion of diet obtained in the treated area |
| $r^2$ | coefficient of determination |
| RfD | reference dose |
| RH | relative humidity |
| RPE | respiratory protective equipment |
| RUD | residue per unit dose |
| s | second |
| SD | standard deviation |
| SF | safety factor |
| SOP | standard operating procedure |
| sp | species (only after a generic name) |
| spp | subspecies |
| sq | square |
| STMR | supervised trials median residue |
| t | tonne (metric ton) |
| $t_{1/2}$ | half-life (define method of estimation) |
| TC | technical material |
| TER | toxicity exposure ratio |
| $TER_I$ | toxicity exposure ratio for initial exposure |
| $TER_{ST}$ | toxicity exposure ratio following repeated exposure |
| $TER_{LT}$ | toxicity exposure ratio following chronic exposure |
| TK | technical concentrate |
| TMDI | theoretical maximum daily intake |
| TWA | time weighted average |
| UDS | unscheduled DNA synthesis |
| UF | uncertainty factor (safety factor) |
| UV | ultraviolet |

## Appendix 2 – abbreviations

| | |
|---|---|
| WHO | World Health Organisation |
| WG | water dispersible granule |
| wk | week |
| wt | weight |
| yr | year |

**Appendix 3 – used compound code(s)**

## APPENDIX 3 – USED COMPOUND CODE(S)

| Code/Trivial name | Chemical name | Structural formula |
|---|---|---|
| Phosphine | Phosphane |  |
| - | Magnesium hydroxide |  |
| - | Phosphoric acid |  |
| - | Phosphonic acid |  |
| - | Hypophosphite |  |
| - | Phosphite |  |