

CONCLUSION ON PESTICIDE PEER REVIEW

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

Issued on 29 September 2008

SUMMARY

Calcium phosphide is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002¹. 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 calcium 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 24 September 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Chemische Fabrik Wülfel 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 a rodenticide and talpicide 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 “Polytanol”, a gas generating product (GE), containing 180 g/kg calcium phosphide. The gas phosphine that is produced is the true active ingredient.

Given the nature and notified use of the product no residues can occur in plants or products of animal origin and therefore methods of analysis are not required. Methods for phosphine in soil are not required as the DT₉₀ 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 and magnesium 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 specification of the active substance was not agreed and there is a data gap for a new specification in line with the 5 batch study. There are also some outstanding issues with an impurity method and some physchem properties.

The mammalian toxicology of calcium phosphide was assessed in a series of tests.

When coming into contact with moisture calcium phosphide decomposes to calcium hydroxide and phosphine which is the toxicologically active and relevant component for the assessment of mammalian toxicology of calcium phosphide. Calcium phosphide is classified as **R29 “Contact with water liberates toxic gas”** and **R32 “Contact with acids liberates very toxic gas”**. 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 the form of hypophosphite or phosphate. Calcium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is a skin and a strong eye irritant but not a skin sensitiser. Based on data on acute toxicity a classification as **Xi; R38 “Irritant; Irritating to skin”**, **Xi; R41 “Irritant; Risk of serious damage to eyes”**, **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 rat inhalation study. Calcium phosphide is not genotoxic. In a 2-year inhalation study with rats a NOAEL of 1.1 mg/kg bw/d was established for phosphine which was the highest dose level tested since no adverse effects were observed. 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 not anticipated, based on the toxicity profile of the substance.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.030 mg/kg bw/d. The acute reference dose (ARfD) was set at 0.051 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).

Based on an estimation of operator exposure when applying calcium phosphide in rodent burrows maximum exposure levels amounted to 63% of the AOEL for operators. For workers and bystanders, however, the actual exposure levels will be lower.

Due to its physico-chemical properties and the envisaged use, no specific studies to evaluate the metabolism and distribution in plants have been submitted. In contact with soil moisture, calcium phosphide is rapidly hydrolysed to produce phosphine (PH₃) and calcium hydroxide, this decomposition depending mainly on temperature and soil/air humidity. After application, the major part of phosphine is volatilised, diluted in air and oxidised to phosphorous oxyacids or re-adsorbed onto soil, and no significant uptake of phosphine by plant is expected. Therefore the setting of a residue definition in plants following the use of calcium phosphide as a soil fumigant to control rodent and non-rodent species was considered as not required by the meeting of experts, and no MRLs for plant and animal commodities were proposed.

When placed in animal burrows (i.e. the soil environment) calcium phosphide will rapidly hydrolyse producing phosphine gas and calcium salts. The phosphine gas produced, which was shown to exhibit very low to 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 calcium 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 use (applied directly into the burrow systems), the exposure to non-target species was considered to be only local. On the basis of the potential exposure of surface water to phosphine where the target organism burrows are adjacent to water bodies, a data gap was identified to further address the risk to aquatic organisms and therefore to provide valid studies.

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: calcium phosphide, peer review, risk assessment, pesticide, rodenticide, talpicide

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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. Calcium 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 calcium 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 24 September 2007 to the Member States and the main applicant Chemische Fabrik Wülfel 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 13 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.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Calcium phosphide is the used name for calcium phosphide (IUPAC). There is no ISO common name.

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

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

The evaluated representative uses are as a rodenticide and talpicide. 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

At the moment no minimum purity of calcium phosphide as manufactured can be given, because further clarification is needed. The meeting of experts considered that the batch data are acceptable but that they do not support the proposed specification, and a new specification has been identified as

a data gap. No FAO specification exists for this compound. The technical material contains no relevant impurities.

The content of calcium phosphide in the representative formulation is 180 g/kg (pure).

Beside the specification, 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 calcium phosphide or the respective formulation. However, the following data gaps were identified:

- Melting point
- Flammability according to methods A10 and A12
- Accuracy data for the method of analysis of one of the impurities in the technical material.

The meeting agreed that the melting point was a data gap, however this is likely to be easily addressed by the applicant due to the nature of this compound.

The main data regarding the identity of calcium 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 calcium 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.

Given the nature and notified use of the product no residues can occur in plants or products of animal origin and therefore methods of analysis are not required. Methods for phosphine in soil are not required as the DT₉₀ 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 are confirmatory methods in the aluminium and magnesium phosphide DARs. 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 acceptable method of analysis for water is GC-NPD with an LOQ of 0.1 µg/L.

2. Mammalian toxicology

Calcium phosphide was discussed at a meeting of experts in July 2008 (PRAPeR 54, round 11, subgroup 2).

Phosphides in contact with moisture readily decompose to metal hydroxides and phosphine. In 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 calcium 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

Calcium phosphide is very toxic by the oral route (based on read-across from aluminium phosphide that has a $LD_{50} = 8.7$ mg/kg bw), harmful by the dermal route (based on read-across from data obtained with aluminium phosphide where a LD_{50} between 460 and 900 mg/kg bw was obtained) and very toxic by the inhalation route (based on read across from magnesium phosphide where a $LC_{50} = 0.072$ mg/L of phosphine generated from magnesium phosphide was obtained). Neither data on skin nor on eye irritation of calcium phosphide have been provided but the experts agreed that, based on the formation of calcium hydroxide in contact with moisture, calcium phosphide had to be considered as a skin irritant and as a strong eye irritant. The experts agreed that, based on the negative results obtained in guinea pigs with zinc phosphide in a Magnusson & Kligman test, calcium phosphide should be considered as not skin sensitising.

Based on the available data on acute effects the experts agreed that a classification of calcium phosphide as **Xi; R38 “Irritant; Irritating to skin”, Xi; R41 “Irritant; Risk of serious damage to eyes”, T+; R28 “Very toxic; Very toxic if swallowed”** (also 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 calcium phosphide are not presented in the DAR. However, the experts agreed that based on the mechanism of phosphine mediated toxicity (inhibition of mitochondrial respiration) no species specific toxicity was anticipated and since the relevant route of exposure was by inhalation 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, although the human evidence presented was contradictory and inconclusive, and concluded that the overall weight of evidence suggested clearly that calcium 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

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 the DAR. From the acute study a NOAEL of 40 ppm phosphine was set based on anatomic pathology, and behavioural and neurological changes while a lower NOAEL of 21 ppm 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 the DAR. These studies have been evaluated by the experts (see section 2.4. Genotoxicity). Furthermore a row 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 for 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 calcium phosphide assuming a maximum liberation of gas of 0.37 g phosphine per g calcium phosphide.

The ADI for was set at 0.030 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 0.030 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 0.051 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 calcium phosphide are available. Considering the evaluations of dermal absorption of phosphine and metal phosphides by the WHO², and the dermal absorption value already set for aluminium phosphide under the scope of Directive 98/8/EC (biocides directive), the experts agreed to set an overall dermal absorption value of 10 % for calcium phosphide.

2.11. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The formulation **Polytanol** is manufactured in the form of granules containing 180 g/kg of calcium phosphide. Polytanol is used for the control of water voles (*Arvicola terrestris*) and moles (*Talpa europea*) for covered application outdoors and is applied at a maximum amount of 1.8 kg a.s./ha. It is usually applied once if required. Additional applications are done if necessary.

No exposure assessment for operators, workers and bystanders with calcium phosphide was presented in the original DAR. The experts requested that an assessment following essentially the assumptions used for aluminium and magnesium phosphide based on the similarities of the actives substances /formulations/uses should be provided.

For the calculations of exposure for aluminium and magnesium phosphide the experts agreed that a lower breathing rate (in the calculations in the original DAR a breathing rate of 3.6 m³/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 exposure.

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

Operator exposure

The calculated operator exposure when Polytanol is applied in rodent burrows and no PPE is used, assuming a maximum concentration of 0.1 ppm of phosphine in the air (value based on highest measured value in a field study), an inhalation absorption of 100%, a density of phosphine of 1390 g/

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

m³, a breathing rate of 1.75 m³/h, a body weight of 70 kg, and a reduced work rate of 2 hrs (in the initial DAR 8 hrs were used), amounts to 63% of the systemic AOEL (0.03 ppm phosphine). Exposure when using RPE was calculated to amount to 5.1% of the AOEL assuming a work rate of 2 hrs and a protection factor of 0.08.

Worker exposure

No individual calculations were carried out but it is assumed that unprotected re-entry workers, when present in the vicinity of the burrow both during and after treatment (considering a treatment duration of two hours) will be at a considerably greater distance to the burrow than the operator. In addition to that phosphine is rapidly degraded in the ambient air (5-28 hours half life). Thus exposure will be lower than that of operators (i.e. 63% of the AOEL).

Bystander exposure

No individual calculations were carried out but it is assumed that a bystander when present in the vicinity of the burrow both during and after treatment (considering treatment duration of two hours) will be at a considerably greater distance to the burrow than the operator. In addition to that, phosphine is rapidly degraded in the ambient air (5-28 hours half life). Thus exposure will be lower than that of operators (i.e. 63% of the AOEL).

3. Residues

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

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

Information was submitted in order to support the use of calcium phosphide as a rodenticide to control rodent and non-rodent species (voles, moles) by fumigation of underground tunnels and burrows in cropland and non-cropland situations. Due to its physico-chemical properties and the envisaged use, no specific studies to evaluate the metabolism and distribution in plants have been submitted. Some information from public literature was reported to support the fate of the active substance after soil application in underground tunnels and burrows. In contact with soil moisture, calcium phosphide is rapidly hydrolysed to produce phosphine (PH₃) and calcium hydroxide [Ca(OH)₂], this decomposition depending mainly on temperature and soil/air humidity. After application, the major part of phosphine is volatilised, diluted in air and oxidised to phosphorous oxyacids (hypophosphite, phosphite and phosphate) or re-adsorbed onto soil and no significant uptake of phosphine by plants is expected. A study performed on sugar cane using soil application of ethanolic solutions of [³²P]-PH₃ confirmed that there was almost no uptake of radioactive residues from the soil by the plant. Therefore the setting of a residue definition in plants was considered as not required by the meeting of experts.

No residue trials were submitted, considering that the direct application of calcium phosphide into underground tunnels or burrows excludes direct contact with plants and therefore, possible residues in plants. This statement was supported by information from public literature. Three days after soil application of aluminium phosphide or calcium phosphide to control voles, residues of phosphine were below 0.01 mg/kg in carrots and radish roots collected in the treated plots. Considering that no residues of concern are expected in plants and soil following the use of calcium phosphide as a soil fumigant to control rodent and non-rodent species, storage stability studies, processing studies and rotational crops studies were not provided.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Since no residues resulting of the use of calcium phosphide are expected in plants, no metabolism and feeding studies were provided and no MRLs were proposed for products of animal origin.

3.3. CONSUMER RISK ASSESSMENT

No consumer risk assessment was performed since the setting of MRLs was considered as not required for calcium phosphide following the use as soil fumigant to control rodent and non-rodent species.

3.4. PROPOSED MRLs

The setting of MRLs was considered as not required since no residues are expected in plants following the use of calcium phosphide as a soil fumigant to control rodent and non-rodent species.

4. Environmental fate and behaviour

Calcium 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 calcium phosphide will undergo relatively rapid chemical hydrolysis producing phosphine gas (the efficacious rodenticide substance, note phosphine is denser than air) and calcium salts (probably mainly calcium hydroxide). The proportion of phosphine produced that readsorbs to soil is expected to oxidise to form phosphate anions.

The applicant and Member State experts compared the quantity of phosphate anions that may originate from the use of calcium phosphide as a rodenticide with agricultural land phosphate fertiliser recommendations (see addendum 2 to the DAR dated May 2008). Phosphorous levels from

the rodenticide use gave a maximum estimate of 0.9 kg/ha (calculated by the RMS in the addendum 2 dated May 2008), fertiliser recommendations are ca. 40 kg phosphorous /ha. The Member State experts considered that the contribution from calcium 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 carried out at 20°C in three different soils, phosphine gas (generated from calcium phosphide in the test system) was estimated to have a DT₅₀ of 8 hours to 13 days.

In a field study calcium phosphide (5g in each experiment) was placed 5 or 10 cm below the soil surface and phosphine concentrations were measured from under a 'tin case' placed over the soil surface above the treated soil. Half lives of phosphine were reported to be 6 to 10 hours, with all phosphine being degraded within 2 days.

The Member State experts agreed the soil PEC in appendix 1 for phosphine as appropriate for the applied for intended use that used a biocides emission scenario³.

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 calcium phosphide and phosphine gas, leaching in soil for these two compounds can be precluded as a concern for the applied for intended uses. The transformation product of phosphate anions was considered further. The Member State comments on the DAR did not identify any concerns regarding the calcium salts that are formed. Calcium reaching groundwater or surface water would not be a concern.

As discussed in section 4.1.1 above the Member State experts considered that the contribution of phosphate from calcium 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 directive⁴ so there is no legal limit against which to assess potential groundwater contamination of phosphate.

³ 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

⁴ 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 calcium phosphide were not available but a study that measured the formation rate of phosphine gas from calcium phosphide at 20°C in air with 55% and 75% humidity indicated that 38 µg phosphine/L air.hour was produced at 55% humidity and 80µg phosphine/L air.hour at 75% humidity.

No information was available in the dossier for calcium phosphide for the hydrolysis rate of phosphine but the following information was provided in the dossier for aluminium phosphide. 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. The applicant had been asked to address this. The statement provided by the applicant in addendum 2 of May 2008 did not address the potential concern that, where treated burrows were immediately adjacent to surface water, 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 3m distance from the 4 pellets) and the Henry's law constant for phosphine of 33269 Pa m³/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 1st 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 uses of calcium phosphide need 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 on phosphine surface water concentrations: 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. 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.

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

Calcium phosphide itself has a low vapour pressure (estimated as $<1 \times 10^{-5}$ hPa at ambient temperature, value extrapolated from measurements on zinc phosphide) so is not volatile. However the phosphine produced by hydrolysis is a dense gas (vapour pressure 3.44×10^6 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 (1.6×10^{-11} cm³/mol.sec) resulted in an atmospheric half life estimated at 24 hours (assuming an atmospheric hydroxyl radical concentration of 5×10^5 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

Calcium phosphide was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 53 – sub-group 2) in July 2008 on the basis of the Draft Assessment Report (DAR) and the Addendum 2 from May 2008.

The representative use evaluated was to control common voles and moles in vegetables, fruit, ornamental plants, agricultural crops and grassland at the maximum application rate of 1.8 kg a.s./ha. The product name is “Polytanol”, a gas generating product containing 180 g/kg calcium phosphide.

Many of the studies provided with the calcium phosphide dossier were taken from literature on phosphine and metal phosphides. These data were taken into account, but not peer reviewed.

Due to the intended use (calcium phosphide is applied directly into the burrow systems) the exposure of non target species was considered to be only local; therefore, no standard risk assessment was conducted.

5.1. RISK TO TERRESTRIAL VERTEBRATES

On the basis of the literature data presented, the RMS calculated the bird toxicity end points for calcium phosphide and phosphine, by extrapolation from the zinc phosphide (Zn_3P_2 , 258.11 g/mol) endpoints. The conversion factors were 0.264 for PH_3 (33.98 g/mol) and 0.706 for Ca_3P_2 (182.15 g/mol).

The lowest calcium phosphide acute and short term values were calculated for bobwhite quail (*Colinus virginianus*); the LD_{50} was 17.7 mg/kg bw and LC_{50} was 330 mg/kg feed (equivalent to a LD_{50} of 6.6 mg/kg bw and a LC_{50} of 124 mg/kg feed for phosphine). Effects on fertilisation rate and eggs-laying rate were observed at concentrations equivalent to calcium phosphide of 2.47 and 0.49 mg/kg bw on Japanese quail (*Coturnix japonica*) (equivalent to 0.92 and 0.18 mg/kg bw for phosphine).

The acute oral LD_{50} (rat) was 72.32 mg Polytanol/kg bw and the acute inhalation LD_{50} was 0.09 mg PH_3 /L. No adverse effects were observed in long term dietary studies, while a NOAEC of 3 ppm (air) (equivalent to 1.13 mg PH_3 /kg bw/day) was observed in a 2-generation inhalation study (metabolite PH_3).

Since the exposure of birds to calcium phosphide containing granules was not expected under the recommended use, the RMS and the experts considered the available data on acute, short-term and long-term effects on birds sufficient and no further studies were required. The RMS underlined that gassing operations are normally conducted in areas where burrows can be sufficiently sealed to contain the phosphine. The calcium phosphide containing pellets are applied directly into the burrow systems, after application the hole is closed with a plug (e.g. stone or grass). The evolved phosphine gas is heavier than air and will mainly remain and spread in the burrows. In the unlikely case that gas is escaping from the burrows via uncovered holes, phosphine will remain close to the ground. Therefore, a risk assessment for birds was not needed.

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 predator birds and mammals had been asked to the applicant and it was presented by the RMS in addendum 2 (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 phosphate. These phosphine metabolites were less toxic than phosphine itself. Moreover, intoxicated target animals do not escape from the treated burrows. The Member State experts agreed that it was reasonable to assume that no bioaccumulation in the food chain was expected.

Overall, the experts concluded that the risk for terrestrial vertebrates from the proposed use of calcium phosphide was low. However, it was recommended to include in the label a sentence to make sure that burrows are closed and that no granules remain on the surface.

5.2. RISK TO AQUATIC ORGANISMS

No studies on aquatic organisms were performed with calcium phosphide. On the basis of the available data on other phosphides, calcium phosphide was classified as R50 “Very toxic to aquatic organisms”, N “Dangerous for the environment”.

According to these data the phosphide compounds were expected to be highly toxic to aquatic organisms. The lowest 96-h EC_{50} value for fish reported in the DAR was 9.7×10^{-3} mg/L (aluminium phosphide, rainbow trout) equivalent to 5.6 µg/L (phosphine). The 24-h EC_{50} value for *Daphnia magna* was 0.2 µg/L (aluminium phosphide) equivalent to 0.117 µg/L (phosphine).

The fate expert meeting agreed that the potential exposure of surface water by phosphine should be further addressed. In a very worst case calculation a phosphine concentration of 25 µg/L was estimated by the fate experts (see point 4.2.1) for the situation when an entrance to treated target organism burrow is 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 to aquatic organisms and consequently to provide valid studies.

5.3. RISK TO BEES

No studies on bees were performed with calcium phosphide. Under the recommended use, exposure was not expected, therefore no data were required.

5.4. RISK TO OTHER ARTHROPOD SPECIES

No studies on non target arthropods were performed with calcium phosphide.

The Member State experts discussed the potential exposure of soil dwelling non-target organisms and whether local effects were of risk to the population. According to the proposed use, relevant exposure of arthropods outside the burrows was not expected. Even when some single individuals would be killed inside or in direct contact with the burrows, eggs and pupae would survive at the low dosages used in the field. Experts concluded that a low risk to the in-field arthropod population was expected from the proposed use of calcium phosphide.

5.5. RISK TO EARTHWORMS

No studies on earthworms were performed with calcium phosphide.

An acute toxicity test with the formulated product (Polytanol) was provided. No mortality was observed at the tested concentration of 100 and 400 mg/kg during the 14-day test duration.

As no relevant exposure to earthworms was expected, a low risk was expected.

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

No studies on other soil non-target macro-organisms were performed with calcium phosphide. Under the recommended use, exposure was not expected, therefore no data were required.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

A study on dehydrogenase activity and nitrogen turnover was provided with calcium phosphide technical. However the validity of the test was peer reviewed and considered not acceptable (the moisture level during the test was low, affecting the results on dehydrogenase activity). As the risk was expected as low no further information was required.

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

Under the recommended use, relevant exposure of non-target organisms (flora and fauna), including those organisms that co-inhabit the tunnel systems, was not expected and therefore a low risk was expected.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The applicant has provided two literature studies aimed at evaluating the spontaneous emission of phosphine from animal slurry treatment processing and free phosphine from the anaerobic biosphere. These studies were considered not appropriate to address the risk to microorganisms in waste water treatment plants. In a third study the effects on biological effluent treatment were tested, but the study was considered not valid.

However, relevant exposure of biological waste water treatment organisms was not 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: not required

Definition for monitoring: not required

Food of animal origin

Definition for risk assessment: not required

Definition for monitoring: not required

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 to low persistence: DT ₅₀ 8 hours to 13 days at 20°C when being consecutively generated from calcium phosphide | 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 | Calcium phosphide is very toxic by inhalation (based on read across from magnesium phosphide where a $LC_{50} = 0.072$ mg phosphine /L air was achieved). Calcium phosphide is classified as T+; R26 “Very toxic; Very toxic by inhalation” |

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

- New specification in line with the supplied batch data (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- Melting point (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- Flammability in accordance with EEC A10 and A12 (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1)
- Accuracy data for the method of analysis of one of the impurities in the technical material (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)
- The potential for exposure of surface water by phosphine moving in the gas phase from the requested uses of calcium phosphide has yet to be adequately addressed (relevant for all the 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 all the 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 all the 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 a rodenticide and talpicide. Full details of the GAP can be found in the attached list of endpoints.

The representative formulated product for the evaluation was “Polytanol”, a gas generating product (GE) containing 180 g/kg calcium phosphide. The gas phosphine that is produced is the true active substance.

Given the nature and notified use of the product no residues can occur in plants or products of animal origin and therefore methods of analysis are not required. Methods for phosphine in soil are not required as the DT₉₀ 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 and magnesium 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 specification of the active substance was not agreed and there is a data gap for a new specification in line with the 5 batch study. There are also some outstanding issues with an impurity method and some physchem properties.

The mammalian toxicology of calcium phosphide was assessed in a series of tests.

When coming into contact with moisture calcium phosphide decomposes to calcium hydroxide and phosphine which is the toxicologically active and relevant component for the assessment of mammalian toxicology of calcium phosphide. Calcium phosphide is classified as **R29 “Contact with water liberates toxic gas”** and **R32 “Contact with acids liberates very toxic gas”**. 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 phosphate. Calcium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is a skin and a strong eye irritant but not a skin sensitizer. Based on data on acute toxicity a classification as **Xi; R38 “Irritant; Irritating to skin”, Xi; R41 “Irritant; Risk of serious damage to eyes”, 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 rat inhalation study. Calcium phosphide is not genotoxic. In a 2-year inhalation study with rats a NOAEL of 1.1 mg/kg bw/d was established for phosphine which was the highest dose level tested since no adverse effects were observed. 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 not anticipated, based on the toxicity profile of the substance.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.030 mg/kg bw/d. The acute reference dose (ARfD) was set at 0.051 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).

Based on an estimation of operator exposure when applying calcium phosphide in rodent burrows maximum exposure levels amounted 63% of the AOEL for operators. For workers and bystanders, however, the actual exposure levels will be lower.

Due to its physico-chemical properties and the envisaged use, no specific studies to evaluate the metabolism and distribution in plants have been submitted. In contact with soil moisture, calcium phosphide is rapidly hydrolysed to produce phosphine (PH₃) and calcium hydroxide, this decomposition depending mainly on temperature and soil/air humidity. After application, the major part of phosphine is volatilised, diluted in air and oxidised to phosphorous oxyacids or re-adsorbed onto soil, and no significant uptake of phosphine by plant is expected. Therefore the setting of a residue definition in plants following the use of calcium phosphide as soil fumigant to control rodent and non-rodent species was considered as not required by the meeting of experts, and no MRLs for plant and animal commodities were proposed.

The Member State experts concluded that in relation to the applied for intended uses, the information available on the fate and behaviour of calcium phosphide, phosphine gas, phosphate and calcium salts in the environment was sufficient to complete an adequate environmental exposure characterisation with one exception. This exception was that where animal 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 calcium 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 legislation⁵ for calcium salts and phosphate.

Due to the representative use (applied directly into the burrow systems), the exposure of non-target species to calcium phosphide was considered to be only local. On the basis of the potential exposure of surface water to phosphine (data gap from the fate meeting) where target organism burrows are adjacent to water bodies, the risk to aquatic organisms needs to be addressed (data gap) and therefore valid studies 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 and workers the use of respiratory protective equipment is necessary.

⁵ Council Directive 98/83/EC on the quality of water intended for human consumption

- 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 specification is not finalised.

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, classification and labelling

| | |
|--------------------------------------|---|
| Active substance (ISO Common Name) ‡ | Calcium phosphide (there is no ISO common name) |
| Function (e.g. fungicide) | Rodenticide, talpicide |

| | |
|-------------------------|-----------------------------|
| Rapporteur Member State | Federal Republic of Germany |
|-------------------------|-----------------------------|

Identity (Annex IIA, point 1)

| | |
|--|--------------------------------|
| Chemical name (IUPAC) ‡ | Calcium phosphide |
| Chemical name (CA) ‡ | Calcium phosphide |
| CIPAC No ‡ | 505 |
| CAS No ‡ | 1305-99-3 |
| EEC No (EINECS or ELINCS) ‡ | 215-142-0 |
| FAO Specification (including year of publication)‡ | none |
| Minimum purity of the active substance as manufactured (g/kg) ‡ | open |
| Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg) | none |
| Molecular formula ‡ | Ca ₃ P ₂ |
| Molecular mass ‡ | 182.19 g/mol |
| Structural formula ‡ | Ca ₃ P ₂ |

Appendix 1 – list of endpoints

Physical-chemical properties (Annex IIA, point 2)

| | |
|--|---|
| Melting point (state purity) ‡ | Open |
| Boiling point (state purity) ‡ | Not applicable |
| Temperature of decomposition | >360 °C |
| Appearance (state purity) ‡ | Solid granules, dark grey with redbrown areas, garlic odour (28 %) |
| Vapour pressure (in Pa, state temperature) ‡ | < 1.0*10 ⁻⁵ hPa [PH ₃ : 3.44 x 10 ⁶ Pa (20 °C); 3.90 x 10 ⁶ Pa (25 °C)] ⁶ |
| Henry's law constant (Pa m ³ mol ⁻¹) ‡ | Not applicable |
| Solubility in water (g/L or mg/L, state temperature) ‡ | Not applicable |
| | |
| Solubility in organic solvents (in g/L or mg/L, state temperature) ‡ | Not applicable |
| | |
| | |
| Surface tension | Not applicable |
| Partition co-efficient (log P _{OW}) (state pH and temperature) ‡ | Not applicable |
| | |
| | |
| Dissociation constant ‡ | Not applicable |
| UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡ | Not applicable |
| Flammability ‡ | Open However, the ECB has classified calcium phosphide as F (highly flammable) |
| Explosive properties ‡ | no explosive properties (expert statement) |
| Oxidising properties ‡ | no oxidising properties (expert statement) |

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

Appendix 1 – list of endpoints

Summary of representative uses evaluated (Calcium phosphide)*

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks: (m) |
|------------------------------|-------------------------|--------------|-----------------|---|---------------|--------------------|---|------------------------------|-----------------------|-------------------------------------|--------------------------------|-----------------------|---|-------------------|-----------------|
| | | | | | 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 | | |
| Vegetables | Germany | Polytanol | F | <i>Arvicola terrestris</i> | GE | 180 g/kg | Covered application with ancillary tools (e.g. drop gun, drop tube) | All stages | If required | without waiting-time | Not applicable | Not applicable | 1.44 kg as/ha (min. 8 kg product/ha) | Not required | [1] |
| Fruit | (Northern europe) | | | <i>Talpa europaea</i> | | | | | | | | | 1.8 kg as/ha (max. 10 kg product/ha) | | |
| Ornamental Plants | | | | | | | | | | | | | | | |
| Agricultural Crops | | | | | | | | | | | | | | | |
| Grassland | | | | | | | | | | | | | | | |

[1] No agreed specification

- 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

* Uses for which the risk assessment can not be concluded are marked grey.

Appendix 1 – list of endpoints

Methods of analysis

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

| | |
|--|---------------------------------------|
| Technical as (principle of method) | volumetry, IR, GC-MS, titration |
| Impurities in technical as (principle of method) | AAS, photometry, ICP-AES, calculation |
| Plant protection product (principle of method) | volumetry, IR, GC-MS, titration |

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

| | |
|-----------------------|---|
| Food of plant origin | Outdoor use: not relevant, no MRL, no residue definition for monitoring |
| Food of animal origin | Not relevant, no MRL, no residue definition for monitoring |
| Soil | Not relevant, DT ₉₀ < 3 days |
| Water surface | Phosphine |
| drinking/ground | None |
| Air | Phosphine |

Monitoring/Enforcement methods

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Not relevant, no MRL, no residue definition for monitoring |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | not required, since no MRL is proposed |
| Soil (analytical technique and LOQ) | Not relevant |
| Water (analytical technique and LOQ) | GC-NPD 0.1 µg/L (surface water) Open for confirmatory method |
| 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 (toxicokinetics) (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 ‡ | 8.7 mg/kg bw (Aluminium 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 ‡ | no information, based on calcium hydroxide there is skin irritation potential | Xi; R38 |
| Eye irritation ‡ | no information, based on calcium hydroxide there is eye irritation potential | Xi; R41 |
| Skin sensitisation ‡ | No indication of skin sensitisation (Buehler-test, 3 inductions using a product containing 56 % w/w aluminium phosphide and 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 |

Appendix 1 – list of endpoints

| | | |
|-----------------------------|---|--|
| Relevant dermal NOAEL ‡ | No data, no study required | |
| 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 phosphine equivalent to 1.1 mg/kg bw/d (rat 2-yr inhalation) | |
| Carcinogenicity ‡ | Not carcinogenic in the rat Data on mice not required, not necessary | |

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) 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) 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)

| | |
|--|--|
| Study on Heinz body formation | Phosphine induced Heinz bodies in human erythrocytes. |
| Influence on respiration and oxidative phosphorylation | The respiration of liver mitochondria is diminished by phosphine. The oxidative phosphorylation remains at normal level. |

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.

Summary (Annex IIA, point 5.10)

| Calcium phosphide | Value | Study | Safety factor |
|-------------------|-------------------|---------------------------------------|---------------|
| ADI ‡ | 0.030 mg/kg bw/d* | 2-yr inhalation, rat | 100 |
| AOEL systemic ‡ | 0.030 mg/kg bw/d* | 90-d inhalation, rat | 100 |
| ARfD ‡ | 0.051 mg/kg bw* | Developmental study (inhalation), rat | 100 |

Appendix 1 – list of endpoints

Phosphine

| | | | |
|-----------------|--|---|-----|
| ADI | 0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d | 2-yr inhalation, rat | 100 |
| AOEL systemic ‡ | 0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d | 90-d inhalation, rat | 100 |
| ARfD | 0.049 ppm or 0.069 µg/L air or 0.019 mg/kg bw | Developmental study (inhalation), rat | 100 |

* Based on a maximum liberation of gas of 0.37 g PH₃/g calcium phosphide

Dermal absorption ‡ (Annex IIIA, point 7.3)

Default value 10 % for calcium phosphide and PH₃
(based on expert judgement)

Acceptable exposure scenarios (including method of calculation)

| | |
|------------|---|
| Operator | Intended use for the control of rodents in burrows with an enclosed applicator: acceptable without the use of further personal protective equipment (max. 63 % of systemic AOEL). Nevertheless, since temporary exposure concentrations exceeding the AOEL cannot be excluded, PPE/RPE should be recommended. |
| Workers | Acceptable (significantly lower in comparison with operator exposure) |
| Bystanders | An exposure assessment for bystanders has not been provided. |

Appendix 1 – list of endpoints

Classification and proposed labelling (Annex IIA, point 10)

Calcium phosphide

T+; R 15/29-28- (29th ATP)
 Additionally proposed by PRAPeR: Xn; R 21, T+;
 R26, Xi; R38, R41, R32
**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 | not required |
| Rotational crops | not required |
| Metabolism in rotational crops similar to metabolism in primary crops? | not required |
| Processed commodities | not required |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | not required |
| Plant residue definition for monitoring | not required |
| Plant residue definition for risk assessment | not required |
| Conversion factor (monitoring to risk assessment) | not required |

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

| | |
|---|--------------|
| Animals covered | not required |
| Time needed to reach a plateau concentration in milk and eggs | not required |
| Animal residue definition for monitoring | not required |
| Animal residue definition for risk assessment | not required |
| Conversion factor (monitoring to risk assessment) | not required |
| Metabolism in rat and ruminant similar (yes/no) | not required |
| Fat soluble residue: (yes/no) | not required |

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

not required

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

not required

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 | | | |
| 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 required | | | |
| 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 feeding stuffs (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 (a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR (c) | STMR (b) |
|--------------|---|---|-------------------------|---|-----------|-------------|
| not required | | | | | | |

- (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 | 0.030 mg/kg bw/d (calcium phosphide) |
| TMDI (% ADI) according to WHO European diet | not required |
| TMDI (% ADI) according to national (to be specified) diets | not required |
| IEDI (WHO European Diet) (% ADI) | not required |
| NEDI (specify diet) (% ADI) | not required |
| Factors included in IEDI and NEDI | not required |
| ARfD | 0.051 mg/kg bw (calcium phosphide) |
| IESTI (% ARfD) | not required |
| NESTI (% ARfD) according to national (to be specified) large portion consumption data | not required |
| 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 | | | | |

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

| | |
|--------------|--|
| not required | |
| | |

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 calcium phosphide in soil do not exist. Calcium phosphide is an inorganic compound, and is not biologically metabolised as such. Chemical hydrolysis, which occurs very rapidly and leads to evolution of phosphine and residual calcium salts, would be expected to be the predominant mechanism for loss of calcium phosphide when placed in the soil environment. Phosphine is expected to either partition to the atmosphere due to its 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 ‡ | 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 so light will be excluded. |

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

Laboratory studies ‡

| | |
|--------|---|
| Parent | Aerobic conditions: no studies submitted* |
|--------|---|

* Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of calcium phosphide in soil do not exist. Calcium phosphide is an inorganic compound, and is therefore not biologically metabolised as such. Chemical hydrolysis, which occurs very rapidly and leads to evolution of phosphine and residual calcium salts, would be expected to be the predominant mechanism for loss of calcium phosphide when placed in the soil environment. According to laboratory studies analysing the degradation of phosphine maximum PH_3 concentrations in soil occurred 2 h after application of calcium phosphide.

Appendix 1 – list of endpoints

Laboratory studies ‡

| | |
|--------------------------------|---|
| Ca ₃ P ₂ | <p>Aerobic conditions</p> <p>Calcium phosphide is degraded in soil to yield phosphine gas as an intermediate, and Calcium 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.</p> <p>According to laboratory studies performed in 3 soils (dosed with calcium phosphide) the DT₅₀ of PH₃ in the gas phase was found to be 2-13 d (low humus content), 8h (high humus content).</p> |
| Ca ₃ P ₂ | <p>Anaerobic conditions</p> <p>no data available</p> |

Field studies ‡

| | |
|--------|-----------------------------------|
| Parent | Aerobic conditions: not relevant* |
|--------|-----------------------------------|

*Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of calcium phosphide in soil do not exist.

| | | | | | | | | |
|--|--------------------|----------------|----|------------|----------------------|----------------------|-----------------------|-----------------------|
| Metabolite PH ₃ | Aerobic conditions | | | | | | | |
| Soil type | Location | X ¹ | pH | Depth (cm) | DT ₅₀ (d) | DT ₉₀ (d) | St. (r ²) | Method of calculation |
| DT ₅₀ * (only 1 trial site) | | | | | 6 – 10 h | < 2 d | | |

* 10 cm layer

Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of calcium phosphide in soil do not exist. Therefore, a field study was performed analysing the diffusion of PH₃ in soil. The results show that PH₃ is degraded in the gas phase very fast. However, it is always abiotic degradation

pH dependence ‡
(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 calcium phosphide is not considered to be required for the following reasons: The preparation of a solution in water for the

Appendix 1 – list of endpoints

subsequent adsorption/desorption experiments is not possible. As a result, this renders the performance of such studies as technically and scientifically unfeasible.

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

Column leaching ‡

For this type of application and this type of pesticide no guideline exists, that can be followed.*

Lysimeter/ field leaching studies ‡

No lysimeter studies performed

* A study has been submitted demonstrating that the horizontal and vertical spreads are about 30 cm and 25 cm, respectively. However, these results can be used orienting only.

PEC (soil) (Annex IIIA, point 9.1.3)

The standard scenarios are not feasible for these type of applications. However, an emission scenario document for biocides used as rodenticides can be used to estimate a PEC_{soil} for the metabolite PH_3 .

Based on this scenario and assuming 5 kg and 10 kg dose of the product per ha initial concentrations of 3.457 to 6.914 mg/kg can be estimated for the metabolite PH_3 in the soil surrounding the burrows. In case of two applications within 2 - 4 days as worst case assumption the PEC_{soil} value can be duplicated.

| | |
|--|--|
| PEC soil | |
| PECsoil-calculation according to Emission Scenario Documents PT14 for Biocides used as Rodenticides ⁷ | |
| Input | |
| Amount of product used in control campaign per treated area | $Q_{prod} := 2000 \text{ g} (= 8 \text{ g Polytanol per } 8 \text{ m length of hole})$ |
| Fraction of active substance in product | $F_{ai} := 0.18$ |
| Number of applications | $N_{app} := 1$ |
| Fraction of product released to soil | $F_{release \text{ soil}} := 0.99$ |
| Fraction of phosphine formed out of rodenticide | $F_{formed} := 0.373$ |
| Output | |
| $E_{local \text{ soil campaign}} = 132.937 \text{ g}$ | |
| Radius of exposed soil around the hole | $Radius_{soil} := 0.14 \text{ m}$ |
| Radius of hole | $Radius_{hole} := 0.04 \text{ m}$ |
| Length of exposed hole | $Length := 2000 \text{ m}$ |
| $V_{soil \text{ exposed}}$ | 113.097 m^3 |
| Density of wet exposed soil | $RHO_{soil} := 1700 \text{ kg m}^{-3}$ |
| PECsoil PH_3 | 0.691 mg kg^{-1} |

⁷ Supplement to the methodology for risk evaluation of biocides; Emission scenario document for biocides used as rodenticides; May 2003; Danish EPA; J. Larsen; CA-Jun03-Doc.8.2-PT14

Appendix 1 – list of endpoints

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

| | |
|---|--|
| Hydrolytic degradation of the active substance and metabolites > 10 % ‡ | Active substance: Too rapid to estimate ⁸ 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 $\lambda > 290$ nm | Not relevant |
| Readily biodegradable ‡ (yes/no) | Not relevant |
| Studies on hydrolytic degradation cannot be performed because calcium phosphide will instantly form PH ₃ . | |
| Degradation in water / sediment: | Not relevant |
| Mineralisation and non extractable residues: | Not relevant |

⁸ These endpoints originate from the dossier / DAR for aluminium phosphide and are not included in the DAR for calcium phosphide.

Appendix 1 – list of endpoints

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

The calculation of predicted environmental concentrations in surface waters (PEC_{sw}) for calcium 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 calcium 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 and consequently in sediments for calcium phosphide is excluded by the specific conditions of use. 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.

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

It is concluded that there is no risk of contamination of ground water by calcium 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).

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 applicable

Photochemical oxidative degradation in air ‡

not applicable

Volatilisation ‡

not relevant (vapour pressure $\ll 10^{-5}$ hPa)

Metabolites

PH_3 (gas, vapour pressure 3.44×10^6 Pa, 20 °C):
DT₅₀ of 24 hours. OH (24 h) concentration assumed = 5×10^5 OH/cm³ (rate constant 1.6×10^{-11} cm³/mol sec)

Appendix 1 – list of endpoints

PEC_{air}

PEC_(air)

Maximum concentration

Due to the high vapour pressure of PH₃ discharge into the air caused by aeration after application is possible. However, PH₃ degrades rapidly in the upper atmosphere (DT₅₀ 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: PH₃
Surface Water: PH₃
Sediment: PH₃
Ground water: PH₃
Air: PH₃

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

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

No labelling

Appendix 1 – list of endpoints

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 ‡ | | | | |
| <i>Colinus virginianus</i> | (Literature summary) Zinc phosphide Phosphine (calculated) Ca ₃ P ₂ (calculated) | Acute | LD ₅₀ 25-35 LD ₅₀ 6.6-9.2 LD ₅₀ 17.7-24.7 | Not relevant |
| <i>Colinus virginianus</i> | Zinc phosphide Phosphine (calculated) Ca ₃ P ₂ (calculated) | Short-term | | LC ₅₀ 469 LC ₅₀ 124 LC ₅₀ 330 |
| <i>Anas platyrhynchos</i> | Zinc phosphide Phosphine (calculated) Ca ₃ P ₂ (calculated) | Short-term | | LC ₅₀ 2885 LC ₅₀ 762 LC ₅₀ 2037 |
| <i>Coturnix japonica</i> | (Literature summary) Zinc phosphide 1/10 and 1/50 of LD ₅₀ of 35 mg/kg bw Ca ₃ P ₂ (calculated) | Long-term | Effects on fertilisation rate and egg-laying rate: 3.5 and 0.7 Zn ₃ P ₂ 2.47 and 0.49 Ca ₃ P ₂ | |
| Mammals ‡ | | | | |
| Rat | Product Polytanol (17.6 % as) | Acute, oral | LD ₅₀ 72.32 Polytanol | Not relevant |
| Rat | Product Polytanol (17.6 % as) | Acute, inhalation 4 hours | LD ₅₀ 0.090 mg PH ₃ /L | Not relevant |
| Rat | Metabolite PH ₃ | Acute, inhalation 4 hours | LD ₅₀ 0.015 mg/L air / 11 ppm 2.8 mg PH ₃ /kg bw | Not relevant |

Appendix 1 – list of endpoints

| Species | Test substance | Time scale | Endpoint (mg/kg bw/d) | Endpoint (mg/kg feed) |
|--|---|--|--|--|
| Rat | Metabolite PH ₃ generated from Aluminium phosphide | Long-term 2 years dietary study | | No adverse effects at average residual phosphine levels of 5 ppb in diet (2000 ppm PH ₃ during fumigation) |
| Rat | Metabolite PH ₃ | Long-term, 2-generation inhalation study: | NOAEC 3 ppm (air) (1.13 mg/kg bw/day) | |
| Additional higher tier studies ‡ No data submitted – justification accepted. Not relevant | | | | |

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

Not relevant. Exposure not expected from the intended use.

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 | | | | |
| No tests performed, not required. Justification accepted | | | | |
| <i>Lepomis macrochirus</i> Literature data, summary | Phosphine | 96 hr (static) not validated | Mortality, LC ₅₀ | 0.105 ¹⁾ |
| <i>Oncorhynchus mykiss</i> Literature data | Phosphine | 96 hr (static) not validated | Mortality, LC ₅₀ | 5.6 ¹⁾ |

Appendix 1 – list of endpoints

| Group | Test substance | Time-scale (Test type) | Endpoint | Toxicity ¹ (µg/L) |
|--|--|---------------------------------|----------------------------------|---|
| <i>Oncorhynchus mykiss</i> | PH ₃ (tested as Aluminium phosphide) Ca ₃ P ₂ (recalculated from PH ₃) | 96 hr acute (static) | Mortality, LC ₅₀ | 4.68 _{nom} 12.5 ²⁾ |
| Not performed, not required Justification accepted | | Long-term | | |
| Aquatic invertebrate | | | | |
| Not performed, not required. Justification accepted | | | | |
| <i>Daphnia magna</i> Literature data | Phosphine | 24 hr (static) not validated | Immobilisation, EC ₅₀ | 0.117 ¹⁾ |
| Sediment dwelling organisms | | | | |
| Not performed, not required Justification accepted | | | | |
| Algae | | | | |
| No tests performed, not required. Justification accepted | | | | |
| Higher plant | | | | |
| Not performed, not relevant | | | | |
| Microcosm or mesocosm tests | | | | |
| Not performed, not relevant | | | | |

¹⁾ calculated from values given for Aluminium phosphide with conversion factor 0.597

²⁾ calculation based on conversion factor of 2.68

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

Data gap (in case target organism burrows are adjacent to surface water). Risk assessment to be finalised when PEC_{sw} are available.

Appendix 1 – list of endpoints

| Bioconcentration | | | | |
|---|--|----------------------------------|--------------|--------------|
| | Active substance | Metabolite Phosphine | Metabolite 2 | Metabolite 3 |
| Log Pow | Determination not possible due to fast hydrolysis. | 0.9 (estimated using Zn_3P_2) | - | - |
| Bioconcentration factor (BCF) ¹ ‡ | Not relevant | | | |
| Annex VI Trigger for the bioconcentration factor | 100 | 100 | | |
| Clearance time (days) (CT ₅₀) | Not relevant | | | |
| (CT ₉₀) | Not relevant | | | |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | Not relevant | | | |

¹ only required if log Pow > 3.

‡ based on total ¹⁴C or on specific compounds

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) |
|---------------------------|---|--|
| calcium phosphide ‡ | No studies were performed: Bees will not be exposed when calcium-phosphide is used in the field for control of <i>Arvicola terrestris</i> and <i>Talpa europaea</i> . Therefore no data are required. | |
| Preparation ¹ | | |
| Metabolite 1 | | |
| Field or semi-field tests | | |
| not required | | |

¹ for preparations indicate whether end point is expressed in units of as or preparation

Appendix 1 – list of endpoints

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Crop and application rate

| Test substance | Route | Hazard quotient | Annex VI Trigger |
|-------------------|---------|-----------------|------------------|
| calcium phosphide | Contact | - | 50 |
| calcium 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 (LR50 g/ha ¹) |
|--------------------------------|----------------|-----------|--|
| <i>Typhlodromus pyri</i> ‡ | --- | Mortality | No studies were performed: Out-door application: fumigated area is very small compared to the whole field; diffusion rate into soil is small and half-life is very short. |
| <i>Aphidius rhopalosiphi</i> ‡ | --- | Mortality | |

¹ for preparations indicate whether endpoint is expressed in units of as or preparation

Calcium phosphide is a rodenticide which is laid out only on discrete sites in tunnels, and is not a subject to broadcast or widespread application to soil

| Test substance | Species | Effect (LR ₅₀ g/ha) | HQ in-field | HQ off-field ¹ | Trigger |
|----------------|------------------------------|--------------------------------|-------------|---------------------------|---------|
| -- see above | <i>Typhlodromus pyri</i> | -- see above | -- | -- | 2 |
| -- see above | <i>Aphidius rhopalosiphi</i> | -- see above | -- | -- | 2 |

¹ indicate distance assumed to calculate the drift rate

| Test substance | Species | Effect (LR ₅₀ g/ha) | TER off-field ¹ | Trigger value |
|----------------|---------|--------------------------------|----------------------------|---------------|
| -- 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

Appendix 1 – list of endpoints

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: Fumigated area is very small compared to a whole field; diffusion rate into soil is small and half-life is very short. | | | | | | 50 % |

¹ indicate whether initial or aged residues

² for preparations indicate whether dose is expressed in units of as or preparation

³ indicate when the effect is not adverse

| |
|--|
| Field or semi-field tests |
| No field or semi-field tests were performed: Fumigated area is very small compared to a whole field; diffusion rate into soil is small and half-life is very short (PH ₃ : 6-10 hours = DT _{50 field} for decomposition in soil). |

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 |
|---|-------------------------------|------------|---|
| Earthworms | | | |
| <i>Eisenia foetida</i> | Polytanol (28 % Ca-phosphide) | 14 days | LC ₅₀ > 400 mg product/kg dry weight |
| Due to the special application method and the results of a degradation study in soil (see Annex IIA point 7.1.1.1.1/01) earthworms are not considered to be adversely effected by the use of calcium phosphide as a rodenticide | | | |
| Other soil macro-organisms | | | |
| | | | |
| Soil micro-organisms | | | |
| Field studies | | | |
| not required | | | |

Toxicity/exposure ratios for soil organisms

Crop and application rate

Polytanol is laid out as granule in underground burrows

| Test organism | Test substance | Time scale | Soil PEC ¹ | TER | Trigger |
|-----------------------------|---|------------|-----------------------|-----|---------|
| Earthworms (acute, chronic) | not relevant, justification accepted (no relevant exposure) | | | | |

Appendix 1 – list of endpoints

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) |

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 |

Appendix 1 – list of endpoints

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

| | |
|-----------------------|--|
| Active substance | According to Annex I to Directive 67/548/EEC |
| | N, R ₅₀ Dangerous for the environment Very toxic to aquatic organisms |
| Phosphine, metabolite | N, R ₅₀ Dangerous for the environment Very toxic to aquatic organisms |
| | |
| Product | RMS/peer review proposal in compliance with Directive 1999/45/EC |
| | N, R ₅₀ Dangerous to the environment Very toxic to aquatic organisms |

Appendix 2 – abbreviations

APPENDIX 2 – ABBREVIATIONS

| | |
|------------------|--|
| ADI | acceptable daily intake |
| AOEL | acceptable operator exposure level |
| approx | approximate |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| a.s. | active substance |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| bp | boiling point |
| bw | body weight |
| c | centi- ($\times 10^{-2}$) |
| °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 |
| dna | designated national authority |
| DO | dissolved oxygen |
| DOC | dissolved organic carbon |
| DT ₅₀ | period required for 50 percent dissipation (define method of estimation) |
| DT ₉₀ | period required for 90 percent dissipation (define method of estimation) |
| dw | dry weight |
| 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 |
| ELISA | enzyme linked immunosorbent assay |
| EMDI | estimated maximum daily intake |
| ER50 | emergence rate, median |
| EU | European Union |
| FAO | Food and Agriculture Organisation of the United Nations |

Appendix 2 – abbreviations

| | |
|------------------|--|
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| fp | freezing point |
| f(twa) | time weighted average factor |
| g | gram |
| GAP | good agricultural practice |
| GC | gas chromatography |
| GE | Gas generating product |
| GLP | good laboratory practice |
| GM | geometric mean |
| GS | growth stage |
| h | hour(s) |
| H | Henry's Law constant (calculated as a unitless value) (see also K) |
| ha | hectare |
| HDT | highest dose tested |
| hL | hectolitre |
| HPLC | high pressure liquid chromatography or high performance liquid chromatography |
| IEDI | international estimated daily intake |
| IGR | insect growth regulator |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| inh | inhalation |
| k | kilo |
| K | Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) ¹³ |
| K _{ads} | adsorption constant |
| 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 |
| LDLo | lethal dose low |
| LOAEC | lowest observable adverse effect concentration |
| LOAEL | lowest observable adverse effect level |

Appendix 2 – abbreviations

| | |
|-------|--|
| LOD | limit of detection |
| LOEC | lowest observable effect concentration |
| LOEL | lowest observable effect level |
| LOQ | limit of quantification (determination) |
| LPLC | low pressure liquid chromatography |
| LT | lethal threshold |
| m | metre |
| M | molar |
| MAF | multiple application factor |
| µm | micrometer (micron) |
| MC | moisture content |
| 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 |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| n | normal (defining isomeric configuration) |
| NAEL | no adverse effect level |
| nd | not detected |
| NEDI | no effect daily intake (mg/kg body wt/day) |
| NESTI | national estimated short term intake |
| ng | nanogram |
| NIR | near-infrared-(spectroscopy) |
| nm | nanometer |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOED | no observed effect dose |
| NOEL | no observed effect level |
| NPD | nitrogen-phosphorus detector or detection |

Appendix 2 – abbreviations

| | |
|-------------------|--|
| 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 |
| PEC _S | predicted environmental concentration in soil |
| PEC _{SW} | predicted environmental concentration in surface water |
| PEC _{GW} | predicted environmental concentration in ground water |
| PED | plasma-emissions-detector |
| pH | pH-value |
| PHED | pesticide handler's exposure data |
| PHI | pre-harvest interval |
| pK _a | negative logarithm (to the base 10) of the dissociation constant |
| PNEC | predicted no effect concentration |
| ppb | parts per billion (10 ⁻⁹) |
| 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 |
| RH | relative humidity |
| RPE | respiratory protective equipment |
| RUD | residue per unit dose |
| s | second |
| SF | safety factor |
| sp | species (only after a generic name) |
| spp | subspecies |
| sq | square |
| STMR | supervised trials median residue |
| t _{1/2} | half-life (define method of estimation) |
| TC | technical material |
| TER | toxicity exposure ratio |
| TK | technical concentrate |
| TLV | threshold limit value |
| TMDI | theoretical maximum daily intake |
| TWA | time weighted average |
| UDS | unscheduled DNA synthesis |

Appendix 2 – abbreviations

| | |
|-----|---------------------------|
| UV | ultraviolet |
| 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 | $\begin{array}{c} \text{H} & & \text{H} \\ & \diagdown & / \\ & \text{P} \\ & / \\ \text{H} \end{array}$ |
| - | Calcium hydroxide | $\text{Ca}^{2+} \text{HO}^- \text{HO}^-$ |
| - | Phosphoric acid | $\begin{array}{c} \text{OH} \\ \\ \text{O}=\text{P}-\text{OH} \\ \\ \text{OH} \end{array}$ |
| - | Phosphonic acid | $\begin{array}{c} \text{OH} \\ \\ \text{HP}=\text{O} \\ \\ \text{OH} \end{array}$ |
| - | Hypophosphite | $\begin{array}{c} \text{O}^- \\ \\ \text{H}_2\text{P}=\text{O} \end{array}$ |
| - | Phosphite | $\begin{array}{c} \text{O}^- \\ \\ \text{O}^--\text{P} \\ \\ \text{O}^- \end{array}$ |