



# **Draft Assessment Report (DAR)**

**- public version -**

**Initial risk assessment provided by the rapporteur Member State  
Germany for the existing active substance**

**CALCIUM PHOSPHIDE**

**of the third stage (part B) of the review programme  
referred to in Article 8(2) of Council Directive 91/414/EEC**

**Volume 1**

**October 2007**

# **Draft Assessment Report**

12 June 2007

**Calcium phosphide**

**Volume 1**

**Report and  
Proposed Decision**

**Rapporteur Member State: Germany**

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# **Level 1**

**Calcium phosphide**

**Statement of Subject Matter and  
Purpose of Draft Assessment Report**

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# **1 Statement of subject matter and purpose for which the DAR was prepared**

## **1.1 Purpose for which the DAR was prepared (Dossier Document A)**

## **1.2 Summary and assessment of information relating to collective provision of dossiers (Dossier Document B)**

As Chemische Fabrik Wülfel is the only notifier of the active ingredient Calciumphosphid, this point is not relevant.

## **1.3 Identity of the active substance (Annex IIA 1) (Dossier Documents J, K-II and L-II)**

### **1.3.1 Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)**

**Applicant:**

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Germany

**Contact:**

Name: Uta Köhler  
Phone: +49 (0511) 98496 20  
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Email: CFW@wuelfel.de

### **1.3.2 Common name and synonyms (Annex IIA 1.3)**

Calcium phosphide  
Polytanol (synonym)

### **1.3.3 Chemical name (Annex IIA 1.4)**

IUPAC Tricalcium diphosphide  
CAS Calcium phosphide

### **1.3.4 Manufacturer's development code number (Annex IIA 1.5)**

**Applicant:**

Chemische Fabrik Wülfel  
Hildesheimer Strasse 305  
30519 Hannover  
Germany

**Contact:**

Name: Uta Köhler  
Phone: +49 (0511) 98496 20  
Fax: +49 (0511) 98496 40  
Email: CFW@wuelfel.de

### 1.3.5 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS	1305-99-3
EC (EEC)	215-142-0
CIPAC	505

### 1.3.6 Molecular and structural formulae, molecular mass (Annex IIA 1.7)

Molecular formula:  $\text{Ca}_3\text{P}_2$

Molecular mass: 182.19 g/mol

Structural formula:  $\text{Ca}_3\text{P}_2$

### 1.3.7 Manufacturer or manufacturers of the active substance (Annex IIA 1.2)

**Manufacturer:**

Chemische Fabrik Wülfel GmbH & Co. KG  
Hildesheimer Str. 305  
30519 Hannover  
Germany

**Contact:**

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Email: CFW@wuelfel.de

### 1.3.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C.

### 1.3.9 Specification of purity of the active substance (Annex IIA 1.9)

Clarification on the specification of the technical material is still needed.

### 1.3.10 Identity of isomers, impurities and additives (Annex IIA 1.10)

Confidential information, see Annex C.

Concerning relevant impurities: Clarification on the specification of the technical material is still needed.

### 1.3.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C.

#### **1.4 Identity of the plant protection product (Annex IIA 3.1; Annex IIIA 1) (Dossier Documents J, K-II, L-II, K-III, and L- III) (to be included for each preparation for which an Annex III dossier was submitted)**

##### **1.4.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)**

Trade name: Polytanol

##### **1.4.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)**

###### **1.4.2.1 Applicant (Annex IIIA 1.1)**

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###### **1.4.2.2 Manufacturer of the plant protection product (Annex IIIA 1.2)**

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##### **1.4.3 Type of the preparation and code (Annex IIIA 1.5)**

Gas generating product (GE)

##### **1.4.4 Function (Annex IIA 3.1; Annex IIIA 1.6)**

Rodenticide

#### **1.4.5 Composition of the preparation (Annex IIIA 1.4)**

Confidential information, see Annex C.

### **1.5 Use of the plant protection product (Annex IIA 3.2 to 3.4; Annex IIIA 3.1 to 3.7, 3.9, 12.1) (Dossier Documents C, D, and E) (to be included for each preparation for which an Annex III dossier was submitted)**

#### **1.5.1 Field of use (Annex IIA 3.3; Annex IIIA 3.1)**

Calcium phosphide is an inorganic rodenticide used in vegetables, fruits, ornamental plants, agricultural crops and grassland to control rodents (*Arvicola terrestris*) and other mammalian pests such as moles (*Talpa europaea* L.). Calcium phosphide is formulated as a gas generating product (GE) to be used for covered application with ancillary tools (e.g. drop gun, drop tube).

#### **1.5.2 Effects on harmful organisms (Annex IIA 3.2; Annex IIIA 3.2)**

Calcium phosphide yields phosphine on contact with atmospheric water or rodent stomach acid. The lethal concentration for animals appears to be related to both the time of exposure and the concentration of phosphine. Phosphine is highly toxic to organisms undergoing oxydative respiration. At the intended application rate, death of burrowing animals usually occurs within 2 days, although a second application may be required to control any surviving animals.

#### **1.5.3 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 to 3.7, 3.9)**

Formulated calcium phosphide Polytanol (GE) is used in vegetables, fruits, ornamental plants, agricultural crops and grassland to control rodents (*Arvicola terrestris*) and moles (*Talpa europaea*) in Northern Europe. Polytanol is a gas emitting formulation containing 180 g as/kg. The product is applied all-season using ancillary tools (e.g. drop gun, drop tube) against all stages of the above mentioned pest species at 8 g/run, with a minimum field rate of 1440g as/ha (min. 8 kg product/ha) to control *Arvicola terrestris* and 1800 g as/ha (max. 10 kg product/ha) for *Talpa europaea* control.

#### **1.5.4 Information on authorisations in EU Member States (Annex IIIA 12.1)**

The plant protection product POLYTANOL is authorised in following countries: Austria, France, Germany and Luxembourg.

## Level 2

**Calcium phosphide**

Overall Conclusions

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## 2 Reasoned statement of the overall conclusions

### 2.1 Identity, physical and chemical properties

#### 2.1.1 Identity

All points (Annex II and III) have been addressed and the information supplied is acceptable.

#### 2.1.2 Physical and chemical properties

Calcium phosphide (in POLYTANOL) is produced as dark grey solid granules with redbrown areas and garlic odour. It has a melting point of approx. 1600 °C and a density of 1.274 g/cm<sup>3</sup>. The active substance is an inorganic salt with an ionic structure and is therefore insoluble in organic solvents. Calcium phosphide is instable in water at pH 4 to 10 because of decomposition. By contact with water (air humidity) it rapidly evolves phosphine, a colourless gas which is toxic and highly flammable. Calcium phosphide is not flammable and has no explosive or oxidising properties.

Polytanol is a grey to dark grey gas generating product (granules) with a garlicky odour. It has neither explosive nor oxidising properties and it is not highly flammable, but will evolve highly flammable gas in contact with water. The results of the accelerated storage test and the shelf life test confirm its stability at least for two years under practical conditions. Its technical properties indicates no particular problems when used as recommended.

#### 2.1.3 Details of uses and further information

##### 2.1.3.1 Details of uses

###### Field of use

Polytanol is an effective rodenticide to control rodents and moles in the field.

###### Effects on harmful organisms

Polytanol as a granular formulation is a rodenticide fumigant (GE) containing 18 % calcium phosphide for the control of voles (*Arvicola terrestris*) and moles (*Talpa europea*). The good biological efficacy of Polytanol against the target animals such as common field mouse, the European mole and the water vole, was demonstrated in large scale field trials.

###### Details of intended use

The intended use of Polytanol is the protection of agricultural crops, vegetables, fruits, ornamental crops and grassland against damage by water voles (*Arvicola terrestris*) and common voles (*Microtus arvalis*) all-season. Voles are widely spread in all types of crops, damaging plants by eating roots, bulbs and seeds. Due to their high fertility, populations of voles can rapidly increase and may cause extensive damage in crops. Polytanol is highly effective against voles.

### Application rate

The useful recommended mode of application is at a rate of 8 g/tunnel (21 pieces granule/tunnel). Depending on the degree of infestation, this is considered to correspond to a maximum field application rate of 8 - 10 kg/ha. Usually, 1 application is needed. Additional applications might be necessary, if 2-4 days after treatment runs are still inhabited.

### Method of application

Polytanol is a ready-to-use solid granule for covered application outdoors.

### Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

No impact on succeeding crops is to be expected, because there is no risk for significant residues to remain in soil or in plant materials. Based on soil degradation studies with calcium phosphide, it is expected that degradation will be complete within approx. 4 - 5 days after contact with soil.

For the list of uses evaluated for Annex I inclusion see point 2.8.3.1, Appendix III.

### 2.1.3.2 Further information

Information on handling, storage, transport or fire, destruction or decontamination, and emergency measures for the active substance as manufactured and information on packaging, cleaning procedures, handling, storage, transport or fire, emergency measures, and procedures for destruction or decontamination for the gas generating product have been supplied and are acceptable.

### 2.1.4 Classification and labelling

#### Active Substance: Calcium phosphide

The following is proposed in accordance with the latest classification and labelling guidance under Directive 67/548/EEC (i.e. in the 29<sup>th</sup> ATP published as Directive 2004/73/EC):

Hazard symbol:	T+	N	F
Indication of danger:	Very toxic	Dangerous for the environment	Highly flammable
Risk phrases:	R 15/29	Contact with water liberates toxic extremely flammable gas.	
	R 28	Contact with water liberates toxic gas.	
	R 32	Very toxic if swallowed	
	R 50	Contact with acids liberates very toxic gas.	
		Very toxic to aquatic organisms.	

Additional proposal of the RMS:

Hazard symbol:	Xn
Indication of danger:	Harmful



Risk phrase: R 21 Harmful in contact with skin.

### Phosphine

The following is proposed in accordance with the latest classification and labelling guidance under Directive 67/548/EEC (i.e. in the 29<sup>th</sup> ATP published as Directive 2004/73/EC):

Hazard symbol: T+ N F+  
 Indication of danger: Very toxic. Dangerous for the environment Extremely flammable

Risk phrases: R 12-17 Extremely flammable,  
 Spontaneously flammable in air  
 R 26-34 Very toxic by inhalation,  
 Causes burns.  
 R 50 Very toxic to aquatic organisms.

### Preparations

Notifier	Preparation	
Chemische Fabrik Wülfel	Polytanol	Gas generating product GE as pellets

The following is proposed in accordance with Directive 1999/45/EC:

Hazard symbol: T N F  
 Indication of danger: Toxic Dangerous for the environment Highly flammable

Risk phrases: R 15/29 Contact with water liberates toxic, extremely  
 flammable gas.  
 R 21 Harmful in contact with skin.  
 R 25 Toxic if swallowed.  
 R 32 Contact with acids liberates very toxic gas.  
 R 36 Irritating to eyes.  
 R 50 Very toxic to aquatic organisms.

### Justification

Although some studies are only considered supplementary or insufficient to make a decision regarding the respective classification/labelling, the overall information to metal phosphide containing preparations (see also monograph to aluminium phosphide) is considered sufficient to assess the preparations and for the sake of animal welfare and protection no further studies should be required. Based on the amount of pure active ingredient in Polytanol (180 g/kg CaP, pure) the acute oral toxicity was tested to be “toxic if swallowed” (R 25). With respect to the similarity of all phosphine generating formulations in discussion, the RMS proposes the above listed additional classification/labelling also for Polytanol. The proposed classification with regard to the environment is based on aquatic toxicity data for the active substance and its content in the preparation.

## 2.2 Methods of analysis

### 2.2.1 Analytical methods for analysis of the active substance as manufactured

Analytical methodology is available for the determination of the active substance and the impurities in the technical material as manufactured.

Calcium phosphide in the active substance as manufactured is determined as phosphine after acid hydrolysis using gas volumetry, IR measurements, GC-MS or titration. The methods are fully validated.

Inorganic impurities in the technical active substance are determined by photometry, AAS, ICP-AES and calculation respectively. The methods are not fully validated. Validation data in terms of the accuracy are missing for some of the methods.

### 2.2.2 Analytical methods for formulation analysis

Analytical methodology is available for the determination of the active substance in the formulation.

Calcium phosphide in the formulated product is determined by volumetry, IR or GC-MS.

The methods are not fully validated.

### 2.2.3 Analytical methods for residue analysis

For the assessment of the analytical methods for the determination of calcium phosphide residues the following criteria were used:

- The submitted methods enable the enforcement of the following relevant residue limits (at the time of evaluation):

Matrix	Limit	Comment
plants and plant products (outdoor use)	-	no MRL proposed by the RMS no residue definition for monitoring
animal products	-	no MRL proposed by the RMS no residue definition for monitoring
soil	-	no method required, DT <sub>90</sub> < 3 days
drinking water (outdoor use)	0.1 µg/L	EU drinking water limit residue definition: phosphine
surface water (outdoor use)	4.7 µg/L	based on NOEC of <i>Oncorhynchus mykiss</i> residue definition: phosphine
air	3.3 µg/m <sup>3</sup>	based on a proposed AOEL <sub>systemic</sub> of 0.011 mg/kg bw/d residue definition: phosphine

tissues and blood - no method required, since phosphine will be quickly exhaled or metabolised to phosphates should it be incorporated

- Mean recovery rates at each fortification level in the range of 70 to 110 % with a relative standard deviation of  $\leq 20$  %
- No interfering blanks ( $< 30$  % of the LOQ)
- Methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.
- The enforcement method for food must be suitable for the determination of all compounds included in the residue definition (see B 7.3) and must be checked in an independent laboratory.
- The enforcement methods for environmental matrices must be able to analyse for all compounds of toxicological and/or ecotoxicological significance in soil, water and air (see B 8.9).
- An additional confirmatory method for all matrices is supplied.

According to these criteria adequate analytical methods are listed in the table B.5.5-1. This overview shows, that analytical methods are available for determination of phosphine in all relevant matrices. However, the proposed method for the determination of phosphine in air is insufficient for monitoring a concentration of  $3.3 \mu\text{g}/\text{m}^3$  (LOQ calculated on basis of the AOEL). But, the analytical method is considered to be appropriate for enforcement of the occupational exposure level.

**Table 2.2-1: Methods for the determination of residues**

Matrix-type	Matrix	Residue component	Method	Limit of quantification		Reference
Animal products	milk, liver, muscle	phosphine	GC/NPD	0.0025	mg/kg	Witte, 2001 MET2002-60
Water	surface water	phosphine	GC/NPD	0.1	$\mu\text{g}/\text{L}$	Werle, 1999 MET2000-49
	drinking and ground water river, pond and sea water	phosphine	GC/FPD	0.1	$\mu\text{g}/\text{L}$	Shrimali, 2001 MET2002-40
Air	air ambient temperature, humidity 40 – 50 %	phosphine	Photometric detection at 625 nm	25	$\mu\text{g}/\text{m}^3$	Breuer, 1993 MET2000-424

## 2.3 Impact on human and animal health

### 2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

#### 2.3.1.1 Metabolism / Toxicokinetics

Metal phosphides in contact with moisture (GI tract) readily decompose to metal or calcium hydroxide and phosphine, the toxicological principle. Due to the decomposition by moisture other phosphides are regarded as adequate model compounds. Studies with zinc phosphide and phosphine are available. Once formed from the metal phosphide, phosphine is rapidly and completely excreted by exhalation or via urine after oxidation to hypophosphite or phosphite. The phosphine metabolites hypophosphite or phosphite are regarded as less toxic than phosphine itself. Due to the inorganic nature of the metal phosphides and its degradation products and their respective metabolites it is reasonable to assume that residues of these phosphides are expected to be minimal or non-existent. Following oral administration of zinc phosphide, [ $^{32}\text{P}$ ] was rapidly absorbed from the gastrointestinal tract. Inhaled  $\text{PH}_3$  is considered to be rapidly and quantitatively absorbed through the lungs. [ $^{32}\text{P}$ ] was detectable in all organs and tissues, with temporary higher levels in liver and medulla oblongata.  $\text{PH}_3$  is excreted as such with the expired air or, after metabolic oxidation, with the urine in the form of hypophosphite and phosphite. In the absence of experimental data, for dermal absorption of both calcium phosphide and  $\text{PH}_3$  a default value of 10 %, based on expert judgement, was assumed.

#### 2.3.1.2 Acute toxicity studies, local irritation and skin sensitising properties

No acute oral toxicity study for calcium phosphide has been submitted by the applicant and no justification was given for that. However, there exist respective studies with other phosphides. Metal phosphides in contact with moisture (GI tract) readily decompose to metal or calcium hydroxide and phosphine, the toxicological principle. Due to the decomposition by moisture other phosphides are regarded as adequate model compounds. Studies with aluminium phosphide and magnesium phosphide are available and are considered to be of high toxicity when administered orally to animals. Therefore calcium phosphide has to be classified as 'very toxic if swallowed' (T+; R 28).  $\text{PH}_3$ , which is developed after contact of calcium phosphide with water by spontaneous hydrolysis of the phosphide, is very toxic by inhalation. According to Annex I to Directive 67/548/EEC classification and labelling of the gas is appropriate (T+; R 26), but calcium phosphide itself is like aluminium phosphide not classified with regard to inhalation toxicity. No dermal toxicity study for calcium phosphide has been submitted. However, regarding calcium phosphide no higher acute dermal toxicity than observed in aluminium phosphide e.g. is expected ( $\text{LD}_{50}$  460 – 900 mg/kg bw). Therefore, for calcium phosphide classification as 'harmful in contact with skin' (Xn; R 21) is required. No skin irritation study for calcium phosphide has been submitted. However, calcium phosphide reacts like aluminium and zinc phosphide. For both substances no irritation was noted after application to the skin of rabbits. Therefore, for calcium phosphide no classification according to Commission Directive 2001/59/EC (adaptation to 67/548/EEC) is required, too.

No eye irritation study for calcium phosphide has been submitted. However, studies for aluminium and zinc phosphide revealed no eye irritation potential. Therefore, for calcium phosphide no classification according to Commission Directive 2001/59/EC (adaptation to 67/548/EEC) is required. No skin sensitisation study has been presented using calcium phosphide. However, the study for zinc phosphide revealed no skin sensitisation potential. Therefore, calcium phosphide is considered to be not a sensitising substance, too, and classification according to Commission Directive 2001/59/EC (adaptation to 67/548/EEC) is not required.

#### 2.3.1.3 Short-term toxicity

Calcium phosphide like other metal phosphides in contact with moisture readily decompose to metal and phosphine, the toxicological principle. Due to the decomposition by moisture other phosphides are regarded as adequate model compounds. Studies with aluminium phosphide, zinc phosphide and phosphine are available. In an oral 90-day gavage test, mortality was increased at 2 mg aluminium phosphide/kg bw/d (corresponding to 1.18 mg PH<sub>3</sub>/kg bw/d) in both sexes, the NOAEL being 1 mg aluminium phosphide/kg bw/d, equivalent to 0.59 mg/PH<sub>3</sub> bw/d, respectively. However, these values are considered to be of limited reliability due to methodological deficiencies of the respective study report. A subchronic study in a second, non-rodent species was not submitted. An expert statement has been provided: The toxicological profile of calcium phosphide/PH<sub>3</sub> does not differ significantly between rodents and non-rodents and thereby justified non-submission of such data. Male and female rats and mice were exposed up to 0, 1.25, 2.5 or 5 ppm PH<sub>3</sub> for 2 weeks. Under the conditions of this investigation the NOAEL was determined as 2.5 ppm PH<sub>3</sub> (0.95 mg/kg bw/day for rats, 0.1 mg/kg bw/day for mice) based on decreased lung weights in male rats/mice, increased heart weight in female rats/mice and increased urea nitrogen in mice at 5 ppm PH<sub>3</sub> (1.9 mg/kg bw/day for rats, 0.2 mg/kg bw/day for mice). After inhalative administration of up to 3 ppm PH<sub>3</sub> gas (equivalent to ca. 1.1 mg/kg bw/d) to rats over a period of 90 days, no substance-related adverse effects were observed. Two satellite groups at 5 and 10 ppm, respectively, were introduced during the course of the study. In the 5 ppm satellite group, which received the test item for only 2 weeks, no relevant effects were observed (which is in accordance with the NOAEL of 4.9 ppm in the inhalative developmental study in rats, see below). Inhalative administration of 10 ppm PH<sub>3</sub> (3.8 mg PH<sub>3</sub>/kg/bw/d) was terminated after 3 days, when already 4/10 females had died. In summary, a short-term NOAEL of 1.1 mg PH<sub>3</sub>/kg bw/d was established.

#### 2.3.1.4 Genotoxicity studies

All submitted *in vitro* bacterial reverse mutation tests showed negative results. No clear result was obtained for the potential of PH<sub>3</sub> to cause clastogenic effects in CHO cells *in vitro*. The results of the test were equivocal, however, the ability of the test design to detect potential clastogenic effects caused by PH<sub>3</sub> could not be demonstrated convincingly. 6 submitted *in vivo* tests showed negative results. In a subchronic (13 weeks, mice) *in vivo* test the formation of micronuclei was increased at the highest test concentration (approaching the LD<sub>50</sub>). However, such exposure conditions are unlikely to be encountered in an occupational environment. In a dominant-lethal-test in mice with aluminium phosphide in peanut oil the post implantation loss was increased and the number of live implants was reduced. In the only dose level also toxic effects have been observed. However, the study was considered to be

supplementary. An inhalative dominant-lethal test in mice was negative. Overall, calcium phosphide/ $\text{PH}_3$  is not likely to be genotoxic in humans on relevant exposure conditions.

### 2.3.1.5 Long-term toxicity / carcinogenicity studies

Phosphine was assessed for chronic inhalation toxicity and carcinogenicity in a combined 104 week study in rats. The gas was produced by aluminium phosphide. In the inhalation study, body weight, food consumption, routine haematology, serum biochemical, and urinary analyses were all similar to control animals. Ophthalmological observations, gross pathology, organ weights and histopathology indicated no adverse effects from phosphine exposures. The NOAEL was 3.0 ppm, the highest concentration tested. This dose level is equivalent to 1.1 mg/kg bw/day. In two older limited dietary studies, rats received diets treated with phosphine released from aluminium phosphide. Behaviour, general appearance, survival, body weight, food consumption, haematology, blood chemistry, urine analyses and bone smear data, as well as gross and microscopic findings and rate of tumour development, did not reveal any toxic effects from the aluminium phosphide treated diet. However, the test design of both studies was insufficient. Therefore, the oral studies are considered to be not acceptable. Based on lack of exposure and the absence of genotoxic concern waiving of a long term /carcinogenicity study in a second species was seen as justified.

### 2.3.1.6 Reproductive toxicity / developmental (teratogenicity) studies

An acceptable two generation reproduction study with calcium phosphide was not submitted. However, long-term exposure is negligible and there is a very steep dose response curve of  $\text{CaP}/\text{PH}_3$  toxicity from which it can be expected that maternal toxicity would dominate over reproductive effects. A 2-generation oral study in rats with fumigated diet (fumigation with phosphine) was published. No effects have been observed, however, the study was considered to be not acceptable. The effects of Phosphine gas on pregnancy/embryo-foetal development were evaluated in a developmental toxicity study in the rat. Treatment was by inhalation with phosphine, the gas produced by aluminium phosphide. Phosphine administered by whole body inhalation to pregnant female rats at target exposure levels up to 5.0 ppm for 6 hrs/day over the day 6-15 gestation interval was not maternally toxic, embryotoxic, foetotoxic or teratogenic. However at the 7.5 ppm exposure, the first 14 mated females on test died during the day 8-15 gestation interval after receiving three to 10 days of exposure. Therefore, the No Observed Effect Level (NOEL) for the maternal and developmental toxicity for this study in rat was 5 ppm. The analytical concentration of this target dose was 4.9 ppm, equivalent to 0.007 mg/L air or 1.9 mg/kg bw/day.

### 2.3.1.7 Neurotoxicity / Delayed neurotoxicity studies

The neurotoxicity of phosphine has been assessed in rats in an acute and a 90-day inhalation study. In the acute neurotoxicity study, rats were exposed to 0, 20, 30 and 40 ppm phosphine gas (nominal conc.) administered via whole body inhalation exposure for one session of four hours duration. The No Observable Adverse Effect Level (NOAEL) of phosphine in rats was 40 ppm (analytical conc. 38 ppm) with regard to anatomic pathology and the behavioural and neurological status observed in the functional observational battery, and less than 20 ppm with regard to changes in motor activity on day 1.

In the subchronic neurotoxicity study, rats were exposed to phosphine gas via whole body exposure at levels of 0.3, 1 and 3 ppm, 6 hours per day, 5 days per week, for 13 weeks. Due to equivocal effects seen in high dose males, and the lack of effects seen in females the No Observed Adverse Effect Level (NOAEL) of phosphine for systemic/neurotoxic effects in rats exposed over a 90-day period is 3 ppm, the highest dose tested in this study.

### 2.3.1.8 Further toxicological studies

It was demonstrated that phosphine or other phosphide- derived reaction products induced Heinz body formation in relatively low concentrations (1.25 ppm) in normal human erythrocytes. The time course for the induction of Heinz bodies is relatively slow (4 h). The formation of Heinz bodies by phosphine is oxygen-dependent, consistent with earlier work regarding the insecticidal properties of the chemical. Finally, these in vitro data lead to the speculation that prolonged in vivo exposure to phosphine in concentrations exceeding the PEL might have an adverse effect on haemoglobin in susceptible segments of the worker population exposed to the chemical. The results of another study show that after acute poisoning of rats by phosphine the respiration of the isolated liver-mitochondria is diminished. The oxidation of  $\alpha$ -ketoglutarat turned out to be the most sensitive. The oxidative phosphorylation, however, remains on a normal level. In general, the disturbance equals that of phosphine action on isolated mitochondria in vitro. Similar effects have been observed on the isolated sarcosomes of heartmuscle of poisoned animals on an early state of intoxication. But in the sarcosome respiration and phosphorylation is uncoupled at the same time. Since the respiration of *Neurospora crassa* is also decreased by phosphine it is to assume that this agent acts by this mechanism on living cells in general. The same kind of disturbance can be demonstrated in the mitochondria after chronic administration of doses which are far below the toxic ones of phosphine and by which animals don't show any sign of damage. There is a small but considerable fall of CoA in the liver of acute poisoned animals.

### 2.3.1.9 Human Data

Among the examined persons, occupied in the production of Polytanol (calcium phosphide), no health impairment was detected over a period of 3 to 16 years. The case reports submitted by the applicants are considered to be representative of the numerous records of poisoning cases, mainly in connection with suicide, which are available from the literature. Diagnosis is mainly based on the history of intake, gastrointestinal symptoms, shock symptoms and silver nitrate impregnated paper test. Main symptoms are severe circulatory, cardiac, and renal failure, uraemia, hepatic damage, changes in ECG, and respiratory distress connected with a high mortality rate. Histopathological changes have mainly been observed in lungs, liver, heart and kidney. Since an antidote is not available, therapy relies on treatment of the clinical symptoms and administration of high doses of corticoids.

### 2.3.2 ADI

The most relevant study to derive the ADI is the long term study in rats. The NOAEL in the 2-yr inhalation study was 3 ppm (equivalent to 1.1 mg  $\text{PH}_3$ /kg bw/day). In the absence of experimental data, it is assumed, that after ingestion of calcium phosphide, phosphine gas would be liberated stoichiometrically (0.37 g  $\text{PH}_3$ /g calcium phosphide) and successively be

quantitatively absorbed. Based on the NOAEL for PH<sub>3</sub> of 1.1 mg/kg bw/day, the maximum liberation of gas of 0.37 g PH<sub>3</sub>/g calcium phosphide and a safety factor of 100 an

**ADI of 0.030 mg/kg bw/d** is derived.

### 2.3.3 ARfD (acute reference dose)

The most relevant study to derive the ARfD is the developmental study in rats. The NOAEL in the developmental study in rats was 4.9 ppm (equivalent to 1.9 mg PH<sub>3</sub>/kg bw/day). In the absence of experimental data, it is assumed, that after ingestion of calcium phosphide, phosphine gas would be liberated stoichiometrically (0.37 g PH<sub>3</sub>/g calcium phosphide) and successively be quantitatively absorbed. Based on the NOAEL for PH<sub>3</sub> of 1.9 mg/kg bw/day, the maximum liberation of gas of 0.37 g PH<sub>3</sub>/g calcium phosphide and a safety factor of 100 an **ARfD of 0.051 mg/kg bw** is derived.

### 2.3.4 AOEL

The most relevant study to derive the AOEL is the 90-day inhalation study in rats. The NOAEL in the 90-day inhalation study was 3 ppm (equivalent to 1.1 mg PH<sub>3</sub>/kg bw/day). In the absence of experimental data, it is assumed, that after ingestion of calcium phosphide, phosphine gas would be liberated stoichiometrically (0.37 g PH<sub>3</sub>/g calcium phosphide) and successively be quantitatively absorbed. Based on the NOAEL for PH<sub>3</sub> of 1.1 mg/kg bw/day, the maximum liberation of gas of 0.37 g PH<sub>3</sub>/g calcium phosphide and a safety factor of 100 an **AOEL of 0.030 mg/kg bw/d** is derived.

### 2.3.5 Drinking water limit

The determination of a MAC value is not necessary, because according to Directive 91/414/EC only the ADI and AOEL values have to be determined. Therefore, the establishment of a maximum admissible concentration for drinking water from an ADI value is not yet confirmed by a harmonised EU proposal. In addition to that, the maximum admissible concentration of an active substance is 0.1 µg/L, as established by the Directive 89/778/EEC.

### 2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

According to the toxicological properties of calcium phosphide harmful effects on the health of operators, bystanders, workers or consumers are not to be expected when the plant protection product is used in accordance with good plant protection practice. The available data for calcium phosphide do not support evidence of genotoxic, carcinogenic and the fertility damaging properties of the active substance.

With regard to the intended use as also assessed in the DAR to aluminium phosphide for 4 different AIP-containing preparations the respective risk assessment should be considered for Polytanol, too. The respective risk assessment is supported by the submitted data of the notifier.



Thus, as it is partly approved by estimations and/or measurements it can be concluded that the risk to operators from exposure to phosphine following rodent burrow treatment is considered acceptable without the use of personal protective equipment (no PPE/RPE). It was also demonstrated that bystander exposure and worker exposure will be acceptable.

The estimation of the potential and actual exposure through diet and other means of calcium phosphide following the proper use of the calcium phosphide containing fumigants are not considered to be required, since no residues of calcium phosphide and phosphine in plants, food or feed of plant or animal origin are to be expected, due to the reasons given in chapter B.7.

In view of the recommended uses and application techniques, harmful effects on the health of domestic or other than the target animals are not to be expected.

## 2.4 Residues

Studies with regard to residue data must always be performed unless it can be justified that no residues will remain on plants or plant products which are used as food or feed. In the case of outdoor use of calcium phosphide the submission of residue data or the performance of adequate tests is in principle not necessary, for the following reasons:

Calcium phosphide, as constituent of products for fumigation in underground tunnel systems of non-rodent and rodent species, is not intended for direct application to growing crops. The application of the products directly in animal burrows excludes the direct contact with the plants, therefore, no residues in plants are to be expected.

Unlike conventional crop protection products, which must be applied over relatively large crop areas, the calcium phosphide containing products are predominantly applied to discrete sites (no widespread area application). Even if calcium phosphide containing fumigants are spilled, the phosphide will not be taken up by plants. Due to the hydrolytic instability calcium phosphide will not be washed out.

In soil calcium phosphide is degraded rapidly to calcium hydroxide and phosphine. Calcium hydroxide is not toxic to plants. The latter is expected either to be volatilised, or re-adsorbed onto soil and degraded rapidly to phosphate, so that no accumulation needs to be considered. Moreover, calcium is an essential component of alive matter. Also phosphate as normal soil constituent is taken up by plants as nutrient. As a consequence, residues of concern are not to be expected.

The indoor use of the calcium phosphide containing product „Polytanol“ as a fumigant for insect control in storage protection is not intended.

## Conclusion

Thus, the submission of residue data for the active substance calcium phosphide is not considered to be required in the majority of cases.

## **2.4.1 Definition of the residues relevant to MRLs**

### **Plant matrices**

The definition of a residue in plants is not considered to be required, since no residues of phosphine and residual calcium phosphide in plants or foodstuff of plant origin following the proper use of calcium phosphide containing fumigants in the field are to be expected, due to the reasons given in chapter 2.4 above.

However, for formal reasons, concerning the definition of residues in the environment, the following is proposed:

Residue analytical methods for calcium phosphide are principally identical to those for phosphine. Any calcium phosphide released to soil or water environment may be expected to be associated with phosphine formation due to its inherent susceptibility to hydrolysis in aquatic media or in contact with soil moisture. Consequently, it is only logical to propose to regulate calcium phosphide residues in plants, if any, as the sum of the parent compound and any phosphine present, defined as the amount of phosphine that may be released upon analysis.

### **Animal Matrices**

The submission of data on the definition of the residues in food of animal origin of calcium phosphide is not considered to be required, since no residues in plants or feed of plant origin are to be expected, due to the reasons given in chapter 2.4 above. Therefore, any uptake by domestic animals is not anticipated.

## **2.4.2 Residues relevant to consumer safety**

### **Metabolism, distribution and expression of residues in plants**

The submission of data or the performance of tests on metabolism, distribution and expression of residues in plants of the active substance calcium phosphide is not considered to be required, since no residues of calcium phosphide or phosphine are to be expected in plants, due to the reasons given in chapter 2.4 above.

Besides, any metabolism of phosphine in plants will be dominated by oxidation to phosphorus oxides of no concern, as well as by volatilisation and expiration from plants. Thus, the nature of the molecule phosphine does not allow to trace back the metabolism of the radiolabelled compound in plants. Therefore, no metabolism studies are required or submitted in plants. Nevertheless, data on residues in plants were searched for in the public domain (see chapter B.7.1).

### **Metabolism, distribution and expression of residues in livestock**

Any uptake of phosphine and residual calcium phosphide by domestic animals following the proper use of calcium phosphide containing fumigants in the field is not presumably.

Therefore, the submission of data or the performance of tests on metabolism, distribution and expression of residues in domestic animals is not considered to be required for calcium phosphide since no significant residues in plants or feed of plant origin are to be expected, due to the reasons given in chapter 2.4 above.

### **Residues resulting from supervised trials**

The submission of data or the performance of residue trials for calcium phosphide is not considered to be required, since no residues of phosphide and phosphine in plants and food are to be expected, due to the reasons given in chapter 2.4 above.

### **Storage stability**

The submission of data or the performance of tests on stability of residues during storage of samples of calcium phosphide is not considered to be required, since no residues of phosphide and phosphine in plants are to be expected, due to the reasons given in chapter 2.4 above.

### **Effects of industrial processing and/or household preparation**

The submission of data or the performance of tests on effects of industrial processing and/or household preparation of calcium phosphide is not considered to be required, since no residues of phosphide and phosphine in plants and food of plant origin are to be expected, due to the reasons given in chapter 2.4 above.

### **Livestock feeding studies**

The submission of data or the performance of livestock feeding studies for calcium phosphide is not considered to be required, since no residues of phosphine and calcium phosphide are to be expected in plants and plant commodities used as animal feed, due to the reasons given in chapter 2.4 above.

### **Residues on succeeding or rotational crops**

The submission of data or the performance of tests on residues in succeeding crops for calcium phosphide is not considered to be required for reasons given in chapter 2.4 above.

### **Estimates of potential and actual dietary exposure through diet and other means**

The estimation of the potential and actual exposure through diet following the proper use of calcium phosphide containing fumigants are not considered to be required, since no residues of calcium phosphide and phosphine in foodstuff of plant or animal origin are to be expected, due to the reasons given in chapter 2.4 above.

## **2.4.3 Residues relevant to worker safety**

According to the toxicological properties of calcium phosphide harmful effects on the health of operators, bystanders, workers or consumers are not to be expected when the plant protection product is used in accordance with good plant protection practice. The available data for calcium phosphide do not support evidence of genotoxic, carcinogenic and the fertility damaging properties of the active substance.

Thus, as it is partly approved by estimations and/or measurements it can be concluded that the risk to operators from exposure to phosphine following rodent burrow treatment is considered acceptable without the use of personal protective equipment (no PPE/RPE). It was also demonstrated that bystander exposure and worker exposure will be acceptable.

## **2.4.4 Proposed EU MRLs and compliance with existing MRLs**

### **Plant matrices**

The proposal of maximum residue levels (MRLs) is not considered to be required, since no residues of phosphine and residual calcium phosphide in plants or foodstuff of plant origin following the proper use of calcium phosphide containing fumigants are to be expected, due to the reasons given in chapter 2.4 above.

No MRLs are available for calcium phosphide, hence no compliance can be stated. MRLs were not defined in the past either.

### **Products of animal origin**

The proposal of MRLs is not considered to be required, since no residues in plants or feed of plant origin are to be expected, due to the reasons given in chapter 2.4 above. Therefore, any uptake by domestic animals is not anticipated.

## **2.4.5 Proposed EU import tolerances and compliance with existing import tolerances**

EU import tolerances have not been proposed yet.

No import tolerances are proposed, since no residues of calcium phosphide in plants, food or feed of plant origin are to be expected from the proper use of calcium phosphide containing fumigants, due to the reasons given in chapter 2.4 above.

## **2.4.6 Basis for differences, if any, in conclusion reached having regard to established or proposed CAC MRLs**

Not relevant. (Since there are no established or proposed MRLs or CAC MRLs and since data have not yet been submitted to the JMPR for consideration by it, the matter of differences in conclusions reached, does not arise.)

## **2.5 Fate and behaviour in the environment**

### **2.5.1 Definition of residues relevant to the environment**

Residue analytical methods for calcium phosphide are principally identical to those for phosphine. Any calcium phosphide released to the soil or water environment may be expected to be associated with phosphine due to its inherent susceptibility to hydrolysis in aquatic media or in contact with soil moisture. Therefore, the relevant environmental residue of calcium phosphide is defined as phosphine including any  $\text{PH}_3$  that may be evolved from residual calcium phosphide.

### **Soil**

Due to the reasons mentioned above a relevant contamination of soil is not to be expected, since the special kind of application excludes a wide spreading of phosphine in soil and the half-life of phosphine in soil is very short. An accumulation of phosphine in soil can therefore be excluded. The residue for monitoring purposes is, by default, defined as phosphine.

### Surface water

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. The residue for monitoring purposes is, by default, defined as phosphine.

### Groundwater

Due to the type of application and the type of compound it is concluded that there are no relevant residues of calcium phosphide and  $\text{PH}_3$  in groundwater following proper use. The residue for monitoring purposes is, by default, defined as phosphine.

## 2.5.2 Fate and behaviour in soil

### Route of degradation

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 molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual calcium cations will prevail. The former 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.

### Rate of degradation

Calcium phosphide is degraded in soil to yield phosphine gas as an intermediate, and calcium cations (2 h after application of calcium phosphide maximum concentrations of the metabolite  $\text{PH}_3$  were observed). 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. Based on results of a field study the  $\text{DT}_{50}$  of  $\text{PH}_3$  was estimated in the range of 6 to 10 hours ( $\text{DT}_{90}$  below 2 day).

### Fate in soil

For this type of application and this type of plant protection product no guideline exists that can be followed to determine the movement in soil. Also the standard scenarios for estimating predicted environmental concentrations in soil are not feasible for this type of application. However, an emission scenario document for biocides used as rodenticides can be used to estimate a  $\text{PEC}_{\text{soil}}$  for the metabolite  $\text{PH}_3$ . Based on this scenario and assuming 5 kg and 10 kg dose of the product per hectare the initial concentration for the metabolite  $\text{PH}_3$  in the soil surrounding the burrows can be estimated to amount to 3.457 mg/kg and 6.914 mg/kg, respectively.

## 2.5.3 Fate and behaviour in water

Due to the type of application and its short half life it is not expected that calcium phosphide will reach surface water or groundwater. The estimation of predicted environmental concentrations in surface waters ( $\text{PEC}_{\text{sw}}$ ) for calcium phosphide was therefore considered to be unnecessary due to the type of application. 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.

#### 2.5.4 Fate and behaviour in air

No emission into air of calcium phosphide is to be expected. In contrast, upon contact with soil, calcium phosphide will be degraded. The degradation product phosphine is volatile and is decomposed rapidly in air. Direct reactions of phosphine with ozone can not be expected to be quantitatively important, since the degradation via reaction with OH-radicals will degrade the phosphine before it will reach the ozone-rich upper atmosphere layer. Degradation by direct photolysis is not expected to be quantitatively relevant for phosphine, since direct photolysis is only possible if the compounds definitely absorb light over 300 nm (lower limit of the sunlight spectrum in the lower troposphere). This does not apply to phosphine.

### 2.6 Effects on non-target species

#### 2.6.1 Effects on terrestrial vertebrates

##### 2.6.1.1 Effects on birds

No studies on birds were performed with calcium phosphide. According to the state of knowledge the toxicity of calcium phosphide is solely caused by release of phosphine ( $\text{PH}_3$ ). Therefore, toxic effects of phosphine and metal phosphides can be considered together and effects of calcium phosphide can be extrapolated from studies with other metal phosphides or phosphine. The presented data on effects on birds are partly taken from literature and these studies do not fully comply with current standards for the testing of plant protection products. Due to missing raw data a validation of the studies is not possible. The studies taken from literature can be used as additional information for the risk assessment. However, the presented data on acute, short-term and long-term effects on birds is considered sufficient and no further studies are required, since exposure of birds to calcium phosphide containing granules is not expected during the recommended use of POLYTANOL. Additionally, reasons of animal welfare are considered.

The  $\text{LD}_{50}$  values of 25 and 35 mg zinc phosphide/kg body weight are equivalent to 6.6 and 9.2 mg  $\text{PH}_3$ /kg body weight and can be extrapolated to 17.7 and 24.7 mg  $\text{Ca}_3\text{P}_2$ /kg/body weight, respectively.

The median lethal dietary toxicity concentrations ( $\text{LC}_{50}$ ) for bobwhite quails (*Colinus virginianus*) were between 469 and 849 mg zinc phosphide/kg diet equivalent to  $\text{LC}_{50}$  values of 330 and 599 mg  $\text{Ca}_3\text{P}_2$ /kg diet. In a study with *Anas platyrhynchos* the obtained  $\text{LC}_{50}$  value was 2885 mg  $\text{Zn}_3\text{P}_2$ /kg diet (equivalent to a  $\text{LC}_{50}$  of 2037 mg  $\text{Ca}_3\text{P}_2$ /kg diet). The dietary  $\text{LC}_{50}$  for *Coturnix japonica* is reported to be 960 mg  $\text{Zn}_3\text{P}_2$ /kg diet equivalent to 678 mg  $\text{Ca}_3\text{P}_2$ /kg diet. Oral administration of  $\text{Zn}_3\text{P}_2$  at dose levels of 1/10 and 1/50 of the  $\text{LD}_{50}$  (3.5 and 0.7 mg/kg) to male and female Japanese quails affected the fertilisation rate and egg-laying rate.

Due to the special kind of application of the dry granular solid POLYTANOL, which is used only underground (15 – 25 cm), minimal possibilities for access by birds is expected. Outdoor 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). It is therefore excluded that a bird would swallow the pellets. 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 the burrows via uncovered holes phosphine will remain close to the ground and the strong smell of garlic, ammonia and carbide will drive off any bird coming near. Poisoned voles contain only minimal quantities of phosphine. After inhalation of phosphine, the rapid process of conversion into non-hazardous phosphite and phosphate by oxidising in the voles begins. Therefore, the risk of secondary poisoning for birds of prey is negligible. It is concluded that there is no unacceptable risk from the proposed use of POLYTANOL to birds.

#### 2.6.1.2 Effects on terrestrial vertebrates other than birds

The special conditions of use minimise the possibility that non-target terrestrial vertebrates other than birds come into contact with calcium phosphide or phosphine gas. Due to the specific application method of calcium phosphide containing formulations as gassing products on agricultural land the hazard of non target mammals, reptiles and amphibians can principally not be excluded. These products are applied as pellets or tablets to the underground tunnels of the target organisms (*Arvicola terrestris*, *Talpa europaea* (mole)). Other organisms which are using these tunnels as a part of their habitat (*Mustela nivalis* (least weasel)) or living in similar holes in the same habitat (*Spermophilus* (gopher), *Cricetus cricetus* (hamster)) are potentially endangered; areas where these animals can be expected must therefore not be treated. Under certain registrations this is a condition of approval and should be considered in the national authorisation on MS-level. Carnivorous and scavenging terrestrial vertebrates are identified theoretically at risk from consumption of intoxicated target animals. However, adverse or lethal effects in these species are considered to be of minor relevance since phosphine does not accumulate in the target animals but is metabolised to the non-hazardous phosphite and phosphate rapidly. Therefore it is concluded, that during the recommended use of calcium phosphide containing products any relevant exposure of terrestrial vertebrates outside the burrows is not expected. It is concluded that there is no unacceptable risk from the proposed use of calcium phosphide containing product POLYTANOL to non-target terrestrial vertebrates.

#### 2.6.2 Effects on aquatic species

Calcium phosphide is a dry granular solid which decomposes very rapidly in contact with water to produce calcium hydroxide and phosphine gas. Phosphine is of very low water solubility (0.322 g/L). The use of calcium phosphide containing plant protection products involves laying out of such products in burrow systems. Any exposition of aquatic organisms by contamination of surface waters due to events related in general to pesticide application, such as over-spray, drift, run-off, atmospheric deposition, etc. is not expected. In contrast, a chronic contamination of surface waters is excluded by the specific conditions of use, which prevent a contact of the active substance with water. Furthermore, the insolubility of calcium phosphide in water and the rapid degradation in soil and water minimises the risk for aquatic organisms. An estimation of predicted environmental concentrations in surface waters  $PEC_{SW}$  and

consequently in sediments is not considered to be required (see B.8.6.1) and estimations of TER values are unnecessary.

### **2.6.3 Effects on bees and other arthropod species**

#### **2.6.3.1 Effects on bees**

Bees will not be exposed when calcium-phosphide is used in the field for control of *Arvicola terrestris* and *Talpa europaea*. Therefore no data are required.

#### **2.6.3.2 Effects on other arthropod species**

No studies have been conducted on the toxicity of phosphine to arthropods. Regarding the kind of application, only a very small quantity of arthropods will be affected from fumigation. Even when some single individuals will be killed inside or in direct contact to the burrows, eggs and pupae will survive the low dosages used in the field. Therefore, it is concluded that there is no unacceptable risk from the proposed use of POLYTANOL to the whole arthropod population.

### **2.6.4 Effects on earthworms and other soil macro-organisms**

#### **2.6.4.1 Effects on earthworms**

POLYTANOL was tested for acute effects on earthworms. Up to the highest concentration tested (400 mg POLYTANOL per kg soil) no mortality occurred. Regarding the kind of application, only a very small quantity of earthworms will be affected from fumigation and possible mortality will be equalised very quickly. It is expected that TER values exceed the relevant Annex VI triggers obviously. It is concluded that there is no unacceptable risk from the proposed use of POLYTANOL to the whole earthworm population.

#### **2.6.4.2 Effects on other soil non-target macro-organisms**

Studies with calcium phosphide regarding effects on other soil non-target macro-organisms are not considered to be required. Calcium phosphide containing products are placed in underground tunnel systems. It is therefore excluded that non-target macro-organism populations are exposed significantly. POLYTANOL is considered to pose a negligible risk to the soil non-target macro-organisms.

### **2.6.5 Effects on soil non-target micro-organisms**

Studies with calcium phosphide regarding effects on non-target micro-organisms are not considered to be required. Calcium phosphide containing products are placed at distinct spots in underground tunnel systems. It is therefore excluded that non-target micro-organism populations are exposed significantly. POLYTANOL is considered to pose a negligible risk to the soil non-target micro-organisms.



## **2.6.6 Effects on other non-target organisms (flora and fauna) believed to be a risk**

Studies with calcium phosphide regarding effects on other non-target organisms are not considered to be required. The application of the products in underground tunnel systems excludes direct contact with plants. Other non-target fauna are not considered to be effected significantly.

## **2.6.7 Effects on biological methods of sewage treatment**

Tests on biological methods for sewage treatment are not considered to be required. During the recommended use of POLYTANOL any relevant exposure of biological waste water treatment organisms is not expected. It is concluded that there is no unacceptable risk from the proposed use of POLYTANOL to the efficiency of sewage treatment plants.

## **2.7 Overall conclusion (metabolism schemes)**

### **2.7.1 Toxicology (laboratory animals)**

#### **Proposed metabolic pathway of calcium phosphide in rats**

Calcium phosphide is hydrolysed to phosphine and calcium cation. The phosphine gas is eliminated in expired air and in oxidised form in urine. The nature of the molecule phosphine does not allow to trace back the kinetics and metabolism of the radiolabelled compound.

### **2.7.2 Residues (plant, plant products, livestock animals)**

The submission of data or the performance of tests on metabolism, distribution and expression of residues in plants and domestic animals of the active substance calcium phosphide is not considered to be required, since no residues of calcium phosphide or phosphine are to be expected in plants, food or feed of plant origin, due to the reasons given in chapter 2.4 above.

Therefore, no metabolism schemes are required or submitted in plants and livestock.

### **2.7.3 Fate and behaviour in the environment (soil, water, air)**

#### **Soil**

Calcium phosphide is an inorganic molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual calcium cations will prevail. Any phosphine generated through hydrolysis will be rapidly transformed in soil by oxidative processes to yield phosphate anions.

#### **Water**

Calcium phosphide is an inorganic molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual calcium cations will prevail.

### **Air**

Calcium phosphide is an inorganic molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual calcium cations will prevail. Any phosphine released to the atmosphere will be rapidly departed via reaction with OH-radicals.

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# **Appendix 1**

## **Calcium phosphide**

### **Standard Terms and Abbreviations**

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## 2.8 Appendices

### 2.8.1 Appendix I: Standard terms and abbreviations

#### Part 1 Technical Terms

A	ampere
ACH	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD <sub>50</sub>	approximate median lethal dose, 50 %
ALT	alanine aminotransferase (SGPT)
AMD	automatic multiple development
ANOVA	analysis of variance
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
approx	approximate
AR	applied radioactivity
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	<i>Bacillus thuringiensis</i>
Bti	<i>Bacillus thuringiensis israelensis</i>
Btk	<i>Bacillus thuringiensis kurstaki</i>
Btt	<i>Bacillus thuringiensis tenebrionis</i>
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10 <sup>-2</sup> )
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design

CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAT	days after treatment
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days past inoculation
DRES	dietary risk evaluation system
DT <sub>50</sub>	period required for 50 percent dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E <sub>b</sub> C <sub>50</sub>	effective concentration on the biomass
EC <sub>50</sub>	effective concentration
ECD	electron capture detector
ECU	European currency unit
ED <sub>50</sub>	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
E <sub>r</sub> C <sub>50</sub>	effective concentration on the growth rate
ERL	extraneous residue limit
F	field
F <sub>0</sub>	parental generation

F <sub>1</sub>	filial generation, first
F <sub>2</sub>	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionisation detector
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathione
GV	granulose virus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography

HRGC	high resolution gas chromatography
Hs	Shannon-Weaver index
Ht	haematocrit
I	indoor
I <sub>50</sub>	inhibitory dose, 50 %
IC <sub>50</sub>	median immobilisation concentration
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	in vitro fertilisation
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) <sup>13</sup>
K <sub>ads</sub>	adsorption constant
K <sub>des</sub>	apparent desorption coefficient
K <sub>oc</sub>	organic carbon adsorption coefficient
K <sub>om</sub>	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC <sub>50</sub>	lethal concentration, median
LCA	life cycle analysis
LCLo	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose, median; dosis letalis media
LDLo	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test



LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mol
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue limit or level
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration)
NAEL	no adverse effect level
nd	not detected
NEDI	no effect daily intake (mg/kg body wt/day)
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEAEC	no observed environmentally adverse effect concentration
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported

NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorus pesticide
Pa	Pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC <sub>A</sub>	predicted environmental concentration in air
PEC <sub>S</sub>	predicted environmental concentration in soil
PEC <sub>SW</sub>	predicted environmental concentration in surface water
PEC <sub>GW</sub>	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibition capacity
PIXE	proton induced X-ray emission
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
PNEC	predicted no effect concentration
po	by mouth (per os)
P <sub>ow</sub>	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10 <sup>-9</sup> )
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
ppq	parts per quadrillion (10 <sup>-24</sup> )
ppt	parts per trillion (10 <sup>-12</sup> )
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r <sup>2</sup>	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
R <sub>f</sub>	ratio of fronts
RfD	reference dose

RH	relative humidity
RL <sub>50</sub>	residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	reversed phase material
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
SE	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedure
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
t <sub>1/2</sub>	half-life (define method of estimation)
T <sub>3</sub>	tri-iodothyroxine
T <sub>4</sub>	thyroxine
TADI	temporary acceptable daily intake
TAR	total applied radioactivity
TBC	tightly bound capacity
TCD	thermal conductivity detector
TCLo	toxic concentration low
TID	thermionic detector, alkali flame detector
TDLo	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER <sub>i</sub>	toxicity exposure ratio for initial exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure

tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic chlorine
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

## Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDf	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd

COREPER	Comité des Représentants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environment Health Criteria (number)
EHCD	Environmental Health Criteria Document
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organisation
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organisation of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GIFAP	Groupeement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organisation
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of noxious Animals

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	and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organisation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticides Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organisation
WTO	World Trade Organisation
WWF	World Wide Fund for Nature

## **Appendix 2**

### **Calcium phosphide**

#### **Specific Terms and Abbreviations**

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## **2.8.2 Appendix II: Specific terms and abbreviations**

PAS	pure active substance
TAS	technical active substance
PEL	Permissible exposure limit

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## **Appendix 3**

### **Calcium phosphide**

#### **List of End Points**

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**2.8.3 Appendix III: Listing of end points****2.8.3.1 Appendix III.1: Chapter 1 (identity, physical and chemical properties, details of uses, further information, classification and labelling)**

Active substance (ISO Common Name) ‡	Calcium phosphide
Function (e.g. fungicide)	Rodenticide

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

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

Chemical name (IUPAC) ‡	Tricalcium diphosphide
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) ‡	Further clarification is needed.
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Further clarification is needed.
Molecular formula ‡	Ca <sub>3</sub> P <sub>2</sub>
Molecular mass ‡	182.19 g/mol
Structural formula ‡	Ca <sub>3</sub> P <sub>2</sub>

‡ Items to be included in Appendix I of the draft review report

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

Melting point (state purity) ‡	Approx. 1600 °C (28 %)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition	Not applicable
Appearance (state purity) ‡	Solid granules, dark grey with redbrown areas, garlic odour (28 %)
Relative density (state purity) ‡	$d_4^{22} = 1.274 \text{ g/cm}^3$ (20.7 %)
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature) ‡	$< 1.0 \cdot 10^{-5} \text{ hPa}$
Henry's law constant ( $\text{Pa m}^3 \text{ mol}^{-1}$ ) ‡	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
Partition co-efficient ( $\log P_{ow}$ ) (state pH and temperature) ‡	Not applicable
Hydrolytic stability ( $DT_{50}$ ) (state pH and temperature) ‡	Not applicable
Dissociation constant ‡	Not applicable
UV/VIS absorption (max.) (if absorption > 290 nm, state $\epsilon$ at wavelength) ‡	Not applicable
Photostability ( $DT_{50}$ ) (aqueous, sunlight, state pH) ‡	Not applicable
Quantum yield of direct phototransformation in water at $\Sigma > 290 \text{ nm}$ ‡	Not applicable

‡ Items to be included in Appendix I of the draft review report

Flammability ‡

not highly flammable, but will evolve extremely flammable phosphine at contact with water  
However, the ECB has classified calcium phosphide as F (highly flammable)  
PH<sub>3</sub>: F+, extremely flammable

Explosive properties ‡

no explosive properties (according to structure)

‡ Items to be included in Appendix I of the draft review report

### 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)	Re-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	Not applicable	Not applicable
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	
Fruit	(Northern europe)			<i>Talpa europaea</i>									1.8 kg as/ha (max. 10 kg product/ha)		
Ornamental Plants															
Agricultural Crops															
Grassland															

- 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 sucking 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
- PHI - minimum pre-harvest interval
- (l) Remarks may include: Extent of use/economic importance/restrictions
- (m)

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



**2.8.3.2 Appendix III.2: Chapter 2 (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 proposed by the RMS, no residue definition for monitoring
Food of animal origin	Not relevant, no MRL proposed by the RMS, no residue definition for monitoring
Soil	Not relevant, $DT_{90} < 3$ days
Water surface	Phosphine
drinking/ground	Phosphine
Air	Phosphine

**Monitoring/Enforcement methods**

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant, no MRL proposed by the RMS, no residue definition for monitoring
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-PND 0.0025 mg/kg (milk, muscle, liver)
Soil (analytical technique and LOQ)	Not relevant
Water (analytical technique and LOQ)	GC-PND 0.1 µg/L (surface water) GC-FPD 0.1 µg/L (drinking and surface water)
Air (analytical technique and LOQ)	Photometric determination at 625 nm 25 µg/m <sup>3</sup> (for enforcement of the occupational exposure limit)
Body fluids and tissues (analytical technique and LOQ)	Not relevant, since phosphine will be quickly exhaled or metabolised to phosphates should it be incorporated

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

with regard to physical/chemical data	F
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**2.8.3.3 Appendix III.3: Chapter 3 (impact on human and animal health)****Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)**

Rate and extent of oral absorption ‡	Ready absorption of phosphine through the lungs and after oral exposure
Distribution ‡	Widely distributed
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	Rapid excretion with urine as hypophosphite and phosphite and via lungs as phosphine
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 <sub>50</sub> oral ‡	8.7 mg/kg bw (Aluminium phosphide)	
Rat LD <sub>50</sub> dermal ‡	Ca. 460-900 mg/kg bw (Aluminium phosphide)	
Rat LC <sub>50</sub> inhalation ‡	≤11 ppm (> 0.015 mg PH <sub>3</sub> /L air or > 2.8 mg/kg bw) – 51 ppm (0.072 mg PH <sub>3</sub> /L air) (4 h exposure, whole body) (Phosphine)	
Skin irritation ‡	Not irritant	
Eye irritation ‡	Not irritant	
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 zink phosphide)	

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

Target / critical effect ‡	Mortality	
Relevant oral NOAEL ‡	No reliable data, no study required	
Relevant dermal NOAEL ‡	No data, no study required	
Relevant inhalation NOAEL ‡	NOAEL 3 ppm (equivalent to 1.1 mg/kg bw/d), rat 90-d, the highest dose tested	

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

No evidence of a genotoxic potential	
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### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

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

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

#### Reproduction toxicity

Reproduction target / critical effect ‡	No data, justification given
Relevant parental NOAEL ‡	No data, justification given
Relevant reproductive NOAEL ‡	No data, justification given
Relevant offspring NOAEL ‡	No data, justification given

#### Developmental toxicity

Developmental target / critical effect ‡	Rat: Mortality of dams
Relevant maternal NOAEL ‡	Rat, developmental study, inhalation: 4.9 ppm (equivalent to 1.9 mg/kg bw/d) No data on rabbits, justification given
Relevant developmental NOAEL ‡	Rat, developmental study, inhalation: 4.9 ppm (equivalent to 1.9 mg/kg bw/d) No data on rabbits, justification given

### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL (acute study, inhalation): 40 ppm PH <sub>3</sub> (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): 3 ppm 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 on 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 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
<b>Phosphine</b>			
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 PH<sub>3</sub>/g calcium phosphide

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

Default value 10 % for calcium phosphide and PH<sub>3</sub> (based on expert judgement)

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

Operator	Exposure assessments considering results of different field studies and publications: Use for the control of rodents in burrows: acceptable without the use of personal protective equipment.
Workers	Acceptable
Bystanders	Acceptable

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

Calcium phosphide

T+; R 15/29-28-32 (up to 29<sup>th</sup> ATP)

Xn; R 21 (proposed by BfR)

Phosphine

T+; R 26-34 (up to 29<sup>th</sup> ATP)

### 2.8.3.4 Appendix III.4: Chapter 4 (residues)

#### 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  
(proposed definition: calcium phosphide + phosphine)

Plant residue definition for risk assessment

not required  
(proposed definition: calcium phosphide + phosphine)

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

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

Expected intakes by livestock  $\geq 0.1$  mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues  $\geq 0.01$  mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

Ruminant:	Poultry:	Pig:
Conditions of requirement of feeding studies		
no	no	no
no	no	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		
no	no	no
no	no	no
no	no	no
no	no	no
no		
	no	

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses  (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR  (c)	STM  (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

### 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)
IENTI (% ARfD)	not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not required
Factors included in IENTI 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 trans- ferred (%)  (Optional)
		Transfer factor	Yield factor	
not applicable				

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

not required

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

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### 2.8.3.5 Appendix III.5: Chapter 5 (fate and behaviour in the environment)

#### 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 molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual Calcium cations will prevail. The former 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 and in this open field environment anaerobic conditions are not expected to be relevant

#### 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*
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\* 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 molecule, and therefore “biological degradation” can intrinsically not be a relevant removal mechanism in the environment. Instead, hydrolysis leading to the evolution of phosphine and residual Calcium cations will prevail. According to laboratory studies analysing the degradation of phosphine maximum  $\text{PH}_3$  concentrations in soil occurred 2 h after application of calcium phosphide.

#### Laboratory studies ‡

Ca <sub>3</sub> P <sub>2</sub>	<p>Aerobic conditions</p> <p>Calcium phosphide is degraded in soil to yield phosphine gas as an intermediate, and Calcium cations. 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 the DT<sub>50</sub> of PH<sub>3</sub> in the gas phase was found to be 2-13 d (low humus content), 3 – 11 h (high humus content).</p>
Ca <sub>3</sub> P <sub>2</sub>	<p>Anaerobic conditions</p> <p>According to laboratory studies performed in 2 soils the maximum DT<sub>50</sub> of PH<sub>3</sub> in the gas phase was found to be 15 d.</p>

#### Field studies ‡

Parent	Aerobic conditions: not relevant*
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\*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 <sub>3</sub>	Aerobic conditions							
Soil type	Location	X <sup>1</sup>	pH	Depth (cm)	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	St. (r <sup>2</sup> )	Method of calculation
<b>Geometric mean/median (DT<sub>50</sub>) *</b>					<b>6 h</b>	<b>&lt; 2 d</b>		

\* 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 PH<sub>3</sub> in soil. The results show that PH<sub>3</sub> 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 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.

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

active substance: not relevant  
metabolite  $PH_3$  (gas): not relevant

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

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### 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. In contrast, a contamination of surface waters is excluded by the specific conditions of use. Therefore, an estimation of predicted environmental concentrations in surface waters and consequently in sediments is not considered to be required.

### 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 to any relevant degree, therefore an estimation of a  $PEC_{gw}$  is not considered to be required

### 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 34600 hPa, 20 °C):  
 $DT_{50}$  of 24 hours. OH (24 h) concentration assumed =  $5 \times 10^5$  OH/cm<sup>3</sup> (rate constant  $1.6 \times 10^{-11}$  cm<sup>3</sup>/mol sec)

### $PEC_{air}$

#### $PEC_{(air)}$

Maximum concentration

Due to the high vapour pressure of  $PH_3$  discharge into the air caused by aeration after application is possible. However,  $PH_3$  degrades rapidly ( $DT_{50}$  air 24 h) and contamination of the environment is unlikely.

### Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).

Soil:  $PH_3$   
Surface Water:  $PH_3$   
Sediment:  $PH_3$   
Ground water:  $PH_3$

Air: PH<sub>3</sub>

#### 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

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#### 2.8.3.6 Appendix III.6: Chapter 6 (effects on non-target species)

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Rat	Metabolite PH <sub>3</sub>	Acute, inhalation 4 hours	LD <sub>50</sub> 0.015 mg/L air / 11 ppm 2.8 mg PH <sub>3</sub> /kg bw	Not relevant
Rat	Metabolite PH <sub>3</sub> gener- ated from AIP	Long-term 2 years dietary study		No adverse effects at aver- age residual phosphine levels of 5 ppb in diet (2000 ppm PH <sub>3</sub> during fumiga- tion)
Rat	Metabolite PH <sub>3</sub>	Long-term, 2-generation inhalation study:	NOAEC 3 ppm (air) (1.13 mg/kg bw/day)	
Rat	Metabolite PH <sub>3</sub> gener- ated from AIP	Long-term 2- generation die- tary reproduction study		No adverse effects  Fed with PH <sub>3</sub> fumigated diet (2000 ppm PH <sub>3</sub> during fumiga- tion)
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)

Polytanol is a solid granule containing 18 % of calcium phosphide as the active ingredient (fumigation agent, the metabolite phosphine is responsible for toxicity).

#### Birds

Polytanol is a dry granular solid which is used only underground (15 – 25 cm) with minimal possibilities for access by birds.

Due to the special application method birds are not considered to be adversely affected by the use of calcium phosphide as a rodenticide.

The risk for secondary poisoning of birds of prey is negligible. Poisoned voles contain only minimal quantities of phosphine. After inhalation of phosphine the rapid process of conversion in non-hazardous phosphate and phosphate by oxidising begins in the voles.

#### Non-target mammals

Due to the GAP use of Polytanol, placing the product underground into target animal runs and tunnels, no short- or long-term risk from dietary exposure is indicated for terrestrial vertebrates. With the exception of rodents, an acute risk arising from consumption of Polytanol can also be excluded due the low attractiveness and the hardness of the granule. Only a theoretical risk arising from spilled material can not totally excluded, but was shown to be very unlikely,

because of the disagreeable, garlic smell of the product. The risk for secondary poisoning was demonstrated to be negligible, and no risk is given from other routes of exposure.

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity <sup>1</sup> (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 <sub>50</sub>	0.105 <sup>1)</sup>
<i>Oncorhynchus mykiss</i> Literature data	Phosphine	96 hr (static) not validated	Mortality, LC <sub>50</sub>	5.6 <sup>1)</sup>
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 <sub>50</sub>	0.117 <sup>1)</sup>
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				

<sup>1)</sup>calculated from values given for AIP

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

In consideration of the intended GAP use of Polytanol as a rodenticide, which is used only underground (15 – 25 cm), any relevant exposure of surface water by Polytanol is not ex-



pected. Due to the special application method aquatic organisms are not considered to be adversely affected by the use of calcium phosphide as a rodenticide. 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. In contrast, a contamination of surface waters is excluded by the specific conditions of use. Therefore, experimental investigations of the toxicity of this product in aquatic organisms are not considered to be required and the risk from the proposed use of polytanol to aquatic organisms is acceptable.

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

<sup>1</sup> only required if log Pow > 3.

‡ based on total <sup>14</sup>C or on specific compounds

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

Test substance	Acute oral toxicity (LD <sub>50</sub> µg/bee)	Acute contact toxicity (LD <sub>50</sub> 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 <sup>1</sup>		
Metabolite 1		
Field or semi-field tests	not required	

<sup>1</sup> for preparations indicate whether end point is expressed in units of as or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
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 (LR <sub>50</sub> g/ha <sup>1</sup> )
<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 rhopalosiphii</i> ‡	---	Mortality	

<sup>1</sup> 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 <sub>50</sub> g/ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
-- see above	<i>Typhlodromus pyri</i>	-- see above	--	--	2
-- see above	<i>Aphidius rhopalosiphii</i>	-- see above	--	--	2

<sup>1</sup> indicate distance assumed to calculate the drift rate

Test substance	Species	Effect (LR <sub>50</sub> g /ha)	TER off-field <sup>1</sup>	Trigger value
-- see above		-- see above	Not relevant	10

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

### Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) <sup>1, 2</sup>	Endpoint	% adverse effect <sup>3</sup>	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 %

<sup>1</sup> indicate whether initial or aged residues

<sup>2</sup> for preparations indicate whether dose is expressed in units of as or preparation

<sup>3</sup> 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 <sub>3</sub> : 6-10 hours = DT <sub>50 field</sub> 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 <sub>50</sub> > 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 7.1.1.1/01) earthworms are not considered to be adversely effected by the use of calcium phosphide as a rodenticide			
Other soil macro-organisms			
Soil micro-organisms			
Nitrogen mineralisation	Polytanol (28 % Ca-phosphide)	28 days	< 25 % effect at day 28 at 66.5 mg product/kg d.w. soil. Not valid
Dehydrogenase activity	Polytanol (28 % Ca-phosphide)	28 days	< 25 % effect at day 28 at 66.5 mg product/kg d.w. soil. Not valid
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 <sup>1</sup>	TER	Trigger
Earthworms (acute, chronic) not relevant, justification accepted (no relevant exposure)					

## 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 <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g/ha) <sup>2</sup>	TER	Trigger
	as ‡ and Preparation	Not relevant	Not relevant			

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

<sup>2</sup> 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 <sub>3</sub>
water	PH <sub>3</sub>
sediment	PH <sub>3</sub>
air	PH <sub>3</sub>
groundwater	PH <sub>3</sub>

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

Active substance

Phosphine, metabolite

According to Annex I to Directive 67/548/EEC
N, R <sub>50</sub> Dangerous for the environment Very toxic to aquatic organisms
N, R <sub>50</sub> Dangerous for the environment Very toxic to aquatic organisms

Product

RMS/peer review proposal in compliance with Directive 1999/45/EC
N, R <sub>50</sub> Dangerous to the environment Very toxic to aquatic organisms

**Appendix 1 - Compound code(s) used in the list of endpoints**

Code/Trivial name	Chemical name	Structural formula
calcium phosphide	calcium phosphide	calcium phosphide: $\text{Ca}_3\text{P}_2$
phosphine	phosphine	phosphine: $\begin{array}{c} \text{H} & & \text{H} \\ & \diagdown & / \\ & \text{P} & \\ &   & \\ & \text{H} & \end{array}$

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## **Level 3**

**Calcium phosphide**

**Proposal for the Decision**

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### **3 Proposed decision with respect to the application for inclusion of the active substance in Annex I**

#### **3.1 Background to the proposed decision**

##### **Identity of the active substance**

Calcium phosphide is a solid that evolves phosphine at contact with water.

##### **Data on application**

Calcium phosphide is a toxic gas for the control of common voles and moles. The evaluation is based on the intended uses in vegetables, fruit, ornamental plants, agricultural crops and grassland with an application rate of min. 8 g (21 pieces granule) per run/tunnel and max. 10 g pro run/tunnel and a maximum field application rate of 8 – 10 kg/ha. The number of treatments usually is 1, at any time of the year.

##### **Analytical methods for formulation analysis**

Analytical methodology is available for the determination of the active substance and the impurities in the technical material as manufactured and for the active substance in the formulation.

Not all methods are fully validated.

##### **Analytical methods for residue analysis**

The available data on analytical methods for determination of residues will be considered sufficient to support an Annex I inclusion of calcium phosphide. Concerning analytical methods (residue) all studies required by Directive 91/414/EEC are available.

##### **Toxicology and metabolism**

Potential effects on human health have been assessed in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC for the uses as proposed by the applicants. For the toxicological evaluation of calcium phosphide a waiving concept was used. The available data and statements of the notifier on mammalian toxicology, mutagenicity and animal metabolism are regarded to fulfil the requirements of Directive 91/414/EEC. The dossier is considered to adequately and sufficiently support the risk assessment of calcium phosphide with regards to human health. Like other metal phosphides calcium phosphide in contact with moisture decomposes to calcium hydroxide and phosphine, the toxicological principle. Therefore, other metal phosphides are regarded as adequate model compounds for calcium phosphide and studies with zinc phosphide, aluminium phosphide, magnesium phosphide and phosphine were taken into account for the evaluation of calcium phosphide. The proposal for the reference values for calcium phosphide is 0.03 mg/kg bw/d for the acceptable daily intake (ADI) as well as for the acceptable operator exposure level (AOEL) and 0.051 mg/kg bw for the acute reference dose (ARfD). The proposal for the reference values for phosphine is 0.011 mg/kg bw/d for the acceptable daily intake (ADI) as well as for the acceptable operator exposure level (AOEL) and 0.019 mg/kg bw for the acute reference dose (ARfD). According to the conclusions of the human health risk assessment of calcium phosphide harmful effects on the health of operators, bystanders, workers or consumers are not to be expected when the plant protection product is used in accordance with good plant protection practice for the control of rodents in burrows.

Based on submitted estimations and/or measurements it can be concluded that the risk to operators from exposure to phosphine following rodent burrow treatment is considered acceptable without the use of personal protective equipment (no PPE/RPE). It was also demonstrated that bystander exposure and worker exposure will be acceptable.

### **Residue data**

The available information with respect to residues is considered sufficient to support an Annex I inclusion of calcium phosphide. The indoor use of the calcium phosphide containing product "Polytanol" as a fumigant for insect control in storage protection is not intended. In case of the outdoor use of calcium phosphide as rodent and non-rodent control in burrows a direct contact with plants is not to be expected. The active substance reacts in contact with moisture to calcium hydroxide and phosphine which itself in soil is finally transformed to phosphorus compounds which are natural soil constituents and plant nutrients. Residues of concern are not to be expected. Therefore, the submission of residue data or the performance of adequate tests is considered not to be necessary.

### **Environmental fate and behaviour**

Calcium phosphide is very rapidly hydrolysed in soil to yield phosphine gas as an intermediate. About 2 hours after application the maximum  $\text{PH}_3$  concentrations were observed. 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 readsorbed onto soil and subsequently be degraded. Based on results of a field study the  $\text{DT}_{50}$  of  $\text{PH}_3$  was estimated in the range of 6 to 10 hours ( $\text{DT}_{90}$  below 2 days). Field experiments also demonstrated that the vertical spreading rate of  $\text{PH}_3$  in soil is very low. Due to the type of application and its fate and behaviour in soil it is not expected that calcium phosphide will reach surface water or groundwater. No emission of calcium phosphide into air is to be expected. The degradation product phosphine is volatile. The half-life can be estimated to be 24 h via reaction with OH radicals. The evolved gas will mainly remain and spread in the burrows, since phosphine gas is heavier than air and the vertical spreading rate in soil is very low. Gas escaping the burrows via uncovered holes will remain close to the soil surface. Gasing operations are normally conducted in areas where burrows can be sufficiently sealed to contain the phosphine. The calcium phosphide containing granules are applied directly into the burrow systems by an applicator, drop tube or drop gun. No quantitatively important exposure of non-target areas have to be expected.

### **Ecotoxicology**

The use of calcium phosphide containing plant protection products involves laying out of such products in burrow systems. Organisms inhabiting burrows, e.g. badgers, foxes and adders could be affected; therefore areas where these animals can be expected must not be treated. This should be considered in the national authorisation on MS-level. The special conditions of use of POLYTANOL exclude the possibility that non-target terrestrial vertebrates outside the burrows come into contact with calcium phosphide or phosphine gas. Additionally, the strong smell of garlic, ammonia and carbide will drive off any bird or mammal coming near. Therefore an unacceptable risk from the proposed use to non-target mammals and birds is not expected. Since any relevant exposure of surface waters with calcium phosphide is not expected, the existing information on toxicity to aquatic organisms is considered sufficient, so that further testing of the effects on other aquatic organisms or aquatic plants was not considered to be required predominantly due to a lack of exposure. Therefore, it is concluded that there is no unacceptable risk from the proposed use of POLYTANOL to aquatic organisms.

No studies have been conducted on the toxicity of phosphine to arthropods. Even when some single individuals will be killed inside or in direct contact to the burrows, eggs and pupae will survive the low dosages used in the field. Therefore no unacceptable risk from the proposed use of POLYTANOL granule is expected to the whole arthropod population. Calcium phosphide does not present a risk to the whole earthworms population for the same reasons as stated above, other soil non-target macro-organisms, soil micro-organisms, non-target plants and biological methods of sewage treatment when used as recommended.

### 3.2 Proposed decision concerning inclusion in Annex I

[REDACTED]

### 3.3 Rationale for the proposal

[REDACTED]

[REDACTED]

The information in sections 3.2 and 3.3 has been removed upon request by the EU Commission as it relates to risk management recommendations or proposals.

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## **Level 4**

**Calcium phosphide**

**Demand for Further Information**

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## **4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I**

### **4.1 Identity of the active substance**

Annex II, point 1.9 and 1.10:

Clarification concerning the proposed specification of the calcium phosphide and the impurity calcium oxide is missing. Furthermore, information on the maximum content for calcium phosphate is missing.

Justification:

The proposed values are not supported by the given batch analyses. The content of calcium phosphide in two batches are below the minimum purity. In the case of calcium oxide the calculated values are far above the proposed maximum content. For calcium phosphate no proposal was given.

Annex II, point 1.9 and 1.10

The notifier should address the possible contamination of calcium phosphide with arsenic and lead, which have to be regarded as relevant impurities. Depending on this, further data could be necessary.

### **4.2 Physical and chemical properties of the active substance and of the formulation**

None.

### **4.3 Data on application and further information**

Annex III, point 4.6.1:

Neutralisation procedures for use in case of an accident are missing.

### **4.4 Classification and labelling**

None.

### **4.5 Methods of analysis**

#### **Analytical methods for formulation analysis**

Annex IIA, point 4.1.3

For the analytical method for the impurities 1 and 2 validation data in terms of the accuracy are missing.

#### **Analytical methods for residue analysis**

None.

## 4.6 Toxicology and metabolism

None.

## 4.7 Residue data

None.

## 4.8 Environmental fate and behaviour

None.

## 4.9 Ecotoxicology

### Effects on birds- Acute toxicity

Annex II, point 8.1.1

An English translation of the reference for the citation Kozhemyakin et al. (1971) is missing.