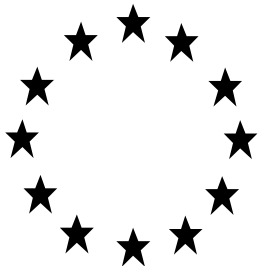
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Phostoxin WM
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Aluminium phosphide releasing phosphine (in the following also “Aluminium phosphide”)
Case No. in R4BP	BC-NK057543-30
Asset No. in R4BP	DE-0001522-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.00011 710-05-14-00011-01-00
Date	10.03.2023

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Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)
NA-APP	DE	No case number (submitted under 98/8/EC)	16.01.2013	First authorisation
NA-ADC	DE	BC-TD006504-51	26.02.2015	Administrative change (new classification)
NA-MIC	DE	BC-JF009027-56	07.05.2015	Minor change (add pack size)
NA-ADC	DE	BC-UG020813-41	17.11.2015	Administrative change (add. active substance manufacturer and trade name)
NA-ADC	DE	BC-LC027197-49	14.10.2016	Administrative change (add. trade name)
NA-AAT	DE	BC-XG034489-21	09.10.2017	Amendment by CA (amendment after appeal and court decision)
NA-AAT	DE	BC-NV037372-15	19.02.2018	Amendment by CA (removal of AS sources after 9th ATP entered into force)
NA-ADC	DE	BC-SR055293-14	29.11.2019	Administrative change (add. active substance manufacturer)
NA-ADC	DE	BC-PJ057411-39	26.02.2020	Administrative change (change of active substance manufacturer)
NA-AAT	DE	BC-QT066761-06	02.06.2021	Amendment by CA (amendment of expiry date)
NA-AAT	DE	BC-QN075950-16	09.06.2022	Amendment by CA (amendment of expiry date)
NA-AAT	DE	BC-XM082727-05	12.12.2022	Amendment by CA (amendment of expiry date)
NA-RNL	DE	BC-NK057543-30	10.03.2023	Renewal 2023
NA-ADC	DE	BC-JX089475-95	19.10.2023	Change of the name of the manufacturer of the biocidal product

NA-MIC	DE	BC-GS088241-24	23.04.2024	Minor change (addition of a target organism)

1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, Phostoxin WM with the active substance Aluminium phosphide (technical: 68% (pure: 56%) w/w) is used as a rodenticide (product-type 14) for the control of brown rats and water voles outdoors (application into burrow systems).

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance Aluminium phosphide including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.
2. The specific provisions from Inclusion Directive for the active substance Aluminium phosphide (Commission Directive 2009/95/EG).

Approval of the active substance
The active substance Aluminium phosphide is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

1. Products shall only be sold to and used by trained professionals;
2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level;

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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

Composition and formulation

The ready-to-use gas generating product Phostoxin WM contains the active substance Aluminium Phosphide.

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

One substance of concern has been identified.

Ammonium carbamate has been identified as substance of concern. Please refer to chapter 2.2.4 for further information.

Please refer to chapter 2.2 (Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were identified (please find more information in chapter 3.3).

The product has to be classified because of identified physical-chemical hazard(s) (see chapter 2.3). However, this does not lead to an unacceptable risk for end users (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

The substance Ammonium carbamate has been identified as substance of concern. However, the hazards resulting from the substance of concern can be sufficiently reduced to acceptable levels by additional risk mitigation measures.

Accordingly, the human health risk assessment for this product is based on the active substance and the substance of concern ammonium carbamate.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and in the Confidential Annex 5.1.1.2).

A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to trained professional users, bystanders and residents. Regarding trained professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and 3.8.4.6).

A risk assessment for the environment has been carried out for professional use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Phostoxin WM

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Detia Freyberg Produktion GmbH
Address of manufacturer	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
Location of manufacturing sites	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany

2.1.3 Manufacturer(s) of the active substance(s)

Active substance	Aluminium phosphide releasing phosphine
Name of manufacturer	Detia Freyberg GmbH
Address of manufacturer	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
Location of manufacturing sites	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany

Active substance	Aluminium phosphide releasing phosphine
Name of manufacturer	Sumitomo Chemicals India Limited
Address of manufacturer	13/14, Aradhana Ind Development Corp, Near Virwani Ind Estate, Goregaon (E) 400063 Mumbai

	India
Location of manufacturing sites	Plot No. 205 to 209, Bhuj - Mundra Road, Near Kera Village, 370 430 Gajod India

Active substance	Aluminium phosphide releasing phosphine
Name of manufacturer	Shenyang Harvest Agrochemical Co, Ltd
Address of manufacturer	100 Jidong Road, Linsheng Town 10108 Shenyang China
Location of manufacturing sites	100 Jidong Road, Linsheng Town 10108 Shenyang China

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Aluminium phosphide releasing phosphine	Aluminium phosphide	Active substance	20859-73-8	244-088-0	technical: 68 (pure: 56)
Ammonium carbamate	Ammonium carbamate	Non-active substance	1111-78-0	214-185-2	21

- Information on the full composition is provided in the confidential[3] annex (see chapter 5).

- Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

[3] Access level: “Restricted” to applicant and authority

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  - Yes ☒
  - No ☒ (The technical equivalence of the active substance from the new sources was established by DE (under BPD) and ECHA, see asset number EU-0007261-0000 and EU-0020493-0000, respectively)

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list, the endocrine disruptor assessment list or any other EU decision there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

2.2.4 Information on the substance(s) of concern

The following substance(s) of concern was/were identified:

- Ammonium carbamate (CAS No. 1111-78-0)

➢ (Further) information on the substance(s) of concern is provided in chapter 3.6.2.8.
➢ (Further) information on the substance(s) of concern is provided in the confidential annex (chapter 5.1.2).

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type of formulation

GE - Gas generating product

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance aluminium phosphide and the substance of concern ammonium carbamate, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance Aluminium phosphide is based on Commission Regulation (EU) No. 790/2009 (1st ATP):
Aluminium phosphide is classified as aquatic acute 1, H400, GHS09.
The biocidal product contains 56 % of the a.s. which triggers the classification of the b.p.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Water-react. 1	H260
Acute Tox. 2 (oral)	H300
Acute Tox. 1 (dermal)	H310
Acute Tox. 1 (inhalation)	H330
Eye Dam. 1	H318
Skin Irrit. 2	H315
Aquatic Acute 1	H400

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS02	
	GHS05	
	GHS06	

4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Labelling	**Code**	**Pictogram / Wording**
	GHS09	
Signal word	-	Danger
Hazard statements	H260	In contact with water releases flammable gases which may ignite spontaneously.
	H300	Fatal if swallowed.
	H310	Fatal in contact with skin.
	H330	Fatal if inhaled.
	H315	Causes skin irritation.
	H318	Causes serious eye damage.
	H400	Very toxic to aquatic life
Supplemental hazard information	EUH029	Contact with water liberates toxic gas.
	EUH032	Contact with acids liberates very toxic gas.
	EUH070	Toxic by eye contact.
		Hazardous to wildlife
Supplemental label elements	-	-
Precautionary statements	P223	Do not allow contact with water.
	P231 + P232	Handle and store contents under inert gas/...* Protect from moisture.
	P260	Do not breathe dust/gas
	P262	Do not get in eyes, on skin, or on clothing
	P270	Do not eat, drink or smoke when using this product.
	P271	Use only outdoors or in well-ventilated areas.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P284	[In case of inadequate ventilation] wear respiratory protection.
	P301 + P330 + P310	IF SWALLOWED: Rinse mouth. Immediately call a POISON CENTER or doctor/…
	P302 + P335 * P352 +P310	IF ON SKIN: Brush off loose particles from skin. Wash with plenty of water/…Immediately call a POISON CENTER/ doctor/…
	P304 + P340 +P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor/…

Labelling		
	Code	**Pictogram / Wording**
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
	P320	Specific treatment is urgent (see First Aid on this label).
	P361	Take off immediately all contaminated clothing.
	P370 + P378	In case of fire: Use ... to extinguish.**
	P402 + P404	Store in a dry place. Store in a closed container.
	P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to in accordance with local/regional/national/international regulations.
Note	-	

* ... Manufacturer/supplier to specify the appropriate liquid or gas if 'inert gas' is not appropriate.

** ... Manufacturer/supplier to specify appropriate media.

H400 would trigger **P273** (Avoid release to the environment.). However, it was not included by the German CA because P 273 is not to be assigned according to Part 1 of Annex IV to Regulation (EC) No 1272/2008, as the intended use (application in soil, burrows) contradicts this.

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[5]

2.4.1 Use 1 appropriate for authorisation – Brown rat

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*), (Juveniles, Adults)
Field(s) of use	Outdoor use (application into clearly locatable burrow systems that are separated from burrow systems of other rodents and building structures); in all types of non-agricultural areas where rodent burrows can cause damage e. g. railway (embankments, tracks, gravel edges, border routes), dams and flood dikes, sport venues (e.g. golf courses), gardens and parks, port traffic areas, airfields and other kinds of technical areas. Use against brown rats (*Rattus norvegicus*)
Application method(s)	Fumigation
Application rate(s) and frequency	1 Tablet (3 g) or 5 Pellets (0.6 g each) every 3-5 m burrow length in light soil or every 8-10 m in all other soil types. Frequency: As often as re-infestation occurs.
Category(ies) of users	Trained professional
Pack sizes and packaging material	90 g, 100 g, 250 g and 1 kg sealed aluminium flasks/cans with a plastic screw lid The sealed aluminium flasks/cans must be compatible for use with an applicator.

2.4.1.1 Use-specific instructions for use

See chapter 2.5

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

5 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See chapter 2.5

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See chapter 2.5

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation – Water voles

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Water voles (*Arvicola amphibius*), (Juveniles, Adults)
Field(s) of use	Outdoor use (application into clearly locatable burrow systems that are separated from burrow systems of other rodents and building structures); in all types of non-agricultural areas where rodent burrows can cause damage e. g. railway (embankments, tracks, gravel edges, border routes), dams and flood dikes, sport venues (e.g. golf courses), gardens and parks, port traffic areas, airfields and other kinds of technical areas.
Application method(s)	Fumigation
Application rate(s) and frequency	1 Tablet (3 g) or 5 Pellets (0.6 g each) every 3-5 m burrow length.
Category(ies) of users	Trained professional
Pack sizes and packaging material	90 g, 100 g, 250 g and 1 kg sealed aluminium flasks/cans with a plastic screw lid The sealed aluminium flasks/cans must be compatible for use with an applicator.

2.4.2.1 Use-specific instructions for use

See chapter 2.5

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See chapter 2.5

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See chapter 2.5

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

See chapter 2.5.2

2.5.2 Risk mitigation measures

1) To avoid risks to man and the environment, comply with the instructions for use.

2) Avoid any unnecessary contact with the product. Misuse may cause adverse effects on health. Use all contents of the flask in one operation.
3) Inhabitants and/or authorised users of premises directly adjacent or in a distance of up to 25 m to the fumigated area shall be informed adequately at least three days before fumigation in writing about the risk posed by the biocidal product. The information includes at least:
    a) the name of the fumigant with the authorisation number and
    b) the name of the active substance,
    c) information about the way of exposure (inhalation) as well as
    d) the limited sensory perception of phosphine through impurities (carbide- or garlic-like, foul-smelling fish),
    e) the request to leave immediately the area after olfactory perception (the smell is often only perceptible above health-based limits),
    f) description of disease symptoms of intoxication after inhalation;
    g) description of recommended first-aid measures and
    h) further sources of information (manufacturer of the biocidal product, name and telephone number of the user, competent poison control centre).
4) The head of fumigation has to set up a danger area for safety of the general public as well as farm and domestic animals. The danger area shall not undercut a size of 10 m around the treated area.
5) If the danger area is accessible for the general public, farm and/or domestic animals, it has to be secured before the beginning of the fumigation and for two consecutive days, at least
    a) by an appropriate cordon (e.g. red-white barrier tape),
    b) a warning sign: acute toxicity symbol (skull and crossbones) with following features:
        i. “Danger because of soil fumigation. Very toxic gases! Danger to life! No trespassing!”
        ii. The name of the biocidal product as well as date and time of the fumigation must be stated.
        iii. The address of the responsible person as well as adequate emergency telephone numbers must be labelled.
6) As a precautionary measure, a safety distance of at least 25 m to vicinal areas that are not used agriculturally or for forestry must be respected. If by organisational measures (signposting, barrier tape, written agreement with the owners or authorised users etc.), it can be ensured that no persons or farm resp. domestic animals stay in the vicinal areas, the safety distance may be reduced. The specifications for the danger area and the duration of the control measures remain unaffected.
7) Outside the established danger area, the fumigant must not be detectable. For detection, a measurement method with a limit of detection (LOD) equal or lower than 0.01 ppm

(corresponding to 0.014 mg/m^3) must be used. Until release, the danger area may only be entered by people who have to perform an activity related to the fumigation.

8) The pest controller (or a person with expert knowledge about chemical analysis of the used fumigant) has to check regularly before signing off if in the ambient air outside the danger area, the concentration of the fumigant is beyond the limit value. The measurement results and, if necessary, the safety measures taken must be recorded in writing and stored with the documentation of the fumigation.
9) The use of eye protection during handling of the product is mandatory. Eye protection shall be indicated on the label and in the safety data sheet to prevent from local effects of eye irritation because of the substance of concern ammonium carbamate.
10) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
11) Appropriate Respiratory personal protective equipment (RPE) shall be available.
12) Use of personal gas detector is mandatory during handling of the product (including cleaning and re-entry). If the phosphine concentration exceeds 0.1 ppm or under unfavourable conditions appropriate, respiratory protective equipment (RPE) should be used. Re-entry without RPE may only take place after checking that the phosphine concentration is below 0.1 ppm.
13) The applicator shall be cleaned after handling. Cleaning shall be done outdoors, preferably during slightly windy conditions (in consideration of wind direction), and by careful avoidance of exposure of humans and animals by dust or phosphine-gas. A container, sufficiently dimensioned, is to be filled with water of reduced surface tension (washing-up liquid). All components of the applicator shall be left in water bath for at least 4 hours. During this period, the area has to be left. Then the applicator shall be washed with fresh water until all parts are clean. Before reusing, all components shall be absolutely dry, and the applicator has to be technically checked.
14) The treated area has to be inspected at appropriate intervals to ensure that all burrows have remained blocked and not reopened by any target-organism.
15) Do not use in case of bad weather conditions (like intense fog, rain, heavy moisture penetration of soil).
16) Treated burrows must be in adequate distance to inhabited houses (at least 10 m).
17) Furthermore, the product must be applied to all burrow entrances, in order to prevent target animals from escaping by untreated burrows.
18) It has to be ensured that treated burrows do not meet cellars or other parts of housings.
19) No use in Water Protection Areas and in surrounding of surface waters (safety distance not less than 10 m).
20) Safely close the hole in which pellets/tablets are applied with a plug.

21) The use is restricted to application by the help of an applicator (according to Dir. 2009/95/EC). The authorisation holder has to specify the type of applicator. At least one adequate applicator shall be indicated (manufacturer, product name).
22) Before fumigation, it has to be controlled that no non-target organisms are staying in the object to be fumigated.
23) Areas where other burrowing animals can be expected must not be treated.
24) At first the target organisms have to be identified, mainly through inspection of the burrow systems (i.e. form of the heap of earth). The underground tunnel system can be located with a search rod.
25) Additionally, the burrow system has to be tested for inhabitation to prevent unnecessary exposure of the environment.
26) Application only into clearly locatable burrow systems that are separated from burrow systems of other vertebrates and building structures.
27) Before application, ensure there is no connection between the burrow system and sewers.
28) This product must not be placed or allowed to remain on the ground surface.
29) Avoid uncontrolled release of the product to the environment.
30) For use against Brown rats (*Rattus norvegicus*) (Use #1): Use this product as accompanying method together with either traps or bait products.

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
Immediately initiate life support measures, thereafter call a POISON CENTRE.

IF IN EYES: Remove any rests of the product. Rinse with plenty of water for at least 15 minutes. Call 112/ambulance for medical assistance.

IF ON SKIN: Take of all contaminated clothing. Remove any rests of the product from skin. Rinse with plenty of water. After washing the skin: Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
Immediately initiate life support measures, thereafter call a POISON CENTRE.

IF SWALLOWED: Do NOT induce vomiting. Immediately call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.

2.5.4 Instructions for safe disposal of the product and its packaging

1)	Conditions for controlled discharge including leachate qualities on disposal: Under normal circumstances practical no residues for disposal will occur during the intended use. For active substance, biocidal product and residues waste code #: 061301 according to Guideline 2001/118/EC is applied. It is recommended that only degassed material should be disposed of under observation of the prevailing regulations (waste code #: 060316 according to Guideline 2001/118/EC)
2)	The product and/or its container must be disposed of as hazardous waste.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

1)	Keep cool.
2)	Protect from moisture/water.
3)	Store in a dry place.
4)	Store in a closed container.
5)	Store in a well-ventilated place.
6)	Keep only in the original container.
7)	Store locked up.
8)	Shelf-life: 60 months

2.5.6 Other information

Hazardous to wildlife.

2.6 Packaging

Table 4

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Flasks	90 g, 100 g, 250 g and 1 kg	Aluminium	PP	Trained professional	Yes
Cans	90 g, 100 g, 250 g and 1 kg	Aluminium	PP	Trained professional	Yes

The sealed aluminium flasks/cans must be compatible for use with an applicator.

3 Assessment of the product

3.1 Intended use(s) as applied for by the applicant

3.1.1 Intended use 1 – Brown rat

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*), (Juveniles, Adults)
Field(s) of use	Outdoor use (application into clearly locatable burrow systems that are separated from burrow systems of other rodents and building structures); Use against brown rats (*Rattus norvegicus*) low and medium infestation. Food protection; health protection; material protection; stored product protection (As long as the indended use is not covered by the scope of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.)
Application method(s)	Fumigation
Application rate(s) and frequency	1 Tablet (3 g) or 5 Pellets (0.6 g each) every 3-5 m burrow length in light soil or every 8-10 m in all other soil types.
Category(ies) of users	Trained professional[6]
Pack sizes and packaging material	90 g, 100 g, 250 g and 1 kg sealed aluminium flasks/cans with a plastic screw lid The sealed aluminium flasks/cans must be compatible for use with an applicator.

6 For harmonisation the wording was changed from the “Specialised professional” (used in the first PAR upon authorisation in 2013) to “Trained professional”

3.1.2 Intended use 2 – Voles

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Voles (*Arvicola terrestris*), (Juveniles, Adults)
Field(s) of use	Food protection; health protection; material protection; stored product protection (As long as the intended use is not covered by the scope of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.)
Application method(s)	Fumigation
Application rate(s) and frequency	1 Tablet (3 g) or 5 Pellets (0.6 g each) every 3-5 m burrow length in light soil or every 8-10 m in all other soil types.
Category(ies) of users	Trained professional[6]
Pack sizes and packaging material	90 g, 100 g, 250 g and 1 kg sealed aluminium flasks/cans with a plastic screw lid The sealed aluminium flasks/cans must be compatible for use with an applicator.

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visible inspection	-	solid, pellet or tablet	-
	SOP-PR-015 (Visible inspection)	PHOSTOXIN 56 GE tablets Purity 56 % AlP Batch no. 473208-8	solid, tablet	BioGenius GmbH.; Report no.: Mo4498
Colour at 20 °C and 101.3 kPa	Visible inspection	-	grey	-
	SOP-PR-015 (Visible inspection)	PHOSTOXIN 56 GE tablets Purity 56 % AlP Batch no. 473208-8	black-greyish	BioGenius GmbH; Report no.: Mo4498
Odour at 20 °C and 101.3 kPa	Olfactory inspection	-	“fishy”, “garlicy”	-
Acidity / alkalinity	-	-	The determination of the pH value respectively acidity / alkalinity of the product in aqueous solution is technically not feasible due to the violent reaction of aluminium phosphide in contact with water.	Waiving[7]

[7] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Relative density / bulk density	96/69/EEC A 3; OPPTS 830.7300	PHOSTOXIN WM Pellets Purity min. 56 % AlP Batch no. 440058	The relative density d_4^{20} of PHOSTOXIN WM Pellets is 2.01470 using the density of water at 4°C (0.999972 kg/L)	eurofins GAB GmbH (2009); report no.: S09-00496
	96/69/EEC A 3 OPPTS 830.7300	PHOSTOXIN Tablets Purity: 56 % AlP Batch no. 440714	The relative density d_4^{20} of PHOSTOXIN Tablets is 1.87864 using the density of water at 4°C (0.999972 kg/L)	eurofins GAB GmbH (2009); report-no: S09-02339
	CIPAC MT 186 (2001)	PHOSTOXIN Pellets Purity: 57.1 % Batch no. 54156-3	The average of the bulk density of the two tests is determined to 1.02 g/mL. The average of the tap density of the two tests is determined to 1.07 g/mL.	consilab Gesellschaft für Anlagensicherheit mbH (2019); report-no: CSL-19-0972.01
	CIPAC MT 186 (2001)	DETIA-GAS-EX T (tablets, other trade name for PHOSTOXIN) Purity: 55.3 % AlP Batch no. 54156-2	The average of the bulk density of the two tests is determined to 0.90 g/mL. The average of the tap density of the two tests is determined to 0.92 g/mL.	consilab Gesellschaft für Anlagensicherheit mbH (2019); report-no: CSL-19-0963.01
Storage stability test – **accelerated storage**	CIPAC MT 46.3; OECD No. 113	PHOSTOXIN WM Pellets 55.4 % - 58.4 % AlP; Batch no. 020604(1) – 020604(6)	Accelerated storage: 14 days at 54±2°C: The content of aluminium phosphide was decreased around 1.7 % by the conditions of the accelerated storage procedure.	Kesla Forschung & Service KG (2002): report no. KBL/2002/1373 ASTH
	CIPAC MT 46.3 SOP-PR-015 SOP-PR-28 OECD 109	PHOSTOXIN tablets Purity 56 % AlP Batch no. 473208-8	Accelerated storage: 18 weeks at 30±2°C in commercial packaging (aluminium bottles with PP screw cap and lid): **Appearance:**	BioGenius GmbH (2018); Report no.: Mo4498

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Before storage: black-greyish tablet After storage: black-greyish tablet **Weight loss:** No weight loss and no weight gain observed after 18 weeks at 30°C. **Density [g/cm³] (mean values):** Before storage: 1.791 After storage: 1.839 **AlP content [%] (mean values):** Before storage: 55.3 After storage: 57.4 (increase: 3.8%)	
Storage stability test – **long term storage at ambient temperature**	Determination of the AlP content: W. E White, A. H. Bushey, J. Am. Chem. Soc. 1944, 66, 1966-1972.	PHOSTOXIN WM Tablets Purity 56 % AlP Batch no. 410141; PHOSTOXIN WM Pellets Purity 56 % AlP Batch no. 41149	5 year storage test (at 10-28°C): For both products, pellets and tablets, the loss of active ingredient during the storage period of five years is < 5% (pellets: 3.1%, tablets: 0.9%). Degassing / disintegration times do not change significantly for either, pellets and tablets. This finding is also established for attrition and friability. Packaging material used in this test is identical to packaging in the commercially available product.	Detia R&D Laboratory (2011); Report no. Z0020a
	CIPAC MT 46.3 SOP-PR-015	PHOSTOXIN tablets Purity 56 % AlP	Long term storage: 60 months at 20±2°C in commercial packaging (aluminium bottles with PP screw cap and lid) in climatic chamber:	BioGenius GmbH (2018); Report no.: Mo4498

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	SOP-PR-28	Batch no. 473208-8	**Appearance:** Before storage: black-greyish tablet After storage: black-greyish tablet **Weight loss:** No weight loss and no weight gain more than 0.01% observed after 60 months at 20°C. **Density [g/cm³] (mean values):** Before storage: 1.791 After 12 months: 1.856 After 24 months: 1.865 After 36 months: 1.873 After 60 months:1.849 **AlP content [%] (mean values):** Before storage: 55.3 After 12 months: 54.0 (decrease: 2.4%) After 24 months: 54.1 (decrease: 2.2%) After 36 months: 56.6 (increase: 2.4%) After 60 months: 57.4 (increase: 3.8%)	
	CropLife International Technical Monograph N°17 (2009);	PHOSTOXIN Pellets Purity 56.6 % AlP Batch no. 47320-7	Long term storage: 60 months at ambient temperature (14.2 – 26.8°C) in commercial packaging (foil sealed aluminium bottle closed with plastic screw cap containing an aluminium foil seal):	CIP Chemisches Institut Pforzheim GmbH (2018); Report no.: 12D05207-01-SSFO

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	FAO/WHO Specifications for Pesticides (2010); SANCO/3030/99 rev. 4 (11/07/2000)		**Appearance/physical state, colour, odour:** Before storage: greenish-grey pellets with white spots, garlic-like odour After 6 months: no changes observed After 12 months: no changes observed After 24 months: no changes observed After 36 months: no changes observed After 48 months: no changes observed After 60 months: no changes observed **Weight loss:** No weight loss and no weight gain more than 0.02% observed after 60 months at ambient temperature. **AIP content [%] (mean values):** Before storage: 56.6 After 6 months: 57.6 (increase: 1.8%) After 12 months: 57.2 (increase: 1.1%) After 24 months: 56.6 (no change) After 36 months: 56.5 (decrease: 0.2%) After 48 months: 56.4 (decrease: 0.4%) After 60 months: 55.4 (decrease: 2.1%)	
Storage stability test – **low temperature stability test for liquids**			Not applicable (The biocidal product is solid).	Waiving[13]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Since the product is packed in an optically thick metal flask or can, light does not affect the shelf-life.	Waiving[13]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			**Effects of temperature:** The product stabilizer ammonium carbamate decomposes reversibly over about 35 ° C, therefore the product should be stored at lower temperatures. **Effects of humidity:** The product must be stored dry, because it reacts with humidity under release of phosphine.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	DIN 50905	Al-cans (99,5 % Al) filled with Detia-Wühlmauskiller . (a. s. 56 % AlP)	The tested material is corrosion resistant in the medium tested, according to the criteria applicable for transport tanks, and therefore suitable for transport of AlP.	Erning, W; Bäßler, R. (2009): Evaluation of the corrosive effect of aluminium phosphide on Al-cans according EU-Biocide Product Approval and DIN 50905, BAM, Berlin, Germany; unpublished report no.: VI.1/14627-e, September 22, 2009
Wettability			Not applicable. (Data are only required for solid preparations which are to be dispersed in water. The biocidal product (tablet/pellet) reacts with moisture/water and will not be dispersed in water.)	Waiving[13]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Suspensibility, spontaneity and dispersion stability			Not applicable. (Data are only required for wettable powders, water dispersible granules or powders and suspensions on dilutions with water. The biocidal product is a ready to use product (tablet/pellet) which reacts with moisture/water.)	Waiving[13]
Wet sieve analysis and dry sieve test			Not applicable. (Data are only required for wettable powders, suspension concentrates, capsule suspensions, water dispersible granules, dusts and granules. The biocidal product is a ready to use (tablet/pellet) product which reacts with moisture/water.)	Waiving[13]
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable. (Data are only required for dilutions. The biocidal product is a ready to use product (table/pellet) which reacts with moisture.)	Waiving[13]
Disintegration time	In-house method: In a lawn, an about 10 cm deep hole was dug. The soil was of natural wetness (autumn). Temperature of soil: 9 - 16 °C. In this hole 5 compacts, pellets or tablets, were placed in a row. The hole was subsequently covered with cardboard and soil. After the testing periods the hole was opened again. The degassed product was collected	PHOSTOXIN WM Tablets and Pellets Purity 56 % AlP	The PHOSTOXIN WM compacts were degassed nearly completely, pellets after 1 d, tablets after 5 d. Aluminium phosphide contents of up to 2 % are typical for the degassed residues of the product.	Detia R&D Laboratory (2011), report no. Z0020a

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	and divided into two fractions. The aluminium phosphide content of these fractions was determined.			
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 193	PHOSTOXIN WM Tablets and Pellets Purity 56 % AlP	The average friability of PHOSTOXIN WM Pellets was examined as 98.33 % (date of manufacture) and 98.24 % (after 5 years). The average attrition of PHOSTOXIN WM Pellets was examined as 1.5 % (date of manufacture) and 0.84 % (after 5 years). The average friability of PHOSTOXIN WM Tablets was examined as 98.50 % (date of manufacture) and 99.16 % (after 5 years). The average attrition of PHOSTOXIN WM Tablets was examined 1.93 % (date of manufacture) and 1.72 % (after 5 years). (Particle size distribution: Since the material has an attrition resistance of >98%, the particle size of the dust does not have to be determined.)	Detia R&D Laboratory (2011), report no. Z0020a
Persistent foaming			Not applicable. The product is not intended to be applied in water for use. (Data are only required for water diluted preparations.)	Waiving[13]
Flowability/Pourability/Dustability			Not applicable. (Data on flowability are only required for granular preparations, data on pourability are only required for suspensions.)	Waiving[13]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Burning rate — smoke generators			Not applicable. (The biocidal product is not a smoke generator.)	Waiving[13]
Burning completeness — smoke generators			Not applicable. (The biocidal product is not a smoke generator.)	Waiving[13]
Composition of smoke — smoke generators			Not applicable. (The biocidal product is not a smoke generator.)	Waiving[13]
Spraying pattern — aerosols			Not applicable. (The biocidal product is not an aerosol.)	Waiving[13]
Physical compatibility			Not applicable. (The biocidal product is not used together with other products.)	Waiving[13]
Chemical compatibility			Not applicable. (The biocidal product is not used together with other products.)	Waiving[13]
Degree of dissolution and dilution stability			Not applicable. (The biocidal product is a ready to use product (tablet/pellet) which reacts with moisture/water.)	Waiving[13]
Surface tension			Not applicable. (The biocidal product shows a violent reaction in contact with water.)	Waiving[13]
Viscosity			Not applicable (The biocidal product is solid).	Waiving[13]

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. PHOSTOXIN WM is a solid, black-greyish product in form of pellets or tablets, which have a “fishy” respectively “garlicy” odour. The relative density is about 2.015 for the pellets and about 1.879 for the tablets. The average bulk density is 1.02 g/mL for the PHOSTOXIN WM pellets and 0.90 g/mL for the PHOSTOXIN WM tablets. The average tap density is 1.07 g/mL for the PHOSTOXIN pellets and 0.92 g/mL for the PHOSTOXIN WM tablets. The shelf-life of PHOSTOXIN WM is 60 months (tablets and pellets). The product stabilizer ammonium carbamate decomposes reversibly over about 35 °C, therefore the product should be stored at lower temperatures. Since the active substance aluminium phosphide shows a violent reaction in contact with water, the product has to be stored dry. Both, PHOSTOXIN WM pellets and tablets, have an attrition resistance >98%. The PHOSTOXIN WM pellets and tablets were degassed nearly completely, pellets after 1 day, tablets after 5 days.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Screening procedure: DSC (OECD 113);	Phostoxin WM Pellets 56 % (w/w) AlP batch no.: 010919	-	Based on the available thermodynamic information from the DSC measurements, the mixture/biocidal product is not classified as explosive (no significant exothermal decomposition was observed up to a temperature of 500°C and the exothermic decomposition energy was below 500 J/g, therefore the test on explosion properties can be waived.). The test item has no explosive properties in the sense of the European Commission Regulation (EC) No. 440/2008, Method A. 14.	Siemens Axiva GmbH & Co. KG, report no.: 20011378.01
Flammable gases	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[8]
Flammable aerosols	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[7]
Oxidising gases	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[7]

[8] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified	-	-	Not applicable. (The definition of gases under pressure under CLP does not apply to PHOSTOXIN WM being a solid, intended to release phosphine only under conditions of application.)	Waiver[14]
Flammable liquids	study scientifically unjustified	-	-	Not applicable. (The biocidal product is neither a liquid nor a lowmelting point solid.)	Waiver[14]
Flammable solids	Preliminary test according to EU Method A.10	Phostoxin WM Pellets 56 % (w/w) AlP batch no.: 010919	-	It was not possible to ignite the test item. The test item is not a flammable solid.	Kesla Forschung & Service KG , report No. KBL/2001/1216 EZF
Self-reactive substances and mixtures	Expert statement/Justification for non-submission	-	-	Not applicable. (The DSC measurement of the product demonstrates no significant exothermal decomposition up to a temperature of 500 °C. Furthermore, the study does not need to be conducted since there are no chemical groups present in the components of the biocidal product which are associated with explosive or self-reactive properties with reference to the screening procedures in Appendix 6 of the UN-MTC, see Tables A6.1 and A6.3.)	Waiver[14]
Pyrophoric liquids	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[14]
Pyrophoric solids	Expert statement/Jus	-	-	Not applicable. (From the composition of the biocidal product and the structural formula of	Waiver[14]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	tification for non-submission			the components it can be concluded that the product is stable at room temperature and is not pyrophoric.)	
Self-heating substances and mixtures	Expert statement/Justification for non-submission	-	-	The main component and active substance of the biocidal product Aluminium phosphide is not a self-heating substance. As the further ingredients of the product composition are also not self-heating substances and as the DSC measurement of the product demonstrates no significant exothermal decomposition up to a temperature of 500 °C, the requested UN-Test N.4 (Section 33.3.1.6 UN-MTC) is obsolete.	Waiver[14]
Substances and mixtures which in contact with water emit flammable gases	Expert statement	-	-	The main component and active substance of the biocidal product aluminium phosphide evolves extremely flammable gases in contact with water or humid air (H260). The same classification applies for the biocidal product. Further testing is not required. The product should be classified as water-react. 1 according to CLP.	
Oxidising liquids	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[14]
Oxidising solids	Expert statement/Justification for	-	-	Determination of the oxidizing properties is scientifically unjustified. From the structural formula and composition of the product it can	Waiver[14]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	non-submission			be concluded that the product has no oxidizing properties.	
Organic peroxides	study scientifically unjustified	-	-	Not applicable. (The biocidal product does not contain organic peroxides.)	Waiver[14]
Corrosive to metals	Expert statement/Justification for non-submission	-	-	The UN-MTC Test C.1 is to be applied to liquids and solids that may become liquid during transport only or having a melting point less 55 °C. As the melting point of the main component aluminium phosphide is higher than 500 °C and also the DSC measurement of the product demonstrates that the transition from solid to liquid does not occur up to a temperature of 500 °C, no test needs be performed.	Waiver
Auto-ignition temperature (liquids and gases)	study scientifically unjustified	-	-	Not applicable. (The biocidal product is a solid.)	Waiver[14]
Relative self-ignition temperature for solids	EU Method A.16	Phostoxin WM Pellets 56 % (w/w) AlP batch no.: 010919	Relative self-ignition temperature: -	No self-ignition observed under the test conditions up to 404 °C.	Siemens Axiva GmbH & Co. KG; report no.: 20011378.02;
Dust explosion hazard	Expert statement/Justification for non-submission-	-		Not applicable. (The biocidal product is not a dustable powder, please refer to section 3.2 of the PAR – Particle size distribution, content of dust/fines, attrition, friability. Furthermore, materials that cannot be oxidised are exempt from testing. Since the	Waiver[14]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				main component and active substance is an inorganic non-combustible material and therefore cannot be oxidized, the test is obsolete.	

Table 8

Conclusion on the physical hazards and respective characteristics
The DSC measurements on the solid biocidal product Phostoxin WM show no significant exothermal decomposition up to a temperature of 500°C and that the exothermic decomposition energy was below 500 J/g. Therefore it can be concluded that the biocidal product has no explosive properties. Phostoxin WM is not a highly flammable solid in the sense of the preliminary test according the EU Method A. 10. There are no chemical groups present in the components of the biocidal product Phostoxin WM which are associated with explosive or self-reactive properties with reference to the screening procedures in Appendix 6 of the UN-MTC. From the structural formula and composition of the biocidal product it can be concluded that the product is stable at room temperature and is not pyrophoric. Based on the composition of the biocidal product Phostoxin WM and the results of the DSC measurements, it can be concluded that the product is not a self-heating mixture. The main component and active substance of the biocidal product AlP evolves extremely flammable gases in contact with water or humid air (H260). Therefore, the product Phostoxin WM is classified as water-react. 1 according to CLP. From the structural formula and composition of the product it can be concluded that the product has no oxidizing properties. Furthermore, the biocidal product does not contain organic peroxides. No self-ignition was observed up to the maximum test temperature of 404°C.

3.4 Methods for detection and identification

Quantification of aluminium phosphide:

The content of aluminium phosphide is determined by hydrolysis in sulphuric acid. The released phosphine reacts with mercury chloride to generate hydrogen chloride. The amount of hydrogen chloride is determined by titration.

Equation of reaction:

$2\ AlP + 3H_2O \rightarrow 2\ PH_3 + Al_2O_3$ (1)

$PH_3 + 3HgCl_2 \rightarrow P(HgCl)_3 + 3HCl$ (2)

$HCl + NaOH \rightarrow H_2O + NaCl$ (3)

Table 9

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
aluminium phosphide (active substance)	Titration with NaOH	Based on the preparation steps of the analytical method and the (non-active) components/matrix yof the biocidal product, the method is specific for AlP respectively phosphine.	$r^2 > 0.999$, 6-31 mg (active P) The calibration range covered more than ± 20% of the expected nominal content a.s. in the test item.	4 - 18 mg (active P) (5 measurements)	89.7 - 95.9	92.2	2.87	n.a.	eurofins GAB GmbH, Report No. 20061336/01-UVX

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	No relevant residues expected	-	DT_{90} < 3 d (phosphine) AR aluminium phosphide releasing phosphine PT 14 ; 05/2008, LoEP
Drinking water	Phosphine	0.1 µg/L	minimal requirement of the Drinking Water Act
Surface water	No relevant residues expected	-	Evaluation Report, Doc II aluminium phosphide releasing phosphine PT 14 ; 06/2008, 1.4.2
Air			Professional use only
Animal and human body fluids	No relevant residues expected	-	Aluminium phosphide hydrolyses rapidly to phosphine. Inhaled phosphine is rapidly absorbed in lung but not stable (i.e. not detectable) in human blood.
Animal and human tissues	Phosphine	0.1 mg/kg	AR aluminium phosphide releasing phosphine PT 14 ; 05/2008, LoEP
Food of plant origin	No relevant residues expected from the intended use		AR aluminium phosphide releasing phosphine PT 14 ; 05/2008, 2.2.1.3
Food of animal origin	No relevant residues expected from the intended use		AR aluminium phosphide releasing phosphine PT 14 ; 05/2008, 2.2.1.3

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Phosphine	headspace GC-NPD, PoraPlot U column	< 30 % LOQ	16 – 1293 ng/mL corresponding to 0.02 – 1.6 µg/L R^2=0.99985	0.1 µg/L / 5 1.0 µg/L / 5	74.3-79.5 79.1–84.4	77 82	2 2	0.1 µg/L	CAR, Doc IIIA 4.2 c, Werle (1999)

Table 12:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Phopshane (gas)	Silica adsorption, Photometry	Interference from orthophosphates in air, and compounds which forming molybdate complexes and being soluble in isobutane/toluene	0.5 µg – 20 µg PH_3 (R=0.9958)	0.025-0.25 µg/m3 / 30		96		0.5 µg PH_3 absolute (= 0.0125 mg/m^3 for an air sample volumen of 100 L)	Breuer, D. (2012) Breuer, D. (2012). Phosphine [Air Monitoring Methods, 2002]. In The MAK-Collection for Occupational Health and Safety (eds and)

Table 13

Analytical methods for animal and human tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Zinc phosphide determined as phosphine	headspace GC-NPD, Poraplot Q capillary	< 30% LOQ	0.025 – 10 ng/mL phosphine corresponding to 0.0024 – 0.95 mg/kg Zn_3P_2 R^2=0.9991	Liver 0.0025 mg/kg/5 0.025 mg/kg/5 Meat 0.0025 mg/kg/5 0.025 mg/kg/5	 85-123 68-106 60-92 70-99	 101 87 83 85	 14 18 16 13	0.0025 mg/kg	CAR, Doc IIIA 4.2 d (02), Witte (2001)

Table 14

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method for substance of concern in the biocidal product 2. 5.2.1. Soil 3. 5.2.2. Air: Ammonium carbamate (CAS-No.: 1111-78-0) is identified as a substance of concern. But no further methods for detection of residues in air at the workplace are needed because the grounds for concern primarily are the local effect of eye irritation. 4. 5.2.4. Body fluids 5. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[9]
Justification	No relevant residues of phosphine are expected in soil, in food and feedingstuff and in body fluids.

Table 15

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s) was/were acceptable. The methods provided regarding the residues of phosphine in water and in tissues of animal origin were acceptable. Methods regarding residues of substances of concern were not necessary.

[9] Not necessary if neither the active substance nor the material treated with it come into contact with food-producing animals, food of plant and animal origin or feeding stuffs

3.5 Efficacy against target organisms

3.5.1 Function and field of use

Main Group 03: Pest Control
Product type 14: Rodenticides
“Phostoxin WM” contains the active substance Aluminium phosphide (technical: 68% (pure: 56%) w/w). It is intended to be used as fumigant (gas generating product) to control Brown rats (*Rattus norvegicus*) (Use #1) and European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) (Use #2) in underground tunnel systems (outdoor burrows). The product is inserted into burrows in form of pellets or tablets by an applicator.

The overall data package is only suitable to prove the efficacy of the product “Phostoxin WM” against Brown rats (*Rattus norvegicus*) for outdoor use in burrows as an accompanying method together with either traps or bait products (Use #1). Due to missing valid field studies Use #2 against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) cannot be authorised.
Minor change in 2024: addition of water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) as target organism.
The submitted studies are suitable to prove the efficacy of the product “Phostoxin WM” against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) for outdoor use in burrows (Use #2).

3.5.2 Organisms to be controlled and products, organisms or objects to be protected

The product “Phostoxin WM” is intended to be used for outdoor control of Brown rats (*Rattus norvegicus*) and European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) in clearly locatable burrow systems that are separated from burrow systems of other rodents and building structures in all types of non-agricultural areas where rodent burrows can cause damage, e. g. railways (embankments, tracks, gravel edges, border routes), dams and flood dikes, sport venues (e.g. golf courses), gardens and parks, port traffic areas, airfields and other kinds of technical areas.

3.5.3 Effects on target organisms, including unacceptable suffering

Assuming a relatively short duration of severe symptomatology, it may be concluded that the phosphine-generating chemicals cause suffering, but at high doses are more humane vertebrate killing agents than

anticoagulant rodenticides. As rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage, it is considered that products containing this active substance can still be authorised until better alternatives become available (less painful biocidal products with a different mode of action, non-biocidal alternatives).

3.5.4 Mode of action, including time delay

The active ingredient Aluminium phosphide reacts with moisture in soil and air to release the toxic gas phosphine. Phosphine acts as an inhibitor of important enzymes in tissue cells, and in high concentrations it causes alternations to blood haemoglobin by formations of methaemoglobin.

3.5.5 Efficacy data

The efficacy evaluation of the renewal is based on the requirements of the Transitional Guidance on the Biocidal Products Regulation for PT14 from December 2016. Therefore, efficacy has to be demonstrated in a laboratory trial and a field trial or alternatively in a semi-field trial and a field trial for each target organism with the product for which the authorisation is sought (TG on the BPR for PT14, 2016; chapter 1.2 and 2).

The applicant submitted one field trial against Brown rats (*Rattus norvegicus*) and one field trial against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) with the product “Detia-Wühlmauskiller” (56% Aluminium phosphide, corresponding to the product “Phostoxin WM”) (study summaries: Table 16).

Brown Rats (*R. norvegicus*) (Use #1)

Instead of a laboratory or semi-field test the applicant provided a document for read-across, demonstrating the efficacy of Aluminium phosphide against rats in toxicity data (IUCLID section 6.7: “Further Information on Section 6.7 read across instead of laboratory or simulated use test”), which demonstrated mortality in rats after 1 to 2 hours at phosphine concentrations between 290 – 360 ppm. As the mode of action of phosphine is undoubtedly and in order to minimise the number of tests with animals we consider this read-across approach as appropriate to substitute missing laboratory or semi-field tests.

The field trial was conducted in nine burrows (six burrows were low to medium infested and three burrows were high-infested with rats) on two farms with pig-rearing.100% population reduction was demonstrated in only six of the nine burrows. All rat-eradicated sites were infested with low to medium numbers of rats. On sites with high abundances, the effectiveness in controlling rats was not satisfying, measured in the formation of open holes and tracking activity two days after product application. Obviously, eradication is difficult on sites where burrows are connected with other devices which enable the target organisms

escaping from the treated burrow, where the burrows are densely populated and/or too spacious to receive a sufficiently high concentration of the active ingredient.
In accordance with the TG on the BPR for PT14 (2016; chapter: 4.1) in field test ≥90% decrease of the population has to be demonstrated. 100% efficacy was only demonstrated in burrows infested with low to medium numbers of rats. A claim for use at low to medium infested sites is not in line with the TG on the BPR for PT14 (2016). However, in chapter 4.1 of the TG on the BPR it is stated: "In order to promote the development of new types of products (less toxic, more humane), a mortality <90% could be acceptable when the product is used as an accompanying method, (i.e. used with another product to demonstrate efficacy), but not as a standalone product. However, mortality of these new type of products should not be <50%. The use of a product as an accompanying method should be reflected in the use instructions in the draft SPC." Even though the product "Phostoxin WM" is not a new type, the applicant submitted an acceptable statement that phosphine-generating chemicals are more humane vertebrate killing agents than anticoagulant rodenticides (IUCLID section 6.7: "Further Information on Section 6.7 to study KLN_DD_2005_1 humaniness and combined treatment").
Therefore, the overall data package is suitable to prove the efficacy of the product "Phostoxin WM" with the active ingredient Aluminium phosphide against Brown rats (*Rattus norvegicus*) for outdoor use in burrows as an accompanying method together with either traps or bait products (Use #1).

European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) (Use #2)

Instead of a laboratory or semi-field test the applicant provided a document for read-across, demonstrating the efficacy of Aluminium phosphide against rats in toxicity data (mortality after 1 to 2 hours at phosphine concentrations between 290 – 360 ppm) and the similarity of rats and voles (size, body weight) (IUCLID section 6.7: "Further Information on Section 6.7 read across instead of laboratory or simulated use test").
As the mode of action of phosphine is undoubtedly and in order to minimise the number of tests with animals we consider this read-across approach as appropriate to substitute missing laboratory or semi-field test.
The field test was conducted in forest sites against water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*). In three of six infestation sites effectiveness was 100%, while it was 69%, 76% and 88% on the other sites. Therefore, efficacy of the product was proved to be approximately 89%.
In accordance with the TG on the BPR for PT14 (2016; chapter: 4.1) in field test ≥90% decrease of the population has to be demonstrated. Furthermore, the TG on the BPR for PT14 (2016; chapter: 1.2) requires that efficacy studies should be performed to evaluate whether the product is effective for the intended uses. Efficacy trials in forests do not comply with the intended field of use as biocide in non-agricultural areas where rodent burrows can cause damage e. g. railways (embankments, tracks, gravel edges, border routes), dams and flood dikes, sport venues (golf course), gardens and parks, port traffic areas, airfields and other kinds of technical areas.

Therefore, the submitted field test is insufficient to prove the efficacy of the product against water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*). In line with the outcome of the informal enquiry on field tests with water voles (*Arvicola amphibius*) (Interact ID:345884) the DE CA decided to require at least two proofs that the applicant has found non-agricultural areas that document the need of the biocidal product. This is highly in line with the concept of sustainable use of biocidal products, in order to be sure that use of biocides in non-agricultural areas is needed and realistic, and that it is not a way from the applicant to avoid plant protection product regulation. In addition, two valid field trials with high water vole population density (in accordance to the Guidance on the BPR, chapter 5.6.2.2.6, Field test with voles; requires “at least 10 galleries”) on “agricultural” areas (one trial on “grassland” is mandatory) were requested. However, the applicant did not submit new field studies. Consequently, the intended Use #2 against water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) cannot be authorised.

Minor change in 2024: addition of water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) as target organism

In line with the outcome of the informal enquiry on field tests with water voles (*Arvicola amphibius*) (Interact ID:345884) the applicant provided a statement that several pest control companies and a dyke association were contacted to find a suitable non-agricultural area with a sufficiently large infestation of water voles for a field study. Two potential areas (a retention area and Neuwerk Island in the North Sea) with heavy infestation were identified, but due to the Corona measures in 2021, it was not possible to inspect them by third parties, or the weather conditions were unfavourable for the use of the product (excessive soil moisture due to continuous rain on Neuwerk Island) in November 2021. In addition, two sports fields were found, but only with low infestation. A heavy infestation on a dyke could not be controlled because of the presence of water voles and moles, which are not allowed to be controlled in Germany as they are protected under the Species Protection Act.

Therefore, the applicant submitted in accordance with the informal enquiry two field studies in “agricultural” areas (one in an orchard and one on grassland). In both studies the water vole population density was high (18 to 19 occupied galleries). 5 days after product application (5 pellets per 3 – 5 m gallery), population reduction of 93.75% and 94.14% were observed in the orchard and grassland, respectively. Activity in the untreated control plots remained stable.

The overall data package is suitable to demonstrate the efficacy of the product “Phostoxin WM” against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) for outdoor use in burrows with an application rate of 1 tablet or 5 pellets per 3 – 5 m gallery (Use #2).

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rodenticide	outside in burrows	"Detia-Wühlmauskiller" (56% Aluminium phosphide) corresponding to the product "Phostoxin WM"	Brown rats (*Rattus norvegicus*)	Field trial	2 pig farms in Germany 9 different sites (5 medium to high infested burrows around the farm and 4 low infested burrows in banks of farm pond (burrow no: 6 to 9); number of holes per burrow: 2 to 7) soil typs: light soil (burrow no: 1 to 4), heavy soil (burrow no: 5 to 9) total number of pellets per burrow: 2 to 5 number of holes with pellets per burrow: 1 to 3 pre-control census and post-control census (2 days after application) by „hole reopening" and „tracking activity" PH_3-concentration was measured in 5 burrows 7; 24 and 48 hours after product application	100% effectiveness in 6 burrows; 3 burrows with high infestation showed rat activity in post-control (burrow no: 1; 2; 5) PH_3-concentration after application: 2 - >40 ppm after 7 hours; 10 – 20 ppm after 24 hours; <1 ppm after 48 hours	Report no. KLN/DD/2005-1 and Supplementary data to the report KLN/DD/2005-01
Rodenticide	outside in burrows	"Detia-Wühlmauskiller" (56% Aluminium phosphide) corresponding to the product "Phostoxin WM"	European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*)	Field trial	different forest sites in Germany light soil: 5 pellets per 3 – 5 m burrow length normal soil: 5 pellets per 8 – 10 m burrow length infestation level: medium – high pre-control census and post-control census by „hole reopening"	100% effectiveness in 3 burrows; 3 burrows showed vole activity in post-control (effectiveness: 69 - 88%)	Anonymous 2002

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						Average degree of effectiveness: 88.83% untreated contol burrows: normal activity	
Rodenticide	outside in burrows	"Detia-Wühlmauskiller" (56% Aluminium phosphide) corresponding to the product "Phostoxin WM"	European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*)	Field trial	agricultural land: orchard in Germany 18 occupied galleries were located for each plot (treatment and control) heavy soil: 5 pellets per 3 – 5 m gallery pre-control census and post-control census (5 days after product application) by „hole reopening"	93.75% effectiveness (1 gallery of 18 opened galleries was refilled after 24 h) untreated control: normal activity (16 galleries of 18 opened galleries were refilled after 24 h)	RIFCON GmbH; Report No. R2140055; Study No. 540
Rodenticide	outside in burrows	"Detia-Wühlmauskiller" (56% Aluminium phosphide) corresponding to the product "Phostoxin WM"	European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*)	Field trial	grassland in Germany 18 occupied galleries were located in the treatment plot and 19 in the control plot heavy soil: 5 pellets per 3 – 5 m gallery pre-control census and post-control census (5 days after product application) by „hole reopening	94.14% effectiveness (1 gallery of 18 opened galleries was refilled after 24 h) untreated control: normal activity (18 galleries of 19 opened	RIFCON GmbH; Report No. R2140055; Study No. 576

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						galleries were refilled after 24 h)	

3.5.6 Occurrence of resistance and resistance management

The applicant did not provide data of the biocidal product to evaluate the potential for resistance. Resistance against Aluminium phosphide has not occurred in relevant susceptible pests and is unlikely to occur due to the inorganic nature of the active ingredient and its acute toxicity. If the product is used according to label instructions, development of resistance should be excluded. However, ineffective sealing of treated burrows and other inaccurate applications may reduce the effectiveness of the treatment and therefore the proposed instructions should strictly be followed to obtain satisfying results.

3.5.7 Known limitations

The studies show, that effectiveness of the product obviously is dependent on the intensity of placement, correct identification of all burrow entrances (in case of rat burrows) and the infestation strength. Therefore, “Phostoxin WM” has to be applied only by trained professional users who are experienced in assessment of the sites to be treated. Furthermore, the product must be applied to all burrow entrances, in order to prevent target animals from escaping by untreated burrows.
The efficacy of the product for control of high abundances of *Rattus norvegicus* has not been demonstrated, hence the product can only be applied as an accompanying method together with either traps or bait products.

3.5.8 Evaluation of the label claims

The overall data package is only suitable to prove the efficacy of the product “Phostoxin WM” against Brown rats (*Rattus norvegicus*) for outdoor use in burrows as an accompanying method together with either traps or bait products (Use #1). Due to missing valid field studies Use #2 against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) cannot be authorised.
Minor change in 2024: addition of water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) as target organism
The submitted studies are suitable to prove the efficacy of the product “Phostoxin WM” against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) for outdoor use in burrows (Use #2).

3.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not applicable.

3.5.10 Data waiving and conclusion

Table 17

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 18

Conclusion on the efficacy
The efficacy of the product “Phostoxin WM” is proven against Brown rats (*Rattus norvegicus*) for outdoor use in burrows as an accompanying method together with either traps or bait products (Use #1). Use #2 against European water voles (*Arvicola amphibius*, formerly *Arvicola terrestris*) cannot be authorised.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 19

Aluminium phosphide	Value	Study	Safety factor
AEL long-term	0.019 mg/kg bw/d*[1]	2-yr inhalation, rat Newton, P. E. (1998)	100
AEL medium-term	0.019 mg/kg bw/d*[1]	90-d inhalation, rat Newton, P. E. (1990)	100
AEL acute	0.032 mg/kg bw/d*[1]	Developmental inhalation, rat Schroeder, R.E. (1989)	100

*Based on a maximum liberation of gas of 0.59 g/PH_3/g aluminium phosphide
[1] Based on Assessment-Report (DE, 2008)

Table 20

PH_3	Value	Study	Safety factor
AEL long-term	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d[1]	2-yr inhalation, rat Newton, P. E. (1998)	100
AEL medium-term	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d[1]	90-d inhalation, rat Newton, P. E. (1990)	100
AEL acute	0.049 ppm or 0.070 µg/L air or 0.019 mg/kg bw/d [1]	Developmental inhalation, rat Schroeder, R.E. (1989)	100

[1] Based on Assessment-Report (DE, 2008)

Table 21

Aluminium phosphide	Value	Reference
Inhalative absorption	100% - Default	Not established Ready absorption of phosphine through the lungs AR, 2008 (RMS DE)
Oral absorption	100% - Default	Not established Ready absorption of phosphine after oral exposure AR, 2008 (RMS DE)
Dermal absorption	Refer to chaper 3.6.2.7 for dermal absorption used in RA.	-

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 22

Data waiving was acceptable for the following information requirements	
Information requirement	8.1 Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product was derived according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 22

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritating to the skin.
Justification for the value/conclusion	Ammoniun carbamate (CAS No 1111-78-0): Skin Irrit. 2, H315 (SDS); concentration: 21 % (w/w), GCL for Skin Irrit. 2: 10 %
Classification of the product according to CLP	Skin Irrit. 2, H315

3.6.2.2 Eye irritation

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye-damaging or eye irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow

	classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal product for eye irritation was derived according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 24

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes severe eye damage.
Justification for the value/conclusion	Ammonium carbamate (CAS No 1111-78-0): Eye Dam. 1, H318 (SDS); concentration: 21 % (w/w); GCL for Eye Dam. 1: 3 %
Classification of the product according to CLP	Eye Dam. 1, H318

3.6.2.3 Respiratory tract irritation

Table 25

Data waiving	
Information requirement	8.10 Other data
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be derived according to the rules of the Regulation (EC) No 1272/2008.

Table 26

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not corrosive to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory irritation. However, phosphine gas released from aluminium phosphide by contact with water or acids is classified with Skin Corr. 1. Hence, next to acute toxic effects also irritation or even corrosion of the respiratory tract by phosphine gas might occur.
Classification of the product according to CLP	Not classified for respiratory tract irritation.

3.6.2.4 Skin sensitisation

Table 27

Summary table of animal studies on skin sensitisation					
Method Guideline GLP status Reliability	**Species Strain Sex No/group**	**Test substance Vehicle Dose levels Duration of exposure Route of exposure**	**Results**	**Remarks**	**Reference**
Method / Guideline: OECD 406 (Buehler, 3 inductions) GLP: no Reliability: 2	Albino guinea pigs, 20 treated (sex not mentioned) 10 controls (sex not mentioned)	DETIA GAS-EX-T-Pastilhas de 3 g (according to the applicant identical to Phostoxin WM) Induction : Dose : 0.5 g ; topical application on day 0; 7 and 14 Challenge : Dose : 0.5 g ; topical application on day 28	0/20 (0.5 g product) 0/10 (control, 0.9 % saline)	According to the identity in the study report the ammonium carbamate concentration in test substance is only 4 % (Phostoxin WM: 21 %)	Report no. 428.192.02

Based on the low content of ammonium carbamate in the test formulation the biocidal product cannot be considered as sufficiently similar. Therefore, the study is considered only supportive for the biocidal product to exclude skin-sensitising properties.

However, according to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.”
As the composition of the biocidal product is well known and sufficient data on the intrinsic properties of them are available, classification of the biocidal product is assessed on the properties of the single components. Based on safety data sheets and other information for each of the individual components the biocidal product does not require classification for skin sensitisation. There is no information or indication on synergistic effects between any of the components.

Table 28

Justification for the value/conclusion	Based on the toxicological properties of the components and supported by study result.
Classification of the product according to CLP	Not classified for skin sensitisation.

3.6.2.5 Respiratory sensitisation (ADS)

Table 29

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 30

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components, which are known to have sensitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified for respiratory sensitisation.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 31

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status Reliability	**Species Strain Sex No/group**	**Test substance Dose levels Type of administration**	**Signs of toxicity**	**Value LD_{50} (acc. to study report)**	**Remarks**	**Refer-ence**
Guideline: not reported, similar to OECD 401 GLP: no Reliability: 2	Rat Spraque-Dawley Sex: m/f 5/group	Degesch Phostoxin Formulation 3; 6; 8; 10; 12 mg/kg bw Administration: gavage	Mortality: 3 mg/kg bw: m/f: 0/5 of each group 6 mg/kg bw: m: 0/5 f: 1/5 8 mg/kg bw: m: 0/5 f: 3/5 10 mg/kg bw: m: 1/5 f: 3/5 12 mg/kg bw: m: 2/5 f: **3**/5	m: 12.4 mg/kg bw f: 8.9 mg/kg bw m/f: 11.5 mg/kg bw	According to the applicant the biocidal product is identical to the test substance. However, there is no information on the compositio n in the study report. Based on	project No. 2038-103

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status Reliability	**Species Strain Sex No/group**	**Test substance Dose levels Type of administration**	**Signs of toxicity**	**Value LD_{50} (acc. to study report)**	**Remarks**	**Refer-ence**
					the clear outcome and the LD_{50} estimated according to the calculation method of Regulation (EC) No 1272/2008 (see table 32) this is considered acceptable.	

Table 32

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral): 11.5 mg/kg bw (study) LD_{50} (oral): 12.7 mg/kg bw (calculation method)
Justification for the selected value	Based on an animal acute oral toxicity study. According to Regulation (EC) No 1272/2008 the estimated LD_{50} (oral) is in the range for Acute Tox. Category 2. Based on the calculation method according to the equation in Annex I, section 3.1.3.6.1 of Regulation (EC) No1272/2008 estimated LD_{50} (oral) is in the range for Acute Tox. Category 2: Relevant components: Aluminium phosphide (68 %); LD_{50}: 8.7 mg/kg bw (CAR, RAC opinion) Ammonium carbamate (21 %); LD_{50}: 681 mg/kg bw (SDS) ATE_{mix} = 12.7 mg/kg bw
Classification of the product according to CLP	Acute Tox. 2 (oral), H300

3.6.2.6.2 Acute toxicity by inhalation

Table 33

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required.

Data waiving was acceptable for the following information requirements	
	According to Annex III of the BPR (Regulation (EU) No 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the biocidal products was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 34

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation): 0.036 mg/L
Justification for the selected value	This value is calculated from the LC_{50} (inhalation) of 0.02 mg/L for aluminium phosphide (pure 56 %; w/w) as reported in the RAC opinion ECHA/RAC/CLH-O-0000002201-92-01/F from 2011-12-02. Other components do not contribute to this classifcation. According to Regulation (EC) no 1272/2008 the estimated LC_{50} (inhalation) is in the range for Acute Tox. Category 1.
Classification of the product according to CLP	Acute Tox. 1 (inhalation), H330

3.6.2.6.3 Acute toxicity by dermal route

Table 35

Summary table of animal studies on acute dermal toxicity						
Method Guideline GLP status Reliability	**Species Strain Sex No/group**	**Test substance Vehicle Dose levels Surface area**	**Signs of toxicity**	**Value LD_{50} (acc. to study report)**	**Remarks**	**Reference**
OECD 402 GLP: not reported Reliability: 2	Species: Rats Strain: Charles Foster Sex: m/f 5/group	Aluminum Phosphide RT containing 58.99 % active substance; tablets, homogenised before application Vehicle: peanut oil Dose levels: 0; 50; 71; 100 mg/kg bw Surface area: appr. 10 % of total body surface	Mortality: 0 mg/kg bw: m/f: 0/5 of each group 50 mg/kg bw: m: 2/5 f: 3/5 71 mg/kg bw: m: 4/5 f: 4/5 100 mg/kg bw: m: 5/5 f: 5/5 Symptoms: Tremor, piloerection and abdominal breathing were observed in most animals at dose levels from 50 to 100 mg/kg bw	50 mg/kg bw	This study was submitted for the plant protection product Quickfume Presskörper. The test substance is considered as identical to this formulation. Quickfume Presskörper has a very similar composition compared to Phostoxin WM. For details refer to the Confidential Annex	Report number 1464/JRF/TOXT/95
OPPTS 870-1200.EPA 712-C-98-192 GLP: yes	Species: Rats Strain: Wistar	Granulars, partly homogenised before applicati-on, containing	Mortality: 0 mg/kg bw: f: 0/5 400 mg/kg bw: f: 0/5	663 mg/kg bw	This study was submitted for the plant protection product	Study number 2551

Summary table of animal studies on acute dermal toxicity						
Method Guideline GLP status Reliability	**Species Strain Sex No/group**	**Test substance Vehicle Dose levels Surface area**	**Signs of toxicity**	**Value LD_{50} (acc. to study report)**	**Remarks**	**Reference**
Reliability: 2	Sex: m/f, male animals only in the highest dosing group 5/group	58 % active substance Vehicle: peanut oil Dose levels: 0; 400; 560; 784 mg	560 mg/kg bw: f: 2/5 560 mg/kg bw: f: 3/5 m: 1/5 Symptoms: Tremor, lethargy and partly lacrimation was observed on day one in most animals at dose levels from 400 to 784 mg/kg bw		Quickfume Presskörper. The test substance is considered as identical to this formulation. Quickfume Presskörper has a very similar composition compared to Phostoxin WM. For details refer to the Confidential Annex	
OECD 404 [1)] GLP: yes Reliability: 2	Species: Rats, Strain: Wistar (strain Winkelmann) Sex: m/f 5/group	Aluminium phosphide, reduced to smallest pieces, 500; 1000; 2000 mg/kg bw	Mortality: 500 mg/kg bw: m/f: 0/5 of each group 1000 mg/kg bw: m: 3/5 f: 3/5 2000 mg/kg bw: m: 5/5 f: 5/5	1520 mg/kg bw	The study report stated that OECD 404 (skin irritation) is applied. It is assumed that OECD 402 was applied. According to section 3.3 the study was performed with the solid active substance without a vehicle. According to section 3.1 a **fluid** substance was applied to the skin.	Report number: 1-4-142-87

[1)] As given in the study report. It is assumed that OECD 402 is applied.

According to the report, the study with the report number 1-4-142-87 was performed with the active substance and not with a product. As products often contain components, controlling the release of phosphine gas the toxicolgical effects in studies with the active substance can usually not be adopted directly to products. Hence, this study contains only supportive information

The classification for acute dermal toxicity is based on a study with the report number 146/JRF/TOXT/95 submitted for the national authorisation of a plant protection product (Quickfume Presskörper) in DE. This biocidal product is very similar to Phostoxin WM. For details, refer to the Confidential Annex.

According to the LD_{50} from this study classification as Acute Tox. Cat. 1, H310 is necessary. However, a second study with the same formulation (study number 2551) was also submitted resulting in a classification as Acute Tox. Cat. 4, H312.

It is acknowledged that the results of both acute dermal toxicity studies differ significantly. The reasons for these differences remain unclear. Based on the study report none of both studies suffers from flaws that may explain these differences. The differences in the conduction of both studies are summarised in the Confidential Annex of the PAR. These differences should not have a significant influence on the study results.

For precautionary reasons the biocidal product is classified as Acute Tox. Cat. 1, until an appropriate study with the corresponding biocidal product is available. The dermal toxicity of the biocidal product is based on the active substance. Therefore, without further data this classification is necessary for all formulations with a comparable toxicological profile. Note that the studies with the report number 1464/JRF/TOXT/95 and the study number 2551 have not been evaluated during the assessment of the RAC.

Table 36

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal): 50 mg/kg bw
Justification for the selected value	Based on an animal acute dermal toxicity study. According to Regulation (EC) No 1272/2008 the estimated LD_{50} (dermal) is in the range for Acute Tox. Category 1.
Classification of the product according to CLP	Acute Tox. 1 (dermal), H310

3.6.2.7 Information on dermal absorption

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	According to the active substance assessment reports for aluminium phosphide (PT14 and 18, 2008 and PT20, 2013) it was concluded that as a main reason, dermal absorption of aluminium phosphide can be excluded since any dermal absorption requires solution in water or another solvent to pass the skin barrier. As the active substance is not soluble in water or many other solvents (see phys.-chem. data package section 2.2 and phys-chem-data of the active substance (IUCLID section 3)), dermal absorption of aluminium phosphide is highly unlikely. Thus, a default of 10 % dermal absorption can be considered as very conservative worst-case assumption.

Table 38

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s)	All scenarios
Value	10 %
Justification for the selected value	Expert judgement provided in the CAR for aluminium phosphide (PT14, 2008).

3.6.2.8 Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Ammonium carbamate (CAS No. 1111-78-0)

Classification	
Current with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008 as given in the SDS	Acute Tox. 4, H302; LD_{50} (oral): > 681- < 1470 mg/kg bw Skin Irrit. 2, H315 Eye Dam. 1, H318

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

In three animal studies available to the eCA conducted for the assessment of eye irritating effects of aluminium and magnesium phosphide containing plant protection products, animals died after instillation of the test substance into the eye. These studies are summarised in the Confidential Annex. In conclusion, the biocidal product Phostoxin WM requires labelling with EUH070.

The active substance aluminium phosphide requires labelling with EUH029 and EUH032. Based on the high concentration of the active substance in the biocidal product and the mode of action of metal phosphide containing products this labelling is also required for the biocidal product Phostoxin WM.

3.6.2.11 Assessment of the endocrine-disrupting properties of the biocidal product

Aluminium phosphide was not assessed for endocrine disrupting properties during the first active substance evaluation. There is no indication for endocrine-disrupting properties from the evaluation as a plant protection product, ECHA ED-list, ECHA registration dossier, ECHA PACT list, ECHA CoRap list or ECHA SVHC list.
No co-formulant of the biocidal product was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. Therefore, the co-formulants of the biocidal product family are not considered to have endocrine disrupting properties.
The full composition of biocidal product as well as the results of the ED-assessment of the co-formulants and the active substance are summarised in the Confidential Annex.

3.6.2.12 Summary of effects assessment

Table 39

Endpoint	Brief description
Skin corrosion and irritation	Skin Irrit. 2, H315 Based on toxicological information on single components and the additivity approach according to Regulation (EC) No. 1272/2008.
Eye irritation	Eye Dam. 1, H318 Based on toxicological information on single components and the additivity approach according to Regulation (EC) No. 1272/2008.
Respiratory tract irritation	Not classified Based on toxicological information on single components.
Skin sensitisation	Not classified

Endpoint	Brief description
	Based on information on the single components. Supported by an animal sensitisation study.
Respiratory sensitization (ADS)	Not classified Based on toxicological information on the single components.
Acute toxicity by oral route	Acute Tox. 2 (oral), H300 Based on an animal study and calculation method according to Regulation (EC) No 1272/2008. LD_{50} (oral): 11.5 mg/kg bw (study) LD_{50} (oral): 12.7 mg/kg bw (calculation method)
Acute toxicity by inhalation	Acute Tox. 1 (inhalation), H330 Based on toxicological information on single components and the additivity approach according to Regulation (EC) No. 1272/2008. Estimated LC_{50} (inhalation): 0.036 mg/L
Acute toxicity by dermal route	Acute Tox. 1 (dermal), H310 Based on an animal study. LD_{50} (dermal): 50 mg/kg bw
Information on dermal absorption	10 % for all scenarios Default for aluminium phosphide containing products in accordance to the assessment reports from the active substance evaluation (PT14; PT18; PT20)
Available toxicological data relating to non-active substance(s)	Ammonium carbamate (SDS): Classification: Acute Tox. 4, H302; LD_{50} (oral): > 681- < 1470 mg/kg bw Skin Irrit. 2, H315 Eye Dam. 1, H318
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	EUH070, Toxic by eye contact Based on animal eye irritation studies. Animals died after instillation of the test substance into the eye. EUH029, Contact with water liberates toxic gas EUH032, Contact with acids liberates very toxic gas. Both statements are listed in Annex VI of Regulation (EC) No 1272/2008 for aluminium phosphide. Based on the high concentration of the active substance in the biocidal product and the mode of action of metal phosphide containing products this labelling is also required for the biocidal product Phostoxin WM.

3.6.3 Exposure assessment

The product Phostoxin WM is identical to the representative product of the active substance approval and the active substance renewal. Phostoxin WM contains the active substance aluminium phosphide 68 % w/w (purity ≥ 83%) and the substance of concern ammonium carbamate 21 % w/w. The content of the active substance phosphane is 560 g/kg of aluminium phosphide.

For exposure assessment, no new exposure studies have been submitted. Phostoxin WM is used for the control of rodents in burrows. The application with an applicator is obligatory.

3.6.3.1 Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Table 40

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	n.a.	n.a.	No	Yes	n.a.
Dermal	n.a.	Yes	n.a.	n.a.	No	No	n.a.
Oral	n.a.	No	n.a.	n.a.	No	No	n.a.

List of scenarios

Table 41

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
1	Fumigation with aluminium phosphide pellets	Primary exposure: application of pellets outdoor in underground burrow systems with an applicator	Trained professionals
2	Fumigation with aluminium phosphide tablets	Primary exposure: application of tablets outdoor in underground burrow systems with an applicator	Trained professionals
3	Re-entry	Re-entry of the general public after application	Residents
4	Bystander	General public staying near the application site	Bystander

3.6.3.1.1 Professional exposure

General Hint: The exposure assessment of the first authorisation of Phostoxin WM for the professional user is also valid for the renewal of the product.

- **Scenario 1 Fumigation with aluminium phosphide pellets**

Table 42

Description of Scenario 1		
The product Phostoxin WM is used as outdoor control of rodent species (voles, rats) for all types of non-agricultural purposes, such as embankments and dikes. The application rate is 5 pellets (solid grey, 0.6 g) placed in burrows or holes every 3-5 m in light soil respectively every 8-10 m in all other soil types. Phostoxin WM is delivered in sealed aluminium flasks/cans (90 g, 100 g, 250 g and 1 kg; with a plastic screw lid compatible for use with an application tool). For the operator exposure assessment, the following operations need to be considered: **Filling of application device:** The application of the pellets into the burrows of the target organisms is performed by tools e.g. an applicator First, the packaging is directly screwed to the lance, *i.e*. there is no contact of the pellets by hand. The design of the lance ensures that pellets are released from the opening at the bottom end of the lance directly into the soil when pressing the hand gear at the top. **Application into burrows:** First, the operator uses a probe to detect the burrows of rodents under the soil surface where the gassing pellets are to be placed. In any case, the pellets are located into the burrows and each burrow has to be carefully closed immediately after application e.g. by soil or grass sods to avoid distribution of phosphane to air and to maintain a significant concentration in the burrows for high efficacy against the target organisms. The entry of other persons than the operator into the treated area is strictly prohibited (and indicated by a clear safety barrier). **After application:** The application tool shall be cleaned after handling. Cleaning shall be done outdoors, preferably during slightly windy conditions (in consideration of wind direction), and by careful avoidance of exposure of humans by aluminium phosphide or phosphane. A container, sufficiently dimensioned, has to be filled with water of reduced surface tension (washing-up liquid). All components of the application tool shall be left in water bath for at least 4 hours. During this period, the area has to be left. Then the application tool shall be washed with fresh water until all parts are clean. Before reusing, all components shall be absolutely dry, and the application tool has to be technically checked. **Re-entry into treated area**: The operator re-enters the treated area and measures the phosphane concentration level. As soon as the concentration is below 0.014 mg/m³ (0.01 ppm), the re-entry for other persons than the operator is allowed. The main risks of aluminium phosphide containing products for professionals are caused by inhalation of phosphane. The inhalation exposure assessment is based on a Rentokil report 264/3. This data was also used by the Rapporteur Member State Germany for the annex I (Directive 98/8/EC) inclusion of aluminium phosphide. For dermal contact solid aluminium phosphide is relevant. The dermal exposure is based on expert judgment. Potential dermal exposure is focused to hands during application (blockage) and cleaning the application tool. The described exposure assessment is valid for trained professional users (users with competence certificate). The frequency is assumed to be 110 days/year. No secondary exposure to professionals is expected.		
	Parameters	Value

Tier 1	Single pellet	0.6 g
	Diameter of a pellet	0.83 cm
	Density	2.02 g/cm^3
	Duration	480 min
	Frequency	330 burrows/day
	Thickness layer	0.0001 cm
	Inhalation exposure (to phosphane)	exposure monitoring data
	Dermal exposure (to aluminium phosphide)	calculation based on expert judgment
Tier 2	Protective gloves (EN 374)	10 %

Calculations for Scenario 1

Inhalation exposure assessment of phosphine: For the outdoor uses of Phostoxin WM the Rentokil Report 264/3 (1999) needs to be considered for the operator exposure assessment by using the application tool. For the risk assessment, only data which originated from an application in accordance with the intended uses of aluminium phosphide products were used from the study. The sampling of phosphane in air in this study included all aspects of the treatment including can opening, transfer of the product to the applicator, application of the product and cleaning of the applicator. The cleaning process of the applicator is not described in detail in the study but it is expected that the exposure to the evolved phosphane lasts only for seconds. Phosphane exposure was monitored using personal monitoring devices and static monitoring devices fitted with the appropriate monitoring tubes. Personal samplers were clipped to the workers' lapel in the breathing zone and static measuring devices were placed around the treated area. The study consisted of two four-hour rabbit hole treatments on consecutive days on different areas on a farm. For the treatments 360 - 540 g Phostoxin WM were used.

All personal and static samples were below the limit of detection of 0.1 mg PH_3/m^3. Thus, half of the limit of detection was used (*i.e.* 0.05 mg/m^3) for the exposure calculation of the operators, in line with current guidance for a worst-case consideration.[10] This value is supported by measurement results of Lloyd et al. (1987) [11] where a similar applicator was used but determination was performed with a more sensitive method. The highest personal monitoring measurement result in this study was 0.01 mg/m^3.

After application, the operator re-enters the treated area for very short durations to measure the residual phosphane concentration level. Due to the rapid degradation in soil and air, it can be assumed that already a short period after the application the phosphane evolution will have been completed. However under unfavourable conditions an exceedance of the reference values could not be excluded.

Therefore, to ensure a safe re-entry, measurements to control the phosphane levels are mandatory. The related risk mitigation measures (e.g. warning signs, restricted areas, measurements) are listed under section 2.5.2 Risk mitigation measures.

10 OECD (2002), Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application, OECD Series on Testing and Assessment, No. 9, OECD Publishing, Paris, https://doi.org/10.1787/9789264078079-en.

11 Lloyd. G.A., Bell, G.J., Samuels, S.W., Respiratory Exposure to Phosphine: Rabbit Gassing in Woodland Areas, Pesticide Safety directorate, Ministry of Agriculture, Fisheries and Food, UK, 1987

Inhalation exposure assessment of aluminium phosphide particle:

During the use of Phostoxin WM exposure to particles is not expected.

Dermal exposure assessment to phosphane:

Any phosphane gas arising from the contact with skin is covered by the inhalative exposure assessment of aluminium phosphide.

Dermal exposure assessment to aluminium phosphide:

During the use of the application tool, a direct contact with the biocidal product is incidental. Lloyd et al. (1987) described that it is necessary to clear soil from the outlet of the delivery tube. If pellets in the applicator tube, it is reasonable that a dermal contact could occur. Contamination of hands during application is also supported by Baker, R.O. (1992).[12]

For the assessment of dermal exposure during application, no dermal measurements are available. Therefore, the assessment is based on expert judgment. As a worst case, the duration for the use of Phostoxin WM is assessed to be 8 hours. The applied amount in the Rentokil Report 264/3 was 360-540 g during 4 hour treatments with an applicator. This is in accordance with other information that an amount of up to 1 kg (1667 pellets) is typically used for a whole day treatment in a field. Therefore, for the estimation of dermal exposure, 1 kg is expected to represent a worst case situation and a dermal contact to 15 pellets is assumed. The dermal assessment is based on the expert judgment, which is described in detail in Annex 4.3.1. After the application aluminium phosphide completely reacts with moisture, releasing phosphane.

Further information and considerations on scenario 1

Exposure to eyes: Eye contact to the product cannot be excluded. The product is classified as Eye Dam. 1 (H318). This information is relevant for risk characterisation of local effects.

12 Baker. R.O., Exposure of persons to phosphine gas from aluminium phosphide application to rodent burrows, Proceedings of the 15th Vertebrate Pest Conference (1992)

- **Scenario 2 Fumigation with aluminium phosphide tablets**

Table 43

Description of Scenario 2		
The product Phostoxin WM is used as outdoor control of rodent species (voles, rats) for all types of non-agricultural purposes, such as embankments and dikes. The application rate is 1 tablet (solid grey, 3 g), applied every 3-5 m burrow length or hole in light soil or every 8-10 m in all other soil types. Phostoxin WM is delivered in sealed aluminium flasks/cans (90 g, 100 g, 250 g and 1 kg; with a plastic screw lid compatible for use with an application tool). For the operator exposure assessment, the following operations need to be considered: **Filling of application device:** The application of the tablets into the burrows of the target organisms is performed by tools e.g. a lance. First, the packaging is directly screwed to the application lance, i.e. there is no contact of the tablets by hand. The Design of the application lance ensures that when pressing the hand gear at the top, one tablet is released from the opening at the bottom end of the lance directly into the soil. **Application into burrows:** First, the operator uses a probe to detect the burrows of rodents under the soil surface where the gassing tablets are to be placed., The tablets are located into the burrows and each burrow is to be carefully closed immediately after application e.g. by soil or grass sods to avoid distribution of phosphane to air and to maintain a significant concentration in the burrows for high efficacy against the target organisms. The entry of other persons than the operator into the treated area is strictly prohibited (and indicated by a clear safety barrier). **After application:** The application tool shall be cleaned after handling. Cleaning shall be done outdoors, preferably during slightly windy conditions (in consideration of wind direction), and by careful avoidance of exposure of humans by aluminium phosphide or phosphane. A container, sufficiently dimensioned, has to be filled with water of reduced surface tension (washing-up liquid). All components of the applicator shall be left in water bath for at least 4 hours. During this period, the area has to be left. Then the application tool shall be washed with fresh water until all parts are clean. Before reusing, all components shall be absolutely dry, and the application tool has to be technically checked. **Re-entry into treated area:** The operator re-enters the treated area and measures the phosphane concentration level. As soon as the concentration is below 0.014 mg/m³ (0.01 ppm), the re-entry for other persons than the operator is allowed. The main risks of aluminium phosphide containing products for professionals are caused by inhalation of phosphane. The inhalation exposure assessment is based on a Rentokil Report 264/3. This data was also used by the Rapporteur Member State Germany for the annex I (Directive 98/8/EC) inclusion of aluminium phosphide. For dermal contact aluminium phosphide is relevant. The dermal exposure is based on expert judgment. Potential dermal exposure is focused to hands during application (blockage) and cleaning the applicator. The described exposure assessment is valid for trained professional users (users with competence certificate). The frequency is assumed to be 110 days/year. No secondary exposure to professionals is expected.		
	Parameters	Value
Tier 1	single tablet	3 g
	Diameter of a tablet	1.45 cm
	Density	1.88 g/cm³

	Duration	480 min
	Frequency	330 burrows/day
	Thickness layer	0.0001 cm
	Inhalation exposure (to phosphane)	exposure monitoring data
	Dermal exposure (to aluminium phosphide)	calculation based on expert judgment
Tier 2	Protective gloves (EN 374)	10 %

Calculations for Scenario 2

Inhalation exposure assessment of phosphine:

For the outdoor uses of Phostoxin WM the Rentokil Report 264/3 (1999) needs to be considered for the operator exposure assessment by using the application tool. For the risk assessment, only data which originated from an application in accordance with the intended uses of aluminium phosphide products were used from the study. The sampling of phosphane in air in this study included all aspects of the treatment including can opening, transfer of the product to the application tool, application of the product and cleaning of the application tool. The cleaning process is not described in detail in the study but it is expected that the exposure to the evolved phosphane lasts only for seconds. Phosphane exposure was monitored using personal monitoring devices and static monitoring devices fitted with the appropriate monitoring tubes. Personal samplers were clipped to the workers' lapel in the breathing zone and static measuring devices were placed around the treated area. The study consisted of two four-hour rabbit hole treatments on consecutive days on different areas on a farm. For the treatments 360 - 540 g Phostoxin WM were used.

All personal and static samples were below the limit of detection of 0.1 mg PH_3/m^3. Thus, half of the limit of detection was used (*i.e.* 0.05 mg/m³) for the exposure calculation of the operators, in line with guidance for a worst-case consideration.[13] This value is supported by measurement results of Lloyd et al. (1987) [14] where a similar application tool was used but determination was performed with a more sensitive method. The highest personal monitoring measurement result in this study was 0.01 mg/m³.

After application, the operator re-enters the treated area for very short durations to measure the residual phosphane concentration level. Due to the rapid degradation in soil and air, it can be assumed that already a short period after the application the phosphane evolution will have been completed. However under unfavourable conditions an exceedance of the reference values could not be excluded.

Therefore, to ensure a safe re-entry, measurements to control the phosphane levels are mandatory.. The related risk mitigation measures (e.g. warning signgs, resrited areas, measurements) are listed under section 2.5.2 Risk mitigation measures.

Inhalation exposure assessment of aluminium phosphide particle:

During the use of Phostoxin WM exposure to particles is not expected.

[13] OECD (2002), Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application, OECD Series on Testing and Assessment, No. 9, OECD Publishing, Paris, https://doi.org/10.1787/9789264078079-en.

[14] Lloyd. G.A., Bell, G.J., Samuels, S.W., Respiratory Exposure to Phosphine: Rabbit Gassing in Woodland Areas, Pesticide Safety directorate, Ministry of Agriculture, Fisheries and Food, UK, 1987

Dermal exposure assessment to phosphane:

Any phosphane gas arising from the contact with skin is covered by the inhalative exposure assessment of aluminium phosphide.

Dermal exposure assessment to aluminium phosphide:

During the use of the application tool, a direct contact with the biocidal product is incidental. Lloyd et al. (1987) described that it is necessary to clear soil from the outlet of the delivery tube. If one tablet is in the applicator tube, it is reasonable that a dermal contact could occur. Contamination of hands during application is also supported by Baker, R.O. (1992)[15].
For the assessment of dermal exposure during application, no dermal measurements are available. Therefore, the assessment is based on expert judgment. As a worst case the duration for the use of Phostoxin WM is assessed to be 8 hours. The applied amount in the Rentokil Report 264/3 was 360-540 g during 4 hour treatments with an applicator. This is in accordance with other information that an amount of up to 1 kg (334 tablets) is typically used for a whole day treatment in a field. Therefore, for the estimation of the dermal exposure, 1 kg is expected to represent a worst case situation and a dermal contact to 3 tablets are assumed. The dermal assessment is based on the expert judgment, which is described in detail in chapter 4.3.1. After the application aluminium phosphide completely reacts with moisture, releasing phosphane.

Further information and considerations on scenario 2

Exposure to eyes:

Eye contact to the product cannot be excluded. The product is classified as Eye Dam. 1 (H318). This information is relevant for risk characterisation of local effects.

Table 44

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure mg/m³**	**Estimated dermal exposure mg/person/day**	**Estimated oral exposure**	
Scenario 1 Fumigation with alumonium phosphide pellets	Tier 1	0.05	3.65	-	
Scenario 2 Fumigation with aluminium phosphide tablets	Tier 1	0.05	2.09	-	

[15] Baker. R.O., Exposure of persons to phosphine gas from aluminium phosphide application to rodent burrows, Proceedings of the 15th Vertebrate Pest Conference (1992)

- **Combined scenarios**

As no secondary exposure to professionals is expected, the calculation of combined scenarios for professional user is considered not relevant.

3.6.3.1.2 Non-professional exposure

The biocidal product is for professional use only. Non-professional use is not intended.

3.6.3.1.3 Secondary exposure of the general public

Exposure scenarios for the general public were adopted from the first PAR. Some parameters were adapted in accordance with the current Guidance (e.g. HEAdhoc recommendation No. 14, 2017).

- **Scenario [3]**

Table 45

Description of Scenario [3]		
Exposure to phosphine from phosphine releasing biocidal products may occur to individuals that re-enter treated areas directly after clearance by the operator. According to the applicant, re-entry for other persons than the operator is only allowed if the clearance is granted and the concentration of phosphine is below 0.01 ppm (corresponding to 0.014 mg/m^3). A worst case scenario under the above mentioned realistic conditions was calculated: If a person stays in treated areas for 24 h and the concentration remains stable over this period of time (no degradation, no ventilation), the person is exposed to 0.28 mg/d (adults) or 0.056 mg/d (infants) assuming a inhalation rate of 16 m^3/d (adults) or 5.4 m^3/d (infants). If a body weight of 60 kg and 8 kg, respectively, and an inhalation absorption of 100 % is expected, this results in an internal dose of 0.00373 mg/kg bw/(d) for adults and 0.00945 mg/kg bw/(d) for infants		
	Parameters	Value
Tier 1	Maximum concentration of phosphine gas (applicant)	0.01 ppm = 0.014 mg/m^3
	Inhalation rate adult (HEAdhoc recommendation No. 14, 2017)	16 m^3/d
	Inhalation rate infant (HEAdhoc recommendation No. 14, 2017)	5.4 m^3/d
	Body weight adult (HEAdhoc recommendation No. 14, 2017)	60 kg
	Body weight infant (HEAdhoc recommendation No. 14, 2017)	8 kg
	Inhalation absorption (default)	100 %

Calculations for Scenario [3]

Exposure (inhalation) = maximum concentration phosphine gas x inhalation rate x inhalation absorption / body weight

Adult:

Exposure (inhalation) = 0.014 mg/m^3 x 16 m^3 x 100 % / 60 kg

= 0.00373 mg/kg bw/d

Infant:

Exposure (inhalation) = 0.014 mg/m^3 x 5.4 m^3 x 100 % / 8 kg

= 0.00945 mg/kg bw/d

- **Scenario [4]**

Description of Scenario [4]		
Secondary exposure of bystanders during application can occur. According to a study provided by the applicant (Old, 2003) and evaluated for the first authorisation, no phosphine gas is detectable outside of buildings, if biocidal products containing aluminium phosphide are applied appropriately for insecticidal treatment in buildings. Since this study only examined indoor concentrations of phosphine gas, the results of this study are not applicable for rodenticidal outdoor use (application in burrows). For renewal, the applicant also refers to the Rentokil Report 264/3 (1999). In this study, aerial concentrations during the work of the operator were determined. According to the study report, the concentration of phosphine gas was below 0.05 mg/m³. However, phosphine gas may be released from aluminium phosphide not instantaneously but with a certain delay. This may lead to higher aerial concentrations after the actual application process. Therefore, this study has not been considered relevant for bystander exposure. In any case, exposure of bystanders has to be below the $AEC_{medium-term}$ for phosphine gas (0.03 ppm). In addition, the applicant proposed a clearance concentration of 0.01 ppm phosphine gas. If it is assumed as a worst case that a bystander is exposed for 24 h to this concentration (inhalation absorption 100 %; body weight 60 kg for adults and 8 kg for infants; inhalation rate 16 m³/d for adults and 5.4 m³/d for infants). These concentrations would result in internal doses as calculated below.		
	Parameters	Value
Tier 1	$AEC_{medium-term}$ of phosphine gas (CAR)	0.03 ppm = 0.042 mg/m³
	Clearance concentration of phosphine gas (applicant)	0.01 ppm = 0.014 mg/m³
	Inhalation rate adult (HEAdhoc recommendation No. 14, 2017)	16 m³/d
	Inhalation rate infant (HEAdhoc recommendation No. 14, 2017)	5.4 m³/d
	Body weight adult (HEAdhoc recommendation No. 14, 2017)	60 kg
	Body weight infant (HEAdhoc recommendation No. 14, 2017)	8 kg
	Inhalation absorption (default)	100 %

Calculations for Scenario [4]

Exposure (inhalation) = maximum concentration phosphine gas x inhalation rate x inhalation absorption / body weight

For $AEC_{medium-term}$ (0.03 ppm = 0.042 mg/m³)

Adult:

Exposure (inhalation) = 0.042 mg/m³ x 16 m³ x 100 % / 60 kg

= 0.011 mg/kg bw/d

Infant:

Exposure (inhalation) = 0.042 mg/m³ x 5.4 m³ x 100 % / 8 kg

= 0.028 mg/kg bw/d

For clearance concentration (0.01 ppm = 0.014 mg/m³)

Adult:

Exposure (inhalation) = 0.014 mg/m³ x 16 m³ x 100 % / 60 kg

= 0.00373 mg/kg bw/d

Infant:

Exposure (inhalation) = 0.014 mg/m³ x 5.4 m³ x 100 % / 8 kg

= 0.00945 mg/kg bw/d

Table 46

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
[3] Resident exposure	1	0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d	Not relevant	Not relevant	0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d
[4] Bystander exposure	1	0.03 ppm 0.042 mg/m³ Adult: 0.011 mg/kg bw/d Infant: 0.028 mg/kg bw/d 0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d	Not relevant	Not relevant	003 ppm 0.042 mg/m³ Adult: 0.011 mg/kg bw/d Infant: 0.028 mg/kg bw/d 0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d

- **Combined scenarios**

Not relevant.

3.6.3.2 Dietary exposure

Table 47

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Aluminium phosphide releasing phosphine
Type of formulation	ready-to-use gas-generating pellets
Substance(s) of concern	Ammonium carbamate (21 % (w/w)
Field(s) of use	outdoors in rodent underground tunnel systems (for the protection of food, health, materials and stored products)
Target organism(s)	Rattus norwegicus, Arvicola terrestris
Application rate(s) and frequency	- 3 g and 0.6 g biocidal product pellets (containing 56 % (w/w) a.s.) - 1 Tablet (3 g) or 5 Pellets (0.6 g each) every 3-5 m burrow length in light soil or every 8-10 m in all other soil types.
Category(ies) of users	Trained professional
Waiting periods after treatment	/
Further information	/

Conclusion

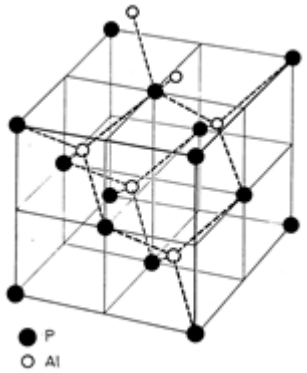
The intended use description of the aluminium phosphide-containing biocidal product for which authorisation is sought indicates that the uses are not relevant in terms of residues in food and feed. The product is to be used for control of rodent pests in underground tunnel systems with gas-generating pellets that do not come in direct contact with food, feed stuff or livestock animals.

No further data are required concerning the residue behaviour.

The intended uses are not relevant in terms of consumer health protection.

3.6.3.2.1 General information on active substance(s)

Table 48

Active substance (Common Name)	Aluminium phosphide
CAS number	20859-73-8
Chemical structure	
Molecular formular	AlP
Molar mass	57.96
Log Po/w	CAR: technically not feasible (hydrolysis)
Active substance approval	PT: 14; RMS: DE
Restrictions	-
Current regulations on MRLs	-

3.6.3.2.1.1 Information of non-biocidal use of the active substance

Information on the residue definitions is provided in chapter 3.6.4.2. Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report as in Table 19, Table 20 and Table 21 of Section 3.6.1 Assessment of effects of the active substance on human health.

Table 49

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant Protection Product	Insecticide, rodenticide, talpicide and leporicide used by professional users	MRLs according to Reg. (EU) 2016/1785 range: 0.01*-0.7 mg /kg

**MRL set at LOQ*

3.6.3.3 Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not relevant.

3.6.3.5 Summary of exposure assessment

Table 50

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake aluminium phosphide [mg/kg bw/d]**	**Estimated external exposure phosphane [mg/m³]**
1. Fumigation with aluminium phosphide pellets	Trained professional user	Tier 1: Protective gloves Eye protection	6.09×10^{-3}	0.05
2. Fumigation with aluminium phosphide tablets	Trained professional user	Tier 1: Protective gloves Eye protection	3.48×10^{-3}	0.05

Table 51

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier**	**Estimated total uptake**
[3] Resident exposure	General public (residents)	1	0.01 ppm 0.014 mg/m^3 Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d
[4] Bystander exposure	General public (bystanders)	1	0. 03 ppm 0.042 mg/m^3 Adult: 0.011 mg/kg bw/d Infant: 0.028 mg/kg bw/d 0.01 ppm 0.014 mg/m^3 Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report as in Table 19, Table 20 and Table 21 of Section 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

Residue definitions

Phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts)) determined and expressed as phosphane.

Table 52

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reg (EU) 2016/1785	Food of plant and animal origin	0.01* -0.7 mg/kg

*MRL set at LOQ

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list and the endocrine disruptor assessment list there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

3.6.4.5 Risk for industrial users

No industrial applications are intended.

3.6.4.6 Risk for professional users

The risk assessment is performed for the active substances aluminium phosphide and phosphane as well as the substance of concern ammonium carbamate.
The occupational risk assessment for the biocidal product Phostoxin WM takes into account systemic effects of aluminium phosphide as well as systemic effects of phosphane – the active component that is developed after contact of aluminium phosphide with water by spontaneous hydrolysis.

The occupational risk assessment for systemic effects of the active substance aluminium phosphide is based on the internal reference value (AEL). The occupational risk assessment for systemic effects of phosphane is based on the quantitative risk assessment with the European OEL.
In the biocidal product ammonium carbamate is identified as a substance of concern based on self-classification with H315 and H318 in the safety data sheet submitted by the applicant.

Active substance aluminium phosphide

No significant substance-related adverse effects of the active substance aluminium phosphide were observed with the highest tested concentration of 1.9 mg aluminium phosphide/kg bw/d in an inhalative developmental study in rats. The risk characterisation for systemic effects of aluminium phosphide is performed with the AEL approach that compares total internal body burden (total uptake) with the reference value (AEL) respectively. The quantitative risk characterisation for professional users using the AEL takes into account dermal exposure to aluminium phosphide resulting from use of the biocidal product Phostoxin WM.

Details of risk characterisation

Reference value

As systemic reference values the $AEL_{long\text{-}term}$ of 0.019 mg aluminium phosphide/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

Inhalation exposure is not considered relevant for aluminium phosphide. Thus, the total uptake equals the dermal exposure to aluminium phosphide.

The dermal uptake referring to aluminium phosphide that results from the use of the biocidal product Phostoxin WM is determined according to the following equations:

> Dermal uptake (mg/kg bw/d) = dermal exposure to aluminium phosphide (mg/kg bw/d) x 10 % dermal absorption / 100%

The total uptake is compared to the reference value AEL to determine AEL exhaustion. AEL exhaustion is expressed as percentage (%).

A risk for professional users referring to the active substance aluminium phosphide resulting from the use of the biocidal product Phostoxin WM is unlikely, if the AEL exhaustion for each scenario is below the value of 100 %. Table 53 gives a detailed overview of the risk assessment results referring to the active substance aluminium phosphide. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places. However, the underlying calculations are based on unrounded values.

As shown in Table 53, for the scenarios ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’ a risk for the professional user is unlikely already in Tier 1.

Table 53: Overview of detailed risk assessment results referring to the active substance aluminium phosphide in the biocidal product Phostoxin WM

Scenario		$AEL_{long-term}$ mg/kg bw/d	Estimated inhalation uptake mg/kg bw/d	Inhalation uptake / AEL %	Estimated dermal uptake mg/kg bw/d	Dermal uptake / AEL %	Estimated total uptake mg/kg bw/d	Estimated total uptake / AEL %	Acceptable (yes/no)
Fumigation with aluminium phosphide - pellets	Tier 1	0.019	not expected	-	$6.09x10^{-3}$	32	$6.09x10^{-3}$	32	**yes**
Fumigation with aluminium phosphide - tablets	Tier 1	0.019	not expected	-	$3.48x10^{-3}$	18	$3.48x10^{-3}$	18	**yes**

Conclusion

Based on the risk assessment of the active substance aluminium phosphide via the dermal route, a risk for professional users resulting from the uses 'Fumigation with aluminium phosphide - pellets' and 'Fumigation with aluminium phosphide - tablets' with the biocidal product Phostoxin WM is unlikely after Tier 1 consideration.

Active substance phosphane (PH_3)

A quantitative risk characterisation for professional users is carried out since there is an European OEL of 0.14 mg/m³ for phosphane.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to phosphane from the biocidal product Phostoxin WM, the European OEL (0.14 mg/m³; 8 h TWA) is used as an external inhalation reference value and directly compared with airborne concentrations of phosphane as the CAR PT14 (DE, 2008) states:

„For phosphine, an occupational exposure limit of 0.14 mg/m³ (0.1 ppm) for air monitoring at the workplace is recommended by SCOEL which has been confirmed by the data evaluated in this report. This value shall be taken into account for authorisation of aluminium phosphide containing products which are effective as biocides by phosphine generation."

Calculation of OEL exhaustion (%)

The substance specific OEL exhaustion (%) resulting from use of the biocidal product Phostoxin WM is determined according to the following equations:

OEL exhaustion (%) = inhalation exposure to phosphane (in mg/m³) / European OEL of phosphane (mg/m³).

A risk for professional users referring to phosphane resulting from the use of the biocidal product Phostoxin WM is acceptable if the OEL exhaustion (%) for each scenario is below the value of 100 %.

Table 54 gives a detailed overview of the systemic risk assessment results for inhalation route referring to phosphane in the biocidal product Phostoxin WM. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 54. However, the underlying calculations are based on unrounded values.

As shown in Table 54, for the scenarios 'Fumigation with aluminium phosphide - pellets' and 'Fumigation with aluminium phosphide - tablets' a risk for the professional user is unlikely already in Tier 1

Table 54: Overview of detailed systemic risk assessment results for inhalation route referring to PH_3 in the biocidal product Phostoxin WM

Scenario		**Reference value inhalative EU-OEL**	**Estimated inhalation exposure**	**Estimated inhalation exposure / OEL** OEL exhaustion	**Acceptable**
		mg/m³	mg/m³	**%**	(yes/no)
		TWA		**TWA**	**TWA**
Fumigation with aluminium phosphide - pellets	Tier 1	0.14	0.05	36	yes
Fumigation with aluminium phosphide - tablets	Tier 1	0.14	0.05	36	yes

Conclusion

Based on the risk assessment of phosphane via the inhalation route, a risk for professional users resulting from the intended uses 'Fumigation with aluminium phosphide - pellets' and 'Fumigation with aluminium phosphide - tablets' is unlikely after Tier 1 consideration. The risk characterisation shows that the European OEL of phosphane can be met.

Substance of concern ammonium carbamate

The SoC ammonium carbamate exerts local effects. In Table 55 the classification and assigned band according to the banding evaluation scheme of the SoC Guidance (Annex A to the Guidance on the

Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)) are shown.

Table 55: Overview of the relevant classification and assigned band from the banding evalution scheme according to the SoC-Guidance for the SoC ammonium carbamate

Resulting classification according to Regulation (EC) No. 1272/2008	**Relevant band from Banding evaluation scheme**	**Associated evaluation/risk management requirements**	**Implementation**
Skin Irrit. 2, H315	A	Application of S-phrases/P-statements normally associated with concerned R-phrases/H statements	See section 2.3
Eye Dam. 1, H318	B	Qualitative exposure and risk assessment to determine whether S-phrases/P-statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied	See chapter Local effects- qualitative, since the product is also classified with H318

Local effects - qualitative

The local toxicity profile of the biocidal product is considered and therefore, a qualitative risk assessment for local effects regarding contact with skin and eye is necessary. The qualitative local risk assessment takes into account the concentrated biocidal product. Table 56 gives an overview of the relevant classifications and the hazard category for the qualitative local risk assessment of the biocidal product Phostoxin WM.

Table 56: Relevant classification and resulting hazard categories of Phostoxin WM

b.p. concentration [%]	**Resulting classification according to Regulation (EC) No. 1272/2008**	**Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)**
100	Skin Irrit. 2, H315 Eye Dam. 1, H318	low high

For the concentrated biocidal product local risk assessment is triggered by the eye damage (Eye Dam. 1, H318) as this classification is allocated to the hazard category “high” (Table 56). The classification for skin irritation is allocated to the hazard category “low”.

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017), the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin and eyes of the biocidal product Phostoxin WM for the intended uses ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’ (Table 57). With the proposed RMM the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses.

Table 57: Summary of qualitative conclusions for local risk assessment for the scenarios ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’

Tasks, uses, processes	Concentration b.p. (max.)	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
fumigation	100%	Eye Dam. 1, H318 Skin Irrit. 2, H315	high	daily 110 days/ year	Skin: Contact to hands, eyes expected	Technical Measure: - Automatic application system Organisational measure: [1)] PPE: - Protective gloves (EN 374) - Eye/face protection	acceptable

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

In Table 26 is stated that “next to acute toxic effects also irritation or even corrosion of the respiratory tract by phosphine gas might occur”. As mentioned in chapter 3.6.3.1.1 to ensure a safe re-entry, measurements to control the phosphane levels are mandatory. The related risk mitigation measures (e.g. warning signs, restricted areas, measurements) are listed under section 2.5.2 Risk mitigation measures.

Conclusion

Concerning the corrosive and irritating properties of the biocidal product Phostoxin WM, exposure should be minimised with RMM. If the proposed RMM are implemented, a risk for professional users

resulting from the intended uses ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’ is unlikely.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Phostoxin WM is unlikely for the intended uses ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’.

Safe application of this biocidal product requires that a number of measures are performed as well as specific knowledge is required. This is laid out in more detail in chapter 3.6.4.8. A prerequisite for a safe use of the professional user is therefore the specific training in fumigation and thus the authorization of this biocidal product is to be restricted to the user category “trained professional”. In Germany this training is regulated by national law and mandatory for the professional user.
Further RMM described in chapter 2.5.2 have to be taken into account by a trained professional user (training in fumigation) in order to ensure a safe use of the biocidal product Phostoxin WM.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.7 Risk for non-professional users

Not relevant. The biocidal product is for professional use only.

3.6.4.8 Risk for the general public

Table 58: Systemic effects

Task/ Scenario	Tier	$AEC_{medium-term}$ $AEL_{medium-term}$	Estimated uptake	Estimated uptake / AEC or AEL (%)	Acceptable (yes/no)
3 Resident exposure	1	0.03 ppm 0.042 mg/m³ 0.011 mg/kg bw/d	0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d	33 33 34 86	Yes (with additional RMM)
4 Bystander exposure	1	0.03 ppm 0.042 mg/m³ 0.011 mg/kg bw/d	003 ppm 0.042 mg/m³ Adult: 0.011 mg/kg bw/d Infant: 0.028 mg/kg bw/d 0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d	100 100 100 255 33 34	Yes (with additional RMM)

Task/ Scenario	Tier	$AEC_{medium\text{-}term}$ $AEL_{medium\text{-}term}$	Estimated uptake	Estimated uptake / AEC or AEL (%)	Acceptable (yes/no)
			Infant: 0.00945 mg/kg bw/d	86	

- **Local effects**

Based on the severe acute systemic effects, local exposure is considered not relevant for the general public.

Conclusion

Based on the exposure and risk assessment, it can be assumed that the intended use of the biocidal product is safe if persons of the general public do not enter treated areas unless the phosphine gas concentration is below 0.01 ppm. This has to be ensured by appropriate risk mitigation measures.

1. The application has to be performed by trained professionals.

2. Due to the high acute toxicity and the corresponding high risk of severe poisoning, a general remark to comply with instructions for use is appropriate:
   To avoid risks to man and the environment, comply with the instructions for use.

3. Based on the high risk of acute poisoning and the potential risk of gas release, inhabitants in the vicinity have to be informed that a treatment will take place (at least 3 days before the start of the fumigation). Inhabitants and users of premises in the vicinity must be able to prepare (e.g. remove or protect their property from the affected areas if necessary). As it is known that phosphine gas distributes in burrows and other vicinities (which are not always known), a distance of 25 m is considered appropriate to protect the concerned persons. Hence, the following risk mitigation measure is required:
   Inhabitants and/or authorised users of premises directly adjacent or in a distance of up to 25 m to the fumigated area shall be informed adequately at least three days before fumigation in writing about the risk posed by the biocidal product. The information includes at least:
   a) the name of the fumigant with the authorisation number and
   b) the name of the active substance,
   c) information about the way of exposure (inhalation) as well as
   d) the limited sensory perception of phosphine through impurities (carbide- or garlic-like, foul-smelling fish),
   e) the request to leave immediately the area after olfactory perception (the smell is often only perceptible above health-based limits),
   f) description of disease symptoms of intoxication after inhalation;
   g) description of recommended first-aid measures and

h) further sources of information (manufacturer of the biocidal product, name and telephone number of the user, competent poison control centre).

4. For correct application of the biocidal product and to protect humans and animals, a danger zone has to be defined:
The head of fumigation has to set up a danger area for safety of the general public as well as farm and domestic animals. The danger area shall not undercut a size of 10 m around the treated area.

5. + 6. Application might be performed in areas accessible for the general public or animals. To protect these persons and animals, the concerned areas have to be secured. Based on the high risk of acute poisoning and the potential risk of gas release, the following risk mitigation measures are appropriate:
If the danger area is accessible for the general public, farm and/or domestic animals, it has to be secured before the beginning of the fumigation and for two consecutive days, at least

a) by an appropriate cordon (e.g. red-white barrier tape),
b) a warning sign: acute toxicity symbol (skull and crossbones) with following features:
i. "Danger because of soil fumigation. Very toxic gases! Danger to life! No trespassing!"
ii. The name of the biocidal product as well as date and time of the fumigation must be stated.
iii. The address of the responsible person as well as adequate emergency telephone numbers must be labelled.

As a precautionary measure, a safety distance of at least 25 m to vicinal areas, which are not used agriculturally, or for forestry must be respected. If by organisational measures (signposting, barrier tape, written agreement with the owners or authorised users etc.) it can be ensured that no persons or farm resp. domestic animals stay in the vicinal areas, the safety distance may be reduced. The specifications for the danger area and the duration of the control measures remain unaffected.

7. Based on the risk assessment presented above, a human health risk cannot be excluded if the aerial phosphine concentration is above 0.01 ppm for a longer time interval. As many analytical methods have detection limits above or in the range of this level it is appropriate to demand that an appropriate method is used to ensure that no phosphine gas is detectable outside the safety distance. Therefore, the following risk mitigation measure is necessary.
Outside the established danger area, the fumigant must not be detectable. For detection, a measurement method with a limit of detection (LOD) equal or lower than 0.01 ppm must be used. Until release, the danger area may only be entered by people who have to perform an activity related to the fumigation.
In this context, it should be noted that in the current German TRGS (2012) a level of 0.1 ppm phosphine gas is listed. This level is not in accordance with the risk assessment for Phostoxin WM and therefore not relevant.

8. The detailed distribution of phosphine gas in the burrow systems and other cavities cannot be predicted precisely in all cases. Therefore, it is always possible that aerial phosphine gas concentration increases and reach critical levels. Hence, it is necessary to check these levels regularly:
   The pest controller (or a person with expert knowledge about chemical analysis of the used fumigant) has to check regularly before signing off if in the ambient air outside the danger area, the concentration of the fumigant is beyond the limit value. The measurement results and, if necessary, the safety measures taken must be recorded in writing and stored with the documentation of the fumigation.

9. Phosphine gas is released from aluminium phosphide by contact with moisture. Therefore, under specific weather and ground conditions (e.g. fog, rain. heavy moisture penetration of soil) the release of phosphine gas cannot be controlled adequately. Therefore, the biocidal product is not to be used under these weather conditions.
   Do not use in case of bad weather conditions (like intense fog, rain, heavy moisture penetration of soil).

10. + 12. The architecture and course of burrows and other cavities cannot be predicted precisely. It is possible that burrows near inhabited houses are in direct contact to house walls. Under adverse conditions these walls are leaky or contain holes (e.g. old pipe junctions) leading phosphine gas directly into such buildings. For this reasons a specific distance to inhabited houses and a non-contact to the corresponding parts of the house are necessary:
    Treated burrows must be in adequate distance to inhabited houses (at least 10 m).
    It has to be ensured that treated burrows do not meet cellars or other parts of housings.

3.6.4.9 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

3.6.4.10 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Professional user

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not performed as the risk characterisation for the inhalation route was performed with the external OEL approach and the risk characterisation for the dermal route was

performed using the internal AEL approach. The substance of concern ammonium carbamate has solely local effects and is therefore not considered for cumulative risk assessment.

3.6.4.11 Summary of risk characterisation

3.6.4.11.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.11.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Phostoxin WM is unlikely for the intended uses ‘Fumigation with aluminium phosphide - pellets‘ and ‘Fumigation with aluminium phosphide - tablets’ (Table 53 to Table 57). RMM described in chapter 2.5.2 have to be taken into account in order to ensure a safe use of the biocidal product Phostoxin WM.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.11.3 Summary of risk characterisation for non-professional user

Not relevant.

3.6.4.11.4 Summary of risk characterisation for indirect exposure

Table 59

Scenario, Tier	Relevant reference values	Estimated uptake	Estimated uptake / reference value (%)	Acceptable (yes/no)
3 Resident exposure, Tier 1	0.03 ppm 0.042 mg/m³ 0.011 mg/kg bw/d	0.01 ppm 0.014 mg/m³ Adult: 0.00373 mg/kg bw/d Infant: 0.00945 mg/kg bw/d	33 33 34 86	Yes (with additional RMM)
4 Bystander exposure, Tier 1	0.03 ppm 0.042 mg/m³ 0.011 mg/kg bw/d	0.5 ppb = 0.0005 ppm 0.0007 mg/m³ Adult: 0.00019 mg/kg bw/d Infant: 0.00047 mg/kg bw/d	2 2 2 4	Yes (with additional RMM)

Exposure of the general public to phosphine gas released during the application of Phostoxin WM is considered acceptable if the biocidal product is used as intended and all risk mitigation measures listed in section 3.6.4.8 are followed.

3.7 Risk assessment for animal health

The exposure and risk assessment for the general public (refer to sections 3.6.3.1.3 and 3.6.4.8) covers also health risks for animals. Risk mitigation measures listed in section 3.6.4.8 are also valid for pets and livestock (domestic) animals. To protect particularly pets and other smaller non-target animals, the following additional advice is considered appropriate:

Before fumigation, it has to be controlled that no non-target organisms are staying in the object to be fumigated.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product contains no substance of concern which is relevant for the risk assessment for the environment. Therefore, the environmental risk assessment for the product is based on the active substance Aluminium phosphide releasing phosphine (see Assessment Report Aluminium phosphide releasing phosphine PT 14, 30 May 2008 and CAR Aluminium phosphide releasing phosphine for use in PT 14 (Detia Freyberg GmbH; RMS Germany); June 2008).

Aluminium phosphide (AlP) reacts with moisture forming phosphine gas (PH_3). Any toxicity observed in the available tests is therefore caused by the reaction product PH_3. As the intended use of aluminium phosphide also leads to the formation of PH_3 (the actual active substance), the tests are adequate for the assessment of the effects of aluminium phosphide on environmental organisms.
The second reaction product, $Al(OH)_3$ is ubiquitous in the environment and is nearly insoluble. The formation of freely available and toxic Al^{3+} from $Al(OH)_3$ and other aluminium compounds is mainly dominated by the properties of the soil compartment, especially by the pH value of the soil. Aluminium is only soluble in acid soils with pH values around 4 and below. Therefore, rather the acidification of soils than the release of $Al(OH)_3$ from the local restricted use of AlP causes an increase in the concentration of toxic Al^{3+}. It can be assumed that the release of this reaction product from the locally restricted intended use of aluminium phosphide as a fumigant in underground burrow systems will not significantly increase the environmental concentration of this compound or of freely available Al^{3+}. Therefore, the second reaction product is not further regarded for the environmental risk assessment.

The product Phostoxin WM applied for authorisation is identical to the representative product in the CAR for active substance approval. The intended use as well as the application rate and the exposure to the environment are identical. No new data / information for the biocidal product or active substance are provided by the applicant. All the studies supporting environmental fate and toxicity properties of the product PHOSTOXIN WM are based on the active substance Aluminium phosphide releasing phosphine as reported in the CAR document.

3.8.2 Effects assessment

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

Exposure due to the use of the b.p. is possible/relevant for the environmental compartments air, soil and groundwater. Please refer to the details in the sections “environmental fate and behaviour” and “exposure assessment”

- **Screening Step 2:**

The biocidal product contains no substance of concern for the environment Therefore, no mixture toxicity assessment is required.

3.8.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

No new information compared to the CAR from 2008 has been provided.
In the CAR a **$PNEC_{aqua}$ of 7.98 ng/L** was derived from the lowest effect value obtained from a valid study with *Oncorhynchus mykiss* using an assessment factor of 1000. Related to the PH_3 concentration the $PNEC_{aqua}$ is 4.68 ng/L.

Neither aluminium phosphide nor the reaction product phosphine is expected to accumulate in sediments. In addition, no exposure of the aquatic compartment (incl. sediment) occurs from the intended use of aluminium phosphide as fumigant in rodent underground tunnel systems. Therefore, it is not necessary to derive a $PNEC_{sediment}$.

No exposure of sewer systems occurs from the intended use of aluminium phosphide as fumigant in rodent underground tunnel systems. Therefore, it is not necessary to derive a $PNEC_{stp}$.

3.8.2.3 Terrestrial compartment (including groundwater)

No new information compared to the CAR from 2008 has been provided. In the CAR a $PNEC_{soil}$ of 8.9 µg/kg dw (corresponding to 7.9 µg/kg ww) was derived for AlP based on a study with soil microorganisms using an assessment factor of 1000. Related to the reaction product PH_3 the $PNEC_{soil}$ is 5.2 µg/kg dw (4.6 µg/kg ww).

3.8.2.4 Atmosphere

No ecotoxicological data are available.

3.8.2.5 Non-compartment specific effects

3.8.2.5.1 Further ecotoxicological studies

Effects on birds

No new information compared to the CAR has been provided.

Although data on the toxicity to birds belong to the additional data requirements for biocides in PT 14 (rodenticides), no data have been provided by the applicant with the justification that the special conditions of use exclude the possibility that birds come into contact with aluminium phosphide or phosphine gas. In the CAR it was agreed that the submission of data on toxicity of aluminium phosphide to birds is not considered to be required as the intended use in burrow systems make a direct exposure of birds negligible.

Effects on mammals

No new information compared to the CAR has been provided.

As stated by the applicant, all non-target vertebrates which are using the tunnels of the target organisms as a part of their habitat (least weasel: *Mustela nivalis*) or living in similar holes in the same habitat (mole: *Talpa europaea,* ground squirrels: *Spermophilus,* hamster*: Cricetus cricetus*) are highly endangered by the arising PH_3.

3.8.2.6 Summary of effects assessment

Table 60

Summary table on calculated PNEC values	
Compartment	**PNEC**
water	7.98 ng/L (= 4.68 ng/L PH_3)
soil	7.9 µg/kg ww (= 4.6 µg/kg ww PH_3)

3.8.3 Exposure assessment

Phostoxin-WM (56 % aluminium phosphide) is intended to be used for fumigation of target rodent species vole (*Arvicola terrestris*) and Norway rat (*Rattus norvegicus*) in underground tunnel systems (burrows) of non-agricultural areas, where rodent burrows can cause damage (e.g. embankments,

dikes, dams).

The intended use of the b.p. is assessed in line with Revised Emission Scenario Document for Product Type 14, Rodenticides (August 2018), the Guidance BPR IV ENV B+C (2017) and the assessment report of Aluminiumphosphid (Assessment Report Aluminiumphosphid PT 14, June 2008, RMS Germany). The current Revised Emission Scenario Document for Product Type 14 for rodenticides was published in August 2018 by the ECHA. However, no changes concerning the open area gassing scenario were implemented. Thus, the existing emission estimations from the previous active substance and product authorisations remain valid.

Table 61

Assessed PT	PT 14
Assessed scenarios	Scenario 1: open areas (outdoor) – gassing of underground burrow systems
ESD(s) used	Revised Emission Scenario Document for Product Type 14, Rodenticides (August 2018), hereafter named rev. ESD PT14
Approach	Scenario 1: Average consumption
Distribution in the environment	Calculation based on Guidance on the Biocidal Products Regulation Vol. IV Environment – Assessment and Evaluation (Parts B + C) Version 2.0, October 2017 (Guidance BPR IV ENV B+C (2017)),
Groundwater simulation	Not necessary
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1: Production: Yes Formulation: Yes Use: Yes Service life: No
Remarks	-

3.8.3.1 Fate and distribution in exposed environmental compartments

No new studies or information on environmental exposure compared to the CAR from 2008 have been submitted by the applicant.

The environmental exposure assessment for the product Phostoxin WM is based on the concept of releases to the environment occurring at all life cycle stages of the b.p. and phosphine (PH3) as its degradation product and actual a.s., respectively.

Both, solid aluminium phosphide and released gaseous PH3, as well as the aluminium entity are inorganic compounds and thus not susceptible to biological degradation in the environment.

Phosphine released into the aquatic compartment is poorly soluble in water (24 ml/100 ml water at 24° C). In water, aluminium phosphide is decomposed into hydrogen phosphide (PH3). PH3 is not stable in water for more than one week independent of the pH of the test solutions. The DT50 values are approximately 4-5 days at each pH.

Aluminium phosphide has a negligible vapour pressure (<<10-5 Pa at 25°C). No emission into air of aluminium phosphide is to be expected. In contact with soil and air humidity, aluminium phosphide will be degraded rapidly. The degradation product phosphine is volatile and is decomposed rapidly in air. According to the references, the maximum half-life of phosphine in air is estimated to be 28 hours. Based on this half-life, an accumulation of phosphine in the air is not to be expected.
The use pattern of Phostoxin WM inside of burrows and the spontaneous reaction with water precludes the active substance itself from leaching. Phosphine has a very high vapour pressure (3295 kPa at 22°C). The Henry's law constant is estimated to be > 320000 Pa m³ mol-1. Thus, considerable transport of dissolved phosphine in the pore water of soil is most unlikely. In addition, phosphine is oxidised to phosphoric acid by atmospheric O2 already in the air phase of the treated burrows. This fact further reduces the amount of phosphine that can potentially leach. Therefore, contamination of groundwater by phosphine can be excluded.
The low log Pow = 0.9 of PH3 indicates that PH3 has a low potential to bioaccumulate in organisms.
Parameters which describe the fate and distribution of Aluminium phosphide and Phosphine in the environment are summarised in Table 62.

Table 62

Input parameters (only set values) for calculating the fate and distribution in the environment for Aluminiumphosphide			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	57.96	g/mol	
Melting point	no melting point up to 500 °C	°C	purity 86.5 %
Boiling point	no boiling point up to 500 °C at 1013.3 hPa	°C	purity 86.5 %
Vapour pressure (at 25°C)	<< 10^{-5}	Pa	purity 86.5 %
Water solubility	-	mg/L	technically not feasible
Henry's Law Constant	n.c.	Pa x m^3/mol	negligible vapour pressure and violent reaction in water

Input parameters (only set values) for calculating the fate and distribution in the environment for Phosphine			
Input	**Value**	**Unit**	**Remarks**
Melting point	-133	°C	purity unknown
Boiling point	-87	°C	purity unknown
Vapour pressure (at 22°C)	3295	kPa	
Water solubility (at 24°C)	24	mL/100 mL water	

Input parameters (only set values) for calculating the fate and distribution in the environment for Phosphine			
Input	**Value**	**Unit**	**Remarks**
Henry's Law Constant	320480	Pa x m^3/mol	calculated
DT_{50} for hydrolysis in surface water	4-5	d (pH-independent)	
DT_{50} for degradation in soil	n.a.	d or hr (at 12ºC)	inorganic substance
DT_{50} for degradation in air	approx. 28	hr	24-hour-day, $5.0 \cdot 10^5$ OH/cm^3

Foreseeable routes of entry into the environment on the basis of the use envisaged

Following compartments might be exposed by application of the product Phostoxin WM:

Table 63

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Other**
Scenario 1	No	No	No	No	No	Yes	No	Yes	Neither

Environmental exposure assessment

Release from production of active substance and formulation of the biocidal product:
According to the restriction in the national German ("TA Luft") regulation a maximum concentration of 0.5 mg/m^3 in the exhaust stream and a magnitude of 2.5 g PH_3 /h (which is equivalent to 0.06 kg/d) must not be exceeded.
Monitoring measurements during maintenance work at the mixing equipment at a production site resulted in PH3-concentrations in the range of 0.12 ppm to 8.32 ppm corresponding to 1.8 x 10^{-4} to 0.013 g/m^3. With respect of a release of phosphine into air during formulation of the a.s into the b.p. (Phostoxin-WM, 56% a.s) it can be expected that the restrictions of the "TA-Luft"-regulation are generally applicable. The value of 2.5 g PH_3 /h is used by the RefMS as the worst case value for an exemplary exposure assessment for the life cycle stages production and formulation. The assessment is performed by applying Guidance BPR IV ENV B+C (2017), taking into account the OPS-model for calculation of $Clocal_{air}$ and the deposition rate, resulting in 1.668 E-5 mg/m^3 and 1.8 E-5 mg/m^2 d, respectively. For detailed calculations please refer to Annex 9 of the Product Authorisation Report for Phostoxin WM (2013).

Release from professional use:

The product Phostoxin WM applied for authorisation is identical to the representative product in the CAR from 2008 and the intended use as well as the application rate and thus the exposure to the environment are identical. The b.p. is used in form of pellets or tablets and is inserted into rodent burrows by an applicator. Based on the worst case scenario recommendation to apply 5 pellets (à 0.6 g) every 3 m of the burrow, maximal 833 pellets will be applied per ha, corresponding to 500 g/ha.

3.8.3.2 Aquatic compartment (including sediment and STP)

No direct exposure of the aquatic compartment (surface water incl. sediment and sewage treatment plant) occurs from the intended use of Phostoxin WM as fumigant in rodent underground tunnel systems. Therefore, no PEC for the aquatic compartment is calculated.

3.8.3.3 Terrestrial compartment (including groundwater)

Emission of the b.p. and phosphine (PH3) as its degradation product and actual a.s. to soil is the most relevant contribution to the local environmental exposure resulting from Phostoxin WM application in underground tunnel systems (burrows) of non-agricultural areas. No relevant exposure of groundwater will occur from the intended use of Phostoxin WM, therefore no $PEC_{groundwater}$ was estimated.

The emission of Phosphine to soil following the application of Phostoxin WM is estimated according to chapter 3.5.4.2 in the rev. ESD PT14 (Table 18) and the predicted environmental concentration in soil (PEC_{soil}) is estimated using Table 20 in rev. ESD PT14. The input parameters are summarised in Table 64.

Table 64 Overview of input parameters and output values for estimation of PEC_{soil} of Phosphine following application of Phostoxin WM due to gassing

	Symbol	Value	Unit	Remarks
Determinants of the emission scenario according to chapter 3.5.4.2, rev. ESD PT14 (Aug. 2018)				
Input				
Amount of product used in one control operation for an area of 2 ha	Q_{prod}	1000	[g]	S
Fraction of active substance in the product	$Fc_{product}$	0.56	[-]	S
Fraction of gas formed from the precursor product	Fc_{gas}	0.586	[-]	P
Number of applications	N_{appl}	1	[-]	D
Fraction of active ingredient released directly	$F_{release-D,soil}$	0.99	[-]	D
Radius of exposed soil around a hole	R	0.14	[m]	D

	Symbol	Value	Unit	Remarks
Radius of a hole	r	0.04	[m]	D
Length of exposed hole	l	1000	[m]	D
Mathematical constant Pi	π	3.1416	[-]	D
Bulk density of wet soil	RHO_{soil}	1700	[kg wwt.m^{-3}]	D
Output				
Local direct emission rate to soil after one application (for an area of 2 ha)	$Elocal_{soil-D}$	324.88	[g]	O
Soil volume exposed to rodenticide	$V_{soilexposed}$	56.55	[m^3]	O
Local concentration of active ingredient in soil resulting from direct exposure	$Clocal_{soil-D}$	**3.4**	[mg.kg wwt^{-1}]	O
Calculations				
$Elocal_{soil-D} = Q_{prod} \cdot Fc_{product} \cdot Fc_{gas} \cdot N_{appl} \cdot F_{release-D,soil}$				
$Vsoil_{exposed} = (R^2 - r^2) \cdot \pi \cdot l$				
$Clocal_{soil-D} = Elocal_{soil-D} \cdot 10^3 / (Vsoil_{exposed} \cdot RHO_{soil})$				

In addition, the soil concentration of the second reaction product $Al(OH)_3$ resp. aluminium (Al) have been calculated: realistic worst case scenario: Clocal $_{soil}$_Al = 0.543 mg Al /kg ww. For detailed calculations please refer to Annex 9 of the Product Authorisation Report for Phostoxin WM (2013).

3.8.3.4 Atmosphere

Due to the low vapour pressure of the Aluminiumphosphide (<<10 -5 Pa at 25°C) a release into air is not to be expected.

The emission of Phosphine to air following the application of Phostoxin WM is estimated according to chapter 3.5.4.2 in the rev. ESD PT14 (Table 22) and the local concentration in air after 24 hours is estimated using Table 23 in rev. ESD PT14. The input parameters are summarised in Table 65.

Table 65 Overview of input parameters and output values for estimation of PEC_{air} of Phosphine following application of Phostoxin WM due to gassing

	Symbol	Value	Unit	Remarks
Determinants of the emission scenario according to chapter 3.5.4.2, rev. ESD PT14 (Aug. 2018)				
Input				
Amount of product used in one control operation per m2	Q_{prod}	0.00005	[$kg.m^{-2}$]	S
Fraction of active substance in the product	$Fc_{product}$	0.56	[-]	S
Fraction of gas formed from the precursor product	Fc_{gas}	0.586	[-]	P
Average source strength	$Estd_{field,air,24h}$	0.9	[-]	D
Fraction of active ingredient released to air	$F_{release, air}$	0.01	[-]	D
Air height	$HEIGHT_{air}$	2	[m]	D
Output				

	Symbol	Value	Unit	Remarks
Local direct emission rate to air during 24 hours	$Elocal_{air}$	1.45 E-7	[$kg.m^{-2}$]	O
Local concentration in air after 24 hours	$clocal_{air}$	**0.074**	[$mg.m^{-3}$]	O
Calculations				
$Elocal_{air,\ 24\ h} = Q_{prod} \bullet Fc_{product} \bullet Fc_{gas} \bullet Estd_{field,air,24h} \bullet F_{release,air}$				
$Clocal_{air} = Elocal_{air,\ 24\ h}$ / $HEIGHT_{air} \bullet 10^6$				

In conclusion, PEC $local_{soil}$ of 3.4 mg/kg ww and the local concentration in air after 24 hours PEC $local_{air}$ of 0.074 mg/m^3 have been calculated.

3.8.3.5 Calculated PEC values

Table 66

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air} (after 24h)**
	[mg/m^3]	**[mg/l]**	**[mg/kg_{wwt}]**	**[mg/l]**	**[mg/kg_{wwt}]**	**[mg/m^3]**	**[µg/l]**	**[mg/m^3]**
Scenario 1	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	3.4	Not relevant	0.074

3.8.3.6 Aggregated exposure (combined for relevant emission sources)

Not relevant. An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

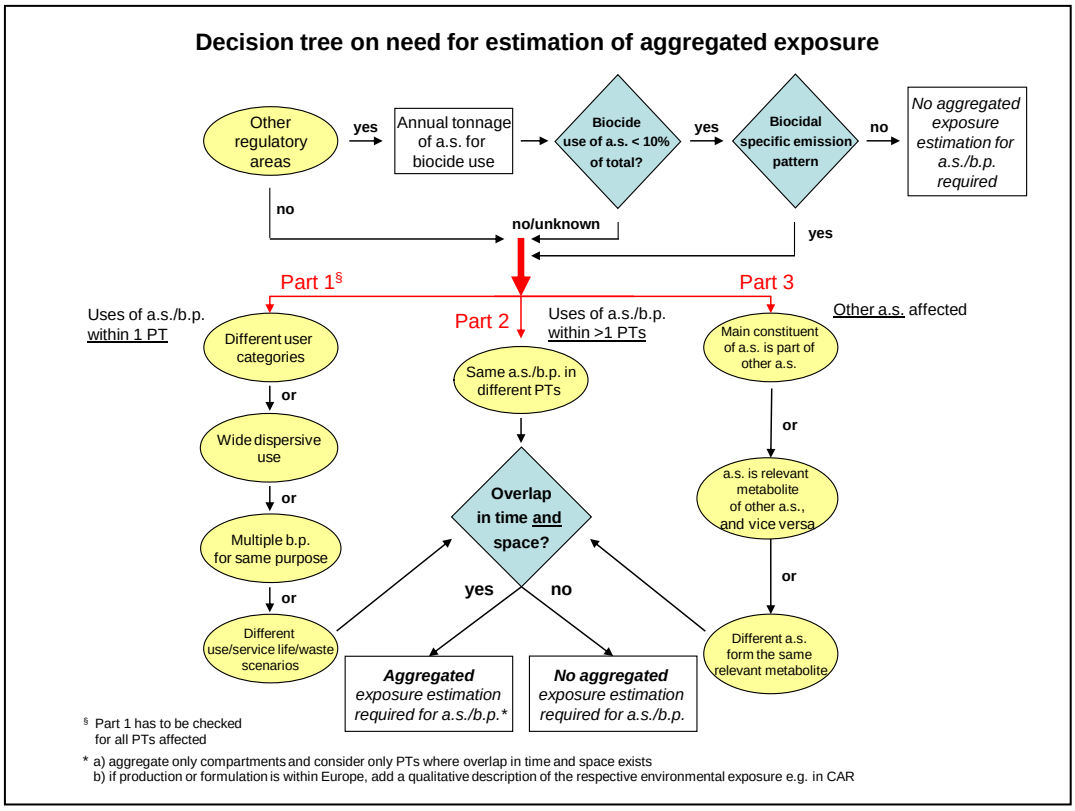


Figure 1: Decision tree on the need for estimation of aggregated exposure

3.8.4 Risk characterisation

The product Phostoxin WM applied for authorisation is identical to the representative product in the CAR for active substance approval. The intended use as well as the application rate and thus the exposure to the environment and the risk characterisation are identical.

3.8.4.1 Aquatic compartment (sediment and STP)

No direct exposure of the aquatic compartment (surface water incl. sediment and sewage treatment plant) occurs from the intended use of Phostoxin WM as fumigant in rodent underground tunnel systems. However, because of the high aquatic toxicity of the a.s. and b.p. general there exists a possible potential risk for the aquatic environment compartment (e.g. in case of accidental release or intense rain) and therefore special care should be taken in handling and applying these products. Nevertheless, the risk for the aquatic environment compartment is negligible if the pellets are properly

handled by trained professionals and precaution measures will be carefully attended (see Chapter 2.5.2). Therefore, no risk characterisation is performed for this environmental compartment.

Conclusion

No unacceptable risks occur from the intended use of b.p. Phostoxin WM for the aquatic compartment. Nevertheless, because of the high aquatic toxicity of the a.s. and b.p in general there exists a possible potential risk for the aquatic environment compartment (e.g. in case of accidental release or intense rain).

3.8.4.2 Terrestrial compartment (Soil/Groundwater)

- **Soil**

The terrestrial compartment is the most relevant compartment at risk because of the direct release during the application of the biocidal product. A PEC/PNEC ratio of 739 for Phosphine is calculated for this environmental compartment indicating a clear risk from the use of AlP as fumigant in rodent underground tunnel systems. Data improvement may theoretically be possible on the effects side, as the $PNEC_{soil}$ is based on only one study with soil micro-organisms, in which no EC50 could be derived. However, from the high acute toxicity of PH_3 it can be concluded that all soil organisms inhabiting the soil compartment in the target area (e.g. earthworms, arthropods…) will be killed by the arising PH_3 concentrations. Therefore, the performance of further tests with such soil organisms is not deemed necessary as these tests will only show what is already known. Improvement of the $PNEC_{soil}$ resulting in a PEC/PNEC ratio < 1 by performing further tests seems not possible. As the exposure is limited both spatially and temporarily, it can be assumed that the non-target organisms will resettle the exposed area within a short time after use of Phostoxin WM as a fumigant for rodent control.

After application to burrows for rodent control also the second reaction product Al(OH)3 resp. aluminium will remain in the soil. The soluble and toxic forms of aluminium (Al^{3+}) are only present in soil under soil pH values of less than 4.5. Nevertheless, the amount of aluminium added by use of AlP as rodenticide is negligible compared to the natural background level and also spatially restricted. Aluminium is the most commonly occurring metallic element in the earth crust. From literature it is known that the typical range of aluminium in European soils is from 1 percent to 30 percent (10.000 to 300.000 mg Al/kg), with naturally occurring concentrations varying over several orders of magnitude. The median Al_2O_3 content is 11.7 % in subsoil and 11.0 % in topsoil, the average total concentration of aluminium in global soil is reported as 80.000 mg Al/kg. The comparison of the calculated aluminium concentration in soil after application with the available literature data of natural aluminium occurrence has been shown that the release of this reaction product from the use of aluminium phosphide as rodenticide will not significantly increase the environmental concentration of this compound or of freely available aluminium (Al^{3+}).

Table 67

Calculated PEC/PNEC values			
	PEC_{soil} related to PH_3	**$PNEC_{soil}$ related to PH_3**	**$PEC/PNEC_{soil}$ related to PH_3**
Application of biocidal product as fumigant in rodent underground tunnel systems, professional use	3.4 mg/kg ww	4.6 µg/kg ww	739

- **Groundwater**

The use pattern of b.p. Phostoxin WM inside of burrows and the spontaneous reaction of the a.s. with humidity, precludes the active substance itself from leaching. Phosphine is poorly water soluble (24 ml/100 ml water at 24 °C) and has a very high vapour pressure (3295 kPa at 22 °C). The Henry's law constant is estimated to be > 320000 Pa m^3 mol^{-1}. Thus, considerable transport of dissolved phosphine in the pore water of soil is most unlikely. In addition, phosphine is oxidised to phosphoric acid by atmospheric O_2 already in the air phase of the treated burrows. This fact further reduces the amount of phosphine that can potentially leach. Therefore, no relevant exposure of groundwater will occur.

In the case of the second reaction product $Al(OH)_3$ resp. aluminium, it can be assumed that the use of aluminium phosphide as requested will not lead to a significant groundwater contamination. From literature, it is known that aluminium has a low mobility under most environmental conditions. The mobility of aluminium in soil is very much depended on soil pH. Aluminium hydroxide will further react to produce mineral phases. Aluminium minerals occur naturally in the environment. The natural back ground level in groundwater in Germany normally varies from < 0.01 – 0.1 mg Al/L depending on the geogenic nature of the area. According to Directive 98/83/EC, the drinking water indicator parametric level for aluminium is fixed to 0.2 mg Al/L.
The mobility of aluminium is difficult to calculate and very much dependent on geogenic aspects. Therefore, not the total values of anthropogenically added aluminium by the intended use of Phostoxin WM is important for ground water aluminium concentration but the pH of the receiving soil compartment which is decisive for the aluminium ground water concentration. However, the very small aluminium input to soil is not judged as a decisive input to ground water aluminium concentration, as the difference to natural occurring aluminium soil concentration is four - five orders of magnitude with respect to the average total concentration of aluminium up to 80.000 mg Al /kg in the earth crust.

Conclusion

The terrestrial compartment is the most relevant compartment at risk because of the direct release during the application of the biocidal product. However, as the exposure is limited both spatially and temporarily, it can be assumed that the non-target organisms will resettle the exposed area within a

short time after use of Phostoxin WM as a fumigant for rodent control.
No relevant exposure of groundwater will occur from the intended use of b.p.
No unacceptable risks were identified for the intended use of b.p. Phostoxin WM for the groundwater.

3.8.4.3 Atmosphere

Aluminium phosphide (AlP) has a negligible vapour pressure (<<10-5 Pa at 25 °C). No emission into air of AlP is to be expected. In contact with soil and air humidity, AlP will be degraded rapidly. The degradation product phosphine is volatile and is decomposed rapidly in air. According to the references, the maximum half life of phosphine in air is estimated to be 28 hours using a 24-hours-day with an OH radical concentration of 5.0 x 105 radicals cm^3 which is regarded as the global 24-hours-mean concentration. Based on this half life, an accumulation of phosphine in air is not to be expected.
Direct reactions of phosphine with ozone are not expected to be quantitatively important, since the degradation via reaction with OH-radicals will degrade the phosphine before it will reach the ozone-rich upper atmosphere layer.
Therefore, phosphine has no potential to deplete stratospheric ozone as well it does not contain any chlorine, bromine, or iodine atoms.
In the German regulations concerning the emission in air “TA Luft” it is laid down that 2.5 g phosphine/h in the exhausted stream must not be exceeded. The maximum value of 2.5 g PH_3 /h or 0.5 mg/m^3 in the exhausted stream is used as the worst case value for an exemplary exposure assessment of the atmosphere for the life cycle stages production a.s. and formulation b.p.. It can be expected that the restrictions of the German “TA Luft” are generally applicable.

For the use phase a local PEC of 0.074 mg/m^3 phosphine for the atmospheric compartment is estimated.
In view of the spatially and temporarily restricted application of the biocidal product (Phostoxin-WM 56 % a.s.) for fumigation of rodents in underground tunnel systems (burrows) and the results mentioned above no unacceptable risk for the atmosphere can be indicated.

Conclusion
No unacceptable risks were identified for live cycle stages production of the a.s., formulation of the b.p and the intended use of b.p. Phostoxin WM for the atmosphere.

3.8.4.4 Non-compartment specific

- **Primary poisoning**

According to the ESD for biocides used as rodenticides, primary poisoning may occur if dogs are going to dig out a hole where aluminium phosphide pellets have been applied and eat them. This scenario

may also be relevant for certain wildlife mammals. In this case, these non-target organisms are highly endangered of being severely intoxicated.
To illustrate the risk for primary poisoning, the following estimation can be made: if one pellet weighting 0.6 g is eaten by a non-target organism like a dog, the amount of aluminium phosphide taken up is 0.6 g * 0.56 (content of a.s. in pellet) = 336 mg. With a body weight of 10 kg for dogs, the resulting dose is 33.6 mg/kg bw. No toxicity data for dogs are available. For rats a LD_{50} of 8.7 mg/kg bw is reported. As it is assumed that the toxicity of aluminium phosphide to all mammals is comparable, this value is used for further assessment. There is no guidance available how to derive a $PNEC_{oral}$ from an LD50 value. However, a direct comparison of the dose of 33.6 mg/kg bw with the LD_{50} of 8.7 mg/kg bw already shows a risk for dogs (ratio 3.8). Although this is not a standard scenario for the assessment of primary poisoning for rodenticides, this estimation shows clearly that there is a potential risk for primary poisoning for non-target organisms if they dig out a pellet and swallow it.

To mitigate this potential risk, it has to be assured that the holes in which the pellets are applied are safely closed to avoid easy access of non-target organisms like dogs.
Nevertheless, the formulation is not an attractive bait for ingestion/feeding but a supporter for the fumigant, and the generated phosphine has a strong smell of garlic, ammonia and carbide and is likely to act as a repellent.

In addition to the risk through primary poisoning, there is a risk to all non-target mammals which are using the tunnels of the target organisms as a part of their habitat (least weasel: Mustela nivalis) or living in similar holes in the same habitat (mole: Talpa europaea, ground squirrel: Spermophilus, hamster: Cricetus cricetus) by inhalation of the arising PH_3. No quantitative risk assessment can be performed for this scenario as there is no guidance for the derivation of a $PNEC_{mammal}$ for inhalative exposure. However, it can be assumed that the concentration of PH3 that kill the target organism will also be lethal for non-target mammals.

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

- **Secondary poisoning**

The product, the a.s. and its reaction product phosphine may theoretically pose a risk for carnivorous and scavenging terrestrial vertebrates that feed on intoxicated target animals. However, according to the intended use of the product in underground tunnel systems, the presence of intoxicated animals on the soil surface should be negligible. In addition, in the target organisms, phosphine is metabolised to

non-toxic phosphates. Thus, a relevant exposure of these non-target organisms via the food chain can be excluded and there seems to be no risk of secondary poisoning.

3.8.4.5 PBT assessment

Even though the T criterion is fulfilled, Aluminium phosphide releasing phosphine resp. phosphine is neither PBT- nor vPvB – candidate as the P and B criteria are not fulfilled.
Taking into account the measured log Pow of 0.9 there is a low potential to bioaccumulate. The estimated BCF_{fish} (=1.16) and the $BCF_{earthworm}$ (=0.94) for the aquatic and terrestrial environment are low and confirm this conclusion.

3.8.4.6 Endocrine disrupting properties

According to the CAR for aluminium phosphide releasing phosphine (RMS DE, 2008) there are no indications for potential endocrine disrupting properties of the active substance on environmental non-target organisms. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the product is listed in the “Confidential Annex”. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA’s endocrine disruptor assessment list. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature. The details of the ED assessment of the co-formulants of the biocidal product “Phostoxin WM” are included in section 5.1.1 of the confidential Annex.

3.8.4.7 Summary of risk characterisation

Besides production of the a.s. and formulation of the b.p., the risk characterisation is performed only for the professional use of the biocidal product.

Despite of the high aquatic toxicity there is no unacceptable risk for the aquatic compartment (incl. sediment) from the professional use according to the intended application. Nevertheless uncontrolled (or accidental) release to surface waters have to avoided (e.g. in case of intense rain).

The fumigant causes no unacceptable risk to the atmosphere.

There is a risk for the terrestrial compartment because of the direct release into soil according to the intended use. However, as the exposure is spatially and temporarily restricted and no residues can be expected. It can be assumed that the affected non-target organisms will resettle the exposed area within a short time after use of AlP-containing products as rodenticide.
There is a potential risk for primary poisoning of non-target organisms like dogs if they dig out a pellet and swallow it. In addition, there is a risk to all non-target mammals which are using the tunnels of the target organisms as a part of their habitat (least weasel: Mustela nivalis) or living in similar holes in the same habitat (mole: Talpa europaea, ground squirrel: Spermophilus, hamster: Cricetus cricetus) by inhalation of the arising PH_3.

There is no unacceptable risk for secondary poisoning.

To mitigate these potential risks, appropriate risk reduction measures and precautions concerning the special conditions of proper use and handling of the b.p. must be applied (see Chapter 2.5.2).

The effect value for aquatic toxicity of the a.s. aluminium phosphide is the 96h-LC50 for the fish Oncorhynchus mykiss of 7.98 µg/L triggers the classification as GHS09, H400 of the b.p. Phostoxin WM (56 % a.s.).

Table 68

	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**	**PEC/ $PNEC_{GW}$**
Application of biocidal product as fumigant in rodent underground tunnel systems, professional use	Not relevant	Not relevant	Not relevant	739	Not relevant

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Author(s)	Year	Annex III requirement	Title and Report number	Source (where different from company) and Study sponsor
Anonymous	2009	3.3	Relative Density of Phostoxin Tablets, S09-02339	Detia Freyberg GmbH
Anonymous	2009	3.3	Relative Density of Phostoxin Pellets, S09-00496	Detia Freyberg GmbH
Anonymous	2019	3.3	DETIA-GAS-EX T Determination of physico-chemical properties Bulk and tap density before storage (CIPAC MT 186) Relative density before and after storage of 18 weeks (OECD 109) Dustiness of granular products before and after storage of 18 weeks (CIPAC MT 1	Detia Freyberg GmbH
Anonymous	2019	3.3	PHOSTOXIN PELLET Determination of physico-chemical properties Bulk and tap density before storage (CIPAC MT 186) Relative density before and after storage of 18 weeks (OECD 109) Dustiness of granular products before and after storage of 18 weeks (CIPAC MT	Detia Freyberg GmbH
Anonymous	2002	3.4.1	Evaluation of Storage stability of PHOSTOXIN Pellets by Accelarated Storage Procedure, KBL/2002/1373ASTH	Delicia Freyberg GmbH
Anonymous	2011	3.4.1	Storage Stability and technical characteristics of PHOSTOXIN WM, Z0020a	Detia Freyberg GmbH
Anonymous	2018	3.4.1	Determination of physical-chemical Properties and Storage Stability Tests for Phostoxin 56 GE as Tablets in Bottles made of Aluminium	Detia Freyberg GmbH

Anonymous	2018	3.4.1	Physico-chemical properties of Detia Phostoxin Pellets over5 years at ambient conditions, 12D05207-01-SSFO	Detia Freyberg GmbH
Anonymous	2009	3.4.1	Untersuchung des korrosiven Einflusses von Aluminiumphosphid auf Al-Verpackungen gemaft EU-Biozidproduktzulassung und DIN 50905 / Evaluation of the Corrosive Effect of Aluminum Phosphide on Al-Cans According EU-Biocide Product Approval and DIN 50905, VI.1/14627	Detia Freyberg GmbH
Anonymous	2016	3.4.1	Zulassungsschein / Certificate of Approval No. 9937/1B1 rev.Version 4 für die Bauart einer Verpackung zur Beförderung gefährlicher Güter, 3.12/303177	Novelis Deutschland GmbH
Anonymous	2016	3.4.1	Zulassungsschein / Certificate of Approval No. 9601/1B1 rev.Version 3 für die Bauart einer Verpackung zur Beförderung gefährlicher Güter, 3.12/303178	Novelis Deutschland GmbH
Anonymous	2011	3.5	Storage Stability and technical characteristics of PHOSTOXIN WM, Z0020a	Detia Freyberg GmbH
Anonymous	2011	3.5	Storage Stability and technical characteristics of PHOSTOXIN WM, Z0020a	Detia Freyberg GmbH
Anonymous	2010	3.5	Determination of the friability and attrition of Phostoxin Tablets, Z0002	Detia Freyberg GmbH
Anonymous	2010	3.5	Determination of the friability and attrition of Phostoxin Pellets, Z0003	Detia Freyberg GmbH
Anonymous	2002	4.1	Explosive properties Phostoxin Pellets, 20011378.01	Delicia Freyberg GmbH
Anonymous	2001	4.2	Determination of inflammability of Phostoxin Pellets, KBL/2001/1216EZF	Delicia Freyberg GmbH
Anonymous	2002	4.17.1	Phostoxin Pellets: Auto-flammability, 20011378.02	Delicia Freyberg GmbH
Anonymous	2006	5	Validation of an Analytical Method for Determination of aluminium Phosphide and Arsenic in Phostoxin, 20061336/01-UVX	Detia Freyberg GmbH
Anonymous	2002	6.1	Versuchsbericht zur Prüfung von Detia Wühlmauskiller gegen Schermäuse im Forst	Detia Freyberg GmbH

Anonymous	2005	6.1	Field tests to determine the efficacy of aluminium phosphide (Detia-Wühlmauskiller, 56 %) in controlling the Norway rat (*Rattus norvegicus*) in nine burrows on farms in Germany, KLN/DD/2005-1	Detia Freyberg GmbH
Anonymous	1999	6.6	Rentokil Report 264/3 “Respiratory Exposure to phosphine using PHOSTOXIN WM in the Rentokil Applicator – Pest Control Technical Committee Report RPC 99/14”	Rentokil Limited R & D Division
Anonymous	2002	6.7	Versuchsbericht zur Prüfung von Detia Wühlmauskiller gegen Schermäuse im Forst	Detia Freyberg GmbH
Anonymous	2005	6.7	Field tests to determine the efficacy of aluminium phosphide (Detia-Wühlmauskiller, 56 %) in controlling the Norway rat (*Rattus norvegicus*) in nine burrows on farms in Germany, KLN/DD/2005-1	Detia Freyberg GmbH
Anonymous	2020	6.7	Supplementary data to the report KLN/DD/2005-01, KLN/DD/2005-01	Detia Freyberg GmbH
Anonymous	2021	6.7	Efficacy study for testing the rodenticide Detia Wühlmauskiller against water voles (*Arvicola terrrestris*) using census methods based on reading of signs according to EPPO Guideline PP 1/169(2)	
Anonymous	2002	8.3.1	Evaluation of Skin senzitization of test substance Detia Gas-Ex-T Patilhas de 3 g, R.E. 428.192.02	Degesch do Brasil Industria e comercio Ltda.
Anonymous	1983	8.5.1	Acute Oral Toxicity Study in Rats: DEGESCH PHOSTOXIN Formulation, 2038-103	Degesch America Inc.
Anonymous	1987	8.5.3	ACUTE TOXICOLOGICAL STUDY ON COMPOUND ALUMINIUMPHOSPHID AFTER DERMAL APPLICATION TO THE RAT, 1-4-142-87	Detia Freyberg GmbH
Anonymous	2004	9.2	Statement on the necessity of aqua toxic tests with the phosphine evolving product magnesium phosphide	Detia Freyberg GmbH
Anonymous	1994	9.2.1.1	Acute toxicity of Gastoxin Tecnico to zebrafish (Brachydanio rerio), D.3.1-28/94	Casa Bernardo Ltda.
Anonymous	1994	9.2.1.2	Acute toxicity of GASTOXIN TÉCNICO to Daphnia similis, D.2.1 - 57/94	Casa Bernardo Ltda.
Anonymous	2000	9.2.1.3	AlGA (Selenastrum capricornutum), GROWTH INHIBITION TEST WITH ALUMINIUM PHOSPHIDE PELLET, 2503	Prosanitas GmbH

Anonymous	1994	9.2.1.3	Toxicity effect of Gastoxin Tecnico to Selenastrum capricornutum, D.4.1-051/94	Casa Bernardo Ltda.
Anonymous	1988	9.2.1.7	Phosphine and Selected Metal Phosphides	
Anonymous	1989	9.2.2.1	Studies on effects of Phostoxin on activity of soil microflora, V-67.079	Degesch GmbH
Anonymous	1983	10.1	Distribution of PH3 in soil horizontal/vertical spreading	Detia Freyberg GmbH

4.2 List of studies for the active substance(s)

4.2.1 Aluminium phosphide

- The applicant has access to the data from the active substance approval. The applicant was participant in the procedure for approval (respectively the inclusion into Annex I of Directive 98/8/EC[16]) of the active substance Aluminium phosphide for use as rodenticide (product-type 14). Please, refer to the corresponding Assessment Report for a reference list.

16 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Professional users

PhostoxinWM_output_table_Expo_HH.xl