CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbide[1]

European Food Safety Authority[2]

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SUMMARY

Calcium carbide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Calcium carbide was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Portugal being the designated rapporteur Member State submitted the DAR on calcium carbide in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 4 July 2007. The peer review was initiated on 13 June 2008 by dispatching the DAR for consultation to the notifier the Calcium Carbide Task Force, and on 20 October 2010 to the Member States. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on calcium carbide.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of calcium carbide as a repellent in grassland, fruit, vegetable and agricultural crops, and ornamental cultivation as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00272, issued on 14 October 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p.19
[5] OJ L 309, 24.11.2009, p.1
[6] OJ L 153, 11.6.2011, p.1
[7] OJ L 153, 11.6.2011, p.187
[8] OJ L 37, 10.2.2010, p.12

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It should be emphasized that the active ingredient of the substance notified as calcium carbide is the calcium phosphide contained in the technical calcium carbide, which is a phosphine (phosphane) generator.

Data gaps were identified in the section identity, physical and chemical properties and analytical methods.

No data gaps or critical areas of concern were identified during the peer review of the mammalian toxicology section.

For the representative use there are no residue issues and no consumer exposure.

No data gaps were identified for the environmental fate and behaviour section. Acetylene gas, released through the reactions of calcium carbide in contact with humid air, has a potential for long-range transport through the atmosphere, based on its estimated atmospheric half-life. This was identified as a critical area of concern.

No data gaps or critical areas of concern were identified during the peer review for the ecotoxicology section.

KEY WORDS

Calcium carbide, calcium phosphide, phosphine, phosphane, peer review, risk assessment, pesticide, repellent

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BACKGROUND

Calcium carbide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Calcium carbide was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Portugal being the designated rapporteur Member State submitted the DAR on calcium carbide in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 4 July 2007 (Portugal, 2007). The peer review was initiated on 13 June 2008 by dispatching the DAR for consultation and comments to the notifier the Calcium Carbide Task Force, and on 20 October 2010 to the Member States. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the Commission on 16 March 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration and additional information to be submitted by the notifier were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a repellent in grassland, fruit, vegetable and agricultural crops, and ornamental cultivation as proposed by the notifier A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues

[9] OJ L 379, 24.12.2004, p.13
[10] OJ L 246, 21.9.2007, p.19
[11] OJ L 309, 24.11.2009, p.1
[12] OJ L 153, 11.6.2011, p.1
[13] OJ L 153, 11.6.2011, p.187
[14] OJ L 37, 10.2.2010, p.12

raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (17 March 2011),
- the Evaluation Table (4 October 2011),
- the comments received on the additional information assessment,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of May 2011 containing all individually submitted addenda (Portugal, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Calcium acetylide (IUPAC) notified as calcium carbide is considered by the International Organization for Standardization not to require a common name. Calcium phosphide is the used name for tricalcium diphosphide (IUPAC). No ISO common name is required. Calcium phosphide is a phosphine (phosphane, IUPAC) generator.

The representative formulated product for the evaluation is 'PRONTOX Wühlmausgas', a gas generating product (GE) containing 0.08-0.52 g/kg calcium phosphide.

The representative uses evaluated comprise applications by placing the formulation in the holes made by moles and voles to act as a repellent. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

Since the active ingredient of the substance notified as calcium carbide is the calcium phosphide contained in the technical calcium carbide, the dossier, the DAR, and the EFSA Conclusion on calcium phosphide have been considered in the peer review of calcium carbide.

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/10597/2003 rev. 8.1 (European Commission, 2009), and SANCO/825/00 rev. 7 (European Commission, 2004).

Calcium carbide was included in Annex I with a minimum purity of 765 g/kg containing 0.08-0.52 g/kg calcium phosphide[15]. The activity of calcium carbide as a repellent is due to the presence of calcium phosphide (European Commission, 2008), which is an existing active substance. The action of technical calcium carbide as a repellent is based on the release of phosphine (phosphane) when the impurity calcium phosphide is in contact with the soil humidity.

The specification of the active substance content range in the calcium carbide is open as a data gap was identified for batch analytical data for calcium phosphide, based on a validated analytical method. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of calcium carbide or the representative formulation. Data gaps were identified for the description of the methods for the determination of the components of the technical materials, and for a storage stability test of the formulation. Data gaps identified for the physical and chemical properties of calcium phosphide in the EFSA conclusion for calcium phosphide are valid also for this conclusion.

Full description of the method(s) and validation data for the determination of the calcium phosphide content in the technical material and formulation were identified as a data gap.

Given the nature and representative use of the product the need for methods of analysis for monitoring for this compound in food of plant and animal origin has been waived. Monitoring methods in soil are not required as the DT_{90} in soil is < 3 days for phosphine (phosphane). The acceptable method of analysis for water is GC-NPD with an LOQ of 0.1 µg/L, but a confirmatory method has been identified as a data gap. The method of analysis for air has a LOQ of 0.025 mg/m^3. A method of analysis for body fluids and tissues is not necessary even though the active substance is classified as very toxic, since phosphine (phosphane) will be quickly exhaled or metabolised to phosphates.

[15] Commission Directive 2008/127/EC of 18 December 2008, OJ L 344, 20.12.2008, p.92

2. Mammalian toxicity

The toxicological database submitted for the peer review of calcium carbide is rather limited.

Calcium carbide being a caustic substance, no acute oral and dermal studies were performed, or skin and eye irritation tests (the active substance was proposed for classification as C, R35 and Xi; R41 based on reports on human data). In addition to this, it was proposed for classification as an acute toxicant via inhalation (Xi; R37) based on human data. No data are available on skin sensitisation, however there is no evidence of such a property based on the analysis of the single components of the technical material.

No studies were submitted for short- and long-term toxicity, genotoxicity, carcinogenicity, reproductive or developmental toxicity. However, based on the representative uses, the waiving of these data was accepted. Similarly, setting an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) for calcium carbide was not deemed necessary as no residues in plants or plant food are expected. As for the operator exposure, the ready-to-use repellent containing calcium carbide is placed underground in target animal runs and tunnels by means of a spoon or another aid; even in the case of an operator exposure to phosphine (phosphane) release, the amount of such exposure would be very limited, considering that the proposed application rate of calcium carbide is lower than the one proposed during the calcium phosphide peer review, which gave a worst case estimate of operator exposure of 63% of the AOEL. As exposure is considered negligible, an Acceptable Operator Exposure (AOEL) was not set. The use of Personal Protective Equipment (PPE) is not necessary for decreasing exposure, but could be considered based on the reported effects on skin. No exposure of workers and bystanders is anticipated.

3. Residues

Calcium carbide ('PRONTOX Wühlmausgas') is not intended for direct application to growing crops and no residues in plants or plant food are to be expected. It does not enter the human food chain.

'PRONTOX Wühlmausgas' is used as a repellent after introduction of the compound in the entrance of burrows. The decomposition will take place rapidly in the humidified atmosphere of the soil; the repellent action on the mole and vole is the result of the developing odour.

A complete mineralization of the technical product calcium carbide occurs within 4-5 days. The metabolites of 'PRONTOX Wühlmausgas' are acetylene and calcium hydroxide, respectively. Hereafter calcium hydroxide reacts with carbon dioxide to form calcium bicarbonate and calcium carbonate, respectively.

Phosphine (phosphane) evolved in minor quantities is oxidized to phosphoric acids and phosphates.

With regard to the absorption of acetylene and phosphine (phosphane) through the root, it is assumed that the majority disappears through diffusion, as has been demonstrated in practice during food protection fumigation. The calcium and phosphate residues are identical to soil constituents and act as fertilizers.

4. Environmental fate and behaviour

No specific information on calcium carbide was submitted by the notifier for the environmental fate and behaviour section. However, after the commenting period of the peer review process of calcium carbide, it was agreed to include in a revised DAR (May 2011) the pertinent fate and behaviour evaluations available in the DAR of calcium phosphide and its subsequent addendum (EFSA, 2008).

Calcium carbide is very reactive in the presence of water, soil moisture or air humidity, with degradation into solid calcium oxide (calcium hydroxide), acetylene gas and phosphine (phosphane) gas. Considering the representative use, only the soil compartment will be exposed to the substance or its degradation products.

In soil, underground, calcium hydroxide reacts with carbon dioxide to form calcium bicarbonate and calcium carbonate, other calcium carbide impurities as carbon aluminium oxide, iron oxide and silicon dioxide. Acetylene released underground inhibits the activity of nitrifying bacteria transforming ammonium into nitrites involved in the nitrogen cycle. The exact amount of phosphine (phosphane) released is not known, but it is very likely that only a small amount will be produced and will be adsorbed and degraded in soil into phosphates, used as trace nutrients for plants. In a laboratory soil incubation carried out at 20°C in three different soils, phosphine (phosphane, generated from calcium phosphide in the test system) was estimated to have a DT_{50} of 8 hours to 13 days. In a field study where calcium phosphide was placed 5 or 10 cm below the soil surface, phosphine (phosphane) concentrations were measured under a "tin case" placed over the soil surface above the treated soil. Half-lives of phosphine were reported to be 6 to 10 hours, with all phosphine (phosphane) being degraded within 2 days.[16]

Calcium carbide reacts very vigorously in water with spontaneous decomposition into calcium hydroxide, acetylene and phosphine (phosphane) gas. Acetylene gas dissipates to atmosphere and phosphine (phosphane) evolved in minor quantities is oxidized to phosphoric acids and phosphates. Contamination of surface waters and consequently of sediments by calcium carbide is excluded by the specific conditions of use in underground tunnels or burrows. No risk of contamination of groundwater by calcium carbide or phosphine is expected.

Calcium carbide technical is not volatile, but in contact with humid air reacts with spontaneous decomposition into calcium hydroxide, acetylene and phosphine (phosphane) gas. Phosphine (phosphane) in the atmosphere is rapidly degraded with a half-life in air of 2 days (end point agreed in the assessment of calcium phosphide). The Atkinson calculation for the rate of photooxidative reaction of acetylene with OH radicals (1.5×10^6 radicals cm^{-3}) was provided in a revised DAR (May 2011) and resulted in an atmospheric half-life of 13.124 days (AOP v1.92 in EPI Suite TM v4.10). Based on this calculation there is a potential for long-range transport of acetylene through the atmosphere and a critical area of concern was identified.

5. Ecotoxicology

There were no ecotoxicological studies available in the calcium carbide dossier, only the mandatory studies on aquatic organisms and a non-valid field study with earthworms were submitted. The endpoints for birds, mammals and soil-micro-organisms agreed in the EFSA conclusion on calcium phosphide (EFSA, 2008) were considered valid for this conclusion as well. These studies were partly taken from literature.

The risk of direct exposure (e.g. ingestion of granules) by birds and mammals should be considered as low for the representative use. However, birds and mammals could be exposed to the product by ingestion of contaminated food items like insects and earthworms. Such exposure will be negligible providing the product is applied according to the representative use (calcium carbide is applied directly into the burrow systems)

Based on the available data, calcium carbide is toxic to aquatic organisms. Contamination of surface waters and consequently of sediments by calcium carbide was excluded based on the representative use. Therefore the risk of calcium carbide to aquatic organisms was considered to be low.

For the representative use, exposure to bees, non-target arthropods, earthworms, soil micro-organisms, non-target plants and functioning of waste water treatment plants was considered to be negligible. Therefore, the risk to non-target species was considered to be low for the representative use.

[16] Evaluations of these soil laboratory and field studies were taken from the EFSA conclusion for calcium phosphide (EFSA, 2008).

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Phosphine (phosphane) [(a)]	Very low to low persistence: DT_{50} 8 hours to 13 days at 20ºC when being consecutively generated from calcium phosphide.	The risk to soil organisms was considered to be low.

(a): Provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide

6.2. Ground water

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

(a): Provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Phosphine (phosphane) [(a)]	No data available, and not required.

(a): Provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide

6.4. Air

Compound (name and/or code)	Toxicology
Phosphine (phosphane) [(a)]	Very toxic via inhalation (T+; R26) NOAEL for repeated exposure: 3 ppm phosphine (equivalent to 1.1 mg/kg bw/d, highest dose tested)
Acetylene[(a)]	No data available

(a): Provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Specification of the calcium phosphide content in the calcium carbide based on data obtained with a validated analytical method (relevant for all representative uses evaluated; submission date proposed by the notifier: study report of a 5-batch analysis is available, however according to Regulation (EC) No 1095/2007 cannot be taken into account in the peer review; see section 1)

- Description of the methods for the determination of the components of the technical materials (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Storage stability test of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Full description of the method(s) and validation data for the determination of the calcium phosphide content in the technical material and formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Confirmatory method of analysis for water (relevant for all representative uses evaluated; see section 1 and EFSA conclusion for calcium phosphide)

- Melting point (relevant for all representative uses evaluated; see section 1 and EFSA conclusion for calcium phosphide)

- Flammability in accordance with EEC A10 and A12 (relevant for all uses evaluated, see section 1 and EFSA conclusion for calcium phosphide)

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

- None

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

- None

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance

will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

1. Acetylene gas, formed by hydrolysis of calcium carbide, has the potential for long-range transport through the atmosphere[17].

[17] Note this is not a criteria in the Uniform Principles of Annex VI to Directive 91/414/EEC for decision making on product authorisations, but is a criteria that managers from Member States have asked to be informed about in relation to obligations Member States have under certain international treaties.

10. Overview of the assessments for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Repellent in grassland, fruit, vegetables, ornamental plants and agricultural crops**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

REFERENCES

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance calcium phosphide. EFSA Scientific Report (2008) 183, 1-59.

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance calcium carbide.

EPI SuiteTM v4.10, AOP v1. 92, U.S. Environmental Protection Agency

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

European Commission, 2004. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2008. Review Report for the active substance calcium carbide finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of calcium carbide in Annex I of Directive 91/414/EEC. SANCO/2605/08 rev.2, 01 August 2008.

European Commission, 2009. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council Directive 91/414/EEC. Sanco/10597/2003 rev. 8.1, May 2009.

Portugal, 2007. Draft Assessment Report (DAR) on the active substance calcium carbide prepared by the rapporteur Member State Portugal in the framework of Directive 91/414/EEC, July 2007.

Portugal, 2011. Final Addendum to Draft Assessment Report on calcium carbide, compiled by EFSA, May 2011.

APPENDICES

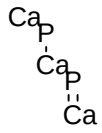
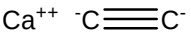
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Calcium phosphide (there is no ISO common name) contained in Calcium carbide
Function (*e.g.* fungicide)	Repellent

Rapporteur Member State	Portugal
Co-rapporteur Member State	Not available

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Calcium phosphide: Tricalcium diphosphide	Calcium carbide: Calcium acetylide
Chemical name (CA) ‡	Calcium phosphide	Calcium carbide
CIPAC No ‡	505	910
CAS No ‡	1305-99-3	75-20-7
EC No (EINECS or ELINCS) ‡	215-142-0	200-848-3
FAO Specification (including year of publication) ‡	Not available	
Minimum purity of the active substance as manufactured ‡	Open	
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities are present in the active substance as manufactured	
Molecular formula ‡	Ca_3P_2	CaC_2
Molecular mass ‡	182.19 g/mol	64.10 g/mol
Structural formula ‡		

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Calcium data gap Calcium carbide 1845 ºC (800 g/kg)
Boiling point (state purity) ‡	Not relevant
Temperature of decomposition (state purity)	> 360°C
Appearance (state purity) ‡	Calcium phosphide - Solid granules, dark grey with red brown areas, garlic odour (28 %) Calcium carbide - grey solid granules with garlic odour (800 g/kg)
Vapour pressure (state temperature, state purity) ‡	Calcium phosphide - < $1.0*10^{-5}$hPa Calcium carbide - Not volatile. Stable when dry, but decomposes slowly in moist air (800 g/kg)
Henry's law constant ‡	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
Solubility in water (state temperature, state purity and pH) ‡	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
Solubility in organic solvents ‡ (state temperature, state purity)	Calcium phosphide – Not applicable Calcium carbide – very low solubility expected in organic solvents (prediction based on chemical structure)
Surface tension ‡ (state concentration and temperature, state purity)	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
Partition co-efficient ‡ (state temperature, pH and purity)	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
Dissociation constant (state purity) ‡	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Calcium phosphide - not applicable – reacts with water to produce phosphine. Calcium carbide - not applicable – reacts with water to produce acetylene
Flammability ‡ (state purity)	Open However, the ECB has classified calcium phosphide as F (highly flammable) PH3: F+, extremely flammable Calcium carbide - Highly flammable

Explosive properties ‡ (state purity)	Calcium phosphide - no explosive properties (according to structure) Calcium carbide - Not explosive (purity not stated)
Oxidising properties ‡ (state purity)	Calcium carbide - Not oxidising (statement) The Atkinson rate of photo oxidative reaction of acetylene with OH radicals is performed with AOP v1. 92 in EPI SuiteTM v4.10. OH-Rate Constant = 0.8150 E-12 cm^3/molecule•sec atmospheric half-life = 13.124 days (Scenario used: 12-hr day; OH concentration: 1.5E6 OH/cm^3) Calcium phosphide - no oxidising properties (expert statement)

Summary of representative uses evaluated (*calcium phosphide contained in calcium carbide*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g formulation/ ha min – max (l)		
Vegetables Fruit Ornamental plants Agricultural crops Grassland	Germany (Northern Europe)	PRON-TOX Wühl-mausgas	F	*Arvicola terrestris* (ARVCTE), *Talpa europaea* (TALPEU)	GE	0.08-0.52 g/kg calcium phosphide contained in circa 800 g/kg calcium carbide	covered application	all stages	if/ when required	without waiting-time	not applicable	not applicable	4-8g/hole 16g/hole (2-8kg/ha for a maximum infestation level of 500 holes/ha)	not required	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	Calcium phosphide - GC Full description of the method and validation data are required Calcium carbide – AES-ICP and gasification (DIN 53992) Full description of the methods and validation data are required
Impurities in technical as (analytical technique)	Full description of the methods and validation data are required
Plant protection product (analytical technique)	Calcium phosphide - GC Full description of the method and validation data are required Calcium carbide – AES-ICP and gasification (DIN 53992) Full description of the methods and validation data are required

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition is proposed
Food of animal origin		No residue definition is proposed
Soil		Not relevant, DT_{90} < 3 days
Water	surface	Phosphane
	drinking/ground	No residue definition is proposed
Air		Phosphane

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required – no residue definition is proposed
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required – no residue definition is proposed
Soil (analytical technique and LOQ)	Not required – no residue definition is proposed
Water (analytical technique and LOQ)	GC-NPD 0.1 µg/L (surface water) Open for confirmatory method
Air (analytical technique and LOQ)	Photometric determination LOQ: 0.025 mg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not relevant, since phosphine will be quickly exhaled or metabolised to phosphates should it be incorporated

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	Calcium carbide: F: Highly flammable R15 – Contact with water liberates extremely flammable gases S8 – Keep container dry S43 – In case of fire, use sand. Never use water

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Calcium carbide: no data available, not needed Calcium phosphide: ready absorption of phosphine through the lungs and after oral exposure to zinc phosphide
Distribution ‡	Calcium carbide: no data available, not needed Calcium phosphide: widely distributed
Potential for accumulation ‡	Calcium carbide: no data available, not needed Calcium phosphide: no potential for accumulation
Rate and extent of excretion ‡	Calcium carbide: no data available, not needed Calcium phosphide: excretion with urine as hypophosphite and phosphite and via lungs as phosphine
Metabolism in animals ‡	Calcium carbide: no data available, not needed Calcium phosphide: hydrolysis to phosphine, oxidation to hypophosphite and phosphite
Toxicologically relevant compounds ‡ (animals and plants)	Calcium carbide: calcium carbide Calcium phosphide: phosphine
Toxicologically relevant compounds ‡ (environment)	Calcium carbide: calcium carbide Calcium phosphide: phosphine

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Calcium carbide: no data available, not needed: based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals. Calcium phosphide: 8.7 mg/kg bw (based on aluminium phosphide) T+; R28	
Rat LD_{50} dermal ‡	Calcium carbide: no data available, not needed: based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals. Calcium phosphide: 460-900 mg/kg bw (Aluminium phosphide) Xn; R21	
Rat LC_{50} inhalation ‡	Calcium carbide: no data available, not needed: because calcium carbide is a granule 4 – 7 mm, the particle size in dust < 50µm is smaller than 10 % w/w. Human data support classification with R37. Calcium phosphide: >11 ppm (> 0.015 mg PH_3/L air or > 2.8 mg/kg bw) – 51 ppm (0.072 mg PH_3/L air) (4 h exposure, whole body) (Phosphine) T+; R26	Xi; R37

Skin irritation ‡	Calcium carbide: no data available, not needed: based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.	C; R35
Eye irritation ‡	Calcium carbide: no data available, not needed: based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.	[Xi; R41]
Skin sensitisation ‡	Calcium carbide: no data available, not needed: based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals. Non-sensitiser according to literature data on components.	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Calcium carbide: no data available, not needed: does not enter the human food chain. Calcium phosphide: mortality	
Relevant oral NOAEL ‡	Calcium carbide: no data available, not needed. Calcium phosphide: no data available, not needed	
Relevant dermal NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: no data available, not needed	
Relevant inhalation NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: 3 ppm phosphine (equivalent to 1.1 mg/kg bw/d), rat 90-d, the highest dose tested	

Genotoxicity ‡ (Annex IIA, point 5.4)

Calcium carbide: no data available, not needed: calcium carbide does not enter the human food chain. Calcium phosphide: no genotoxic potential relevant at human exposure levels	

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

Target/critical effect ‡	Calcium carbide: no data available – not needed: calcium carbide-does not enter the human food chain.	
Relevant NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: 3 ppm phosphine equivalent to 1.1 mg/kg bw/d (rat 2-yr inhalation)	
Carcinogenicity ‡	Calcium carbide: no data available, not needed Calcium phosphide: not carcinogenic in the rat; no data in the mouse	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available – not needed: calcium carbide does not enter the human food chain.	
Relevant parental NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: no data available, not needed	
Relevant reproductive NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: no data available, not needed	
Relevant offspring NOAEL ‡	Calcium carbide: no data available, not needed Calcium phosphide: no data available, not needed	

Developmental toxicity

Developmental target / critical effect ‡	No data available – not needed calcium carbide does not enter the human food chain. Calcium phosphide: mortality of dams	
Relevant maternal NOAEL ‡	No data available – not needed Calcium phosphide: rat, developmental study, inhalation: 4.9 ppm phosphine (equivalent to 1.9 mg/kg bw/d). No data on rabbits, not necessary	
Relevant developmental NOAEL ‡	No data available – not needed Calcium phosphide: rat, developmental study, inhalation: 4.9 ppm phosphine (equivalent to 1.9 mg/kg bw/d). No data on rabbits, not necessary	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Calcium carbide: no data available, not needed. Calcium phosphide: NOAEL (acute study,	

	inhalation): 40 ppm PH3 (analytical conc. 38 ppm) (with regard to anatomic pathology, behavioural and neurological status); < 21 ppm (with regard to changes in motor activity)	
Repeated neurotoxicity ‡	Calcium carbide: no data available, not needed Calcium phosphide: NOAEL (subchronic study 90 days): 3 ppm phosphine equivalent to 1.1 mg/kg bw/d	
Delayed neurotoxicity ‡	Calcium carbide: no data available, not needed Calcium phosphide: no data available, not needed	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Not applicable
Studies performed on metabolites or impurities ‡	Literature data were submitted on metabolites: calcium hydroxide, acetylene and phosphine; on impurities: calcium oxide; and on sensitisation of silicon dioxide, carbon and calcium dihydroxide.

Medical data ‡ (Annex IIA, point 5.9)

Calcium carbide has been produced for decades at the Hart location. Up to date, some 100 people have been exposed to calcium carbide during production. Previously it was significantly more and the production conditions were less favourable. During these years and in previous years according to the records, no specific effects damaging to health of calcium carbide have been observed. From time to time skin and eye irritation were apparent among workers. As a rule these were associated with heavy perspiration particularly when working with ovens. No such effects were known during reconditioning and maintenance. Because of eye irritation, which reduces in a few hours after ocular rinsing and non-specific therapy with Bepanthen eye cream, some 20 treatments were carried out annually. Due to skin irritation, which similarly reduced rapidly following short-term topical cortisone therapy, there were ca. 15 treatments annually. The high number results from the urgent requirements of factory management to medical report even such small incidents around the clock. In the years of his practice, two workers were moved by mutual agreement from carbide production, due to recurrent conjunctival inflammation. Routine occupational medical examinations were offered to workers every three years. The main emphasis being on noise, dust masks, driving ability, working in hot conditions and fully continuous shift work. A specific examination for calcium carbide does not exist naturally. Furthermore, during these comprehensive examinations, which include a hearing test, sight test, lung function, ECG under exercise, blood and urine examinations, no dust or carbide-related signs appeared.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
Calcium carbide			
ADI ‡	Not allocated – not necessary		
AOEL ‡	Not allocated – not necessary		
ARfD ‡	Not allocated – not necessary		
Calcium phosphide			

ADI ‡	0.030 mg/kg bw/d*	2-yr inhalation, rat	100
AOEL systemic ‡	0.030 mg/kg bw/d*	90-d inhalation, rat	100
ARfD ‡	0.051 mg/kg bw*	Developmental study (inhalation), rat	100

Phosphine

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

* Based on a maximum liberation of gas of 0.37 g PH_3 /g calcium phosphide

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (PRONTOX Wühlmausgas)	No data available – not needed.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Calcium carbide: PRONTOX Wühlmausgas represents a ready-to-use repellent, which is placed underground into target animal runs and tunnels by means of a spoon or another aid, designed as both an applicator and a dosage measuring system. Exposure is considered negligible; skin contact is effectively prevented by wearing general-purpose protective clothing, gloves and eye/face protection. Calcium phosphide: max. 63 % of systemic AOEL. PPE/RPE recommended for temporary exposures exceeding the trigger.
Workers	Calcium carbide: no exposure is anticipated. Calcium phosphide: significantly lower in comparison to operator exposure
Bystanders	Calcium carbide: no exposure is anticipated. Calcium phosphide: significantly lower in comparison to operator exposure

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

RMS/peer review proposal

Substance classified (calcium carbide)	Calcium carbide: C Corrosive R35 Causes severe burns. R37 Irritating to respiratory system Comment from Reporting Table: Based on the available literature data on humans summarised in the DAR and based on read-across from calcium dihydroxide, the proposal of the notifier Xi (irritant); risk phrases R37/38 (irritating to respiratory system and skin), and R41 (risk of serious damage to eyes) seems reasonable for calcium carbide only. Some medical data reported in the DAR would support the classification as C (Corrosive), R 35 (Causes severe burns) in case of use of the diluted a.s. (the issue is also supported by the pH >11.5 of a 1% water solution; no animal data available). This issue has to be addressed by EChA
Calcium phosphide	T+; R 15/29-28- (29th ATP) Additionally proposed by Pesticides Peer Review: Xn; R 21, T+; R26, Xi; R38, R41, R32
Phosphine	T+; R 26-34 (up to 29th ATP)

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

Plant groups covered Rotational crops Metabolism in rotational crops similar to metabolism in primary crops? Processed commodities Residue pattern in processed commodities similar to residue pattern in raw commodities? Plant residue definition for monitoring Plant residue definition for risk assessment Conversion factor (monitoring to risk assessment)	Justification for non-submission: The submission of data or the performance of a test on metabolism, distribution and expression of residues in plants of calcium carbide is not required, since no residues of calcium carbide in plants are expected, due to the rapid hydrolysis of the active substance in the soil generating acetylene and calcium hydroxide.

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

Animals covered Time needed to reach a plateau concentration in milk and eggs Animal residue definition for monitoring Animal residue definition for risk assessment Conversion factor (monitoring to risk assessment) Metabolism in rat and ruminant similar (yes/no) Fat soluble residue: (yes/no)	Justification for non-submission: The submission of data or the performance of a test on metabolism, distribution and expression of residues in livestock of calcium carbide is not required, since no residues of calcium carbide in plants are expected, due to the rapid hydrolysis of the active substance in the soil generating acetylene and calcium hydroxide

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

not applicable

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

not applicable

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	not applicable	not applicable	not applicable
Potential for accumulation (yes/no):	not applicable	not applicable	not applicable
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	not applicable	not applicable	not applicable

	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	not applicable	not applicable	not applicable
Liver	not applicable	not applicable	not applicable
Kidney	not applicable	not applicable	not applicable
Fat	not applicable	not applicable	not applicable
Milk	not applicable		
Eggs		not applicable	

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
not applicable						

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

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

ADI	not applicable
TMDI (% ADI) according to WHO European diet	not applicable
TMDI (% ADI) according to national (to be specified) diets	not applicable
IEDI (WHO European Diet) (% ADI)	not applicable
NEDI (specify diet) (% ADI)	not applicable
Factors included in IEDI and NEDI	not applicable
ARfD	not applicable
IESTI (% ARfD)	not applicable
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not applicable
Factors included in IESTI and NESTI	not applicable

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

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

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

not applicable

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

Mineralization after 100 days ‡	No study available.
Non-extractable residues after 100 days ‡	No study available.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No study available.

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

Anaerobic degradation ‡

Mineralization after 100 days	No study available. Not required.
Non-extractable residues after 100 days	No study available. Not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No study available. Not required.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No study available. Not required.

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[18]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median	No study available						

Phosphine	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
	According to laboratory studies performed in 3 soils (dosed with calcium phosphide) the DT_{50} of PH_3 in the gas phase was found to be 2-13 d (low humus content), 8h (high humus content).							

[18] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Geometric mean/median					No study available				

Phosphine[#]	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation
DT_{50} * (only 1 trial site where calcium phosphide was applied)					6-10 h	< 2d	n.a.	n.a.	n.a.

* 10 cm layer
# Evaluation taken from the EFSA conclusion for calcium phosphide (EFSA, 2008)

pH dependence ‡ (yes / no) (if yes type of dependence)	No data available
Soil accumulation and plateau concentration ‡	No data available

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[19]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median			No study available				

Met 1	Anaerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median			No study available					

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							
pH dependence, Yes or No			No study available				

Metabolite 1 ‡

[19] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							
pH dependence (yes or no)			No study available				

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

Column leaching ‡	No study available. No data required.
	No study available
Aged residues leaching ‡	No study available
Lysimeter/ field leaching studies ‡	No study available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	Not calculated
Application data	

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial					
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				
Plateau concentration		x mg/kg after n yr			

Metabolite I Method of calculation	Not calculated
Application data	

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial					
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				
Plateau concentration		x mg/kg after *n* yr			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: No study available
	pH 7: No study available
	pH 9: No study available
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : No study available
Quantum yield of direct phototransformation in water at Σ > 290 nm	No study available
Readily biodegradable ‡ (yes/no)	No study available

Degradation in water / sediment

Parent	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
No study available										
Geometric mean/median										

Metabolite 1	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
No study available										

Geometric mean/median								
Mineralization and non extractable residues								
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)			
No study available								

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

Parent	Not calculated.
Parameters used in FOCUSsw step 1 and 2	Not calculated.
Parameters used in FOCUSsw step 3 (if performed)	Not calculated.
Application rate	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

Metabolite X	Not calculated.
Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	Not calculated.
Application rate	
Main routes of entry	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h				
	24h				
	2d				
	4d				
	7d				
	14d				
	21d				
	28d				
	42d				

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Not calculated.
Application rate	Not calculated.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

Model /Crop	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
	Chateaudun	-	-	-	-
	Hamburg	-	-	-	-
	Jokioinen	-	-	-	-
	Kremsmunster	-	-	-	-
	Okehampton	-	-	-	-
	Piacenza	-	-	-	-
	Porto	-	-	-	-
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	No study available		

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)	No study available		

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

Direct photolysis in air ‡	No study available. No data requested.
Quantum yield of direct phototransformation	No study available. No data requested.
Photochemical oxidative degradation in air ‡	No study available. No data requested. The Atkinson rate of reaction of photooxidative reaction of acetylene with OH radicals is performed with AOP v1. 92 in EPI SuiteTM v4.10. OH-Rate Constant = 0.8150 E-12 cm^3/molecule•sec atmospheric half-life = 13.124 days (Scenario used: 12-hr day; OH concentration: 1.5E6 OH/cm^3)
Volatilisation ‡	No study available. No data requested.
	No study available. No data requested.
Metabolites	No study available. No data requested.

PEC (air)

Method of calculation	Not calculated

$PEC_{(a)}$

Maximum concentration	Not calculated

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: phosphine (provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide) Surface Water: phosphine (provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide) Sediment: phosphine (provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide) Ground water: phosphine (provisional as a data gap was identified for the specification of the calcium phosphide content in the calcium carbide) Air: phosphine, acetylene (provisional as a data gap was

identified for the specification of the calcium phosphide content in the calcium carbide)

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

Soil (indicate location and type of study)	No study available
Surface water (indicate location and type of study)	No study available
Ground water (indicate location and type of study)	No study available
Air (indicate location and type of study)	No study available

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

No labelling

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

Species	Test substance	Time scale	Endpoint [#] (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	(Literature summary) Zinc phosphide Phosphine (calculated) Ca_3P_2 (calculated)	Acute	 LD_{50} 25-35 LD_{50} 6.6-9.2 LD_{50} 17.7-24.7	Not relevant
Colinus virginianus	Zinc phosphide Phosphine (calculated) Ca_3P_2 (calculated)	Short-term		LC_{50} 469 LC_{50} 124 LC_{50} 330
Anas platyrhynchus	Zinc phosphide Phosphine (calculated) Ca_3P_2 (calculated)	Short-term		LC_{50} 2885 LC_{50} 762 LC_{50} 2037
Coturnix japonica	(Literature summary) Zinc phosphide 1/10 and 1/50 of LD_{50} of 35 mg/kg bw Ca_3P_2 (calculated)	Long-term	Effects on fertilisation rate and egg-laying rate: 3.5 and 0.7 Zn_3P_2 2.47 and 0.49 Ca_3P_2	
Mammals ‡				
Rat	Product Polytanol (17.6 % as)	Acute, oral	LD_{50} 72.32 Polytanol	Not relevant
Rat	Product Polytanol (17.6 % as)	Acute, inhalation 4 hours	LD_{50} 0.090 mg PH_3/L	Not relevant
Rat	Metabolite PH_3	Acute, inhalation 4 hours	LD_{50} 0.015 mg/L air / 11 ppm 2.8 mg PH_3/kg bw	Not relevant
Rat	Metabolite PH_3 generated from AlP	Long-term 2 years dietary study		No adverse effects at average residual phosphine levels of 5 ppb in diet (2000 ppm PH_3 during fumigation)
Rat	Metabolite PH_3	Long-term, 2-generation inhalation study:	NOAEC 3 ppm (air) (1.13 mg/kg bw/day)	
Additional higher tier studies ‡ No data submitted – justification accepted. Not relevant				

[#] Evaluation taken from the EFSA conclusion for calcium phosphide (EFSA, 2008)

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

Not relevant. Exposure not expected for the representative use.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Rainbow trout	calcium carbide	96 hr (flow-through)	Mortality, EC_{50}	> 50
Aquatic invertebrate				
Daphnia magna	calcium carbide	48 h (static)	Mortality, EC_{50}	4.62
Algae				
Scenedesmus subspicatus	calcium carbide	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	12.4 46.5
Microcosm or mesocosm tests				
Not required				

[1] indicates whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

Not relevant. Exposure not expected for the representative use.

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	No studies submitted and not required			
Bioconcentration factor (BCF)[1] ‡				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	No studies submitted, and not required.	

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Preparation[1]		
Metabolite 1		
Field or semi-field tests		
not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	Not calculated	50
a.s.	oral		50
Preparation	Contact		50
Preparation	oral		50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡		Mortality	No studies submitted, and not required.
Aphidius rhopalosiphi ‡		Mortality	

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri		Not calculated		2
	Aphidius rhopalosiphi				2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
No studies were submitted						50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
Not required

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	a.s. ‡	Acute 14 days	Acute study submitted but not reliable.
	a.s. ‡	Chronic 8 weeks	
	Preparation	Acute	
	Preparation	Chronic	
	Metabolite 1	Acute	
	Metabolite 1	Chronic	
Other soil macro-organisms			
Soil mite	a.s. ‡		No studies submitted
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	No studies submitted
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		A study submitted but not reliable.
	Metabolite 1		
Carbon mineralisation	a.s. ‡		No studies submitted
	Metabolite 1		
Field studies[2]			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute	Not calculated		10
	a.s. ‡	Chronic			5
	Preparation	Acute			10
	Preparation	Chronic			5
	Metabolite 1	Acute			10

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	Metabolite 1	Chronic			5
Other soil macro-organisms					
Soil mite	a.s. ‡		Not calculated		
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

No studies were submitted and not required.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Not calculated						

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

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

Not required

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

Test type/organism	end point
Activated sludge	No study submitted and not required
Pseudomonas sp	No study submitted and not required

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

Compartment	
soil	Phosphine.
water	Phosphine.
sediment	Phosphine.
groundwater	Phosphine.

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

	RMS/peer review proposal
Active substance	R51/53

	RMS/peer review proposal
Preparation	R51/53

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AES-ICP	Atomic Emission Spectrometry with Inductively Coupled Plasma
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography

GC-NPD	Gas Chromatography with Nitrogen Phosphorus Detection
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GE	gas generating product
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year