CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium silicate[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Aluminium silicate 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].

Aluminium silicate 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.

Hungary being the designated rapporteur Member State submitted the DAR on aluminium silicate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 31 March 2008. The peer review was initiated on 22 July 2008 by dispatching the DAR to the notifier Tessenderlo Chemie NV and on 20 October 2010 to the Member States for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on aluminium silicate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of aluminium silicate as an insect repellent on pear trees and vines, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

There is an outstanding data gap for a finalised and supported specification as well as data gaps for a method of analysis and a shelf life study.

[1] On request from the European Commission, Question No EFSA-Q-2009-00269, adopted on 16 December 2011.
[2] Correspondence: praper@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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An area of concern was identified for aluminium silicate in the mammalian toxicology section as it was not possible to assess either the compliance of the batches tested or the representativeness of the test substance used for deriving the occupational exposure limit to the proposed specification (both unavailable).

Aluminium silicate is an inert substance. No residues are expected on pears as the fruit is not present at application and aluminium silicate is not taken up by plants. For grapes the maximum theoretical residue given the application rate will not exceed the amount allowed as a food additive. This is very much a worst case assumption and in reality when the grapes are consumed it is highly unlikely that there will be any significant residue of aluminium silicate.

Aluminium silicate is a stable inorganic compound. Its chemical composition is similar to common clay. Once released it is expected to be stable in the environment and undistinguishable from clay minerals naturally present in soil.

The risk to non-target organisms from the representative use of aluminium silicate was considered to be low. A data gap was however identified for algal toxicity.

KEY WORDS

Aluminium silicate peer review, risk assessment, pesticide, insect repellent.

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BACKGROUND

Aluminium silicate 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]

Aluminium silicate 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.

Hungary being the designated rapporteur Member State submitted the DAR on aluminium silicate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 31 March 2008 (Hungary, 2008). The peer review was initiated on 22 July 2008 by dispatching the DAR to the notifier Tessenderlo Chemie NV and on 20 October 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the rapporteur Member State 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 rapporteur Member State in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the rapporteur Member State, and the European Commission on 15 February 2011. On the basis of the comments received and the rapporteur Member State' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

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, including those issues to be considered in consultation with Member State experts, 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 rapporteur Member State, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, 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 November/December 2012.

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 an insect repellent on pear trees and vines, 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

[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

supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues 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 (15 February 2011),
- the Evaluation Table (9 December 2011)
- the report(s) of the scientific consultation with Member State experts (where relevant)
- 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 (Hungary, 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

Aluminium silicate is the IUPAC name there is no ISO common name.

The representative formulated product for the evaluation was 'Surround WP' a wettable powder (WP) formulation containing 950 g/kg aluminium silicate.

The representative uses evaluated comprise outdoor application by broadcast spraying to pear trees and vines. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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).

The minimum purity of the active substance and a specification cannot be concluded on as a data gap has been identified for a specification with supporting batch and analytical data.

The available data regarding the identity of aluminium silicate and its physical and chemical properties are given in Appendix A.

Data gaps are identified for storage stability of the formulation and a method of analysis capable of identifying and quantifying aluminium silicate.

The need for methods of analysis for monitoring this compound in food of plant and animal origin and in the environment has been waived due to the nature of the compound.

2. Mammalian toxicity

Aluminium silicate was discussed at the PRAPeR TC 55 Experts' Meeting on mammalian toxicology.

Based on the available data it is not possible to assess either the compliance of the batches tested in the available toxicological studies or the representativeness of the test substance used for deriving the workplace exposure limit to the proposed specification (both unavailable, see data gap in section 1) leading to a critical area of concern.

The risk assessment has been mainly based on published information. The only GLP-compliant acute toxicity studies provided to the rapporteur Member State show low acute toxicity when aluminium silicate is administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed and there was not potential for skin sensitisation.

Based on its physical-chemical properties aluminium silicate does not hydrolyse in the digestive tract (regardless of pH) or in the skin and oral and dermal absorption are considered negligible. Therefore aluminium silicate is expected to be of low concern by the oral and dermal route of administration. As for the inhalation route, a potential for pneumoconiosis has been described for chronic inhalation of respirable aluminium silicate dust in occupational settings.

The database is not suitable either to establish NOAELs, to set references values or to assess adequately the hazard (except for acute toxicity properties). However, there is no need to set the acceptable daily intake (ADI) and acute reference dose (ARfD) because consumer exposure is very unlikely (see section 3). Regarding operator exposure the use of the workplace exposure limit (WEL)-time weighted average (TWA) of 2 mg/m^3 (8 hours; equivalent to 36.6 mg/day) established for aluminium silicate for occupational settings is considered adequate in the absence of an adequate operator exposure level (AOEL) although this probably represents a conservative exposure estimate for an agricultural setting.

The representative use in pears is considered as the worst-case scenario compared to grapes. Inhalation operator exposure is below 36.6 mg/day (91.36 %) without respiratory protective equipment (RPE) according to the German Model but using the UK POEM model exposure is above 36.6 mg/day (118.74 %) even with the use of RPE during mixing and loading. Bystander inhalation exposure is below 36.6 mg/day (1.13 %). As for workers, re-entry exposure was considered not to be a concern because inhalation exposure of dried formulation is not expected.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Aluminium silicate is an inert substance. No residues are expected on pears as the fruit is not present at application and aluminium silicate is not taken up by plants. For grapes the maximum theoretical residue given the application rate will not exceed the amount allowed as a food additive. This is very much a worst case assumption and in reality when the grapes are consumed it is highly unlikely that there will be any significant residue of aluminium silicate.

Aluminium silicate could be considered a candidate for the inclusion in Annex IV of Commission Regulation (EC) No 396/2005.

4. Environmental fate and behaviour

Aluminium silicate (kaolin) is a stable inorganic compound. Its chemical composition is similar to common clay. It is insoluble and known to be inert to mineral acids and bases and not to be affected by photolytic processes under natural light.

The amount of aluminium silicate entering the soil was estimated by worst case calculations. The added mass to the soil correspond to 0.0128 % of the 5 cm soil horizon. This added mass will produce and increase of the clay fraction of soil. This amount is not significant with respect to the normal clay content observed in agricultural soils.

The amount of aluminium silicate entering surface water bodies was estimated by worst case calculations taking into consideration spray drift at the time of application. Estimates of aluminium silicate suspended in water as a result of single application and as result of the accumulated seasonal applications were provided. The notifier claims that sedimentation of suspended kaolin will be quick and that therefore single application values are more relevant for the risk assessment. However no experimental measurement of sedimentation times is available. Natural levels of clay suspended in surface waters are expected to be highly variable and highly dependent of sediment characteristics and water regime. A natural range of suspended clay has not been established. In surface water aluminium silicate would be analytically undistinguished from natural suspended clay of the same size. The total amount of kaolin deposited in the sediment per season was also calculated.

Aluminium silicate is insoluble in water. The only potential route to reach ground water would be percolation through soil pores. In groundwater, kaolin would be analytically indistinguishable from natural suspended clay of the same size.

5. Ecotoxicology

The risk assessment was conducted following the guidance document on aquatic ecotoxicology (European Commission, 2002).

Only a few studies were submitted for the ecotoxicological assessments. However, considering the nature of the active substance and that it is a widespread element of the environment to which wildlife will often be exposed; it was considered that the risk to non-target organisms from the representative use of aluminium silicate will be low.

Some data that were available from the open literature confirmed that no classification for toxicity of aluminium silicate to aquatic organisms was necessary. The TER values considering these endpoints were above the relevant Annex VI triggers. It is noted however that the PECsw value used in this TER calculations considered only a single application of 50 kg/ha to orchards. This was based on the assumption that sedimentation of suspended kaolin will be quick and therefore single application values are appropriate to be used in the risk assessment. No experimental effect data were available for algae; moreover kaolin clays are known to be used in very high concentrations to control algal-blooms (some orders of magnitude higher concentrations compared to the calculated PECsw values). A data gap was therefore identified during the peer-review for effect data of aluminium silicate on algae.

Available standard laboratory studies on honey bees also confirmed the low toxicity of aluminium silicate, however a standard Tier I risk characterization (calculation of HQ values) was not conducted. It was noted that due to the high application rate, these calculations would have indicated a contact HQ above the relevant Annex VI trigger. Considering however the results of the available field studies, a low risk to honey bees was concluded for the representative uses of aluminium silicate.

Several field studies for non target arthropods were available where the WP formulation of aluminium silicate was applied to orchards (multiple applications) up to the dose of 56 kg/ha. The results demonstrated that aluminium silicate had no adverse effects on the populations of beneficial arthropods that were investigated in these trials. However, in some trials a reduction in the populations of predatory mites and *Anthocoris* predators was noted. It was considered that this reduction might be attributed to the repellent effect of aluminium silicate and the limited availability to prey animals on the treated plants.

On the whole, it was concluded that the risk to birds and mammals, aquatic organisms, bees and other non-target arthropods, earthworms, soil macro- and micro- organisms, terrestrial non-target plants or to the biological methods for sewage treatments from the representative uses of aluminium silicate is low.

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
Aluminium silicate	Stable	The risk to soil dwelling organisms was considered to be low.

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
Aluminium silicate	Not applicable	Not applicable	Yes	Not applicable	The risk to aquatic organisms was considered to be low.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Aluminium silicate	The risk to aquatic organisms was considered to be low.

6.4. Air

Compound (name and/or code)	Toxicology
Aluminium silicate	LC_{50} > 2.18 mg/L/4h (rat)

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).

- Finalised specification with supporting batch analysis. The analysis should include heavy metals, dioxins and PCBs (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Method of analysis able to identify and quantify aluminium silicate (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Shelf life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- A study on algal toxicity (relevant for all representative uses evaluated; submission date proposed by the notifier: applicant indicated that a relevant study was already available, the study was however not peer-reviewed; see section 5).

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. Based on the available data it is not possible to assess either the compliance of the batches tested in the available toxicological studies or the representativeness of the test substance used for deriving the workplace exposure limit to the proposed specification leading to a critical area of concern.

9.3. 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.)

All columns are grey as it is not possible to assess either the compliance of the batches tested in the available toxicological studies or the representativeness of the test substance used for deriving the workplace exposure limit to the proposed specification.

Representative use		**Pears**	**Vines**
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			

The superscript numbers in this table relate to the numbered points indicated as concerns
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

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 aluminium silicate.

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.

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, 2002. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

European Commission, 2008. Review report for the active substance aluminium silicate 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 aluminium silicate in Annex I of Directive 91/414/EEC. SANCO/2603/08 – rev. 1, 1 August 2008.

Hungary, 2008. Draft Assessment Report (DAR) on the active substance aluminium silicate prepared by the rapporteur Member State Hungary in the framework of Directive 91/414/EEC, March 2008.

Hungary, 2011. Final Addendum to Draft Assessment Report on aluminium silicate, compiled by EFSA, May 2011.

JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

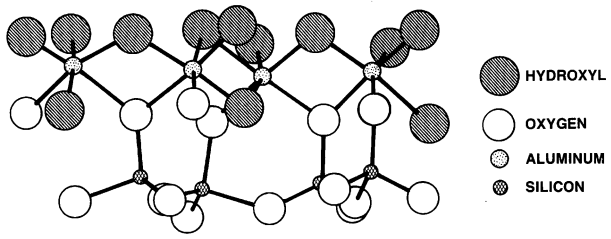
APPENDICES

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) ‡	Aluminium silicate
Function (*e.g.* fungicide)	Insect repellent
Rapporteur Member State	Hungary
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	-
Chemical name (CA) ‡	Aluminium silicate
CIPAC No ‡	-
CAS No ‡	1332-58-7
EC No (EINECS or ELINCS) ‡	EINECS: 310-127-6 (E559)
FAO Specification (including year of publication) ‡	-
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	Open
Molecular formula ‡	Hydrous aluminium silicate: $Al_4 Si_4 0_{10} (OH)_8$, Calcined Aluminium silicate: $Al_4Si_4O_{14}$
Molecular mass ‡	A single molecule cannot exist, approx. 258 g/mol of hydrous aluminium silicate
Structural formula ‡	Structural formula: hydrous aluminium silicate 

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Out of determination range
Boiling point (state purity) ‡	Out of determination range
Temperature of decomposition (state purity)	Aluminium silicate does not sublime or decompose.
Appearance (state purity) ‡	Pure material: white powdered solid (99.9 %).
	Technical material: white powdered solid.
Vapour pressure (state temperature, state purity) ‡	Aluminium silicate is involatile.
Henry's law constant ‡	Aluminium silicate is involatile.
Solubility in water (state temperature, state purity and pH) ‡	Aluminium silicate is insoluble in water.
Solubility in organic solvents ‡ (state temperature, state purity)	Aluminium silicate is insoluble in organic solvents.
Surface tension ‡ (state concentration and temperature, state purity)	Aluminium silicate does not have a surface tension.
Partition co-efficient ‡ (state temperature, pH and purity)	Aluminium silicate is insoluble in all organic liquids and water.
Dissociation constant (state purity) ‡	Aluminium silicate is stable in water and will naturally become part of the sediment.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/VIS: Not applicable. Due to insolubility and lack of volatility. NMR: Not applicable. IR: Broad bands for Si-O, Al-O and OH. These bands are representative of all aluminium silicates and cannot be used to identify Aluminium silicate. MS: Not applicable.
Flammability ‡ (state purity)	Aluminium silicate is inert and therefore not flammable.
Explosive properties ‡ (state purity)	Aluminium silicate is not explosive.
Oxidising properties ‡ (state purity)	Aluminium silicate is not oxidising.

Summary of representative uses of Aluminium silicate

Crop and/or situation (a)	Country	Product Name	F G or I (b)	Pests or Group of Pests Controlled	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	kg as/hL min max (l)	Water L/ha min max	kg as/ha min max (l)		
Pears	All EU	Surround WP Crop Protectant	F	*Cacopsylla pyri*	WP	950 g/kg	Broadcast using air blast orchard sprayer.	BBCH 51 - 69 Jan-April	2 to 5 Typically 2 app. of 50 kg/ha and 3 app. of 20 kg/ha	7 days	1.9 – 9.5	500-1000	19.0 – 47.5 2 x 47.5 kg 3 x 19 kg	90	First application at beginning of egg laying by over-wintering females. Use sufficient spray volume, apply to near drip but avoid run-off Re-apply each 7 to 21 days, depending on rainfall and crop development.
Vines	All EU	Surround WP Crop Protectant	F	*Lobesia botrana* *Empoasca vitis*	WP	950 g/kg	Broadcast using air blast orchard sprayer.	BBCH 53 - 79 May - July	2 to 5 Typically 3 app. of 30 kg/ha and 2 app. of 10 kg/ha	7 days	1.6 - 9.5	200-600	9.5 – 28.5 3 x 28.5 kg 2 x 9.5 kg	50	First application just before flight for Ist generation adults. Use sufficient spray volume, apply to near drip but avoid run-off Re-apply each 7 to 21 days, depending on rainfall and crop development.

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)	Open
Impurities in technical as (analytical technique)	Open
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	The Notifier requests a waiver from the requirement of a residue tolerance and an analytical method for residues in and/or on plants, plant products foodstuffs, feedstuffs, soil, water and air.
Food of animal origin	-
Soil	-
Water surface	-
drinking/ground	-
Air	-

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	-
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	-
Soil (analytical technique and LOQ)	-.
Water (analytical technique and LOQ)	-
Air (analytical technique and LOQ)	-
Body fluids and tissues (analytical technique and LOQ)	Not required. Aluminium silicate is not classified as toxic (T) or very toxic (T^+).

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

	RMS/peer review proposal
Active substance	No classification proposed

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Oral absorption considered negligible based on its physico-chemical properties.
Distribution ‡	-
Potential for accumulation ‡	-
Rate and extent of excretion ‡	-
Metabolism in animals ‡	-
Toxicologically relevant compounds ‡ (animals and plants)	Aluminium silicate.
Toxicologically relevant compounds ‡ (environment)	Aluminium silicate

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	-
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	-
Rat LC_{50} inhalation ‡	> 2.18 mg/L/4h	-
Skin irritation ‡	Non-irritant	-
Eye irritation ‡	Slightly irritant	-
Skin sensitisation ‡	Not sensitizing.	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data available – not required	
Relevant oral NOAEL ‡	No data available – not required	-
Relevant dermal NOAEL ‡	No data available – not required	-
Relevant inhalation NOAEL ‡	No data available – not required	-

Genotoxicity ‡ (Annex IIA, point 5.4)

No data available – not required	-

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

Target/critical effect ‡	No data available – not required	
Relevant NOAEL ‡	No data available – not required	
Carcinogenicity ‡	No data available – not required	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity		
Reproduction target / critical effect ‡	Data available of limited validity-no further data needed.	-
Relevant parental NOAEL ‡	No data available	-
Relevant reproductive NOAEL ‡	No data available	-

Relevant offspring NOAEL ‡	No data available	-
Developmental toxicity		
Developmental target / critical effect ‡	Data available of limited validity-no further data needed.	
Relevant maternal NOAEL ‡	No data available	
Relevant developmental NOAEL ‡	No data available	
Neurotoxicity (Annex IIA, point 5.7)		
Acute neurotoxicity ‡	No data available – not required	
Repeated neurotoxicity ‡	No data available – not required	
Delayed neurotoxicity ‡	No data available – not required	
Other toxicological studies (Annex IIA, point 5.8)		
Mechanism studies ‡	No data available – not required	
Studies performed on metabolites or impurities ‡	No data available – not required	
Medical data ‡ (Annex IIA, point 5.9)	On the basis of medical surveys no case of primary sensitivity or carcinogenicity was found as a result of exposure to aluminium silicate in its solid, liquid or respirable forms. Pneumoconiosis due to aluminium silicate inhalation was found only in cases of chronic exposure to aluminium silicate dust.	

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data available – not required	-	-
AOEL (mg/kg bw/day) ‡	No suitable data available to set an AOEL. Inhalation exposure limit (IEL) of 36.6 mg/day derived from the WEL-TWA value of 2 mg/m^3 (8 hours) based on a potential for pneumoconiosis after chronic inhalation exposure.	-	-
ARfD ‡	No data available – not required	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)	Negligible based on its physico-chemical properties

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Use in pear as a worst-case scenario compared to grapes. <u>Tractor mounted equipment</u> German Model Without RPE: 91.36% IEL With RPE (M&L): 22.32% IEL UK POEM Without RPE: 486.66% IEL RPE (M&L): 118.74/% IEL
Workers	Negligible: inhalation exposure of a dried formulation is not expected.
Bystanders	1.13% IEL.

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

	Peer review proposal
Substance classified (aluminium silicate)	No classification proposal for acute toxicity properties. For other endpoints: data available of limited validity to conclude. No further data needed.

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)	Aluminium silicate is insoluble and is therefore not taken-up and translocated by plants. It is also chemically inert and is not transformed into other compounds.

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)	Aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall.

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

Aluminium silicate is insoluble and not taken-up and translocated in flora or fauna.

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) Potential for accumulation (yes/no): Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall.		
	Feeding studies: - Residue levels in matrices: -		
Muscle Liver Kidney Fat Milk Eggs	Aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall.		

[1] State whether intake by specified animals is ≥ 0.1 mg/kg diet/day or not, based on a dry weight basis as given in table 1 of Guidance Document Appendix G

[2] Fill in results from appropriate feeding studies at appropriate dose rates according to Guidance Document Appendix G. State 'not required' when the conditions of requirement of feeding studies according to directive 91/414/EEC are not met.

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

No critical residue data known for aluminium silicate mineral.

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)7

ADI	-
TMDI (% ADI) according to WHO European diet	Not applicable. Aluminium silicate in not acutely or chronically toxic. Aluminium silicate is an approved food additive and an ingredient in pharmaceutical preparations. It is impossible to assess the extent of intake.
TMDI (% ADI) according to national (to be specified) diets	-
IEDI (WHO European Diet) (% ADI)	Not required
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI and NEDI	Not required
ARfD	Not required.
IESTI (% ARfD)	Not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required
Factors included in IESTI and NESTI	Not required

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

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 [8]	Yield factor [8]	
	No data required: Aluminium silicate is insoluble and not taken-up and translocated in flora or fauna. Deposits on the crop surface will be removed before marketing.			

[8] See separate examples at the beginning of the section

[9] Mention whether case B1 or case B2

Proposed MRLs

No proposed MRL.
An "active substance for which no MRLs are required" status is requested (Candidate for the Annex IV. of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC)

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	Not applicable, aluminium silicate does not degrade in soil.
Non-extractable residues after 100 days ‡	Not applicable, aluminium silicate does not degrade in soil.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable, aluminium silicate does not degrade in soil.

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

Anaerobic degradation ‡

Mineralization after 100 days	Not applicable, aluminium silicate does not degrade in soil.
Non-extractable residues after 100 days	Not applicable, aluminium silicate does not degrade in soil.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable, aluminium silicate does not degrade in soil.
Soil photolysis ‡	Aluminium silicate photolytically stable.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites.

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

Laboratory studies ‡	Not applicable, aluminium silicate does not degrade in soil.
Field studies ‡	Not applicable, aluminium silicate does not degrade in soil.
pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Based on worst case PEC soil calculation the annual application of aluminium silicate increases the mass of the upper layer of the soil with 0.0128%.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡	Not applicable

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

Column leaching ‡	Not applicable
Aged residues leaching ‡	Not applicable
Lysimeter/ field leaching studies ‡	Not applicable

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	Initial worst case.
Application data	Crop: pears Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 40% Number of applications: 2x50kg/ha + 3x20 kg/ha Interval (d): - Application rate(s): 160 kg as/ha

PEC$_{(s)}$ (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	128 mg/kg		x	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Aluminium silicate does not degrade in water, thus hydrolytically stable.
Photolytic degradation of active substance and metabolites above 10 % ‡	Aluminium silicate is photolytically stable.
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment ‡	Aluminium silicate does not degrade in water/sediment systems.

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

Parent	Aluminium silicate
Method of calculation	Exposure route: spray drift Application rate: 2x50 kg/ha; + 3x20 kg/ha; (Cumulative:160 kg/ha) Crop: pears Spray drift: 29.2% Water body: 300 l/m^2 (30 cm deep ditch) Sediment depth. 5 cm Sediment bulk density: 0.8 g/cm^3
PECsw and PECsed	
Maximum concentration for single application	PECsw: 4.9 mg/l PECsed: 37 mg/kg
Maximum concentration for multiple application	PECsw: 16 mg/l PECsed: 117 mg/kg

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No calculation and not required.
Application rate	-

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

Direct photolysis in air ‡	Aluminium silicate is photolytically stable.
Photochemical oxidative degradation in air ‡	Aluminium silicate is photolytically stable.
Volatilisation ‡	Aluminium silicate is non volatile.

PEC (air) Method of calculation	Expert judgement.
PEC$_{(a)}$ Maximum concentration	Negligible

Residues requiring further assessment

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

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

Soil (indicate location and type of study)	No data provided – not requested
Surface water (indicate location and type of study)	No data provided – not requested
Ground water (indicate location and type of study)	No data provided – not requested
Air (indicate location and type of study)	No data provided – not requested

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

Not ready biodegradable

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw)	End point (mg/kg feed)
Birds				
	Kaolin	Acute	-	-
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
	Kaolin	Short-term	-	-
	Kaolin	Long-term	-	-
Mammals				
Rat	Kaolin	Acute	> 5000	-
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
	Kaolin	Long-term	-	-
Additional higher tier studies				
not required				

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
	Acute		-	10
	Short-term		-	10
	Long-term		-	5
Higher tier refinement (Birds)				
	Acute		-	10
	Short-term		-	10
	Long-term		-	5
Tier 1 (Mammals)				
	Acute		-	10
	Long-term		-	5
Higher tier refinement (Mammals)				
	Acute		-	10
	Long-term		-	5

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg a.s./L)
Laboratory tests				
Fish				
Larvea of *Pagrus major*, *Oplegnathus fasciatus* and *Parapristipoma trilineatum*	Kaolin	12 hr (static)	Mortality, LC_{50}	$494_{(nom)}$ (geometric mean)
Oncorchynchus mykiss	Kaolin	30 d (static)	Mortality, NOEC	100 $_{(nom)}$
	Preparation	96 hr (flow-through)	Mortality, EC_{50}	No data submitted – justification accepted
	Preparation	28 d(flow-through)	Growth NOEC	No data submitted – justification accepted
	Metabolite 1	96 hr (flow-through)	Mortality, EC_{50}	No data submitted – justification accepted
Aquatic invertebrate				
Cancer magister	Kaolin	200 hr (flow-through)	Mortality, LC_{50}	32000 $_{(nom)}$
	a.s.	21 d (static)	Reproduction, NOEC	No data submitted – justification accepted
	Preparation	48 h (static)	Mortality, EC_{50}	No data submitted – justification accepted
	Preparation	21 d (static)	Reproduction, NOEC	No data submitted – justification accepted
	Metabolite 1	48 h (static)	Mortality, EC_{50}	No data submitted – justification accepted
Sediment dwelling organisms				
	a.s.	28 d (static)	NOEC	No data submitted – justification accepted
	Metabolite 1	28 d (static)	NOEC	No data submitted – justification accepted
Algae				
	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted – justification accepted
	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted - data required

	Metabolite 1	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted – justification accepted
Higher plant				
Fronds, EC_{50}	No data submitted – justification accepted	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted – justification accepted
Fronds, EC_{50}	No data submitted – justification accepted	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted – justification accepted
Fronds, EC_{50}	No data submitted – justification accepted	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data submitted – justification accepted
Microcosm or mesocosm tests				
Not required.				

[1] Based on nominal $_{(nom)}$, or mean measured $_{(mm)}$ concentrations.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)
Pear, 50 kg/ha preparation

Test substance	**Organism**	**Toxicity end point (mg a.s./l)**	**Time scale**	**PEC_{swi} (mg a.s./l)**	**TER**	**Annex VI Trigger**
Kaolin	Fish	494	Acute	4.9	100.8	100
Kaolin	Fish	100	Chronic	4.9	20	10
Kaolin	Aquatic invertebrates	32000	Acute	4.9	6531	100
a.s.	Aquatic invertebrates	-	Chronic	-	Not required	10
Preparation	Algae	-	Chronic	-	Data required	10
a.s.	Higher plants	-	Chronic	-	Not required	10
a.s.	Sediment-dwelling organisms	-	Chronic	-	Not required	10

Bioconcentration	
	Active substance
$logP_{OW}$	-
Bioconcentration factor (BCF)	Not required
Annex VI Trigger for the bioconcentration factor	Not relevant
Clearance time (days) (CT50)	Not relevant
(CT90)	Not relevant
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not relevant

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

Test substance	Acute oral toxicity (LD_{50})	Acute contact toxicity (LD_{50})
Kaolin	LC_{50} > 1000 ppm	LD_{50} > 100 µg/bee
Preparation	not required	not required
Metabolite 1	not required	not required
Field or semi-field tests		
Field studies in flowering pear and apple orchards in US demonstrated that the application of a kaolin preparation at 56 kg/ha did not have adverse effects on numbers of bees foraging and their behaviour.		

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

Test substance	Route	Hazard quotient	Annex VI Trigger
Kaolin	contact	It is not appropriate to conduct a typical hazard quotient calculation based upon the limit doses used in the acute oral and contact tests.	50
Kaolin	oral		50
Preparation	contact	not required	50
Preparation	oral	not required	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)
Typhlodromus pyri ‡	-	No data submitted – justification accepted	-
Aphidius rhopalosiphi ‡	-	No data submitted – justification accepted	-

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Kaolin	*Typhlodromus pyri*	-	-	-	2
Kaolin	*Aphidius rhopalosiphi*	-	-	-	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Not required	-	-	-	No data submitted – justification accepted	-	50 %

Field or semi-field tests
Nine field studies (in many of them several applications of high doses were applied) demonstrated that Surround is not harmful to many groups of beneficials, including lacewings (chrysoperlids), ladybirds (coccinellids), hoverflies (syrphids), some heteropteran bugs (eg mirids), parasitic hymenopterans and spiders. However, in some trials a reduction in predatory mites (*Amblyseius*) and anthocorid bugs was noted.

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
Earthworms			
Eisenia fetida	Kaolin	Acute 14 days	No data submitted – justification accepted
	Kaolin	Chronic 8 weeks	No data submitted – justification accepted
	Preparation	Acute	-
	Preparation	Chronic	-
	Metabolite 1	Acute	-
	Metabolite 1	Chronic	-
Other soil macro-organisms			
Soil mite	Kaolin		-
	Preparation		-
	Metabolite 1		-
Collembola			
	Kaolin	Chronic	-
	Preparation		-
	Metabolite 1		-
Soil micro-organisms			
Nitrogen mineralisation	Kaolin	28 days	No data submitted – justification accepted
	Metabolite 1		-
Carbon mineralisation	Kaolin	28 days	No data submitted – justification accepted
	Metabolite 1		-
Field studies			
Not required			

Toxicity/exposure ratios for soil organisms
Crop and application rate

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	Kaolin	Acute		-	10
	Kaolin	Chronic		-	5
	Preparation	Acute		-	10
	Preparation	Chronic		-	5
	Metabolite 1	Acute		-	10
	Metabolite 1	Chronic		-	5
Other soil macro-organisms					
Soil mite	Kaolin			-	
	Preparation			-	
	Metabolite 1			-	
Collembola	Kaolin			-	
	Preparation			-	
	Metabolite 1			-	

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

No data submitted – justification accepted

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

Test type/organism	end point
Activated sludge	Not required

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

Compartment	
soil	Parent: aluminium silicate
water	Parent: aluminium silicate
sediment	Parent: aluminium silicate
groundwater	Parent: aluminium silicate

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

	RMS/peer review proposal
Active substance	Hazard symbol: None Indication of danger: None Risk phrases: None Safety phrases: None

	RMS/peer review proposal
Preparation	Hazard symbol: None Indication of danger: None Risk phrases: None Safety phrases: None

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
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
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 Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
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
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
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
mN	milli-newton
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