CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

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SUMMARY

Sodium 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]

Sodium 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 sodium 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 31 July 2008 by dispatching the DAR to the notifier Fluegel GmbH 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 sodium aluminium silicate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of sodium aluminium silicate as a game repellent on deciduous and coniferous trees in forestry and trees in orchards, 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-2009-00291, issued on 2 December 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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The identity and specification for sodium aluminium silicate could not be concluded on and a data gap has been identified. Data gaps are also identified for storage stability data and a method of analysis for the active substance in the formulation.

Based on the representative uses no areas of concern or data gaps were identified in the mammalian toxicology section.

Sodium aluminium silicate is used as a game repellent, which is applied only as a protective coating to the outside of tree trunks, and therefore no residues in food or feed occur. A quantitative consumer risk assessment is therefore not necessary.

Sodium aluminium silicate is a natural mineral of volcanic origin (pumice stone). Sodium aluminium silicate is known to be insoluble, photolytically stable and inert even to mineral acids and bases. Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for sodium aluminium silicate.

The risk to non-target organisms from the representative use of sodium aluminium silicate was considered to be low.

KEY WORDS

Sodium aluminium silicate, peer review, risk assessment, pesticide, repellent

TABLE OF CONTENTS

BACKGROUND

Sodium 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]

Sodium 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 sodium 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 31 July 2008 by dispatching the DAR to the notifier Fluegel GmbH 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's 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, 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 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 October – November 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

[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

game repellent on deciduous and coniferous trees in forestry and trees in orchards, 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 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 (30 November 2011),
- the report of the scientific consultation with Member State experts,
- 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

Sodium aluminium silicate is the IUPAC name there is no ISO common name.

The representative formulated product for the evaluation was 'Morsuvin' a paste formulation containing 87.5 g/kg sodium aluminium silicate.

The representative uses evaluated comprise outdoor application by brushing to deciduous and coniferous trees in forestry and trees in orchards. 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 document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

The identity of the active substance 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 sodium 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 for the active substance in the formulation.

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

2. Mammalian toxicity

Sodium aluminium silicate was discussed at the PRAPeR TC 55 Experts' Teleconference on mammalian toxicology.

The risk assessment has been based on published information including the risk assessment performed by other institutions. The original studies have not been available to the rapporteur Member State for evaluation.

The limited database indicated that sodium aluminium silicate may be partly hydrolysed in the digestive tract resulting in release of aluminium and silicate ions. Oral absorption of silicon and aluminium from administered sodium aluminium silicate is considered low. Low acute toxicity is expected when sodium aluminium silicate is administered by the oral, dermal and inhalation routes. No skin or eye irritation and no potential for skin sensitisation are expected. Oral short-term and long-term toxicity studies in rats indicate adverse effects on the urogenital track. As for the inhalation route inflammation reactions were described in a long-term inhalation exposure of sodium aluminium dust to monkeys. No carcinogenic potential is expected for sodium aluminium silicate when it is administered by the oral and inhalation route. No genotoxic or teratogenic potential is expected for sodium aluminium silicate.

The database is not suitable either to establish NOAELs, to set references values, or to adequately assess the hazard. However, the uncertainties from the limited database did not affect the risk assessment, as the paintbrush application of a paste was not considered to be a source of significant exposure based on the unlikely dermal absorption of sodium aluminium silicate and the negligible inhalation exposure. It was agreed that there is no need to set an acceptable operator exposure level (AOEL), an acceptable daily intake (ADI) or an acute reference dose (ARfD) based on the representative uses (see section 3).

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).

Sodium aluminium silicate is used as a game repellent, which is applied only as a protective coating to the outside of tree trunks (coniferous and deciduous trees and in orchards). After treatment, sodium aluminium silicate will remain on the outer surface of the tree and will not be translocated to the growing fruit, therefore no residues in food or feed occur. A quantitative consumer risk assessment is therefore not necessary.

4. Environmental fate and behaviour

Sodium aluminium silicate has been notified as a game repellent for use on trees by application with a brush onto the trunk.

Sodium aluminium silicate exists as a natural mineral of volcanic origin (pumice stone). Sodium aluminium silicate is known to be stable. Sodium aluminium silicate is known to be insoluble, photolytically stable and inert even to mineral acids and bases. The preparation 'Morsuvin' is a game repellent which will be used only as a protective coat on the outside of tree trunks. Negligible soil contamination is expected to occur during a proper application. The preparation dries within two hours and forms a protective coating. The dried preparation is not water soluble. Based on the nature of the active substance and the formulation it is unlikely that residues of the preparation would be detected in air.

5. Ecotoxicology

Considering the nature and the representative use of the substance, and also the negligible exposure of the environmental matrices, it was considered that the risk to non-target organisms from the representative use of sodium aluminium silicate will be low. It was also considered that sodium aluminium silicate is a widespread element in the environment in some regions, and therefore wildlife will often be exposed to and tolerate this substance.

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
Not applicable. Considering the nature of the substance and the limited exposure from the representative use a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for sodium aluminium silicate.	Not applicable	Not applicable

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
Not applicable. Considering the nature of the substance and the limited exposure from the representative use a definition of residue in the environment for ground water exposure assessment is deemed to be unnecessary for sodium aluminium silicate.	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable. Considering the nature of the substance and the limited exposure from the representative use a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for sodium aluminium silicate.	Not applicable

6.4. Air

Compound (name and/or code)	Toxicology
Not applicable. Considering the nature of the substance and the limited exposure from the representative use a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for sodium aluminium silicate.	Not applicable

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, supporting batch data and methods of analysis. This should include the analysis of heavy metals, dioxins and PCBs (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Stability of the active substance before and after accelerated storage (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).
- Method of analysis for the active substance in the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).

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.

None.

9.3. Overview of the concerns 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		**Deciduous and coniferous trees in forestry**) (10 kg / 1000 plants)	**Deciduous and coniferous trees in forestry**) (3 kg / 1000 plants)	**Orchard** (10 kg / 1000 plants)	**Orchard** (3 kg / 1000 plants)
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					

(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 sodium 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, 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 sodium 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 sodium aluminium silicate in Annex I of Directive 91/414/EEC. SANCO/2635/08 – rev. 1, 01 August 2008.

Hungary, 2008. Draft Assessment Report (DAR) on the active substance sodium 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 sodium 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) ‡	Sodium aluminium silicate (no ISO common name)
Function (*e.g.* fungicide)	Game repellent
Rapporteur Member State	Hungary
Co-rapporteur Member State	-
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	Sodium aluminium silicate
Chemical name (CA) ‡	-
CIPAC No ‡	-
CAS No ‡	Open
EC No (EINECS or ELINCS) ‡	Open
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 ‡	Open
Molecular mass ‡	Open
Structural formula ‡	Open

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	>1200-1700 °C (100 %)
Boiling point (state purity) ‡	Not applicable.
Temperature of decomposition (state purity)	> 700 °C (100 %)
Appearance (state purity) ‡	Pure material: solid, grey, no odour (100 %)
Vapour pressure (state temperature, state purity) ‡	Not applicable
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	Not soluble: < 1 g/l at 20 °C
Solubility in organic solvents ‡ (state temperature, state purity)	Not soluble.
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable.
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable. Sodium aluminium silicate is insoluble in organic liquids and water.
Dissociation constant (state purity) ‡	Not applicable.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not applicable.
Photo stability	Stable
Flammability ‡ (state purity)	Not flammable or auto-flammable.
Explosive properties ‡ (state purity)	Not explosive.
Oxidising properties ‡ (state purity)	Not oxidising.

Summary of representative uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of Pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (days)	kg as/hL min max (l)	water L/ha min max	kg as/ha min max (l)		
Deciduous and coniferous trees in forestry	All EU Member State	Morsuvin	F	Game repellent	PA	87.5 g/kg	coating with brush; individual plants; entire plants	September-March	1-2	6-7 months	n. a.	0-20 %	10 kg / 1000 plants	n. a.	
Deciduous and coniferous trees in forestry	All EU Member State	Morsuvin	F	Game repellent	PA	87.5 g/kg	coating with brush; individual plants; terminal sprouts	September-March	1-2	6-7 months	n. a.	0-20 %	3 kg / 1000 plants	n. a.	
Orchard	All EU Member State	Morsuvin	F	Game repellent	PA	87.5 g/kg	coating with brush; individual plants; entire plants	November-March	1-2	6-7 months	n. a.	0-20 %	10 kg / 1000 plants	n. a.	
Orchard	All EU Member State	Morsuvin	F	Game repellent	PA	87.5 g/kg	coating with brush; individual plants; terminal sprouts	November-March	1-2	6-7 months	n. a.	0-20 %	3 kg / 1000 plants	n. a.	

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 Food of animal origin Soil Water surface drinking/ground Air	No residue definition was recommended therefore no analytical methods are needed.

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. Sodium 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 ‡	Data available of limited validity. No further data needed.
Distribution ‡	Data available of limited validity. No further data needed.
Potential for accumulation ‡	Data available of limited validity. No further data needed.
Rate and extent of excretion ‡	Data available of limited validity. No further data needed.
Metabolism in animals ‡	Data available of limited validity. No further data needed.
Toxicologically relevant compounds ‡ (animals and plants)	-
Toxicologically relevant compounds ‡ (environment)	-

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Data available of limited validity. No further data needed.	
Rat LD_{50} dermal ‡	Data available of limited validity. No further data needed.	
Rat LC_{50} inhalation ‡	Data available of limited validity. No further data needed.	
Skin irritation ‡	Data available of limited validity. No further data needed.	
Eye irritation ‡	Data available of limited validity. No further data needed.	
Skin sensitisation ‡	Data available of limited validity. No further data needed.	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Data available of limited validity. No further data needed.	
Relevant oral NOAEL ‡	-	
Relevant dermal NOAEL ‡	-	

Relevant inhalation NOAEL ‡	-	
Genotoxicity ‡ (Annex IIA, point 5.4)	Data available of limited validity. No further data needed.	
Long term toxicity and carcinogenicity (Annex IIA, point 5.5)		
Target/critical effect ‡	Data available of limited validity. No further data needed.	
Relevant NOAEL ‡	-	
Carcinogenicity ‡	-	
Reproductive toxicity (Annex IIA, point 5.6)		
Reproduction toxicity		
Reproduction target / critical effect ‡	No data available. Not needed.	
Relevant parental NOAEL ‡	-	
Relevant reproductive NOAEL ‡	-	
Relevant offspring NOAEL ‡	-	

Developmental toxicity		
Developmental target / critical effect ‡	Data available of limited validity. No further data needed.	
Relevant maternal NOAEL ‡	-	
Relevant developmental NOAEL ‡	-	

Neurotoxicity (Annex IIA, point 5.7)		
Acute neurotoxicity ‡	No data available. Not needed	
Repeated neurotoxicity ‡	No data available. Not needed	
Delayed neurotoxicity ‡	No data available. Not needed	

Other toxicological studies (Annex IIA, point 5.8)	
Mechanism studies ‡	No data available. Not needed
Studies performed on metabolites or impurities ‡	No data available. Not needed

Medical data ‡ (Annex IIA, point 5.9)
No evidence of systemic, generalized or local reactions have ever been found.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data available. Not needed	-	-
AOEL ‡	No data available. Not needed	-	-
ARfD ‡	No data available. Not needed	-	-

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

Exposure scenarios (Annex IIIA, point 7.2)
Operator
Paintbrush application of sodium aluminium silicate formulated as a paste was not considered a source of significant exposure.

Workers	Paintbrush application of sodium aluminium silicate formulated as a paste was not considered a source of significant exposure.
Bystanders	Paintbrush application of sodium aluminium silicate formulated as a paste was not considered a source of significant exposure.

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

	peer review proposal
Substance classified (sodium aluminium silicate)	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)	Sodium 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. It is used as game repellent on trunks of trees. Sodium aluminium silicate is an additive to food stuff (E 554).

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)	Sodium aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals. It is used as game repellent on trunks of trees. Sodium aluminium silicate is an additive to food stuff (E 554).

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) Potential for accumulation (yes/no): Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Sodium aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals.		
	Feeding studies - Residue levels in matrices: -		
Muscle Liver Kidney Fat	Sodium aluminium silicate is chemically inert, not bioavailable and not metabolised in mammals.		

Milk Eggs	

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 residue data available for Sodium aluminium silicate.

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

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

[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]	
Deciduous and coniferous trees in forestry	Not applicable			
Orchard	Not applicable			

[8] See separate examples at the beginning of the section
[9] Mention whether case B1 or case B2

Proposed MRLs	No proposed MRL

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, Na-Al-Si does not degrade in soil.
Non-extractable residues after 100 days ‡	Not applicable, Na-Al-Si does not degrade in soil.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable, Na-Al-Si 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, Na-Al-Si does not degrade in soil.
Non-extractable residues after 100 days	Not applicable, Na-Al-Si 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, Na-Al-Si does not degrade in soil.
Soil photolysis ‡	Na-Al-Si is 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, Na-Al-Si does not degrade in soil.
Field studies ‡	Not applicable, Na-Al-Si does not degrade in soil.
pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not applicable, Na-Al-Si does not reach the soil.

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	No calculation and not required. Na-Al-Si does not reach the soil.
Method of calculation	-
Application data	

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

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Na-Al-Si does not degrade in water, thus hydrolytically stable.
Photolytic degradation of active substance and metabolites above 10 % ‡	Na-Al-Si is photolytically stable.
Readily biodegradable ‡ (yes/no)	No
Degradation in water / sediment ‡	Na-Al-Si does not degrade in water/sediment systems.

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

Parent	
Method of calculation	No calculation and not required. No spray drift and negligible soil contamination.
PECsw and PECsed	
Maximum concentration	-

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. Only negligible amounts of Na-Al-Si may be expected to reach the soil.
Application rate	-

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

Direct photolysis in air ‡	
Photochemical oxidative degradation in air ‡	Na-Al-Si is photolytically stable.
Volatilisation ‡	Na-Al-Si is non volatile.
PEC (air)	
Method of calculation	No calculation and not required.
PEC$_{(a)}$	
Maximum concentration	-

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines	Sodium aluminium silicate i

(toxicology and ecotoxicology).	

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/day)	End point (mg/kg feed)
Birds				
	Sodium aluminium silicate	Acute	No data - not required	-
	Preparation	Acute	No data - not required	-
	Metabolite 1	Acute	No data - not required	-
	Sodium aluminium silicate	Short-term	No data - not required	-
	Sodium aluminium silicate	Long-term	No data - not required	-
Mammals				
Rat	Sodium aluminium silicate	Acute	No peer-reviewed data[a] – no further data required	-
	Preparation	Acute	No data - not required	-
	Metabolite 1	Acute	No data - not required	-
	Sodium aluminium silicate	Long-term	No peer-reviewed data[a] – no further data required	-
Additional higher tier studies				
No data - not required				

[a]: Data from open literature available (see section for mammalian toxicology), however could not be peer-reviewed for the EU level evaluation

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		Not required	10
	Short-term		Not required	10
	Long-term		Not required	5
Higher tier refinement (Birds)				
	Acute		Not required	10
	Short-term		Not required	10
	Long-term		Not required	5
Tier 1 (Mammals)				
	Acute		Not required	10
	Long-term		Not required	5
Higher tier refinement (Mammals)				
	Acute		Not required	10
	Long-term		Not required	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)	End point	Toxicity (mg a.s./L)
Laboratory tests ‡				
Fish				
Brachydanio rerio	Zeolite A, Calcium form	96 hr (semistatic)	Mortality, LC_{50}	>1000 $_{(nom)}$ [b]
Pimephales promelas	Zeolite A, Calcium exchanged	30 d (flow-through)	Growth and behaviour NOEC	86.7 [b]
Brachydanio rerio	Morsuvin	96 hr (static)	Mortality, LC_{50}	>100 $_{(nom)}$ [a]
-	Preparation	28 d(flow-through)	Growth NOEC	No data - not required
-	Metabolite 1	96 hr (flow-through)	Mortality, EC_{50}	No data - not required
Aquatic invertebrate				
Daphnia magna	Zeolite A, preexchanged	96 hr (static)	Mortality, EC_{50}	377.2 $_{(nom)}$ [b]
Daphnia magna	Zeolite type 4 A	21 d (semi-static)	Reproduction, NOEC	10 $_{(nom)}$ [b]
Daphnia magna	Morsuvin	48 h (static)	Immobility, EC_{50}	>100 $_{(nom)}$ [a]
-	Preparation	21 d (static)	Reproduction, NOEC	No data - not required
-	Metabolite 1	48 h (static)	Mortality, EC_{50}	No data - not required
Sediment dwelling organisms				
-	a.s.	28 d (static)	NOEC	No data - not required
-	Metabolite 1	28 d (static)	NOEC	No data - not required
Algae				
Microcystis aeruginosa	Zeolite type 4 A	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	180-320 $_{(nom)}$ [b] -
Desmodesmus subspicatus	Morsuvin	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 $_{(nom)}$ [a] >100 $_{(nom)}$ [a]
-	Metabolite 1	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data - not required
Higher plant				
-	a.s.	14 d (static)	Fronds, EC_{50}	No data - not required
-	Preparation	14 d (static)	Fronds, EC_{50}	No data - not required
-	Metabolite 1	14 d (static)	Fronds, EC_{50}	No data - not required
Microcosm or mesocosm tests				
No data - not required				

[a] End point is presented as unit of preparation
[b]: data from the open literature, could not be peer-reviewed for the EU level evaluation

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

Not required – justification accepted.

Test substance	Organism	Toxicity end point (mg/l)	Time scale	PEC_{swi} (mg/l)	TER	Annex VI Trigger
Morsuvin	Fish	>100	Acute	-	Not required	100
a.s.	Fish	86.7	Chronic	-	Not required	10
Morsuvin	Aquatic invertebrates	>100	Acute	-	Not required	100
a.s.	Aquatic invertebrates	10	Chronic	-	Not required	10
Morsuvin	Algae	>100	Chronic	-	Not required	10
a.s.	Higher plants	-	Chronic	-	Not required	10
a.s.	Sediment-dwelling organisms	-	Chronic	-	Not required	10

Bioconcentration	
	Na-Al-Si
$logP_{O/W}$	-
Bioconcentration factor (BCF)	No data - not required
Annex VI Trigger for the bioconcentration factor	Not relevant
Clearance time (days) (CT_{50})	Not relevant
(CT_{90})	Not relevant
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not relevant

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})
Sodium aluminium silicate	No data - not required	No data - not required
Preparation	No data - not required	No data - not required
Metabolite 1	No data - not required	No data - not required
Field or semi-field tests		
No data - not required		

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

Test substance	Route	Hazard quotient	Annex VI Trigger
Sodium aluminium silicate	contact	Not required	50
Sodium aluminium silicate	oral		50
Preparation	contact	Not required	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)
Typhlodromus pyri ‡	-	No data - not required	-
Aphidius rhopalosiphi ‡	-	No data - not required	-

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Sodium aluminium silicate	*Typhlodromus pyri*	-	Not required	Not required	2
Sodium aluminium silicate	*Aphidius rhopalosiphi*	-	Not required	Not required	2

Further laboratory and extended laboratory studies ‡

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

Field or semi-field tests
No data - 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
Earthworms			
Eisenia fetida	Sodium aluminium silicate	Acute 14 days	No data - not required
	Sodium aluminium silicate	Chronic 8 weeks	No data - not required
	Preparation	Acute	No data - not required
	Preparation	Chronic	No data - not required
	Metabolite 1	Acute	No data - not required
	Metabolite 1	Chronic	No data - not required
Other soil macro-organisms			
Soil mite	Sodium aluminium silicate		No data - not required
	Preparation		No data - not required
	Metabolite 1		No data - not required

Test organism	Test substance	Time scale	End point
Collembola			
	Sodium aluminium silicate	Chronic	No data - not required
	Preparation		No data - not required
	Metabolite 1		No data - not required
Soil micro-organisms			
Nitrogen mineralisation	Sodium aluminium silicate	28 days	No data - not required
	Metabolite 1		No data - not required
Carbon mineralisation	Sodium aluminium silicate	28 days	No data - not required
	Metabolite 1		No data - not required
Field studies			
No data - not required			

Toxicity/exposure ratios for soil organisms
Crop and application rate

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	Sodium aluminium silicate	Acute		Not required	10
	Sodium aluminium silicate	Chronic		Not required	5
	Preparation	Acute		Not required	10
	Preparation	Chronic		Not required	5
	Metabolite 1	Acute		Not required	10
	Metabolite 1	Chronic		Not required	5
Other soil macro-organisms					
Soil mite	Sodium aluminium silicate			Not required	
	Preparation			Not required	
	Metabolite 1			Not required	
Collembola	Sodium aluminium silicate			Not required	
	Preparation			Not required	
	Metabolite 1			Not required	

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

No data - not required

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

Test type/organism	End point
Activated sludge	No data - not required

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

Compartment	
soil	Sodium aluminium silicate (parent)
water	Sodium aluminium silicate (parent)
sediment	Sodium aluminium silicate (parent)

groundwater	Sodium aluminium silicate (parent)

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

Active substance

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

Preparation

RMS/peer review proposal
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