

Aluminium silicate (kaolin)

DOCUMENT N2

Listing of Endpoints

Annex to EU Regulation 283/2013

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
28/02/2018	Initial applicant dossier	Doc N2_2018-02-28

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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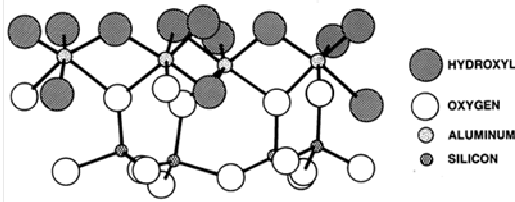
Rapporteur Member State	Month and year	Active Substance
Greece	February 2018	Aluminium silicate (Kaolin)

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Aluminium silicate.
Function (<i>e.g.</i> fungicide)	Insect repellent.
Rapporteur Member State	Greece.
Co-rapporteur Member State	France.

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	Not available.														
Chemical name (CA)	Aluminium silicate														
CIPAC No	841														
CAS No	1332-58-7														
EC No (EINECS or ELINCS)	EINECS: 310-127-6 (E559)														
FAO Specification (including year of publication)	Not available														
Minimum purity of the active substance as manufactured	999.8 g/kg														
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	<table> <tr> <td>Arsenic</td><td>< 0.5 mg/kg</td></tr> <tr> <td>Lead:</td><td>< 3.75 mg/kg</td></tr> <tr> <td>Cadmium</td><td>< 0.2 mg/kg</td></tr> <tr> <td>Mercury</td><td>< 0.02 mg/kg</td></tr> <tr> <td>TEQ-WHO PCDD/F *</td><td>< 0.9 ng/kg</td></tr> <tr> <td>TEQ-WHO dl-PCB *</td><td>< 0.029 ng/kg</td></tr> <tr> <td>TEQ-WHO ndl-PCB *</td><td>< 0.003 mg/kg</td></tr> </table> <p>*: based on LoQs and Toxic Equivalency Factors (TEFs) (WHO 2005)</p>	Arsenic	< 0.5 mg/kg	Lead:	< 3.75 mg/kg	Cadmium	< 0.2 mg/kg	Mercury	< 0.02 mg/kg	TEQ-WHO PCDD/F *	< 0.9 ng/kg	TEQ-WHO dl-PCB *	< 0.029 ng/kg	TEQ-WHO ndl-PCB *	< 0.003 mg/kg
Arsenic	< 0.5 mg/kg														
Lead:	< 3.75 mg/kg														
Cadmium	< 0.2 mg/kg														
Mercury	< 0.02 mg/kg														
TEQ-WHO PCDD/F *	< 0.9 ng/kg														
TEQ-WHO dl-PCB *	< 0.029 ng/kg														
TEQ-WHO ndl-PCB *	< 0.003 mg/kg														
Molecular formula	Hydrous aluminium silicate: $\text{Al}_4\text{Si}_4\text{O}_{10}(\text{OH})_8$, Calcined aluminium silicate: $\text{Al}_4\text{Si}_4\text{O}_{14}$.														
Molar mass	A single molecule cannot exist, approx. 258 g/mol of hydrous aluminium silicate														
Structural formula	 <p>Hydrous aluminium silicate</p>														

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, 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 (> 99.98 %). Technical material: white powdered solid. (min 999.8 g/kg)
Vapour pressure (state temperature, state purity)	Aluminium silicate is non-volatile.
Henry's law constant (state temperature)	Aluminium silicate is non-volatile.
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 coefficient (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.

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*Aluminium silicate*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s. /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Grapevine	GR	SURRO UND® WP CROP PROTECTANT	F	<i>Frankliniella occidentalis</i>	WP	950 g/kg	Broad cast spray	BBCH 00- BBCH 69	1 - 4	7 days	2.85 – 5.7	500 - 1000	28.5	Not applicable	First spraying at emergence of overwintering females Renewal of the application - as soon as the mineral white film is damaged by rain, wind or crop growth - according to pest pressure

- | | |
|---|---|
| <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|---|

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)

Regulation (EC) N° 1107/2009 Article 8.1(g)

Aluminium silicate (aka kaolin) is included in Annex IV of Regulation (EC) No 396/2005 as per Commission Regulation (EC) No 839/2008.

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Aluminium silicate (kaolin) is an effective insect repellent in pome fruits, stone fruits and vines.
Aluminium silicate is applied to form a particle film on the target crop. The particle film acts as a barrier against pests.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

None.
Aluminium silicate (kaolin) is a natural substance mainly present in soils. Aluminium silicate is part of the soil substrate and therefore has no adverse effect on crops.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The supported GAP is currently approved and marketed in Greece.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

There are no metabolites of aluminium silicate.

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Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Physico-chemical properties
Impurities in technical a.s. (analytical technique)	GC-MS, ICP-MS
Plant protection product (analytical technique)	Combination of methods including thermal gravimetric analysis, spectrometry and carbon analysis.

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

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	--
Sediment	--
Water surface	--
drinking/ground	--
Air	--
Body fluids and tissues	--

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+).

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Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance

Aluminium silicate

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹:

No classification proposed.

Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008:

No classification proposed.

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Oral absorption considered negligible based on its physico-chemical properties. Aluminium silicate is not absorbed.
Toxicokinetics	--
Distribution	--
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Oral absorption considered negligible based on its physico-chemical properties. Aluminium silicate is not absorbed.
Metabolism in animals	Oral absorption considered negligible based on its physico-chemical properties. Aluminium silicate is not absorbed nor metabolised.
<i>In vitro</i> metabolism	Negligible based on its physico-chemical properties.
Toxicologically relevant compounds (animals and plants)	None.
Toxicologically relevant compounds (environment)	None.

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, 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 air /4h (whole body)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Not sensitizing (M&K)	
Phototoxicity	Not phototoxic	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / 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.	

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Section 2 Mammalian Toxicology

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	No data available – not required.	
<i>In vivo</i> studies	No data available – not required.	
Photomutagenicity	No data available – not required.	
Potential for genotoxicity	Not genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	No data available – not required.	
Relevant long-term NOAEL	No data available – not required.	
Carcinogenicity (target organ, tumour type)	No data available – not required.	
Relevant NOAEL for carcinogenicity	No data available – not required.	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, 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 (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No data available – not required.	
Repeated neurotoxicity	No data available – not required.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data available – not required.	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	No data available – not required.	
Endocrine disrupting properties	No data available – not required.	

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Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

No data available – not required.

Medical data (Regulation (EU) N° 283/2013, Annex Part A, 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.

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	No data available – not required.	--	--
Acute Reference Dose (ARfD)	No data available – not required.	--	--
Acceptable Operator Exposure Level (AOEL)	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.	--	--
Acute Acceptable Operator Exposure Level (AAOEL)	No data available – not required.	--	--

³ If available include also reference values for metabolites

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Section 2 Mammalian Toxicology

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (*indicate name, type e.g. EC and concentration of active substance*)

SURROUND® WP CROP PROTECTANT, WP, 950 g/kg
Dermal absorption negligible based on its physico-chemical properties.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Use: grapes

<u>Exposure estimates</u> (EFSA calculator):	<u>% of AOEL</u>
Without PPE:	36%

Workers

Negligible as dermal absorption is negligible and no inhalation exposure under outdoor conditions

Bystanders and residents

Use: grapes

<u>Exposure estimates</u> (EFSA Calculator):	<u>% of AOEL</u>
Child (all pathways mean):	1.4%
Adult (all pathways mean):	0.3%

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Aluminium silicate

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴ :

No current harmonised classification.

Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

No classification proposal for acute toxicity properties.
For other endpoints: data available of limited validity to conclude. No further data needed.

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) OECD Guideline 501	Crop groups	Crop(s)	Application(s)	DAT (days)
	Fruit crops			
	Root crops			
	Leafy crops			
	Cereals/grass crops			
	Pulses/Oilseeds			
	Miscellaneous			
Not required. Aluminium silicate (kaolin) will not be present within the edible fruit of treated pear trees based on its inherent properties and the intended treatment regime. Kaolin is ubiquitous within the environment and is widely used within industry and in commercial products - no additional exposure to consumers is expected based on the intended use.				
Rotational crops (metabolic pattern) OECD Guideline 502	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops			
	Leafy crops			
	Cereal (small grain)			
	Other			
Rotational crop and primary crop metabolism similar? Not required. Kaolin is a mineral solid with an infinite two-dimensional structure, and consequently is insoluble within water and all organic solvents; it is not feasible for the substance to be uptaken by plant root systems and translocated within plant tissues. Kaolin is also relatively inert and does not degrade unless subjected to extreme conditions. Furthermore, kaolin is naturally present within the environment and is ubiquitous within soil.				
Processed commodities (standard hydrolysis study) OECD Guideline 507	Conditions			
	20 min, 90°C, pH 4			
	60 min, 100°C, pH 5			
	20 min, 120°C, pH 6			
Residue pattern in processed commodities similar to residue pattern in raw commodities? As a solid mineral, kaolin is not readily degraded by typical household / industrial processes. It may only be structurally changed by extreme temperatures / pressures (diagenesis or metamorphism, which are geological processes), or by harsh acidic conditions (by digestion with concentrated nitric acid at reflux, for several hours). Consequently, kaolin will remain stable under the typical conditions described within OECD Guideline 507.				

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Section 3 Residues

Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Not proposed and not required
Plant residue definition for risk assessment (RD-RA)	Not proposed and not required
Conversion factor (monitoring to risk assessment)	Not applicable

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen			
	Goat/Cow			
	Pig			
	Fish	mg/kg DM		
	Not provided and not required			
Time needed to reach a plateau concentration in milk and eggs (days)	Not applicable			
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Not applicable			
Animal residue definition for risk assessment (RD-RA)	Not applicable			
Conversion factor (monitoring to risk assessment)	Not applicable			
Metabolism in rat and ruminant similar (Yes/No)	Not applicable			
Fat soluble residues (Yes/No) (FAO, 2009)	Not applicable			

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502	Not required. Kaolin is a mineral solid with an infinite two-dimensional structure, and consequently is insoluble within water and all organic solvents; it is not feasible for the substance to be uptaken by plant root systems and translocated within plant tissues. Kaolin is also relatively inert and does not degrade unless subjected to extreme conditions. Furthermore, kaolin is naturally present within the environment and is ubiquitous within soil.
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Section 3 Residues

Field rotational crop study

OECD Guideline 504

Not provided and not required

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
High water content						
High oil content						
High protein content						
High starch content						
High acid content						
Not provided and not required						
Animal	Animal commodity	T (°C)	Stability (Month/Year)			
	Muscle					
	Liver					
	Kidney					
	Milk					
	Egg					
Not provided and not required						

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Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) [OECD Guideline 509](#), [OECD Guidance, series on pesticides No 66](#) and [OECD MRL calculator](#)

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses (row to be deleted if not relevant)						
Pear trees	N+S EU	Not required. Applications of the product are made to pear trees well in advance of the formation of the edible fruit. Due to the inherent properties of the compound, it is not possible for kaolin to accumulate / translocate within plant systems. The potential for kaolin to be present in / on the edible pear fruit (as a result of treatment with Surround WP) is negligible.	No MRL is necessary for the use of kaolin on pear trees.	-	-	-

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring and Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR_{Mo}).

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Section 3 Residues

Inputs for animal burden calculations

Assessment of the animal burden is not required, as pears are not routinely fed to livestock within the EU.

Furthermore, Aluminium silicate (kaolin) is relatively inert and will not breakdown within the animal digestive tract / become bioavailable. Based on the nature of the active, all potential residues of kaolin ingested by livestock would be excreted

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Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
Highest expected intake (mg/kg bw/d)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
(mg/kg DM for fish)	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey		Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Not relevant		Not relevant		Not relevant		Not relevant		Yes/No	
Feeding study submitted	Not relevant		Not relevant		Not relevant		Not relevant		Not relevant	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals
Muscle	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Fat	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Meat ^(b)	Not relevant		Not relevant		Not relevant		Not relevant			
Liver	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant		
Kidney	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant		
Milk ^(a)	Not relevant	Not relevant	Not relevant	Not relevant						
Eggs										
Method of calculation ^(c)										

(a): Estimated HR calculated at 1N level (estimated mean level for milk).

(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	February 2018	Aluminium silicate

Section 3 Residues

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey			
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N
Muscle	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Fat	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Meat ^(a)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant		
Liver	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant		
Kidney	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant		
Milk	Not relevant	Not relevant	Not relevant	Not relevant						
Eggs										
Method of calculation ^(c)										

^(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

^(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	February 2018	Aluminium silicate

Section 3 Residues**Conversion Factors (CF) for monitoring to risk assessment**

Not applicable.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	February 2018	Aluminium silicate

Section 3 Residues

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

The need for processing studies is not triggered – residues are expected to be negligible on the surface of the grape.

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI	Not proposed and not required
TMDI according to EFSA PRIMo	Highest TMDI: not required
NTMDI, according to (to be specified)	Highest NTMDI: not required
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: not required
NEDI (% ADI), according to (to be specified)	Highest NEDI: not required
Factors included in the calculations	Not relevant
ARfD	Not proposed and not required
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: not required
NESTI (% ARfD), according to (to be specified)	Highest NESTI: not required
Factors included in IESTI and NESTI	Not relevant

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

No proposed MRL.

Aluminium silicate (aka kaolin) is included in Annex IV of Regulation (EC) No 396/2005 as per Commission Regulation (EC) No 839/2008.

Code ^(a)	Commodity/Group	MRL/Import tolerance ^(b) (mg/kg) and Comments
Plant commodities		
Representative uses		
Grape vine		Not required
Animal commodities		
		Not relevant – the representative use is not fed to livestock.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation 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 (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation 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)	No metabolites.

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Aluminium silicate is photolytically stable
Mineralisation at study end	Aluminium silicate is photolytically stable
Non-extractable residues at study end	Aluminium silicate is photolytically stable

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not applicable, aluminium silicate does not degrade in soil.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not applicable, aluminium silicate does not degrade in soil.

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Not applicable, aluminium silicate does not degrade in soil.

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Not applicable, aluminium silicate does not degrade in soil.

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

No metabolites

Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean

No metabolites

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles.

Based on worst case PEC soil calculation the annual application of aluminium silicate increases the mass of the upper layer of the soil by 0.0128%.

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not applicable, aluminium silicate does not degrade in soil.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not applicable, aluminium silicate does not degrade in soil.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Not applicable, aluminium silicate does not degrade in soil.

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in soil.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in soil.

Aluminium silicate is the ultimate degradation product of rock. There are no metabolites of aluminium silicate.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in soil.

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not relevant

Aluminium silicate is the ultimate degradation product of rock. There are no metabolites of aluminium silicate.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in soil.

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Aluminium silicate is hydrolytically stable.

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

Aluminium silicate is photolytically stable.

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

Not applicable. Aluminium silicate is photolytically stable.

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable
(yes/no)

Not readily biodegradable.

Aluminium silicate is stable.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in sediment.

Aluminium silicate is the ultimate degradation product of rock. There are no metabolites of aluminium silicate.

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Not relevant.

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant protection product are indistinguishable from naturally present kaolin particles and will agglomerate with other clays present in sediment or as suspended particles.

Aluminium silicate is the ultimate degradation product of rock. There are no metabolites of aluminium silicate.

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air

Not studied - no data requested
Aluminium silicate has no vapour pressure.

Photochemical oxidative degradation in air

Not studied - no data requested
Aluminium silicate is stable to photochemical oxidative degradation.

Volatilisation

From plant surfaces:
Not studied - no data requested
Aluminium silicate has no vapour pressure.

From soil surfaces:
Not studied - no data requested
Aluminium silicate has no vapour pressure.

Metabolites

There are no metabolites of aluminium silicate (kaolin).

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

Soil: None
Surface water: None
Sediment: None
Ground water: None
Air: None

Aluminium silicate is also known as kaolin, a specific type of clay mineral. Kaolin particles applied as plant

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Section 4 Environmental fate and behaviour

protection product are indistinguishable from naturally present kaolin particles.
Aluminium silicate (kaolin) is the ultimate product of rock degradation.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

None. Not required.

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)	None. Not required.
Surface water (indicate location and type of study)	None. Not required.
Ground water (indicate location and type of study)	None. Not required.
Air (indicate location and type of study)	None. Not required.

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent	DT ₅₀ (d): Stable.
Method of calculation	Kinetics: Not applicable. Field or Lab: Not applicable.
Application data	Crop: vine Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ % plant interception: 40% (early-season vine) Number of applications: 4 Interval (d): 7 Application rate(s): 30 kg a.s./ha

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	24.0		96.0	
Short term 24h				
2d				
4d				
Long term 7d				
28d				

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
50d				
100d	24.0		96.0	
Plateau concentration	ca. 1.7 g/kg after 20 years			

Metabolite I

Method of calculation

Not applicable. There are no metabolites of aluminium silicate (kaolin)

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.

Surround® WP Crop Protectant contains 95% kaolin. Kaolin is not soluble in water, but forms suspended particles in water. Therefore, Surround® WP Crop Protectant can only reach groundwater via mechanical percolation through soil pores, and not through conventional dissolution in water and leaching through the soil column.

Clay, including kaolin, is present in some natural groundwater reservoirs. Percolation through soil pores or the presence of clay seams allow naturally present clays to form suspensions in these water bodies. It is possible (but highly unlikely) that kaolin from Surround® WP Crop Protectant may percolate through soil and reach groundwater, where it will not be possible to be distinguished by analytical means from natural clays.

Application rate

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

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

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.

PEC_(gw) From lysimeter / field studies

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in FOCUSsw step 1 and 2

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.
Calculations have been performed using Rautmann drift values.

Parameters used in FOCUSsw step 3 (if performed)

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.

Application rate

4 x 30 kg/ha
the initial worst-case PEC_{Surface Water} for kaolin has been calculated for vines taking into consideration spray drift only, for one application at the maximum dose and also assuming total accumulation of kaolin between applications

PEC_{SW} are calculated as follows:

$$PEC_{SW} \text{ (mg/L)} = \frac{\text{Application rate (g/ha)} \times \text{drift (decimal)}}{300 \text{ L/m}^2 \times 10 \text{ (conversion factor)}}$$

Worst case PEC_{sw} for kaolin in surface waters with 3 m buffer zone – use in pears

	Max single spray	Total season
Application rate (pears)	30 000 g/ha	120 000 g/ha*
Spray Drift**	0.0802	0.0802
Spray deposit (mg/m ²)	240.6	962.4
Water volume (L)	300	300
PEC_{sw} (mg/L)	0.802	3.208

* based on a maximum application rate of 4 x 30 kg/ha

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Greece	February 2018	Aluminium silicate SURROUND® WP CROP PROTECTANT

Section 4 Environmental fate and behaviour

** Early season vine, 3 m from water body, SANCO/4145/2000

Metabolite	Not applicable. There are no metabolites of aluminium silicate (kaolin).
Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	Not applicable. There are no metabolites of aluminium silicate (kaolin).
Application rate	Not applicable. There are no metabolites of aluminium silicate (kaolin).
Main routes of entry	Not applicable. There are no metabolites of aluminium silicate (kaolin).

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	Not applicable. Aluminium silicate is a natural form of clay that is present the world over. Exposure to clay particles is ubiquitous in the form of dust, suspended particles in water, sediment or soil. Estimating exposure to one of the most common mineral substances on Earth is meaningless.
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PEC

Maximum concentration	Not applicable.
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Not relevant	a.s.	Acute	LD ₅₀	Not toxic to birds
Not relevant	Preparation	Acute	LD ₅₀	Not toxic to birds
Not relevant	a.s.	Long-term	LD ₅₀ /10	Not toxic to birds
Not relevant	a.s.	Long-term	NOEC/NOAEC/NOAEL	Not toxic to birds
Mammals				
Rat	Aluminium silicate (kaolin)	Acute	LD ₅₀	>5000
Not relevant	Preparation	Acute	LD ₅₀	Not toxic to mammals
Not relevant	a.s.	Long-term	NOAEL	Not toxic to mammals
Endocrine disrupting properties (Annex Part A, points 8.1.5) No evidence for endocrine disruption properties.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): Not required.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No available data.				

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

[Representative use] at [application rate] g a.s./ha [x number of applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Not relevant	Acute	Acceptable risk		10
All	Not relevant	Long-term	Acceptable risk		5
Tier 1 (Birds)					
	Not relevant				
Higher tier (birds): Not applicable					
Screening Step (Mammals)					
All	Not relevant	Acute	Acceptable risk		10
All	Not relevant	Long-term	Acceptable risk		5
Tier 1 (Mammals)					
	Not relevant				

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger												
Higher tier (Mammals): Not applicable																	
Risk from bioaccumulation and food chain behaviour Not relevant. Aluminium silicate is not soluble in polar or non-polar solvents and thus has no octanol/water partition coefficient.																	
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger												
Earthworm-eating birds		Long-term	Acceptable risk		5												
Earthworm-eating mammals		Long-term	Acceptable risk		5												
Fish-eating birds		Long-term	Acceptable risk		5												
Fish-eating mammals		Long-term	Acceptable risk		5												
Higher tier : Not applicable																	
Risk from consumption of contaminated water <table> <tr> <th>Scenarios</th><th>Indicator or focal species</th><th>Time scale</th><th>PEC_{dw}x DWR</th><th>TER</th><th>Trigger</th></tr> <tr> <td>Leaf scenario</td><td>Birds</td><td>acute</td><td>Acceptable risk</td><td></td><td>5</td></tr> </table>						Scenarios	Indicator or focal species	Time scale	PEC _{dw} x DWR	TER	Trigger	Leaf scenario	Birds	acute	Acceptable risk		5
Scenarios	Indicator or focal species	Time scale	PEC _{dw} x DWR	TER	Trigger												
Leaf scenario	Birds	acute	Acceptable risk		5												
Puddle scenario, Screening step Acceptable risk; TER calculation not needed																	

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Laboratory tests				
Fish				
Fish (geomean)	Aluminium silicate (kaolin)	Acute	Mortality, LC ₅₀	36,577 mg a.s./L (geomean)
Not relevant	Preparation	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC ₅₀	Not relevant
<i>Oncorhynchus mykiss</i>	Aluminium silicate (kaolin)	Chronic (static)	ELS NOEC	100 mg a.s./L _(nom)
Aquatic invertebrates				
<i>Cancer magister</i>	Aluminium silicate (kaolin)	200 h (flow-through)	Mortality, LC ₅₀	3200 mg a.s./L _(nom)
<i>Daphnia magna</i>	Surround WP	48 h (static)	Mortality, EC ₅₀	>600 mg prep./L (> 570 mg a.s./L _(nom))

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Not relevant	a.s.	21 d (static, or semi-static or flow-through)	Reproduction or development, NOEC	Not relevant
Sediment-dwelling organisms				
Not relevant	a.s.	(static, or semi-static or flow-through)	Mortality, EC ₅₀	Not relevant
Algae				
<i>Scenedesmus subspicatus</i>	Surround WP	72 h (static)	ErC ₅₀ / EyC ₅₀ (NOEC)	>600 mg prep./L (>570 mg a.s./L _(nom))
Higher plant				
Not relevant	a.s.	(static, or semi-static or flow-through)	Fronds number, EC ₅₀ (NOEC) Fronde area/fresh weight/dry weight, ErC ₅₀ (NOEC)	Not relevant
Further testing on aquatic organisms:				
Not relevant				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3):				
No evidence for endocrine disruption properties.				

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)

Section 5 Ecotoxicology**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

	Active substance	Metabolite1	Metabolite2	Metabolite3
logP _{O/W}	Not relevant	Not relevant	Not relevant	Not relevant
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	Not relevant	Not relevant	Not relevant	Not relevant
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	Not relevant	Not relevant	Not relevant	Not relevant
Annex VI Trigger for the bioconcentration factor	Not relevant	Not relevant	Not relevant	Not relevant
Clearance time (days) (CT ₅₀)	Not relevant	Not relevant	Not relevant	Not relevant
(CT ₉₀)	Not relevant	Not relevant	Not relevant	Not relevant
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not relevant	Not relevant	Not relevant	Not relevant
Higher tier study: Not relevant				

List of end points

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Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} step 1-3 - TERs for [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		Fish (geomean)	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	Not applicable	<i>Scenedesmus subspicatus</i>	Not applicable	Not applicable	Not applicable
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC	NOEC
		36577 mg/L	100 mg/L	>570 mg/L	-	>570 mg/L	-	-	-
PEC Total season	3.208	0.009	0.32	<0.56	-	<0.056	-	-	-
FOCUS Step 2	Not relevant								
FOCUS Step 3*	Not relevant								
D3 / ditch									
D4 / pond									
D4 / stream									
D5 / pond									
D5 / stream									
R1 / pond									
R1 / stream									
R2 / stream									
R3 / stream									
R4 / stream									
Trigger**		100	10	100	10	10	10	10	

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 4 – Not relevant

List of end points

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Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>Apis mellifera</i>	a.s., M-96-018*	Acute	Oral toxicity (LC ₅₀)	> 1000 ppm a.s./bee
<i>Apis mellifera</i>	SURROUND® WP CROP PROTECTANT	Acute	Oral toxicity (LC ₅₀)	> 2.0 mg product/bee (>1900 µg a.s./bee)
<i>Apis mellifera</i>	a.s., M-96-018*	Acute	Contact toxicity (LC ₅₀)	> 100 µg a.s./bee
<i>Apis mellifera</i>	SURROUND® WP CROP PROTECTANT	Chronic	10 d-LC ₅₀	1390.14 µg a.s./bee/day
<i>Apis mellifera</i>	SURROUND® WP CROP PROTECTANT	Bee brood development	NOEC _{larvae}	150 µg a.s./larva (rangefinder)

Potential for accumulative toxicity: No
Semi-field test (Cage and tunnel test)
Not relevant
Field tests
Field studies in flowering pear and apple orchards 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.

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; contact exposure

Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i>	Screening	Aluminium silicate	HQ _{acute, adult contact}	< 285

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; Tier I assessment for contact exposure

Test group	Scenario	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i> (adult-chronic)	Foraging on treated crop	ETR _{chronic adult oral}	NA*	85
	Weeds in treated field		<85.5	42
	Field margin (early application)		<7.7	42
	Field margin (late application)		<22.8	42

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)

Section 5 Ecotoxicology

	Adjacent field (early application)		<7.7	42
	Adjacent field (late application)		<22.8	42
<p>The acute risk to honey bees <i>via</i> contact exposure was demonstrated to be acceptable based on the Tier I risk assessment, except for foraging on treated weeds in field. The toxicity endpoint is a “greater than limit dose value”, and the risk assessment assumes that blooming weed coverage is 100%. Proper weed management is important for a healthy vineyard, therefore, the potential for blooming weeds to be present during application in grapevines is extremely limited and the acute risk from contact exposure to bees potentially foraging on weeds in treated field can be concluded as acceptable. This is confirmed by the results of field studies which demonstrated that 56 kg kaolin preparation/ha did not have adverse effects on numbers of bees foraging or their behaviour.</p>				

* Honey bees are only attracted to the grape pollen and not the nectar, hence not applicable as the pollen consumption of forager honey bees is negligible

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; oral screening assessment

Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i>	Aluminium silicate	ETR _{acute, adult oral}	< 0.16	0.2
<i>Apis mellifera</i>	Aluminium silicate	ETR _{chronic, adult oral}	0.22	0.03
<i>Apis mellifera</i>	Aluminium silicate	ETR _{larvae}	< 1.16	0.2

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; Tier I assessment for chronic adult oral

Test group	Scenario	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i> (adult-chronic)	Foraging on treated crop	ETR _{chronic} adult oral	NA*	0.03
	Adjacent field (early application)		0.0004	0.03
	Weeds in treated field (early application)		0.013	0.03
	Field margin (early application)		0.001	0.03
	Adjacent field (late application)		0.001	0.03
	Weeds in treated field (late application)		0.013	0.03
	Field margin (late application)		0.001	0.03
	Foraging following year		NA*	0.03
The chronic tier 1 risk to adult honey bees is demonstrated to be acceptable for all scenarios. The findings are further supported by the low toxicity observed in the field trials. No further consideration is required.				

* Honey bees only attracted to the grape pollen not the nectar, hence not applicable as the pollen consumption of forager honey bees is negligible.

List of end points

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Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; Tier I assessment for chronic larvae

Test group	Scenario	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i> (adult-chronic)	Foraging on treated crop	ETR _{chronic} larvae	< 0.002	0.03
	Adjacent field (early application)		< 0.0033	0.03
	Weeds in treated field (early application)		< 0.107	0.03
	Field margin (early application)		< 0.010	0.03
	Adjacent field (late application)		< 0.010	0.03
	Weeds in treated field (late application)		< 0.107	0.03
	Field margin (late application)		< 0.010	0.03
	Foraging following year		< 0.0003	0.03
The chronic tier 1 risk to larvae honey bees is demonstrated to be acceptable for all scenarios. The findings are further supported by the low toxicity observed in the field trials. Note that the risk assessment for honey bee larvae will be revised once the definitive study is completed and valid results are available.				

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals]; drinking water assessment

Drinking water: Aluminium silicate (kaolin) is not soluble in water and will not dissipate but settle to the bottom. Exposure would be minimal, hence the risk to bees drinking from surface water <i>via</i> water bodies and puddles present in the agricultural environment is concluded to be acceptable.
Guttation: Based on the overall low risk to bees, exposure <i>via</i> guttation is considered to be minimal, especially in comparison to natural levels in the environment. Furthermore, aluminium silicate is not soluble in water and will settle which significantly reduces exposure.

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	a.s., preparation	Mortality, LR ₅₀ Reproduction, ER ₅₀	Not relevant
<i>Aphidius rhopalosiphii</i>	a.s., preparation	Mortality, LR ₅₀ Reproduction, ER ₅₀	Not relevant
Additional species			

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Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

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First tier risk assessment for – [representative use] at [application rate] g a.s./ha [x number of applications]

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
SURROUND® WP CROP PROTECTANT	<i>Typhlodromus pyri</i>	-	Not relevant		2
SURROUND® WP CROP PROTECTANT	<i>Aphidius rhopalosiphi</i>	-	Not relevant		2

¹indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect	LR/ER ₅₀
<i>Chrysoperla carnea</i>	<12 hr 3 rd instar larvae	Surround WP	-	50 kg product/ha (dried residues)	Mortality	Compared to control no adverse effect on larval development and hatchability of eggs. Larvae did show slightly slower movement and reduced grasping capabilities on kaolin coated surfaces.	LR ₅₀ > 50 kg/ha
<i>Psytalia concolor</i> , <i>Chrysoperla carnea</i> , <i>Chilocorus nigritus</i> and <i>Anthocoris nemoralis</i>	<i>P. concolor</i> : <24 hr <i>C. carnea</i> : <48 hr <i>C. nigritus</i> : adult <i>A. nemoralis</i> : adult	Surround 95 WP Dried residues, glass plates	72 hrs	50 kg product/ha (dried residues)	Mortality, reproduction	<i>P. concolor</i> , <i>C. carnea</i> and <i>C. nigritus</i> : < 50% mortality / <50% reduction in fecundity <i>A. nemoralis</i> : < 50% mortality / 66.6% reduction in fecundity	<i>P. concolor</i> , <i>C. carnea</i> and <i>C. nigritus</i> LR ₅₀ > 50 kg/ha ER ₅₀ > 50 kg/ha <i>A. nemoralis</i> LR ₅₀ > 50 kg/ha ER ₅₀ < 50 kg/ha

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<i>Chrysoperla carnea</i>	L1 larvae	Surround 95 WP, olive leaves	72 hrs	47 kg a.s./L (dried residues)	Mortality, reproduction	0% mortality / 11.6% fecundity Signs of repellency	LC/EC ₅₀ > 47500 mg a.s./L
<i>Anthocoris nemoralis</i> , <i>Chelonus inanitus</i> , <i>Chelonus nigrinus</i> and <i>Scutellista cyanea</i>		Surround 95 WP, olive leaves	72 hrs	50 kg product/ha (dried residues)	Lifespan, reproduction	Reduction in lifespan: <i>C. inanitus</i> : 35% <i>C. nigrinus</i> : 7.1% <i>S. cyanea</i> : 15.8% Reduction in fecundity: <i>A. nemoralis</i> : 32% Signs of repellency	LR/ER ₅₀ > 50 kg product/ha

Positive percentages relate to adverse effects

Risk assessment for – Grapevines at 28.5 kg a.s./ha [4 applications at 7 day intervals] based on extended lab test or aged residue tests

Species	ER ₅₀ (g/ha)	In-field rate	Off-field rate
Not relevant			

Semi-field tests:

Dried residues on sprayed greenhouse cultivated olive trees (47500 mg a.s./L) did not cause mortality or reduced fecundity in *C. carnea*. A 5.4% reduction in fertility compared to control was noted.

Field studies

Eleven field studies are available where the WP formulation of aluminium silicate (kaolin) was applied to orchards (multiple applications) at rates of up to 56 kg/ha. The results demonstrated that SURROUND® WP CROP PROTECTANT is not harmful to many groups of non-target arthropods, including lacewings (chrysopids), ladybirds (coccinellids), hoverflies (syrphids), some heteropteran bugs (e.g., mirids), parasitic hymenopterans and some spiders. However, it has been reported in some studies that a reduction in abundance occurred for predatory mites (*Amblyseius*), orchard bugs (Heteroptera), beetles (Coleoptera), some spiders (Araneae) and different species of *Orius* and the families of Philodromidae, Scelionidae, Pteromalidae, Chrysopidae and Aphelinidae), and anthocorid bugs. However, these noted reductions may be attributed to the repellent effect of aluminium silicate (kaolin) and the limited availability to prey animals on the treated plants.

In one study, the commencement in the recovery of population abundance and diversity was noted in the 6 weeks post last application (following 12 x 45 kg product/ha (10 day interval) in apple orchards), and in another, abundance and diversity of arthropod communities in olive orchards treated with 2 x 30 kg/ha for 3

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years were approaching values comparable to controls within 2 months post last seasonal spray.
Additional specific test
Not relevant

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Earthworms					
Not relevant	a.s.	-	Chronic	Growth, reproduction, behaviour	Not relevant as no exposure above environmental background and aluminium silicate is a natural non-toxic soil component.
Not relevant	preparation	-	Chronic	Growth, reproduction, behaviour	Not relevant
Other soil macroorganisms					
<i>Folsomia candida</i>	a.s.	-	Chronic	Mortality, reproduction, behaviour	Not relevant
<i>Folsomia candida</i>	preparation	-	Chronic	Mortality, reproduction, behaviour	Not relevant
<i>Hypoaspis aculeifer</i>	a.s.	-	Chronic	Mortality, growth, reproduction, behaviour	Not relevant
<i>Hypoaspis aculeifer</i>	preparation	-	Chronic	Mortality, growth, reproduction, behaviour	Not relevant

Higher tier testing (e.g. modelling or field studies)

Nitrogen transformation	a.s. preparation	-	Not relevant, acceptable risk
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Toxicity/exposure ratios for soil organisms

[Representative use] at [application rate] g a.s./ha [x number of applications]

Test organism	Test substance	Time scale	Soil PEC _{initial, max}	TER	Trigger
Earthworms					
Not relevant	a.s.	Chronic	0.24 g/kg	Not relevant	5
Not relevant	preparation	Chronic	0.24 g/kg	Not relevant	5
Other soil macroorganisms					
Not relevant	a.s.	Chronic	0.24 g/kg	Not relevant	
Not relevant	preparation	Chronic	0.24 g/kg	Not relevant	

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not relevant

Laboratory dose response tests

Species	Test substance	ER ₅₀ (g/ha) vegetative vigour	ER ₅₀ (g/ha) emergence	Exposure ¹ (g/ha) ²	TER	Trigger
Not relevant	SURROUND® WP CROP PROTECTANT	-	-	Not relevant as no exposure above environmental background and aluminium silicate is a natural non-toxic soil component.	Not relevant	5
Extended laboratory studies : Not relevant						
Semi-field and field test : Not relevant						

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	Not relevant
<i>Pseudomonas sp</i>	Not relevant

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. : Not applicable.
Available monitoring data concerning effect of the PPP : Not applicable.

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Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

Compartment	
soil	Parent (aluminium silicate (kaolin))
water	Parent (aluminium silicate (kaolin))
sediment	Parent (aluminium silicate (kaolin))
groundwater	Parent (aluminium silicate (kaolin))

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Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Aluminium silicate (kaolin)
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ⁶ :	None
Peer review proposal ⁷ for harmonised classification according to Regulation (EC) No 1272/2008:	

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

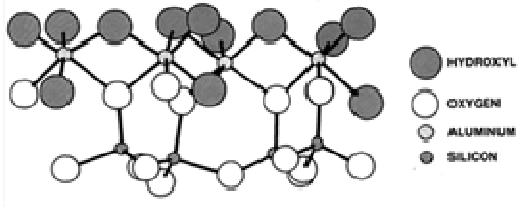
⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Appendix

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
Name: Aluminium silicate (Kaolin) Code: M99-SP1 Development code: None Manufacturing code: None	Aluminium silicate (kaolin) <chem>O=[Al]O[Si](=O)O[Si](=O)O[Al]=O</chem>	 <p><i>Hydrous aluminium silicate</i></p>

* The compound code / trivial name in bold is the name used in the list of endpoints.

