European Commission

Renewal Assessment Report
prepared according to the Commission Regulation (EU) N° 1107/2009

Aluminium silicate Calcined (Kaolin Calcined)

List of Endpoints

Rapporter Member State: Greece
Co-Rapporter Member State: France

May 2020

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Rapporteur Member State	Month and year	Active Substance (Name)
Greece	May 2020	Aluminium silicate calcined (Kaolin Calcined)

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

Version History

When	What
May 2020	Renewal Assessment Report (RAR) – prepared by RMS EL in the context of the application for renewal of approval of the a.s. according to Reg (EU) No 1107/2009. *NOTE: The RAR is a stand-alone document containing the evaluations already displayed in the initial DAR, as well as the new assessments.*

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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 calcined (Kaolin calcined)
Function (*e.g.* 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)	-
Chemical name (CA)	Aluminium silicate calcined
CIPAC No	841
CAS No	92704-41-1 ~~1332-58-7~~
EC No (EINECS or ELINCS)	296-473-8 ~~EINECS: 310-127-6 (E559)~~
FAO Specification (including year of publication)	-
Minimum purity of the active substance as manufactured	~~Open~~ Tessenderlo: 999.0 g/kg minimum SOKA: Open (Alternatively, 1000 g/kg)

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Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

~~Open~~

	Tessenderlo	SOKA
Arsenic:	< 1.0 mg/kg	12 mg/kg
Lead:	< 5.0 mg/kg	15 mg/kg
Cadmium	< 0.20 mg/kg	< 2 mg/kg
Mercury	< 0.02 mg/kg	< 0.1 mg/kg
TEQ-WHO PCDD/F (sum of congeners)	< 0.20 ng/kg	< 0.5 ng/kg
TEQ-WHO dl-PCB (sum of congeners)	< 0.15 ng/kg	< 0.5 ng/kg
TEQ-WHO PCDD/F/dl-PCB (sum of congeners)	< 0.35 ng/kg	< 0.5 ng/kg
Sum of ndl-PCB:	< 5.0 µg/kg	< 0.5 µg/kg
Respirable crystalline silica (< 10 µm)	< 1.0 g/kg	(open)

Molecular formula

~~Hydrous aluminium silicate: $Al_4Si_40_{10}(OH)_8$,~~

Calcined Aluminium silicate: $Al_4Si_4O_{14}$

Note: A single molecule cannot exist

Molar mass

A single molecule cannot exist~~, approx. 258 g/mol of hydrous aluminium silicate~~

Not applicable

Structural formula

Not applicable

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Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	Out of determination range (theoretical estimation)
Boiling point (state purity)	Out of determination range (theoretical estimation)
Temperature of decomposition (state purity)	Not applicable ~~Aluminium silicate does not sublime or decompose~~.
Appearance (state purity)	~~Pure material:~~ ~~white powdered solid, odorless (99.9 %).~~ Technical material: white powdered solid, odorless
Vapour pressure (state temperature, state purity)	Not applicable ~~Aluminium silicate is involatile.~~
Henry's law constant (state temperature)	Not applicable ~~Aluminium silicate is involatile.~~
Solubility in water (state temperature, state purity and pH)	Aluminium silicate calcined is insoluble in water
Solubility in organic solvents (state temperature, state purity)	Aluminium silicate calcined is insoluble in organic solvents
Surface tension (state concentration and temperature, state purity)	Not applicable ~~Aluminium silicate does not have a surface tension~~
Partition coefficient (state temperature, pH and purity)	Not applicable. Aluminium silicate calcined is insoluble in all organic liquids and water
Dissociation constant (state purity)	Not applicable. Aluminium silicate calcined is stable in water and will naturally become part of the sediment.

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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. Very broad and undefined peaks between 1500 cm^{-1} and 400 cm^{-1}. These bands are representative of all aluminium silicates and cannot be used to identify aluminium silicate calcined. MS: Not applicable.
Flammability (state purity)	Aluminium silicate calcined is ~~inert and therefore~~ not flammable. (theoretical estimation)
Explosive properties (state purity)	Aluminium silicate calcined is not explosive (theoretical estimation)
Oxidising properties (state purity)	Aluminium silicate calcined is not oxidizing (theoretical estimation)

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Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

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

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl) (l)	Water l/ha min max	Kg a.i./ha min max (*) (g/ha) (l)		
Grapevine	All zones	SURROUND WP CROP PROTECTANT	F	*Frankliniella occidentalis*	WP	950 g/kg	Broadcast spraying of entire plant	Up to BBCH 65	a) 1-4 b) 1-4	7	a) 2.85 - 5.70 kg/hl b) 22.80 kg/hl	500 – 1000 L/ha	a) 28.5 kg/ha b) 114 kg/ha	N/A	First spraying at emergence of overwintering females Use sufficient spray volume, apply to near drip but avoid run-off. Re-apply each 7 to 21 days, depending on rainfall and crop development.

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Apricot tree	All zones	SOKALCIARBO WP	F	*Brachycaudus schwartzi* and *Hyalopterus amygdali*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Almond tree	All zones	SOKALCIARBO WP	F	*Brachycaudus amygdalinus, Hyalopterus pruni* and *Brachycaudus persicae*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Cherry tree	All zones	SOKALCIARBO WP	F	*Myzus cerasi*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

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Hazel tree	All zones	SOKALCIARBO WP	F	*Corylobium avellanae* and *Myzocallis coryli*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Walnut tree	All zones	SOKALCIARBO WP	F	*Rhagoletis completa*	WP	1000g/kg	Foliar spray	From the first capture of insect	a) 6 b) 6	10 days after the 1st application and then 20 days	a) 1st: 6.00-10.00 2nd-6th: 3.00-5.00 b) 35.00	600-1000 L/ha	a) 1st: 60 2nd to 6th: 30 b) 210	-	-
Peach tree	All zones	SOKALCIARBO WP	F	*Myzus persicae*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd to 4th: 30 b) 140	1	-

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Pome tree (apple, pear, quince, nashi)	All zones	SOKALCIARBO WP	F	*Dysaphis pyri, Aphis pomi* and *Rhopalosiphum insertum*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Pear tree, quince tree, nashi tree	All zones	SOKALCIARBO WP	F	*Melanaphis pyraria* and *Anuraphis farfarae*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Apple tree	All zones	SOKALCIARBO WP	F	*Dysaphis plantaginea*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

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Apple tree	All zones	SOKALCIARBO WP	F	*Psylla pyrisuga, Psylla mali, Psylla costalis, Cacopsylla pyricola* and *Cacopsylla pyri*	WP	1000g/kg	Foliar spray	1st generation: BBCH 01-59 Following generation: BBCH 69-79	a) 7 b) 7	7	a) 3.00-5.00 b) 35.00	600-1000 L/ha	a) 30 b) 210	1	-
Plum tree	All zones	SOKALCIARBO WP	F	*Brachycaudus schwartzi, Hyalopterus pruni* and *Brachycaudus helichrysi K*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Citrus tree	All zones	SOKALCIARBO WP	F	*Empoasca vitis*	WP	1000g/kg	Foliar spray	At beginning of fruit ripening and the first capture of insect	a) 6 b) 6	7 days after the 1st application and then 21 days	a) 1st: 5.00-8.33 2nd-6th: 3.00-5.00 b) 33.33	600-1000 L/ha	a) 1st: 50 2nd to 6th: 30 b) 200	-	-
Lavender, lavandin	All zones	SOKALCIARBO WP	F	*Hyalesthes obsoletus*	WP	1000g/kg	Foliar spray	At the first capture of insect	a) 5	7	a) 1st: 7.50-10.00	150-200 L/ha	a) 1st: 15 2nd to 5th:	-	-

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								(except from the flowering period)	b) 5		2nd to 5th: 6.00-8.00 b) 42.00		12 b) 63		
Olive tree	All zones	SOKALCIARBO WP	F	*Bactrocera oleae*	WP	1000g/kg	Foliar spray	At the first capture of insect (with olives on the trees)	a) 6 b) 6	10 days after the 1st application and then 20 days	a) 1st: 5.00-8.33 2nd-6th: 3.00-5.00 b) 33.33	600-1000 L/ha	a) 1st: 50 2nd to 6th: 30 b) 200	-	-
Grapevine (wine and table)	All zones	SOKALCIARBO WP	F	*Empoasca vitis*	WP	1000g/kg	Foliar spray	BBCH 69-85	a) 4 b) 4	7	a) 6.66-10.00 b) 40.00	200-300 L/ha	a) 20 b) 80	1	-
Walnut tree	All zones	SOKALCIARBO WP	F	*Panaphis juglandis, Chromaphis juglandicola*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

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											b) 23.33				

(a) For crops, the EU and Codex classification (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 sucking insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes – GIFAP Technical Monograph N° 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 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

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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))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

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)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Not relevant.															

(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 sucking insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

(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 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

(k) Indicate the minimum and maximum number of applications 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

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(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	(m) PHI - minimum pre-harvest interval

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Further information, Efficacy

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

The registered uses of Aluminium Silicate products have been evaluated under the Uniform Principles based on assessments of relevant efficacy data set. No other efficacy documentation is deemed necessary at this stage.

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

The registered uses of Aluminium Silicate products have been evaluated under the Uniform Principles based on assessments of relevant selectivity data set. No other documentation is deemed necessary at this stage.

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

The registered uses of Aluminium Silicate products have been evaluated under the Uniform Principles based on assessments of relevant data set. No other efficacy documentation is deemed necessary at this stage.

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

Activity against target organism	-

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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)	**Tessenderlo & SOKA :** No common typical analytical method is applicable ~~Open~~
Impurities in technical a.s. (analytical technique)	**Tessenderlo :** HRGC-HRMS HR-ICP-MS AAS - Cold Vapour X-ray diffraction **SOKA :** GC-MS/MS ICP-OES AAS-Graphite AAS AAS-Cold vapour ~~Open~~
Plant protection product (analytical technique)	**Tessenderlo & SOKA :** No common typical analytical method is applicable. ~~Open~~

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		-

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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^+).~~

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

Substance	Aluminium silicate calcined
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 harmonised classification
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification regarding the physicochemical safety properties.

[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	The rate and extension of absorption is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance.
Toxicokinetics	No data - not required
Distribution	The rate and extension of distribution is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance.
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	No data - not required
Metabolism in animals	The rate and extension of metabolism is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance.
In vitro metabolism	No data - not required
Toxicologically relevant compounds (animals and plants)	Aluminium silicate Calcined
Toxicologically relevant compounds (environment)	Aluminium silicate Calcined

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/4h~~ > 5.07 mg/L, 4h (nose-only, dust)	-
Skin irritation	Non-irritant	-
Eye irritation	~~Slightly irritant~~ Non-irritant	-
Skin sensitisation	Not sensitising (LLNA & Magnusson and Kligman test)	-
Phototoxicity	Not required	-

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Section 2 Mammalian Toxicology

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

Target organ / critical effect	~~No data – Not required.~~ 2-week inhalation study, rats (snout only, 5 days/week, 6 hours/ day): Effects at 103 mg/m^3 Nasal turbinates effects (mucous cell hyperplasia/metaplasia) Lung effects (changes in differential white blood cell counts, minimal alveolar macrophage aggregates, increased adjusted weight of lungs/bronchi)	
Relevant oral NOAEL	No data – Not required.	
Relevant dermal NOAEL	No data – Not required.	
Relevant inhalation NOAEL	~~No data – Not required.~~ NOAEC: 47.6 mg/m^3 (kaolin)	

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

In vitro studies	~~No data – Not required.~~ *In vitro* bacterial mutagenicity (*S. typhimurium* & *E.coli*): negative	
In vivo studies	No data – Not required.	
Photomutagenicity	No data – Not required.	
Potential for genotoxicity	No genotoxic potential	

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 – Not required.	
Relevant long-term NOAEL	No data – Not required.	
Carcinogenicity (target organ, tumour type)	Not carcinogenic	
Relevant NOAEL for carcinogenicity	No data – Not required.	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	~~Reduced birth weight at parental toxic dose~~ No effect on litter size and fertility at 20% of the diet.	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 2 Mammalian Toxicology

Relevant parental NOAEL	~~< 20% of the diet~~ Not set due to limited information	
Relevant reproductive NOAEL	~~< 20% of the diet~~ Not set due to limited information	
Relevant offspring NOAEL	~~< 20% of the diet~~ Not set due to limited information	

Developmental toxicity

Developmental target / critical effect	~~Reduced birth weight at parental toxic dose~~ No effects on fetal development at 20% of the diet	
Relevant maternal NOAEL	~~< 20% of the diet~~ Not set due to limited information	
Relevant developmental NOAEL	~~< 20% of the diet~~ Not set due to limited information	

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

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

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

Supplementary studies on the active substance	No data – Not required.
Endocrine disrupting properties	Aluminium silicate does not exert endocrine disrupting activity.
Studies performed on metabolites or impurities	No data – Not required.

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 2 Mammalian Toxicology

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~~ mainly in cases of chronic and massive exposure to hydrous aluminium silicate dust. Under current working conditions in aluminium silicate industry, employees are not expected to develop pneumoconiosis. ~~During spraying aluminium silicate to crops a water suspension of the substance is used, therefore exposure to dust is regarded as very limited.~~

Summary[3] (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)	Not required		
Acute Reference Dose (ARfD)	Not required		
Acceptable Operator Exposure Level (AOEL)	AOEC = 1.4 mg/m^3 ~~Not required Limit for daily inhalation exposure for operators value of 28.8 mg/day is used instead~~	2-week inhalation, rat	25*
Acute Acceptable Operator Exposure Level (AAOEL)	Not required		

* Uncertainty factor of 25 estimated as 10 (intraspecies variability, default) x 2.5 (interspecies variability in toxicodynamics, toxicokinetic differences are not relevant for local effects in the nose and lungs).
NOAEC is obtained after 6-hour inhalation exposure of rats in the subacute study is normalised for 8 hours exposure for an occupational setting.

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

SOKALCIARBO WP, SURROUND WP	Dermal absorption is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance.

[3] If available include also reference values for metabolites

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 2 Mammalian Toxicology

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

Operators

SOKALCIARBO WP

Use (professional):

Citrus

Application rate: 50 kg a.s./ha

Exposure estimates with the EFSA Calculator 2015

Application method	RPE Level	% of AOEC*
Tractor-mounted	No RPE	114
Tractor-mounted	Closed cab	101
Hand-held (manual)	RPE	112
Hand-held (knapsack)	No RPE	21

Application method	PPE Level	% of WEL**
Tractor-mounted	No PPE	80
Hand-held (manual)	No PPE	85
Hand-held (knapsack)	No PPE	15

Use (professional):

Lavender

Application rate: 15 kg a.s./ha

Exposure estimates with the EFSA Calculator 2015

Application method	RPE Level	% of AOEC*
Tractor-mounted	No RPE	69
Hand-held (manual)	No RPE	60
Hand-held (knapsack)	No RPE	3.6

Application method	PPE Level	% of WEL**
Tractor-mounted	No PPE	49
Hand-held (manual)	No PPE	42

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 2 Mammalian Toxicology

	Hand-held (knapsack) No PPE 2.6 ***SURROUND WP*** Use (professional): **Grapes** Application rate: 28.5 kg a.s./ha Exposure estimates with the EFSA Calculator 2015 Application method / PPE Level / % of AOEC* Tractor-mounted / No PPE / 95 Hand-held (manual) / No PPE / 93 Hand-held (knapsack) / No PPE / 13 Application method / PPE Level / % of WEL** Tractor-mounted / No PPE / 66 Hand-held (manual) / No PPE / 65 Hand-held (knapsack) / No PPE / 9 *AOEC = 1.4 mg/m^3 (8hrs-TWA) **WEL = 2 mg/m^3 (8hrs-TWA)
Workers	***SOKALCIARBO WP*** Not relevant. ***SURROUND WP*** Not relevant.
Bystanders and residents	***SOKALCIARBO WP*** Use (professional): **Citrus** Application rate: 50 kg a.s./ha Exposure estimates with the EFSA Calculator 2015 % of AOEC* Resident: Adult Child Mean exposure *via* all pathways[#] 1.1 0.87 Exposure estimates with the EFSA Calculator 2015 % of WEL* Resident: Adult Child

Mean exposure *via* all pathways[#]	0.78	0.61

Lavender

Application rate: 15 kg a.s./ha

Exposure estimates with the EFSA Calculator 2015 % of AOEC*

Resident:	Adult	Child
Mean exposure *via* all pathways[#]	0.16	0.20

Exposure estimates with the EFSA Calculator 2015 % of WEL*

Resident:	Adult	Child
Mean exposure *via* all pathways[#]	0.11	0.14

SURROUND WP

Use (professional):

Grapes

Application rate: 28.5 kg a.s./ha

Exposure estimates with the EFSA Calculator 2015 % of AOEC*

Resident:	Adult	Child
Mean exposure *via* all pathways[#]	0.80	0.62

Exposure estimates with the EFSA Calculator 2015 % of WEL*

Resident:	Adult	Child
Mean exposure *via* all pathways[#]	0.55	0.43

*AOEC = 1.4 mg/m^3 (8hrs-TWA)

**WEL = 2 mg/m^3 (8hrs-TWA)

[#] Drift &Vapour

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 2 Mammalian Toxicology

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

Substance:	Aluminium Silicate Calcined
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 classification is required.
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification is required.

[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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

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)
-	-	-	-
	-	-	-
-	-	-	

No data required.

Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds. Therefore, metabolism study is not required.

Rotational crops (metabolic pattern)

OECD Guideline 502

Rotational crop and primary crop metabolism similar?

Crop groups	Crop(s)	PBI (days)	Comments
-	-	-	-

No data required.

Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds. Furthermore, Aluminium silicate is intended to be used on perennial crops only. According to the Commission Regulation (EC) No 839/2008, aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. Furthermore, Aluminium silicate is intended to be used on perennial crops only. Therefore, metabolism study in rotational crops nor trials regarding the magnitude of residues in rotational crops are not required.

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					

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 3 Residues

Residue pattern in processed commodities similar to residue pattern in raw commodities?	No data required. As a solid mineral, aluminium silicate (kaolin) is not readily degraded by typical household / industrial processes. It may only be structurally transformed by extreme temperatures / pressures (diagenesis or metamorphosis, which are two geological processes), or digested under harsh acidic conditions (concentrated nitric acid at reflux, for several hours). Consequently, kaolin will remain stable under the typical processing conditions described within OECD Guideline 507. A hydrolysis study is therefore not deemed to be necessary. Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds. Furthermore, according to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. Therefore, no data/information on processing study is required.
Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	
Plant residue definition for risk assessment (RD-RA)	According to Regulation (EC) No 839/2008, the active substance is included under Annex IV of Reg. (EC) Nº 396/2005, no MRLs are necessary (SANCO 11188/2013)
Conversion factor (monitoring to risk assessment)	-

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	-	-	-	-
	-	-	-	-
Time needed to reach a plateau concentration in milk and eggs (days)	Kaolin is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall. Any livestock metabolism study is therefore not required.			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 3 Residues

Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	According to Regulation (EC) No 839/2008, the active substance is included under Annex IV of Reg. (EC) Nº 396/2005, no MRLs are necessary (SANCO 11188/2013)
Animal residue definition for risk assessment (RD-RA)	
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (Yes/No)	-
Fat soluble residues (Yes/No) **(FAO, 2009)**	-

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.
Field rotational crop study **OECD Guideline 504**	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/Days)			
			-	-	-	-
No data submitted, not required. According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no study or analysis is required regarding the storage stability of residues.						
Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year/ Days)			
			-	-	-	-

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 3 Residues

No data submitted, not required.

According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no study or analysis is required regarding the storage stability of residues.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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)	**STMR** (mg/kg) (d)	**HR** (mg/kg) (c))	**MRL** proposals (mg/kg)	**Recommendations/comments** (OECD calculations)
Representative uses (row to be deleted if not relevant)						

(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 **Mo**nitoring and **R**isk **A**ssessment.
(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 ($STMR_{Mo}$).

No data submitted, not required.

According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no trial is required regarding the magnitude of residues in plants.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses				
-	-	-	-	-
MRL application (row to be deleted if not relevant)				
-	-	-	-	-

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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) (mg/kg DM for fish)										
Intake >0.004 mg/kg bw										
Feeding study submitted										
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										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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	
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 and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

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

Crop (RAC)/Edible part or Crop (RAC)/Processed product	**Number of studies[(a)]**	**Processing Factor** (PF)		**Conversion Factor** (CF_P) **for RA[(b)]**
		Individual values	Median PF	
Representative uses				
-				

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

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

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

Code[(a)]	**Commodity/Group**	**MRL/Import tolerance[(b)]** (mg/kg) **and Comments**
Plant commodities		
Representative uses		
According to Regulation (EC) No 839/2008, the active substance is included under Annex IV of Reg. (EC) Nº 396/2005, no MRLs are necessary (SANCO 11188/2013)		
Animal commodities		

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

According to Regulation (EC) No 839/2008, the active substance is included under Annex IV of Reg. (EC) Nº 396/2005, no MRLs are necessary (SANCO 11188/2013)

(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.

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	-
Non-extractable residues after 100 days	-
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not applicable

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

Mineralisation after 100 days	-
Non-extractable residues after 100 days	-
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable

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)	Not applicable
Mineralisation at study end	-
Non-extractable residues at study end	-

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)

-

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

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)

-

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)

-

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 relevant	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Not relevant	Not relevant
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Not relevant	Not relevant

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

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	-

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)

-

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)

-

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

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

Soil photolysis	Not applicable.

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)

-

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)

-

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 required

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 required

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 required

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

Hydrolytic degradation of the active substance and metabolites > 10 %	-

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 %	-

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

Quantum yield of direct phototransformation in water at > 290 nm	-

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

Readily biodegradable (yes/no)	-

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)

-

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	**pH water phase**	**pH sed**	**Mineralisation**	**Non-extractable residues. max *x* % after *n* d (suspended sediment test)**	**Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)**
-					

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)

-

Mineralisation and non-extractable residues (from parent dosed experiments)					
Water / sediment system	**pH water phase**	**pH sed**	**Mineralisation after 104 d. (end of the study).**	**Non-extractable residues in sed. max % after 104 d**	**Non-extractable residues in sed. max % after 104 d (end of the study)**
-					

Irridiated water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.3)

Parent									
Water / sediment	**pH system [a)]**	**t. °C**	**DT_{50} /DT_{90}**	**St. (χ^2)**	**DT_{50} /DT_{90}**	**St. (χ^2)**	**DT_{50} /DT_{90}**	**St. (χ^2)**	**Method of calculatio**

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

system			**whole sys.**		**water**		**sed**		**n**
-									
Geometric mean at 20°C[b)]									

[a)] Measured in KCL

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

Direct photolysis in air	-
Photochemical oxidative degradation in air	-
Volatilisation	-

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	Not applicable

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

	See section 5, Ecotoxicology

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

Soil (Background levels screening study: 3 European countries (Denmark, France and Germany))	-
Surface water (Background levels screening study: 3 European countries (Denmark, France and Germany))	-
Sediment (Background levels screening study: 3 European countries (Denmark, France and Germany))	-
Ground water	-
Air	-

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

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

SOKALCIARBO WP

Parent

Method of calculation

DT_{50} (d): n.a.
Kinetics: n.a.
-

Application data

Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (gas/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Crop interception (%)	60	50	50	80	20	70	60
Depth of soil	5	5	5	5	5	5	5

PECsoil							
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{soil} for single application	26.67	40.00	20.00*	13.33	16.00	20.00	10.67

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

(mg/kg)							
Initial PEC_{soil} for multiple applications – cumulated applications (mg/kg)	74.67	140.00	**140.00***	53.33	67.20	80.00	42.67

* The worst case PECsoil for Apples (7*30 kg, considering 0% crop interception) has been calculated and equals to 40 mg/kg for single application and 280 mg/kg for multiple applications

SURROUND® WP	DT_{50} (d): n.a.
Parent	Kinetics: n.a.
Method of calculation	-
Application data	**Crop:** Vine Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 0 Number of applications: 4 Interval (d): 7 Application rate(s): 30 kg a.s./ha Growth Stage: Up to BBCH 65 (40% interception)[#]

PECsoil	**Max single spray**	**Total season**
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Interception (vines, without leaves)	0.4	0.4
Spray deposit (g/m^2)	1.8	7.2
Soil weight (1 m^2 x 5 cm depth x 1.5 g/cm^3)	75 kg	75 kg
PEC_{SOIL} (mg/kg)	**24.0[#]**	**96.0[#]**

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

[#] The respective worst case considering 0% crop interception has been calculated by the RMS after coRMS proposal and equals to 40 mg/kg for single and 120 mg/kg for multiple application as proposed in the GAP.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

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

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)

SOKALCIARBO WP

Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Spray drift for single application*	15.73	15.73	29.20	15.73	2.77	15.73	8.02
Spray drift for multiple applications*	10.12	9.21	22.69	9.21	1.75	9.21	6.71
Initial PEC_{sw} for single application (mg/l)	2.62	3.14	2.92	2.62	0.14	2.62	0.53
Initial PEC_{sw} for multiple application (mg/l)	4.72	6.45	**15.88**	6.14	0.37	6.14	1.79
Initial PEC_{sed} for single application (mg/kg)	12.10	14.52	13.48	12.10	0.64	12.10	2.47
Initial PEC_{sed} for multiple application	21.80	29.75	**73.31**	28.34	1.70	28.34	8.26

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

(mg/kg)							

*Based on Rautmann drift values, no FOCUS modelling was submitted.

SURROUND® WP

Parent Parameters used in FOCUSsw step 1 and 2	Approach A: non-FOCUS, spray drift only Approach B: FOCUS, adapted Version control no.'s of FOCUS software: Steps 1-2, ver. 3.2 Water solubility (mg/L): 0,000001 mg/L DT_{50} soil (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 DT_{50} system (d): 1000 Koc = 1 000 000 L/g (highest value for a natural soil component) North and South Europe Early application (minimal crop cover) Late application (full canopy) (repeated by the RMS considering minimal cover as worst case) Treatment in October to February, March to May and June to September
Parameters used in FOCUSsw Step 3	n.a.
Application rate	Vines Number of applications: 4 Application interval: 7 days Application Rate: 30 kg a.s./ha Growth stage: Up to BBCH 65

Approach A

	Max single spray	**Total season**
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Spray drift** (%)	8.02	8.02
Spray deposit (mg/m^2)	240.6	962.4

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

Water volume (L)	300	300
PEC$_{SW}$ (mg/L)	**0.802**	**3.208**
Sediment weight (1 m^2 x 5 cm depth x 1.3 g/cm^3)	65 kg	65 kg
Transfer to sediment	100 %	100 %
PEC$_{SED}$ (mg/kg)	**3.70**	**14.81**

* based on a maximum application rate of 4 x 30 kg/ha
**Late season vines, 3 m from water body, SANCO/4145/2000

Approach B

STEP 1-2	**Vine Early**					
	PECsw (µg/L)			PECsed (µg/kg)		
STEP1	1.11E+03			~~30000~~ 3.08E+05		
			PECsw Mult App	PECsw Single App	PECsed Mult App	PECsed Single App
STEP2	North EU	Oct - Feb	250.8474	269.9	96400	24400
		Mar - May	250.8474	269.9	43000	11000
		Jun - Sep	250.8474	269.9	43000	11000
	South EU	Oct - Feb	250.8474	269.9	78600	19900
		Mar - May	250.8474	269.9	78600	19900
		Jun - Sep	250.8474	269.9	60800	15500
STEP 1-2	**Vine Late**					
	PECsw (µg/L)			PECsed (µg/kg)		
STEP1	3240			~~30000~~ 3.24E+05		
			PECsw Mult App	PECsw Single App	PECsed Mult App	PECsed Single App
STEP2	North EU	Oct - Feb	665.6138	**802.8***	~~79000~~ 1.09E+5	20900
		Mar - May	665.6138	802.8	~~43400~~ 5.53E+5	12000
		Jun - Sep	665.6138	802.8	~~43400~~ 5.53E+5	12000
	South EU	Oct - Feb	665.6138	802.8	~~67100~~ 9.08E+4	17900
		Mar - May	665.6138	802.8	~~67100~~ 9.08E+4	17900
		Jun - Sep	665.6138	802.8	~~55300~~ 7.3E+4	15000

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 4 Environmental fate and behaviour

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

Method of calculation	Not applicable

PEC

Maximum concentration	Not applicable

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)

Based on this and the reasons explained below, the applicant asks for a waiver to perform toxicity studies on terrestrial vertebrates (birds and mammals). Indeed, the available (unprotected) data in the initial DAR of Aluminium silicate (Kaolin), as well as the cited papers, show that the risk for birds and mammals is expected to be very low, and therefore, unnecessary animal testing can be avoided in order to respect the protection and welfare of animals (vertebrates) used for experimental aims, as proposed in the Regulation (EC) No 1107/2009.

Furthermore, there is one study, showing minimal avian toxicity at four dose levels after intentional consumption via their diets. The findings are summarised in the following table and full details of the study are provided in the respective section.

Species	Substance	Exposure System	Results	Reference
Gallus gallus domesticus	Kaolin	Dietary,56 d Subchronic	LD50 >30,000 mg a.s./kg diet (ppm) (>2444 mg/kg bw/d)*	Owen et al., (2012) Published ref (KCA 8.1.1.3/01)

No new studies have been submitted for terrestrial vertebrates other than birds. For more details please refer to Volume 3, Section 6 (Toxicology Section).

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

RMS has evaluated the cited references provided in argumentation of the two applicants. According to this, no toxicity testing is not necessary due to the nature and properties of the active substance. Risk assessment has not been conducted.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

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.

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
Acute fish				
Cymatogaster aggregata	200h (flow through)	Aluminium silicate	LC_{50}: **3000** mg/l (nominal)	B.9.2.1/02 McFarland, V. A. and Peddicord, R. K. (1980)
Brevoortia tyrannus, Anchoa mitchilli, Fundulus majalis, F.Heteroclitus, Rissola marginata, Menidia menidia, Morone saxatilis, M. Americana, Leiostomus xanthurus, Micropogon undulatus, Cynoscion regalis, Trinectes maculatus, Pomatomus saltatrix, Opsanus tau	24-48h (static)	Aluminium silicate	LC_{50}: >140000 mg/l (nominal)	B.9.2.1/03 Sherk, J. A. Jr., (1973)
Long-term fish				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Test species	**Test system**	**Test substance**	**Endpoint (mg/L)**	**Reference**
Oncorhynchus mykiss	30 days (ELS) (static)	Aluminium silicate	NOEC: **100** mg/l (nominal)	B.9.2.2.1/01 Hashimoto et al., (1986)
Acute aquatic invertebrates				
Cancer magister	200h (flow through)	Aluminium silicate	LC_{50}: 32000 mg/l (nominal)	B.9.2.4.1/01 McFarland, V. A. and Peddicord, R. K. (1980)
Daphnia magna	48h (static)	Surround WP (Tessenderlo)	EC_{50} >600 mg product/L (>**570** mg a.s./L) (nominal)	B.9.2.4.1/02 - (refer to Vol 3-CP) Goodband (2006)
Long-term aquatic invertebrates				
Daphnia magna	21 day	Aluminium silicate	NOEC: **50** mg/l (mm)	B.9.2.5.1/01 Robinson (2009)
Algae				
Scenedesmus subspicatus	72h (static)	Surround WP (Tessenderlo)	ErC_{50} >600 mg product/L (>570 mg a.s./L) (nominal)	B.9.2.6.1 (refer to Vol 3- CP) Vryenhoef (2006)
Pseudokirchneriella subcapitata	72h (static)	SOKALCIARBO WP (SOKA)	ErC50 >100 mg product/L (>**100** mg a.s./L) (nominal)	B.9.2.6.1 (refer to Vol 3- CP) Vryenhoef (2018)

Endpoints highlighted in bold have been used in the following risk assessment

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance
$logP_{O/W}$	-

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	not assessed
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	
Annex VI Trigger for the bioconcentration factor	2000
Clearance time (days) (CT_{50})	
(CT_{90})	
Level and nature of residues (%) in organisms after the 14 day depuration phase	

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

REGULATORY ACCEPTABLE CONCENTRATIONS

A Regulatory Acceptable Concentration (RAC) is calculated for each of the relevant groups of aquatic organisms, by dividing the toxicity endpoint by the relevant assessment factor (AF).

For the acute risk assessment for fish and aquatic invertebrates, the $RAC_{sw,ac}$ is calculated with the following equation:

$$RAC_{sw,ac} = \frac{EC_{50} \,/\, LC_{50}}{100}$$

For the chronic risk assessment for fish and aquatic invertebrates, the $RAC_{sw,ch}$ is calculated with the following equation:

$$RAC_{sw,ch} = \frac{EC_{10} \,/\, NOEC}{10}$$

The $RAC_{sw,ch}$ for algae and aquatic plants is calculated by the following equation:

$$RAC_{sw,ch} = \frac{E_rC_{50}\ or\ EC_{50}}{10}$$

Taking into account all of the above, the endpoints and relative RAC values shown in Table below have to be used in the risk assessment for aquatic organisms.

Table: Endpoints and RAC values for aquatic organisms used in the risk assessment

Substance	**Time span**	**Species group**	**Test organism**	**Selected endpoint for use in risk assessment**	**Assessment factor**	**RAC (mg/L)**
Aluminium silicate	Acute	Fish	*Cymatogaster aggregata*	LC_{50} = 3000 mg a.s./L	100	30
		Aquatic Invertebrates	*Daphnia magna*	EC_{50} = 570 mg a.s./L	100	5.7
	Chronic	Fish	*Oncorhynchus mykiss*	NOEC = 100 mg a.s./L	10	10
		Aquatic Invertebrates	*Daphnia magna*	NOEC = 50 mg a.s./L	10	5
		Algae	*Pseudokirchneriella subcapitata*	E_rC_{50} = 100 mg a.s./L	10	10

EXPOSURE OF SURROUND WP CROP PROTECTANT

Aquatic organisms may be exposed to the active substance urea from the application site into adjacent water bodies. Exposure of aquatic organisms from these routes was estimated by calculating Predicted Environmental Concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}). PEC_{sw} and PEC_{sed} values have been calculated for the proposed use using FOCUS surface water modelling. PEC calculations are presented in detail in Volume 3, B.8-AS.

TIER-1 RISK ASSESSMENT ON THE BASIS OF STANDARD TEST SPECIES

The risk assessment is conducted for the active substance aluminium silicate. The RACs have been calculated as described in point B.9.4.2 and Table B.9.4.2-1. Assessment factors 100 and 10 for the acute and chronic studies respectively have been applied to the lowest endpoints for each test group to detemine the RACs.

The RACs have then been compared with the maximum PEC_{sw} value; use in vines -late treatment taking into consideration spray drift only, for one application at the maximum dose 120,000 g/ha (worst-case).

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

In the following table, the calculated ratios between the PEC_{SW} and RACs for aquatic organisms are given for the intended uses.

Table (a): Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SURROUND WP CROP PROTECTANT in vines

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
Test species		Cymatogaster aggregata	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Pseudokirchneriella subcapitata
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw-max (mg/L)	3m buffer zone					
	3.208	0.11	0.32	0.56	0.64	0.32

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Following the request of the co-RMS, the FOCUS STEPS 1-2 model was used to calculate PECsw values (please refer to Volume 3-CP_B8).
All possible scenario combinations were modelled:

- North and South Europe
- Early application (minimal crop cover)
- Late application (full canopy)
- Treatment in October to February, March to May and June to September
- Single application rate: 30 000 g/ha
- 4 applications, 7-day interval

Vines late application affords the highest PECsw value, which is identical in all time periods and for North and South scenario. Due to the inorganic nature of the active substance, the model proposes higher surface water contamination for single application rather than multiple applications.
The values are as follows:

- PECSW = 0.8028 mg/L (Single application)
- PECSW = 0.6656 mg/L (Multiple application)

Therefore, **the higher single application value is used for worst-case risk assessment**.
In the following table, the calculated ratios between the PECSW and RACs for aquatic organisms are given for the intended uses.

Table (b): Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SURROUND WP CROP PROTECTANT in vines

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
Test species		Cymatogaster aggregata	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Pseudokirchneriella subcapitata
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw-max (mg/L)	3m buffer zone					
	0.8028	0.027	0.080	0.140	0.161	0.080

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Overall Conclusion:

For the intended uses in **vines** (1-4 applications; single application 28.5 g a.s./ha) the risk to all organism groups from exposure to aluminium silicate is considered acceptable with the use of a 3m buffer zone.

Crop		**aluminium silicate**
		a.s
Vines	single application	acceptable: 3m buffer zone
	multiple application	acceptable: 3m buffer zone

EXPOSURE OF SOKALCIARBO WP

Aquatic organisms may be exposed to the active substance urea from the application site into adjacent water bodies. Exposure of aquatic organisms from these routes was estimated by calculating Predicted Environmental Concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}). PEC_{sw} and PEC_{sed} values have been calculated for the proposed use using FOCUS surface water modelling. PEC calculations are presented in detail in Volume 3, B.8-AS.

TIER-1 RISK ASSESSMENT ON THE BASIS OF STANDARD TEST SPECIES

The risk assessment is conducted for the active substance aluminium silicate. The RACs have been calculated as described in point B.9.4.2 and Table B.9.4.2-1. Assessment factors 100 and 10 for the acute and chronic studies respectively have been applied to the lowest endpoints for each test group to detemine the RACs. The RACs have then been compared with the maximum PECsw value for each concerned crop/use (single and multiple application). Please refer to Volume 3, B.8-AS.

Table 1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in stone fruits, pome fruits and nuts fruits

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	2.62	0.09	0.26	0.46	0.52	0.26

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
multiple application (mg/l)	4.72	0.16	0.47	0.83	0.94	0.47

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 2: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in walnut tree

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	3.14	0.1	0.31	0.55	0.63	0.31
multiple application (mg/l)	6.45	0.22	0.65	1.13	1.29	0.65

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Table 3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in apple tree

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	2.92	0.1	0.29	0.51	0.58	0.29
multiple application (mg/l)	15.88	0.53	1.59	2.79	3.18	1.59

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in citrus and olive tree

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	2.62	0.09	0.26	0.46	0.52	0.26
multiple application (mg/l)	6.14	0.2	0.61	1.08	1.23	0.61

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in lavender

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
PEC sw (mg/L)						
single application (mg/l)	0.14	0.005	0.01	0.02	0.03	0.01
multiple application (mg/l)	0.37	0.01	0.04	0.06	0.07	0.04

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SOKALCIARBO WP in in grapevine

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	0.53	0.02	0.05	0.09	0.11	0.05

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
multiple application (mg/l)	1.79	0.06	0.18	0.31	0.36	0.18

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Overall conclusion for aquatic organisms

Crop		**aluminium silicate**
		a.s
stone fruits, pome fruits, nuts fruits (use no 1, 2, 3, 4, 6, 7, 8, 9, 11, 16)	single application	acceptable
	multiple application	acceptable
walnut tree (use no 5)	single application	acceptable
	multiple application	**unacceptable**
apple tree (use no 10)	single application	acceptable
	multiple application	**unacceptable**
Citrus (use no 12)	single application	acceptable
	multiple application	**unacceptable**
Lavender (use no 13)	single application	acceptable
	multiple application	acceptable
olive tree (use no 14)	single application	acceptable
	multiple application	**unacceptable**
Grapevine (use no 15)	single application	acceptable

	multiple application	acceptable

For the **single application** of the intended uses in stone fruits, pome fruits, nuts fruits, walnut tree, apple tree, citrus, lavender, olive and grapevine, the risk to aquatic organisms is **acceptable** without use of any mitigation measures.

However, for the **multiple application** of the intended uses, the risk to aquatic organisms is **unacceptable** for:

- walnut tree (use no 5)
- apple tree (use no 10)
- Citrus (use no 12)
- olive tree (use no 14)

:

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

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)

Species	Test item	Time scale/method	Endpoint	Reference
Acute toxicity				
	Aluminium silicate calcined 98.8% (M-96-018)	48 h contact toxicity	LD_{50} > 100 µg a.s./bee	Palmer et al., 1997 Report no.: 469-101 KCA 8.3.1.1.2/01 (EFSA Conclusion, 2012)
	SOKALCIARBO WP	48 h contact toxicity	LD_{50} > 500 µg a.s./bee	Mamet O., 2008
Chronic toxicity				
Apis mellifera Adults	SOKALCIARBO WP	Oral, 10d repeated exposure	LC_{50} = 90919 mg a.s./kg diet LDD_{50} = 2636 µg a.s./bee/day NOEC = 29997 mg a.s./kg diet NOEDD = 882 µg a.s./bee/day	Mamet O., 2019
	SURROUND® WP CROP PROTECTANT	Oral, 10d repeated exposure	LDD_{50} = 1390 µg a.s./bee/day LC_{50} = 56410 mg a.s./kg diet NOEDD = 660 µg a.s./bee/day NOEC = 29319 mg a.s./kg diet	Ansaloni, 2019 Report no.: TRC17-208BA KCP 10.3.1.2/01
Effects on honeybee development and other honeybee life stages				
Apis mellifera Larvae	SURROUND® WP CROP PROTECTANT	22d Larvae toxicity Repeated exposure	NOED = 405 µg a.s./larva NOEC = 2.893 mg a.s./mL diet	Ansaloni, 2019 Report no.: TRC17-184BA KCP 10.3.1.3/01
Higher-tier studies (tunnel test, field studies)				
Field studies in flowering pear and apple orchards in US demonstrated that the application of an Aluminium silicate preparation at 56 kg/ha did not have adverse effects on numbers of bees foraging and their behaviour (Mayer D.F., 1999a and 1999b)*				

Endpoints in bold are the lowest toxicity values
* Acceptable as supporting evidence

List of end points

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Risk assessment

Test item	Use	Application rate (g a.s./ha)	Oral LD_{50} (µg a.s./bee)	Contact LD_{50} (µg a.s./bee)	HQoral	HQcontact
Aluminium silicate	All uses	50000	-	>100	-	<500
SOKALCIARBO WP	Stone fruits, pome fruits, nuts fruits, citrus, olive tree	50000		>500		<100
	Grapevine	20000				<40
	Lavender	15000				<30
SURROUND® WP	Grapevine	28500	-	-	-	-

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)

Species	Substance	Exposure System	Results	Reference
Laboratory studies				
No GLP-compliant studies were conducted.				
Field or semi-field tests				
Puterka, 1997; Lepine J. 2004; Fraser, H. 2002a,b,c,d,e; G Peusens & P Creemers 2004a,b (EFSA Conclusion 2012; KCP 10.3.2.4/01 to /09) Nine field studies (in many of them several applications of high doses were applied) demonstrated that Surround is not harmful to many groups of beneficials, including lacewings (chrysoperlids), ladybirds (coccinellids), hoverflies (syrphids), some heteropteran bugs (eg mirids), parasitic hymenopterans and spiders. However, in some trials a reduction in predatory mites (*Amblyseius*) and anthocorid bugs was noted. Pascual *et al.*, 2010a A 3-year field experiment was conducted from 2005 to 2007 at Villarejo de Salvanes, Spain to assess the effects of Surround WP (2 x 3 kg/100L) on the arthropod community of olive trees and on natural enemies. The principal response curve (PRC) analysis revealed a significant deleterious effect of Surround WP on the natural enemy arthropod community of the olive grove. Both the abundance and the diversity of arthropods were reduced. The most affected taxa were the following: *Scymnus mediterraneus, Stethorus punctillum, Hyperaspis reppensis, Brachynotocoris ferreri* and different species of *Orius* and the families of				

List of end points

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Species	Substance	Exposure System	Results	Reference
Philodromidae, Scelionidae, Pteromalidae, and Aphelinidae, and Chrysopidae. Marko V. et al., 2010 Application of kaolin particle film (10-12 x 45 kg/ha; 10-d intervals) reduced the abundance and species richness of the apple orchard heteropteran, beetle and spider communities, the main guilds and the most common species. It also altered the composition and diversity of communities. The degree of reduction was different in many taxa, causing differences between the composition and diversity of the communities in the kaolin-treated and control plots. The treatments disrupted many non-target groups notably mycophagous, predacious and tourist beetles, zoophagous bugs and spiders. Among spiders, wanderer spiders (Thomisidae, Philodromidae) were most affected, whereas web building spiders (Dictynidae) were least affected. The very strong negative effect both on abundance and number of genera was apparent even at the end of the monitoring period (approximately 6 weeks after last application). Sackett *et al*., 2007 Surround WP applied 4 times in apple orchards (60 kg/ha) altered the species composition of the generalist predator assemblages and reduced the relative abundances of certain generalist predators, most notably Salticidae and Philodromidae, Reduviidae, Formicidae and Coccinellidae, after the fourth application of kaolin. Effects was still present one month after the last application in August. In contrast, the relative abundances of web-spinning spiders (Araneidae, Dictynidae, Theridiidae) were not affected. Kaolin did not affect the proportion of parasitized *C. rosaceana* larvae or the relative proportions of parasitoid taxa. Sánchez-Ramos *et al*., 2017 The effects on the non-target arthropod fauna of the almond trees canopy in fields treated with 2 applications of Surround WP at 5 kg/100 L over a 2-year treatment period reduced the abundance of natural enemies (2009 and 2010) and the abundance of other non-target arthropods compared to the control plots (2010). Potential for recovery was not addressed within the limited timeframe of this field study. Knight *et al.*, 2001 Population density of natural enemy populations were measured after 7 or 10 applications of 56 kg M96-018/ha in the apple orchards in Washington State (USA) over a 2 year period. Beneficials analysed were spiders (Araneae), ants (Hymenoptera: Formicidae), ladybird beetle larvae and adults (Coleoptera: Coccinellidae) and earwig, *Forficula auricularia* L. (Dermaptera: Forficulidae). The abundance of these species were lower in the treated crops compared to control. The potential for recovery was not addressed. Iannotta *et al*., 2007 Surround WP applied at a rate of 2 x 5 kg/hL (50 kg/ha) in olive groves. Kaolin reduced the abundance of arthropods at canopy level (timimg/frequency of sampling not indicated). On the canopy, only Lepidoptera were unaffected by the kaolin spraying, the other species were other Hymenoptera, Ichneumonoidea, Macrolepiotera, Neurptera, Mecoptera, Syrphidae, Coccinellidae, Aranease and Opiliones. Kaolin had no impact on the soil arthropods communities (included: Araneae, Isopoda, Carabidae, Staphylinidae, other Coleoptera and Formicidae). Markó *et al.*, 2006 Hydrophobic kaolin, M96-018, was applied at a rate of 45 kg/ha in a suspension of 30 g kaolin M96-018 and 40 mL methanol/L of water. The treatments were applied about every ten days, between March 25 and August 5. The numbers of the most important predators, *Forficula auricularia*, *Allothrombium fuliginosum* and *Exochomus quadripustulatus*, were significantly lower on the kaolin treated plots. This also was the case for spiders. A month after the last treatment, the population density of spiders was still lower in the treated plots. Showler & Sétamou, 2004 Surround at a rate of 42.3 L/ha applied weekly or biweekly from mid-April to the end of June (approximately 7 to 10 applications) in a 2-year field trial in cotton fields. Populations of dipterans, *Orius* spp., and wasps were reduced in the kaolin treatments (specific samplings), but differences were				

List of end points

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Species	Substance	Exposure System	Results	Reference
statistically confirmed only in 1 of 20 sampling dates over the two seasons. Pascual *et al.*, 2010b Surround WP (2 x 3 kg/100L) was tested in a olive grove in Madrid in 2006. Both PRC and two-way ANOVA identified the coccinellid *Scymnus mediterraneus* and the spider family Philodromidae as the taxa the most affected by kaolin. Kaolin treatment caused a significant reduction in numbers of predators compared to the untreated control, while trichlorfon treatment had less pronounced effects. Other affected taxa (taxon weight > 0.5) include other Salticidae, *Hyperaspis reppensis*, Chrysopidae, other coccinellidae, *Brachynotocoris ferreri*, *Stethorus punctillum*, *Araniella cucurbitina*, other Thomisidae, *Orius laevigatus* and other Theridiidae. Tacoli *et al*., 2019 Surround WP applied 2 times (20 kg/ha) reduced the abundance of predatory mite populations (Araci: Phytoseiidae) in vineyards located in north-eastern Italy in 2015-2016 (4 field trials). Kaolin caused a gradual decrease in population density levels of *Kampimodromus aberrans* and *Typhlodromus pyri* with the maximum reduction ranging from 49 to 91% and with a complete population recovery in the next spring. Laboratory data showed that kaolin (190-200 kg/ha) reduced the fecundity of *K. aberrans* and *T. pyri* females but not their survival. Jaastad *et al*., 2006 Kaolin particle film (Surround) was applied twice (3 kg/hL) in an organic plum field and in two IPM apple fields in Western Norway in 2003-2005. The population of beneficial mites was negatively affected by kaolin treatment in both apples and plums in 2004 and 2005. The most common species of beneficial mites recorded were *Tydeus* sp., *Typhlodromus* sp. and *Amplyseius* sp.				

Effects on non-target soil meso- and macro fauna (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).

TASK FORCE: SOKA // SOKALCIARBO WP

Aluminium silicate is present in most natural soils and agricultural soils, and the use of SOKALCIARBO WP in agriculture will not significantly alter the normal background levels. The calculated maximum PECsoil Following the use of SOKALCIARBO WP is 140 mg/kg, which is equal to 0.014%. Given that soils typically contains between 5-50% clay, the quantity of clay (Aluminium silicate) added through the use of SOKALCIARBO WP will not be significant to cause any measurable increase in the clay content of agricultural soils. In this context, the use of SOKALCIARBO WP is not expected to have any impact on other soil macro-organisms as Aluminium silicate will mix with, behave in an identical manner to and will immediately become indistinguishable from naturally present clay. Therefore, the risk for non-target soil microorganisms is considered to be very low.

Conclusions: The long-term risk of Aluminium Silicate is acceptable for non-target soil meso- and macrofauna following the intended uses SOKALCIARBO WP.

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

No toxicity endpoints are available and therefore the risk assessment could not be provided. The justification provided is considered acceptable.

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Conclusion: Overall, exposure to aluminium silicate (kaolin) resulting from the use of SURROUND® WP CROP PROTECTANT in grapevines is minimal compared to its natural presence in the environment. Therefore, adverse effects to soil organisms is concluded to be low and the request for toxicity studies and conventional EU risk assessments are not considered necessary for a non-toxic, non-bioavailable, routinely ingested natural mineral such as kaolin clay as was reported in the EFSA Conclusion for aluminium silicate (2012).
In light of these considerations, no toxicity testing with macro or micro soil organisms with the formulated product is considered to be necessary for the purposes of renewal and the risk to soil organisms is concluded to be low.

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).

TASK FORCE: SOKA // SOKALCIARBO WP

Aluminium silicate is present in most natural soils and agricultural soils, and the use of SOKALCIARBO WP in agriculture will not significantly alter the normal background levels. The calculated maximum PEC_{soil} Following the use of SOKALCIARBO WP is 140 mg/kg, which is equal to 0.014%. Given that soils typically contain between 5-50% clay, the quantity of clay (Aluminium silicate) added through the use of SOKALCIARBO WP will not be significant to cause any measurable increase in the clay content of agricultural soils. In this context, the use of SOKALCIARBO WP is not expected to have any impact on soil micro-organisms as Aluminium silicate will mix with, behave in an identical manner to and will immediately become indistinguishable from naturally present clay.

Conclusion: The risk of Aluminium Silicate is acceptable for soil nitrogen transformation processes following the intended uses of SOKALCIARBO WP.

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

No additional data/study with the representative formulation SURROUND® WP CROP PROTECTANT was submitted and therefore risk assessment could not be calculated.

Conclusion: The risk of Aluminium Silicate is acceptable for soil nitrogen transformation processes following the intended uses of SURROUND® WP CROP PROTECTANT.

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).

TASK FORCE: SOKA // SOKALCIARBO WP

No additional data submitted, not required.
SOKALCIARBO WP is not intended to be used as an herbicide or a plant growth regulator and is not known to have any herbicidal activities.

No additional data/study with the representative formulation SOKALCIARBO WP was performed, since it is possible to extrapolate from data obtained with the active substance [due to the composition

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

of the representative formulation SOKALCIARBO WP (please refer to Document J)]. Aluminium silicate is used as an insect repellent only, it is a systemic substance, and therefore is not absorbed or metabolized by plants. Furthermore, in this document, it has been shown that:

- Aluminium silicate (Kaolin) is a natural inert component of the environment, and therefore, non-target organisms eat and are naturally in contact with Aluminium silicate (Kaolin)
- Some OECD guidelines require the use of Aluminium silicate (Kaolin) in the tested soil material (to be close to the natural soil composition)
- In all the open literature presented on point 8.3.2 (non-target arthropods other than bees) and performed in field, no adverse effect to plants have been raised.

Based on these data/reasons, the applicant asks for a waiver to perform studies on non-target plants. The justification is considered acceptable.

Overall, it is concluded that the risk to non-target higher terrestrial plants is considered acceptable.

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

No studies on toxicity of SURROUND® WP CROP PROTECTANT are provided and therefore no risk assessment was performed. The justification provided is considered acceptable.

Overall it is concluded that the risk to non-target higher terrestrial plants is considered acceptable.

Effects on other terrestrial organisms (flora and fauna) treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8).

No studies were provided and therefore no risk assessment was performed.

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

No studies were provided and therefore no risk assessment was performed.

Greece	April 2020	Aluminium silicate calcined (Kaolin Calcined)

Section 5 Ecotoxicology

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	-
water	-
sediment	-
groundwater	-

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

Substance	Aluminium silicate (calcined)
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]:	No harmonised classification and labelling
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	Not classified for both acute and chronic toxicity

[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.

Substances and metabolites; structures, codes, synonyms

Compound	Denomination (IUPAC)	Structure	Compound found in