European Commission

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

Aluminium Silicate Calcined
(Kaolin calcined)
SOKALCIARBO WP
SOKA

Volume 3
Annex B.9 (PPP)
Ecotoxicology

Rapporteur Member State: Greece
Co-Rapporteur Member State: France

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Version history

Date	**Data points containing amendments or additions and brief description**	**Document identifier and version number**
March 2008	Initial DAR. Draft Assessment Report (DAR) – prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC.	
May 2011	Addendum of the DAR (Aluminium silicate – Annex B, B.9, Hungary, May 2011).	
May 2020	Renewal Assessment Report (RAR)-prepared in the context of the application for renewal of approval of the a.s. according to Regulation (EC) No 1107/2009. Note: RAR contains the summaries already presented in the original DAR dated March 2008, as well as the new studies submitted for the Renewal. The new studies are summarized, evaluated and presented below (being highlighted by yellow shading), along with the older studies from DAR (no colour-shadow).	

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B.9 ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

Introduction

Aluminium Silicate (kaolin) has previously been evaluated as a plant protection product and was included in the Annex I to Directive 91/414/EEC (2008/69/EC, and re-affirmed in 2010/39/EU). The evaluation of the original RMS (Hungary) is set out in the Draft Assessment Report (DAR) of March 2008 and its addenda in May 2011.

Critical ecotoxiclogical endpoints used in risk assessments, were published in the EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance Aluminium Silicate (**EFSA Journal 2012;10(2):2517**).

Greece, the RMS for Aluminium Silicate renewal will re-evaluate all studies that have been originally submitted and those that are relied upon for renewal. The conclusions have been updated to meet current scientific standards. Changes as compared to the first version are highlighted in yellow, in order to facilitate the lecture and to draw the attention to parts which were re-assessed by the RMS.

The Task Force **SOKA** supports the renewal of approval of **Aluminium Silicate** with the representative formulation **SOKALCIARBO WP**.

SOKALCIARBO WP is the representative formulation supporting the application for the renewal process of the active substance Aluminium Silicate in Europe. Exposure assessment were conducted based on agricultural use pattern as summarized in the table below.

Proposed use pattern

Use No.	1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 16	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 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/minium interval	4/7	7/7	6/7	5/7	6/10	4/7
Crop growth stage (BBCH)	1st: BBCH 51-59 2nd-3th: BBCH 69-79 4th: post harvest	1st generation: BBCH 01-59 2nd generation: BBCH 69-79	At beginning of fruit ripening and the first capture of insect	At the first capture of insect	At the first capture of insect (with olives on the trees)	BBCH 69-85
Application method	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray

B.9.1 EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.1.1 EFFECTS ON BIRDS

B.9.1.2 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

B.9.2 RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.2.1 RISK ASSESSMENT FOR BIRDS

No adverse effect of Aluminium silicate to terrestrial vertebrates is expected following the use of SOKALCIARBO WP. Please refer to CA- Section 9 of Volume 3 . Furthermore, it can be noted that the risk assessment based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438), is not adapted to this type of mineral/clay active substance.

In addition, according to the data provided in the document M-CA 8 and summarized on point 10.1 (above), it can be concluded that Aluminium silicate is a non-toxic substance for which birds are naturally exposed in the environment or which is used by poultry farmer (by oral or contact routes) for healthy poultries. Furthermore, it can be noted that birds concerned by the exposure of Aluminium silicate following the use of SAKALCIARBO WP are granivorous birds (eating seeds), insectivorous/worm feeding birds, omnivorous birds and frugivorous birds (for the use on grapevine only).

Following the applications of the product SOKALCIARBO WP, according to the intended uses, the maximum initial PECsoil is 0.027 g/kg and the maximum cumulated PECsoil is 0.14 g/kg. This represents a minor quantity of the Aluminium silicate naturally present in soil. Even OECD guidelines request to use 200 g Kaolin/kg soil for toxicity studies requiring artificial soil material (like for earthworms, predatory mite (Hypoaspis aculeifer) etc…). Due to its nature (not soluble in all organic liquids and water, and not considered as a lipophilic substance), Aluminium silicate cannot be considered as bio-accumulative substance. Therefore, weeds, seeds, earthworms and arthropods available on soil of crops treated with SOKACIARBO WP are not exposed to a greater Aluminium silicate quantity than is naturally occurring in the environment. In this context, it can be concluded that granivorous birds, insectivorous/worm feeding birds, omnivorous birds will not be exposed to a greater Aluminium silicate quantity than the one they are naturally exposed to.

As regards to frugivorous birds (for the use on grapevine only), a vineyard contains between 3000 and 5000 plant per hectare. On grapevine, SOKALCIARBO WP is applied at the dose of 20 kg/ha, this means that each plant is exposed to maximum 7 g of Aluminium Silicate. Considering that each vine is able to produce more than 1 kg of bunches, frugivorous birds are able to ingest maximum 7 g Aluminium Silicate/kg of bunches, i.e., 7 g/kg diet. In the document M-CA 8, one study on the effects of dietary Kaolin was provided (Owen O.J. et al., 2012), in which 30 g kaolin/kg diet were administrated to chickens. It was observed that the repeat ingestion of Kaolin (Aluminium Silicate) has beneficial effects on the growth performance of broiler chickens, without observation of any adverse effect for the chickens. In this context, it can be concluded that 7 g Aluminium Silicate/kg of bunches will not have any adverse effect on frugivorous birds.

Based on these data/reasons, the risk for birds exposed to Aluminium Silicate following the applications of the product SOKALCIARBO WP according to the intended uses, is expected to be very low.

B.9.2.2 RISK ASSESSMENT FOR TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

The risk assessment based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438), is not adapted to this type of mineral/clay active substance. However, no adverse effect of Aluminium silicate to terrestrial vertebrates is expected following the use of SOKALCIARBO WP.

It can be noted that mammals concerned by the exposure of Aluminium silicate following the use of SAKALCIARBO WP are small and large herbivorous mammals, insectivorous mammals, omnivorous mammals and frugivorous mammals (for the uses on orchards only). Following the applications of the product SOKALCIARBO WP, according to the intended uses, the maximum initial PEC_{soil} is 0.027 g/kg and the maximum cumulated PEC_{soil} is 0.14 g/kg. This represents a minor quantity of the Aluminium silicate naturally present in soil. Even OECD guidelines request to use 200 g Kaolin/kg soil for toxicity studies requiring artificial soil material (like for earthworms, predatory mite (*Hypoaspis aculeifer*) etc…). Due to its nature (not soluble in all organic liquids and water, and not considered as a lipophilic substance), Aluminium silicate cannot be considered as bio-accumulative substance. Therefore, weeds, seeds, earthworms and arthropods available on soil of crops treated with SOKACIARBO WP are not exposed to a greater Aluminium silicate quantity than is naturally occurring in the environment. In this context, it can be concluded that small and large herbivorous mammals, insectivorous mammals and omnivorous mammals will not be exposed to a greater Aluminium silicate quantity than the one they are naturally exposed to. As regards to frugivorous mammals (for the uses on orchards only), the LD_{50} for mammals (rat) is greater than 5000 mg Aluminium Silicate/kg bw. However, at this dose, no mortality was observed in the tested rats. Furthermore, according to the data provided in the document M-CA 8 and summarized on point 10.1 (above), it can be concluded that Aluminium silicate is a non-toxic substance for which mammals are naturally exposed in the environment (by oral or contact routes). In this context, based on all of these data/reasons, the risk for mammals exposed to Aluminium Silicate following the applications of the product SOKALCIARBO WP according to the intended uses, is expected to be very low.

B.9.3 EFFECTS ON AQUATIC ORGANISMS

B.9.3.1 ACUTE TOXICITY TO FISH, AQUATIC INVERTEBRATES, OR EFFECTS ON AQUATIC ALGAE AND MACROPHYTES

Aquatic toxicity data from the open literature are available for aluminium silicate with fish and aquatic invertebrates (acute and long-term) were submitted by the applicant during the previous EU review and were re-evaluated for the renewal. For endpoints and summaries on a.s. aluminium silicate please refer to Volume 3CA_B9.

During the initial EU evaluation, a data gap for algae was identified and new data were submitted with the formulated product to support the renewal. Full details and summary of the study is provided below.

B.9.3.1.1 Acute toxicity to fish

Aluminium silicate does not dissolve in water; therefore, any exposure of fish to kaolin involves simply the physical contact of particles. Regarding the aspect of the potential impact of kaolin on fish please refer to Volume 3CA_B9.
Moreover, Regulation (EC) No 1107/2009 states that "Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort." Therefore, no further testing is performed with the formulated product for the welfare of the animals.

In addition, the formulation SOKALCIARBO WP is composed of 100% Aluminium Silicate concern (Please refer to Volume 4 for details on product composition). Therefore, all studies or data available on the Aluminium Silicate are suitable for the formulation SOKALCIARBO WP.

B.9.3.1.2 Acute toxicity to aquatic invertebrates

The formulation SOKALCIARBO WP is composed of 100% Aluminium Silicate concern (Please refer to Volume 4 for details on product composition). Therefore, all studies or data available on the Aluminium Silicate are suitable for the formulation SOKALCIARBO WP.

B.9.3.1.3 Effects on algae

B.9.3.1.3/01

Reference	Vryenhoef, H. 2018 SOKALCIARBO WP: Algal Growth Inhibition Test Report No: HM69VD
Guideline	OECD 201
GLP/QA	Yes
Previous evaluation	No, submitted for the purpose of the renewal
Validity/Acceptance	Yes/ Yes
Material and methods	
Test substance	SOKALCIARBO WP Batch number: 17287 Molecular formula: $Al_4Si_4O_{14}$ Purity: SiO_2 54.00% Al_2O_3 42.00%

	Appearance: white powder
Test species	*Pseudokirchneriella subcapitata*
Test concentrations	100 mg test item/L (nominal)
Test groups	6 replicates per concentration and control
Duration	72 h -static test
Test design	Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group, using a haemocytometer and light microscope. Samples were taken at 22, 46 and 72 hours and the cell densities determined using a haemocytometer and light microscope. Three determinations were made for each sample. The nominally inoculated cell concentration (5.00 x 10^3 cells/mL) was taken as the starting cell density. The shape and size of the algal cells was inspected microscopically and any abnormalities recorded. The pH of the control and 100 mg/L loading rate WAF was determined at initiation of the test and after 72 hours exposure. The temperature within the incubator was recorded daily. The appearance of the test media was recorded daily.
Test conditions	constant illumination and shaking at a temperature of 24 ± 1 °C.
Parameters tested	Cell density (growth rate inhibition) -initial density 5,000 cells/mL
Endpoint(s)	72h ErC50 > 100 mg form/l (100 mg a.s./l) 72h NOEC = 100 mg form/l (100 mg a.s./l)
Analytics	Not available
Statistics	A Student's t-test incorporating Bartlett's test for homogeneity of variance (Sokal and Rohlf, 1981) was carried out on the growth rate and yield data after 72 hours for the control and the 100 mg/L loading rate to determine any statistically significant differences between the test and control groups. All statistical analyses were performed using the SAS computer software package (SAS, 1999 - 2001).

Findings

<u>Analytical results:</u>

The test concentrations in the test preparations were not determined by analysis at the request of the Sponsor.

<u>Biological results:</u>

SOKALCIARBO WP effects on *Pseudokirchneriella subcapitata*

Nominal concentration (mg/L)	Cell densities / ml				Biomass inhibition (%)	Growth rate inhibition (%)
	0 h	22 h	46 h	72 h		
0	-	25500	117100	1210000	-	-
100	-	24500	167000	1010000	17	3

The cell concentration of the control cultures increased by a factor of 243 after 72 hours. This increase was in line with the OECD Guideline that states the enhancement must be at least by a factor of 16 after 72 hours. The mean coefficient of variation for section by section specific growth rate for the control cultures was 12% and hence satisfied the validation criterion given in the OECD Guideline which states the mean must not exceed 35%. The coefficient of variation for average specific growth rate for the control cultures over the test period (0 – 72 h) was 4% and hence satisfied the validation criterion given in the OECD Guideline which states that this must not exceed 7%.

Conclusion:

The following results were determined: ErC50 (72h) > 100 mg form/L (100 mg a.s./L) and NOEC = 100 mg/L

Study deviations:

The study followed in general the procedures indicated in the aforementioned guideline and fulfilled the validity criteria. However, no analytical measurements of the test concentrations are available; they were not determined at the request of the Sponsor. Nevertheless, kaolin is not soluble and extremely stable in water. Thus, the results of the test are considered valid for risk assessment.

B.9.3.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No data submitted.

B.9.3.3 Further testing on aquatic organisms

No data submitted.

B.9.4 RISK ASSESSMENT FOR AQUATIC ORGANISMS

The following aquatic risk assessment has been conducted in according to the new **EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013: 11(7): 3290).**

B.9.4.1 TOXICITY

Literature data assessing the effects of aluminium silicate on aquatic organisms were submitted and evaluated in Volume 3CA_B9. An additional aquatic toxicity study on algae that was not available for the first Annex I inclusion has been provided to address the data gap identified during the initial EU evaluation.

A summary of the available aquatic toxicity endpoints for aluminium silicate is presented in the Table B.9.4.1-1.

Table B.9.4.1-1: Summary of available aquatic toxicity endpoints for aluminium silicate

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
Acute fish				
Larvae of Pagrus major, Oplegnathus fasciatus and Parapristipoma trilineatum	12h (static)	Aluminium silicate	LC_{50}: 494 (geometric mean)*	B.9.2.1/01 Isono et al. (1998)
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)
Oncorhynchus kisutch & Oncorhynchus mykiss	48 hr (flow-through)	Aluminium silicate	LC_{50}: >4000 mg/l (nominal)*	B.9.2.1/04 Redding, Schreck, & Everest (1987)
Long-term fish				
Oncorhynchus mykiss	64 days (semi-static)	Aluminium silicate	NOEC: 1017 mg/l (nominal)*	B.9.2.2/01 Goldes et al. (1988)
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)

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
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)

*** :** these studies are considered invalid after evaluation; thus their endpoints were excluded from the risk assessment and were sorted as supplementary data

Note: Endpoints highlighted in bold have been used in the following risk assessment.

B.9.4.2 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 B.9.4.2-1 have to be used in the risk assessment for aquatic organisms.

Table B.9.4.2-1: 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

B.9.4.3 EXPOSURE

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.

B.9.4.4 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 B.9.4.4-1: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(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

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 B.9.4.4-2: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(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

Table B.9.4.4-3: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(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)						

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
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 B.9.4.4-4: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(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 B.9.4.4-5: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10

Group		**Fish acute**	**Fish long-term**	**Invertebrates acute**	**Invertebrates Long-term**	**Algae**
RAC (mg/L)		30	10	5.7	5	10
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 B.9.4.4-6: 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		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}
(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
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

<u>Overall conclusion for aquatic organisms</u>

Crop		**aluminium silicate**
		a.s
stone fruits, pome fruits, nuts fruits	single application	acceptable

(use no 1, 2, 3, 4, 6, 7, 8, 9, 11, 16)	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)

B.9.4.5 HIGHER-TIER RISK ASSESSMENT ON THE BASIS OF ADDITIONAL TOXICITY DATA

No data submitted.

B.9.5 EFFECTS ON ARTHROPODS

B.9.5.1 EFFECTS ON BEES

Study on the acute oral and contact toxicity to honeybees were carried out with aluminium silicate and were submitted in support of the active substance during the previous EU review. Full details of these studies are provided in the previous EU DAR (2008) and related documents.

An additional acute toxicity study with the representative formulation SOKALCIARBO WP was submitted. In accordance with Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, chronic risk data to worker bees was submitted. No study was conducted to address the chronic toxicity of SOKALCIARBO WP in bee larvae (the notifier stated that it will be available at a later stage).

Table B.9.5.1-1: Toxicity endpoints relevant for consideration for the honeybee risk assessment

Species	Test item	Time scale/method	Endpoint	Reference
Acute toxicity				
Apis mellifera	Aluminium silicate 98.8% (M-96-018)	48 h oral toxicity	**LD_{50} > 100 µg a.s./bee****	Hoxter et al., 1997 Report no.: 469-102 (EFSA Conclusion, 2012)
	Aluminium silicate 98.8% (M-96-018)	48 h contact toxicity	**LD_{50} > 100 µg a.s./bee**	Palmer et al., 1997 Report no.: 469-101 (EFSA Conclusion, 2012)
	SOKALCIARBO WP	48 h contact toxicity	**LD_{50} > 500 µg a.s./bee**	Mamet O., 2008
Chronic toxicity				
Apis mellifera	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
Effects on honeybee development and other honeybee life stages				
-				
Higher-tier studies (tunnel test, field studies)				
Field studies in flowering pear and apple orchards in US demonstrated that the application of a 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 used for the risk assessment
* Non-reliable study. Validity criteria were not met
** Acceptable as supporting evidence

B.9.5.1.1 Acute toxicity to bees

B.9.5.1.1/01

Reference	Mamet O., 2008 (CP 10.3.1.1.2/1)
	Determination de la DL_{50} de contact sur abeille domestique (*Apis mellifera*) par differentes applications de SOKALCIARBO WP
	Report No.: 139-2008
Guidelines	CEB 230 and EPPO 170
GLP	Yes
Previous evaluation	None; submitted for the purpose of active substance renewal
Validity/Acceptance	Yes/Yes (with reservations)

~~Material and methods~~

Test item	SOKALCIARBO WP
	Batch Number: 08210
	Purity: kaolin 100%
Vehicle	In each solution, 0.5 g/L of wetting agent (Agral 90, at 945 g/L of polyethoxylated nonylphenol) is added.
Test species	Worker honeybees (*Apis mellifera L.*)
Reference item	Dimethoate (0.1 and 0.25 mg/mL)
	Lot no.: 60725; code: Testapi 2008S15
Test concentrations	100, 200, 300, 400 and 500 mg/mL (1µL/bee)
Test groups	Three replicates per control, reference and test item were tested, each with 20 bees. The study was repeated 3 times (different colonies for each study).
Test design /methodology	This study was performed to assess the effect of the test item on *Apis mellifera*. The test organisms *Apis mellifera* were exposed to a range of 5 concentrations of the test item (100, 200, 300, 400 and 500 mg/mL) for 48 hours by contact (3 replicates including 20 worker bees for each conditions). The test had been repeated 3 times. Each repetition include 3 replicates of each tested condition. The experimental phase includes several tests: 2 preliminary tests and 3 repetitions of the determination test. For each of the tests, the bees came from a single colony.
Test conditions	Non reported.
Parameters tested	Mortality at T + 24 hours and T + 48 hours
Endpoint(s)	Contact 48h LD_{50}
Statistics	The data are analysed with SAS ver.8.2.0 from the data corrected according to Abott's formula, taking into account the mortality in the controls

Findings

No relevant mortality was observed in the replicates exposed to SOKALCIARBO WP. It has to be noted that some replicates of the 2nd repetition of the test have to be excluded of the results because the bees died from starvation (1 replicate of the manipulation control group, 2 replicates for 100 mg/mL and 1 replicate for 400 mg/mL). The toxic reference dimethoate induced the expected mortality.

Table B.9.5.1.1/01-1: Results of the Acute Oral Toxicity Test (results from 3 tests)

	Concentration (mg/mL)	Number by box	T + 4:00 Mortality	T + 4:00 %	T +24:00 Mortality	T +24:00 %	T + 48:00 Mortality	T + 48:00 %
MANIP CONTROL	0	60	0	1	2	3	6	5
		60	0		0		1	
		60	2		4		2	
VEHICULE CONTROL (WATER)	0	60	0	0	1	1	2	2
		60	0		0		0	
		60	0		0		2	
DOSE 1	100	60	0	0	1	1	3	6
		60	0		0		2	
		60	0		1		5	
DOSE 2	200	60	0	0	0	1	2	3
		60	0		2		3	
		60	0		0		0	
DOSE 3	300	60	0	1	0	2	1	3
		60	1		3		3	
		60	0		0		2	
DOSE 4	400	60	0	2	0	2	0	3
		60	1		1		1	
		60	2		2		4	
DOSE 5	500	59	0	1	0	1	8	12
		60	0		0		4	
		60	1		1		10	
Dimethoate (µg/µl)	0,1	60	0	0	14	27	19	42
		60	0		22		25	
		60	0		13		32	
Dimethoate (µg/µl)	0,25	60	8	12	58	97	58	98
		60	10		59		60	
		60	4		57		58	

Table 2 : Raw data and adjusted total considered for the study

DOSE (mg/mL)	N	24h TOTAL	48h TOTAL	24h TOTAL adjusted	48h TOTAL adjusted
0	180	6	9	-	-
0 (Vehicule control)	180	1	4	-5,17241379	-5,26315789
100	180	2	10	6,97206704	14,8295455
200	180	2	5	6,97206704	9,97159091
300	180	3	6	7,94413408	10,9431818
400	180	3	5	7,94413408	9,97159091
500	179	1	22	5,97206704	26,4602273

Conclusion

LD_{50} >500 µg a.s./bee

The studies were evaluated based on the currently accepted guideline (OECD 214). The study is acceptable with reservations. The validity criteria of the OECD 214 with regard to the average mortality in the control (actual value: 1-6%) and the LD_{50} of the toxic reference were fulfilled in every study (between 0.1 and 0.30 µg a.s./bee).

Methodological deficiencies/deviations: A group of 20 bees was confined in each cage. The OECD 214 recommends 10 bees/cage. The sublethal effects were not recorded. Details on the administration of doses is absent.

Other limitations:

- The age of the worker bees was not defined
- The test conditions (temperature, relative humidity) were not monitored and reported.
- The toxic reference was tested in just two dose levels

B.9.5.1.2 Chronic toxicity to bees

A 10-day chronic feeding test in the laboratory was performed for the representative formulation SOKALCIARBO WP. The study summary is presented below.

B.9.5.1.2/01

Reference	Mamet Olviier, 2019 (K-CP 10.3.1.2-01)
	Evaluation of the chronic oral toxicity of Sokalciarbo WP on honey bees (*Apis mellifera* L.). Calculation of Lethal Concentration (LC50) and Lethal Dietary Dose (LDD_{50}). Laboratory conditions.
	Report No.: 371-2018
Guideline	OECD 245 Honey Bee (*Apis mellifera* L.), Chronic Oral Toxicity Test (10-Day Feeding)
GLP	Yes
Previous evaluation	None; submitted for the purpose of active substance renewal
Validity/Acceptance	Yes/Yes
Material and methods	
Test item	Sokalciarbo WP
	Sokalciarbo WP is an WP formulation containing 99.99 % kaolin
	Lot/Batch no.: Sokalciarbo 17287
Vehicle	Distilled water and sugar (50% w/v sucrose syrup)
Test species	Worker bees (*Apis mellifera* L.) (<2 days old)
Reference item	Danadim EC (dimethoate 400 g/L)
Test concentrations	Tested concentrations: 30, 12, 4.8 and 1.92 mg eq. kaolin /g diet
	Dimethoate: 1 mg a.s./kg feeding solution

Test groups	Each treatment group consisted of 30 test organisms (divided into 3 replicates, containing 10 test organisms each).
Test design/methodology	The feeding solutions were offered ad libitum to the honey bees via feeders (plastic syringes without tip). The bees in one replicate shared the feeding solution (trophallaxis) and thus can be expected to be all exposed. Identified feeders were filled daily and weighed on a calibrated scale. Feeders were then introduced in the respective identified cages. From D1 to D10, removed feeders with remaining diet were also weighed in order to calculate the actual amount of diet ingested over the period. At least 1 mL of syrup is distributed in each test cage every day over a period of 10 days (interval of about 24h ± 2h). In order to adjust for possible evaporation of test solutions from the feeders, additional test cages were set up at the main test. These cages contained only pre-weighed feeders containing diet of untreated control (each tested with 3 replicates). These cages were placed in the test environment alongside the test units. At the daily feeder exchange the feeders were re-weighed and replaced with new feeders. This evaporation measure was then subtracted from the calculated food consumption to give the corrected food consumption accounting the loss by evaporation.
Test conditions	During the whole experimental phase, test cages were placed into incubators at a temperature of 33 ± 2°C, with relative humidity from 50% to 70% (short deviations were recorded, without any impact on honeybees).
Parameters tested	The criterion of effect in this study to calculate the LC_{50} and LDD_{50} was the absence of response to physical stimulation. The number of dead bees found in each test unit (cage) was counted and recorded every day from D1 day to D10, where D0 was the first supply of the contaminated diet. The mortality is expressed in percentage of the initial population before application. The possible behavioural abnormalities of the bees were observed in the test units. These procedures were carried out when the mortality assessment was recorded. Behavioural abnormalities were quantitatively observed according to the following categories: **m** = moribund (bees cannot walk and show only very feeble movements of legs and antennae, only weak response to stimulation; *e.g.* light or blowing; bees may recover but usually die), **a** = affected (bees still upright and attempting to walk but showing signs of reduced coordination; hyperactivity; aggressiveness; increased self-cleaning behaviour; rotations; shivering), **c** = cramps (bees contracting abdomen or entire body), **ap** = apathy (bees show only low or delayed reactions to stimulation *e.g.* light or puff of air; bees are sitting motionless in the unit). **v =** vomiting
Analytical verification	-
Endpoint(s)	10-day continuous feeding oral LDD_{50}

	10-day NOEDD
Statistics	Calculated and analysed by the statistical method Probit with 95% confidence limits.

Findings

VALIDITY CRITERIA

The first validity criterion was the average mortality in water control that was below 15% after 10 days:

- First test (invalidated), 50% reached.
- **second test (validated)**, 13% reached

The second validity criterion was the mortality in the toxic reference units (mortality over or close to 50% with 1 mg dimethoate/kg syrup). Typical data are obtained with 70% mortality reached after 10 days, 50% mortality was reached between 8 and 9 days. This validates the laboratory test design with standardised data and enough valid groups.

CUMULATIVE MORTALITY

Mortality after 10 days of exposure was dose related. A very low mortality was recorded in the lowest three concentrations (10 to 17% for 1920 mg kaolin/kg to 11999 mg kaolin/kg), increasing to 47% for the highest concentration (74993 mg kaolin/kg).

Table 10.3-2: Summarised cumulated mortality (in %)

treatment group	Concentration (mg a.s./kg)	Day 10 cumulative mortality (%)
Water control	-	13.3
	-	13.3
SOKALCIARBO WP	1920	13.3
	4800	10.0
	11999	16.7
	29997	30.0
	74993	46.7
Dimethoate	1.0	70.0

BEHAVIOURAL ABNORMALITIES

Behavioural abnormalities after 10 days of exposure were dose related. Few affected bees were observed in concentrations of 11999 mg kaolin/kg and 1920 mg kaolin/kg. Few moribund bees were recorded in the highest concentration 74993 mg kaolin/kg as well as in the toxic reference treatment.

Table 10.3-3: Summarised behavioural abnormalities (in %)

Treatment group	Concentration (mg a.s./kg)	day 1	day 2	day 3	day 4	day 5	day 6	day 7	day 8	day 9	day 10

Water control	-	0	0	0	0	0	0	0	0	0	0
	-	0	0	0	0	0	0	0	0	0	0
SOKALCIARBO WP	1920	0	0	0	0	0	0	0	3.3[(1)]	0	3.3[(1)]
	4800	0	0	0	0	0	0	0	0	0	0
	11999	0	0	0	0	0	0	0	0	6.7[(1)]	0
	29997	0	0	0	0	0	0	0	0	0	0
	74993	0	0	0	6.7[(2)]	0	0	0	0	0	6.7[2)]
Dimethoate	1.0	0	0	6.7[2)]	0	0	3.3[2)]	0	0	6.7[2)]	0

[(1)]affected bees only, without any consequence on survival
[(2)]presence of moribund bee, with possible consequence on survival

TOXICITY ENDPOINTS

The 10 days LC_{50} was over 74993 mg a.s./kg diet and was estimated at 90919 mg a.s./kg diet (equivalent to 90.9 µg Sokalciarbo WP /mg diet) and the 10 days LC_{30} was calculated at 11602 mg a.s./kg diet (equivalent to 11.6 µg Sokalciarbo WP /mg diet). The 10 days LDD_{50} was over 2263 µg a.s./bee/day (equivalent to over 2263 µg Sokalciarbo WP/bee/day) and was estimated at 2636 µg a.s./bee/day, the 10 days LDD_{30} was calculated at 353 µg a.s./bee/day (equivalent to 353 µg Sokalciarbo WP/bee/day). The 10 days NOEC is evaluated at 29997 mg a.s./kg diet (equivalent to 30000 mg Sokalciarbo WP /kg diet). The 10 days NOEDD is evaluated at 882 µg a.s./bee/day on 10 days (equivalent to 882 µg Sokalciarbo WP/bee/day).

ANALYTICS

The study does not report stability analysis and analysis of “low” and “high” rates of feeding solution. An analysis of “low” and “high” rates of feeding solution is on-going and will be provided later by the applicant to the RMS.

Conclusions

The estimated 10 days LC_{50} is 90919 mg a.s./kg diet (equivalent to 90.9 µg Sokalciarbo WP /mg diet). The estimated 10 days LDD_{50} is 2636 µg a.s./bee/day. The estimated 10 days NOEC is 29997 mg a.s./kg diet (equivalent to 30000 mg Sokalciarbo WP /kg diet). The estimated 10 days NOEDD is 882 µg a.s./bee/day on 10 days (equivalent to 882 µg Sokalciarbo WP/bee/day).

<u>Study limitations:</u>

Major limitation: Analytical verification of the feeding solutions is missing.

Feedback from the applicant: Accoroding to the applicant, aluminium silicate is not soluble and extremely stable. Thus, the analytical verification of the feeding solutions should be not relevant and the results of the test should be considered valid. The applicant is working on a validation, but due to the nature of Aluminium silicate, no current method can be used and therefore, this validation seems to be technically very difficult to demonstrate.

Minor limitation: During the experimental phase, the relative humidity felt below 50%. Values outside the recommended range was recorded during all 10 days of the monitoring.

B.9.5.1.3 Effects on honey bee development and other honey bee life stages

No data were submitted.

B.9.5.1.4 Sublethal effects

No data were submitted.

B.9.5.1.5 Cage and tunnel tests

No data were submitted.

B.9.5.1.6 Field tests with honeybees

Two non-GLP field tests were carried out to assess the impact of kaolin as an insect repellent on bees when applied during flowering in apple and pear orchards. These studies were submitted previously and have been reviewed as part of the EU assessment for the first approval of aluminium silicate. The summary of these studies is available in the CA document (B.9.3.1.6 Field tests with honeybees).

B.9.5.2 EFFECTS ON NON-TARGET ARTHROPODS OTHER THAN BEES

During the initial EU review (DAR 2008, B.9.5), a waiver from conducting standardised tests on non-target arthropods was accepted because aluminium silicate (kaolin) does not have any direct toxic effects on arthropods.

No GLP-compliant toxicity data on the sensitive indicators are provided. Since toxicity results on the two sensitive indicators is a regulatory requirement, the absence of data is identified data gap. Laboratory toxicity data from the open literature studies are available for aluminium silicate, which involves glass-plate and leaf-disc bioessays on representative NTA species (including the ESCORT 2 indicators *Typhlodromous pyri* and *Chrysoperla carnea*). None of the studies followed a commonly accepted guideline and therefore the results of these studies were considered as indicative evidence of possible direct toxic effects of aluminium silicate to non-target arthropod community. Studies included testing on predators i.e. *Chrysoperla carnea* (5 studies), *Eriopis connexa* larvae, *Anthocoris nemoralis* (3 studies), phytoseiideae mites (1 study) as well as the parasitoids i.e. *Chelonus inanitus, Chelonus nigritus, Psyttalia concolor, Trichogramma cacoeciae* and *Scutellysta cyanea.* No unacceptable direct toxic effects at a dose covering the highest application dose were recorded in most of these studies. In one study, application of aluminium silicate at 50 kg f.p./ha resulted in a 66.6% reduction on the number of eggs laid by female *Anthocoris nemoralis* per day. In another study, application of aluminium silicate at a rate of 190-200 kg/ha (grapevine leaf discs) resulted in reduction of fecundity of *Typhlodromous pyri* and *Kampimodromus aberrans* by more than 50%, but not in reduction of female survival.

A number of field studies conducted between 1997 and 2004 were available in the original DAR. The formulated aluminum silicate was applied in orchards up to the rate of 56 kg/ha (multiple applications). Additional semi- and field open literature studies are reviewed for the purposes of the renewal of the active substance. The WP formulation of aluminum silicate was applied to orchards and cotton (multiple applications) up to 60 kg/ha. Considering the uncomplicated composition of the aluminum silicate formulations, all data were deemed relevant for the evaluation f the representative formulations. Details of these studies are provided in the CA document.

Additional semi- and field open literature studies have been submitted for the purposes of the renewal of the active substance where the WP formulation of aluminum silicate was applied to orchards (multiple applications), grapevine and cotton up to the dose of 60 kg/ha. Details of these studies are provided below.

The findings are summarised in the following table and full details of the studies are provided in the respective sections below.

Table B.9.3.2-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

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 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				

Species	Substance	Exposure System	Results	Reference
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 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.				

B.9.5.2.1 Standard laboratory testing for non-target arthropods

No GLP-compliant studies were conducted.

B.9.5.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

No GLP-compliant studies were conducted.

B.9.5.2.3 Semi-field studies with non-target arthropods

The available open literature studies are presented in the CA document.

B.9.5.2.4 Field studies with non-target arthropods

The available open literature studies are presented in the CA document.

B.9.6 RISK ASSESSMENT FOR ARTHROPODS

B.9.6.1 RISK ASSESSMENT FOR BEES

The risk assessment for bees has been conducted in line with the current Terrestrial Guidance Document (SANCO/10329/2002). A new guidance document has been published but not yet noted by the Standing Committee on Plants, Animals, Food and Feed (EFSA Journal 2013;11(7):3295)[1]. A risk assessment for chronic risk to bees as described in the new guidance will be included for illustration purposes but will not be part of the List of Endpoints. It should be noted that under the EFSA Technical Report (2015)[2] when data on bumblebees and solitary bees are not available, it cannot be recommended to routinely perform a risk assessment.

In accordance with Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, the chronic risk to bees including adult and larval life stages shall be addressed. A chronic worker bee study with the formulation SOKALCIARBO is available. In the absence of a larvae study conducted for SOKALCIARBO (the notifier stated that it will be available at a later stage) a provisional risk assessment considering the NOED of the active substance (tested as SURROUND® WP) was considered.

The representative uses of SOKALCIARBO include stone fruits, pome fruits, nuts fruits (4 applications with a maximum of 50000 g a.s./ha), citrus, Olive tree (6 applications with a maximum of 50000 g a.s./ha), apple tree (7 applications with a maximum of 30000 g a.s./ha), grapevine (4 applications with a maximum of 20000 g a.s./ha), lavender (5 applications with a maximum of 15000 g a.s./ha).

B.9.6.1.1 Risk assessment for honeybees according to SANCO/10329/2002

Acute risk to honeybees

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food. The potential acute risk from use of SOKALCIARBO WP was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients in accordance with the current Terrestrial Guidance Document[3]

$$\text{Hazard Quotient} = \frac{\text{Maximum single application rate (g formulation/ha)}}{\text{Acute LD}_{50}\ (\mu\text{g/bee})}$$

The results of the risk assessment are summarised in the following tables.

Table B.9.6.1.1-1: Acute Risk to bees from oral exposure to aluminium silicate

[1] European Food Safety Authority (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295.
[2] EFSA, 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology.
[3] Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

Test substance	Application rate (g a.s./ha)	Oral LD_{50} (µg a.s./bee)	Hazard quotient	Trigger
Stone fruits, pome fruits, nuts fruits, Citrus, Olive tree				
Aluminium silicate	50000	>100*	<500	**50**
Grapevine				
Aluminium silicate	20000	>100*	<200	**50**
Lavender				
Aluminium silicate	15000	>100*	<150	**50**

* Not all validity criteria met. Risk assessment for illustration purposes

Table B.9.6.1.1-2: Acute Risk to bees from contact exposure to aluminium silicate

Test substance	Application rate (g a.s./ha)	Contact LD_{50} (µg a.s./bee)	Hazard quotient	Trigger
Stone fruits, pome fruits, nuts fruits, Citrus, Olive tree				
Aluminium silicate	50000	>100	<285	**50**
SOKALCIARBO WP		>500	<100	
Grapevine				
Aluminium silicate	20000	>100	<200	**50**
SOKALCIARBO WP		>500	<40	
Lavender				
Aluminium silicate	15000	>100	<150	**50**
SOKALCIARBO WP		>500	<30	

The hazard quotients (Q_{HO}) and (Q_{HC}) for oral and contact exposure of bees to aluminium silicate exceed the trigger value of 50, with the exception of contact exposure of bees to SOKALCIARBO WP in grapevine and lavender. Exceeding of the trigger value is associated with the high application rate of the product. The oral toxicity values derive from limit tests, where no effects were recorded. However, this test did not fulfil the validity criteria. In the contact toxicity test for the representative formulation, only slight effects were recorded at the highest tested level (500 g a.s./bee).

B.9.6.1.2 Risk assessment for honeybees according to EFSA (2013)

Calculations were performed using the EFSA bee tool v.3.

Contact exposure

Screening acute contact assessment

A screening assessment has been conducted considering the endpoints from the honeybee studies conducted with the active substance (illustration purposes; the test from which the endpoint was derived did not fulfil the validity criteria). Acute contact hazard quotients (HQs) for honeybees are presented in the following table. The HQs have been calculated assuming sideward spray application.

Table B.9.6.1.2-1: Screening assessment for contact route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	$HQ_{contact}$	Trigger value	Acceptable risk?
Honey bee (adults)	Acute contact	50000	>500	<100	>85	**No**

The hazard quotient (HQ) for contact exposure of bees to aluminium silicate exceeds the trigger value. A Tier I assessment has therefore been conducted to refine the risk to bees foraging on the treated crop, weeds in the treated field, the field margin and adjacent crops.

Tier I assessment for contact route of exposure

The risk assessment is conducted for the relevant scenarios.

Table B.9.6.1.2-2: Tier I assessment for contact route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	f_{dep}	$HQ_{contact}$	Trigger value	Acceptable risk?
Stone fruits, pome fruits, nuts fruits [1]							
Honey bee (adults)	treated crop	50000	>500	1	<100	85	**No**
	weeds			0.3 (BBCH >40)	<30	42	Yes
	field margin			0.157 (BBCH >40)	<15.7	42	Yes
Citrus, Olive tree [2]							
Honey bee (adults)	treated crop	50000	>500	1	<100	85	**No**
	weeds			0.3 (BBCH >40)	<30	42	Yes
	field margin			0.157 (BBCH >40)	<15.7	42	Yes
Apple tree							

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	f_{dep}	$HQ_{contact}$	Trigger value	Acceptable risk?
Honey bee (adults)	treated crop	30000	>500	1	<60	85	Yes
	weeds			0.3 (BBCH >40)	<18	42	Yes
	field margin			0.157 (BBCH >40)	<9.4	42	Yes
Grapevine							
Honey bee (adults)	treated crop	20000	>500	1	<40	85	Yes
	weeds			0.3 (BBCH >40)	<12	42	Yes
	field margin			0.08 (BBCH >40)	<3.2	42	Yes
Lavender [3]							
Honey bee (adults)	treated crop	15000	>500	1	<30	85	Yes
	weeds			1 (BBCH <50) 0.3 (BBCH >50)	<30 <9.0	42	Yes
	field margin			0.028	0.8	42	Yes

[1] orchards 1 scenario was selected in bee tool
[2] orchard 2 scenario was selected in bee tool
[3] leafy vegetables scenario was selected in bee tool

The hazard quotients (HQ) for contact exposure of bees to SOKALCIARBO WP exceeded the trigger value of 85 in orchards (only the treated crop scenario). The risk to bees for use in grapevines, apple trees and lavender is acceptable.

Oral exposure

Screening acute oral assessment

No study on honeybee development was conducted with SOKALCIARBO WP. The NOED 405 µg a.s./larva of the active substance (tested as SURROUND® WP) was considered in the calculations (provisional risk assessment).

Table B.9.6.1.2-3: Screening assessment for oral route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

Test group	Exposure scenario	Appl. rate (kg a.s./ha)	Short-cut value	Endpoint	ETR_{oral}	Trigger value	Acceptable risk?
Honey bee (adults)	Acute oral	50	10.6	LD_{50} >100 µg a.s./bee*	<5.3	0.2	**No**
	Chronic oral		10.6	LDD_{50} 2636 µg a.s./bee/d	0.201	0.03	**No**
Honey bee (larvae)	Chronic oral		6.1	NOED 405 µg a.s./larvae	0.75	0.2	**No**

* Not all validity criteria met. Risk assessment for illustrative purposes

The acute and chronic oral ETR_{oral} values exceed the trigger value indicating a potential concern for survival and development of colonies for all proposed uses. Therefore, Tier I assessment is required.

Tier I assessment for oral route of exposure

When concern has been raised regarding the potential risk to bees from the consumption of pollen and nectar in the screening assessment, the initial step of the Tier I risk assessment is to refine the exposure estimate used in the above calculations. In order to do this, it is necessary to consider all relevant routes of exposure:

- risk from foraging on weeds in the treated field
- risk from foraging in the field margin
- risk from foraging on an adjacent crop
- risk from foraging the following year on the crop

The calculated ETR for all relevant exposure scenarios are summarised in the following table.

Table B.9.6.1.2-4: First tier assessment for oral route of exposure

Category	**scenario**	**BBCH**	**Ef**	**SV**	**twa**	**Honeybee**	
						ETR	**trigger**
Stone fruits, pome fruits, nuts fruits (4 applications with a maximum of 50000 g a.s./ha) [1]							
acute	treated crop	40 - 69	1	10.6	1	**5.30**	0.2
	treated crop	≥ 70	1	0		0.00	
	weeds	40 - 69	0.3	3.7		**0.56**	
	weeds	≥ 70	0.3	3.7		**0.56**	
	field margin	40 - 69	0.052	3.7		0.10	
	field margin	≥ 70	0.052	3.7		0.10	
	adjacent crop	40 - 69	0.031	7.6		0.12	
	adjacent crop	≥ 70	0.031	7.6		0.12	
	next crop	40 - 69	1	0.7		**0.35**	
	next crop	≥ 70	1	0.7		**0.35**	
chronic	treated crop	40 - 69	1	8.2	0.72	**0.11**	0.03
	treated crop	≥ 70	1	0		0.00	
	weeds	40 - 69	0.3	2.9		0.01	
	weeds	≥ 70	0.3	2.9		0.01	
	field margin	40 - 69	0.052	2.9		0.00	
	field margin	≥ 70	0.052	2.9		0.00	
	adjacent crop	40 - 69	0.031	5.8		0.00	
	adjacent crop	≥ 70	0.031	5.8		0.00	
	next crop	40 - 69	1	0.54		0.01	
	next crop	≥ 70	1	0.54		0.01	
larva	treated crop	40 - 69	1	6.1	0.85	**0.64**	0.2
	treated crop	≥ 70	1	0		0.00	
	weeds	40 - 69	0.3	2.2		0.07	
	weeds	≥ 70	0.3	2.2		0.07	
	field margin	40 - 69	0.052	2.2		0.01	
	field margin	≥ 70	0.052	2.2		0.01	
	adjacent crop	40 - 69	0.031	4.4		0.01	

	adjacent crop	≥ 70	0.031	4.4		0.01	
	next crop	40 - 69	1	0.4		0.04	
	next crop	≥ 70	1	0.4		0.04	
Citrus, Olive tree (6 applications with a maximum of 50000 g a.s./ha) [2]							
acute	treated crop	≥ 70	1	0	1	0.00	0.2
	weeds		0.3	3.7		**0.56**	
	field margin		0.052	3.7		0.10	
	adjacent crop		0.031	7.6		0.12	
	next crop		1	0.7		**0.35**	
chronic	treated crop		1	0	0.72	0.00	0.03
	weeds		0.3	2.9		0.01	
	field margin		0.052	2.9		0.00	
	adjacent crop		0.031	5.8		0.00	
	next crop		1	0.54		0.01	
larva	treated crop		1	0	0.85	0.00	0.2
	weeds		0.3	2.2		0.07	
	field margin		0.052	2.2		0.01	
	adjacent crop		0.031	4.4		0.01	
	next crop		1	0.4		0.04	
Apple tree (7 applications with a maximum of 30000 g a.s./ha)							
acute	treated crop	< 10	1	0.7	1	**0.21**	0.2
	treated crop	10 - 19	1	10.6		**3.18**	
	treated crop	20 - 39	1	10.6		**3.18**	
	treated crop	40 - 69	1	10.6		**3.18**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	3.7		**1.11**	
	weeds	10 - 19	0.8	3.7		**0.89**	
	weeds	20 - 39	0.6	3.7		**0.67**	
	weeds	40 - 69	0.3	3.7		**0.33**	
	weeds	≥ 70	0.3	3.7		**0.33**	
	field margin	< 10	0.052	3.7		0.06	
	field margin	10 - 19	0.052	3.7		0.06	
	field margin	20 - 39	0.052	3.7		0.06	
	field margin	40 - 69	0.052	3.7		0.06	
	field margin	≥ 70	0.052	3.7		0.06	
	adjacent crop	< 10	0.031	7.6		0.07	
	adjacent crop	10 - 19	0.031	7.6		0.07	
	adjacent crop	20 - 39	0.031	7.6		0.07	
	adjacent crop	40 - 69	0.031	7.6		0.07	
	adjacent crop	≥ 70	0.031	7.6		0.07	
	next crop	< 10	1	0.7		**0.21**	
	next crop	10 - 19	1	0.7		**0.21**	
	next crop	20 - 39	1	0.7		**0.21**	
	next crop	40 - 69	1	0.7		**0.21**	
	next crop	≥ 70	1	0.7		**0.21**	
chronic	treated crop	< 10	1	0.54	0.72	0.00	0.03
	treated crop	10 - 19	1	8.2		**0.07**	
	treated crop	20 - 39	1	8.2		**0.07**	
	treated crop	40 - 69	1	8.2		**0.07**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.9		0.02	

	weeds	10 - 19	0.8	2.9		0.02	
	weeds	20 - 39	0.6	2.9		0.01	
	weeds	40 - 69	0.3	2.9		0.01	
	weeds	≥ 70	0.3	2.9		0.01	
	field margin	< 10	0.052	2.9		0.00	
	field margin	10 - 19	0.052	2.9		0.00	
	field margin	20 - 39	0.052	2.9		0.00	
	field margin	40 - 69	0.052	2.9		0.00	
	field margin	≥ 70	0.052	2.9		0.00	
	adjacent crop	< 10	0.031	5.8		0.00	
	adjacent crop	10 - 19	0.031	5.8		0.00	
	adjacent crop	20 - 39	0.031	5.8		0.00	
	adjacent crop	40 - 69	0.031	5.8		0.00	
	adjacent crop	≥ 70	0.031	5.8		0.00	
	next crop	< 10	1	0.54		0.00	
	next crop	10 - 19	1	0.54		0.00	
	next crop	20 - 39	1	0.54		0.00	
	next crop	40 - 69	1	0.54		0.00	
	next crop	≥ 70	1	0.54		0.00	
larva	treated crop	< 10	1	0.4	0.85	0.03	0.2
	treated crop	10 - 19	1	6.1		**0.38**	
	treated crop	20 - 39	1	6.1		**0.38**	
	treated crop	40 - 69	1	6.1		**0.38**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.2		0.14	
	weeds	10 - 19	0.8	2.2		0.11	
	weeds	20 - 39	0.6	2.2		0.08	
	weeds	40 - 69	0.3	2.2		0.04	
	weeds	≥ 70	0.3	2.2		0.04	
	field margin	< 10	0.052	2.2		0.01	
	field margin	10 - 19	0.052	2.2		0.01	
	field margin	20 - 39	0.052	2.2		0.01	
	field margin	40 - 69	0.052	2.2		0.01	
	field margin	≥ 70	0.052	2.2		0.01	
	adjacent crop	< 10	0.031	4.4		0.01	
	adjacent crop	10 - 19	0.031	4.4		0.01	
	adjacent crop	20 - 39	0.031	4.4		0.01	
	adjacent crop	40 - 69	0.031	4.4		0.01	
	adjacent crop	≥ 70	0.031	4.4		0.01	
	next crop	< 10	1	0.4		0.03	
	next crop	10 - 19	1	0.4		0.03	
	next crop	20 - 39	1	0.4		0.03	
	next crop	40 - 69	1	0.4		0.03	
	next crop	≥ 70	1	0.4		0.03	
Grapevine (4 applications with a maximum of 20000 g a.s./ha)							
acute	treated crop	≥ 70	1	0	1	0.00	0.2
	weeds		0.3	3.7		**0.22**	
	field margin		0.027	3.7		0.02	
	adjacent crop		0.0143	7.6		0.02	
	next crop		1	0.7		0.14	
chronic	treated crop		1	0	0.72	0.00	0.03

	weeds		0.3	2.9		0.00	
	field margin		0.027	2.9		0.00	
	adjacent crop		0.0143	5.8		0.00	
	next crop		1	0.54		0.00	
larva	treated crop		1	0	0.85	0.00	0.2
	weeds		0.3	2.2		0.03	
	field margin		0.027	2.2		0.00	
	adjacent crop		0.0143	4.4		0.00	
	next crop		1	0.4		0.02	
Lavender (5 applications with a maximum of 15000 g a.s./ha) [3]							
acute	treated crop	< 10	1	0.7	1	0.11	0.2
	treated crop	10 - 49	1	7.6		**1.14**	
	treated crop	50 - 69	1	7.6		**1.14**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	3.7		**0.56**	
	weeds	10 - 49	1	3.7		**0.56**	
	weeds	50 - 69	0.3	3.7		0.17	
	weeds	≥ 70	0.3	3.7		0.17	
	field margin	< 10	0.0092	3.7		0.01	
	field margin	10 - 49	0.0092	3.7		0.01	
	field margin	50 - 69	0.0092	3.7		0.01	
	field margin	≥ 70	0.0092	3.7		0.01	
	adjacent crop	< 10	0.0033	7.6		0.00	
	adjacent crop	10 - 49	0.0033	7.6		0.00	
	adjacent crop	50 - 69	0.0033	7.6		0.00	
	adjacent crop	≥ 70	0.0033	7.6		0.00	
	next crop	< 10	1	0.7		0.11	
	next crop	10 - 49	1	0.7		0.11	
	next crop	50 - 69	1	0.7		0.11	
	next crop	≥ 70	1	0.7		0.11	
chronic	treated crop	< 10	1	0.54	0.72	0.00	0.03
	treated crop	10 - 49	1	5.8		0.02	
	treated crop	50 - 69	1	5.8		0.02	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.9		0.01	
	weeds	10 - 49	1	2.9		0.01	
	weeds	50 - 69	0.3	2.9		0.00	
	weeds	≥ 70	0.3	2.9		0.00	
	field margin	< 10	0.0092	2.9		0.00	
	field margin	10 - 49	0.0092	2.9		0.00	
	field margin	50 - 69	0.0092	2.9		0.00	
	field margin	≥ 70	0.0092	2.9		0.00	
	adjacent crop	< 10	0.0033	5.8		0.00	
	adjacent crop	10 - 49	0.0033	5.8		0.00	
	adjacent crop	50 - 69	0.0033	5.8		0.00	
	adjacent crop	≥ 70	0.0033	5.8		0.00	
	next crop	< 10	1	0.54		0.00	
	next crop	10 - 49	1	0.54		0.00	
	next crop	50 - 69	1	0.54		0.00	
	next crop	≥ 70	1	0.54		0.00	
larva	treated crop	< 10	1	0.4	0.85	0.01	0.2

	treated crop	10 - 49	1	4.4		0.14	
	treated crop	50 - 69	1	4.4		0.14	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.2		0.07	
	weeds	10 - 49	1	2.2		0.07	
	weeds	50 - 69	0.3	2.2		0.02	
	weeds	≥ 70	0.3	2.2		0.02	
	field margin	< 10	0.0092	2.2		0.00	
	field margin	10 - 49	0.0092	2.2		0.00	
	field margin	50 - 69	0.0092	2.2		0.00	
	field margin	≥ 70	0.0092	2.2		0.00	
	adjacent crop	< 10	0.0033	4.4		0.00	
	adjacent crop	10 - 49	0.0033	4.4		0.00	
	adjacent crop	50 - 69	0.0033	4.4		0.00	
	adjacent crop	≥ 70	0.0033	4.4		0.00	
	next crop	< 10	1	0.4		0.01	
	next crop	10 - 49	1	0.4		0.01	
	next crop	50 - 69	1	0.4		0.01	
	next crop	≥ 70	1	0.4		0.01	

[1] orchards 1 scenario was selected in bee tool
[2] orchard 2 scenario was selected in bee tool
[3] leafy vegetables scenario was selected in bee tool

The exposure toxicity ratios (ETR) for oral exposure to SOKALCIARBO exceed the respective trigger value in orchards (treated crop, next year and weed scenarios), in grapevines (weed scenario) and lavender (treated crop and weeds scenarios). An acceptable risk is identified for exposure in field margin and adjacent crops for all uses of the product.

Assessment of risk from exposure to metabolites

The methodology in the EFSA bee guidance is followed to identify which metabolites should be assessed. Metabolites formed in amounts of >10% (TRR) in any plant matrix other than roots must be considered in the assessment of the risk from oral uptake in pollen and nectar.

There are no ecologically relevant metabolites to be considered in the risk assessment to honeybees for this active substance.

Risk assessment for accumulative effects

No information regarding possible accumulative effects is available as no relevant testing has been carried out. However, considering the mode of action of aluminium silicate, accumulative effects are not expected.

Sublethal effects

No specific studies were carried out. Behavioural abnormalities after 10 days of exposure to SOLALCIARBO were recorded in the chronic bee study. Effects were dose related. Few affected bees were observed in concentrations of 11999 mg kaolin/kg and 1920 mg kaolin/kg. Few moribund bees were recorded in the highest concentration 74993 mg kaolin/kg. Possible sublethal effects on bees could not be obtained from the available acute or chronic toxicity studies. No effects on foraging behaviour was recorded in the two non-GLP field studies.

Honey bee exposure *via* drinking water

Bees may potentially be exposed to the applied product *via* drinking water. Therefore, in line with the EFSA Bee Guidance (2013) the risk to honeybees from this route of exposure has been assessed. Exposure to bees *via* drinking water is based on the maximum PECsw value of 15.88 mg/L (total season; worst case). Since kaolin is practically insoluble to water, the solubility was set to 0. The PEC_{puddle} were not calculated in the fate and behaviour section. The ETR_{oral} values for honeybees *via* exposure from drinking water are presented in the following table.

Table B.9.6.1.2-5: Drinking water assessment for honeybees

Exposure scenario	**PEC (µg/µL)**	**W [a] (µL/bee)**	**Timescale (life stage)**	**Toxicity endpoint**	**ETR_{oral}**	**Trigger value**	**Acceptable risk?**
Surface water	0.0159	11.4	Acute (adult)	LD_{50} >100 µg a.s./bee*	0	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 2636 µg a.s./bee/d	0	0.03	Yes
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	0	0.2	Yes
Guttation fluid	0	11.4	Acute (adult)	LD_{50} >100 µg a.s./bee*	0	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 2636 µg a.s./bee/d	0	0.03	Yes
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	0	0.2	Yes
Puddle	-	11.4	Acute (adult)	LD_{50} >100 µg a.s./bee*	-	0.2	-
		11.4	Chronic (adult)	LDD_{50} 2636 µg a.s./bee/d	-	0.03	-
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	-	0.2	-

[a] W = daily water consumption * Not all validity criteria met. Risk assessment for illustrative purposes

The risk to honeybees *via* drinking water is demonstrated to be acceptable. No further consideration to bees *via* drinking water is required.

Discussion/Overall conclusion

The acute and chronic Tier 1 risk to adult and larvae honeybees is demonstrated to be acceptable for field margin and adjacent crop scenarios. Further, no unacceptable risk is expected from the exposure to contaminated water sources.

A possible risk to bees for the treated crop scenario (orchards except citrus and olive trees, lavender), weed scenario (all representative uses) and the succeeding crop/following year scenario (stone fruits, pome fruits, nuts fruits) is identified at Tier I level when the risk assessment is conducted according to the new EFSA bee GD.

The absence of unacceptable effects on foraging activity is observed in the available field trials. Studies in flowering pear and apple orchards indicate that applications of a kaolin preparation at 56 kg/ha did not affect the numbers of foraging bees or their behaviour. However, considering the methodological deficiencies of the field studies, no clear conclusion is possible.

The absence of unacceptable effects on bees from the use of the representative formulation SOKALCIARBO cannot be excluded. The co-RMS FR is of the opinion that '*the reliability of the risk assessment scheme of the EFSA guidance for natural and inorganic substance as Kaolin could be considered questionable. In fact, shortcut values used in the ETR calculations and trigger values are calibrated for substances with toxicities due to a chemical mode of action, since aluminium silicate is an inorganic compound with a physical mode of action, the risk assessment could be considerate as too conservative. Considering the uncertainties on the appropriateness of the risk assessment scheme of the EFSA guidance for aluminium silicate, FR considered that the risk for bees could be refined using a weight of evidence based on the nature of the substance and its mode of action'*. The RMS agrees with the opinion that the risk to bees could be refined using a weight-of-evidence approach.

B.9.6.2 RISK ASSESSMENT FOR NON-TARGET ARTHROPODS

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the SANCO/10329/2002 rev.2, and in consideration of the recommendations of the guidance document ESCORT 2[4].

Risk assessment based on laboratory studies

No GLP glass plate or extended laboratory toxicity study was presented. Considering that aluminium silicate exhibit repellent/deterrent effects rather than direct toxicity action, **standardised laboratory testing are of low significance in the risk assessment for this active substance**. Nevertheless, the availability of toxicity endpoints on the two sensitive indicators (*T. pyri* and *A. rhopalosiphi*) is a regulatory requirement and thus the absence of toxicity data is identified as a data gap.

Laboratory toxicity data from the open literature studies are available for aluminium silicate, which involves glass-plate and leaf-disc bioessays on representative NTA species (including the ESCORT 2 indicators *Typhlodromous pyri* and *Chrysoperla carnea*). None of the studies followed a commonly accepted guideline and therefore the results of these studies were considered as indicative evidence of possible direct toxic effects of aluminium silicate to non-target arthropod community. Studies included testing on predators i.e. *Chrysoperla carnea* (5 studies), *Eriopis connexa* larvae, *Anthocoris nemoralis* (3 studies), phytoseiideae mites (1 study) as well as the parasitoids i.e. *Chelonus inanitus, Chelonus nigritus, Psyttalia concolor, Trichogramma cacoeciae* and *Scutellysta cyanea.* No unacceptable direct toxic effects at a dose covering the highest application dose were recorded in most of these studies. In one study, application of aluminium silicate at 50 kg f.p./ha resulted in a 66.6% reduction on the number of eggs laid by female *Anthocoris nemoralis* per day. In another study, application of aluminium silicate at a rate of 190-200 kg/ha (grapevine leaf discs) resulted in reduction of fecundity of *Typhlodromous pyri* and *Kampimodromus aberrans* by more than 50%, but not in reduction of female survival.

Risk assessment based on semi-field and field studies

[4] Candolfi MP, Barrett KL, Campbell P, Forster R, Grandy N, Huet M-C, Lewis G, Oomen P A, Schmuck R, Vogt H. 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with nontarget arthropods. Report of the SETAC/ESCORT 2 Workshop, Wageningen, The Netherlands, SETAC-Europe, Brussels, Belgium.

Off-field area: None of the presented field studies is suitable to address possible effects to non-target arthropods in the off-field area from the use of the product.

In-field area:

Field studies considered in the previous evaluation of the active substance

Nine field studies conducted in Europe and North America examined possible harmful effects of aluminium silicate on targeted beneficial arthropods, including lacewings (chrysoperlids), ladybirds (coccinellids), hoverflies (syrphids), some heteropteran bugs (e.g. mirids), parasitic hymenopterans and spiders. A reduction in the number of captured predatory mites (*Amblyseius*; 2 trials) and anthocorid bugs (2 trials) was recorded. These trials were not considered suitable for the risk assessment of aluminium silicate due to methodological deficiencies and poor reporting (insufficient information on the trial design and setup)

- the non-target arthropod counts per sampling event are limited

- studies are tailored for addressing effectiveness of aluminium silicate on phytophagous pests in orchards, and are not suitable not to address adverse effects on non-target populations

- no acceptable guideline was followed

Additional open literature studies

A total of 11 open literature field studies were considered. Detailed information on these products is available in the Aluminium silicate_RAR_CA report_B-9. These studies were considered **suitable to get insight into possible adverse effects on non-target community in the in-field area resulting from the use of the product.** A summary of main findings in the field trial and potential for recovery is summarised in Table 10.3.2-4. Studies were conducted in orchards (covering olive trees, nuts and pome/stone fruit), grapevines and cotton. The information on the test product which was used in the studies is not always complete. However, considering the uncomplicated composition of kaolin formulations, any differences in the composition of the tested products and SOKALCIARBO are deemed of minor importance. Considering the selected sampling method (usually beating or examination of sampled leaves), the studies are more suitable for foliage-dwelling populations. Further, studies focused on addressing effects on specific functional groups (beneficial arthropods) rather than on a representative NTA community. As a result, several taxa (e.g. soil-dwelling arthropods) are underrepresented.

Application of kaolin generally reduced the abundance and species richness of the non-target arthropods compared to the untreated control in every study. It is unlikely that the recorded alteration of community composition and species richness of NTA assemblages is the results of direct lethal effects. Effects are more probably associated with the repellent nature of the particle film causing the predators to avoid the treated areas and/or the repelling of prey. To be noted that the continuous coverage of the plants by kaolin for an extensive part of the growing season is essential for the effectiveness of this product and might lead to long-term effects on the NTA community. Different functional groups are affected, including predaceous, parasitoids and arthropods with other feeding habits.

The furthermost represented taxa include Araneae (reduction of abundance in 9 reliable studies) and Coleopteran predators (adverse effects on 8 studies), Heteropteran bugs (effects observed in 5 field studies), Neuroptera (4 studies), Diptera (4 studies), Dermaptera (3 studies) and Phytoseiidae mites (2 studies). Effects were recorded even after a single application event (Pascual et al., 2010a, Pascual et al., 2010b). An impact on soil-dwelling arthropod community was observed in one of the studies (Iannotta et al., 2007).

The presented field trials are not designed to examine the duration of the adverse effects after multiple applications of the product. However, in a number of studies (Pascual et al., 2010a; Markó et al., 2010;

Knight, et al., 2001; Pascual, et al., 2010b; Sánchez-Ramos, et al., 2017; Sackett, et al., 2007; Tacoli et al., 2019) some information can be obtained (Table 10.3.2-4). In Pascual et al., 2010a, Sánchez-Ramos, et al., 2017 and Tacoli et al., 2019, a recovery over the winter was observed. However, the product was applied only twice and/or at lower dose (worst-case application scheme not covered). In Pascual et al., 2010b (2 x 3 kg/hl), differences in the number of abundance between treated and untreated plots were still observed approximately 2 months after the last application, although a trend for recovery after the initial adverse effect was observed. No sign of recovery one month or 10 weeks after the last application (last sampling event) was reported in two studies (Knight, et al., 2001; Markó et al., 2006) where the test item was applied 7 to 10 times per season.

Overall conclusion

The risk to non-target arthropods in both in-field and off-field areas from the representative use of the product in grapevines cannot be excluded. Further refinement of the risk, based on field data, is necessary.

The co-RMS FR is of the opinion that standardized laboratory or extended laboratory studies could also be considered reliable to complete the provided data set. The RMS considers that aluminium silicate exhibit repellent/deterrent effects rather than direct toxicity action and standardised laboratory testing are of low significance.

Table 10.3.2-4: Summary of main findings in the field trial and potential for recovery

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
KCA 8.3.2/01 Puterka, G.J. 1997	Orchard (apple) 1 season USA 4	7 applications unknown dose	Not reliable	- poor reporting - insufficient information is obtainable - the NTA counts per sampling event are limited	Different life stages of naturally occurring insect predators: Ladybirds (Coccinelids); Lacewings (Chrysoperlids); Spiders (Araneae)	No harmful effects		
KCP 10.3.2.4/01 Lepine, 2004	Orchard (pear) 1 season France 1 (420 m^2)	1 x 50 kg/ha, 1 x 50 kg/ha + 3 x 25 kg/ha (~ 10 d interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - actions to avoid contamination of untreated plots unknown - dose verification unknown - unreliable study design	Parasitic Hymenoptera Hymenopteran bugs	No harmful effects	~ 1 to 2 month Not relevant	Assessment on 10 shoots in four different areas of each plot.
KCP 10.3.2.4/02 Fraser, 2002a	Orchard (apple) 1 season 3 (0.8 ha)	11 x 56 kg/ha (7-14 d interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - no toxic reference - actions to avoid contamination of untreated plots unknown - dose verification unknown	Coleoptera: Coccinellidae Diptera: Syrphidae Neuroptera: Chrysoperlidae Heteroptera: *Orius*	No harmful effects	Immediately after application	Beating of 25 branches/plot mites: examination of 50 leaves/plot
KCP 10.3.2.4/03 Fraser, 2002b	Orchard (apple) 1 season 3 (0.8 ha)	8 x 56 kg/ha (7-14 interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - no toxic reference - actions to avoid contamination of untreated plots unknown - dose verification unknown	Coleoptera: Coccinellidae Neuroptera: Chrysoperlidae Heteroptera: *Campylomma*	Not harmful to insect predators compared to non-toxic reference item.	Immediately after application	
Fraser, 2002c	Orchard (apple)	8 x 56 kg/ha	Not reliable	- poor test reporting	Ladybirds (Coccinellids), Lacewings (Chrysoperlids),	Slight effect on predatory mites compared to non-	Around time of application	Beating of 25

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
	1 season 3 (0.8 ha)	(7-14 d interval)		- the NTA counts per sampling event are limited - no toxic reference - actions to avoid contamination of untreated plots unknown - dose verification unknown	Pirate (*Orius)* Mullein bugs (*Campylomma*).	toxic reference item (significance not reported)		branches/plot mites: examination of 50 leaves/plot
KCP 10.3.2.4/05 Fraser, 2002d	Orchard (apple) 1 season 2 (0.8 ha)	6 x 56 kg/ha (7-14 d interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - no toxic reference - actions to avoid contamination of untreated plots unknown - dose verification unknown	Coleoptera: Coccinellidae Diptera: Syrphidae Neuroptera: Chrysoperlidae Araneae	Slight effect on very low numbers of predatory mites compared to non-toxic reference item (significance not reported)	~ 2 months	Beating of 25 branches/plot mites: examination of 50 leaves/plot
KCP 10.3.2.4/06 Fraser, 2002e	Orchard (apple) 2 (0.4 ha)	15 x 56 kg/ha (7-14 d interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - no toxic reference - actions to avoid contamination of untreated plots unknown - dose verification unknown	Neuroptera: Chrysoperlidae Heteroptera: Orius Araneae	Not harmful to insect predators compared to non-toxic reference item.	Around time of application	Beating of 25 branches/plot mites
KCP 10.3.2.4/07 Peusens and Creemers, 2004a	Orchard (pear) 1 season Belgium	4 x 7-10 kg/ha (~ 14 d interval)	Not reliable	- poor test reporting - the NTA counts per sampling event are limited - worst-case application scheme not covered - actions to avoid contamination of untreated plots unknown - dose verification unknown	*Anthocoris*	25-80% reduction	1 to 3 months Just one sampling occasion.	Branch beating technique
KCP 10.3.2.4/08 Peusens and	Orchard (pear) 1 season	3 x 6-10 kg/ha (300 or 500 L/ha)	Not reliable	- poor test design - the NTA counts per sampling event are limited - no true replicates	*Anthocoris*	Numbers significantly lower	2 days	5 trees sampled per plot; 3

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
Creemers, 2004b	Belgium	(~ 10 d interval)		- worst-case application scheme not covered				branches per side per tree
KCP 10.3.2.4/10, Pascual *et al*., 2010a	Orchard (olive) 3 yr trial Spain ? (0.8 ha/treatment)	2 x 3 kg/hl (~2-3 month interval)	Yes, with limitations	- worst-case application scheme not covered - actions to avoid contamination of untreated plots unknown - unknown number of plots - unknown water volume - not suitable reference product - dose verification unknown - just one sampling method considered - history/weather data missing	Araneae, Coleoptera, Diptera, Hemiptera, Hymenoptera, Neuroptera, Thysanoptera Usually up to family. Up to species level for Coccinelidae, Anthocoridae, Miridae	Reduced abundance and diversity of NTA community. Most affected taxa: Aranea (Philodromidae) Coleoptera (Coccinelidae) Hymenoptera (mainly parasitoid wasps) Hemiptera (e.g. Anthocorids) Neuroptera	Continuous monitoring for April 2005-December 2007 Possible recovery of community over the winter after 2005 and 2006-applications	Beating method PRC and on-way ANOVA considered in the analysis of the results
KCP 10.3.2.4/11, Markó *et al*., 2010	Orchard (apple) 1 season the Netherlands 4 (0.23 ha)	10 x 45 kg/ha (10 d interval)	Yes, with limitations	- absence of reference product - no pre-application sampling - actions to avoid contamination of untreated plots unknown - dose verification unknown - history/weather data missing - application of fungicides during monitoring	Hemiptera (23 species) Coleoptera (55 species) Araneae (23 genera) Identification up to genera/species level	Reduced total abundance. Hemiptera: differences statistically confirmed at 2 sampling dates	10 weeks No sign for recovery after 10 weeks (species richness was sig. higher in the control compared to kaolin plots	Disruptive effects are mainly evident at repeated applications
Sackett et al., 2007	Orchard (apple) 1 year trials Canada 6-12 (24-54 trees)	4 x 60 kg/ha	Yes, with limitations	- actions to avoid contamination of untreated plots unknown - no toxic reference tested - information on the pre-treatment variation between plots was not provided - history/weather data missing - dose verification unknown	Spiders, *Choristoneura rosaceana* (parasitism)	Reduction of the relative abundance of the most common families of spiders.	~ 2 weeks	Beating (5 branches per tree)

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
				- just one sampling method employed				
Sánchez-Ramos et al., 2017	Orchard (almond) 1 year trials Spain 4-7 (4 trees)	2 x 5 kg/100 L kaolin	Yes, with limitations	- worst-case application scheme not covered - absence of toxic reference - history/weather data missing - dose verification unknown - actions to avoid contamination of untreated plots unknown - results for each sampling date are not available in the report - insufficient plot size - one sampling method employed	Arthropod fauna of almond tree canopy. Specimens were recognised to the family level.	Significant effects on the non-target arthropod fauna of the almond trees canopy. the affected taxa were (in decreasing order of effect) Melandryidae, Curculionidae, Formicidae, Psocoptera, Thysanoptera, Issidae, Phalacridae and Anthicidae.	-	Beating sampling (5-6 samping dates)
KCP 10.3.2.4/14, Knight, *et al.*, 2001	Orchard (apple) 2 yr trial USA 10 (4 trees)	7 to 10 x 56 kg/ha (~14 to 21 d interval)	Yes, with limitations	- other products (chlorpyrifos and horticultural oil) were applied during the monitoring period - only data on spiders were presented in the report - information on the pre-treatment variation between plots was not provided - no toxic reference - history/weather data missing - dose verification unknown - insufficient plot size - one sampling method employed	Araneae (most abundant), Hymenoptera: Formicidae, Coleoptera: Coccinellidae, Earwig (*Forficula auricularia* L.)	Reduced abundance of spiders and ants, reduced level of larval parasitism	~ 1 month No sign of recovery (1998 data).	Beating-tray method
KCP 10.3.2.4/13, Iannotta *et al.*, 2007	Orchard (olive) 1 season Italy	2 x 50 kg/ha (5-week interval)	Yes, with limitations	- unreplicated study design - results were expressed as ratio after/before treatment A/B_{ratio}, which does not facilitate the assessment	Canopy: Araneae, Opiliones, Hymenoptera, Coleoptera, Macrolepidoptera, Neuroptera, Mecoptera, Diptera	Reduced abundance of arthropods at canopy level (except Lepidoptera)	3 months	Canopy: chromotropic traps Soil: pit-fall traps

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
	1 (200 trees)			- the day of applications is different between treatments - timing/frequency of sampling was not indicated - information on study design and application missing	Soil: Araneae, Crustacea, Isopoda, Coleoptera, Hymenoptera Identified to family level	No significant impact on the soil arthropods communities.		
KCP 10.3.2.4/12, Markó, *et al*., 2006	Orchard (apple) 1 season the Netherlands 4 (0.1 ha)	12 x 45 kg/ha (~10 d interval)	Yes, with limitations	- absence of positive control - no actions to avoid contamination of untreated plots - dose verification unknown - history/weather data missing - insufficient plot size	*Forficula auricularia* (Dermaptera), *Allothrombium fuliginosum* (Acari) *Exochomus quadripustulatus* (Coleoptera), Araneae	Reduced abundance	~ 1 month The presentation of the results does not facilitate evaluation of possible recovery.	
Showler and Sétamou, M., 2004	Cotton 2 year trial Texas, USA 8 (123 m^2)	7-10 x 42.3 L/ha	Yes, with limitations	- absence of positive control - history/weather data missing - dose verification unknown - actions to avoid contamination of untreated plots unknown - insufficient plot size - poor reporting of the results	Geocoris spp. (Lygaeidae), Orius spp. (Anthocoridae), Nabis spp. (Nabidae), reduviids, Coccinellids, Collops spp. (Melyridae), neuropterans, wasps (mostly braconids, eupelmids, eurytomids, ichneumonids, pteromalids, sphecids, and trichogrammatids), and spiders (mostly clubionids, linyphiids, lycosids, salticids, and thomisids).	Populations of dipterans, Orius spp., and wasps were reduced in the kaolin treatments only on 1 of 20 sampling dates over the two seasons. Foliar kaolin spray had no effect on other arthropod groups (Geocoris spp.; Nabis spp.; reduviids; coccinellids; Collops spp.; neuropterans; and spiders).	-	Measurment on randomly selected fully expanded leaves
KCP 10.3.2.4/15, Pascual, *et al*., 2010b	Orchard (olive) 1 yr trial Spain	2 x 3 kg/hl (10-week interval)	Yes, with limitations	- number of replicated plots not reported - insufficient plot size - worst-case application scheme not covered	Araneae (most abundant), Coleoptera, Diptera, Hemiptera, Hymenoptera, Neuroptera, Thysanoptera	Reduced number of predators compared to the untreated control. Most affected taxa:	day of application and ~10 weeks Data indicates a trend of	Beating method PRC and one-way ANOVA

Reference	Crop / duration/ location/plots	Application rate	Reliability	Deficiencies	Taxonomic assignment/precision	Effects reported compared to control	Sampling after last application/Signs of recovery	Remarks
	4 trees/plot			- the water volume not specified - information on history and weather conditions is missing. - dose verification unknown - actions to avoid contamination of untreated plots unknown - the absence of difference in the abundance pre-treatment cannot be confirmed (absence of stat. analysis) - one sampling method employed	Usually up to family. Identification to species level for Coccinelidae, Anthocoridae, Miridae	Aranea (Philodromidae and other Salticidae) Coleoptera (Coccinelidae) Neuroptera Hemiptera (e.g. Anthocorids)	population numbers increasing after both applications. Adverse effects are still seen ~2 months after application	considered in the analysis of the results.
Tacoli *et al.* 2019	Vineyards 1-2 year trials Italy 4 (10-14 trees/plot)	2 x 20 kg/ha	Yes, with limitations	- worst-case application scheme not covered - absence of positive control - history/weather data missing - dose verification unknown - actions to avoid contamination of untreated plots unknown - actual plot size unknown	Phytoseiidae Predatory Mite Populations (mainly *K. aberrans* and *T. pyri)*	Gradual decrease in population density levels of *Kampimodromus aberrans* and *Typhlodromus pyri* with the maximum reduction ranging from 49 to 91%	following year Non-significant differences between kaolin-treated and control plots	Kaolin reduced the fecundity of *K. aberrans* and *T. pyri* females but not their survival in laboratory studies
Jaastad *et al.*, 2006	Orchards (plum, apple) Norway 5 (3 trees/plot)	1-2 x 3 kg/hl	Yes, with limitations	- worst-case application scheme not covered - absence of positive control - history/weather data missing - dose verification unknown - actual plot size unknown - insufficient plot size - limited sample size	Predatory Mite Populations (common species recorded were *Tydeus* sp., *Typhlodromus* sp. and *Amblyseius* sp.)	The population of beneficial mites were negatively affected by kaolin treatment in both apples and plums	Information not provided	5 leaves/tree (15/plot) collected

B.9.7 EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA

No studies of the acute and chronic effects of Aluminium Silicate on earthworms and soil macro-organisms are available in the original DAR. No additional data was submitted in the process of the active substance renewal process. The provided justification is considered acceptable: Aluminium Silicate is a natural mineral present in most soils across the world and the use of SOKALCIARBO WP in agriculture will not significantly alter the normal background levels. Earthworms and other soil macro- and micro- organisms are constantly exposed to natural clay, including Aluminium Silicate. In addition, it is estimated that earthworms contain about 30% soil. Given that soils typically contains between 5-50% clay, earthworms are being continuously exposed to much higher concentration of Aluminium silicate than any that might arise from the use of Aluminium Silicate as a plant protection product.

Concerning the representative formulation SOKALCIARBO WP, no additional data/studies were performed, since it is possible to extrapolate from data obtained with the active substance (due to the composition of the representative formulation SOKALCIARBO WP (please refer to Document J).

A summary of the EU agreed endpoints regarding earthworms, is provided in the Table B.9.7.3-1.

Table B.9.7.3-1: Endpoints and references for non-target soil macro-organisms

Species	Test substance	Exposure System	End point	Reference
Earthworms				
-	-	-	Not required, not relevant	Initial DAR (Aluminium silicate; Hungary, 2008) Addendum of the DAR (Aluminium silicate – Annex B, B.9, Hungary, 2011). EFSA conclusion Aluminium Silicate, 2012

In addition, the Aluminium silicate (Kaolin) in SOKALCIARBO WP is not expected to act any differently from natural clays with which it will be mixed. Furthermore, following the applications of the representative product SOKALCIARBO WP according to the intended uses, the maximum PECsoil is 0.14 g/kg (please refer to Document M-CP B.8). It can be noted that OECD 222, OECD 232 and OECD 226 guideliens (earthworm, collembolan and predatory mite reproduction tests in soil, respectively) require that the used artificial soil material must contains 20% of Kaolin clay, i.e., 200 g/kg. This is much higher than the Aluminium Silicate (Kaolin) brought by the applications of the representative formulation SOKALCIARBO WP (less than 0.14 g/kg) according to the intended uses. Therefore, it can be concluded that Aluminium Silicate (Kaolin) is not expected to be toxic for earthworms.

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%. Therefore, 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 earthworms as Aluminium silicate will mix with, behave in an identical manner to and will immediately become indistinguishable from naturally present clay. In addition, it is estimated that earthworms contain about 30% soil. Given that soils typically contains between 5-50% clay, earthworms are being continuously exposed to much higher concentration of Aluminium silicate than any that might arise from the use of SOKALCIARBO WP.

B.9.7.1 EARTHWORMS – ACUTE EFFECTS

Acute toxicity data is no longer required according to the new data requirements (Regulation (EU) No. 283/2013). No additional studies with the representative formulation SOKALCIARBO WP were performed. Therefore a risk assessment for acute effects on earthworms is not conducted in the current renewal.

B.9.7.2 EARTHWORMS – SUBLETHAL EFFECTS

No additional studies with the representative formulation SOKALCIARBO WP were performed, since it is possible to extrapolate from data obtained with the active substance [due to the composition of the representative formulation SOKALCIARBO WP (please refer to Document J)]. Please refer to Section 9.7 of the present Document for the justification.

Furthermore, higher tier data are not required as the risk for non-target soil microorganisms is considered to be very low.

B.9.7.3 EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA (OTHER THAN EARTHWORMS)

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 of the representative formulation SOKALCIARBO WP (please refer to Document J)].

A summary of the EU agreed endpoints regarding other soil macro-organisms is provided in the Table 9.7.6-01.

Table 9.7.6-01: Summary of toxicity data to other soil macro-organisms

Species	Test substance	Exposure System	End point	Reference
Other soil macro-organisms				
-	-	-	Not required, not relevant	Initial DAR (Aluminium silicate; Hungary, 2008) Addendum of the DAR (Aluminium silicate – Annex B, B.9, Hungary, 2011). EFSA conclusion Aluminium Silicate, 2012

In addition, the Aluminium silicate (Kaolin) in SOKALCIARBO WP, is not expected to act any differently from natural clays with which it will be mixed. Furthermore, following the applications of the representative product SOKALCIARBO WP according to the intended uses, the maximum PECsoil is 0.14 g/kg (please refer to Document M-CP 9). It can be noted that OECD 232 and OECD 226 guidelines (Collembolan Reproduction test in soil, Predatory mite [*Hypoaspis (Geolaelaps) aculeifer*] reproduction test in soil, respectively) require that the used artificial soil material must contains 20% of Kaolin clay, i.e., 200 g/kg. This is much higher than the Aluminium silicate (Kaolin) brought by the applications of the representative formulation SOKALCIARBO WP (less than 0.14 g/kg) according to the intended uses. Therefore, it can be concluded that Aluminium silicate (Kaolin) is not expected to be toxic for soil microorganisms. In this context, the applicant asks for a waiver to perform additional toxicity studies on these non-target soil microorganisms.

B.9.7.3.1 Species-level toxicity testing with non-target soil macro-organisms other than earthworm

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 of the representative formulation SOKALCIARBO WP (please refer to Document J)]. Please refer to point 9.7 of the present document for justification.

B.9.8 RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA

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.

B.9.9 EFFECTS ON SOIL NITROGEN TRANSFORMATION

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 of the representative formulation SOKALCIARBO WP (please refer to Document J)].

A summary of the EU agreed endpoints regarding soil micro-organisms is provided in the **Table 9.7.7-01**.

Table 9.7.7-01: Summary of toxicity data to soil micro-organisms

Species	Test substance	Exposure System	End point	Reference
Soil micro-organisms				
-	-	-	Not required, not relevant	Initial DAR (Aluminium silicate; Hungary, 2008) Addendum of the DAR (Aluminium silicate – Annex B, B.9, Hungary, 2011). EFSA conclusion Aluminium Silicate, 2012

B.9.10 RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION

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.

B.9.11 EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

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 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.

B.9.11.1 SUMMARY OF SCREENING DATA

No studies on toxicity of SOKALCIARBO WP for non-target terrestrial plants are provided. The justification provided in Section 9.11 is considered acceptable.

B.9.11.2 TESTING ON NON-TARGET PLANTS

No studies on toxicity of SOKALCIARBO WP for non-target terrestrial plants are provided. The justification provided in Section 9.11 is considered acceptable.

B.9.11.3 EXTENDED LABORATORY STUDIES ON NON-TARGET PLANTS

No studies on toxicity of SOKALCIARBO WP are provided.

B.9.11.4 SEMI-FIELD AND FIELD TESTS ON NON-TARGET PLANTS

No studies on toxicity of SOKALCIARBO WP , re provided.

B.9.12 RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS

Since no studies on toxicity of SOKALCIARBO WP were conducted, no risk assessment could be performed.

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

B.9.13 EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

No additional studies with the representative formulation SOKALCIARBO WP were performed, since it is possible to extrapolate from data obtained with the active substance [due to the composition of the representative formulation SOKALCIARBO WP (please refer to Document J)].

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. Aluminium silicate is inert and has no known toxic effects on any organisms. The use of SOKALCIARBO WP is not expected to have any harmful impact on flora and fauna.

B.9.14 RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

Since no studies on toxicity of SOKALCIARBO WP were conducted, no risk assessment could be performed.

B.9.15 MONITORING DATA

No additional data were required. Aluminium silicate is ubiquitous in soil (including agricultural soils), water bodies and aquatic sediments, and applied Aluminium silicate will be indistinguishable from naturally present clay. Therefore, the concept of monitoring does not apply to Aluminium silicate, nor to SOKALCIARBO WP.

B.9.15 REFERENCES

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.3.1.2 (refer to K-CP 10.3.1.2/01)	Mamet O.	2019	Evaluation of the chronic oral toxicity of Sokalciarbo WP on honey bees (*Apis mellifera* L.). Calculation of Lethal Concentration (LC_{50}) and Lethal Dietary Dose (LDD_{50}). Laboratory conditions. TESTAPI, Report No. 371-2018 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA
K-CP 10.3.1.1.2/1	Mamet O.	2008	«Determination de la DL_{50} de contact sur abeille domestique (*Apis mellifera*) par différentes applications de SOKALCIARBO WP » Testapi, Report N°139-2008 GLP: Yes Published: No	N	Y	Required according to Reg. (EU) no. 284/2013.	SOKA
KCA 8.3.1.1.1/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute Dietary Toxicity Study with the Honey Bee Report no.: 469-102 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCA 8.3.1.1.2/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute ContactToxicity Study with the Honey Bee Report no.: 469-101 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.

Data point	**Author(s)**	**Year**	**Title Company Report No. Source (where different from company) GLP or GEP status Published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KCP 10.3.1.6/01	Mayer, D.F.	1999a	Honey bee foraging in pear orchards treated with kaolin particle film Report number: - Non-GLP Unplublished	N	N	Data out of protection,	Tessenderlo Group N.V.
KCP 10.3.1.6/02	Mayer, D.F.	1999b	Honey bee foraging in apple orchards treated with kaolin particle film Report number: - Non-GLP Unplublished	N		Data out of protection	Tessenderlo Group N.V.
KCA 8.3.2/01	Puterka, G.J.	1997	Report on the Effect of M-96-018 Kaolin on Insect Predators Report no.: - GEP: No Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCP 10.3.2.4/01	Lepin, J.	2004	Evaluate the efficacy of Surround against *Cacopsylla pyri*, applied just after the end of the winter period Report number: FENG045059 SOLEVI GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/02	Fraser, H.	2002a	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-1 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.4/03	Fraser, H.	2002b	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-2 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/04	Fraser, H.	2002c	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-5 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/05	Fraser, H.	2002d	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-6 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/06	Fraser, H.	2002e	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-7 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.4/07	Peusens, G., and Creemers, O.	2004a	Biological efficacy evaluation of Surround WP against the pear sucker, *Cacopsylla pyri* L., on pear Report number: 20040617 412 BE 388 GEP RSF GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/08	Peusens, G., and Creemers, O.	2004b	Biological efficacy evaluation of Surround WP against the pear sucker, *Cacopsylla pyri* L., on pear Report number: 20040617 460 BE 421 GEP RSF GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/10	Pascual, S., Cobos, G., Seris, E., and Gonzalez-Nunez, M.	2010a	Effects of processed kaolin on pests and non-target arthropods in a Spanish olive grove Report number: - GEP: - Published in: J Pest Sci 83:121-133	N	N	Not relevant	Public literature
KCP 10.3.2.4/11	Marko, V., Bogya, S., Kondorosy, E., and Blommers, L.H.M	2010	Side effects of kaolin particle films on apple orchard bug, beetle and spider communities Report number: - GEP: - Published in: International Journal of Pest Management vol 56: 189-199	N	N	Not relevant	Public literature
KCP 10.3.2.4/17	Sackett, T.E., Buddle, C.M., Vincent, C.	2007	Effects of kaolin on the composition of generalist predator assemblages and parasitism of *Choristoneura rosaceana* (Lep., Tortridae) in apple orchards Report number: - GEP: - Published in: J. Appl. Entomol. 131(7): 478-485	N	N	Not relevant	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.4/16	Sánchez-Ramos, I., Marcotegui, A., Pascual, S., Fernández, C.E., Cobos, G, González-Núñez, M.	2017	Compatibility of organic farming treatments against *Monosteira unicostata* with non-target arthropod fauna of almond trees canopy Report number: - GEP: - Published in: Spanish Journal of Agricultural Research 15(2), e1004	N	N	Not relevant	
KCP 10.3.2.4/14	Knight, A.L., Christian-son, B.A., Unruh, T.A.	2001	Impacts of seasonal kaolin particle films on apple pest management Report number: - GEP: - Published in: The Canadian Entomologist 133: 413-428	N	N	Not relevant	
KCP 10.3.2.4/13	Iannotta, N., Belifiore, T., Noce, M.E., Scalerico, S., Vizzarri, V.	2007	The impact of some compounds utilized in organic olive groves on the non-target arthropod fauna: canopy and soil levels Report number: - GEP: - Published in: Ecoliva 2007, VI Jornadas Internacionales de Olivar Ecologico, Puente de Génave (Jaén), España, 22-25 marzo 2007	N	N	Not relevant	
KCP 10.3.2.4/12	Markó, V., Blommers, L.H.M., Bogya, S., Helsen, H.	2006	The effect of kaolin treatments on phytophagous and predatory arthropods in the canopies of apple trees Report number: - GEP: - Published in: J Fruit Ornam Plant Res, 14 (suppl 3): 79-87	N	N	Not relevant	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.4/18	Showler, A.T, and Sétamou, M.	2004	Effects of kaolin particle film on selected arthropod populations in cotton in the lower Rio Grande Valley of Texas Report number: - GEP: - Published in: Southwestern Entomologist, 29(2): 137-146	N	N	Not relevant	
KCP 10.3.2.4/15	Pascual, S., Cobos, G., Medina, P., Budia, F., Viñuela, E., González-Núñez, M.	2010b	Field assessment of effects of control strategies against the olive fruit fly (*Bactrocera oleae* (Rossi)) on predatory arthropods: comparison of different methods of data analysis Report number: - GEP: - Published in: Pesticides and Beneficial Organisms IOBC/wprs Bulletin vol 55: 11-18	N	N	Not relevant	
	Tacoli, F., Cargnus, E., Pozzebon, A., Duso, C., Tirello, P., & Pavan, F	2019	Side Effects of Kaolin and Bunch-Zone Leaf Removal on Predatory Mite Populations (Acari: Phytoseiidae) Occurring in Vineyards. Report number: - GEP: - Published in: Journal of economic entomology, 112(3), 1292-1298.	N	N	Not relevant	
	Jaastad, G., Røen, D., Hovland, B., & Opedal, O.	2006	Kaolin as a possible treatment against lepidopteran larvae and mites in organic fruit production. In ecofruit-12th International Conference on Cultivation Technique and Phytopathological Problems in Organic Fruit-Growing Report number: - GEP: - Proceedings to the Conference from 31st January to 2nd February 2006 at Weinsberg/Germany (pp. 31-35). Fördergemeinschaft Ökologischer Obstbau eV (FÖKO), Traubenplatz 5, D-74189 Weinsberg.	N	N	Not relevant	