European Commission

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

Aluminium Silicate Calcined (Kaolin calcined)

SURROUND® WP CROP PROTECTANT Tessenderlo

Volume 3 (CP) - B.9 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 **TESSENDERLO GROUP N.V.** supports the renewal of approval of **Aluminium Silicate** with the representative formulation **SURROUND® WP CROP PROTECTANT**.

SURROUND® WP CROP PROTECTANT is a foliar insect repellent for application to grapevines. It contains 95% w/w kaolin (aluminium silicate) as the active substance. The worst-case critical GAP is 30 kg product/ha (28.5 kg a.s./ha) applied 4 times a season with a minimum interval of 7 days to grapevines. Applications occur from BBCH 51 to 65.

SURROUND® WP CROP PROTECTANT was included into Annex I of Directive 91/414 (2008/127/EC). This product was the representative formulation.

Proposed use pattern

Crop and/ or situation (crop destination / purpose of crop)	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures**
			Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**	
Grapevines	F	*Frankliniella occidentalis.*	Broadcast spraying of entire vine	BBCH 51 - 65	a) 1-4 (7) b) 1-4 (7)	a) 30 kg/ha b) 120 kg/ha	a) 28.5 kg/ha b) 114 kg/ha	a) 500 – 1000 L/ha b) 2000 – 4000 L/ha	First spraying at emergence of overwintering females. Use sufficient spray volume, apply to near drip but avoid run-off. Re-apply each 7 to 21 days, depending on rainfall and crop development.

Consideration of metabolites

Aluminium silicate is not metabolised and does not degrade or react. SURROUND® WP CROP PROTECTANT containing 95% aluminium silicate (kaolin) a stable compound, hence there is no formation of metabolites.

B.9.1 EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

No risk assessment is needed for aluminium Silicate according to justification provided in Volume 3 CA.

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

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B.9.2.2 RISK ASSESSMENT FOR TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

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, along with an acute Daphnia magna study. Full details and summary of the studies are 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, SURROUND WP CROP PROTECTANT is composed of 95% kaolin clay, 4.3% of food-grade additives and 0.7% of well-known additives of no toxicological concern (Please refer to Volume 4 for details on product composition). Therefore, the formulated product is highly unlikely to be of higher toxicity compared to the active substance.

B.9.3.1.2 Acute toxicity to aquatic invertebrates

B.9.3.1.2/01

Reference	Goodband (2006). Surround WP Crop Protectant: Acute toxicity to Daphnia magna Report No: 2120/0004
Guideline	OECD 202
GLP/QA	Yes

Previous evaluation	No, submitted for the purpose of the renewal
Validity/Acceptance	Yes/ Yes

Material and methods

Test substance	Surround WP Batch number: AL060727 Purity: 95% kaolin (analysed) Appearance: Off-white powder
Test species	Daphnia magna (1st instar, < 24 hr old)
Test concentrations	100 and 600 mg test item/L (nominal)
Test groups	20 animals (2 replicates of 10 animals)
Duration	48 h
Test design	All test daphnids were observed for immobility and abnormal behavior or appearance, if any, at 24 and 48 h of exposure. Mobility of the daphnids was assessed by gently swirling the test container for 15 seconds and observing their swimming behaviour. Temperature, dissolved oxygen and pH of the test media were measured at 0 and 48 h after the commencement of exposure.
Test conditions	Test vessels: 250 mL glass jars, approximately 200 mL of test preparation were used. Temperature: 20.1 to 20.3 □C pH: 7.9 to 8.0 Dissolved oxygen: 8.7 to 8.9 mg/L Photoperiod: 16 hours light : 8 hours dark
Parameters tested	Immobility
Endpoint(s)	48h EC50 > 600 mg form/l (570 mg a.s./l)
Analytics	Not available
Statistics	The EC50 value and associated confidence limits at 24 hours and the slope of the response curve and its standard error were calculated by the maximum-likelihood probit method (Finney, 1971). The EC50 value and associated confidence limits at 48 hours a were calculated using the trimmed Spearman-Karber method.

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>

There was no immobilisation in 40 daphnids exposed to test concentrations of 100 and 600 mg/L or the control for a period of 48 hours. Resulting in a 48 hours EC50 > 600 mg test item/L Correspondingly, the NOEC was 600 mg test item/L.

Immobilisation of Daphnia magna exposed to Surround WP

Nominal test conc. (mg/L)	**Number of larvae tested**	**Number of immobilised *Daphnia* after**		**% of immobilised *Daphnia* after**	
		24 h	**48 h**	**24 h**	**48 h**
Control	20	0	0	0	0
100	20	0	0	0	0
600	20	0	0	0	0

Conclusion:

The acute toxicity of the test material to the freshwater invertebrate Daphnia magna has been investigated and gave a 48 hours EC50 > 600 mg test item/L (equivalent to >570 mg a.s./L). Correspondingly, the NOEC was 600 mg test item/L. Results were based on nominal test concentrations.

Study deviations:

The study followed in general the procedures indicated in the aforementioned guideline and fulfilled the corresponding 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.9.3.1.3 Effects on algae

B.9.3.1.3/01

Reference	Vryenhoef, H. 2006 Surround WP Crop Protectant: Algal inhibition test Report No: 2120/0003
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	Surround WP Batch number: AL060727 Purity: 95% kaolin (analysed) Appearance: Off-white powder
Test species	Freshwater green algae, Scenedesmus subspicatus strain CCAP 276/20
Test concentrations	100 and 600 mg test item/L (nominal)
Test groups	three replicate flasks per concentration and control
Duration	72 h
Test design	Samples of the algal populations were removed daily (0. 24, 48 and 72 hours) and cell concentrations were determined for each

	control and treatment group, using a haemocytometer and light microscope. The pH of each control and test flask was determined at initiation of the study and after 72 hours exposure. The temperature within the incubator was recorded daily.
Test conditions	Test vessels: 250 mL conical flasks each containing 100 mL of test solution. With continual shaking at 150 rpm Temperature: 24 ± 1°C pH: 7.3 -8.3 Photoperiod: Continuous lighting
Parameters tested	Cell density (growth rate inhibition) -initial density 10,000 cells/mL
Endpoint(s)	72h ErC50 > 600 mg form/l (570 mg a.s./l) -static test
Analytics	Not available
Statistics	The EbC50 (72h) (biomass) was determined by inspection of the area under growth curve data after 72 hours. The ERC50 (0 -72h) (growth rate) was determined by the inspection of the growth rates for the period 0 – 72 hours. One way analysis of variance incorporating Bartlett's test for homogeneity of variance (Sockal and Rohlf 1981) and Dunnett's multiple comparison procedure for comparing several treatments with a control (Dunnett's 1955) was carried out on the 0-72 hour growth rate data for the control and the 100 and 600 mg/L test concentrations to determine any statistically significant differences between the test and the control groups.

Findings

Analytical results:

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

Biological results:

At 0 hours the control cultures were clear colourless solutions, the 100 mg/L cultures were cloudy white dispersions and the 600 mg/L cultures were milky white dispersions After the 72 hour exposure period the control cultures were green dispersions, the 100 mg/L cultures were cloudy green dispersions and the 600 mg/L cultures were milky green dispersions. The green colouration at 72 hours was due to growth of algal cells.

The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period; actual value = by a factor of 51.

Neither the growth nor the biomass of Scenedesmus subspicatus were significantly affected by the presence of the test item over the 72-hour exposure period.

Inhibition of growth rate and biomass

Nominal application rate (mg/L)	Area under curve at 72 hr	Inhibition (%)**	Growth rate (0-72hr)	Inhibition (%)**
Untreated control	9400000	NA	0.055	NA
100	8460000	10	0.054	2
600	8110000	14	0.053	4

NA not applicable.

Statistical analysis of the growth rate data was carried out for the control and the 100 and 600 mg/L test item concentrations. There were no statistically significant differences ($P \geq 0.05$) between the control and the 100 and 600 mg/L test groups and therefore the NOEC was 600 mg/L

Conclusion:

The effect of the test material on the growth of *Scenedesmus subspicatus* has been investigated and gave ErC_{50} values greater than 600 mg test item/L (equivalent to >570 mg a.s./L). Correspondingly the NOEC was 600 mg test item/L. Results were based on nominal test concentrations.

Study deviations:

The study followed in general the procedures indicated in the aforementioned guideline.
However, 2 of the validity criteria are not reported. Applicant is requested to provide: the mean coefficient of variation in the control cultures (must not exceed 35%) and the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures (must not exceed 7% in tests with Pseudokirchneriella subcapitata).
In addition, 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. Additional aquatic toxicity studies on Daphnia magna and algae that were not available for the first Annex I inclusion have 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)

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

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

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

Table B.9.4.4-1(a): Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SURROUND WP CROP PROTECTANT in vines

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

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

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

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

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

- PEC_{SW} = 0.8028 mg/L (Single application)
- PEC_{SW} = 0.6656 mg/L (Multiple application)

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

Table B.9.4.4-1(b): Aquatic organisms: acceptability of risk (PEC/RAC < 1) for aluminium silicate for each organism group based on PECsw calculations for the use of SURROUND WP CROP PROTECTANT in vines

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

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

Overall Conclusion:

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

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

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 CA document.

An acute oral study with the formulation SURROUND® WP is available and is summarised in Table B.9.5.1-1. However, this study is not considered valid as not all validity criteria were met. Acute contact honeybee data are not available for the representative formulation. However, considering the uncomplicated composition of the formulation, the acute effects on honey bees of SURROUND® WP CROP PROTECTANT can be predicted based on the active substance data (SURROUND® WP CROP PROTECTANT is composed of 95% aluminium silicate (kaolin) and 5.0% of well know additives of no toxicological concern; refer to Part C for details on formulation composition). In accordance with Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, chronic risk data to bees including adult and larval life stages were submitted.

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 Adults	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 KCA 8.3.1.1.1/01 (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 KCA 8.3.1.1.2/01 (EFSA Conclusion, 2012)
	SURROUND® WP CROP PROTECTANT	48 h oral toxicity	LD_{50} > 2000 µg/bee*	Goodband, 2006 Report no.: 2120/0005 KCP 10.3.1.1/01
Chronic toxicity				
	SURROUND® WP CROP PROTECTANT	Oral, 10d repeated exposure	**LDD_{50} = 1390 µg a.s./bee/day** LC_{50} = 56410 mg a.s./kg diet NOEDD = 660 µg a.s./bee/day NOEC = 29319 mg a.s./kg diet	Ansaloni, 2019 Report no.: TRC17-208BA KCP 10.3.1.2/01
Effects on honeybee development and other honeybee life stages				

Apis mellifera *Larvae*	SURROUND® WP CROP PROTECTANT	22d Larvae toxicity Repeated exposure	**NOED = 405 µg a.s./larva** NOEC = 2.893 mg a.s./mL diet	Ansaloni, 2019 Report no.: TRC17-184BA KCP 10.3.1.3/01
Higher-tier studies (tunnel test, field studies)				
Field studies in flowering pear and apple orchards in US demonstrated that the application of 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-valid 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	Goodband. T.J. 2006 (KCP 10.3.1.1.1/01) Surround WP Crop Protectant: Acute toxicity to honeybees (*Apis mellifera*) Report No.: 2120/0005
Guidelines	OECD 213 (1998) OECD Guideline for the Testing of Chemicals, Honeybees, Acute Oral Toxicity Test, (adopted 21st September 1998)
GLP	Yes
Previous evaluation	None; submitted for the purpose of active substance renewal
Validity/Acceptance	No (see study limitations)/No

Material and methods

Test item	SURROUND® WP CROP PROTECTANT Lot/Batch no.: AL060727
Vehicle	-
Test species	Worker honeybees (*Apis mellifera L.*) (considered to be greater than 20 days old)
Reference item	Dimethoate technical, 97% purity
Test concentrations	Limit test: 2 mg/bee (not specified if the concentration refers to the test item or the active substance). Reference: 0.05, 0.08, 0.13, 0.21 and 0.33 µg a.s./bee
Test groups	Three replicates per control, reference and test item were tested, each with 10 bees
Test design /methodology	The test material (1000 mg) was dispersed directly in 50% w/v sucrose solution and the volume adjusted to 10 mL to

	give 1000 mg/10 mL stock solution. An aliquot of 200 µL of the 1000 mg/10 mL stock dispersion was added to these feeding tubes to give the 2.0 µg/bee test concentration. Groups of bees were the transferred impartially to the test cages. The bees were initially fed with 200 µL of the treated diet. After approximately 6 hours, the feeding tubes were empty and the bees were fed 500 µL of a 50% w/v sucrose solution. A further 200 µL of a 50% w/v sucrose solution was given after 24 hours.
Test conditions	Temperature: approximately 24.9-25°C Relative humidity: approximately 59.8-60.3% Photoperiod: Constant darkness
Parameters tested	All the bees were observed for signs of mortality as well as any abnormal behavioural symptoms viz., regurgitation, disorientation, lethargy, distended abdomen, erratic movement, aggressiveness, trembling and tumbling at 4, 24 and 48 h post dosing.
Endpoint(s)	Oral 48h LD_{50}
Statistics	Not required. An estimate of the LD_{50} value was given by inspection of the mortality data for the test material. For the reference item, the LD_{50} values were calculated by the maximum-likelihood probit method (Finney 1971) using the ToxCalc computer software package. Probit analysis was used where two or more partial responses to exposure were shown.

Findings

There were no mortalities in 30 honeybees exposed to a test concentration of 2.0 mg test item/bee for a period of 48 hours. It is concluded that the median oral lethal dose (LD_{50}) of SURROUND® WP CROP PROTECTANT was greater than 2 mg test item/bee. Correspondingly, the No Observed Effect Concentration (NOEC) was 2.0 mg test item/bee. No adverse effects of exposure were observed throughout the study.

Inspection of the mortality data for the reference item at 4 hours and analysis of the mortality data by the probit method at 24 and 48 hours based on the nominal test concentrations resulted in a 48 hr LD_{50} of 0.25 µg dimethoate/bee and a NOEC of 0.08 µg dimethoate/bee.

Table B.9.5.1.1/01-1: Results of the Acute Oral Toxicity Test

Nominal Concentration (mg per bee)		Cumulative Mortality (Initial Population: 10 Per Replicate)								
		4 Hours			24 Hours			48 Hours		
		No. Per Replicate	Total	%	No. Per Replicate	Total	%	No. Per Replicate	Total	%
Control	R_1	0			0			1		
	R_2	0	0	0	0	0	0	0	1	3
	R_3	0			0			0		
2.0	R_1	0			0			0		
	R_2	0	0	0	0	0	0	0	0	0
	R_3	0			0			0		

Table 2 **Cumulative Mortality Data in the Positive Control**

Nominal Concentration (µg per bee)		Cumulative Mortality (Initial Population: 10 Per Replicate)								
		4 Hours			24 Hours			48 Hours		
		No. Per Replicate	Total	%	No. Per Replicate	Total	%	No. Per Replicate	Total	%
Control*	R_1	0			0			1		
	R_2	0	0	0	0	0	0	0	1	3
	R_3	0			0			0		
0.050	R_1	0			0			0		
	R_2	0	0	0	0	0	0	0	0	0
	R_3	0			0			0		
0.080	R_1	0			0			0		
	R_2	0	0	0	0	0	0	0	0	0
	R_3	0			0			0		
0.13	R_1	0			0			0		
	R_2	0	0	0	2	4	13	2	4	13
	R_3	0			2			2		
0.21	R_1	0			0			0		
	R_2	0	0	0	1	5	17	4	8	27
	R_3	0			4			4		
0.33	R_1	0			1			8		
	R_2	0	0	0	3	6	20	8	24	80
	R_3	0			2			8		

Conclusion

The median oral lethal dose (LD_{50}) of SURROUND® WP CROP PROTECTANT was > 2 mg test item/bee (>2000 µg/bee). Correspondingly, the NOEC was 2.0 mg/bee.

Average mortality was <10% in control after 48 hrs (actual value: 3%).

The toxic reference LR_{50} was >0.33 µg dimethoate/bee (actual effect: 20% at the 0.33 µg dimethoate/bee) after 24 hours.

<u>Major limitations:</u>

- Not all validity criteria were met. The 24-h LD_{50} of the toxic reference dimethoate was >0.33 µg dimethoate/bee (actual effect-24h: 20% at 0.33 µg dimethoate/bee). Therefore, the susceptibility of the test system was not verified.

- The composition of the test item is not reported. It remains unknown if the test concentration (2 mg/bee) refers to the test item or the active substance.

Minor limitations:

- The feeding tubes were not weighted after consumption. It is reported that the feeding tubes were empty 6 hours after placement.

- The OECD guideline recommends the collection of young worker bees for testing. In this case the worker bees were >20 days old.

B.9.5.1.2 Chronic toxicity to bees

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

B.9.5.1.2/01

Reference	Ansaloni, T. 2019 (KCP 10.3.1.2/01)
	Effects of Surround WP – Chronic oral toxicity to adult worker honey bees, *Apis mellifera* L. under laboratory conditions
	Report No.: TRC17-208BA
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	Surround WP (Kaolin Clay based partical film)
	Lot/Batch no.: AL170530

Vehicle	0.1% Xanthan (stabilizer to improve homogeneity of the treatment solutions)
Test species	Worker bees (*Apis mellifera* L.) (<2 days old)
Reference item	BAS 152 11 l (405.2 g/L dimethoate)
Test concentrations	Nominal doses: 470.78, 776.79, 281.70, 2114.81, 3489.44, 5757.58 and 9500.00 µg a.s./bee/day Dimethoate: 0.107 mg a.s./kg feeding solution C (50 % (w/v) aqueous sucrose solution) Cs (50 % (w/v) aqueous sucrose solution + 0.1% Xanthan)
Test groups	Each treatment group consisted of 50 test organisms (divided into 5 replicates, containing 10 test organisms each).
Test design/methodology	The chronic feeding test was carried out as dose-response test with test duration of 10 days. The test comprised of two control treatment groups (C – untreated sucrose solution and Cs – aqueous sucrose solution + 0.1% Xanthan as a stabilizer), seven test item treatment groups and one reference item treatment group (0.107 µg dimethoate bee/day). Additionally, 10 test units without bees were placed in the climatic chamber for the evaluation of the evaporation: five with full food syringes containing pure 50 % (w/v) aqueous sucrose solution and five with full food syringes containing pure 50 % (w/v) aqueous sucrose solution + 0.1% Xanthan. Freshly prepared feeding solutions replaced daily were offered to the test organisms of each test unit in feeders (plastic syringes, approx. 5 mL). The tip of each feeder was removed to give access to the feeding solution to the bees. A feeding volume of 1 mL/ replicate was offered to the bees ad libitum. The amount of feeding solutions consumed was determined by weighing the feeders before and after feeding using calibrated equipment. The syringes of 10 additional cages were filled with 1 mL of either pure 50 % (w/v) aqueous sucrose solution (5 cages) or 50 % (w/v) aqueous sucrose solution + 0.1% Xanthan (5 cages) and weighed daily for the determination of the evaporation. The amounts of test item needed for the daily preparation of the test item solutions were measured using a calibrated balance. The test feeding solutions were freshly prepared every day by mixing the required (weighed) amounts of test item with 50 % (w/v) aqueous sucrose solution + 0.1% Xanthan. Xanthan gum was used as a stabilizer to improve homogeneity of the treatment solutions. For the reference item treatment, a stock solution was prepared daily by dissolving a defined amount of the reference item in a defined amount of 50 % (w/v) aqueous sucrose solution as solvent. The definitive feeding solution was prepared fresh every day from the stock solution by dissolving a defined aliquot of the stock solution with 50 % (w/v) aqueous sucrose solution.
Test conditions	Temperature: 30.66*– 34.03 °C (*short-term deviation less than 1 hr) Relative humidity: 25.10* – 66.46 % (*short-term deviation less than 1 hr)

	Photoperiod: 24 hrs darkness (except during observation)
Parameters tested	Mortality and sub-lethal effects were recorded daily at about the same time of the day (every 24 h ± 2 h), starting 24 ± 2 hours after start of the test period (initial feeding). Sub lethal effects were quantitatively observed according to the following categories: m: moribund a: affected c: cramps ap: apathy v: vomiting
Analytical verification	Samples of each freshly prepared control (C and Cs) and treated solution (T1 to T7) from D9 were taken directly after preparation and analysed by a digestion - ICP-OES analytical method for total aluminum and total silicon content.
Endpoint(s)	10-day continuous feeding oral LDD_{50} 10-day NOEDD
Statistics	The percentage of cumulative mortality was calculated for each treatment group and assessment from the number of dead individuals in relation to the number of introduced test organisms. The cumulative mortality of the test item treatments was corrected for the pooled controls mortality according to the formula ABBOTT (1925), modified by SCHNEIDER-ORELLI (1947). The consumption of feeding solution per bee per day was calculated by dividing the total daily consumption per replicate by the number of living bees at the beginning of the respective feeding interval. For each treatment group, the mean consumption of feeding solution per bee per day was calculated by averaging the replicate values. Statistical calculations were made by using the statistical program ToxRat Professional®. In order to determine the LDD_{50} and the LC_{50} values a Trimmed Spearman-Karber procedure was used. A Multiple Sequentially-rejective U-test after Bonferroni-Holm (α= 0.05) was used to compare consumption data of the pooled controls and each test item treatment group and to determine if rejection of the test item solutions occurred. A Williams multiple sequential t-test procedure (one sided greater, α= 0.05) was used to compare mortality data of the pooled controls and each test item treatment group and to determine the NOEDD.

Findings

The test was considered valid because the following criteria were satisfied:

- Average mortality for the control did not exceed 15% at the end of the test (actual value: 10% in C and 4% in Cs);
- Average mortality in the reference item treatment was ≥50% at the end of the test (actual value: 100.0%).

Feed consumption

The overall mean daily consumption of feeding solution over the entire test period was 21.71 µL/bee/day for the control group C (untreated 50 % (w/v) aqueous sucrose solution) and it was 20.43 µL/bee/day for the control group Cs (untreated 50 % (w/v) aqueous sucrose solution + 0.1% Xanthan). Since no statistical significant difference in mean daily consumption between the two controls was observed, statistical analysis for consumption data was performed with the pooled controls values.

The overall mean daily consumption of feeding solution at the test item concentrations of 3957.98, 6529.41, 10773.11, 17773.11, 29319.33, 48386.55 and 79831.93 mg a.s./kg food was 21.35, 21.63, 21.13, 20.30, 18.91, 19.16 and 22.56 µL a.s./bee/day, respectively. In the reference item treatment group, the overall mean daily consumption of feeding solution was 19.34 µL/bee/day. No significant differences in consumption of the sucrose solution was observed between any of the treatments with the test item and the pooled controls.

After 10 days of continuous exposure the accumulated mean uptake of kaolin at the treatment levels of 470.78, 776.79, 1281.70, 2114.81, 3489.44, 5757.58 and 9500.00 µg a.s./bee/day were 1005.25, 1680.39, 2708.46, 4293.57, 6597.45, 11028.96 and 21429.76 µg a.s./bee, respectively.

Table B.9.5.1.2/01-1: Overall mean consumption of feeding solution

Treatment (µg a.s./bee)	**Concentration nominal (mg a.s./kg)**	**Overall mean consumption of feeding solution (µL/bee/day)**	**Dietary dose (µg a.s./bee/day)**	**Accumulated mean uptake (µg a.s./bee)**
Control	C (0.0)	21.70	-	-
Solvent control	Cs (0.0)	20.39	-	-
Pooled control	0.0	21.04	-	-
Reference item: dimethoate*	R (0.107)	19.34	0.021	0.186
Test item: Surround WP	T1 (470.78)	21.35	100.53	1005.25
	T2 (776.79)	21.63	168.04	1680.39
	T3 (1281.70)	21.13	270.85	2708.46
	T4 (2114.81)	20.30	429.36	4293.57
	T5 (3489.44)	18.91**	659.74	6597.45
	T6 (5757.58)	19.16	1102.90	11028.96
	T7 (9500.00)	22.56	2142.98	21429.76

* Cumulative over 9 days

** Statistically significantly lower than the pooled control (Multiple Sequentially-rejective U-test After Bonferroni-Holm, $\alpha = 0.05$)

Mortality

On average, 10.0% mortality was observed in control C (untreated 50 % w/v aqueous sucrose solution) and 4.0% mortality in control Cs (untreated 50 % w/v aqueous sucrose solution + 0.1% Xanthan) was observed after 10 days of continuous feeding. Since no statistically significant difference in mortality between the two controls was observed, statistical analysis for mortality data was performed with the pooled controls values.

In the test item groups, at the concentrations of 3957.98, 6529.41, 10773.11, 17773.11, 29319.33, 48386.55 and 79831.93 mg a.s./kg food, mean cumulative mortalities of 14.0, 2.0, 2.0, 8.00, 10.0, 24.0 and 90.0 % were observed at the final evaluation after 10 days, respectively. Corrected mortality (with the pooled controls) was 7.53, -5.38, -5.38, 1.08, 3.23, 18.28 and 89.25 %, respectively.

The mean values for mortality are summarised in the following table.

Table B.9.5.1.2/01-2: Mortality in the chronic 10-d oral honey bee test

Treatment (µg a.s./bee)	Concentration nominal (mg a.s./kg)	10d Cumulative mortality (%)	10d Corrected [1] mortality (%)
Control	C (0.0)	10.00	3.23
Solvent control	Cs (0.0)	4.00	-3.23
Pooled control	0.0	7.00	-
Reference item: dimethoate	R (0.107)	100.0	100.0
Test item: Surround WP	T1 (470.78)	14.00	7.53
	T2 (776.79)	2.00	-5.38
	T3 (1281.70)	2.00	-5.38
	T4 (2114.81)	8.00	1.08
	T5 (3489.44)	10.00	3.23
	T6 (5757.58)	24.00*	18.28
	T7 (9500.00)	90.00*	89.25

[1] Mortality corrected with the pooled controls mortality according to Schneider-Orelli, O. (1947)
* significantly different compared to the control (Williams multiple sequential t-test, one-sided greater, α = 0.05)

Behavioural

Symptoms of intoxication were observed sporadically for a few of the bees exposed to all of the test item concentrations starting on the second day of dosing. Symptoms observed throughout the study were mainly affected bees (lack of coordination). By the end of the study (day 10), the percentage of affected bees based on the surviving individuals ranged between 0.00 % at the three lowest concentrations (3957.98, 6529.41 and 10773.11 mg a.s./kg food) and 20.00 % at the highest concentration (79831.93 mg a.s./kg food).

Table B.9.5.1.2/01-3: Behavioural abnormalities

TRT	Dose (µg as/bee/day)	D1					D2					D3					D4					D5			
		Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C
C	--	49	0	0	0	0	48	0	0	0	0	47	0	0	0	0	47	0	0	0	0	47	0	0	0
Cs	--	49	0	0	0	0	49	0	0	0	0	49	0	0	0	0	49	0	0	0	0	49	0	0	0
T1	470.78	50	0	0	0	0	50	0	0	0	1	49	0	0	0	0	49	1	0	0	1	47	1	0	0
T2	776.79	50	0	0	0	0	50	0	0	0	0	50	0	0	0	0	50	1	0	0	0	50	0	0	0
T3	1281.70	50	0	0	0	0	50	0	0	0	0	50	0	0	0	0	50	0	0	0	0	50	1	0	0
T4	2114.81	50	1	0	0	0	50	1	0	0	0	49	2	0	0	0	49	0	0	0	0	49	3	0	0
T5	3489.44	50	0	0	0	0	50	0	0	0	0	50	2	0	0	0	49	2	0	0	0	48	1	0	0
T6	5757.58	48	0	0	0	0	48	0	0	0	0	48	1	0	0	0	47	2	0	0	0	47	3	0	0
T7	9500.00	49	0	0	0	0	47	0	0	0	0	45	3	0	0	0	42	1	0	0	0	39	1	0	0

TRT	Dose (µg as/bee/day)	D6					D7					D8					D9					D10			
		Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C	Mb	Al	A	Ap	C
C	--	47	0	0	0	0	47	0	0	0	0	46	0	0	0	0	46	3	0	0	1	45	0	0	0
Cs	--	48	0	0	0	0	48	0	0	0	0	48	0	0	0	0	48	0	0	0	0	48	0	0	0
T1	470.78	46	0	0	0	0	46	0	0	0	0	46	0	0	0	0	45	2	0	0	0	43	0	0	0
T2	776.79	50	0	0	0	0	50	1	0	0	0	50	0	0	0	0	50	1	0	0	0	49	0	0	0
T3	1281.70	50	0	0	0	0	49	0	0	0	0	49	0	0	0	0	49	2	0	0	0	49	0	0	0
T4	2114.81	49	1	0	0	0	49	0	0	0	0	49	1	0	0	0	48	3	0	0	0	46	1	0	0
T5	3489.44	48	1	0	0	0	48	0	0	0	0	48	0	0	0	0	46	3	0	0	0	45	1	0	0
T6	5757.58	47	1	0	0	1	46	0	0	0	0	44	3	0	0	0	43	1	0	0	1	38	2	0	0
T7	9500.00	36	1	0	0	0	31	8	0	0	0	17	2	0	0	0	9	4	0	0	0	5	1	0	0

Al = Alive; A = Affected; Ap = Apathy; C = Cramps; Mb = Moribund. No individuals with cramps or vomiting were observed throughout the test.

Toxicity endpoints
In summary, the toxicity endpoints for 10-d chronic feeding exposure to honey bee based on nominal test concentrations are as following:

Table B.9.5.1.2/01-4: Honey bee toxicity endpoints for bees continuously exposed *via* the diet for 10-d to Surround WP under laboratory conditions

Treatment	Surround WP (Kaolin Clay based partical film)
LDD_{50} (95 % confidence limits) [1]	1389.55 µg kaolin/bee/day (1264.41 to 1527.08 µg kaolin/bee/day)
NOEDD [1]	659.74 µg kaolin/bee/day
LC_{50} (95 % confidence limits)	56409.64 kaolin/kg diet (51809.48 - 61418.25 mg kaolin/kg diet)
NOEC [1]	29319.33 mg kaolin/kg diet

[1] Based on actual consumption

Analytics
The analytical methods for determination of total aluminium and total silicon were successfully validated according to guideline SANCO/3029/99 rev.4 (2000) with regards to linearity, precision (repeatability), specificity and accuracy (recovery).

The specificity for the analysis of aluminium or silicon was demonstrated by using a highly specific method (ICP-OES, independent quantification and confirmation wavelengths). Mean recoveries for total aluminium were 92% and 94% respectively (overall: 93%). The mean recoveries for total silicon were 95% and 92% respectively (overall: 93%). Therefore, the SANCO requirement that mean recoveries for each level should be in the range 70% - 110% were fulfilled.

The limit of quantification (LOQ) was confirmed at 12 mg/L aluminium and silicon in final solution used for ICP analysis. Limit of detection (LOD) is defined as 30% of the LOQ. Therefore, the LOD was 3.6 mg/L aluminium and 3.6 mg/L silicon. The SANCO criteria for precision (repeatability) was fulfilled. The relative standard deviation for aluminium was 2.51% and 0.63%, respectively (overall 1.89%), and for silicon was 3.06% and 0.45% respectively (overall 2.59%). Linearity was also shown for both aluminium (r^2 = 0.9996) and silicon (r^2 = 0.9997).

Conclusions

The estimated LDD_{50}-value (Lethal Dietary Dose that kills 50% of the exposed individuals) for Surround WP corresponded to the mean consumed dose of 1390 µg kaolin/bee/day. The estimated NOEDD, based on the actual consumption for the respective feeding solutions, was determined to be 660 µg kaolin/bee/day.

Sub-lethal effects (i.e. affected bees) were observed throughout the exposure phase for some of the test item doses. By the end of the study (day 10), the percentage of affected bees based on the surviving individuals ranged between 0.00 % at the three lowest doses (470.78, 776.79 and 1281.70 µg kaolin/bee/day) and 20.00 % at the highest dose (9500.00 µg kaolin/bee/day).

Study limitations:

- The applied dose of dimethoate is slightly higher than the OECD 245 recommended range (0.5-1 mg a.s./kg feeding solution)

The identified limitation is not expected to compromise the reliability of the test results.

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

Reference	Ansaloni, T. 2019 (KCP 10.3.1.3/01) Surround WP - Honey Bee Larval (*Apis mellifera* L.) Toxicity Test following Repeated Exposure under laboratory conditions Report No.: TRC17-184BA
Guideline	OECD 239 (2016)
GLP	Yes
Previous evaluation	None; submitted for the purpose of active substance renewal
Validity/Acceptance	Yes/Yes
Material and methods	
Test item	Surround WP Lot/Batch no.: AL170530
Vehicle	Deionised water
Test species	Honeybees (*Apis mellifera* L.) (1st instar larvae)
Reference item	BAS 152 11 l (dimethoate)
Test concentrations	Nominal doses: 0.107, 0.321, 0.964, 2.893 and 8.679 mg kaolin/mL diet, equivalent to cumulative doses of 15, 45, 135, 405 and 1215 µg kaolin/larva /developmental period Dimethoate: cumulative dose of 7.40 µg dimethoate/larva
Test groups	Each hive equates to one replicate, 16 larvae from each replicate were used.
Test design/methodology	The diet was prepared with deionized water using the following ingredients: • Diet A (D1, volume administered: 20 µL/larva): 50.00 % weight of royal jelly + 37.00 % weight of deionized water + 1.00 % weight of yeast extract, 6.00 % weight of glucose and 6.00 % weight of fructose. • Diet B (D3, volume administered: 20 µL/larva): 50.00 % weight of royal jelly + 33.50 % weight of deionized water + 1.50 % weight of yeast extract, 7.50% weight of glucose and 7.50 % weight of fructose. • Diet C (from D4 to D6, volume administered: 30 µL/larva on D4, 40 µL/larva on D5 and 50 µL/larva on D6): 50.00 % weight of royal jelly + 30.00 % weight of deionized water + 2.00 % weight of yeast extract + 9.00 % weight of glucose and + 9.00 % weight of fructose. The larval Diet A was prepared freshly at D1 of the test; Diets B and C were prepared at the beginning of the test and then stored refrigerated (≤ 5 ºC) until each use. Each larva was fed once a day (except on day 2 (D2)) with a standardized amount of artificial diet until day 6 (D6).

	Larvae were transferred into crystal polystyrene grafting cells (NICOTPLAST, Ø = 9 mm) sterilised by submerging for 30 min in ethanol 70 % (v/v), and then dried. Each cell was placed into a well of a sterile 48-well cellular culture plate (Greiner Bio-One), and the so prepared experimental units were placed under UV light for 15 minutes. The open plates of the control group and of all test product groups were individually placed into hermetically sealed Plexiglas desiccators, containing dishes filled with a saturated potassium sulphate (K2SO4) solution in order to keep a water saturated atmosphere from day 1 (D1) to day 8 (D8); on day 8 (D8), the well plates were transferred to another Plexiglas desiccator, containing a saturated sodium chloride (NaCl) solution in order to keep the established relative humidity until day 15 (D15). All desiccators were placed into the same incubator with forced air circulation. After the assessment on day 15 (D15), the test units were transferred to an emergence box (approx. 18 x 13 x 7 cm) with ventilated lids and placed inside the incubator. Each emergence box was supplied with 50 % (w/v) aqueous sucrose solution ad libitum. For the preparation of the treated diets, a stock solution containing 22.8383 g test item with up to 250 mL deionized water was diluted into the series of four test solutions and aliquots of the stock solution and each dilution was mixed with the corresponding diet. The volume of the aliquots amounted for ≤ 10% of the final volume of the treated diet. A unique stock solution (S5) was prepared on D3 and used for all dilutions (S1 to S4). All dilutions were prepared on the same day and stored in a refrigerator. Diet B was spiked on D3 for all application doses and, subsequently, stock solution S5 and associated dilutions were stored in the fridge. On D4, stock solution and dilutions were used to spike diet C for the applications of D4, D5 and D6. Spiked diet C was stored in the fridge between application days D4, D5 and D6. A unique stock solution of the reference item was prepared on D3 with 0.0265 g dimethoate in up to 5 mL deionized water and was stored in the refrigerator to be used until D6 (last application). Larvae of the control group (C) were fed with pure untreated diet from day 3 (D3) until day 6 (D6). Daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period; the cumulative feeding volume from day 3 (D3) until day 6 (D6) of 140 µL diet per larva and the density of the diet (1.1 g/cm^3) were used to calculate the cumulative doses per larva. The treated diet was homogenized with a vortex mixer.
Test conditions	Temperature: 30.4– 35.3 °C Relative humidity: 50.4-100.0% Photoperiod: 24 hrs darkness (except during observation)
Parameters tested	Assessment of larval mortality was conducted before feeding on day 4 (D4), day 5 (D5), day 6 (D6), day 7 (D7) and day 8 (D8). On day 15 (D15) larvae that had not transformed into pupae were recorded as dead. Assessment of adult emergence was carried out on day 22 (D22). With the assistance of a stereo microscope, larvae were recorded as dead if no

	respiration (movement of spiracles) was observed. At each assessment time, dead larvae were removed for sanitary reasons. Other observations (larval appearance and size) were recorded. On day 8 (D8) during the assessment of mortality the presence of uneaten food was qualitatively recorded.
Analytical verification	Analytical verification on samples of the stock solution S5 and its dilutions S1 to S4 was carried out by a digestion - ICP-OES analytical method. Since the test item is a natural mineral substance of undefined molecular mass, aluminium and silicone, which occur in a fairly constant ratio in kaolin, were quantified in the analytical verification.
Endpoint(s)	22-day NOED value
Statistics	A Chi² 2x2 Table Test with Bonferroni Correction was used to compare mortalities observed in the test item groups with mortalities of the pooled controls to determine the NOED / NOEC (No Observed Effect Dose / Concentration) on D22. The statistics program ToxRatPro Version 3.2.1® was used. Since no clear dose-response relationship was obtained, the ECx / EDx values could not be estimated.

Findings

The test was considered valid because the following criteria were satisfied:

- The cumulative larval mortality in the control group from day 3 (D3) to day 8 (D8) was ≤ 15 % across all replicates (actual value: 6.25 %);
- On day 22 (D22) the adult emergence rate in the control group was ≥ 70 % across all replicates (actual value: 85.42 %);
- The cumulative larval mortality in the reference item groups was ≥ 50 % across all replicates on Day 8 (D8) (corrected mortality 97.56 %).

Mortality

In the control group (C), cumulative larval mortality on day 8 (D8) was 4.17%. On day 22 (D22), the adult emergence rate in the control group was 85.42% of the initial grafted larvae. Cumulative mortality (corrected with the control) in the reference item treatment group was 95.83% by D8. On day 8 (D8) in the test item doses of 15, 45, 135, 405 and 1215 µg kaolin/larva/developmental period, the cumulative mean mortality (corrected with the control) was -2.22, 4.44, 0.00, 4.44 and 4.44 %, respectively. On day 15 (D15) in the test item doses of 15, 45, 135, 405 and 1215 µg kaolin/larva/developmental period, the cumulative mean mortality (corrected with the control) was -2.33, 2.33, 0.00, 4.65 and 9.30 %, respectively. In the test item doses of 15, 45, 135, 405 and 1215 µg kaolin/larva/developmental period, the cumulative mean mortalities at 22 days (D22) after grafting were 14.58, 16.67, 12.50, 14.58 and 37.50 %, respectively (corrected mortalities with the control 0.00, 2.44, -2.44, 0.00 and 26.83 %, respectively). A summary of the mortality results over the test period is presented in the following tables.

Table B.9.5.1.3/01-1: Cumulative mortality in the repeated larval test with Surround WP

Treatment Group	Dose		Cumulative Mortality (%)						
			D4	D5	D6	D7	D8	D15	D22
Control	---	---	4.17	6.25	6.25	6.25	6.25	10.42	14.58
Test item SURROUND WP	15	(µg a.i./larva/ developmental period) [a]	2.08	2.08	2.08	4.17	4.17	8.33	14.58
	45		8.33	10.42	10.42	10.42	10.42	12.50	16.67

	135		0.00	4.17	4.17	6.25	6.25	10.42	12.50
	405		0.00	4.17	6.25	10.42	10.42	14.58	14.58
	1215		6.25	8.33	10.42	10.42	10.42	18.75	37.50*
Reference Item (dimethoate)	7.40	(µg a.i./larva/ developmental period)	29.17	56.25	75.00	93.75	95.83	97.92	97.92

[a] Based on the analysed purity of active ingredient (kaolin)
* Significant difference compared to pooled control (Chi² 2x2 Table Test with Bonferroni Correction, α = 0.050; one-sided greater)

Table B.9.5.1.3/01-2: Corrected mortality in the repeated larval test with Surround WP

Treatment Group	Dose		Corrected cumulative Mortality (%)						
			D4	D5	D6	D7	D8	D15	D22
Test item SURROUND WP	15	(µg a.i./larva/developmental period) [a]	-2.17	-4.44	-4.44	-2.22	-2.22	-2.33	0.00
	45		4.35	4.44	4.44	4.44	4.44	2.33	2.44
	135		-4.35	-2.22	-2.22	0.00	0.00	0.00	-2.44
	405		-4.35	-2.22	0.00	4.44	4.44	4.65	0.00
	1215		2.17	2.22	4.44	4.44	4.44	9.30	26.83
Reference Item (dimethoate)	7.40	(µg a.i./larva/developmental period)	26.09	53.33	73.33	93.33	95.56	97.67	97.56

[a] Based on the analysed purity of active ingredient (kaolin)

On day 8 (D8), no uneaten food was observed for any individual of the treatments with the test item and the control group.

The mean emergence rates were 85.42, 83.33, 87.50, 85.42 and 62.50 %, respectively. A significant difference in D22 mortality was observed between the control and the highest test item group (1215 µg kaolin/larva/developmental period), with no significant differences between the control and any of the treatment groups of ≤ 405 µg kaolin/larva/developmental period.

Table B.9.5.1.3/01-3: Pupal mortality and mergence rate of honey bee larva exposed to Surround WP

Treatment Group	Dose		Mean Pupal Mortality % at D15[b]	Mean Pupal Mortality % at D22[c]	Emergence % D22[d]
Control	---	---	4.17	10.42	85.42
Test item SURROUND WP	15	(µg a.i./larva/developmental period) [a]	4.17	10.42	85.42
	45		2.08	14.58	83.33
	135		4.17	8.33	87.50
	405		4.17	10.42	85.42
	1215		8.33	29.17	62.50
Reference Item (dimethoate)	7.40	(µg a.i./larva/developmental period)	2.08	95.83	2.08

[a] Based on the analysed content of active ingredient (kaolin)
[b] Mean mortality at D15 with respect to the surviving larvae at D8

[c] Mean mortality at D22 with respect to the surviving larvae at D8
[d] With respect to the initial larvae at D3

Toxicity endpoints
In the repeated exposure 22-day larval toxicity test with SURROUND WP, the 22-day NOED value based on adult emergence was determined to be 405 µg kaolin/larva/developmental period. The NOEC value based on adult emergence was determined to be 2.893 mg kaolin/mL diet. The 22-day adult emergence ED_x / EC_x values could not be estimated as no clear dose-response relationship was observed. The calculated endpoints are presented in the following table.

Table B.9.5.1.3/01-4: Toxicity endpoints for honey bee larvae repeatedly exposed for 22 days to Surround WP

Endpoint	µg kaolin/larva/developmental period
22-Day NOED	405
22-Day LOED	1215
22-Day ED_{10}	Not determined [a]
22-Day ED_{20}	Not determined [a]
22-Day ED_{50}	Not determined [a]
Endpoint	**mg kaolin/mL diet**
22-Day NOEC	2.893
22-Day LOEC	8.679
22-Day EC_{10}	Not determined [a]
22-Day EC_{20}	Not determined [a]
22-Day EC_{50}	Not determined [a]

a EDx/ECx values could not be determined as no clear dose-response relationship was observed.

Analytical verification
The analytical methods for determination of total aluminium and total silicon were successfully validated according to guideline SANCO/3029/99 rev.4 (2000) with regards to linearity, precision (repeatability), specificity and accuracy (recovery).

The specificity for the analysis of aluminium or silicon was demonstrated by using a highly specific method (ICP-OES, independent quantification and confirmation wavelengths). Mean recoveries for total aluminium were 97.6% and 98.1% respectively (overall: 98%). The mean recoveries for total silicon were 99.5% and 101.9% respectively (overall: 101%). Therefore, the SANCO requirement that mean recoveries for each level should be in the range 70% - 110% were fulfilled (the 116% for silicon was detected in the lowest test concentration where undoubtedly contamination from glass vial (primarily composed of SiO_2), will be noticeable.

The limit of quantification (LOQ) was confirmed at 0.125 mg/L aluminium and silicon used for ICP analysis. Limit of detection (LOD) is defined as 30% of the LOQ. Therefore, the LOD was found at 0.038 mg/L aluminium and at 0.038 mg/L silicon for these solutions. The SANCO criteria for precision (repeatability) was fulfilled. The relative standard deviation for aluminium was found at 0.32% and 0.95%, respectively (overall 0.72%), and for silicon is was found at 0.36% and 0.16% respectively (overall 1.27%). Linearity was also shown for both aluminium (r^2 = 0.9999) and silicon (r^2 = 1.0000).

Results of the analytical verification are given in the following tables.

Table B.9.5.1.3/01-5: Results of determination of total aluminium

Specimen ID	Total aluminium (mg/mL)	Total Kaolin, calculated from aluminium quantification (mg/mL)	Nominal content of kaolin in stock solution (mg/mL)	Recovery of kaolin in samples (%)
TRC17-184-S1-D4-AS	0.25	1.04	1.07	97
TRC17-184-S2-D4-AS	0.81	3.32	3.21	104
TRC17-184-S3-D4-AS	2.50	10.27	9.64	107
TRC17-184-S4-D4-AS	6.52	26.84	28.93	93
TRC17-184-S5-D4-AR1	18.75	77.19	86.79	89

Table B.9.5.1.3/01-6: Results of determination of total silicon

Specimen ID	Total silicon [mg/mL]	Total Kaolin, calculated from silicon quantification (mg/mL)	Nominal content of kaolin in stock solution (mg/mL)	Recovery of kaolin in samples (%)
TRC17-184-S1-D4-AS	0.31	1.24	1.07	116*
TRC17-184-S2-D4-AS	0.87	3.45	3.21	108
TRC17-184-S3-D4-AS	2.62	10.37	9.64	108
TRC17-184-S4-D4-AS	7.42	29.33	28.93	101
TRC17-184-S5-D4-AR1	21.0	83.12	86.79	96

* Increased value is without much doubt traceable to a contamination from the glass vial (primarily composed of SiO_2), which will be only noticeable at lower silicon concentrations as contained in sample TRC17-184-S1-D4-AS.

Conclusions

In the repeated exposure 22-day larval toxicity test with SURROUND WP, the 22-day No Observed Effect Dose (NOED) value based on adult emergence was determined to be 405 µg kaolin/larva/developmental period. The No Observed Effect Concentration (NOEC) value based on adult emergence was determined to be 2.893 mg kaolin/mL diet. The 22-day adult emergence ED_x / EC_x values could not be estimated as no clear dose-response relationship was observed at the tested dose levels.

Study limitations:

- The temperature fell out of range of 34 ± 2°C for a period exceeding 2 hours

- The commercial royal jelly used for the preparation of the diet was not collected during the preceding 12 months before use.

The identified limitations are not expected to compromise the reliability of the test results.

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 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.				

<table>
<tr><th>Species</th><th>Substance</th><th>Exposure System</th><th>Results</th><th>Reference</th></tr>
<tr><td colspan="5">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.</td></tr>
</table>

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 and a larvae toxicity study with the formulation SURROUND® WP are available. The LDD_{50} 1390 µg a.s./bee/day (worker bee) and the NOED 405 µg a.s./larvae of active substance will be used in the risk assessment.

Grapevine is the representative crop for SURROUND® WP. The product is applied up to four times and at a rate of 30000 g a.s./ha (BBCH up to 65).

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

<u>Acute risk to honeybees</u>

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants while bees are foraging on flowers and weeds present in or adjacent to the crop treated. They may also be exposed through contact with fresh or dry residues or by oral uptake of contaminated pollen, nectar, honey dew and contaminated water. The potential acute risk from use of SURROUND® 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]

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

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
Aluminium silicate	28500	>100*	<285	**50**
SURROUND® WP		>1900*	15	

* Non-valid study. Risk assessment for illustration purposes

Table B.9.6.1.1-1: 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
Aluminium silicate	28500	>100	<285	**50**

The hazard quotients (Q_{HO}) and (Q_{HC}) for oral and contact exposure of bees to aluminium silicate exceed the trigger value of 50, indicating a potential acute oral and contact risk to bees.

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 formulated product SURROUND® WP. 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 SURROUND® 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	28500	>100	<285	>85	**No**

The hazard quotient (HQ) for contact exposure of bees to SURROUND® WP 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 SURROUND® 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?
Honey bee (adults)	Acute contact (treated crop)	28500	>100	1*	285	85	**No**
	Acute contact (weeds)			1 (BBCH<10) 0.6 (BBCH 10-19) 0.5 (BBCH 20-39) 0.3 (BBCH >40)	285 171.0 142.5 85.5	42	**No**
	Acute contact (field margin)			0.027 (BBCH <20) 0.08 (BBCH >20)	7.7 22.8	42	Yes

* Honeybees are attracted to the pollen of grapevines

The hazard quotients (HQ) for contact exposure of bees to SURROUND® WP exceeded the trigger value of 42 (treated crop and weed scenario). The risk to bees in the field margin is acceptable.

Oral exposure

Screening acute oral assessment

Table B.9.6.1.2-3: Screening assessment for oral route of exposure for honeybees for the proposed uses of SURROUND® 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	28.5	10.6	LD_{50} >100 µg a.s./bee*	3.02	0.2	**No**
	Chronic oral	28.5	10.6	LDD_{50} 1390 µg a.s./bee/d	0.217	0.03	**No**
Honey bee (larvae)	Chronic oral	28.5	6.1	NOED 405 µg a.s./larvae	0.43	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	E_f	Short-cut value	twa	Honeybee ETR	Honeybee trigger
acute	treated crop	< 10	1	0.7	1	0.20	0.2
	treated crop	10 - 19	1	10.6		**3.02**	
	treated crop	20 - 39	1	10.6		**3.02**	
	treated crop	40 - 69	1	10.6		**3.02**	
	weeds	< 10	1	3.7		**1.05**	
	weeds	10 - 19	0.6	3.7		**0.63**	
	weeds	20 - 39	0.5	3.7		**0.53**	
	weeds	40 - 69	0.3	3.7		**0.32**	
	field margin	< 10	0.009	3.7		0.01	
	field margin	10 - 19	0.009	3.7		0.01	
	field margin	20 - 39	0.027	3.7		0.03	
	field margin	40 - 69	0.027	3.7		0.03	
	adjacent crop	< 10	0.0047	7.6		0.01	
	adjacent crop	10 - 19	0.0047	7.6		0.01	
	adjacent crop	20 - 39	0.0143	7.6		0.03	
	adjacent crop	40 - 69	0.0143	7.6		0.03	
	following year	< 10	1	0.7		0.20	
	following year	10 - 19	1	0.7		0.20	
	following year	20 - 39	1	0.7		0.20	
	following year	40 - 69	1	0.7		0.20	
chronic	treated crop	< 10	1	0.54	0.72	0.01	0.03
	treated crop	10 - 19	1	8.2		**0.12**	
	treated crop	20 - 39	1	8.2		**0.12**	
	treated crop	40 - 69	1	8.2		**0.12**	
	weeds	< 10	1	2.9		**0.04**	

	weeds	10 - 19	0.6	2.9		0.03	
	weeds	20 - 39	0.5	2.9		0.02	
	weeds	40 - 69	0.3	2.9		0.01	
	field margin	< 10	0.009	2.9		0.00	
	field margin	10 - 19	0.009	2.9		0.00	
	field margin	20 - 39	0.027	2.9		0.00	
	field margin	40 - 69	0.027	2.9		0.00	
	adjacent crop	< 10	0.0047	5.8		0.00	
	adjacent crop	10 - 19	0.0047	5.8		0.00	
	adjacent crop	20 - 39	0.0143	5.8		0.00	
	adjacent crop	40 - 69	0.0143	5.8		0.00	
	following year	< 10	1	0.54		0.01	
	following year	10 - 19	1	0.54		0.01	
	following year	20 - 39	1	0.54		0.01	
	following year	40 - 69	1	0.54		0.01	
	treated crop	< 10	1	0.4		0.02	
	treated crop	10 - 19	1	6.1		**0.36**	
	treated crop	20 - 39	1	6.1		**0.36**	
	treated crop	40 - 69	1	6.1		**0.36**	
	weeds	< 10	1	2.2		0.13	
	weeds	10 - 19	0.6	2.2		0.08	
	weeds	20 - 39	0.5	2.2		0.07	
	weeds	40 - 69	0.3	2.2		0.04	
	field margin	< 10	0.009	2.2		0.00	
larva	field margin	10 - 19	0.009	2.2	0.85	0.00	0.2
	field margin	20 - 39	0.027	2.2		0.00	
	field margin	40 - 69	0.027	2.2		0.00	
	adjacent crop	10 - 19	0.0047	4.4		0.00	
	adjacent crop	20 - 39	0.0047	4.4		0.00	
	adjacent crop	40 - 69	0.0143	4.4		0.00	
	following year	< 10	1	0.4		0.02	
	following year	10 - 19	1	0.4		0.02	
	following year	20 - 39	1	0.4		0.02	
	following year	40 - 69	1	0.4		0.02	

The exposure toxicity ratios (ETR) for oral exposure to SURROUND® WP exceed the respective trigger value for treated crop (acute/chronic/larvae toxicity) and weed (acute and chronic toxicity) scenarios. An acceptable risk is identified for exposure in field margin and adjacent/following crop.

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. Possible sublethal effects on bees from the use of the product SURROUND® WP 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 3.208 mg/L (total season). 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	0.0032	11.4	Acute (adult)	LD_{50} >100 a.s./bee*	0.00	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 1390 µg a.s./bee/d	0.00	0.03	Yes
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	0.00	0.2	Yes
Guttation fluid	0	11.4	Acute (adult)	LD_{50} >100 a.s./bee	0	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 1390 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 a.s./bee	-	0.2	-

Exposure scenario	PEC (µg/µL)	W [a] (µL/bee)	Timescale (life stage)	Toxicity endpoint	ETR_{oral}	Trigger value	Acceptable risk?
		11.4	Chronic (adult)	LDD_{50} 1390 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 acceptable for field margin, adjacent crop and following year scenarios. Further, no unacceptable risk is expected from the exposure to contaminated water sources.

A possible risk to worker bees and larva for the treated crop and weeds scenarios 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 SURROUND® WP 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**

[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.

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

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 SURROUND® WP.

In-field area:

<u>Field studies considered in the previous evaluation of the active substance</u>

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

<u>Additional open literature studies</u>

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 SURROUND® WP 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	

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
Fraser, 2002c	Orchard (apple) 1 season 3 (0.8 ha)	8 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	Ladybirds (Coccinellids), Lacewings (Chrysoperlids), Pirate (*Orius)* Mullein bugs (*Campylomma*).	Slight effect on predatory mites compared to non-toxic reference item (significance not reported)	Around time of application	Beating of 25 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)	3 x 6-10 kg/ha	Not reliable	- poor test design - the NTA counts per sampling event are limited	*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	1 season Belgium	(300 or 500 L/ha) (~ 10 d interval)		- no true replicates - 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	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	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
	6-12 (24-54 trees)			- dose verification unknown - 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	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,	Reduced abundance of arthropods at canopy level (except Lepidoptera)	3 months	Canopy: chromotropic 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
	Italy 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	Neuroptera, Mecoptera, Diptera Soil: Araneae, Crustacea, Isopoda, Coleoptera, Hymenoptera Identified to family level	No significant impact on the soil arthropods communities.		Soil: pit-fall traps
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	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	Beating method PRC and one-way

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
	Spain 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)	Data indicates a trend of population numbers increasing after both applications. Adverse effects are still seen ~2 months after application	ANOVA 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. Based on the information provided by the original DAR a low risk can be concluded for soil organisms.

A waiver is requested for studies on earthworms and other soil macro- and micro-organisms with the formulated product based on the following information:

- SURROUND® WP CROP PROTECTANT is composed of 95% kaolin clay, 4.3% of food-grade additives and 0.7% of well-known additives of no toxicological concern (Please refer to Part C for details on product composition). Therefore, the formulated product is highly unlikely to be of higher toxicity compared to the active substance, kaolin.

- Aluminium silicate (kaolin) used in SURROUND® WP CROP PROTECTANT, is an ultra-pure, ultra-fine, calcined kaolin, a natural white clay mined across the world.

- Aluminium silicate (kaolin) is a natural mineral substance composed of silicon, aluminium and oxygen, just like a variety of other minerals.

- Aluminium silicate is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles, at it is part of said soil particles.

- Aluminium silicate's chemical composition is similar to common clay. From "topsoil physical properties for Europe" (based on LUCAS topsoil data): JOINT RESEARCH CENTRE European Soil Data Centre (ESDAC)[5], it can be noted in the diagram that a large area of Europe consists of 28 to 98% clay based soil. Soil Data Centre (ESDAC), it can be noted in the diagram that a large area of Europe consists of 28 to 98% clay based soil (**Figure B.9.7.3-1**).

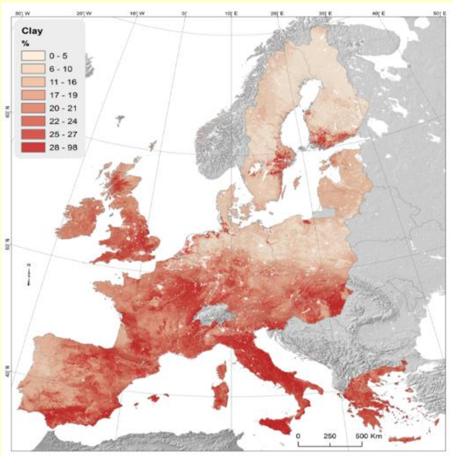

Figure B.9.7.3-1: Clay concentration in European soils (JRC-ESDAC)

- When applied to soil, the aluminium silicate particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the aluminium silicate already existing in the soil. Adsorption and

[5] https://esdac.jrc.ec.europa.eu/content/topsoil-physical-properties-europe-based-lucas-topsoil-data

desorption of aluminium silicate to soil contaminants is therefore well described in regulatory evaluation dossiers as all adsorption/desorption studies involving standard soils will involve aluminium silicate as a soil component.

- The proportion of natural clay in soil varies from 0% in pure sand to 100% in pure clay soil as shown in the following soil diagram. However, agricultural soils normally contain between 5 and 50% clay and therefore, the quantity of kaolin added through the use of SURROUND® WP CROP PROTECTANT will not be enough (the added quantities represent mg/kg soil/year) to cause any measurable increase in the clay (aluminium silicate) content of agricultural soils (**Figure B.9.7.3-2)**.

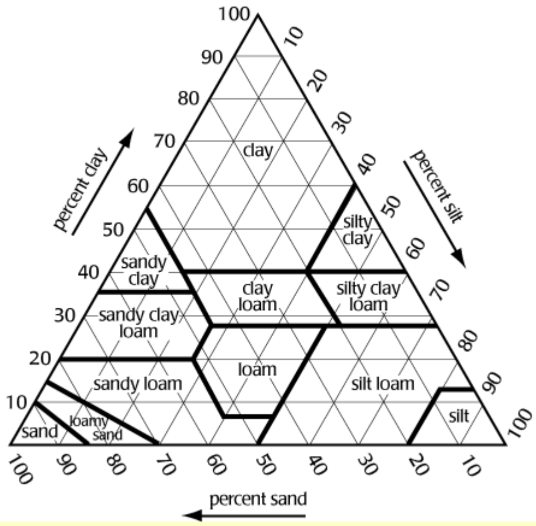

Figure B.9.7.3-1: Soil texture triangle

- The use of SURROUND® WP CROP PROTECTANT in grapevines does not significantly increase the concentrations (PEC_{soil} = 0.024 g/kg per application or 0.096 g/kg total season, please refer to Document MCP, Section 9) of clays in the environment and it is not expected to have any negative effects on soil organisms.

- As detailed in the original DAR (Section B.9.6), it is estimated (Hoerger & Kenaga, 1972) that earthworms contain about 30% soil. Given that soils typically contains between 5-50% clay (see Document MCP, Section 9), earthworms are being continuously exposed to much higher concentrations of aluminium silicate (kaolin) than any that might arise from the use of SURROUND® WP CROP PROTECTANT.

- Kaolin does not translocate in plants, nor is it bioavailable, and therefore it cannot be readily transported through the gut wall of animals.

- Aluminium silicate (kaolin) occurs naturally in most soils and the quantity of kaolin added through the use of SURROUND® WP CROP PROTECTANT will not cause any measurable increase in the clay (aluminium silicate) content of agricultural soils. The agricultural use of SURROUND® WP CROP PROTECTANT therefore is not expected to have any negative effects on soil organisms, including earthworms. On the contrary, the use of kaolin as a replacement of conventional pesticides could help to improve soil conditions through the elimination of potentially harmful residues of synthetic compounds within the soil

Risk assessment for earthworms

No toxicity endpoints are available and therefore the risk assessment could not be provided. For further details please refer to discussion above.

Conclusion: Overall, exposure to aluminium silicate (kaolin) resulting from the use of SURROUND® WP CROP PROTECTANT in grapevines is minimal compared to its natural presence in the environment. Therefore, adverse effects to soil organisms is concluded to be low and the request for toxicity studies and conventional EU risk assessments are not considered necessary for a non-toxic, non-bioavailable, routinely ingested natural mineral such as kaolin clay as was reported in the EFSA Conclusion for aluminium silicate (2012).

In light of these considerations, no toxicity testing with macro or micro soil organisms with the formulated product is considered to be necessary for the purposes of renewal and the risk to soil organisms is concluded to be low.

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). 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 SURROUND® WP CROP PROTECTANT.

A waiver was requested by the Applicant, as was accepted during the initial EFSA review (EFSA, 2012), for a stdy on the chronic toxicity to earthworms based on the information provided above, point CP 10.4.1, which still applies. Furthermore, according to OECD 207 or 222, for the preparation of the artificial soil test substrate used in the earthworm toxicity tests, 20% kaolin clay (kaolinite content preferably above 30%) is indicated as part of the dry constituents of the substrate.

As a comparison, overspray on bare soil with SURROUND® WP CROP PROTECTANT at a rate of 50 kg/ha would result in deposits of 5 g/m2. Based on a standard soil density of 1.5 g/cm3, and soil layer thickness of 5 cm, this deposition of kaolin following application of SURROUND® WP CROP PROTECTANT represents less than 0.01% of the soil weight (i.e. far lower than the 20% kaolin used in standard ecotoxicity tests).

In light of these considerations, no toxicity testing with earthworms on the formulated product is considered to be necessary and the risk to soil organisms is concluded to be low.

B.9.7.2.1 Chronic toxicity testing with earthworm

No additional data/study with the representative formulation SURROUND® WP CROP PROTECTANT was performed.

Conclusion: The long-term risk of Aluminium Silicate and its metabolites is acceptable for earthworms following the intended uses of SURROUND® WP CROP PROTECTANT.

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

No studies are available for non-target soil meso- and macrofauna, nor are they required.

A waiver was requested for studies on other soil macro- and micro-organisms with the formulated product based on the information provided above for earthworms, point M-CP, Section B.9.7.5. Furthermore, according to OECD 232 (Collembolan Reproduction Test in Soil) and OECD 226 (Predatory mite (*Hypoaspis* (Geolaelaps) *aculeifer* reproduction test in soil), for the preparation of the artificial soil test substrate used in these reproductive toxicity tests, 20% kaolin clay (kaolinite content preferably above 30%) is indicated as part of the dry constituents of the substrate.

As a comparison, overspray on bare soil with SURROUND® WP CROP PROTECTANT at a rate of 50 kg/ha would result in deposits of 5 g/m^2. Based on a standard soil density of 1.5 g/cm^3, and soil layer thickness of 5 cm, this deposition of kaolin following application of SURROUND® WP CROP PROTECTANT represents less than 0.01% of the soil weight (i.e. far lower than the 20% kaolin used in standard ecotoxicity tests).

In light of these considerations, no toxicity testing with soil organisms on the formulated product is considered to be necessary and the risk is concluded to be low.

Therefore, the risk for non-target soil microorganisms is considered to be very low.

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 SURROUND® WP CROP PROTECTANT was performed. Please refer to Section B.9.6 and Section B.9.7 of the present Document for justification.

B.9.7.3.2 Higher tier testing

No additional data/study with the representative formulation SOKALCIARBO WP was performed. Higher tier data are not required as the risk for non-target soil microorganisms is considered to be very low.

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

No risk assessment could be performed since toxicological endpoints were not available. For justifications, please refer to Sections B.9.6 and B.9.7 of the present Document.

Conclusions:
The long-term risk of Aluminium Silicate is acceptable for non-target soil meso- and macrofauna other than earthworm following the intended uses of SURROUND® WP CROP PROTECTANT.

B.9.9 EFFECTS ON SOIL NITROGEN TRANSFORMATION

No additional data/study with the representative formulation SURROUND® WP CROP PROTECTANT was submitted.

B.9.10 RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION

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

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

B.9.11 EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

Based on the following justifications, no studies on toxicity of SURROUND® WP CROP PROTECTANT for non-target terrestrial plants are provided.

- SURROUND® WP CROP PROTECTANT is composed of 95% kaolin clay, 4.3% of food-grade additives and 0.7% of well-known additives of no toxicological concern (Please refer to Part C for details on product composition). Therefore, the formulated product is highly unlikely to be of higher toxicity compared to the active substance, kaolin.

- Aluminium silicate (kaolin) as SURROUND® WP CROP PROTECTANT is currently used outside Europe as an insect repellent and a protection against sunburn in fruit bearing vascular plants such as pears, apples, olives or peppers.

- Aluminium silicate is efficacious as an insect repellent and can improve fruit quality through heat protection. There have been no side effects to the use of aluminium silicate (kaolin) other than a slight maturation delay, without any reduction in the quality of the crop (Glenn and Puterka, 2005[6]).

- Aluminium silicate (kaolin) occurs naturally in most soils and the quantity of kaolin added through the use of SURROUND® WP CROP PROTECTANT will not cause any measurable increase in the clay (aluminium silicate) content of agricultural soils (refer to section 10.4.1 above). The agricultural use of SURROUND® WP CROP PROTECTANT therefore is not expected to have any negative effects on non-target terrestrisal plants. On the contrary, the use of kaolin as a replacement of conventional pesticides could help to improve soil conditions through the elimination of potentially harmful residues of synthetic compounds within the soil.

- Aluminium silicate (kaolin) is inert and will not be absorbed or metabolised by plants.

- Aluminium silicate has no known mode of toxicity, is insoluble in water and does not become bioavailable. Hence, it is not bioavailable to plants.

- In a root growth inhibition study by Wang *et al.* (2011[7]), seedlings of four different plants (tomato, cucumber, lettuce and carrot) were exposed to concentrations up to 2000 mg kaolin solution/L for 4 days. Results showed that kaolin suspension had no obvious phytotoxicity on all treated plants (no adverse effect of root length).

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

[6] Glenn, D.M., and Puterka, G.J., 2005. Particle Films, A New Technology for Agriculture. Horticultural Reviews. Vol 31. Edited by Janick K. John Wiley & Sons, Inc
[7] Wang, M., Chen, L, Chen, S. and Ma, Y. (2011). Alleviation of cadmium-induced root growth inhibition in crop seedlings. Y nanoparticles. Ecotoxicology and Environmental Safety 79 (2012): 48-54.

B.9.11.1 SUMMARY OF SCREENING DATA

No studies on toxicity of SURROUND® WP CROP PROTECTANT for non-target terrestrial plants are provided. Please refer to waiver in Section B.9.11.

B.9.11.2 TESTING ON NON-TARGET PLANTS

No additional data submitted. Justification is provided in Section B.9.11 of the present Document.

B.9.11.3 EXTENDED LABORATORY STUDIES ON NON-TARGET PLANTS

No studies on toxicity of SURROUND® WP CROP PROTECTANT are provided.

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

No studies on toxicity of SURROUND® WP CROP PROTECTANT are provided.

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

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

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

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

Aluminium silicate (kaolin) is non-toxic, non-bioavailable and inert to mammals, fish, birds, arthropods and plants. SURROUND® WP CROP PROTECTANT's mode of action is one of repellency through the establishment of a particle film barrier. No additional testing on non-target organisms is required.

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

No studies on toxicity of SURROUND® WP CROP PROTECTANT are provided and therefore no risk assessment was 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 SURROUND® WP CROP PROTECTANT.

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
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.
KCP 10.3.1.1.1/01	Goodband, T.J.	2006	Surround WP crop protectant: Acute toxicity to honeybees (*Apis mellifera*) Report number: 2120/0005 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.
KCP 10.3.1.2/01	Ansaloni, T.	2019	Effects of Surround WP – Chronic oral toxicity to adult worker honey bees, *Apis mellifera* L. under laboratory conditions Report number: TRC17-208BA TrailCamp GLP Unpublished	N	Y	New data in support of submission	Tessenderlo Group N.V.
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.

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 10.3.1.6/02	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.
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.

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 10.3.2.4/04	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.
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.

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 10.3.2.4/08	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	

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
	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	