European Commission

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

Aluminium Silicate Calcined (Kaolin Calcined)

Volume 3
Annex B.9 (AS)
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 active substance 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 active substance 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). It should be noticed that the applicants for the Annex I inclusion of the a.s. Aluminium Silicate are the following: I. Task Force SOKA and II. Task Force TESSENDERLO GROUP N.V. In each section first, the previous DAR evaluation is presented and then the individual data submitted by each Task Force. Whenever possible, and in case of non-protected data, the provided information has been merged in order to present a concrete and easy to follow summary for each endpoint/section.	

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B.9 ECOTOXICOLOGY DATA

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.

Two Task Forces support the renewal of approval of **Aluminium Silicate**, the Task Force **SOKA** with the representative formulation **SOKALCIARBO WP** and the Task Force **TESSENDERLO GROUP N.V.** with the representative formulation **SURROUND® WP CROP PROTECTANT**.

B.9.1 EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.1.1 EFFECTS ON BIRDS

No new avian toxicity data are available for the renewal of aluminium silicate (kaolin). As discussed in the original DAR (Section B.9.1), considering the nature of the active substance and that it is a widespread element of the environment to which wildlife will often be exposed; it has been concluded that the risk to non-target organisms from the representative use of aluminium silicate (kaolin) will be low (EFSA, 2012).

According to the Regulation (EC) No 1107/2009 the use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, tests on vertebrate animals must be replaced, restricted or refined.

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

- Aluminium silicate is a natural inert component of the environment in, therefore any terrestrial vertebrate species eating soil-dwelling organisms routinely consume naturally Aluminium silicate; Furthermore, for a reason of protection against temporary and chronic gastrointestinal distress and of food supplement, the deliberate consumption of earth materials (including Kaolin and Kaolinite – 14 to 19%), is commonly observed for animals, but also for humans in form of medicals (Dominy N.J. et al., 2004; Pebsworth P.A., et al., 2013; Ta C.A.K. et al., 2017). In addition, in the paper published in 2013 (Pebsworth P.A., et al.) has shown that baboons have a clear preference for white soil composed of Kaolinite and illite with minor amounts of goethite, montmorillonite, and hydrated halloysite.

- As detailed in the original DAR (Section B.9.1), aluminium silicate (kaolin) is a natural component of the environment and birds are routinely exposed to kaolin in the soil and through other sources. In addition, no adverse effects have been observed upon birds in the areas where kaolin has been routinely mined for decades.

- As detailed in the original DAR (Section B.9.1), many birds are known to take clay dust baths to help reduce dermal parasites (Martin and Mullens, 2012, Mullens et.al.2012).

- As detailed in the original DAR (Section B.9.1), some birds like the macaw, have even been observed to eat kaolin for the purpose of aiding their digestive systems. The consumption of soil by the parrot has been studied extensively for decades (Brightsmith *et al.*, 2010) and is noted to also be attributed to the animals' search for minerals, which are deficient in their diets, might also protect the birds from dietary toxins, treat ionic imbalance, stabalise gut pH, reduce intestinal parasitism, and reduce diarrhea. The parrots are also known to feed soil to their chicks.

- As detailed in the original DAR (Section B.9.1), birds that eat earthworms and other soil dwelling invertebrates routinely consume soil (hence clay) adhering to the prey and present in their digestive tracts.

- It has been reported that animal feed containing clay minerals such as kaolin promote weight gain and feed efficiency (Mumpton, 1999), reduce bacterial contamination of the guts and reduce the detrimental effects of mycotoxin contaminated diets (Tauqir and Nawaz, 2001).

- As detailed in the original DAR (Section B.9.1), aluminium silicate (kaolin) is inert and insoluble in aqueous and organic solvents. It does not become bioavailable when ingested. Experience has shown it is not absorbed through the gut wall.
- Similar products have been approved by EFSA when used as technological additive for animal species, such as Friedland clay (EFSA Journal 2014;12(11): 3904) and natural mixture of illite, montmorillonite and kaolinite (EFSA Journal 2016;14(1): 4342), to aid in fattening chickens.
    - Friedland clay is typically composed of the major constituents montmorillonite, illite, quartz and kaolin. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concludes that 20,000 mg Friedland clay/kg complete feed is safe for target species (chickens, sows, dairy cows and cattle)/categories and extends this conclusion to all animal species.
    - A natural mixture of illite, montmorillonite and kaolinite with a minor amount of calcite and sanidine, is regarded as safe by FEEDAP as an additive in feeding stuffs for all animal species at a maximum concentration of 50,000 mg/kg.

- In light of these considerations and for animal welfare reasons, unnecessary animal testing should be avoided for a non-toxic, non-bioavailable, routinely ingested natural mineral such as kaolin clay. Therefore, no additional acute oral avian toxicity testing with the active substance is considered necessary for the purposes of renewal, as supported during the initial Annex I approval and no avian data were specified as required in EFSA (2012).

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

Table Σφάλμα! Δεν υπάρχει κείμενο καθορισμένου στυλ στο έγγραφο.**.1-1: Toxicity endpoint for birds**

Species	**Substance**	**Exposure System**	**Results**	**Reference**
Gallus gallus domesticus	Kaolin	Dietary,56 d Subchronic	LD_{50} >30,000 mg a.s./kg diet (ppm) (>2444 mg/kg bw/d)*	Owen *et al.*, (2012) Published ref (KCA 8.1.1.3/01)

B.9.1.1.1 Acute oral toxicity to birds

There were no new studies submitted by the Notifier for the purpose of the active substance's renewal.

B.9.1.1.2 Short-term dietary toxicity to birds

According to the data requirements for active substances under the Commission Regulation (EU) No 283/2013, a study on the short-term dietary (five-day) toxicity to birds shall only be required where the mode of action or results from mammalian studies indicate a potential for the dietary LD_{50} measured by the short-term dietary toxicity study to be lower than the LD_{50} based on an acute oral study. Further, according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438), the short-term avian risk assessment formerly required by SANCO/4145/2000 is now subsumed by the long-term avian risk assessment and is consequently redundant.

B.9.1.1.2/01

Reference	KCA 8.1.1.3/01, Owen, O.J., Nodu, M.B., Dike, U.A., Ideozu, H.M., 2012, Greener Journal of Agricultural Sciences Vol. 2(6): 233-236
Guideline	No guidelines indicated.
GLP/QA	No/No
Previous evaluation	No
Validity/Acceptance	No/Supportive information

Material and methods

Test substance	Kaolin
Vehicle	Commercial broiler starter and finisher diets
Test species	Hubbard strain broiler chickens; 120 days old at the test start; individual body weight at the test start: 60 g
Test concentrations	10, 20, 30 g/kg, control
Test groups	3 test group/treatment, 10 birds/test group randomly assigned.
Test design/methodology	At the expiration of the experiment, all the birds were weighed and 3 birds were selected from each treatment for histological assay.
Test conditions	Food and water were available ad libitum. Birds housed in a deep litter with wood shavings as bedding material.
Parameters tested	food consumption (daily), body weight (weekly)
Endpoint(s)	Not obtained
Analytics	Not reported
Statistics	All the data collected were subjected to Analysis of Variance and the differences in treatments, where it existed was separated using Duncan's New Multiple Range Test (DNMRT).

Findings

Biological results:

The food consumption and the body weight gain of the birds is shown in table 9.1.1.2-1

The food consumption was higher in the control than in the other treatments and there was statistically significant difference. There was no statistically significant difference in body weight among the treatment levels. There was a statistically significant change in gizzard and liver weights. Chickens exposed to kaolin had decreased gizzards and livers but no specific pattern could be observed among the treatment levels.

Table 9.1.1.2-1: Performance characteristics of broiler chickens fed with kaolin diets

Parameter	Treatment			
	Control	10 g kaolin/kg	20 g kaolin/kg	30 g kaolin/kg
Mean initial weight (g)	60.00	60.00	60.00	60.00
Mean final weight (kg)	2.25	2.18	2.10	2.23
Mean total weight gain (kg)	2.20	2.12	2.04	2.23
Mean daily weight gain (g)	39.30	37.85	36.43	38.75
Mean total feed intake (kg)	5.10 [a]	4.70 [b]	4.90 [b]	4.90 [b]
Mean daily feed intake (g)	91.07 [a]	83.93 [c]	87.50 [b]	85.71 [c]
Feed conversion ratio (feed/gain)	2.32 [b]	2.23 [a]	2.40 [b]	2.21 [a]

a, b, c: means within the same rows with different letters are significantly different ($p < 0.05$)

Conversion from ppm to mg as/kg bw/d

For the conversion of doses from ppm (mg substance/kg diet) to mg as/kg bw/d it is needed to multiply the dose in ppm with daily food consumption per bird. If the daily food consumption is not available in the study report, we can use the total consumption and find the average daily consumption by dividing with the number of days. The result until now is the mg of substance that the animal has consumed each day. If we divide this number with the bodyweight of the animal that has consumed the diet, then we get the mg of the active substance per kg of bodyweight per day. It is important to note that the food consumption and bodyweight should be in the same units (whether grams or kilograms).

In this specific study the mean daily food consumption per bird per day and the mean initial and final weight is reported (table 9.1.1.2-1).

Table 9.1.1.2-2: Conversion from g as/kg diet to mg as/kg day

Parameter	Treatment			
	Control	10 g kaolin/kg	20 g kaolin/kg	30 g kaolin/kg
Mean initial weight (kg)	0.06	0.06	0.06	0.06
Mean final weight (kg)	2.25	2.18	2.10	2.23
Mean weight (kg)	1.16	1.12	1.08	1.13
Mean daily feed intake (kg)	0.091	0.084	0.088	0.086
Dose in mg as/kg day	**0**	**784**	**1500**	**2444**

Conclusion

Weight gain was not affected by different concentrations of kaolin in the diet. This was not the case for food consumption which presented significant differences among treatment levels. The highest reduction was observed at 10g/kg diet which was 7.8%. Liver and Gizzard weight reduction was also statistically significant and higher than 10% (19% at dose 30g/kg diet and 14%at dose 20g/kg respectively).

Soka has been submitted M. Safaeikatouli (2012) study that have been summarised in the dossier submission. However, it is ZRMS opinion that this study cannot derive useful toxicity endpoints, since mortality and behavioural changes are not observed in this study. It is more relevant to the Protein and Energy efficiency Ratios.

B.9.1.2 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

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

B.9.1.3 ACTIVE SUBSTANCE BIOCONCENTRATION IN PREY OF BIRDS AND MAMMALS

In accordance with Commission Regulation (EU) No 284/2013, an assessment of the potential risk posed by bioconcentration in the prey of birds and mammals shall be provided for substances with a log Pow >3. Aluminium silicate (kaolin) is not lipophilic and is not soluble in water. In addition, as aluminium silicate is inorganic, partition coefficient information is not considered relevant (see Document M-CA, Section 2). Therefore, it can be classified as not bio-accumulative, hence an assessment for bioconcentration in prey for birds and mammals is not necessary.

B.9.1.4 OTHER DATA ON EFFECTS ON TERRESTRIAL VERTEBRATE WILDLIFE (BIRDS, MAMMALS, REPTILES AND AMPHIBIANS)

No additional studies on other terrestrial vertebrates are required. The literature search carried out by the Notifier did not reveal any additional studies on terrestrial vertebrates including reptiles and amphibians.

B.9.1.5 POTENTIAL FOR ENDOCRINE DISRUPTION

In order to determine whether aluminium silicate calcined exhibits ED properties, the RMS has considered the assessment strategy proposed in the EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No. 528/2012 and (EC) No. 1107/2009 (EFSA Journal 2018;16(6):5331).

According to the aforementioned Guidance: "There may be cases in which due to the knowledge on the physico-chemical and (eco)toxicological properties of the substance an ED assessment does not appear scientifically necessary or testing for this purpose not technically possible (BP Regulation1, Annex IV or PPP Regulation,2 Annex, Point 1.5). In such cases, it should be justified for PPPs (Commission Regulation (EU) No 283/20137) or the general rules for adaptation of the data requirements set out in Annex IV of the BP Regulation1 shall be followed or, for PPPs, used as examples. However, it needs to be considered if possible adaptations would apply to the ED assessment in its entirety or only with respect to humans or non-target organisms."

Aluminium silicate as a natural inorganic mineral, it is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested. Consequently, it is not distributed in the tissues and it is not metabolized. On the basis of this argumentation, short-term, long-term/carcinogenicity and reproductive toxicity data were not provided and were not considered necessary.
Thus, although EATS-mediated adversity has not been sufficiently investigated, no particular concern is raised, and no further data are required. There is no information from the US-EPA Chemistry Dashboard on endocrine activity.

According to the notifier a literature review revealed no information on endocrine disrupting properties of Aluminium silicate in birds and mammals. Based on the results reported in the Tox Section (Volume_3CA_B-6), in combination with the low toxicity referred on the acute aquatic toxicity tests (literature reviews), there is no indication that aluminium silicate undergoes endocrine disrupting properties.

Thus, due to the knowledge on ADME and physico-chemical properties of aluminium silicate, an ED assessment for humans and non-target organism groups does not appear scientifically necessary and testing for this purpose is not considered technically possible (reference to Figure 1, Note b of the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009).

B.9.2 EFFECTS ON AQUATIC ORGANISMS

Aluminium silicate is present in most water bodies across the world, either as sediment or as suspended particles without any cases of toxicity to aquatic organisms ever being reported. Aluminium silicate is insoluble in all organic liquids, water, and non-bioavailable to aquatic organisms. Aluminium silicate can have an impact on aquatic organisms through turbidity or sediment deposition. These phenomena occur naturally through floods or storms and can be caused by man through dredging operations or artificial impoundment around dams, reservoirs. However, the amounts of Aluminium silicate necessary to cause turbidity or sediment deposition of a high enough level to negatively impact aquatic organisms are many orders of magnitude higher than any that could result from the use of Aluminium silicate as a plant protection product.

No new data are available for aquatic organism toxicity since the first approval of aluminium silicate (kaolin) (EFSA, 2012). Information found in the public domain regarding the toxicity of Aluminium silicate to aquatic organisms confirm the low acute and chronic toxicity of Aluminium silicate.

Details of these studies (literature) have been provided in the previous EU DAR and are re-evaluated in the relevant sections below.

During the initial EU evaluation, a data gap for algae was identified and new data were submitted with both formulated products (Surround WP and Sokalciarbo) to support the renewal for the algae endpoint, along with an acute Daphnia magna study with Surround WP.

Table B.9.2-1: Summary of the toxicity of Aluminium silicate to aquatic organisms

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)

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
Oncorhynchus kisutch & Oncorhynchus mykiss	48 hr (flow-through)	Aluminium silicate	LC_{50}: >4000 mg/l (nominal)*	B.9.2.1/04 Redding, Schreck, & Everest (1987)
Long-term fish				
Oncorhynchus mykiss	64 days (semi-static)	Aluminium silicate	NOEC: 1017 mg/l (nominal)*	B.9.2.2/01 Goldes et al. (1988)
Oncorhynchus mykiss	30 days (ELS) (static)	Aluminium silicate	NOEC: 100 mg/l (nominal)	B.9.2.2.1/01 Hashimoto et al., (1986)
Acute aquatic invertebrates				
Cancer magister	200h (flow through)	Aluminium silicate	LC_{50}: 32000 mg/l (nominal)	B.9.2.4.1/01 McFarland, V. A. and Peddicord, R. K. (1980)
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

B.9.2.1 ACUTE TOXICITY TO FISH

Active substance

B.9.2.1/01

Reference Isono, R.S., Kita, J., and Setoguma, T. 1998
Acute effects of kaolinite suspension on eggs and larvae of some marine teleosts
Comparative Biochemistry and Physiology Part C (1998) volume 120, pages 449-455

Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	No / No

Material and methods

Test substance	Kaolinite Description: the dry material had a median particle size of 4.0 µm. Purity: not specified Lot/batch no: 117-100025, Wako Pure Chem, Japan.
Test species	Pelagic eggs of red seabream (Pagus major), black seabream (Acanthopagrus schlegeli), striped beakperch (Oplegnathus fasciatus) and Larvae of red seabream (Pagus major), striped beakperch (Oplegnathus fasciatus) and threeline grunt (Parapristipoma trilineatum
Test concentrations	Groups of 20 eggs at 2-32 cell stages were exposed to 0 (control), 320, 1000, 3200, 10000 mg/L nominal suspended kaolinite concentrations. This test was run in triplicate. Groups of 10 previously unexposed larvae were exposed to 0 (control), 32, 100, 320, 560, 1000, 3200, 5600 and 10000 mg/L nominal suspended kaolinite concentrations. One to three groups were tested at each concentration
Test groups	20 eggs and 10 larvae per replicate per treatment
Duration	Eggs and larvae were exposed over a period of 24 and 12 hours respectively.
Test conditions	For tests on both eggs and larvae, the apparatus consisted of six exposure bottles containing 35 ml, rotating around a horizontal axis once every 10 seconds in order to maintain the kaolinite in suspension. All exposure test were carried out in a room kept at a constant temperature of 20 0C. Dissolved oxygen concentration (DO) and pH was checked at the start and end of each exposure test. DO was over 85 % and pH ranged between 8.0 and 8.3 in all experiments.
Parameters tested	Hatching success, Mortality i.e. absence of respiratory movement /absence of response to physical stimulation
Endpoint(s)	-
Analyticals	Not available
Statistics	Data were subjected to analysis of variance (ANOVA) and regression analysis.

Findings

Analytical results:

Nominal concentrations were used. No further information is available regarding the analytical method.

Biological results:

- Eggs: Hatching success and developmental rates in the eggs of all species were not significantly affected by 10000 mg/L suspension over a 24 h exposure period. During the exposure, it was clearly observed that the appearance of eggs changed from clear to white due to the adhesion of kaolinite particles onto the surface of eggs.

- Larvae: Larvae showed elevated mortalities with kaolin exposure, implying that they are more sensitive to suspended kaolinite than eggs. The LC50 values for O. fasciatus were estimated at 710 mg/l (12h) and for P. trilineatum at 6200 mg/l (1h), 1500 mg/l (3h), 170 mg/l (12h). Over 50% mortality also occurred in larvae of P. major when exposed to 1000 mg/L for 12h. Kaolinite particles readily adhered to the body of P. major larvae at or above concentrations of 320 mg/L. However, even when the larvae were completely covered with kaolinite most still survived and responded to external stimuli. In contrast, larvae of the other two species showed little adherence of kaolinite particles although they were more sensitive overall.

Conclusion:

The LC50 values for O.fasciathus larvae were estimated at 710 mg/L (12h), for P.trilineatum larvae at 170 mg/L (12h) and for P.major larvae at 1000 mg/L (12h), based on nominal exposure concentrations.

In the case of eggs, the no observed effect concentration (NOEC) after 24 h was 10000 mg/kaolinite/L, the highest concentration tested at and below which there was no significant effect on the hatching success and developmental rates in the eggs of all species.

Study deviations:

This test was not designed as a regulatory study, but for fundamental research. RMS considers that the highly agitated particle motion needed in the experiment has increased abrasive effects and therefore is mainly responsible for the mortality of kaolinite-exposed larvae. Larvae are vulnerable to any abrasive effects. The results of the test are not considered valid for risk assessment

B.9.2.1/02

Reference	McFarland, V. A. and Peddicord, R. K. (1980). Lethality of a suspended clay to a diverse selection of marine and estuarine macrofauna. Archives of Environmental Contamination and Toxicology (1980), volume 9, pages 733-741. US Army Engineer Waterways Experiment Station, Vicksburg, Mississippi, USA.
Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	Yes / Yes

Material and methods

Test substance	Kaolin. Description: the dry material had a median particle size of 4.5 mm. Purity: not specified. Lot/Batch no.: hydrite flat D.
Test species	Naturally occurring marine and estuarine fish and invertebrates: Sea

	urchin (Strongylocentrotus purpuratus), Japanese clam (Tapes japonica), hermit crab (Pagurush hirsutiusculus), isopod (Sphaeroma pentodon), mud snail (Nassarius obsoletus), blue mussel (Mytilus edulis), tunicate (Molgula manhattensis), tunicate (Styela montereyensis), coast mussel (Mytilus californianus), spot tailed sand shrimp (Crangon nigromaculata), grass shrimp (Palaemon macrodactylus), Dungeness crab (Cancer magister), polychaete (Neanthes succinea), tunicate (Ascidia ceratodes), amphipod (Anisogammarus confervicolus), English sole (Parophrys vetulus), shiner perch (Cymatogaster aggregate). Fish were juvenile, total length and mean weight were not specified
Test concentrations	The laboratory system was a flow-through system of 16 hemispherical 75-L aquaria supplied with suspended kaolin and a complementary volume of dilution water at estuarine or oceanic salinity. The highest nominal concentration tested was 117g/L.
Test groups	For the mud snail and the blue mussel, the 16 aquaria were arranged into 4 replicates, each consisting of a control and 3 kaolin concentrations. For all the other species, the 16 aquaria were arranged into 2 replicate sets of 8, each consisting of 2 controls and 6 concentrations of kaolin.
Duration	100 h, 200 h, 5-12 days.
Test conditions	The water-quality parameters (pH, D.O., salinity, temperature and suspended solids) were continuously monitored. All experiments were conducted within + 2oC of the temperature and + 3 o/oo of the salinity at which the animals were collected. Fish and crustaceans were fed a diet of adult brine shrimp or chopped squid. Invertebrates other than the crustaceans were not fed. The laboratory facility kept the major physical parameters stable at the desired levels. The pH decreased from about 7.8 in the clear water control aquaria to about 6.8 in 117 g/L suspended kaolin. Dissolved oxygen was maintained near saturation. Mean salinities remained at the collection and mean temperature in each aquarium remained at the set point value.
Parameters tested	Mortality
Endpoint(s)	200-hr LC50 = 3 g suspended kaolin /L (*Cymatogaster aggregata)* 200-hr LC50 = 70-117 g suspended kaolin /L (*Parophrys vetulus*) 200-hr LC50 = 32 g/L (*Cancer magister*) 5-d LC50 >100 g/L (*Nassarius obsoletus*) 200-hr LC50 = 48 g/L (*Neanthes succinea*)
Analyticals	Suspended solids concentrations were determined at approximately 8-hr intervals. The suspended solids sensor was a Densitrol (Princo Instruments, Inc, Southampton), which was calibrated against gravimetrically analyzed samples pipetted directly from the test aquaria.
Statistics	The lethal concentration values (LC50,) were calculated with the logit method of Berkson (1953). These LC values were regressed on exposure time to estimate the time-concentration mortality response.

Findings

Analytical results:

Suspended solids concentrations remained close to the desired levels in each aquarium with standard deviation of about 10 % of the mean values, therefore LC values were based on nominal exposure concentrations

Biological results:

A very wide range of sensitivities to suspended kaolin was observed among the 17 species studied. There seemed to be some correlation between normal habitat of the species and sensitivity to suspended kaolin. Eight species, those whose natural habitat are soft muddy bottoms, were found to be relatively insensitive. They had < 10 % mortality in the length of time during which they were exposed (5-12 days). A variety of species were found to be more sensitive. For these species 200-hr LCx values were estimated. The tests with Ascidia ceratodes, Anisogammarus confervicolus, and Cymatogaster aggregata were all terminated in less than 200 hr, because of high mortality.

Species[a]	**Exposure time**	**LC_{50} (g/L)**
Strongylocentrotus purpuratus	9 days	>100
Tapes japonica	10 days	>100
Pagurush hirsutiusculus	12 days	>100
Sphaeroma pentodon	12 days	>100
Nassarius obsoletus	5 days	>100
Mytilus edulis (2.5 cm)	5 days	>100
Mytilus edulis (10 cm)[b]	11 days	>100
Molgula manhattensis	12 days	>100
Styela montereyensis	12 days	>100
Mytilus californianus	200 hr	96
Crangon nigromaculata	200 hr	50
Palaemon macrodactilus[c]	200 hr	>77
Cancer magister	200 hr	32
Neanthes succinea	200 hr	48
Ascidia ceratodes	100 hr	38
Anisogammarus confervicolus	100 hr	78
Parophrys vetulus	200 hr	70-117
Cymatogaster aggregata	100 hr 200 hr	6 3
[a] Species grouped together were tested simultaneously in the same aquaria. [b] Tested simultaneously in the same aquaria with *Mytilus californianus.* [c] Tested simultaneously in the same aquaria with *Anisogammarus confervicolus*		

Conclusion:

The shiner perch (Cymatogaster aggregata) was the most sensitive fish species studied, with a 200-hr LC50 of 3 g suspended kaolin /L. Moreover, for *Parophrys vetulus* the 200-hr LC50 was 70-117 g suspended kaolin /L. The most sensitive crustacean tested was the dungeness crab (Cancer magister), with a 200-hr LC50 of 32 g/L. The estimated lowest 5-d / 200-hr LC50 for gastropods (Nassarius obsoletus) and sediment dwellers (Neanthes succinea) was >100 and 48 g/L respectively.

Study deviations:

This test was not designed as a regulatory study, but for fundamental research. However, it is considered to be valid and is accepted.

B.9.2.1/03

Reference	Sherk, J. A. Jr., O'Connor J. M., Neumann, D. A., Prince, R. D., Wood, K. V. (1973). Effects of Suspended and Deposited Sediments on Estuarine Organisms, PHASE II, U.S. Department of Commerce, National Technical Information Service. University of Maryland, Solomon's Natural Resources Institute., USA
Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	Yes / Yes

Material and methods

Test substance	Kaolin: Description: the dry material had a median particle size of 0.55 mm. Purity: not specified. Lot/Batch no.: hydrite -10, Georgia kaolin Co. Fuller's earth: Purity: technical grade. Lot/Batch no.: Fisher F-90.
Test species	Estuarine fish: Menhaden (Brevoortia tyrannus), Bay anchovy (Anchoa mitchilli), Striped killifish (Fundulus majalis),Mummichlog (F. Heteroclitus), Cusk eel (Rissola marginata), Atlantic silverside (Menidia menidia), Striped bass (Morone saxatilis), White perch (M. Americana), Spot (Leiostomus xanthurus), Croaker (Micropogon undulatus), Weakfish (Cynoscion regalis), Hogchoker (Trinectes maculatus), Bluefish (Pomatomus saltatrix), Oyster toadfish (Opsanus tau).
Test concentrations	Eleven of the fourteen species were exposed to suspensions of kaolinite, because insufficient numbers of bluefish, cusk eel and bay anchovy were collected. Five groups of test specimens were exposed to suspended solids at four different concentrations and a control simultaneously. Concentrations of particles (up to 140 g/L) varied depending upon the species being tested, and whether the duration of the test was to be 12, 18, 20, 24, or 48 hours.
Test groups	Five groups of test specimens were exposed to suspended solids. Not available number of animals.
Duration	Fish exposed over a period of 12-48 hours
Test conditions	The fish were exposed to suspended solids in 27 litre polyethylene tanks. Temperatures were maintained within + 1.50C by immersing the test tanks in a circulating water bath. Tanks were checked for temperature, pH and dissolved oxygen. The fish were tested at a median temperature of 22 / 250C. Salinity range during test was 18 to 30 / 5.5 0/00.
Parameters tested	mortality, occurrence of sublethal effects (loss of equilibrium, erratic

	swimming, loss of reflex, excitability, discoloration, or change in behaviour)
Endpoint(s)	48h LC50 >140000 mg/L
Analyticals	Not available
Statistics	Lethal concentrations (LC) of suspended solids causing 50 % mortality of test fish were determined by normit analysis (Berkson, 1953).

Findings

Analytical results:

Concentrations in the experimental tanks were determined by weight.

Replicate 5 ml samples were drawn from test and control tanks and dried. The observed differences between the weight of the dried control sample and the various test tanks represented the added resuspended load in gram/L..

Biological results:

All the fishes exposed to kaolinite survived 24 hour exposure in concentrations up to 140 g/L.

Several species (white perch, spot, toadfish, mummichog, hogchoker, menhaden) were exposed to 140 g/L kaolinite for 48 hours with the same result: no deaths directly attributed to the mineral solid.

In almost all cases, the fish became highly active when placed in suspensions of caolinite. However, this reaction was short-lived and became normal after 0.5 to 2 hours.

Conclusion:

Concentrations up to 140 g/L of suspended kaolinite had no lethal effect on 11 species of estuarine fish, based on nominal exposure concentrations.

The no observed effect concentration (NOEC) after 48 h was 140 g/L, the highest concentration tested at and below which there was no toxicant related mortality, or abnormal behaviour.

Thus, LC50 was higher than 140 g/L.

Study deviations:

This test was not designed as a regulatory study, but for fundamental research. However, it is considered to be valid and is accepted.

B.9.2.1/04

Reference	Redding, J. M., Schreck, C. B., Everest, F., (1987). Physiological Effects on Coho Salmon and Steelhead of Exposure to Suspended Solids. Transactions of the American Fisheries Society (1987), volume 116, pages: 737- 744. Oregon State University Agricultural Experiment Station, Corvallis, Oregon, USA.
Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	No / No

Material and methods

Test substance	Kaolin: Description: white powder. Purity: not specified. Lot/Batch no.: Anglo-American Clays, Atlanta, Georgia. Sandy loam topsoil from an excavation near Corvallis, Oregon. Volcanic ash from Mount St. Helens..
Test species	Coho salmon (Oncorhynchus kisutch) and Rainbow trout (Oncorhynchus mykiss). Mean wet weight: 0.3 g.
Test concentrations	Rainbow trout were exposed to either high (2-4 g/L) or low (0.4- 0.6 g/L) concentrations of topsoil, kaolin clay, or volcanic ash.
Test groups	Not available number of animals.
Duration	Fish exposed over a period of 48 hours
Test conditions	The concentration of suspended solids was monitored, as well as temperature, dissolved oxygen, conductivity and alkalinity of the water (temperature 12.5-13.50C, dissolved oxygen 8-10 mg/L, pH 7.0-7.1, conductivity 222-225 mS/cm, alkalinity 60-80 mg CaCO3/L). Fish were fed a standard moist pellet diet before and during the test.
Parameters tested	Plasma cortisol, plasma sodium concentration, and blood hematocrit levels were measured and gill histology was examined.
Endpoint(s)	-
Analyticals	Not available
Statistics	Data were subject to analysis of variance and the means for treatment and control groups were compared by Student’s t-test where appropriate

Findings

Analytical results:

Concentrations in the experimental tanks were determined once daily by evaporating water samples and weighing the residue.

Biological results:

Plasma cortico steroid concentration increased significantly in fish exposed to both concentrations of the three types of suspended solids. Hematocrits were consistently higher than in the control in fish exposed to high concentrations of the three types of suspended solids at 9 and 24 h after onset of the treatment. Plasma sodium concentrations were statistically similar in all treatment and control groups. For Rainbow trout exposed for 2 days to either top soil, kaolin clay, or volcanic ash, gill tissue was examined histologically at magnifications of 10 x and 100 x. The appearance of gill tissue from treated fish was similar to that of control fish in all cases for both species.

Conclusion:

The 48 h LC50 values for Coho salmon (Oncorhynchus kisutch) and Rainbow trout (Oncorhynchus mykiss) were estimated at > 4 g/L, based on nominal exposure concentrations.

Study deviations:
This test was not designed as a regulatory study, but for fundamental research. The test has not been conducted in agreement to the current requirements. Thus, the results of the test are not considered valid for risk assessment.

B.9.2.2 LONG-TERM AND CHRONIC TOXICITY TO FISH

Active substance

B.9.2.2/01

Reference	Goldes, S. A., Ferguson, H. W., Moccia, R.D., and Daoust, P. Y. (1988). Histological effects of the inert suspended clay kaolin on the gills of juvenile rainbow trout, Salmo gairdneri Richardson. Journal of Fish Diseases (1988), volume 11 pages 23-33. Fish Pathology Laboratory, Department of Pathology, Ontario Veterinary College, University of Guelph, Ontario, Canada.
Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	No / No

Material and methods

Test substance	Kaolin. Description: the dry material had a median particle size of 5 mm. Purity: not specified. Lot/Batch no.: hydrite flat D (Georgia Kaolin Ltd., New Jersey, USA)..
Test species	Rainbow trout (*Oncorhynchus mykiss Walbaum*). Juvenile, total length 5.64+0.58 cm, (at the beginning of the test).
Test concentrations	Nominal concentrations were 0 (three control groups: unexposed fed control, unexposed reduced-feed control and optimally reared control) 56, 280, 1400 and 7000 mg kaolin /L. The highest concentration of kaolin was set at 70% of the dose causing 28% mortality in pilot studies. Mean measured concentrations were 0 (control), 36, 171, 1017 and 4887 mg kaolin /L.
Test groups	81 fish per treatment
Duration	64 days
Test design	Treatments were assigned randomly to twelve 200 L fibreglass tanks. Within each tank, 27 fish were placed in each of 3 plastic 8-L perforated buckets that were suspended in the water column, giving a total 81 fish per tank in a semi-static system. The kaolin was kept in suspension during the study by a submersible pump located on the bottom of each tank. Fish were sampled at 0, 4, 8, 16, 32, and 64 days. At each sampling, 6

	fish per tank were arbitrarily chosen, removed, killed, and four gill arches from their right side were examined under light microscopy. The gills were checked for histological alteration and the thickness of their lamellae was measured.
Test conditions	During the experiment, the following water parameters were monitored: temperature, dissolved oxygen, pH, un-ionized ammonia, and turbidity. Water samples were taken every fourth day from 0 to 36 days and every seventh day thereafter. Mean pH over all treatments for the entire experiment was 8.3. Mean temperature was 16.7+1.12 0C. Mean dissolved oxygen was 8.9+0.19 mg/l. Mean un-ionized ammonia was 0.021+0.003 mg/L. Hardness was 100 mg/L calcium carbonate at the beginning of the experiment. Photoperiod was maintained at 12-h dark and 12-h light. During the experiment, fish were fed a commercial diet at the rate of 1 % of body weight twice daily. Reduced feed controls were fed as per principals but only one day per week.
Parameters tested	Gills checked for histological alteration and thickness measurement of their lamellae.
Endpoint(s)	-
Analytics	Not available
Statistics	Differences in lamellar thicknesses and water quality were evaluated using analysis of variance, t-tests and Duncan’s multiple range tests

Findings

Analytical results:

All kaolin concentrations were, on average, within 23 % of desired levels for each treatment at time 0 of the 12-h experimental cycle. On average, turbidity and suspended solids levels dropped 22 and 24 %, respectively, by the end of the 12-h period.

Biological results:

Qualitative histology: All gills samples were found normal, except for those taken at 16 and 32 days in fish exposed to 4887 mg/l kaolin, which showed lesions and the proliferation of a protozoan, Ichtyobodo necator. However, the morphology and parasite numbers returned back to normal at 64 days. Quantitative study: Statistically significant increases in lamellar thickness only occurred at the base of lamellae in fish exposed to 4887 mg/l kaolin.

However, there is no evidence that this loss of surface area had any significant effect on branchial function. The absence of qualitative and quantitative branchial changes at 36, 171 and 1017 mg/L indicates that environmental concentrations of kaolin are unlikely to cause histological alteration and that kaolin alone at these levels probably does not lead to lesions that might facilitate secondary infection. Mortalities were 1.7 % in reduced-feed control and 8 % in optimally reared control. Seventy-three out of 810 (9.0 %) fish died during the experiment. Average percentage mortality per treatment ranged from 2.5 (36 mg/l) to 13.6 (4887 mg/l).

Conclusion:

Based on mean measured exposure concentrations the no observed effect concentration (NOEC) after 64 days was 1017 mg/L, based on histological alteration to gill structure.

Study deviations:
This test was not designed as a regulatory study, but for fundamental research. In principle, the test has not been conducted in agreement to the current requirements. The results of the test are not considered valid for risk assessment.

B.9.2.2.1 Fish early life stage toxicity test

Reference	Hashimoto, Y., Yamaguchi, M., Itō, T., Tōi, J. (1986). Effects of Kaolin on Hatching, Growth and Feeding Behaviour of Rainbow Trout, Salmo gairdneri. Bull. Tokai Reg. Fish. Res. Lab., (1986), volume 120 pages: 39 - 42. (Text in Japanese, English summary + tables.)
Guideline	Not reported
GLP/QA	Not reported, published paper
Previous evaluation	In DAR for original Annex I inclusion (2008)
Validity/Acceptance	Yes/Yes

Material and methods

Test substance	Kaolin. Description: white powder. Purity: not specified. Lot/Batch no.: not stated
Test species	Rainbow trout (Oncorhynchus mykiss Walbaum). Eyed eggs.
Test concentrations	Hatching and growth: 0 (control), 30, 100, and 300 mg kaolin /L. Feeding: 0 (control), 10, 30, and 100 mg kaolin /L. (Nominal concentrations.)
Test groups	30 per replicate
Duration	The number of hatching eggs was monitored from 7 days to 10 days of exposure. Fry survival and growth was estimated after 30 days exposure. Time to consume prey items (carp fry and daphnids) was determined during 30 min.
Test design	Not available
Test conditions	Not available
Parameters tested	The effects of suspended kaolin on hatching, growth, and feeding behaviour of rainbow trout were studied.
Endpoint(s)	-
Analytics	Not available
Statistics	Not available

Findings

Analytical results:
Not available

Biological results:

Turbidity had no impact on hatching. A slight initial delay was observed at 300 ppm kaolin concentration (Table B.9.2.2-1).

Table B.9.2.2-1: The cumulative numbers of sac fry hatched from the eggs exposed to kaolin Suspensions

Treatment (mg a.s./L) [nominal concentrations used]	Replication	Days after the exposure level			
		7	8	9	10
0	A	24	84	99	99
	B	65	83	99	99
30	A	55	84	99	99
	B	58	84	100	100
100	A	55	88	100	100
	B	-	-	98	98
300	A	5	82	94	100
	B	-*	-	97	100

* No observation was made

Turbidity had no impact on growth, although a slight impact on survival was noted at the highest test concentration of 300 ppm (Table B.9.2.2-2).

Table B.9.2.2-2: The effects of kaolin on the survival and growth of rainbow trout

Treatment (mg a.s./L) [nominal concentrations used]	Survival	Average body length (cm)	Average weight (g)
0	30	3.20	0.57
30	28	3.16	0.59
100	28	3.14	0.55
300	23	3.13	0.56

Turbidity had a marked impact on feeding as time taken to consume all offered preys was significantly longer at 30 and 100 ppm. However, no impact was seen at 10 ppm exposure (Table B.9.2.2-3).

Table B.9.2.2-3: The effects of kaolin on the time required for eating all the given prey

Treatment (mg a.s./L) [nominal concentrations used]	100	30	10	0
Time required for eating 100 daphnid (min)	9	3	1	1
	13	1	1	1
Time required for eating 20 carp fry (min)	>30	>30	6	7
	>30	>30	7	7
	25	13	6	11
	>30	22	9	8

Time required for eating 100 carp fry (min)	>30	4	1	1
	>30	28	1	2
	>30	14	2	1

Conclusion:

Not specified. The no observed effect concentration (NOEC) is considered to be 100 mg/L, based on the survival and growth of rainbow trout.

Study deviations:

This test was not designed as a regulatory study, but for fundamental research. However, it is considered to be valid and is accepted.

B.9.2.2.2 Fish full life cycle test

No data submitted or considered necessary.

B.9.2.2.3 Bioconcentration in fish

Aluminium silicate (kaolin) is not soluble in water and as a result has a very limited potential to bioaccumulate in fish, aquatic invertebrates, algae and aquatic plants. Hence no study on the potential bioconcentration of aluminium silicate has been performed.

Justifications:

- Calcined kaolin is practically insoluble in water or organic solvents[1]; the testing to determine the partition of the mineral in either phase is therefore of negligible value.
- Whereas the solubility of calcined kaolin in water has been reported at approximately 1.15 mg/L[2], such solubility is the result of the hydrolysis of lightly bound aluminium and silicon hydroxide moieties [3] and does not describe true solubilization in water. Natural deposits of surface kaolin are extremely stable and are not affected by rainfall. Kaolin exists stably in nature for millions of years.
- Analytical methodology for calcined kaolin is lacking due its inert nature and its unique semi-crystalline structure. The crystal structure of kaolin is disrupted during the calcination process therefore the typical analytical method for minerals, X-Ray Diffraction, provides no information on the identity of calcined kaolin. Atomic Absorption or Emission spectrometry focus on elemental analysis therefore cannot measure if water or octanol have any suspended particles of semi-crystalline calcined kaolin, and furthermore if there are trace solute amounts of aluminium and silicon hydroxide moieties these analytical methods cannot differentiate between clay types.

[1] "Kaolin (Kaolinum)", The International Pharmacopoeia – ed. 8th (2018), http://apps.who.int/phint/pdf/b/6.1.203.Kaolin-(Kaolinum).pdf

[2] "Kaolin, calcined" from ECHA database, https://echa.europa.eu/registration-dossier/-/registered-dossier/13356/4/9

[3] Carroll, D., et al., Reactivity of Clay Minerals with Acids and Alkalies, Clays and Clay Minerals, 1971, Vol. 19, pp. 321-333. http://www.clays.org/journal/archive/volume%2019/19-5-321.pdf

B.9.2.3 POTENTIAL FOR ENDOCRINE DISRUPTION

According to the notifier a literature review revealed no information on endocrine disrupting properties of Aluminium silicate in birds and mammals. Based on the results reported in the Tox Section (Volume_3CA_B-6), in combination with the low toxicity referred on the acute aquatic toxicity tests (literature reviews), there is no indication that aluminium silicate undergoes endocrine disrupting properties.

Please refer to B.9.1.5 POTENTIAL FOR ENDOCRINE DISRUPTION

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B.9.2.4 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

B.9.2.4.1 Acute toxicity to *Daphnia magna*

Active substance

B.9.2.4.1/01
Please refer to B.9.2.1/02

B.9.2.4.1/02
A Daphnia magna study with product under evaluation (i.e. Surround WP (Tessenderlo)] is available and its summary and RMS conclusions is provided in the corresponding K-CP section.

B.9.2.4.2 Acute toxicity to additional aquatic invertebrates

Please refer to B.9.2.4.1/01

B.9.2.5 LONG-TERM AND CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

B.9.2.5.1 Reproductive and development toxicity to *Daphnia magna*

No new data are available for long-term and chronic toxicity to Daphnia magna since the approval of aluminium silicate (kaolin) (EFSA (2012)). It is considered that the risk to non-target organisms from the representative use of aluminium silicate (kaolin) will be low.

A waiver is proposed for long-term and reproductive toxicity studies for daphnids based on the following information:

- Kaolin (as clay) is present in most natural water bodies and the use of kaolin products in agriculture will not significantly alter the normal background levels.

- Aluminium silicate will naturally settle provided water currents are slow enough to permit deposition. Once settled, aluminium silicate will be completely undistinguishable from naturally-present clay particles and become part of the sediment. Since aluminium silicate is not soluble in water, it is not unexpected that 100% of the product entering waterways will transfer to the sediment. This also explains the difficulty in maintaining kaolin-test solution concentrations within the aqueous phase when conducting a GLP laboratory study.

- Chronic toxicity testing with Daphnia magna has not been conducted due to the low acute toxicity of aluminium silicate (kaolin) to aquatic invertebrates as demonstrated in the available acute toxicity studies.

- Fish are demonstrated to have similar sensitivity to acute exposure from kaolin compared to aquatic invertebrates As an ELS study is available for fish and considered in the risk assessment, demonstrated a low toxicity from exposure to kaolin. - In addition, a chronic algae study is available reinforcing the low toxicity.

Moreover, a literature reference on the toxicity of Daphnia magna is available and summarised below, further supporting the low toxicity of kaolin to aquatic invertebrates:

B.9.2.5.1/01

Reference	Robinson, S.E., Capper, N.A., and Klaine, S.J., 2009 The effects of continuous and pulsed exposures of suspended clay on the survival, growth and reproduction of Daphnia magna Environmental Toxicology and Chemistry Vol 29 (1): 168-175
Guideline	Not reported (published paper)
GLP/QA	Not reported
Previous evaluation	No, submitted for the purpose of the renewal
Validity/Acceptance	Yes/ Yes
Material and methods	
Test substance	Kaolinite clay powder (KN) Description: Clay powder Lot/Batch #: Not reported. Obtained from VWR International Purity: Not specified
Test species	Daphnia magna (72 hours old)
Test concentrations	7-day test: 0, 25, 50, 100, and 200 mg/L for KN, 21-day test: The 24 h exposure: 50, 100, 200, and 400 mg/L KN The 12-h exposure: 100, 200, 400, and 800 mg/L KN The double pulse exposures were for 12 h: 800 mg/L KN for the first 12 h of the test period, then after a recovery period of 0, 48, 96, 192, or 384 h, were exposed to a second 12 h pulse of 800 mg/L.
Test groups	Eight test chambers containing one D. magna (2 replicates)

Duration	7-day test and 21-day test
Test design	4 L plastic beakers on a stir plate. Organisms were held in the center of the beaker in glass test chambers within a modified test tube rack. Eight test chambers containing one D. magna each were placed in each test tube rack. Two replicate test beakers, each containing one test tube rack holding eight organisms, were used for each treatment for all tests. Test organisms were fed Selenastrum capricornutum every day at a final concentration of 150,000 cells/mL. Daily renewal of test medium was conducted for the 7 day test. In the 21-day test, episodic exposure bioassays were conducted to examine the effect of sediment pulses on mortality, growth, and reproduction for the majority of the daphnid life span. Organisms underwent a 24 h or less, single or double exposure, and were kept in clean medium for the remainder of the 21 d. For the single exposures, organisms were exposed for 24 h to each of the three types of clay or for 12 h to KN only.
Test conditions	Temperature: Not reported pH: Not reported Dissolved oxygen: Not reported Photoperiod: 16 hours light / 8 hours dark
Parameters tested	The 7 day test was conducted to determine mortality, growth, and reproduction endpoints The 21-day exposure test was conducted to determine the effect of sediment pulses on mortality, growth, and reproduction for the majority of the daphnid life span.
Endpoint(s)	NOEC = 50 mg a.s./L (actual NOEC could be between 50-100 mg/L)
Analytics	Not available
Statistics	Seven-day median lethal concentration (LC50) values were calculated using Trimmed-Spearman-Karber with ToxStat. Differences in days to gravidity, and the number of neonates produced per organism over 21 d, were analyzed using a one-way analysis of variance (ANOVA) and Tukey's multiple comparison test, using the statistical analysis software SAS. Growth rates were compared by defining a nonlinear growth curve model for each treatment, combining them into one model and comparing growth coefficients using a pairwise comparison. Also, the length of organisms recorded each day were compared using one-way ANOVA, and using sequential Bonferroni to adjust for type I and type II error.

Findings

Analytical results:

Concentrations of suspended clay decreased over the 24 h period between renewals, due to adhesion onto surfaces of the test chambers. Consequently, concentrations used to develop exposure response relationships were the average of the measured initial and final concentrations for each renewal.

Biological results:

A. 7-day test:

Daphnia magna exhibited dose-dependent mortality. The 7-d LC50 value was 74.51 (95% conf. intervals 65.08, 85.3) mg/L KN.

Fecundity was characterized by noting the day organisms became gravid. Kaolinite-exposed organisms did not show a difference in mean number of days to gavidity (mean number of days = 5.4) compared to the control (mean number of days = 5.4).

B. 21-day test:

Organisms exposed to a single pulse of KN for 12 or 24 h, did not show any dose-dependent response for survival over 21 days. There were no exposure concentrations that led to a significant decrease in survival from the controls ($p > 0.05$).

For the double pulse consisting of two 12 h KN exposures of 800 mg/L (measured concentration 734.2 mg/L), the organisms with a 0-h recovery time (or 24-h exposure) showed a significant decrease in survival from both the control and organisms with a recovery time greater than or equal to 48 h ($p<0.05$).

Organisms exposed for 24 h to concentrations of 73.9, 152.5, and 312.0 mg/L KN showed a significant increase in days to gravidity compared with control ($p < 0.05$). Days to gravidity for organisms exposed for 24 h at lower concentrations and all 12-h KN exposed organisms were not significantly different from the control ($p > 0.05$). Organisms exposed to all single pulse treatments showed no significant reduction in number of neonates produced over 21 d ($p>0.05$).

Organisms exposed to two 12-h KN exposures with a 0-h recovery time showed a significant increase in time to gravidity compared with control and organisms with a recovery time of 96 h or more ($p < 0.05$). Days to gravidity for the 0-h recovery was not significantly greater than organisms with the 48-h recovery ($p > 0.05$). There was no significant difference in the number of neonates produced for the double pulse exposures compared with controls ($p>0.05$).

A significant difference in growth rate was observed over the 21-d bioassay For the 24-h exposures, there was a significant decrease in length, compared with the control, after the exposure. For day 1 to 14 (KN) there was at least one concentration that had significant difference in length ($p < 0.0056$, 0.0031, and 0.033, respectively). For the 12-h KN exposure, there was no significant difference after the exposure, but by day 16 the controls were significantly smaller than exposed organisms for all concentrations ($p < 0.05$). In the double pulse exposure only, organisms with a 0- or 48 h recovery time were significantly smaller than controls on days 1 through 13, and 5 through 19, respectively ($p < 0.05$).

Conclusion:

Organisms exposed to a single 12- or 24 h pulse of clay exhibited no significant mortality. Given that it required approximately 75 mg/L KN over 7 d for 50% of the organisms to die, it is expected that much higher concentrations would be required for significant mortality to be experienced with exposures of only 12 or 24 h. During the double-pulse exposures with a 0-h recovery time before the second pulse (essentially a 24-h exposure), there was a significant decrease in survival. This double-pulse exposure was at a concentration two times that used for highest 24-h exposures. Recovery times of 48 h or greater allowed organisms enough time to feed normally before being exposed again and having their feeding reduced again.

Single 12 h pulsed exposures did not significantly increase the number of days to gravidity; however, there was a significant increase in days to gravidity for single 24 h exposure at the three highest KN concentrations (73.9, 152.5, and 312 mg/L KN). There was also a significant increase in days to gravidity in the double pulse exposure when the recovery time was 0 h, which is essentially a 24 h exposure. The exposures that elicited a significant increase in days to gravidity (0 h recovery double pulse and the 24-h exposures of 312, 152.5, and 73.9 mg/L) were approximately equal, one-half, one-quarter, and one-tenth, respectively, of the highest 12 h KN exposure which showed no effect. This is one indication that duration of exposure is more important than concentration.

Study deviations:

This test was not designed as a regulatory study, but for fundamental research. However, it is considered to be valid and is accepted.

B.9.2.5.2 Reproductive and development toxicity to additional aquatic invertebrates

No new data are available for long-term and chronic toxicity to an additional aquatic invertebrate species.

Please refer to **B.9.2.5.1**, in light of the weight-of-evidence, the chronic risk to aquatic invertebrates is considered to be low.

B.9.2.5.3 Development and emergence in *Chironomous tetans and Leptocheirus plumulosus*

No new data are available for long-term and chronic toxicity to an additional aquatic invertebrate species. Kaolin is not an insect growth regulator; thus testing on sediment-dwelling organisms is not required according to the Commission Regulation EU 283/2013.

Please refer to **B.9.2.5.1**, in light of the weight-of-evidence, the chronic risk to aquatic invertebrates is considered to be low.

B.9.2.6 EFFECTS ON ALGAL GROWTH

B.9.2.6.1 Effects on growth of green algae

Active substance

Studies with the a.s. are not available for algae. Algae studies with products under evaluation (i.e. Surround WP (95% aluminium silicate and non-toxic inerts) by Tessenderlo and Sokalciarbo (100% of Aluminium silicate) by SOKA] are available and their study summaries and RMS conclusions are provided in the corresponding K-CP sections.

B.9.2.6.2 Effects on growth of additional algal species

Not required

B.9.2.7 EFFECTS ON AQUATIC MACROPHYTES

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

B.9.2.8 FURTHER TESTING ON AQUATIC ORGANISMS

No additional data submitted, not required

B.9.3 EFFECTS ON ARTHROPODS

B.9.3.1 EFFECTS ON BEES

No new data are available for acute bee toxicity since the approval of aluminium silicate (kaolin) (EFSA, 2012). Details of these studies are summarised in the relevant sections below.

New acute toxicity studies on the toxicity to bees with the representative formulations SOKALCIARBO WP and SURROUND® WP CROP PROTECTANT were submitted (Table B.9.3.1-1). Chronic feeding studies on worker bees with SOKALCIARBO WP and SURROUND® WP CROP PROTECTANT and one chronic larvae toxicity study with SURROUND® WP CROP PROTECTANT are also available.

No chronic adult and bee larval life study is available with the active substance (as requested in the Regulation (EU) 283/2013). Considering that the representative formulations consists almost entirely from aluminium silicate and inert materials, the findings from studies with SOKALCIARBO WP and SURROUND® WP CROP PROTECTANT can be extrapolated and referred to the active substance.

Two non-GLP field tests were carried out to assess the impact of aluminium silicate 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.

A summary of all available endpoints is provided in Table B.9.3.1-1.

Table B.9.3.1-1: Summary of data on toxicity of aluminium silicate to honey bees

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)
	SOKALCIARBO WP	48 h contact toxicity	LD_{50} > 500 µg a.s./bee	Mamet O., 2008
	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				
Apis mellifera Adults	SOKALCIARBO WP	Oral, 10d repeated exposure	LC_{50} = 90919 mg a.s./kg diet LDD_{50} = 2636 µg a.s./bee/day	Mamet O., 2019

Species	Test item	Time scale/method	Endpoint	Reference
			NOEC = 29997 mg a.s./kg diet NOEDD = 882 µg a.s./bee/day	
	SURROUND® WP CROP PROTECTANT	Oral, 10d repeated exposure	LDD_{50} = 1390 µg a.s./bee/day LC_{50} = 56410 mg a.s./kg diet NOEDD = 660 µg a.s./bee/day NOEC = 29319 mg a.s./kg diet	Ansaloni, 2019 Report no.: TRC17-208BA KCP 10.3.1.2/01
Effects on honeybee development and other honeybee life stages				
Apis mellifera Larvae	SURROUND® WP CROP PROTECTANT	22d Larvae toxicity Repeated exposure	NOED = 405 µg a.s./larva NOEC = 2.893 mg a.s./mL diet	Ansaloni, 2019 Report no.: TRC17-184BA KCP 10.3.1.3/01
Higher-tier studies (tunnel test, field studies)				
Field studies in flowering pear and apple orchards in US demonstrated that the application of an Aluminium silicate preparation at 56 kg/ha did not have adverse effects on numbers of bees foraging and their behaviour (Mayer D.F., 1999a and 1999b).**				

Endpoints in bold are the lowest toxicity values
* Non-reliable studies. Validity criteria were not met
** Acceptable as supporting evidence

B.9.3.1.1 Acute toxicity to bees

B.9.3.1.1/01

Reference	Hoxter, K.A., Palmer, S.J., and Krueger, H.O. 1997 (KCA 8.3.1.1.1/01)
	M-96-018 Kaolin: An Acute Dietary Toxicity Study with the Honey Bee
	Report No.: 469-102
Guidelines	FIFRA subdivision L, Section 141-1 and EPPO Guideline 170
GLP	Yes
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.1.1/01
Validity/Acceptance	No (not all validity criteria met)/No (considered for illustration purposes)

Material and methods

Test substance	M-096-018
	Lot/Batch no.: 08145; purity: 98.8%
Vehicle	Methanol
Test species	Young worker honeybee (*Apis Mellifera L.*) (one to seven days old, workers)
Reference item	Dimethoate

Test concentrations	Test item: 6.25, 12.5, 25.0, 50.0 or 100.0 µg M-96-018 per bee Reference: 0.05, 0.16 and 0.45 µg M-96-018 per bee
Test groups	60 bees per treatment (3 replicates, each consisting of 20 bees in one cage) for the test item doses and the two controls
Test design /methodology	The test chambers were stainless steel cylinders measuring approximately 9 cm in diameter and 9 cm high, with perforations for ventilation. Each end of the cylinder was covered with a disposable plastic petri dish (approximately 10 cm in diameter). Two inverted 20 ml glass vials containing the appropriate test diet and one containing water, were inserted throught the lid of the chamber. The opening of each vial was covered with gauze to prevent leakage, yet allowed the bees to feed or drink. The food and water was available *ad libitum* to the test bees throughout the test period. The test chambers were identified by study number, test concentration, and replicate. A minimum of 20 bees were placed in each of the containers. After allowing time for the bees to recover from the anesthesia, holding containers were impartially chosen, and the bees in each holding container were again immobilized with nitrogen Twenty bees were impartially placed in each test chamber, and the appropriate test or control diet was placed on the top ofeach chamber. Negative control bees were handled identically to bees in the treatment groups, but were administered honey without the addition of any test substance.
Test conditions	Temperature: 27.4-29.1 ºC Humidity: 70-76% Photoperiod: darkness except during dosing and observation
Parameters tested	Observation took place 1 hour and 15 minutes, 2 hours and 45 minutes, 24 hours and 48 hours after treatment.
Endpoint(s)	Oral 48h LD_{50}
Statistics	The data did not warrant statistical analysis.

Findings

The numbers of mortalities observed in the treatment groups were low and did not occur in a dose-responsive manner. Therefore, the mortalities and clinical signs of toxicity were not considered to be related to treatment with the test substance.

Table 9.3.1.1/01-1: Mortality of honey bees fed with kaolin.

Dose (ppm)	48-h Mortality
62.5	2/60
125	0/60
250	1/60
500	2/60
1000	0/60
Negative control	0/60
Positive control 0.05	51/60 (1/60 at 24-h)
Positive control 0.16	56/60 (10/60 at 24-h)
Positive control 0.45	60/60 (35/60 at 24-h)

Conclusion

The LD_{50} of M-96-018 Kaolin is >100 µg M-96-018/bee and the NOEC is >100 µg M-96-018 /bee. M-96-018 Kaolin is not harmful to bees by the oral route. On the basis of this study, test material does not warrant classification as harmful or toxic to bees when administered as part of the diet.

Study limitations:

The study is not valid.

The LD_{50} of the toxic reference was not calculated in the report. However, based on the reported 24-h mortality data the LD_{50} was calculated by the Rapporteur to 0.382 µg a.i./bee (confidence intervals 0.326-0.464) which is (slightly) above the 0.35 µg a.i./bee limit (log-probit analysis). However, the average mortality of control did not exceed 10% at the end of the test.

The report is missing key information on the bee diet: composition and preparation of solution, nominal and consumed amount of diet per bee.

B.9.3.1.1/02

Reference	Palmer, S.J., and Krueger, H.O. 1997 (KCA 8.3.1.1.2/01)
	M-96-018 Kaolin: An Acute Contact Toxicity Study with the Honey Bee
	Report No.: 469-101
Guidelines	FIFRA subdivision L, Section 141-1 and EPPO Guideline 170
GLP	Yes
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.1.1/02
Validity/Acceptance	Yes/Yes

Material and methods

Test substance	M-096-018
	Lot/Batch no.: 08145; purity: 98.8%
Vehicle	Methanol
Test species	Young worker honeybee (*Apis Mellifera L.*) (one to seven days old, workers)
Reference item	Dimethoate
Test concentrations	Test item: 6.25, 12.5, 25.0, 50.0 or 100.0 µg M-96-018 per bee
	Reference: 0.05, 0.10, 0.20 µg per bee
Test groups	60 bees per treatment (3 replicates, each consisting of 20 bees in one cage) for the test item doses and the two controls
Test design /methodology	The test chambers were stainless steel cylinders measuring approximately 9 cm in diameter and 9 cm high, with perforations for ventilation. Each end of the cylinder was covered with a disposable plastic petri dish (approximately 10 cm in diameter). Two inverted 20 ml glass vials containing the appropriate test diet and one containing water, were inserted throughthe lid of the chamber. The opening of each vial was covered with gauze to prevent leakage, yet allowed the bees to feed or drink. The food and water was available *ad libitum* to the test bees throughout the test period. The test chambers were identified by study number, test concentration, and replicate. A minimum of 20 bees were placed in each of the containers. The holding containers were-impartially distributed to the various treatment and control

	groups during the dosing procedure. After allowing time for the been to recover from the anesthesia, the bees in each holding container were again immobilized with nitrogen. Bees were individually dosed with the appropriate dosing solution and 20 bees were placed in the appropriate test chamber. The bees were dosed by administering a 2 µl droplet of the dosing solution to the abdomen and/or thorax of each bee with an Eppendorf adjustable micropipette. Solvent control bees were dosed with 2 µL of methanol. Negative control bees were handled identically to bees in the treatment and conuol groups, but were not administered any test substance or solvent.
Test conditions	Temperature: 28.6-28.8 ºC Humidity: 64-76% Photoperiod: darkness except during dosing and observation
Parameters tested	Observation took place 1 hour, 1 hour and 30 minutes, 24 hours and 48 hours post dosing
Endpoint(s)	Contact 48h LD_{50}
Statistics	The data did not warrant statistical analysis

Findings

With the exception of one bee that was immobile on day 0 in the negative control group, all bees appeared active and healthy throughout the study.

Table 9.3.1.1/02-1: Doses, mortality / animals treated

Dose (µg)	Mortality (48-h)
6.25	0/60
12.5	0/60
25	0/60
50	1/60
100	0/60
Negative control	1/60
Solvent control	0/60
Positive control 0.05	3/60 (2/60 at 24-h)
Positive control 0.10	24/60 (22/60 at 24-h)
Positive control 0.20	60/60 (60/60 at 24-h)

The 48-h LD_{50} value for honey bees exposed to dimethoate in a topical dose was determined to be 0.11 µg a.i./bee with a 95% confidence interval of 0.05 to 0.20 µg a.i./bee.

Conclusion

The LD_{50} of M-96-018 Kaolin is >100.0 µg/bee and the NOEC is 100.0 µg/bee. M-96-018 Kaolin is not harmful to bees by the contact route. On the basis of this study, test material does not warrant classification as harmful or toxic to bees when administered topically.

Study limitations:

The study is acceptable as validity criteria (mortality in the controls and LD_{50} of the toxic standard) were met.

B.9.3.1.2 Chronic toxicity to bees

No study on the active substance are available.

B.9.3.1.3 Effects on honeybee development and other honeybee life stages

No study on the active substance are available.

B.9.3.1.4 Sublethal effects

No data available.

B.9.3.1.5 Cage and tunnel tests

No data available.

B.9.3.1.6 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.

B.9.3.1.6/01

Reference	Mayer, D.F. 1999a (KCP 10.3.1.6/01) Honey bee foraging in pear orchards treated with kaolin particle film Report No.: -
Guidelines	-
GLP	No
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.1.1/01
Validity/Acceptance	Acceptable as supporting evidence.

Material and methods

Test substance	Kaolin Particle Film Lot/Batch no.: Not specified; purity: Not specified
Vehicle	Water
Test species	Young worker honeybee (*Apis Mellifera L.*) (Mixed – all life stages)
Reference item	-
Trial location	Zillah, Washington State, USA
Trial design /methodology	Twenty-four bee hives were placed around a 2.5 ha mature pear orchard. On 14 April 1999, 90% of the orchard was sprayed with Kaolin particle film at a dose rate of 56 kg/ha, using a commercial air blast sprayer delivering 935 L/ha spray volume. The remaining 10% of the orchard was left unsprayed to serve as an untreated control. At the time of application 50% of the flowers were open

On the day before treatment, 10 randomly selected trees in both the Surround® and untreated plots were marked for making assessments on honey bees and fruit quality and quantity.

Parameters tested

The following assessments were carried out on honey bees:

• Numbers foraging per tree per minute at 2, 4, 8 and 24h after application

• Foraging behaviour (nectar or pollen collectors) at 2h after application

• Time spent foraging individual flowers

Assessments were also made on the quantity and quality of fruit using the following methods:

- Flower clusters were counted on 4 branches on each of the 10 marked trees and the number of fruit was later counted on the same branches to determine % fruit set.
- On 6 August, 10 pears were collected from each of the 10 marked trees and taken to the laboratory where they were weighed, measured, cut open and the number of seeds counted.

Statistics

Studentized Newman-Keuls range test.

Different letters denote significant differences at $P \leq 0.05$

Findings

There was no significant difference in number of foraging bees, foraging behaviour and time spent foraging between kaolin treated and untreated plots.

Table 9.3.1.6/01-1: Summary of kaolin and control honey bee results in pears

Treatment	Mean no. bees/tree/minute				% bee activity		Time (s) /flower	
	2h	**4h**	**8h**	**24h**	**nectar**	**pollen**	**2h**	**4h**
Kaolin	1.6a	3.2a	3.5a	3.7a	0a	100a	6.8a	6.4a
Control	2.7a	2.9a	3.8a	3.6a	0a	100a	6.4a	6.1a

There was no significant difference in percent fruit set and mean fruit diameter between treated and untreated trees. However, mean fruit weight was significantly greater in the treated plot compared to the untreated plot and fruits in the treated plot contained significantly less seeds than fruits in the untreated plot.

Table 9.3.1.6/01-2: Summary of pear fruit parameters in kaolin and control plots

Treatment	% fruit set	Mean weight	Mean diameter	Mean no. seeds
Kaolin	11.5a	125a	59a	2.8a
Control	11.2a	108b	57a	5.8b

Conclusion

Kaolin particle film applied at 56 kg/ha to flowering pear trees had no statistically significant effects on foraging activity (number of visitors, amount of time foragers spent on pear flowers), fruit set and fruit diameter. However, the difference in the number of foraging bees 2 h after application between kaolin and untreated control can be deemed of biological relevance. Pears from the treated trees were significantly heavier and contained fewer seeds than those from the untreated control.

Study limitations:

The study was designed to address effects of kaolin to the foraging activity of bees during pear tree flowering period. Since no acceptable guideline was followed it is not possible to conclude on the suitability of the in-house test design to address possible effect on the foraging activity of bees.

A small part of the pear orchard (0.2 ha) in the northwest served as the untreated check. Since it is uncertain if spray drift was prevented from contaminating the untreated area (buffer zone or tree rows left untreated) the possibility of exposure of foragers to kaolin in the untreated area cannot be excluded.

The duration of the monitoring (24-h monitoring) is insufficient to address possible long-term effects.

B.9.3.1.6/02

Reference	Mayer, D.F. 1999b (KCP 10.3.1.6/02) Honey bee foraging in pear orchards treated with kaolin particle film Report No.: -
Guidelines	-
GLP	No
Previous evaluation	Previously evaluated in DAR B9, III.A 10.4.4/02
Validity/Acceptance	Acceptable as supporting evidence

Material and methods

Test substance	Kaolin Particle Film Lot/Batch no.: Not specified; purity: Not specified
Vehicle	Water
Test species	Young worker honeybee (*Apis Mellifera L.*) (Mixed – all life stages)
Reference item	-
Trial location	Zillah, Washington State, USA
Trial design /methodology	Two separate trials were conducted in different orchards in the same location. **Test 1:** A 1.6 ha apple orchard was split into 2 equal plots. The plot on the west of the orchard was treated with kaolin particle film on 4 May 2002 when 10% of the flowers were in bloom and again on 8 May when 80% of the flowers were in bloom. **Test 2:** A 2.4 ha apple orchard was split into 2 equal plots. The plot on the east of the orchard was treated with kaolin particle film on 11 May when 100% of the flowers were open. Kaolin dose rate: 56 kg/ha Spray volume: 935 L/ha Sprayer: Commercial airblast

Ten randomly selected trees in both the kaolin and untreated plots were marked for making assessments on honey bees, fruit quality and quantity.

Parameters tested

The following assessments were carried out on honey bees:

• Numbers foraging per tree per minute at 2, 4, 8 and 24h after application

• Foraging behaviour (nectar or pollen collectors) at 2h after application

• Time spent foraging individual flowers

Assessments were also made on the quantity and quality of fruit using the following methods:

- Flower clusters were counted on 4 branches on each of the 10 marked trees and the number of fruit was later counted on the same branches to determine % fruit set.
- On 6 August, 10 pears were collected from each of the 10 marked trees and taken to the laboratory where they were weighed, measured, cut open and the number of seeds counted.

Statistics

Studentized Newman-Keuls range test.

Different letters denote significant differences at $P \leq 0.05$.

Findings

Test 1:

There were significantly fewer foraging bees in the treated plot as compared to the untreated plot at two hours after application both at 10% open bloom and 80% open bloom. However, no significant difference was observed at 4 and 24 hours post-application.

There was no significant difference in foraging behaviour and time spent foraging between treated and untreated plots.

Table 9.3.1.6/02-1: Summary of Test 1 honey bee results, apples 10% flowering

Treatment	**Mean no. bees/tree/minute**				**% Foraging behaviour**			**Time (s) /flower***	
	2h	**4h**	**8h**	**24h**	**top**	**side**	**pollen**	**2h**	**4h**
Kaolin	1.0a	2.3a	1.6a	2.2a	3.6a	96.4a	16a	3.0a	2.8a
Control	2.2b	2.2a	1.4a	2.4a	3.8a	96.2a	18a	3.2a	3.2a

* observations for side feeders

Table 9.3.1.6/02-2: Summary of Test 1 honey bee results, apples 80% flowering

Treatment	**Mean no. bees/tree/minute**				**% Foraging behaviour**			**Time(s)/flower***	
	2h	**4h**	**8h**	**24h**	**top**	**side**	**pollen**	**2h**	**4h**
Kaolin	5.6a	6.2a	8.6a	10.1a	5.1a	94.9a	17a	2.9a	3.3
Control	8.2b	6.2a	7.9a	11.4a	5.8a	94.2a	14a	3.0a	3.4

* observations for side feeders

There was no significant difference between treated and untreated trees in percent fruit set, fruit diameter or fruit weight. However, kaolin treated fruit had significantly more seeds than untreated apples.

Table 9.3.1.6/02-3: Summary of Test 1 fruit parameter assessments in apples

Treatment	% fruit set	Mean weight	Mean diameter	Mean no. seeds
Kaolin	11.4a	201a	7.7a	5.0a
Control	11.3a	191a	7.6a	4.2b

Test 2:

There was no significant difference in the number of foraging bees, foraging behaviour and time spent foraging between treated and untreated plots.

Table 10.3.1.6/02-4: Summary of Test 2 honey bee results in apples

eatment	Mean no. bees/tree/minute				% Foraging behaviour			Time (s) /flower*	
	2h	4h	8h	24h	top	side	pollen	2h	4h
olin	10.6a	12.8a	10.9a	7.9a	2.1a	98a	21a	3.0a	3.1a
ntrol	13.7a	13.1a	10.9a	7.7a	2.3a	98a	20a	3.0a	3.4a

* observations for side feeders

There was no significant difference in percent fruit set, fruit diameter, mean weight and number of seeds between treated and untreated trees.

Table 9.3.1.6/02-4: Summary of Test 2 fruit parameter assessments in apples

Treatment	% fruit set	Mean weight	Mean diameter	Mean no. seeds
Kaolin	8.6a	177a	6.6a	3.1a
Control	8.4a	172a	6.8a	3.0a

Conclusion

Application of kaolin particle film slightly reduced the number of foraging bees at 2 hours after application in one test in apples. However, numbers of foraging bees and their behaviour was then the same in both kaolin and untreated plots. No differences were observed between treated and untreated apples, except for a slightly higher number of seeds in fruit from the kaolin plots in one test.

On the basis of this study, Kaolin has no negative effect on numbers of bees foraging, bee behaviour, fruit set, fruit weight and fruit size.

Study limitations:

The study was designed to address effects of kaolin to the foraging activity of bees during flowering. Since no acceptable guideline was followed it is not possible to conclude on the suitability of the in-house test design to address possible effect on the foraging activity of bees.

Part of the orchard served as the untreated check. Since it is uncertain if contamination of the untreated area was prevented (e.g. buffer zone or tree rows left untreated) the possibility of exposure of foragers to kaolin in the untreated area cannot be excluded.

The duration of the monitoring (24-h monitoring) is insufficient to address possible long-term effects.

B.9.3.2 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. Therefore, they were not included in Table B.9.3.2-1 (effect values relevant for the risk assessment).. 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.

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.

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				

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

Species	Substance	Exposure System	Results	Reference
0.5) include other Salticidae, *Hyperaspis reppensis*, Chrysopidae, other coccinellidae, *Brachynotocoris ferreri*, *Stethorus punctillum*, *Araniella cucurbitina*, other Thomisidae, *Orius laevigatus* and other Theridiidae. Tacoli *et al*., 2019 Surround WP applied 2 times (20 kg/ha) reduced the abundance of predatory mite populations (Araci: Phytoseiidae) in vineyards located in north-eastern Italy in 2015-2016 (4 field trials). Kaolin caused a gradual decrease in population density levels of *Kampimodromus aberrans* and *Typhlodromus pyri* with the maximum reduction ranging from 49 to 91% and with a complete population recovery in the next spring. Laboratory data showed that kaolin (190-200 kg/ha) reduced the fecundity of *K. aberrans* and *T. pyri* females but not their survival. Jaastad *et al*., 2006 Kaolin particle film (Surround) was applied twice (3 kg/hL) in an organic plum field and in two IPM apple fields in Western Norway in 2003-2005. The population of beneficial mites was negatively affected by kaolin treatment in both apples and plums in 2004 and 2005. The most common species of beneficial mites recorded were *Tydeus* sp., *Typhlodromus* sp. and *Amplyseius* sp.				

B.9.3.2.1 Effects on *Typhlodromus pyri*

No specific studies with the active substance were conducted.

B.9.3.2.2 Effects on *Aphidius rhopalosiphi*

No specific studies with the active substance were conducted.

B.9.3.2.3 Field studies

B.9.3.2.3/01

Reference	Puterka, G.J. 1997 (KCA 8.3.2/01) Report on the Effect of M 96-018 Kaolin on Insect Predators Report No.: -
Guidelines	-
GLP	No
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

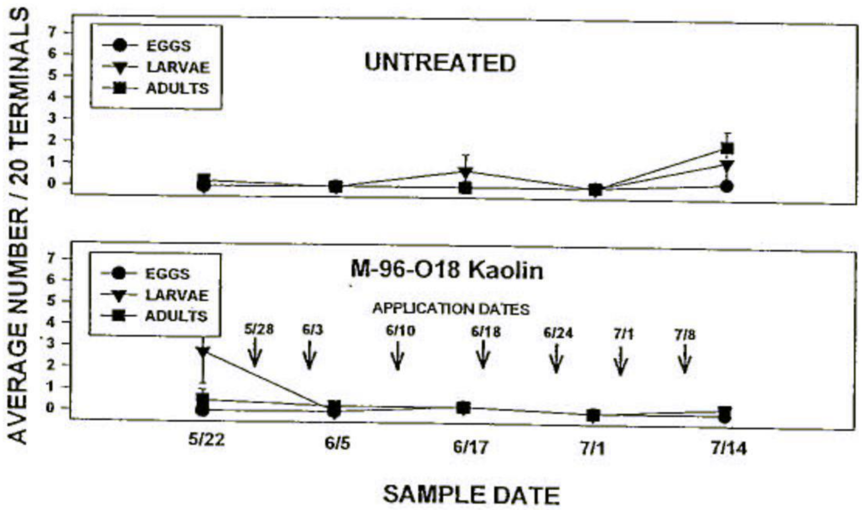
Material and methods

Test substance	M-096-018 (98.8% kaolin) Lot/Batch no.: Not specified
Vehicle	Water solution (+ 4% methanol)
Test species	Different life stages of naturally occurring insect predators: Ladybirds (Coccinelids); Lacewings (Chrysoperlids); Spiders (Araneae)

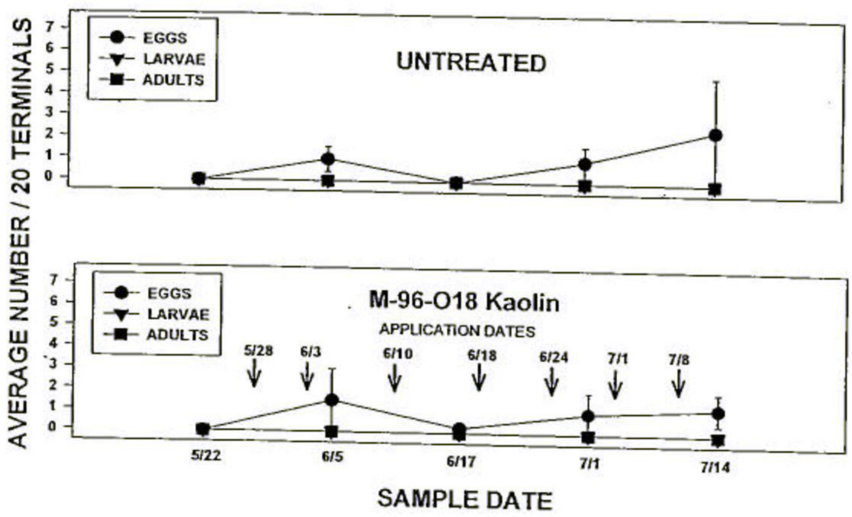
Reference item	-
Treatment	Kaolin applied as indicated on the product label and untreated control.
Trial location	USDA, Appalachian Fruit Research Station, Kearneysville, West Virginia, USA
Trial design /methodology	The trials consisted of 8 plots of apples, 4 were treated with the test substance, M-096-018, and 4 were left untreated. Seven applications of M-096-018, as a 3% solution (+ 4% methanol), were applied at weekly intervals from 28 May 1997 to 8 July 1997. Numbers of predators were observed every two weeks throughout the season from June to August in both treated and untreated plots. Tree terminals (first 20 cm) were inspected for all stages (egg, nymph, adult) of each predator species. In total, 20-25 terminals were inspected per treatment replicate. Differences between the kaolin treated plots and the untreated were assessed using ANOVA.
Statistics	ANOVA

Findings

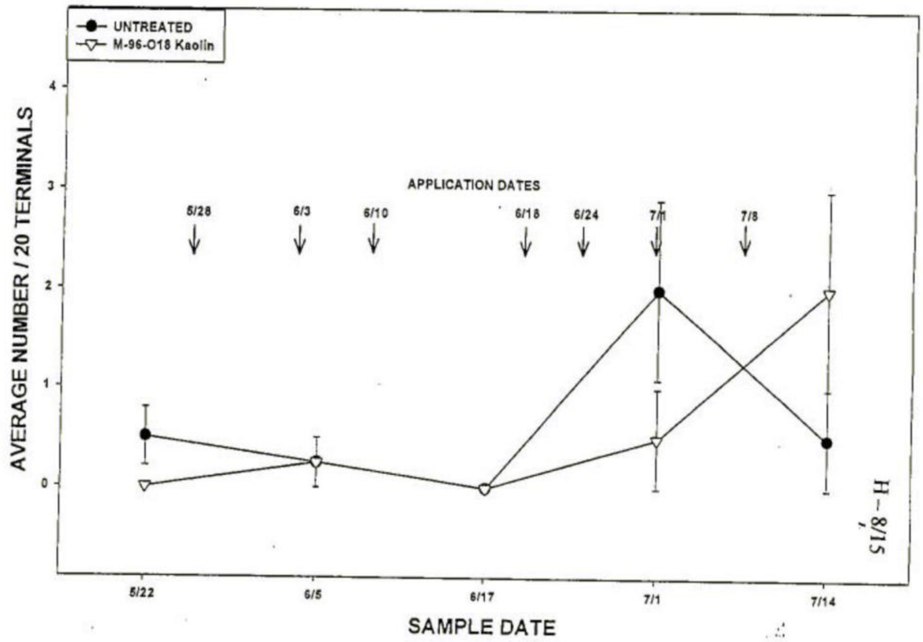
Ladybird beetles: Numbers were generally low throughout the trial. No significant differences were found post-treatment between M-96-018 Kaolin and the untreated control.



Green Lacewing: Numbers were generally low throughout the trial. No significant differences were found between M-96-018 Kaolin and the untreated control.



Spiders: Significantly less spiders in M-96-018 Kaolin treated fields early in season (1 July), but significantly more spiders in M-96-018 treated fields from 14 July onwards



Conclusion

Seven weekly applications of kaolin (M-96-018) as a 3% solution in water + methanol had no significant effects on populations of ladybirds (coccinellids), lacewings (chrysoperlids) and spiders (Araneae).

Study limitations: Due to poor reporting only scarce information on the trial design is available. The predator population is low, and the study cannot be considered reliable.

B.9.3.2.3/02

Reference	Lepine J. 2004 Evaluate the efficacy of Surround against *Cacopsylla piri*, applied just after the end of the winter period. Trial no. S04APC.PSYJL06, Report number FENG045059
Guidelines	CEB Method no.77
GLP	No (conducted to GEP - official code: FENG045059)
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water – spray volume 500 L/ha
Test species	Beneficial arthropods (Ladybirds (coccinelids), hemipterous bugs and hymenopterous parasites)
Reference item	Decis at 17.5 kg ai/ha
Treatment	Four single un-replicated large plots (420 m^2) of pears were treated as follows: - single spray of Surround® WP at 50 kg/ha - Surround® WP at 50kg/ha followed by 3 sprays at 25 kg/ha - single spray of Decis at 17.5 kg ai/ha - untreated as the control.
Trial location	37130 Lignières de Touraine, France
Trial design /methodology	Each assessment was done of larvae on 10 shoots in four different areas of each plot.
Statistics	-

Findings

The most important beneficials were parasitic Hymenoptera and Mirid heteropteran bugs (Philophorus & Deraeocoris). Other predators that were present only infrequently included, pirate bugs (Anthocoris), earwigs (Dermaptera), ladybirds (Propylea, Stethorus) and damsel bugs (Nabis). Overall numbers of beneficial arthropods were rather low in all treatments. However, there were no treatment related effects noted in the numbers of the main two groups, Hymenoptera and Mirid bugs, during the trial (Table B.9.5.1.2-1).

Table B.9.3.2.3/02-1: Beneficial arthropods in Surround® and reference plots

Treatments↓	Sampling Dates 27/04		04/05		18/05		25/05	
	Numbers : 4 x 10 shoots							
	Hym	Mir	Hym	Mir	Hym	Mir	Hym	Mir
Untreated	1	0	1	0	3	3	5	0
Surround® 50	3	0	1	1	0	10	4	0
Surround® 50+25	0	0	2	0	1	7	1	6
Decis 17.5	3	2	1	0	0	4	1	1

Hym = parasitic Hymenoptera, Mir = Mirid bugs (eg *Philophorus, Deraeocoris*)

Conclusion

Beneficial arthropods were mainly parasitic Hymenoptera and Mirid bugs. Numbers were generally low but no major differences were observed between the treatments.

Study limitations:

- Only few Hymenoptera and Mirid heteropteran bugs were sampled. Comparison of the number of individuals between treatments cannot lead to reliable conclusions.

- The study is designed to address effectiveness against phytophagous psyllids in orchards and is not suitable to address possible adverse effects on beneficial arthropods. The sampling size was insufficient for collection of a reliable number of parasitic Hymenoptera or predatory bugs.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- An unreplicated study design was selected. Results cannot be analysed statistically.

- It is not known if the tested application rate was verified.

B.9.3.2.3/03

Reference	Fraser, H. 2002a Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard. Report number 2002-1
Guidelines	-
GLP	-
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water
Test species	Plum curculio (*Conotrachelus nenuphar*), spring feeding lepidoptera complex and internal feeding Lepidoptera complex (e.g *Cydia pomonella, Grapholita molesta*), insect predators (Hoverflies (Syrphids), Lacewings (Chrysopids),

	Pirate bugs (*Orius*), Lady bird beetles (Coccinellids)), phytophagous (*Panonychus ulmi*) and predatory (e.g. *Amblyseius*) mites
Reference item	-
Treatment	Surround® WP (56 kg/ha product in 935 L/ha), untreated as the control.
Trial design /methodology	Surround® WP Crop Protectant was applied to 3 plots of apples of about 0.8 ha each using a commercial air blast sprayer delivering 56 kg/ha product in 935 L/ha. A total of 11 applications were applied at 7 to 14 day intervals between late of April 2002 to end of August. A grower standard of 3 x 0.8 ha plots was used as a reference. These plots were treated with mainly products suited for organic apple production. Pest damage was assessed by external and internal examination of the apples and leaves. Insect predators were collected by beating 25 branches in each plot. Both phytophagous and predatory mites were sampled by examining 50 leaves per plot.
Statistics	-

Findings

Surround® gave significantly better control of the main pests, plum curculio and internal Lepidoptera. Spider mites were more numerous in the Surround® treated plots but still were well below the treatment threshold. There were extremely few predatory mites in either treatment. In general, the numbers of predators were relatively low in both treatment regimes (Table B.9.5.1.2-2) and consisted mainly of ladybirds (coccinellids) hover flies (syrphids), lacewings (chrysoperlids) and pirate bugs (Orius). Overall, the numbers of insect predators in the Surround® WP treated plots were very similar to the grower standard.

Table B.9.3.2.3/03-1: Arthropods predators from beating 25 branches

Treatment	Date	Spider mite destroyers	Lacewings	Ladybirds	*Orius*	Mullein bugs	Other preds
Surround®	26/7/02	10	0	7	0	2	3
Grower	26/7/02	12	0	1	2	1	3
Surround®	23/8/02	5	35	40	4	3	0
Grower	23/8/02	14	9	9	6	1	3

Conclusion

Season long Surround® WP Crop Protectant applications appeared to have a minimal impact on insect predators like ladybirds, lacewings and Orius. On the basis of this test, Surround® WP Crop Protectant is not harmful to insect predators in the field, even when applied 11 times at 56kg/ha.

Study limitations:

- Low numbers of bugs, mites and other predators was recorded. Comparison of the number of individuals between treatments could yield unreliable results.

- The study is designed to address effectiveness against phytophagous psyllids in orchards and is not suitable to address possible adverse effects on beneficial arthropods. The sampling size (25 branches or 50 leaves per plot) is insufficient for collection of a reliable number of specimens.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- No toxic reference was included.

- It is not known if the tested application rate was verified.

B.9.3.2.3/04

Reference	Fraser, H. 2002b Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard. Report number 2002-2
Guidelines	-
GLP	-
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water
Test species	Plum curculio (*Conotrachelus nenuphar*), internal feeding Lepidoptera complex (e.g *Cydia pomonella, Grapholita molesta*), insect predators (Lacewings (Chrysopids), Lady bird beetles (Coccinellids), Mullein bugs (Campylomma)), phytophagous (*Panonychus ulmi*) and predatory (e.g. *Amblyseius*) mites
Reference item	-
Treatment	Surround® WP (56 kg/ha product in 935 L/ha), untreated as the control.
Trial design /methodology	Surround® WP Crop Protectant was applied to 3 plots of apples of about 0.8ha each using a commercial air blast sprayer delivering 56 kg/ha product in 935 L/ha. A total of 8 applications were applied at 7 to 14 day intervals between late of May 2002 to end of August. A grower standard of 3 x 0.8ha plots was used as a reference. These plots were treated following an IPM programme. Major pests present included plum curculio (Conotrachelus nenuphar) and an internal feeding Lepidoptera complex (e.g *Cydia pomonella, Grapholita molesta*). Pest damage was assessed by external and internal examination of the apples and leaves. Predatory mites were collected by beating 25 branches in each plot. Both phytophagous and predatory mites were sampled by examining 50 leaves per plot.
Statistics	-

Findings

Surround® gave significantly better control of the main pests, plum curculio and internal Lepidoptera. Spider mites were more numerous in the Surround® treated plots but still were well below the treatment threshold. There were few predatory mites (*Amblyseius*) in either treatment, although the numbers were generally lower in the Surround® treated plots. Predators consisted mainly of ladybirds (coccinellids), lacewings (chrysoperlids) and Mullein bugs (Campylomma). Overall, the numbers of insect predators in the Surround® WP treated plots were very similar to the grower IPM standard.

Table B.9.3.2.3/04-1: Arthropods predators from beating 25 branches

Treatment	Date	Lacewings	Ladybirds	Mullein bugs	Other preds
Surround®	18/7/02	7	3	7	0
Grower	18/7/02	0	2	5	4
Surround®	15/8/02	6	4	0	1
Grower	15/8/02	0	1	0	4

Conclusion

Season long Surround® WP Crop Protectant applications appeared to have a minimal impact on insect predators like lacewings, ladybirds and Mullein bugs. Numbers of predatory mites were generally low but there were fewer in the Surround® treated plots. On the basis of this trial, Surround® WP is not harmful to insect predators in the field but has an apparent effect on predatory mites when applied 8 times at 56kg/ha.

Study limitations:

- Low numbers of bugs and other predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.

- The study is designed to address effectiveness against phytophagous pests in orchards and is not suitable to address possible adverse effects on beneficial arthropods. The sampling size (25 branches or 50 leaves per plot) is insufficient for collection of a reliable number of NTA individuals.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- No toxic reference was included.

- It is not known if the tested application rate was verified.

B.9.3.2.3/05

Reference	Fraser, H. 2002c Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard. Report number 2002-5
Guidelines	-
GLP	-
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	No/No

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water

Test species	Plum curculio (*Conotrachelus nenuphar*), internal feeding Lepidoptera complex (e.g *Cydia pomonella*, *Grapholita molesta*), insect predators (Lacewings (Chrysopids), Lady bird beetles (Coccinellids), Mullein bugs (Campylomma)), phytophagous (*Panonychus ulmi*) and predatory (e.g. *Amblyseius*) mites
Reference item	-
Treatment	Surround® WP (56 kg/ha product in 935 L/ha), untreated as the control.
Trial design /methodology	Surround® WP Crop Protectant was applied to 3 plots of apples of about 0.8ha each using a commercial air blast sprayer delivering 56 kg/ha product in 935 L/ha. A total of 8 applications were applied at 7 to 14 day intervals between late of May 2002 to end of August. A grower standard of 3 x 0.8ha plots was used as a reference. These plots were treated following an IPM programme. Major pests present included plum curculio (*Conotrachelus nenuphar*) and an internal feeding Lepidoptera complex (e.g *Cydia pomonella*, *Grapholita molesta*). Pest damage was assessed by external and internal examination of the apples and leaves. Predatory mites were collected by beating 25 branches in each plot. Both phytophagous and predatory mites were sampled by examining 50 leaves per plot.
Statistics	-

Findings

Surround® gave significantly better control of the main pests, especially internal Lepidoptera. Spider mite numbers were low and appeared similar in both treatment regimes. There were very few predatory mites (Amblyseius) in either treatment, although the numbers were generally lower in the Surround® treated plots. Predators consisted mainly of ladybirds (Coccinellids), lacewings (Chrysoperlids), Pirate (Orius) and Mullein bugs (Campylomma). Overall, the numbers of insect predators in the Surround® WP treated plots were very similar to the grower IPM standard.

Table B.9.3.2.3/05-1: Arthropods predators from beating 25 branches

Treatment	Date	Lacewings	Ladybirds	Mullein bug	Other preds
Surround®	18/7/02	7	2	4	1
Grower	18/7/02	0	2	2	0
Surround®	15/8/02	11	10	0	1
Grower	15/8/02	6	8	0	3

Conclusion

Season long Surround® WP Crop Protectant applications appeared to have a minimal impact on insect predators like Coccinellids, Chrysoperlids, Pirate and Mullein bugs. Numbers of predatory mites were generally low but there were fewer in the Surround® treated plots. On the basis of this trial, Surround® WP is not harmful to insect predators in the field but had an apparent slight effect on predatory mites when applied 8 times at 56kg/ha.

Study limitations:

- Low numbers of bugs and other predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.

- The study is designed to address effectiveness against phytophagous arthropods in orchards and is not suitable to address possible adverse effects on beneficial arthropods. The sampling size (25 branches or 50 leaves per plot) is insufficient for collection of a reliable number of NTA individuals.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- No toxic reference was included.

- It is not known if the tested application rate was verified.

B.9.3.2.3/06

Reference	Fraser, H. 2002d Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard. Report number 2002-6
Guidelines	-
GLP	-
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water
Test species	Internal feeding Lepidoptera complex (e.g Cydia pomonella, Grapholita molesta), spring feeding Lepidoptera complex, apple maggot (Rhagoletis) and leafrollers (Choristoneura), insect predators (Ladybirds (Coccinellids, Lacewings (Chrysopids), Spiders (Araneae), Predatory mites (Amblyseius)), phytophagous (Panonychus ulmi) and predatory (e.g. Amblyseius, Zetzellia) mites.
Reference item	-
Treatment	Surround® WP (56 kg/ha product in 935 L/ha), untreated as the control.
Trial location	
Trial design /methodology	Surround® WP Crop Protectant was applied to 2 plots of apples of about 0.8ha each using a commercial air blast sprayer delivering 56 kg/ha product in 935 L/ha. A total of 6 applications were applied at 7 to 14 day intervals between May 2002 to end July. A grower standard of 3 x 0.8 ha plots was used as a reference. These plots were treated following an IPM programme. Major pests present included an internal feeding Lepidoptera complex (e.g *Cydia pomonella*, *Grapholita molesta*), spring feeding Lepidoptera complex, apple maggot (Rhagoletis) and leafrollers (Choristoneura). Pest damage was assessed by external and internal examination of the apples and leaves. Insect predators (Ladybirds (Coccinellids, Lacewings (Chrysopids), Spiders (Araneae), Predatory mites were collected by beating 25 branches in each plot. Both phytophagous (*Panonychus ulmi*) and predatory (e.g. Amblyseius, Zetzellia) mites were sampled by examining 50 leaves per plot.

Statistics -

Findings

Surround® gave significantly better control of apple maggots and leafrollers. Spider mite numbers were low but appeared slightly higher in the Surround® plots. There were very few predatory mites (Amblyseius) in either treatment, although the numbers were generally lower in the Surround® treated plots. Predators consisted mainly of ladybirds (coccinellids), lacewings (chrysoperlids), hover flies (syrphids) and spiders. Overall, the numbers of insect predators in the Surround® WP treated plots were very similar to the grower IPM standard.

Table B.9.3.2.3/06-1: Arthropods predators from beating 25 branches

Treatment	Date	Ladybirds	Spiders	Other preds
Surround®	18/7/02	2	3	1
Grower	18/7/02	2	6	2
Surround®	15/8/02	1	1	1
Grower	15/8/02	5	0	2

Conclusion

Season long Surround® WP Crop Protectant applications appeared to have a minimal impact on insect predators like coccinellids, chrysoperlids, spiders and syrphids. Numbers of predatory mites were generally very low but there were fewer in the Surround® treated plots. On the basis of this trial, Surround® WP is not harmful to insect predators in the field but had an apparent slight effect on very low numbers of predatory mites when applied 6 times at 56 kg/ha.

Study limitations:

- Low numbers of bugs, spiders and other predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.

- The study is designed to address effectiveness against phytophagous arthropods in orchards and is not suitable to address possible adverse effects on beneficial arthropods. The sampling size (25 branches or 50 leaves per plot) is insufficient for collection of a reliable number of NTA individuals.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- No toxic reference was included.

- It is not known if the tested application rate was verified.

B.9.3.2.3/07

Reference	Fraser, H. 2002e Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard. Report number 2002-7
Guidelines	-
GLP	-

Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	No/No

Material and methods

Test substance	Surround® WP Crop Protectant Lot/Batch no.: Not specified
Vehicle	Water
Test species	Plum curculio (*Conotrachelus nenuphar*) an internal feeding Lepidoptera complex (e.g *Cydia pomonella, Grapholita molesta)* and a general sucking pest complex. Pest damage was assessed by external and internal examination of the apples and leaves. Insect predators (Pirate bugs (Orius), Lacewings (Chrysopids), Spiders.
Reference item	-
Treatment	Surround® WP (56 kg/ha product in 935 L/ha), untreated as the control.
Trial location	
Trial design /methodology	Surround® WP Crop Protectant was applied to 2 plots of apples of about 0.4ha each using a commercial air blast sprayer delivering 56 kg/ha product in 935 L/ha. A total of 6 applications were applied at 7 to 14 day intervals between end April 2002 and mid August. A grower standard of 2 x 0.4ha plots was used as a reference. These plots were treated following a transitionary organic programme. Pest damage was assessed by external and internal examination of the apples and leaves. General spider mite predators were collected by beating 25 branches in each plot.
Statistics	-

Findings

Table Surround® gave significantly better control of plum curculio, internal Lepidoptera complex and general sucking pests. Predators consisted mainly of lacewings (chrysoperlids), Orius, general spider mite predators and spiders. Overall, the numbers of insect predators in the Surround® WP Crop Protectant treated plots were very similar to the grower IPM standard.

Table B.9.3.2.3/07-1:: Arthropod predators from beating 25 branches

		destroyer			
Surround®	26/7/02	1	0	0	4
Grower	26/7/02	8	1	0	0
Surround®	23/8/02	13	12	4	1
Grower	23/8/02	9	15	12	1

Conclusion

Season long Surround® WP Crop Protectant applications appeared to have a minimal impact on insect predators like ladybirds, lacewings, spiders and general spider mite predators. On the basis of this trial, Surround® WP Crop Protectant is not harmful to insect predators in the field even when applied 15 times at 56 kg/ha.

Study limitations:

- Low numbers of bugs, spiders and other predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.

- The study design is suitable to address effectiveness against phytophagous arthropods in orchards but not to address possible adverse effects on beneficial arthropods. The sampling size (25 branches per plot) is insufficient for collection of a reliable number of NTA individuals.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- No toxic reference was included.

- It is not known if the tested application rate was verified.

B.9.3.2.3/08

Reference	G Peusens & P Creemers 2004a Biological efficacy evaluation of Surround WP against the pear sucker, *Cacopsylla pyri* L., on pear. Report number 20040617 412 BE 388 GEP
Guidelines	EPPO guideline “Cacopsylla”. EPPO Standards (1997)
GLP	No
Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	M99099 Lot/Batch no.: Not specified
Vehicle	Water
Test species	Anthocoris predators
Reference item	
Treatment	
Trial design /methodology	Five trials" were set up in 2002 to test the biological efficacy of Surround WP against the pear sucker *Psylla pyri*. Observations were carried out on the predatory bug, *Anthocoris nemoralis*, in 3 out of 5 trials carried out with Surround® against pear Cacopsylla in Belgium. Surround® WP was applied at 10 to 30 kg/ha to large blocks of pears. Four applications were made from early February to late March at crop stages BBCH 52-56. Assessments were made on Cacopsylla adults, eggs and nymphs. Anthocoris was assessed using a branch beating technique in mid April and/or June
Statistics	Statistics were executed using Unistat software version 4.53 (Unistat Ltd., London, Transformations (log (va1ue+1), sqr (value), arcsin (va1ue)) of the observations were used to stabilise the variance. The homogeneity of variance was tested with a Bart1ett’s Chi-Square and a Bartlett-Box F test. If homogeneity was proved, analysis of variance (ANOVA) was executed. If

significant differences between objects at the 95% confidence level was obtained, a multiple comparison was executed with a Duncan test. Values followed by the same letter are not significantly different ($p<0.05$).

Findings

Numbers of Anthocoris were generally low even in the untreated controls. Nevertheless, they were somewhat reduced in the Surround® treated plots. This reduction was usually between 25-80% and therefore Surround® could be considered slightly to moderately harmful to Anthocoris predators. The effects on Anthocoris are probably due to removal of prey (Cacopsylla nymphs) and the general repellent effect of the Surround® particle film on the mobile adults present at the time of the Surround® applications.

Conclusion of trial 02/PSYLPY.05

	Anthocoris nemoralis				
	14/04	28/05		24/06	
	adults	nymphs	adults	nymphs	adults
	Number				
Untreated	2 a	0.8 a	1 a	15	3
	Mortality (Abbott %)				
Decis	62.5 a	66.7 a	50 a	73.3	33.3
Surround 30 kg	87.5 a	33.3 a	50 a	26.7	66.7

Conclusion of trial 02/PSYLPY.06

	Psylla pyri		***Anthocoris nemoralis***	
	25/03	10/04	25/06	
	Number			
	Eggs	Larvae	Nymphs	Adults
Untreated	89 a	16.3 a	16	8
	Mortality (Abbott %)			
Surround 10 kg	61.2 a	96.9 b	6.3	25
Surround 20 kg	45.5 a	93.8 b	87..5	87.5
Surround 30 kg	64.6 a	98.5 b	50	62.5

Conclusion of trial 02/PSYLPY.08

	Psylla pyri		*Anthocoris nemoralis*			
	25/03	10/04	18/04	24/06		
	Number					
	eggs	larvae	nymphs	nymphs	adults	total
Untreated	115.5 a	17.5 a	1.8 a	6	2	
	Mortality (Abbott %)					
Surround 10 kg	0 a	21.4 a	0 a	25	100	43.8
Surround 20 kg	0 a	92.9 c	100 a	25	25	25
Surround 30 kg	0 a	71.4 b	100 a	33.3	50	37.5

Conclusion

In the 3 trials where observations were made on predatory bugs, Surround® gave good control of pear Cacopsylla, particularly the nymphal stages. Numbers of Anthocoris were generally low even in the untreated control. However, they were reduced in numbers in the Surround® treated plots. This reduction was normally between 25-80% thus indicating that Surround® should be classified as slightly to moderately harmful to Anthocoris. It is considered likely that this effect on Anthocoris is probably due to a combination of the removal of their food supply (e.g. Cacopsylla nymphs) plus a general repellent effect of the Surround® particle film on the mobile adult forms of Anthocoris present at the early stage in the season.

Study limitations:

- Low numbers of Anthocoris predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.

- The study design is suitable to address effectiveness against phytophagous arthropods in orchards but not to address possible adverse effects on Anthocoris population.

- Possible contamination of the untreated plots cannot be excluded as no information on unsprayed area between treatments is specified.

- Worst case application scheme was not covered.

B.9.3.2.3/09

Reference	G Peusens & P Creemers 2004b Biological efficacy evaluation of Surround WP against the pear sucker, *Cacopsylla pyri* L., on pear. Report number 20040617 460 BE 421 GEP
Guidelines	EPPO guideline “Cacopsylla”. EPPO Standards (1997)
GLP	No

Previous evaluation	Previously evaluated in DAR B9, IIA 8.3.2/01
Validity/Acceptance	Not reliable

Material and methods

Test substance	M99099
	Lot/Batch no.: Not specified
Vehicle	Water
Test species	Anthocoris populations
Reference item	-
Treatment	Surround® WP, untreated as the control.
Trial location	
Trial design /methodology	Four single large un-replicated blocks of pear trees were used for the trial. One block was left untreated as the control and the other 3 were treated with Surround® WP as a 2% solution on 3 dates between 14 March and 14 April 2003 (crop stages BBCH 52-59). One of the Surround® blocks was treated using a spray volume of 500 L/ha whilst the other 2 were treated using 300 L/ha. Within each treatment block, four separate plots were established for sampling. Over-wintering adult pear Cacopsylla were assessed by beating 3 branches on each of 10 trees per plot. Cacopsylla eggs and nymphs were assessed by counting numbers on 10 branches of about 20cm long per plot. Branches were tagged before treatments commenced so the same branches could be assessed in post-treatment assessments. Anthocoris populations were assessed by beating 3 branches on each of 10 trees per plot and catching the displaced insects on a tray positioned under the branch. Samples of Anthocoris were collected on 16 April, two days after the last application.
Statistics	% control was calculated using the following formulae: Henderson-Tilton – Cacopsylla eggs and adults corrected for pre-treatment differences. Abbott – Cacopsylla nymphs and Anthocoris adults. Homogeneity of variance was assessed using Bartletts chi-square tests and raw numbers were transformed to their Log+1 values as appropriate. Significant differences between treatments were tested using ANOVA followed by Duncan’s multiple comparison tests.

Findings

Surround® applied at 300 and 500 L/ha gave excellent control of Cacopsylla adults, eggs and nymphs on all assessment dates (Table B.9.5.1.2-7). Anthocoris was assessed only once on 16/04/03. Numbers in the untreated plots were still low (6 adults per 30 branches). However, in all Surround® treated plots there was a significant reduction in Anthocoris compared with the untreated.

Table B.9.3.2.3/09-1: % control of Cacopsylla and effects on Anthocoris

	Cacopsylla pyri								*Anthocoris*
	14/03/03		3/04/03		16/04/03			30/04/03	16/04/04
	Numbers of P. pyri								
	adults	eggs	adults	eggs	adults	eggs	nymphs	nymphs	Total
Untreated	84.5 a	70 a	26 a	56.7 a	10.0 a	15.0 a	4.5 a	11.5 a	6.0 a
	Number		Henderson-Tilton %					Abbott %	
Surround® 2% 500 L/ha	84.5 a	65.5 a	93.3 b	91.9 d	96.2 b	89.4 a	100 b	98.2 b	100 b
Surround® 2% 300 L/ha	91.6 a	67.9 a	81.1 b	74.9 c	91.2 b	100 a	100 b	94.2 b	94 b
Surround® 2% 300 L/ha	98.3 a	73.4 a	90 b	53.1 b	94.6 b	80.4 a	100 b	94.2 b	100 b

Different letter subscripts denote significance difference between treatments at P≤ 0.05

Conclusion

Surround® generally gave excellent control of all life stages of pear Cacopsylla. Numbers of Anthocoris were low but they were significantly lower in the Surround® treated plots. This reduction was probably due to a combination of the removal of their food supply (e.g. Cacopsylla nymphs) plus the general repellent effect of Surround® on the mobile adult forms of Anthocoris present at this early stage in the season.

Study limitations:

- Low numbers of Anthocoris predators was recorded. Comparison of the number of individuals between treatments could yield unreliable conclusions.
- An unreplicated scheme was selected (plots were established within each treatment block).
- The study is designed to address effectiveness against phytophagous arthropods in orchards and is not suitable to address possible adverse effects on Anthocoris population. The sampling size (10 branches per plot) is insufficient for collection of a reliable number of Anthocoris adults.
- Worst-case application scheme was not covered.

B.9.3.2.3/10

Reference	Pascual S, Cobos G., Serris E. and Gonzalez-Numez M., 2010a Effect of processed kaolin on pests and non-target arthropods in a Spanish olive grove Journal of Pest Science 83:121-133
Guidelines	-
GLP	No

Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Surround WP Lot/Batch no.: Not specified
Test species	Foliage-dwelling arthropod community
Reference item	Dipagrex 80 (Trichlorfon (80%)) + protein hydrolysate; 5 g f.p./L+ 10 g f.p./L
Treatment	3 kg/100 L; 2 treatments (beginning of the summer and autumn)
Trial location	Olive grove in Villarejo de Salvane's, south-eastern Madrid, Spain
Trial design /methodology	A 3-year field experiment was conducted from 2005 to 2007 at Villarejo de Salvanes, Spain to assess the effects of Surround WP on the arthropod community of olive trees and on natural enemies. The variety of olive trees was Manzanilla' and they were planted at a density of 100 trees per hectare. To evaluate the effects on arthropod communities in olive groves after the use of Surround WP, two treatments were applied, the first one at the beginning of summer, when olive fruits are big enough for the attack of *B. oleae*, and the second one in autumn, to guarantee the coating until the end of the crop season, for three consecutive years. Each treatment was applied to an area of about 0.8 h. Experimental plots were randomly located in the olive grove. No additional pest control measures were used except for one treatment with Biobit XL (*Bacillus thuringiensis*) applied at bloom to all test plots to control *Prays oleae*. The arthropod fauna from the canopy of olive trees was sampled using a beating method. In the laboratory, samples were kept in a freezer prior to analysis and after thawing and cleaning the specimens were classified into four groups: phytophagous on olive trees, predators, parasitoids and other. Biological diversity was assessed by calculating the Shannon index.
Statistics	In order to investigate the changes in abundance of predators and parasitoids in the canopy of olive trees, a principal response curve (PRC) analysis was carried out using the program CANOCO 4.51 (Biometris, Plant Research International, Wageningen, The Netherlands). In order to determine the effects of Surround WP on different taxa, 'Species Weights' and PRCs for Surround WP relative to the untreated control were calculated for each year.

Findings

Effect of treatments on the abundance and diversity of arthropods

When comparing Surround WP to the control plots, Surround WP treatment reduced the number of arthropods captured per tree for some of the sampling dates and always after the second Surround WP treatment of the season. Overall, Surround WP treatment resulted in a reduction in the number of species and also in the Shannon index. This reduction was observed at the end of the crop season in the 3 years of study. No consistent observation between trichlorfon and control plots were noted.

Effects of treatments on natural enemy communities

The principal response curves (PRCs, figure below) indicated that there was a significant deleterious effect of the Surround WP treatment on the natural enemy arthropod community of the olive grove compared to the untreated control for the 3 years of study. The analysis captured 34.8, 52.3 and 41.0% of the variance caused by the treatment effect in 2005, 2006 and 2007, respectively. On the other hand, trichlorfon-bait sprays did not have a significant effect in any of the years studied. Taxa indicated with a positive weight are expected to decrease in abundance relative to the control after treatment with Surround WP. *S. mediterraneus* had the highest positive weight in 2005 and 2006, and it also had a positive weight in 2007. Other species with positive weights in 2005 and 2006 were *S. punctillum, B. ferreri* and *Hyperaspis reppensis* (Herbst). In 2007, the taxon with the highest weight was the family Philodromidae, which also had a positive weight in 2006. Different species of *Onus* and the family Aphelinidae had high positive weights only in 2007. The families Scelionidae, Pteromalidae and Chrysopidae had positive weights for all 3 years. Taxa with negative weights in the PRCs are expected to increase after Surround WP treatment. Results were not conclusive in this respect as taxa with negative weights were different from one year to another, and the number of taxa with negative weights was very small.

Table B.9.3.2.3/10-1: Total numbers of natural enemies captured by the beating method along 2005–2007 in olive plots sprayed with kaolin (Ka), trichlorfon bait (Tr-b) and the untreated control plot (C)

Taxa	2005			2006			2007			TOTAL	(%)
	C	Ka	Tr-b	C	Ka	Tr-b	C	Ka	Tr-b		
Predators	405	297	352	766	368	873	1,161	561	901	5,684	80.5
Araneae	107	123	111	249	142	316	634	339	512	2,533	35.9
Araneidae	12	8	8	22	8	42	150	55	145	450	6.4
Araniella cucurbitina	4	3	3	14	3	20	86	33	81	247	3.5
Gibbaranea spp.	5	3	3	2	1	8	37	3	30	92	1.3
Other Araneidae	3	2	2	6	4	14	27	19	34	111	1.6
Oxyopidae	1	3	1	7	13	13	24	21	24	107	1.5
Philodromidae	39	38	32	89	32	72	201	95	159	757	10.7
Salticidae	14	21	24	55	31	76	45	33	49	348	4.9
Icius hamatus	2	5	9	7	2	14	7	1	15	62	0.9
Salticus sp.	2	8	5	12	12	10	3	4	8	64	0.9
Thyene imperialis	3	1	0	5	2	10	12	1	7	41	0.6
Other Salticidae	7	7	10	31	15	42	23	27	19	181	2.6
Theridiidae	16	15	17	36	28	47	119	92	67	437	6.2
Theridion sp.	9	9	8	11	11	18	58	23	36	183	2.6
Other Theridiidae	7	6	9	25	17	29	61	69	31	254	3.6
Thomisidae	17	24	18	20	12	45	30	20	36	222	3.1
Tmarus spp.	3	11	9	5	7	27	5	3	18	88	1.2
Other Thomisidae	14	13	9	15	5	18	25	17	18	134	1.9
Other Araneae	8	14	11	20	18	21	65	23	32	212	3.0
Coleoptera	150	60	138	312	77	279	134	23	107	1,280	18.1
Coccinellidae	132	44	109	283	57	235	114	10	93	1,077	15.3
Brumus quadripustulatus	1	0	0	3	0	1	5	0	1	11	0.2
Chilocorus bipustulatus	2	0	1	2	0	0	29	0	1	35	0.5
Hyperaspis reppensis	5	0	3	17	1	6	0	0	0	32	0.5
Nephus spp.	0	4	1	3	2	6	0	2	3	21	0.3
Platynaspis luteorubra	8	0	0	2	0	2	2	0	1	15	0.2
Propylea quatuordecimpunctata	1	0	0	0	0	1	9	0	6	17	0.2
Rhyzobius chrysomeloides	2	6	0	0	4	6	12	2	9	41	0.6
Rhyzobius litura	0	0	0	4	0	5	2	0	1	12	0.2
Scymnus mediterraneus	80	19	79	217	47	168	25	3	24	662	9.4
Stethorus punctillum	31	12	23	17	2	24	4	1	24	138	2.0
Other Coccinellidae	2	4	2	18	1	16	26	2	23	94	1.3
Cybocephalidae—*Cybocephalus* sp.	7	5	4	6	3	11	1	2	1	40	0.6
Dasytidae	8	9	22	20	16	26	10	7	10	128	1.8
Mauroania elegans	8	7	21	19	16	26	10	7	10	124	1.8
Other Dasytidae	0	2	1	1	0	0	0	0	0	4	0.1
Staphylinidae	1	0	1	1	1	4	5	4	3	20	0.3
Other predatory Coleoptera	2	2	2	2	0	3	4	0	0	15	0.2
Diptera											
Empididae	0	1	1	5	1	1	2	0	4	15	0.2
Hemiptera	87	67	57	112	72	185	231	100	165	1,076	15.2
Anthocoridae	30	20	22	31	2	63	175	55	109	507	7.2
Anthocoris nemoralis	29	20	22	13	2	52	48	54	51	291	4.1
Orius laevigatus	0	0	0	12	0	9	42	0	26	89	1.3
Orius majusculus	1	0	0	1	0	0	57	1	10	70	1.0

Table 1 continued

Taxa	2005			2006			2007			TOTAL	(%)
	C	Ka	Tr-b	C	Ka	Tr-b	C	Ka	Tr-b		
Orius niger	0	0	0	2	0	0	21	0	13	36	0.5
Other Anthocoridae	0	0	0	3	0	2	7	0	9	21	0.3
Miridae	55	47	33	81	70	121	55	45	56	563	8.0
Brachynotocoris ferreri n. sp	43	27	18	23	8	21	26	12	28	206	2.9
Phytocoris viberti	5	13	9	18	32	42	22	22	18	181	2.6
Pseudoloxops coccineus	6	6	4	40	30	58	2	10	9	165	2.3
Other predatory Miridae	1	1	2	0	0	1	5	1	1	13	0.2
Hymenoptera											
Vespidae	0	0	0	0	2	0	32	4	24	64	0.9
Neuroptera	54	42	38	84	64	82	116	88	83	651	9.2
Chrysopidae	11	9	8	28	20	29	86	41	50	282	4.0
Coniopterygidae	37	33	30	53	42	50	27	47	32	351	5.0
Other Neuroptera	6	0	0	3	2	3	3	0	1	18	0.3
Thysanoptera											
Aeolothripidae	4	2	1	1	8	8	8	6	1	39	0.6
Other predatory Arthropoda	3	2	6	1	2	2	4	1	5	26	0.4
Parasitoids	93	58	78	161	91	280	262	113	238	1,374	19.5
Hymenoptera	93	58	78	161	91	280	262	113	238	1,374	19.5
Chalcidoidea	61	29	60	83	58	125	197	54	143	810	11.5
Aphelinidae	1	1	3	1	1	3	59	10	54	133	1.9
Encyrtidae	32	18	32	23	32	52	34	21	22	266	3.8
Eulophidae	9	2	5	12	5	16	15	7	14	85	1.2
Eupelmidae	1	1	1	0	1	2	15	0	1	22	0.3
Eurytomidae	1	1	1	0	0	2	4	0	5	14	0.2
Pteromalidae	12	4	11	33	11	37	56	8	33	205	2.9
Other Chalcidoidea	5	2	7	14	8	13	14	8	14	85	1.2
Chrysidoidea-Bethylidae	2	1	3	1	0	1	2	0	2	12	0.2
Ichneumonoidea	4	7	4	5	3	14	3	9	23	72	1.0
Braconidae	3	7	3	4	2	10	1	7	12	49	0.7
Ichneumonidae	1	0	1	1	1	4	2	2	11	23	0.3
Platygastroidea-Scelionidae	24	15	7	69	25	121	54	39	54	408	5.8
Other hymenopteran parasitoids	4	6	4	3	5	19	6	11	16	72	1.0
Total natural enemies captured	498	355	430	927	459	1,153	1,423	674	1,139	7,058	100.0

Figure B.9.3.2.3/10-1: Temporal evolution of the abundance and diversity of arthropods in the olive plots treated with Surround WP, trichlorfon bait or untreated. Parameters shown are: arthropod abundance (a), the number of captured species (b) and the Shannon diversity index (c). Data are means of four replicates. Arrows indicate treatment applications.

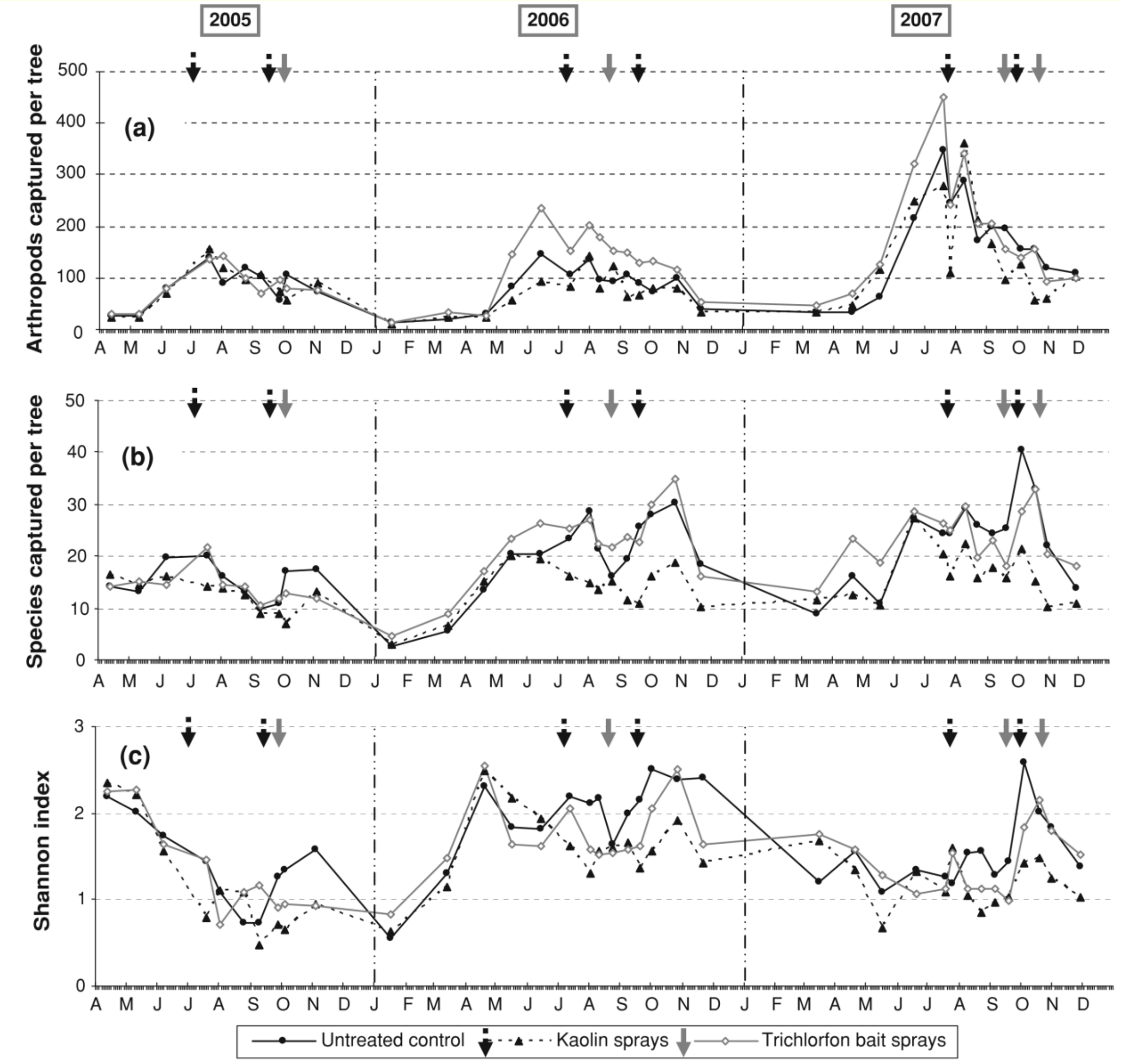
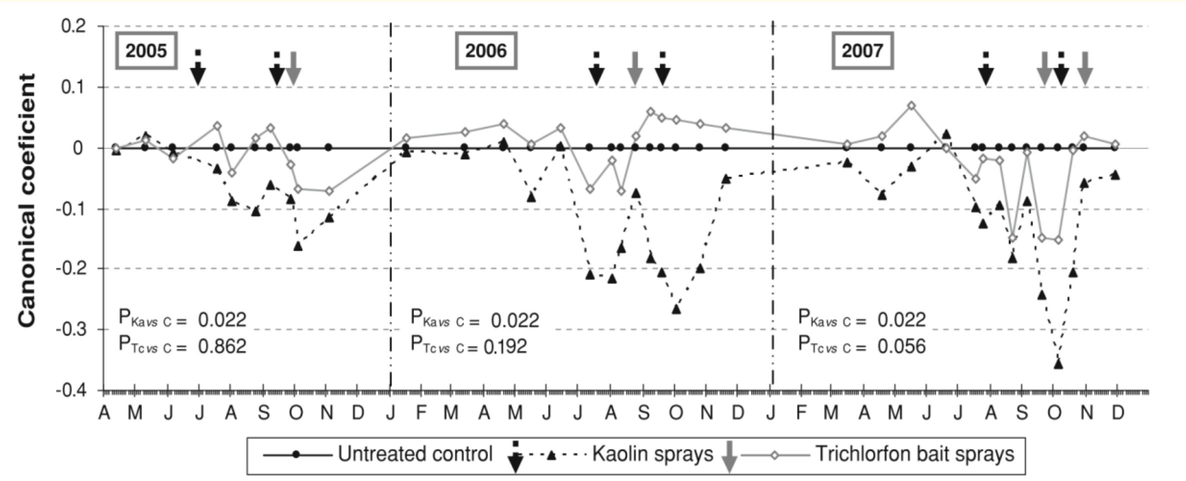


Figure B.9.3.2.3/10-2: PRC diagram showing the effects of Surround WP sprays and trichlorfon bait sprays on the beneficial community of arthropods over the growing seasons between 2005 and 2007 in an olive grove in Madrid. The PRC shows the effect of the treatments relative to an untreated control, which is represented by the y = 0 line. The P values denote the significance of each treatment curve relative to the untreated control over all the dates based on an F-type permutation test (Monte Carlo simulation, 499 permutations). Arrows indicate treatment applications



Conclusion

This study shows that the processed kaolin Surround WP alters the arthropod community in olive trees. Also, it reduces the abundance and diversity of the arthropod community as a whole.

The principal response curve (PRC) analysis revealed a significant adverse effect of Surround WP on the natural enemy arthropod community of the olive grove. 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.

Study limitations:

The field study was evaluated considering the standards and recommendations set in the *Guidance for summarising and evaluating field studies with non-target arthropods* (de Jong et al., 2010) with regard to the reliability and the suitability for the risk assessment.

- The community of non-target arthropods captured is below the recommended range of 150-200 counted taxa (50-80 available for statistical analysis) of the de Jong document. Several taxa that should be evaluated in order to render the study representative of the orchard ecosystem are missing (attributed to the consideration of just one sampling method and the fact that the study focused on effects on the beneficial arthropod community). Overall, the study was considered suitable for addressing possible adverse effects on specific taxa (where an adequate number of specimens allow for a reliable statistical analysis). On the contrary, the study is not suitable for identifying the most sensitive taxonomic group (in view of the absence of representativeness) or to address recovery of the affected populations (limited sampling occasions after the last application; kaolin applications did not cover worst-case exposure).

- The number of replicated plots per treatment were not reported.

- No information on unsprayed area between treatments to avoid contamination of the untreated plots is specified.

-The reference product was used as bait application. This reference product is not suitable to address the susceptibility of the test system. The toxic effects from the use of the reference product are minor (as expected). However, since striking effects on the captured arthropod community was observed throughout the monitoring period, this limitation does not seem to compromise the reliability of the study and the interpretation of the results.

- The actual plot size is not specified. The report mentions only the total area used per treatment (0.8 ha).

- The water volume which was used for application is not specified. Since the application rate is given in kg/hl the ground application dose (L/ha) cannot be calculated. Further, only two applications per year were carried out and therefore the worst-case application scheme (4 applications per year) is not covered.

- Just one sampling method was considered (beating method). Thus, specific taxa (e.g. soil-dwelling populations) were not represented.

- No information on the pre-treatment variation between plots was provided.

- The raw data (effects on taxa at each assessment date) are unavailable.

- Information on history and weather conditions during the 3-year monitoring is missing.

- It is not known if the tested application rate was verified.

B.9.3.2.3/11

Reference	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 International Journal of Pest Management vol 56: 189-199
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Hydrophobic kaolin M96-018 Lot/Batch no.: Not specified
Test species	Foliage-dwelling arthropod community
Reference item	-
Treatment	kaolin M96-018 (10-12 applications; 45 kg/ha + 40 ml methanol/L with 1500L/ha; average intervals of 10 days) in 4 blocks each of 0.23 ha (504-660 trees) Untreated control
Trial location	De Schuilenburg in Kesteren, Netherlands
Trial design /methodology	32-year-old apple orchard De Schuilenburg in Kesteren, Netherlands. Had four blocks each of +0.23 ha (504-660 trees) consisting of cultivars James Grieve M7 (two rows), Golden Delicious M9 (two rows) arid Cox's Orange Pippin M9 (two rows) at a planting distance of 4 x (1.5-2.25 m). The treatments were carried out 12 times (45 kg/ha + 40 ml methanol/L with 1500 L/ha) at average intervals of 10 days, between 24 March and 5 August in

1997. The applications were more frequent after rainstorms and less frequent during prolonged dry periods, and the treatments were interrupted during the apple blooming period between 16 April and 15 May. The treatments were completed earlier on the early (summer) cultivar James Grieve (on 15 July), so at that site only 10 applications of kaolin were made.

Beating-funnel samples were collected by jarring the entire canopy of two randomly chosen trees per plot (eight trees per treatment). Two additional, randomly chosen, trees were sampled in the fourth block, both in the kaolin-treated and control plots, but these samples were used only for calculating Renyi diversity and community composition. The heteropterans and the adults of beetles, and also most spiders collected, were identified to species level. The bug, beetle and spider communities were characterized in terms of abundance, species richness, composition and diversity. Last application was 5 August, while last sampling was 28 September.

Statistics

Percent reduction due to kaolin treatment was determined by Abbott's formula (Abbott, 1925). The numbers of individuals and species richness were compared by Welch's modified t-test with the post hoc Games-Howell test when the data were normally distributed. If the data did not conform to a normal distribution, the adjusted rank Welch test, followed by tests of pairwise stochastic equalities with Bonferroni correction, was applied. Because of small sample size, the comparison of guilds, families and species was performed only on data pooled across the growing season or across that part of the season when the kaolin was being periodically sprayed and after the applications had finished. All the statistical analyses were carried out by using the software package RopStat. Renyi diversity ordering was chosen for calculating the diversity.

Findings

Heteropteran community

The kaolin treatments significantly decreased both the total annual numbers collected and the species richness of the Heteroptera community (Table 8.3-10). Most of the individuals belonged to the predatory guild. This group was most affected by kaolin treatments while the phytophagous guild decreased to a lesser extent. The number of heteropterans was often lower in the kaolin-treated plots, although the difference was statistically significant only at two dates. The mean species richness (number of species collected on two trees) alternated between 0.75 and 4.5 during the growing season. Generally, the number of species was higher in the control plots and on 28 September, more than 10 weeks after the last kaolin application, the species richness of bugs still was significantly higher in the control compared to kaolin plots. The Renyi diversity was significantly greater in the control plots during the part of the season when the kaolin was being periodically sprayed and during the rest of the season after kaolin spraying had ceased. The kaolin application significantly increased the diversity at higher alpha values however after finishing the treatments, the Renyi profiles becomes identical.

Table B.9.3.2.3/11-1: The mean total abundance (individuals/2 trees ± SD) of the heteropteran community, the main guilds and the mean species richness in the kaolin treated and control plots

	Control	**Kaolin**	**Reduction** (%)
Abundance	52.8(20.4)	21.0*(8.4)	60
Species richness	10.8(1.5)	7.8*(0.5)	-
Carnivorous	47.5(18.6)	15.5**(7.6)	67
Omnivorous	3.5(2.1)	1.5(1.0)	57
Phytophagous	1.8(0.5)	4.0(2.7)	-122

Note: Reduction: the corrected percent reduction in abundance was calculated using Abbott’s formula (Abbott, 1925)

*P<0.05, ** P<0.01, calculated according Abbott's formula.

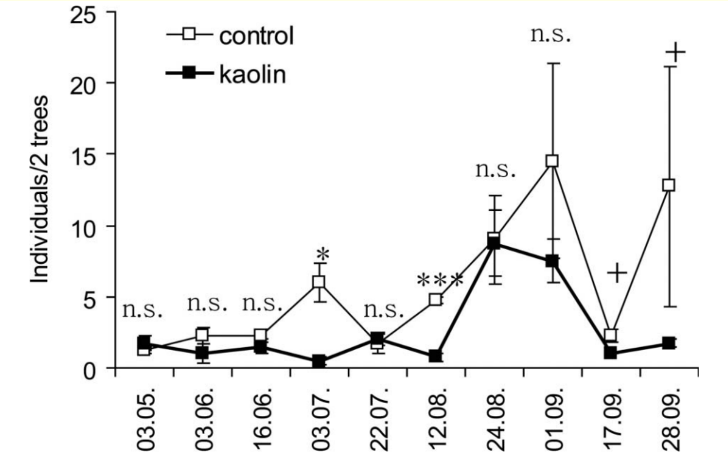


Figure B.9.3.2.3/11-1: Seasonal abundance (individuals/2 trees + SD) of heteropterans in the kaolin-treated and control plots. n.s., non significant, + $P < 0.1$, *$P < 0.05$, ***$P < 0.001$.

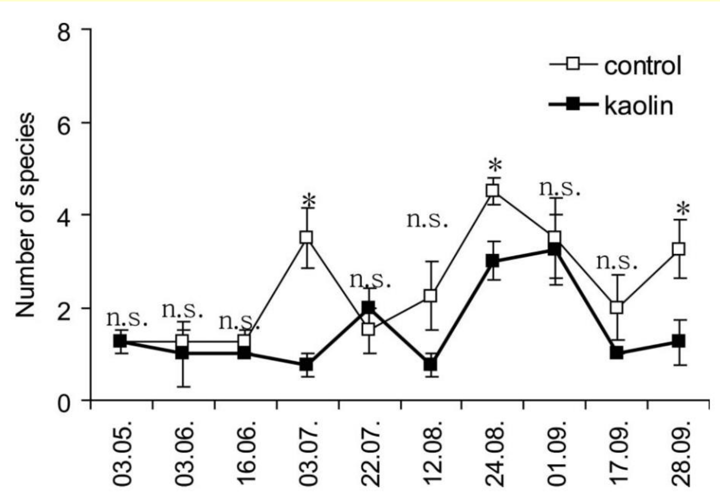


Figure B.9.3.2.3/11-2: Species richness (number of species/2 trees + SD) of heteropterans in the kaolin-treated and control plots during the season. n.s., non significant, *$P < 0.05$.

Beetle community

The kaolin applications were disruptive to the beetle community: both the total annual abundance and the species richness were lower in the kaolin-treated plots (8.3-11). However, there were major differences between the beetle guilds. The kaolin treatments mainly affected the mycophagous and xylophagous guilds and had the lowest efficacy against the guild of apple-feeders. Both abundance and species richness were usually significantly lower in the kaolin-treated plots during the whole season and the increase observed in control plots in late summer early autumn was not observed (abundance) or was so only moderately (species richness). During the treatments, the Renyi diversity of the beetle communities was significantly higher in the kaolin treated plots and became identical at higher alpha values when considering the common species. After ceasing the treatments, the Renyi diversity values increased at alpha > 0 in the kaolin-treated and decreased in the control plots resulting in a clear difference between the treatments and control.

Table B.9.3.2.3/11-2: The mean total abundance (individuals/2 trees± SD) of the Coleoptera community, the main guilds and the mean species richness in the kaolin treated and control plots

	Control	**Kaolin**	**Reduction** (%)
Abundance	240.8(44.7)	57.0**(8.8)	76
Species richness	22.5(4.8)	12.5**(3.5)	-
Mycophagous	109.5(29.2)	12.0**(4.8)	89
Xylophagous	5.5(4.5)	1.3(1.3)	76
Predators	29.3(14.7)	8.3+(2.2)	72
Tourists	12.3(5.0)	3.5**(1.7)	71
Apple feeders	87.5(10.5)	40.0***(5.3)	53

Note: Reduction: the corrected percent reduction in abundance was calculated using Abbott's formula (Abbott, 1925) +P <0.10. *P<0.05, ** P<0.01, calculated according Abbot's formula.

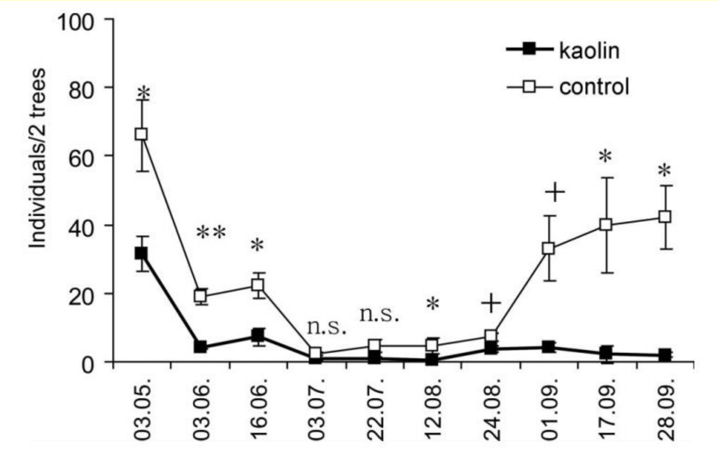


Figure B.9.3.2.3/11-3: Seasonal abundance (individuals/2 trees + SD) of beetles in the kaolin-treated and control plots. n.s., non significant, + $P < 0.1$, *$P < 0.05$, ***$P < 0.001$.

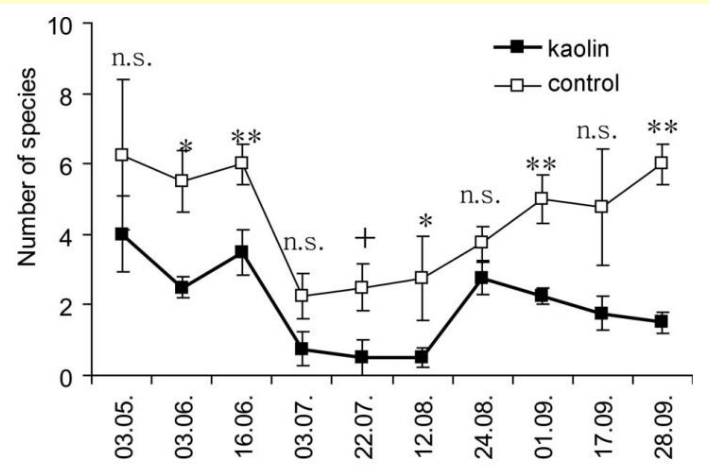


Figure B.9.3.2.3/11-4: Species richness (number of species/2 trees + SD) of beetles in the kaolin-treated and control plots during the season. n.s., non significant, +$P < 0.1$, *$P < 0.05$, **P <0.01

Spider Community

The kaolin formulation reduced both the annual abundance and species richness (Table 8.3-12). Generally, the spider guild 'wanderers' was more sensitive to kaolin applications than the guild 'web-builders' though there were major differences between the families belonging to the same guild. For example, one of the most sensitive families (Theridiidae) and the less sensitive Tetragnathidae both belong to the web-builders. Similarly, within wanderers the kaolin treatments strongly affected Philodromidae but to a much lesser extent Clubionidae. Kaolin applications showed a very strong negative effect both on spider abundance and on the number of genera during not only the applications but also afterwards when the spider community consisted almost exclusively of juveniles. The increase of numbers after the first part of August was apparent in the control plots and negligible in the kaolin treatments. The Renyi diversity was significantly higher not only during but also after kaolin applications. In the first part of the growing season, the kaolin applications reduced the diversity of spiders. Later in the season, the diversity profile of the kaolin and non-kaolin treated plots became identical.

Table B.9.3.2.3/11-3: The mean total abundance (individuals/2 trees ± SD) of the Araneae community, the main families and the mean species richness in the kaolin treated and control plots

	Control	Kaolin	Reduction (%)
Abundance	163.8(9.0)	50.5***(8.2)	69
Species richness1,2	5.5(1.7)	2.5*(1.3)	-
Wanderers	59.0(3.4)	14.3***(4.2)	76
Web-builders	103.0(7.0)	35.8***(11.5)	65
Philodromidae	46.8(6.2)	7.8***(1.7)	83
Thomisidae	4.0(1.8)	0.8*(0.5)	81
Theridiidae	50.8(7.5)	10.0***(3.4)	80
Linyphiidae	12.8(3.6)	3.3**(3.2)	74
Araneidae	6.2(3.9)	2.8(1.0)	55
Dictynidae	31.5(6.2)	18.5*(6.1)	41
Clubionidae	7.5(3.0)	5.0(3.2)	33
Tetragnathidae3	1.8(1.0)	2.0(0.8)	-11

Note: Reduction: the corrected percent reduction in abundance was calculated using Abbott's formula (Abbott, 1925)
[1] Based on adult individuals
[2] Welch test on ranks
[3] All individuals in Tetragnatidae belong to genus *Tetragnatha*
*P<0.01, *** P<0.001, calculated according Abbot's formula.

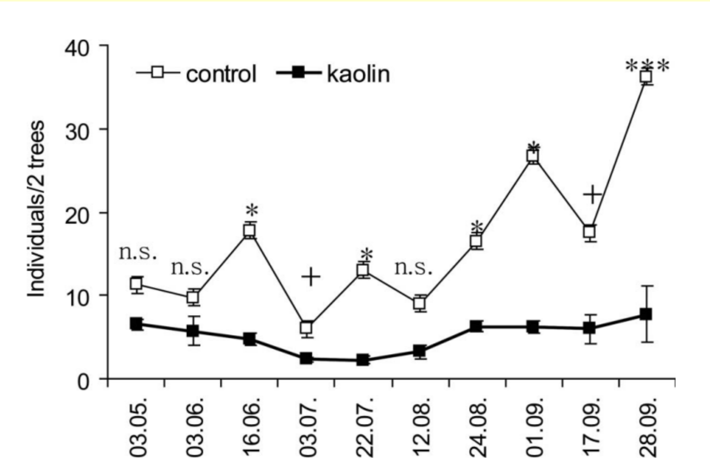


Figure B.9.3.2.3/11-4: Seasonal abundance (individuals/2 trees + SD) of spiders in the kaolin-treated and control plots. n.s., non significant, +P < 0.1, *P < 0.05, ***P < 0.001.

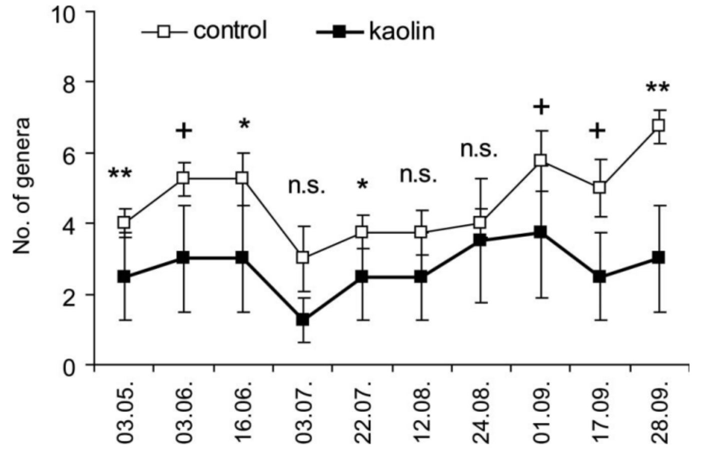


Figure B.9.3.2.3/11-5: Species richness (number of species/2 trees + SD) of spiders in the kaolin-treated and control plots during the season. n.s., non significant, + $P < 0.1$, *$P < 0.05$, **$P < 0.01$

Conclusion

In the field trial, the application of kaolin particle film reduced the abundance and species richness of the apple orchard heteropteran, beetle and spider communities, the main guilds and the most common species. However, 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. After ceasing the applications in July, the differences in abundance and species richness remained for a long time, until the end of September. Many predator species with good colonisation ability recovered slowly after the treatments, mainly due to the scarcity of prey. The trial ended approximately 6 weeks after last application.

Study limitations:

- The study is suitable to address adverse effects on foliage-dwelling Heteroptera, Coleoptera and Aranae communities in an orchard environment. Only one sampling method was selected (beating). The abundance of individuals collected altogether (359 bugs comprising 23 species; 1437 adult beetle specimens representing 55 species; 1075 spider individuals representing 23 genera) is deemed sufficient of a reliable evaluation of the possible effects from multiple applications of aluminium silicate on these taxa. A high taxonomic precision in the selected populations is observed (recognition typically on species level). The duration of the study is sufficient to address effects on the abundance and species richness of these populations but was insufficient to determine the duration of the adverse effects (the monitoring was completed 6 weeks after the last application). The application scheme of the study (up to 12 applications with 45 kg/ha) cover worst case application for the representative use and thus the results of the study can be considered relevant for the scope of the current evaluation.

- The main limitation of the trial design is the absence of a positive control (toxic reference) and therefore the susceptibility of the test system is not confirmed. However, since striking effects on the monitored arthropod community was observed throughout the monitoring period, this limitation does not seem to compromise the reliability of the study and the interpretation of the results.

- No pre-application sampling was carried out and therefore possible differences in the abundance and richness between treated and untreated plots cannot be confirmed.

- There is no information on the presence of an unsprayed area between treatments in the same block or the use of any other measure suitable to avoid contamination of the untreated plots.

- The plot size was 0.23 ha covers the minimum recommended plot size for orchards (0.2 ha in Candolfi *et al.*, 2000). However, it should be taken into consideration that sampling was carried out in random trees within each plot (2 trees/plot; 8 trees/treatment). The total sampling size is probably too small to address recovery of populations especially for less mobile taxa but can be deemed sufficient to address possible adverse effects to certain taxa after application of kaolin.

- No information is also available for a possible verification of the tested application rate. However, considering the excessive number of applications compared to the proposed use in the representative use, this limitation is of low significance.

- Application of a number of other products in the treated area during the monitoring period is specified in the report (fungicides). Considering that the multiple application of fungicides is a common routine for orchards this was not identified as a source of uncertainty, although possible interactions cannot be excluded.

- Information on history and weather conditions during the 3-year monitoring is missing.

B.9.3.2.3/12

Reference	T. E. Sackett, C. M. Buddle and C. Vincent., 2007
	Effects of kaolin on the composition of generalist predator assemblages and parasitism of *Choristoneura rosaceana* (Lep., Tortricidae) in apple orchards.
	J. Appl. Entomol. 131(7), 478–485 (2007)
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Hydrophilic kaolin formulation Surround WP (Engelhard Co, Iselin, NJ)
	Lot/Batch no.: Not specified
Test species	Foliage arthropod predators
Reference item	-
Treatment	Freligshsburg: 6 kg/100 L with 1000 L/ha water volume (4 applications)
	Hilaire: Dose not clearly specified (characterised as 'light application' in the report).
Trial location	Freligshsburg and Mt St Hilaire, Quebec
Trial design /methodology	Freligshsburg 2004: A fixed block design was used. The orchard size was 0.5 ha, divided in 12 blocks, each with 24 trees.
	Freligshsburg 2005: The orchard size was 0.8 ha, divided in 12 blocks, each with 54 trees.
	Hilaire: The orchard size was 2 ha, divided in 6 blocks, each with 45 trees.
	The kaolin trial was made in three approximately 15-year-old orchards during 2004 and 2005. These included two orchards at the Agriculture and Agri-Food Canada Experimental Farm in Freligshsburg, Quebec (McIntosh, semi-dwarf

	root stock), and one commercial orchard near Mt St Hilaire, Quebec (Cortland and McIntosh, standard rootstock). Densities of generalist predators were quantified in orchards F1 and F2 in 2004 and 2005. In Orchard F1 in 2004, three randomly chosen trees per block (five branches per tree/10 beats per branch) were beaten over a 1 m² sheet, and all spiders (Araneae) were collected. There were five collection dates, one after each application of kaolin (20 June, 28 June, 12 July, 26 July), and the final collection 1 month after the final kaolin application (8 August). In Orchard F2 in 2005, four trees per block were sampled using the same technique, but all generalist predators were counted, including spiders, harvestmen (Opiliones), beetles (Coleoptera), ants (Formicidae), stink bugs (Pentatomidae) and assassin bugs (Reduviidae). Insect predators were identified to family and spiders to family and species when possible. Parasitoids were classified to family, and the rate of parasitism and proportion of each family were compared in kaolin and control treatments.
Statistics	The relative abundances of generalist predators, *C. rosaceana* larvae, and the proportion of larvae parasitized, were compared between control and kaolin treatments using Anova (PROC GLM). Relative abundance of generalist predator taxa was analysed using raw data, unless the data for a particular group were non-normal or had heterogeneous variances, in which case they were square root transformed. To compare proportion of larvae parasitized, raw data were arcsine-square root transformed before analysis. SAS V8 (SAS Institute 2000) and statview V5 (SAS Institute 1998) were used for these statistical tests. The proportions of each parasitoid order and family in kaolin and control treatments were compared using Fisher's exact tests. On-line applets with expanded contingency tables (Lowry 2006) were used for Fisher's exact tests.

Findings

Effects of kaolin on generalist predators

In 2004, 654 spiders were collected over the five sampling dates. The relative abundances of spiders in both plots in the first three sampling dates (20 June–12 July) were several times lower than the 26 July (fourth) and 8 August (fifth) samples. There was a significant decrease in the relative abundance of total spiders in the kaolin plots after the fourth application of kaolin in July, but catch rates were no longer significantly lower 1 month after this final application in August. The increase in collected spiders on 26 July was mainly caused by an increase in the number of spiderlings and immature spiders, as many orchard spider species reproduce during July. On this sampling date, both spiderlings and older spiders (includes juveniles and matures) were significantly lower in kaolin plots than control plots. Spiders were the most common generalist predators in the orchards, in both control and kaolin blocks. In 2005, from the two sampling dates pooled, spiders accounted for 59% of the total predators in the control treatment, and 80% in the kaolin treatment. Ants were the second most common taxa in both treatments, accounting for 22 and 16% of individuals in control and kaolin treatments, respectively. Most other groups (harvest-men, beetles and lacewings (Neuroptera)) accounted for <1% each of collected arthropods, except the assassin bugs (mainly *Zelus luridus* Stal), which were 15% of the predators in the control treatment, but <1% in the kaolin treatment. The last two sampling dates of 2004 (July and August), along with the samples from 2005 (July and August), were examined in more detail by determining the response of all generalist predators at the family level.

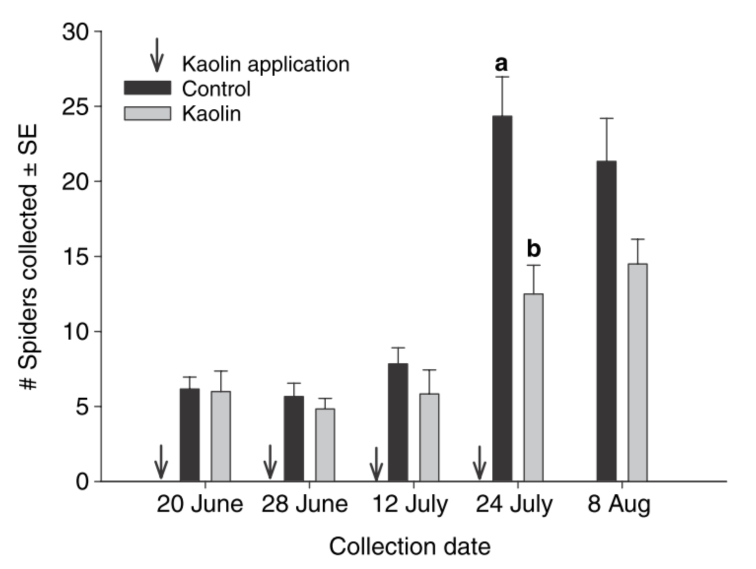


Figure B.9.3.2.3/12-1. Relative abundance of all spiders collected from orchard F1 in 2004 in control and kaolin plots after each of four kaolin applications, and 1 month after the fourth application. Different letters within one sampling event indicate significantly different means ($P < 0.05$)

***Choristoneura rosaceana* parasitism and density**

The proportion of parasitized *C. rosaceana* larvae was not affected by kaolin in either orchard F1 (four kaolin applications) or H3 (two kaolin applications). In F1, the percent parasitism was 47% (11/23 larvae) in control plots and 37% (6/16 larvae) in kaolin blocks, and there was no significant difference between the treatments. In orchard H3, the percent parasitism was 44% (25/61 larvae) in control blocks and 24% (17/71 larvae) in kaolin blocks, and was not significantly different. Four families of parasitoids were collected: one Dipteran family, Tachinidae, and the Hymenoptera families Braconidae, Ichneumonidae and the superfamily Chalcidoidea. There was no significant effect of kaolin on *C. rosaceana* populations in either orchard.

Conclusion

The kaolin treatment significantly altered the species composition of generalist predator assemblages in the Frelighsburg orchards in both years and reduced the relative abundance of the most common families of spiders and insect predators, such as assassin bugs, ants and coccinellids. Kaolin did not affect the overall percent parasitism, or the composition of parasitoids, of *C. rosaceana* larvae.

<u>Study limitations:</u>

The study included results from 3 different trials (two carried out in 2004 and one in 2005). Results from the trial conduced in Hilaire were not considered further as the application rate is not clearly specified. The number of individual spiders is reliable (654 collected spiders over the five sampling dates in 2004 and 571 in two sampling years in 2005). Some information on the effects on abundance of spiders can be obtained from the report. However, little information is obtainable for the effects on species richness for spider community, although some conclusion is reached from the author. The number of applications and the applied dose cover the proposed application scheme in the proposed GAP for the representative use. Several limitations were recorded:

- The duration of the study is sufficient to address adverse effects on the abundance of taxa but was insufficient to identify if recovery can occur (the duration of the monitoring ended 2 weeks after the last application).

- No information on unsprayed area between treatments to avoid contamination of the untreated plots is specified.

- No toxic product was tested for reference
- Just one sampling method was considered (beating method)
- No information on the pre-treatment variation between plots was provided.
- Information on history and weather conditions is missing.
- It is not clear if the tested application rate was verified.

B.9.3.2.3/13

Reference	Ismael Sánchez-Ramos, Aránzazu Marcotegui, Susana Pascual, Cristina E. Fernández, Guillermo Cobos, and Manuel González- Núñez., 2017 Compatibility of organic farming treatments against *Monosteira unicostata* with non-target arthropod fauna of almond trees canopy Spanish Journal of Agricultural research 15(2), e1004, 10 pages (2017)
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Kaolin: Surround WP (95% w:w (wettable powder) Lot/Batch no.: Not specified
Test species	*Monosteira unicostate (*phytophagous pest) Arthropod fauna of almond tree canopy
Reference item	No reference product was tested. Potassium salts of fatty acids combined with thyme essential oil OleatBio-to (40% w:w soybean and sunflower fatty acids; 5% w:w potassium salts; 6% w:w thyme essential oil) (300 mL/100 L PSTEO; TRABE S.A., Murcia, Spain) was also included in the study.
Treatment	5 kg/100 L kaolin
Trial location	Murcia, Spain
Trial design /methodology	The overall arthropod fauna from the canopy of almond trees was sampled using a beating method. Arthropods sampled from the four trees of each treatment were collected in a plastic bag. Beating sampling was performed monthly in spring and summer, with a total of five and six sampling dates in 2009 and 2010, respectively. Samples were taken to the laboratory and the specimens were assigned to the following groups: 1) Natural enemies: Those belonging to families whose main feeding habit is parasitism or predation. 2) Phytophagous (target arthropods): Those causing economic damage on almond trees (pests)

	3) Other arthropods: Those phytophagous not described as pests on almond trees and specimens with other feeding habits or that could not be allocated to a specific feeding guild. This work focused on non-target arthropods, i.e. groups 1 and 3. Specimens were determined to family level when possible. Biodiversity was assessed by the number of morphospecies and the Shannon biodiversity index. The experimental design consisted of randomised blocks with four (2009) or seven (2010) replications. Two applications were given each year: the first one in mid-spring and a second one in early summer.
Statistics	The effect of the factors considered on the number of individuals captured, the number of species and the Shannon biodiversity index was tested by linear mixed-effects models (Littell et al., 1998; Wang & Goonewardene, 2004). Treatment and cultivar (only in 2009) were considered fixed factors, with block as a random factor and sampling date as a repeated measures factor. Interactions among all fixed factors were also considered in the models. The best covariance structure for the repeated-measures (date) factor was selected according to the lowest value of the Akaike and Schwarz's Bayesian information criteria fit statistics (Littell et al., 1998; Wang & Goonewardene, 2004). The models were fitted using a restricted maximum likelihood estimation method. The significance level was always $p < 0.05$. Statistical tests were performed using SPSS statistical program. To investigate changes in abundance and species composition of the non-target arthropod community in the canopy of almond trees, a principal response curve (PRC) analysis was performed using the program CANOCO 4.51 (Van den Brink & Ter Braak, 1999; Leps & Smilauer, 2003).

Findings

Arthropods community in organic almond

In the 2009 orchard, the great majority of arthropods captured were phytophagous potentially harmful on almond trees (87.5-90%), with the other groups appearing in very small proportions (predators: 3.7- 4.7%; parasitoids: 1.9-2.0%; other arthropods: 4.4-5.4%). In 2010, the situation was different, with phytophagous again as the dominant group (53.8-58.8%), but with the "other arthropods" group showing a much higher proportion (37.2-42.0%). Predators (3.1-4.0%) and parasitoids (0.6-1.0%) were again minor groups.

Regarding natural enemies, most of the predatory arthropods captured were spiders belonging to different families like Salticidae, Thomisidae, Philodromidae, Theridiidae, Araneidae or Oxyopidae. Other predatory families that appeared in significant numbers were Chrysopidae, Anthocoridae, Aeolothripidae, Coccinellidae, Phytoseiidae, Erythraeidae or Forficulidae. Among parasitoids, the most abundant families were Eulophidae, Scelionidae and Dryinidae. Kaolin reduced the abundance of natural enemies and other non-target arthropods as well as their diversity and number of species.

Effects of kaolin and potassium salts of fatty acids combined with thyme essential oil (PSTEO) on non-target arthropods

Before the treatment applications both in 2009 and 2010, no significant differences were found between kaolin or PSTEO plots and untreated control plots in abundance of non-target arthropods except for the natural enemies in the PSTEO plots in 2009, which showed lower values compared to the control plots (Table B.9.3.2.3/13-01). After treatment application, it was found a significant reduction in the kaolin-treated plots in the abundance of natural enemies in 2009 and 2010 and in the abundance of other arthropods in 2010 compared to the control plots (Table 8.3-17). PSTEO only produced a significant reduction in the number of natural enemies in 2010. Concerning diversity and number of species of non-target arthropods, no significant differences were found between kaolin or PSTEO plots and the untreated control plots before treatment application both in 2009 and 2010 (Table B.9.3.2.3/13-01). After treatment application, a significant reduction in the Shannon diversity index and in the number of species was observed in the kaolin plots compared with the control plots in both years except for the Shannon index in 2010.

Table B.9.3.2.3/13-01: Abundance, Shannon index and number species per sample of non-target arthropods (natural enemies and other arthropods) captured by beating in almond trees before and after being sprayed with kaolin or potassium soap with thyme essential oil (PSTEO) and in the untreated trees

Plots	Natural enemies [a]		Other arthropods [a]		Shannon index [a]		Number of species [a]	
	Before	After	Before	After	Before	After	Before	After
				2009				
Control	5.6±1.0	11.6±1.6	7.6±1.4	6.7±1.5	1.7±0.1	2.0±0.1	7.9±0.9	12.2±1.5
Kaolin	6.9±1.5	8.7±1.6*	7.4±1.6	5.0±1.1	1.7±0.1	1.8±0.1*	8.1±0.9	9.3±1.3*
F	0.262	13.371	0.391	1.056	0.350	9.905	1.002	8.076
d.f	1.12	1.11	1.12	1.12	1.12	1.11	1.12	1.27
p	0.618	0.003	0.544	0.324	0.565	0.009	0.337	0.008
Control	10.3±1.7	7.6±1.2	8.4±1.3	5.1±1.6	2.0±0.1	1.8±0.1	12.0±1.4	8.2±1.1
PSTEO	7.9±1.4*	7.6±1.0	7.6±1.3	3.8±0.9	1.9±0.1	1.9±0.1	10.3±1.3	8.2±0.8
F	6.532	0.003	1.847	0.112	3.231	0.678	3.454	0.159
d.f	1.9	1.12	1.12	1.12	1.24	1.12	1.12	1.12
p	0.030	0.959	0.199	0.744	0.085	0.426	0.088	0.697
				2010				
Control	3.7±0.7	6.1±0.5	77.6±26.2	13.4±3.0	1.1±0.2	1.9±0.1	6.1±0.6	9.3±0.7
Kaolin	5.0±0.7	4.7*±0.7	92.3±29.1	3.7±0.6*	1.3±0.2	1.6±0.1	8.1±0.6	5.9±0.4*
PSTEO	5.1±0.7	5.6*±0.7	68.8±21.2	13.3±3.5	1.2±0.2	1.7±0.1	7.3±0.6	8.0±0.7
F	1.598	5.489	2.787	11.761	2.387	2.265	2.683	6.317
d.f	2.17	2.18	2.18	2.18	2.18	2.17	2.60	2.18
p	0.230	0.014	0.088	0.001	0.120	0.133	0.077	0.008

[a] Values are mean per sample ± standard error.

* indicates significant differences compared with the control (*p*<0.05, linear mixed-effects model). Kaolin and PSTEO were compared with the control separately in 2009 because of the different time schedule of treatment application that year

No differences in the community composition of non-target arthropods were found among treated and control plots before treatment application either in 2009 and 2010 (Table B.9.3.2.3/13-02). After treatment application, no effect was observed for both Kaolin and PSTEO-treated plots compared to the control in 2009, but a significant effect was observed in 2010 in the PSTEO-treated plots for the natural enemies' community and in the kaolin-treated plots for the other non-target arthropod community (Table B.9.3.2.3/13-02).

Table B.9.3.2.3/13-02: Significance of PCR analyses on the community of natural enemies and other non-target arthropods sampled by branch beating, before and after treatment application

Year	Group	Period	Comparison					
			Global		Kaolin *vs* control		PSTEO *vs* control	
			F ratio	*P* value	F ratio	*P* value	F ratio	*P* value
2009	Natural enemies	Before	-	-	1.140	0.7420	1.529	0.3960
		After	-	-	1.438	0.5420	1.017	0.8260
	Other Arthropods	Before	-	-	1.189	0.5520	0.710	0.9080
		After	-	-	1.277	0.7300	1.094	0.6420
2010	Natural enemies	Before	1.987	0.3620	-	-	-	-
		After	3.691	0.0020*	2.070	0.0640	2.802	0.0060*
	Other Arthropods	Before	3.129	0.1260	-	-	-	-
		After	6.393	0.0040*	5.309	0.0020*	1.427	0.6780

*indicates significant differences ($p<0.05$, PRC analysis). The global comparison for the three treatments altogether could not be performed in 2009 because of the different time schedule of treatment application for kaolin and PSTEO. In 2010, the global comparison was first performed and when significant differences were found, separate comparisons between kaolin and potassium soap with thyme essential oil (PSTEO) vs the untreated control were subsequently performed

With the aim of determining the most affected taxa after applications, PRC analyses were performed. Based on the PRC analyses for the effect of kaolin on other non-target arthropods in 2010, the affected taxa were (in decreasing order of effect) Melandryidae (3.3), Curculionidae (2.8), Formicidae (2.4), Psocoptera (2.0), Thysanoptera (1.4), Issidae (0.6), Phalacridae (0.6) and Anthicidae (0.5).

Conclusion

No differences in the community composition of non-target arthropods were found among treated and control plots before treatment application either in 2009 or 2010.

Field trials had shown that two applications of kaolin resulted in significant effects on the non-target arthropod fauna of the almond trees canopy. Based on the PRC analyses for the effect of kaolin on other non-target arthropods in 2010, the affected taxa were (in decreasing order of effect) Melandryidae (3.3), Curculionidae (2.8), Formicidae (2.4), Psocoptera (2.0), Thysanoptera (1.4), Issidae (0.6), Phalacridae (0.6) and Anthicidae (0.5).

A significant reduction in the Shannon diversity index and in the number of species was observed in the kaolin plots compared with the control plots in both years except for the Shannon index in 2010 and no effect was observed for kaolin treated plots compared to the control in 2009, but a significant effect was observed in the kaolin-treated plots for the other non-target arthropod community in 2010, after treatment.

<u>Study limitations:</u>

The study included results from two different trials (carried out in 2009 and 2010). Information on the pre-treatment variation between plots was provided. No significant differences between kaolin and untreated plots in the abundance of non-target arthropods, and the diversity and were recorded before applications. The following limitations are identified:

- The ground (ha) application dose is not specified. Considering that only two application per season were done, the proposed application scheme is not represented in the study. The worst-case application scheme is not covered.

- Although sampling was performed monthly (5-6 sampling occasions per season), separate results for each sampling date are not available in the report. Therefore, information on the recovery of the affected taxa cannot be obtained.

- The plot size is both treated and untreated plots is not reported.

- No information on unsprayed area between treatments to avoid contamination of the untreated plots is specified.

- Specimens were recognised to the family level.

- No toxic product was tested for reference. Potassium salts of fatty acids combined with thyme essential oil were tested in parallel, but the use of this combination is not suitable for the verification of the sensitivity of the test system (actual effects from the use of potassium salts+thyme oil combination were less pronounced than those of aluminium silicate).

- Just one sampling method was considered (beating method).

- Information on weather conditions is missing.

- It is not known if the tested application rate was verified.

B.9.3.2.3/14

Reference	Knight et al., 2001
	Impacts of seasonal kaolin particle films on apple pest management
	The Canadian Entomologist 133: 413-428
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	M96-018 (Engelhard Corp, Iselin, New Jersey)
Test species	Phytophagous pests
	Araneae, ants (Hymenoptera: Formicidae), generalist predators
Vehicle	Methanol/water (1866 L water/ha in the two-year study)
Reference item	-
Treatment	56 kg f.p./ha
Trial location	Single season study: Moxee, Washington
	Two-year study: Methow, Washington
Trial design /methodology	Single season study: Ten replicated four-tree plots arranged in a completely randomized block design were established at the Garza Orchard in 1998 using only 'Red Delicious' trees. M96-018 was applied at the standard rate on 10 dates during the season on 3 March; 16 April; 4 and 19 May; 1, 10, and 23 June; 14 July; and 1 and 17 August 1998. Two-year study: Twenty, four-tree plots spaced >6.0 m apart were established in 1998 at the Methow Orchard. One half of these plots were randomly selected and treated with M96-018 and the other 10 plots were left untreated. The standard rate of M96-018 was applied to plots on 26 March, 9 and 23 April, 6 and 20 May, and 2 and 17 June 1998. Following the 17 June spray application, each of the four-tree plots treated with M96-018 were subdivided into paired,

	adjacent two-tree plots. One of each of the paired, two-tree subplots was randomly selected and sprayed with M96-018 on 8 and 22 July and 19 August 1998. The other pair was left unsprayed and was protected with a tarp on each of the spray dates. The effects on apple pest management of a 2-year spray program of M96-018 and the potential effects in plots the year following the use of M96-018 were evaluated in the second year of the study in 1999. Five of the plots treated in 1998 were randomly selected to be sprayed with M96-018 during 1999 [M96-018 (1998 + 1999)] and the other five were left untreated [M96-018 (1998)]. In addition, five four-tree plots were randomly selected from among the 10 unsprayed plots monitored in 1998. These were treated with the standard M96-018 rate in 1999 [M96-018 (1999)]. The five remaining plots were left untreated for a second year. M96-018 was applied at the standard rate on 31 March; 17 April; 1, 18, and 31 May; 20 June; 10 July; 8 and 31 August; and 12 September 1999. Beating-tray samples (2025 cm^2) were conducted to assess populations of a number of pests and natural enemies. The canopy of each tree within a plot was tapped twice with a stiff rubber hose and all arthropods dislodged onto the beating tray were identified and counted. Beating-tray samples were taken in the Garza orchard on 22 May 1998 and in the Methow orchard on 6 and 20 May, 22 July, and 26 August 1998; and on 8 May, 6 June, 1 and 19 July, 7 and 22 August, and 5 and 19 September 1999. Data were summed across all trees within a replicate, and data are reported as the mean number per beating tray.
Statistics	All count and proportion data were square root [(x±0.01)0.5] and arcsine square root [arcsin(x)0.5] transformed, respectively, before conducting unpaired t tests and ANOVA. Means were separated with the Neuman-Keuls multiple comparison test where significant differences occurred (P < 0.05). Data were analyzed with GraphPad Prism 3.0 (GraphPad Software, Inc 1999).

Findings

1. Single season study

The population density of a number of apple pests and natural enemies assessed with beating-tray samples differed on trees treated with a 10-spray M96-018 seasonal program versus trees left untreated in the Garza orchard during 1998. A significant reduction of Araneae population in kaolin-treated plots compared to the untreated (P <0.001) was recorded.

2. Two-year study

Natural enemy populations

Spider numbers increased in the untreated plots throughout the season. Spider densities were lower in the plots treated with M96-018 than in the untreated plots during both. Counts of spiders in the beating-tray samples in plots treated with only seven (M96-018 x 7) applications in 1998 were not different from those in plots treated with either nine (M96-018 x 9) or 10 (M96-018 x 10) sprays in July and August, respectively. The density of spiders in 1999 did not differ in plots treated with M96-018 for one (1999) or two (1998 + 1999) consecutive seasons. Several other groups of generalist predators were present at moderate levels in beating-tray samples and their population densities were often lower in the plots treated with M96-018 than in the untreated plots. For example, the mean densities of ants (Hymenoptera: Formicidae) and ladybird beetle larvae and adults (Coleoptera: Coccinellidae) were lower in trees treated with M96-018 than in untreated trees early in the 1998 season. The density of the earwig, *Forficula auricularia L*. was lower in plots treated with M96-018 than in untreated plots in the mid-season beating-tray samples in 1998. The density of ants was also lower in both M96- 018 treatments compared with those of two unsprayed treatments at mid-season in 1999. The proportion of leafminer larvae parasitized during the first generation was significantly lower in the M96-018 treatment than in the untreated control during 1998. During the second and third generations, however, the mean proportion of mines parasitized among treatments differed by less than twofold. Larval parasitism during 1999 was significantly lower in the M96-018 (1999) x 7 plots than in either the M96-018 (1998) or untreated plots.

Table B.9.3.2.3/14-01: Mean ± SE number of spiders (Araneae) per beating tray in samples from trees sprayed with and without particle film M96-018 during 1998 and 1999 in the Methow orchard.

Sampling date	Treatment*	No. of sprays†	No. of spiders per tray	Statistics	
				F_{df}	P
		1998			
20 May	Untreated	—	0.48±0.12	$F_{1,18} = 2.8$	<0.05
	M96-018	4	0.20±0.06		
22 July	Untreated	—	0.96±0.20*a*	$F_{2,27} = 9.27$	<0.001
	M96-018	7	0.20±0.12*b*		
	M96-018	9	0.16±0.10*b*		
26 August	Untreated	—	1.30±0.26*a*	$F_{2,27} = 5.42$	<0.01
	M96-018	7	0.45±0.20*b*		
	M96-018	10	0.50±0.14*b*		
		1999			
6 June	Untreated	—	0.25±0.11*ab*	$F_{3,16} = 3.32$	<0.05
	M96-018 (1998)	—	0.50±0.13*a*		
	M96-018 (1999)	5	0.10±0.06*b*		
	M96-018 (1998 + 1999)	5	0.10±0.06*b*		
19 July	Untreated	—	0.70±0.17*a*	$F_{3,16} = 6.29$	<0.01
	M96-018 (1998)	—	0.75±0.18*a*		
	M96-018 (1999)	7	0.35±0.06*ab*		
	M96-018 (1998 + 1999)	7	0.15±0.06*b*		
22 August	Untreated	—	1.35±0.26*a*	$F_{3,16} = 4.73$	<0.05
	M96-018 (1998)	—	1.50±0.33*a*		
	M96-018 (1999)	8	0.60±0.19*b*		
	M96-018 (1998 + 1999)	8	0.50±0.14*b*		

NOTE: Means within a column for each date followed by a different letter are significantly different (Newman–Keuls multiple comparison test, $P < 0.05$).
* In 1999, density assessments were made on untreated trees, trees sprayed only in 1998 [M96-018 (1998)], trees sprayed only in 1999 [M96-018 (1999)], and trees sprayed in both years [M96-018 (1998 + 1999)].
† Number of M96-018 sprays applied during the season prior to the sample date.

Conclusion

The seasonal use of the particle film formulation M96-018 had a range of impacts on apple pest management in three eastern Washington State orchards during this study. Significant reductions in the population densities of generalist arthropod predators and hymenopteran parasitoids occurred in plots treated with M96-018. Season-long programs of particle film clearly impacted the major parasitoid of the western tentiform leafminer, *Pnigalio flavipes* Ashmead (Hymenoptera: Eulophidae), and several generalist predators. The mean densities of ants (Hymenoptera: Formicidae) and ladybird beetle larvae and adults (Coleoptera: Coccinellidae) were lower in trees treated with M96-018 than in untreated trees. The density of earwig *Forficula auricularia* L. (Dermaptera: Forficulidae) was lower in plots treated with M96-018 than in untreated plots. The density of ants was also lower in M96-018 treatments.

<u>Study limitations:</u>

The study was designed to address effects of kaolin-based particle film on the population density of selected pests of apple and (to a lesser extend) their natural enemy population. The study is suitable to gain insight into the level of effects anticipated from the use of the product to beneficial arthropods in orchards, but without evidence on the duration of the adverse effects. Several limitations were identified:

- Effects on spiders (most abundant and consistently presented predators sampled) and other groups of generalist predators, ants and leafminer parasitoids were recorded. However, data were presented only for spiders. Results for the remaining taxa were not tabulated/presented. The number of spiders per beating tray ranged from 0.25 to 1.35 in the untreated plots, which can be deemed low.

- Information on the pre-treatment variation between plots was not provided.

- No toxic product was tested for reference.

- Just one sampling method was considered (beating method).

- Information on weather conditions is missing.

- The application rate was not verified.

- Although sampling was performed three times per season, separate results for each sampling date are not available in the report.

- Information on unsprayed area between plots is reported only for the two-year study. A six-meter space between plots was respected.

- Application of a number of other products (chlorpyrifos and supreme-type horticultural oil) in the treated area during the monitoring period in the two-year study (1999) is reported. Application of these insecticidal product complicates the interpretation of the results.

- The exact block size is not specified in the report. The total size of the orchards in the single and two-year studies was 2 and 10 ha, respectively.

B.9.3.2.3/15

Reference	Nino Iannotta, Tiziana Belfiore, Marie Elena Noce, Stefano Scalercio, Veronica Vizzarri, 2007 The impact of some compounds utilized in organic olive groves on the non-target arthropod fauna: canopy and soil levels C-Ecological Aspects
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Yes with limitations.

Material and methods

Test substance	Surround® WP Crop Protectant, Engelhard corporation, Iselin, NJ, USA) (MIR7)
Test species	
Vehicle	-
Reference item	Cupravit Blu WG® Bayer Cropscience, Milan, Italy Propoli+® Progetto Geovita Div. Agricom, Turin, Italy

	Rogor 40® Isagro s.p.a., Milan, Italy
Treatment	5 kg/hl (2 applications)
Trial location	Mirto-Crosia, Calabria, Southern Italy
Trial design /methodology	Data were decadly collected from late June to early December 2006, i.e. during the ripening of drupes and until the olive harvest. Six theses composed by 200 plants were randomly chosen. One thesis was treated the 25th of August and the 28th of September with rotenone (300 ml/hl of Rotena® Serbios, Rovigo, Italy) (MIR5). One thesis was treated the 21st of August and the 28th of September with kaolin (5 kg/hl of Surround® WP Crop Protectant, Engelhard Corporation, Iselin, NJ, USA) (MIR7). One thesis was treated the 25th of August and the 28th of September with a mixture of copper oxychloride (250 g/hl of Cupravit Blu WG® Bayer Cropscience, Milan, Italy) and propolis (150 ml/hl of Propoli+® Progetto Geovita Div. Agricom, Turin, Italy) (MIR8), utilized against both diseases and olive fly (*Bactrocera oleae* Gmel.) (Diptera Tephritidae). Two thesis were treated the 2nd of August, the 1st September and the 2nd of October with dimethoate (150ml/hl of Rogor 40® Isagro s.p.a., Milan, Italy) (MIR1, MIR2). One untreated thesis was utilised as control (MIR6).
	Due to different actions of active agents involved in this research, arthropods were sampled at canopy and soil levels. The sampled taxa were known for their sensitivity to environmental perturbations. At the canopy level the occurrence and the abundance of nine taxa (Arachnida: Araneae and Opiliones; Insecta: Hymenoptera Ichneuomonoidea, other Hymenoptera, Coleoptera Coccinellidae, Macrolepidoptera, Neuroptera, Mecoptera, Diptera Syrphidae) was registered by using three yellow chromotropic traps per thesis, usually utilised for the monitoring of olive fly population trend. At the soil level the occurrence and the abundance of six taxa (Arachnida: Araneae; Crustacea: Isopoda; Insecta: Coleoptera Carabidae, Coleoptera Staphylinidae, other Coleoptera, Hymenoptera Formicidae) was registered by using pit-fall traps, usually utilized for the monitoring of Carabid beetles species assemblages.
Statistics	Collected data were submitted to various analyses in order to detect the differences in community structure, the responses of sampled taxa to treatments, and the effects of compounds on the efficiency of trophic levels.In order to assess the responses of treatments of a given taxon an index of phenological dynamics was utilised. Although intrinsic differences among sampled stands and seasonal changes in the composition of communities occur as confounding factors, the effect of treatments is detectable in the field carrying out comparison of a stand with itself. Phenological dynamics, homogeneous within a given thesis, are differently influenced by the insecticide spray depending on the taxon sensitivity. This is emphasized by partitioning the season in a 'before' and in an 'after' treatments. The ratio after/before treatments (A/B ratio) of the abundance of sampled taxa gave good information on the effect of treatments (Iannotta et al., 2007). This analysis was carried out at canopy and soil levels.

Findings

1. **Canopy level**

A total of 2,902 individuals belonging to selected taxa were collected. The most abundant taxon was other Hymenoptera, followed by Ichneumonoidea. The highest number of individuals was collected within control thesis (MIR6), whilst the lowest one was collected within kaolin thesis (MIR7). Neuroptera, Macrolepidoptera and Syrphidae were more abundant in conventional olive groves, Araneae was more abundant in the rotenone thesis (MIR5), other taxa were more abundant in control thesis. The ratio after/before treatments (A/B_{ratio}) shown the dimethoate, the kaolin and the rotenone as the compounds having the higher knock-down effect on the sampled arthropod community at the canopy level. Conventional theses were grouped and successively analysed as a unique sample. No ratios are disposable for Opiliones and Mecoptera because of any individuals were collected before the treatments. Data about Syrphidae were not significant because of the late appearance of the adult stage.

Tab. 2. The ratio after/before treatments (A/B_{ratio}) at canopy level. Conventional theses were grouped and successively analysed as an unique sample. No ratios are disposable for Opiliones and Mecoptera because of any individuals were collected before the treatments. Data about Syrphidae were not significant because of the late appearance of the adult stage.

	MIR1,2	MIR5	MIR7	MIR8	MIR6
Araneae	1.64	0.12	1.46	2.82	2.49
other Hymenoptera	1.17	1.00	0.56	1.29	0.90
Ichneumonoidea	2.31	1.00	1.21	1.74	2.85
Coccinellidae	1.30	1.85	0.34	2.00	0.53
Macrolepidoptera	1.18	1.55	1.78	1.13	0.48
Neuroptera	0.17	1.97	1.00	4.85	11.61
Syrphidae	8.66	0.43	-	9.41	0.00
TOTAL	0.85	0.98	0.93	1.75	1.57

2. **Soil level**

A total of 23,393 individuals belonging to selected taxa were collected. The most abundant taxon was Formicidae followed by Isopoda. The highest number of individuals was collected within the rotenone thesis (MIR5), whilst the lowest one was collected within a dimethoate thesis (MIR1). All taxa were very scarce in conventional theses, while no significant differences have been showed by organic theses and the control. The ratio after/before treatments (A/B_{ratio}) shown the rotenone, the dimethoate and the mixture copper/propolis as the compounds having the higher knock-down effect on the sampled arthropod community at the soil level. Carabidae and Staphylinidae, both generalist predators, have been seriously affected by dimethoate. The kaolin was the compound having the lowest incidence on the arthropod populations at the soil level. Conventional theses were grouped and successively analysed as an unique sample. No ratios are disposable for Opiliones because of any individuals were collected before the treatments. Data about Staphylinidae were not significant because of the collection of very scarce populations.

Tab. 5. The ratio after/before treatments (A/B_{ratio}) at soil level. Conventional theses were grouped and successively analysed as an unique sample. No ratios are disposable for Opiliones because of any individuals were collected before the treatments. Data about Staphylinidae were not significant because of the collection of very scarce populations.

	MIR1,2	MIR5	MIR7	MIR8	MIR6
Araneae	0.40	0.23	0.36	0.21	0.54
Isopoda	1.39	1.55	1.26	0.92	1.24
Carabidae	0.22	1.38	1.65	1.55	1.36
Staphylinidae	0.16	0.72	2.42	10.64	2.55
other Coleoptera	0.42	0.03	0.20	0.36	0.59
Formicidae	0.66	0.26	0.58	0.62	0.65
TOTAL	0.55	0.47	0.67	0.65	0.86

Conclusion

The results obtained at canopy level were in some cases different from results obtained at soil level, showing different responses of arthropods communities to treatments according to both their behavioural features and the properties of their habitat. The kaolin reduced the abundance of arthropods at canopy level but have no impact on the soil arthropods communities.

On the canopy, only Lepidoptera were unaffected by the kaolin spraying. The affected taxa include other Hymenoptera, Ichneumonoidea, Macrolepiotera, Neurptera, Mecoptera, Syrphidae, Coccinellidae, Aranease and Opiliones.

Study limitations:

An unreplicated study design composed of 200 plants per treatment was selected. All results were expressed as ratio after/before treatment (A/B_{ratio}), which does not facilitate the interpretation of the results. As the exact date selected for sampling pre- and post-application is not reported and the day of application(s) is different between treatments, direct comparison between treatments (including the untreated control) is not possible. Further, the timing/frequency of sampling was not indicated.

B.9.3.2.3/16

Reference	Viktor Marko, Leo H.M Blommers, Sandor Bogya and Herman Helsen, 2006 The effects of kaolin treatments on phytopagous and predatory arthropods in the canopies of apple trees Journal of fruit and Ornamental Plant Research Vol 14 (Suppl 3), 2006
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Hydrophobic kaolin M96-018
Test species	Phytophagous and predatory arthropods in the canopies of apple trees
Vehicle	Water and methanol
Reference item	-
Treatment	45 kg/ha in a suspension of 30 grams kaolin M96-018 and 40 ml methanol per liter of water
Trial location	Kesteren, the Netherlands
Trial design /methodology	Each plot chosen for the experiment was planted with 260 trees of ‘Golden Delicious’, ‘James Grieve’ and ‘Cox’s O.P’. Four 0.2-hectare plots were divided into two parts. One part was treated with kaolin particle film, while the other part served as the control. Kaolin was applied in the form of hydrophobic kaolin M96-018 (Engelhard Corporation, Iselin, New Jersey), which was applied at a rate of 45 kilograms per hectare in a suspension of 30 grams kaolin M96-018 and 40 ml methanol per liter of water. The treatments were applied about every ten days twelve times between March 25 and August 5. Between

	May 3 and September 17, beating-tray samples were collected nine times by tapping the entire canopies of ten trees per treatment.
Statistics	Data on the population densities of *Allothrombium fuliginosum* and *Exochomus quadripustulatus* were compared using Welch's modified t-test

Findings

The most common predators encountered were spiders, followed by the common earwig (*Forficula auricularia*). Throughout the growing season, they were less numerous on treated plots than on control plots. Between May 5 and August 24, significantly fewer individuals of the predatory mite *Allothrombium fuliginosum* were found on the treated plots than on the control plots. An average of 0.30 ±0.45 individuals per tree were found on the treated plots, while an average of 3.30 ±1.52 individuals per tree were found on the control plots. Between May 5 and August 24, significantly fewer individuals of the pine ladybird (*Exochomus quadripustulatus*) were found on the treated plots than on the control plots. An average of 1.30 ±0.75 individuals per tree were found on the treated plots, while an average of 4.90 ±2.16 individuals per tree were found on the control plots.

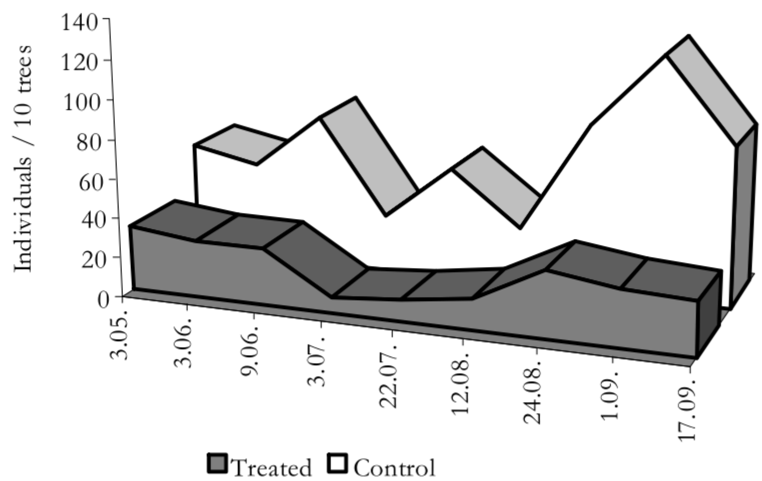


Figure 3. Number of spiders collected during the season

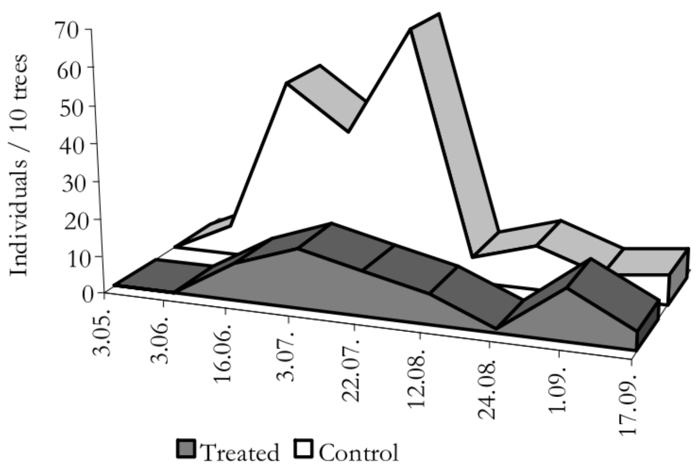


Figure 4. Number of common earwigs (*Forficula auricularia*) collected during the season

Conclusion

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.

Study limitations:

The study is suitable to address adverse effects on spiders, common earwig (*Forficula auricularia*) amd the predatory mite *Allothrombium fuliginosum* in an apple orchard environment. Only one sampling method was selected (beating). The number of individuals collected in the untreated plot ranged roughly from 5-14 spiders/tree and 0-7 earwigs/tree during the season. The study design is not suitable for identifying the duration of the adverse effects. The application scheme of the study (12 applications with 45 kg/ha) cover worst case application for the representative use and thus the results of the study can be considered relevant for the scope of the current evaluation. Several limitations were identified:

- The trial design did not include a positive control (toxic reference), hence the susceptibility of the test system is not confirmed.

- There is no information on the presence of an unsprayed area between treatments in the same block or the use of any restrictive measure to avoid contamination of the untreated plots.

- The plot size of 0.2 ha covers the minimum recommended plot size for orchards (Candolfi *et al.*, 2000). This plot size may be too small to address recovery of populations especially for less mobile taxa, but since the study was mainly focused on the identification of the adverse effects rather than the establishing of the recovery, this limitation does not affect the reliability of the results.

- No information is available for a possible verification of the tested application rate. However, considering the excessive number of applications compared to the proposed uses of kaolin, this limitation is of low significance.

- Information on history and weather conditions is missing.

B.9.3.2.3/17

Reference	Showler, A.T, and Sétamou, M., 2004 KCP 10.3.2.4/18, Effects of kaolin particle film on selected arthropod populations in cotton in the lower Rio Grande Valley of Texas Published in: Southwestern Entomologist, 29(2): 137-146
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Yes, with limitations

Material and methods

Test substance	Surround (wettable powder) (>85% kaolin) Batch number: Not reported.
Test species	Herbivorous arthropods and selected natural enemies (Geocoris spp. (Lygaeidae), Orius spp. (Anthocoridae), Nabis spp. (Nabidae), reduviids, Coccinellids, Collops spp. (Melyridae), neuropterans (mostly chrysopids and

	hemerobiids), wasps (mostly braconids, eupelmids, eurytomids, ichneumonids, pteromalids, sphecids, and trichogrammatids), and spiders (mostly clubionids, linyphiids, lycosids, salticids, and thomisids).
Vehicle	-
Reference item	-
Treatment	42.3 L f.p./ha
Trial location	Weslaco, Texas
Trial design /methodology	Twenty-four randomized design plots, each 8.1 m wide (8 rows) x 15.2 cm long with a 1 m bare ground buffer between plots were used. Kaolin suspensions were applied with a tractor-mounted boom sprayer at 42.3 L/ha. Treatments were reapplied weekly to eight plots and fortnightly to 8 plots for a year, starting mid-April until end of June. Each application consisted of two passes by the tractor to maximize coverage. Three weeks after the first application each year, larger application nozzles were used to increase coverage. The remaining 8 plots were not treated (control). No insecticides were applied to any of the plots. Treatment occurred for 2 years. Kaolin retention on cotton leaves at 4 hour, 1 week and 2 weeks after the first application the first year was measured on randomly selected fully expanded leaves collected from the biweekly treated plots. Other arthropods were sampled using a dvac orifice on several cotton plants (n = 8) at fortnightly intervals in April and June (i.e. within the period of applications).
Statistics	Repeated measures analysis was used to detect significant differences between treatments and sampling dates, and interactions. Insect numbers were log(x+1)-transformed before repeated measures analysis. However, transformed means are presented (Analytical Software).

Findings

Kaolin retention:

Mean particle density on leaves 4 hours after the first application was 360.0 ± 18.7 µg kaolin/cm^2 leaf surface. After 1 and 2 weeks in the field (with biweekly applications), particle densities were 319.9 ± 20.8 and 201.0 ± 13.2 µg kaolin/cm^2, respectively.

Natural enemies were comprised of *Geocoris* spp., *Orius* spp., *Nabis* spp., reduviids; coccinellids, *Collops* spp., neuropterans, wasps and spiders. Kaolin sprays significantly decreased mean numbers of cicadellids and dipterans the first year. In the second year, kaolin significantly increased aphids, but reduced the mean number of cicadellids, dipterans, *Orius* spp., and wasps. The effects of time were significant for 16 and 15 of the 18 arthropod groups in the first and second year, respectively. Only Collops beetles were not affected over time, but mean populations were always low. Interactions between treatment and time effects were detected for collected pest aphid populations in the first year, and for aphids, dipterans, *Orius* spp., and coccinellids in the second year.

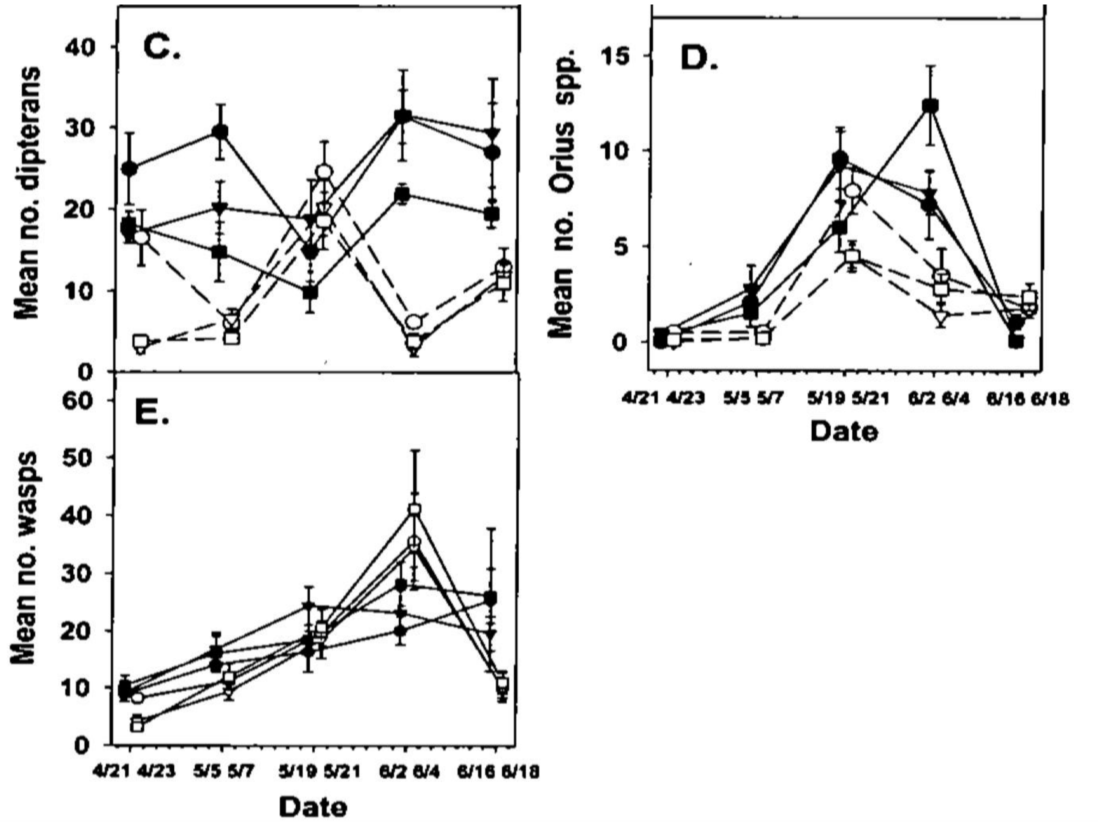


Figure 10.3.2.4/17-1: Mean numbers of selected arthropod groups collected from cotton plants

Conclusion

In the 2-year field trial, kaolin was applied 7 to 10 times at a rate of 42.3 L/ha to cotton (from mid-April until end of June) (7-14 day interval). 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 identified in this study (*Geocoris* spp.; *Nabis* spp.; reduviids; coccinellids; *Collops* spp.; neuropterans; and spiders).

Study limitations:

The study was designed to address effects on non-target populations in an arable crop environment. Several limitations are identified:

- The trial design did not include a positive control (toxic reference), hence the susceptibility of the test system is not confirmed.

- The plot size was 0.0125 ha does not cover the minimum recommended plot size for arable land (1 ha according to Candolfi *et al.*, 2000).

- No information is also available for a possible verification of the tested application rate. However, considering the excessive number of applications compared to the proposed use in the representative use, this limitation is of low significance.

- Information on history and weather conditions are missing.

- A 1 m buffer zone was respected in order to avoid contamination of untreated plots with kaolin. However, this restrictive measure may be insufficient.

- The application rate of kaolin was not verified.

- Poor reporting of the results

B.9.3.2.3/18

Reference	Susana Pascual, Guillermo Cobos, Pilar Medina, Flor Budia, Elisa Viñuela, Manuel González-Núñez, 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 Pesticides and Beneficial Organisms IOBC/wprs Bulletin Vol. 55, 2010 pp. 11-18
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Surround WP; Kaolin 95%, Engelhard Corp., Iselin, New Jersey, USA
Test species	Foliage-dwelling arthropod community
Reference item	Dipagrex 80® (trichlorfon 80%, DEQUISA, Paterna, Valencia, Spain) at 5 g/l the protein hydrolysate Nu-Lure® (Miller Chemical & Fertilizer Corp., Hanover, Pensylvania, USA) at 10 g/l. Trichlorfon bait was sprayed on 2-3 m^2 spots on the tree canopy.
Treatment	3 kg f.p./hL (two applications – 8th July and 16th September)
Trial location	Madrid, Spain
Trial design /methodology	The field trial was conducted in a 4.0 ha olive grove in Madrid in 2006. Three different treatments were compared: kaolin, trichlorfon bait spray used as positive control and unsprayed control. Each treatment was applied to an area of about 0.8 ha and experimental plots were randomly located in the olive grove. Predatory arthropod fauna of the canopy of olive trees was monitored periodically using a beating method. In every sampling, four olive trees were randomly chosen per plot and four branches per tree (one in each orientation) were beaten three times. A total of 14 samplings were done during the year of study.
Statistics	Numbers of predators captured were analysed by two different methods: Analysis of variance (ANOVA) and Principle Response Curve analysis (PRC). One-way ANOVA ($P \leq 0.05$) was carried out on total numbers of predators captured at each sampling date and when differences were detected means were separated by a HSDTukey test. Also, a two-way ANOVA was applied on numbers of specimens of the most abundant taxa of predators (accounting for at least 1.5% of the total predators captured), with “treatment” and “sampling date” as variable factors. ANOVA tests were performed using the software Statgraphics® Centurion XV (StatPoint, 2005). Changes in abundance of the different taxa of predators were also investigated using the multivariate method

PRC analysis. PRC analysis was carried out using the program CANOCO 4.51 (Biometris, Plant Research International, Wageningen, The Netherlands) which detects significant differences between curves by means of an F-type permutation test (Monte Carlo simuation, 499 permutations in our case) and provides the parameters necessary to generate PRCs (canonical coefficients) and "Taxon Weights" (Leps & Smilauer, 2003). Values of taxon weight between 0.5 and –0.5 are likely to show either a weak response or a response that is unrelated to that shown in the PRC (Van den Brink & Ter Braak, 1999) and therefore are not considered significant. Data on the number of captures of each taxon were transformed to ln(x+1) prior to analysis.

Findings

The most abundant group of predators was the order Araneae, followed by the family Coccinellidae and the orders Hemiptera and Neuroptera. One single species, *Scymnus mediterraneus* Iablokoff-Khnzorian (Coleoptera: Coccinellidae) added up 21.55% of the total numbers of predators captured. Results show a deleterious effect of kaolin sprays on populations of predators (ANOVA and the PRC analysis). Numbers of predators captured in the olive trees treated with kaolin were lower than those from the untreated control and trichlorfon plot in five dates. Numbers in the treated trees (kaolin and trichlorfon) dropped after sprays were applied. Kaolin treatment caused a significant reduction in numbers of predators compared to the untreated control, while trichlorfon treatment did not affect these numbers. The data of this study shows taxon weights from the PRC analysis comparing kaolin versus untreated control plot, and results from two-way ANOVA analysis on the most numerous groups of predators. All data indicate that the main taxa of predators affected by kaolin treatment were the coccinellid *S. mediterraneus* and the spiders belonging to the family Philodromidae. Other important groups of predators are shown by the PRC analysis as groups affected by the kaolin treatment because their taxon weights are positive and higher than 0.5, while the ANOVA analysis did not detect significant differences between control and kaolin treatment. Some of these groups are for example chrysopids, *Stethorus punctillum* Weise, *Araniella cucurbitina* (Clerck) or *Brachynotocoris ferreri n.* sp. Baena (in litteris).

Table B.9.3.2.3/18-1: Total numbers of predatory arthropods captured in by the beating method in olive plots sprayed with kaolin (Ka), trichlorfon bait (Tr-b) and the untreated control plot (C).

Taxa	C	Ka	Tr-b	Total	%
ARANEAE	249	142	316	707	*35.26*
Araneidae	22	8	42	72	*3.59*
Araniella cucurbitina	14	3	20	37	*1.85*
Gibbaranea spp.	2	1	8	11	*0.55*
Other Araneidae	6	4	14	24	*1.20*
Oxyopidae	7	13	13	33	*1.65*
Philodromidae	89	32	72	193	*9.63*
Salticidae	55	31	76	162	*8.08*
Icius hamatus	7	2	14	23	*1.15*
Salticus sp.	12	12	10	34	*1.70*
Thyene imperialis	5	2	10	17	*0.85*
Other Salticidae	31	15	42	88	*4.39*
Theridiidae	36	28	47	111	*5.54*
Theridion sp.	11	11	18	40	*2.00*
Other Theridiidae	25	17	29	71	*3.54*
Thomisidae	20	12	45	77	*3.84*
Tmarus spp.	5	7	27	39	*1.95*
Other Thomisidae	15	5	18	38	*1.90*
Other Araneae	20	18	21	59	*2.94*
COLEOPTERA	312	77	279	668	*33.32*
Coccinellidae	283	57	235	575	*28.68*
Brumus quadripustulatus	3	0	1	4	*0.20*
Chilocorus bipustulatus	2	0	0	2	*0.10*
Hyperaspis reppensis	17	1	6	24	*1.20*
Nephus spp.	3	2	6	11	*0.55*
Platynaspis luteorubra	2	0	2	4	*0.20*
Propylea quatuordecimpunctata	0	0	1	1	*0.05*
Rhyzobius chrysomeloides	0	4	6	10	*0.50*
Rhyzobius litura	4	0	5	9	*0.45*
Scymnus mediterraneus	217	47	168	432	*21.55*
Stethorus punctillum	17	2	24	43	*2.14*
Other Coccinellidae	18	1	16	35	*1.75*
Cybocephalidae - *Cybocephalus* sp.	6	3	11	20	*1.00*
Dasytidae	20	16	26	62	*3.09*
Mauroania elegans	19	16	26	61	*3.04*
Other Dasytidae	1	0	0	1	*0.05*
Staphylinidae	1	1	4	6	*0.30*
Other predatory Coleoptera	2	0	3	5	*0.25*
DIPTERA - Empididae	5	1	1	7	*0.35*
HEMIPTERA	112	72	185	369	*18.40*
Anthocoridae	31	2	63	96	*4.79*
Anthocoris nemoralis	13	2	52	67	*3.34*
Orius laevigatus	12	0	9	21	*1.05*
Orius majusculus	1	0	0	1	*0.05*
Orius niger	2	0	0	2	*0.10*
Other Anthocoridae	3	0	2	5	*0.25*
Miridae	81	70	121	272	*13.57*
Brachynotocoris ferreri n.sp	23	8	21	52	*2.59*
Phytocoris viberti	18	32	42	92	*4.59*
Pseudoloxops coccineus	40	30	58	128	*6.38*
Other predatory Miridae	0	0	1	1	*0.05*
HYMENOPTERA- Vespidae	0	2	0	2	*0.10*
NEUROPTERA	84	64	82	230	*11.47*
Chrysopidae	28	20	29	77	*3.84*
Coniopterygidae	53	42	50	145	*7.23*
Other Neuroptera	3	2	3	8	*0.40*
THYSANOPTERA - Aeolothripidae	1	8	8	17	*0.85*
Other predatory Arthropoda	1	2	2	5	*0.25*
TOTAL predatory Arthropoda	**764**	**368**	**873**	**2005**	**100.00**

Table B.9.3.2.3/18-2: Assessment of predator populations from plots treated with trichlorfon, kaolin or untreated. A) One-way ANOVA, mean numbers of predators captured in different treatment plots. Different letters in a sampling date indicate significant difference (P≤0.05, HSD Tukey). B) PRC analysis showing the effect compared to an untreated control (y = 0 line). The P values denote the significance of each treatment relative to control based on an F-type permutation test (Monte Carlo simulation, 499 permutations).

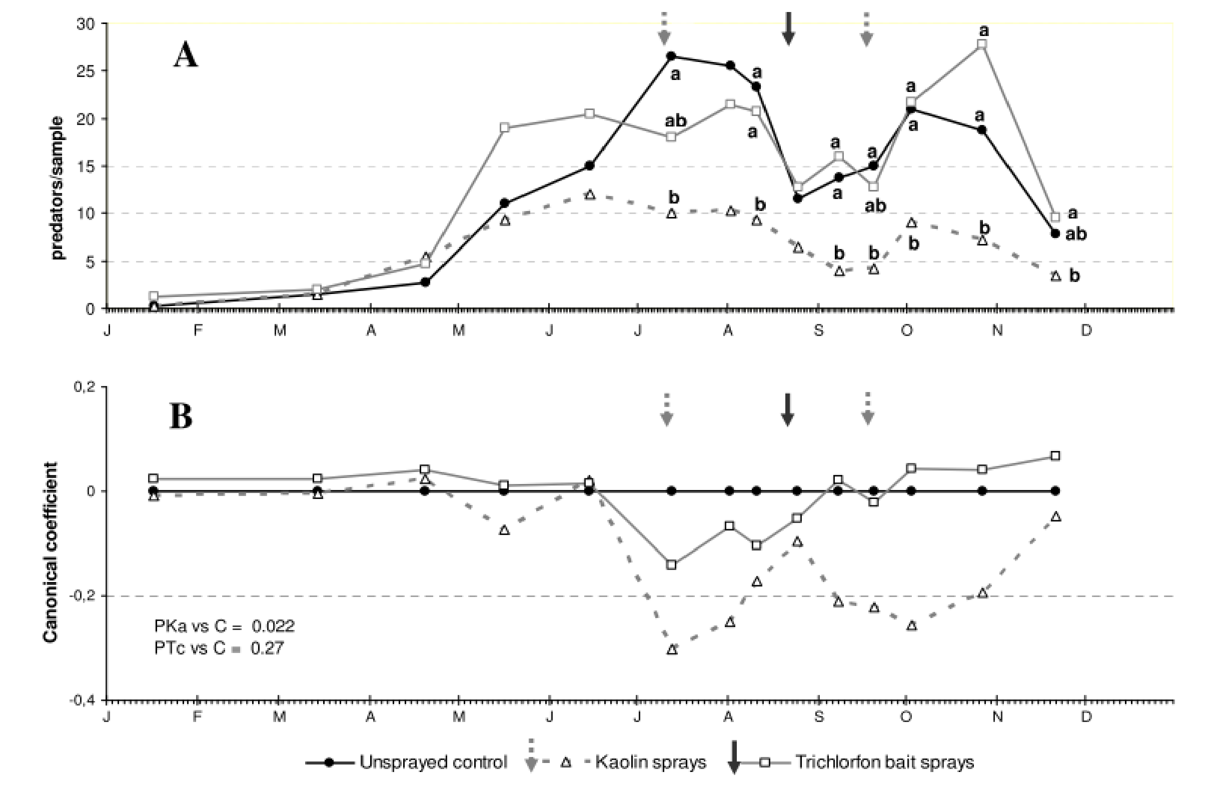


Table B.9.3.2.3/18-3: "Taxon weights" for predatory arthropods obtained by PRC analysis, comparing the captures from the Surround WP-sprayed olive trees to untreated control. Responses of taxa with positive weights followed the PRC patterns, whereas those with negative weights showed the opposite pattern.

Taxon	Taxon Weight	Taxon	Taxon Weight	Taxon	Taxon Weight
Scymnus mediterraneus	5.4797	*Salticus* sp.	0.2712	*Orius majusculus*	0.081
Philodromidae	2.7624	*Thyene imperialis*	0.2703	*Tmarus* spp	0.0456
Other Salticidae	1.3763	*Cybocephalus* sp.	0.2343	Aeolothripidae	0.0251
Hyperaspis reppensis	1.0862	*Mauroania elegans*	0.2094	Staphylinidae	0
Chrysopidae	0.9644	*Brumus*	0.2074	Nephus spp.	- 0.0006
Other Coccinellidae	0.905	*Rhyzobius litura*	0.2024	Other Dasytidae	- 0.0104
Brachynotocoris ferreri n.sp	0.8782	Other Araneidae	0.2	Other predatory Arthropoda	- 0.0104
Stethorus punctillum	0.8439	Other Araneae	0.1993	*Pseudoloxops coccineus*	- 0.0204
Araniella cucurbitina	0.7484	*Adalia 10-p*	0.1845	*Rhyzobius chrysomeloides*	- 0.0416
Other Thomisidae	0.6714	*Platynaspis luteorubra*	0.1822	*Theridion* sp.	- 0.0501
Orius laevigatus	0.6522	*Gibbaranea* spp.	0.1437	Other predatory Miridae	- 0.0667
Other Theridiidae	0.6072	Other Anthocoridae	0.134	Vespidae	- 0.0786
Icius hamatus	0.3858	Empididae	0.1237	Oxyopidae	- 0.4802
Coniopterygidae	0.3634	*Chilocorus bipustulatus*	0.1114	*Phytocoris viberti*	- 0.9861
Anthocoris nemoralis	0.3469	Other predatory Coleoptera	0.109		

Conclusion

Both PRC and two-way ANOVA identified the coccinellid *Scymnus mediterraneus* Iablokoff-Khnzorian 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 did not affect these numbers. 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.

<u>Study limitations:</u>

The field study was evaluated considering the standards and recommendations set in the *Guidance for summarising and evaluating field studies with non-target arthropods* (de Jong et al., 2010) with regard to the reliability and the suitability to the risk assessment.

- The community of non-target arthropods captured is below the recommended range of 150-200 counted taxa (50-80 available for statistical analysis) of the de Jong document. Several taxa that should be evaluated in order to render the study representative of the orchard ecosystem are missing (mostly attributed to the selection of just one sampling method). Overall, the study was considered suitable for addressing possible adverse effects on specific taxa (where an adequate number of specimens allow for a reliable statistical analysis). On the contrary, the study is not suitable for identifying the most sensitive taxonomic group (in view of the insufficient representativeness) or to address recovery of the affected populations (limited sampling occasions after the last application; kaolin applications did not cover worst-case exposure).

- Information on the pre-treatment variation in the number of captured predator populations between plots was provided. However, results were not analysed statistically and therefore the absence of difference in the abundance pre-treatment cannot be confirmed. Further, pre-treatment variations in the diversity and species richness of the community between plots/treatments cannot be excluded.

- The number of replicated plots per treatment are not reported.

- No information on unsprayed area between treatments to avoid contamination of the untreated plots is provided.

- The actual plot size is not specified. The report mentions only the total area used per treatment (0.8 ha).

- The presentation of the results is suitable to address adverse effects on specific taxa but little information on the duration of the adverse effects is obtainable. Comparison of the predator population in treated and untreated plots indicate that predators captured in kaolin-treated plots remain affected even at the last sampling occasion (two months after the last application).

- The water volume which was used for application is not specified. Since the application rate is given in kg/hl it is unknown if the ground dose (kg/ha) cover the worst-case application rate. Further, only two applications per year were carried out and therefore the worst-case application scheme is not covered.

- Just one sampling method was considered (beating method). Non-target groups of different habitat requirements such as ground-dwelling populations were not represented.

- Information on history and weather conditions is missing.

- It is not known if the tested application rate was verified.

- No information on possible maintenance of unsprayed area between treatments to avoid contamination of the untreated plots is presented.

- Trichlorfon is applied in the form of bait application (with protein hydrolysate). This reference product is not suitable to verify the susceptibility of the test system. The toxic effects from the use of the reference product to the main predator taxa captured in the olive trees were less severe compared to the effects caused from kaolin (see Table B.9.3.2.3/19-3).

B.9.3.2.3/19

Reference	Tacoli et al., 2019 Side Effects of Kaolin and Bunch-Zone Leaf Removal on Predatory Mite Populations (Acari: Phytoseiidae) Journal of economic entomology, 112(3), 1292-1298.
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Acceptable with limitations

Material and methods

Test substance	Surround WP, Tessenderlo Kerley Inc., Phoenix, AZ
Test species	Phytoseiidae Predatory Mite Populations (mainly *K. aberrans* and *T. pyri)*
Vehicle	Water
Reference item	-

Treatment	20 kg f.p./ha (2 applications)
Trial location	Three vineyards in north-eastern Italy (Gorizia district)
Trial design /methodology	<u>Field trials</u> In the four trials (Vineyard A 2015, Vineyard B 2015, Vineyard A 2016, and Vineyard C 2016), kaolin (Surround WP, Tessenderlo Kerley Inc., Phoenix, AZ, 2% w/v, Surround WP/water) was sprayed at the rate of 1,000 liter/ha, and an untreated control was included for a comparison. Kaolin was applied twice in 2015 (18 and 24 June both in Vineyards A and B) and three times in 2016 (10, 20, and 28 June in Vineyard A; 10 and 24 June and 1 July in Vineyard C). In all cases, kaolin was applied with a backpack sprayer (Oleo-Mac, Sp-126, Emak S.p.A., Bagnolo in Piano, RE, Italy). In all trials, a randomized block design with four replicates was adopted. Each block consisted of a vineyard row divided into two plots (kaolin and control) of 28 (Vineyard A both 2015 and 2016), 20 (Vineyard B), or 24 (Vineyard C) vines. Plots were divided into two subplots of 14 (Vineyard A), 10 (Vineyard B), or 12 (Vineyard C) vines that were subjected or not to bunch-zone leaf removal (17 June 2015 and 10 June 2016). In Vineyard A, the plots and subplots submitted, respectively, to kaolin applications were the same in both years. Preliminary observations revealed that the dominant species were *K. aberrans* in Vineyards A and B and *T. pyri* in Vineyard C. To assess phytoseiid densities, five samplings were carried out in each year and trial (2015: 11, 22, and 29 June, 06 July, and 20 August both in Vineyard A and Vineyard B; 2016: 6, 20, and 28 June, 6 July, and 24 August in Vineyard A; 7 and 21 June, 1 and 8 July, and 24 August in Vineyard C). On each sampling date, 10 leaves were collected from the mid parts of the main vine shoots in each subplot (40 leaves per subplot); they were enclosed in plastic bags and cool stored until being transferred to the laboratory. The leaves were checked under a dissecting microscope to assess mite numbers. At least 100 specimens per trial were slide mounted in Berlese medium and identified under 400× magnification. <u>Laboratory Experiments</u> Laboratory experiments were performed to evaluate the effects of kaolin on *K. aberrans* and *T. pyri* populations. toxicological tests were performed using insecticide-free grapevine leaf discs (4.5 cm in diameter). Kaolin (Surround WP, 4% w/v, Surround WP/water) was applied to leaf discs with a Potter spray tower (Burkard Scientific Ltd, Uxbridge, United Kingdom) spraying 1.4 ml of suspension per leaf disc at 103 kPa (15 psi) to obtain an amount of fluid of 1.9–2.0 mg/cm 2 , as recommended by the IOBC guidelines. The untreated eaf discs (control) were sprayed with water following the same procedure. Leaf discs were subsequently placed on wet cotton pads and wet cotton barriers were created along their perimeter to prevent predatory mites from escaping. Two mated females (about 12-d old) were placed on each leaf disc. Fresh pollen was provided every 2 d as food. The experiments were conducted under controlled conditions (25°C, 70% RH, and photoperiod of 16:8 [L:D] h). Female mortality was checked at 72 h after spraying and fecundity was assessed daily for four additional days. After 7 d, the remaining females and juvenile stages were removed, and eggs were monitored until they had completely hatched in the control. In total, 50 and 38 females per treatment were assessed for *K. aberrans* and *T. pyri*, respectively.
Statistics	To compare field data, one-way and mixed analysis of variance (ANOVA) with Bonferroni adjustment and Tukey's post hoc test were performed after

logarithmic transformation using IBM SPSS Statistics 20 (SPSS 2011). The reduction effect of kaolin was calculated according to Henderson and Tilton (1955). To compare field data in the sampling before the first kaolin application, a Student's unpaired t-test was used. Data on fecundity were analyzed with a one-way ANOVA using GLM procedure of SAS (SAS Institute Inc. 1999)

Findings

Field Trials

Vineyard A 2015 and 2016

In both years, *K. aberrans* was the only species recorded and its population density in the control plots ranged from 6.0 to 17.0 motile forms per leaf. In both years, phytophagous mite densities were negligible.In both years, *K. aberrans* densities were not significantly different in the two treatments in the sampling made before the first kaolin application (2015: t = 0.69; df = 6; P = 0.52; 2016: t = 1.49; df = 6; P = 0.19). After kaolin applications, phytoseiid densities were significantly lower in the kaolin than in the control plots (2015: F = 9.013; df = 1,12; P = 0.011; 2016: F = 80.802; df = 1,12; P = 0.0001). *Kampimodromus aberrans* densities became significantly lower in the kaolin compared with the control plots after the second application in 2015 and after the first application in 2016 (i.e., 18 and 11 d after first application, respectively). The reduction effect of kaolin at about 10 d from the last application was higher in 2016 (Henderson-Tilton reduction of 69%) than in 2015 (49%). After two successive years of kaolin applications (2015 and 2016) in the same plots, the overwintered populations were not significantly different between the kaolin and the control (F = 0.735; df = 1; P = 0.424).

Vineyard B

Phytoseiid identification revealed the dominance of *K. aberrans* (89%) over *Amblyseius andersoni* (Chant) (11%) and their population densities in the control plots ranged from 1.8 to 2.3 motile forms per leaf. Phytophagous mite densities were negligible. In the sampling before the first kaolin application, phytoseiid densities in kaolin and the control plots were not significantly different (t = 0.40; df = 6; P = 0.70). After two kaolin applications, phytoseiid densities were significantly lower in kaolin than in the control plots (F = 16.575; df = 1,12; P = 0.002). In particular, K. aberrans densities were significantly lower in kaolin plots 10 d after the first application. The reduction effect of kaolin at about 10 d from the last application was substantial (Henderson–Tilton reduction: 91%).

Vineyard C

Typhlodromus pyri (97%) dominated over *A. andersoni* (3%) and their population densities in the control plots ranged from 0.6 to 1.6 motile forms per leaf. In the sampling before the first kaolin application, T. pyri densities in kaolin and the control plots were not significantly different (t = 0.70; df = 6; P = 0.51). Kaolin applications significantly reduced phytoseiid densities in the kaolin plots compared with the control plots (F = 8.218; df = 1,12; P = 0.014). *Typhlodromus pyri* densities were significantly lower in the kaolin plots 7 d after the second kaolin application (i.e., 24 d after first application). As in Vineyard B, the negative effect of kaolin at about 10 d from the last application was substantial (Henderson–Tilton reduction of 88%).

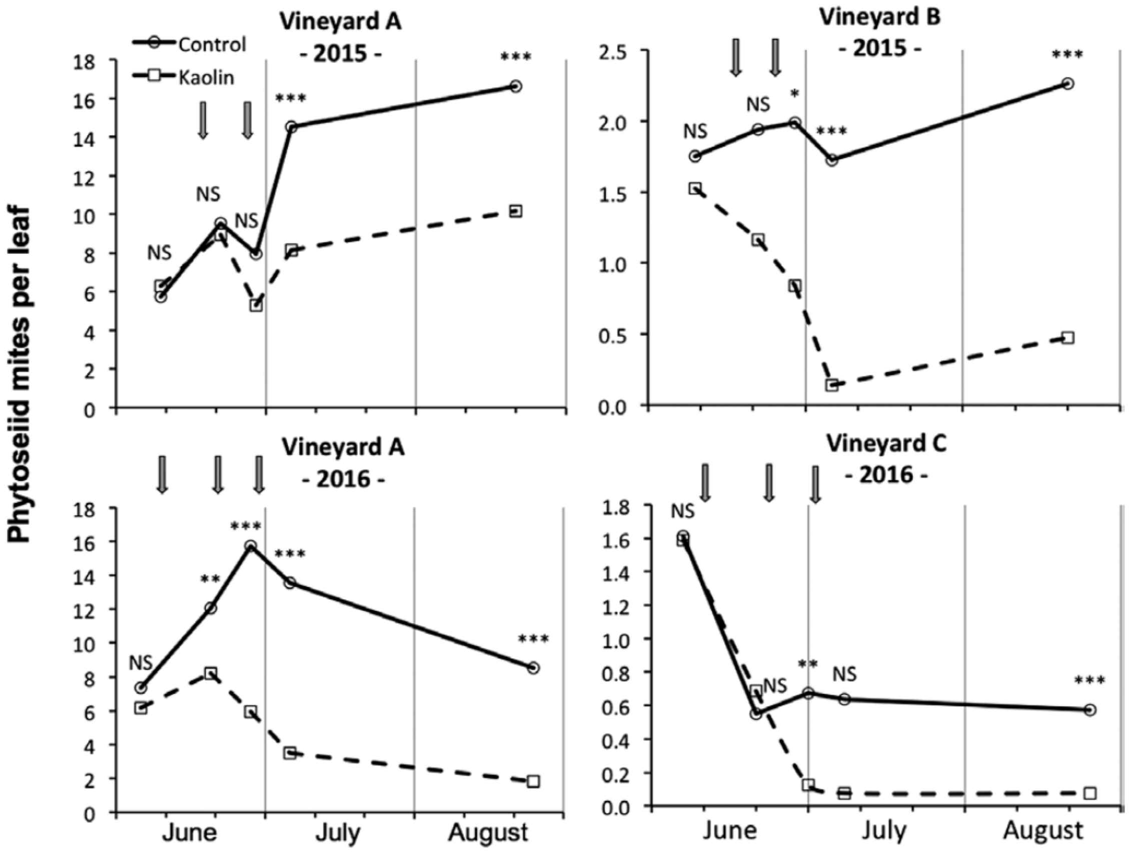


Figure B.9.3.2.3/19-01: Number of phytoseiid mites recorded in kaolin and the control plots of the four trials before the first (early June) and after two (2015) or three (2016) kaolin applications (arrows). NS, *, **, *** indicate nonsignificant and significant differences for α = 0.05, α = 0.01, α = 0.0001, respectively, between treatments according to Tukey's post hoc test.

Laboratory Experiments

In the control, the fecundity rates (mean ± SD) of both *K. aberrans* and *T. pyri* were 0.78 ± 0.23 and 0.88 ± 0.14 eggs/female/day, respectively. *Kampimodromus aberrans* female survival was 100% in both treatments but kaolin significantly reduced fecundity (F = 124.78; df = 45; P < 0.0001) affecting the toxicity coefficient E (62.8%). In both treatments, the hatching rate was 100%. *Typhlodromus pyri* female survival was 100% in both treatments. However, kaolin significantly reduced female fecundity (F = 94.26; df = 33; P < 0.0001) affecting the toxicity coefficient E (62.5%). In both treatments, the hatching rate was 100%.

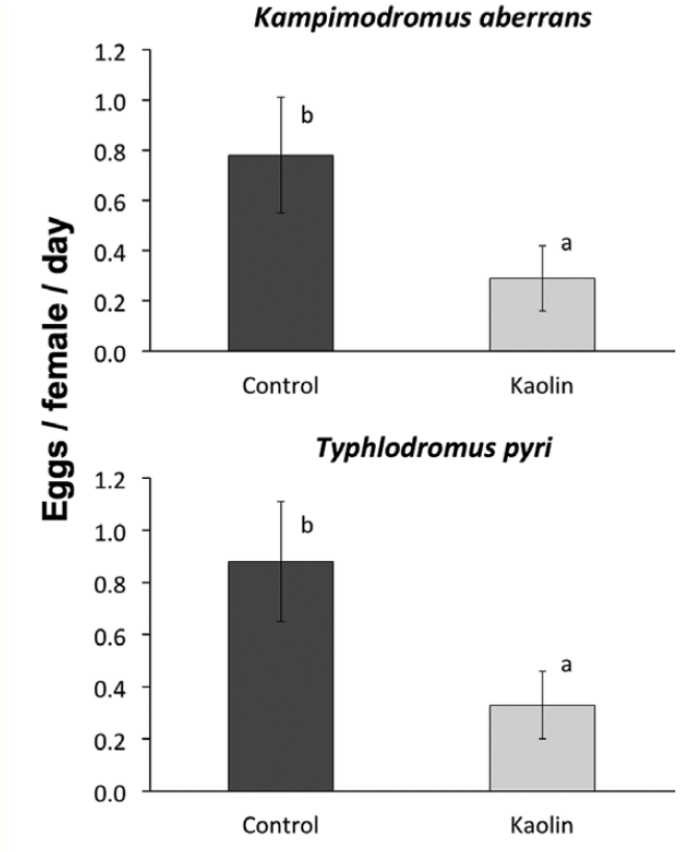


Figure B.9.3.2.3/19-02: Daily number of eggs (mean ± SD) laid on grapevine leaf discs by females of the two phytoseiid species in the kaolin and the control. Different letters indicate significant differences for $\alpha = 0.001$ according to Tukey's post hoc test.

Conclusion

In field trials, kaolin affected *K. aberrans* and *T. pyri* populations negatively. For both species, the differences between treatments reached maximum levels on the second or third sampling date after the first kaolin application, i.e., after about 20 d, the negative effect on *K. aberrans* densities observed in the summer of 2015 was no longer recorded in the pretrial sampling in 2016 and that observed in the summer of 2016 had no consequence on the abundance of overwintering females.

Laboratory data showed that kaolin reduced the fecundity of *K. aberrans* and *T. pyri* females but not their survival. Therefore, the decrease observed in fecundity did not occur as a consequence of a decrease in survival.

<u>Study limitations:</u>

The study was designed to address adverse effects of kaolin-based particle film on the population density of phytoseiid mites. Some information on the duration of the adverse effects can be obtained from the field trial *Vineyard A*. A suitable sampling method was employed. The number of phytoseiid mites per leaf in the untreated control is sufficient for all trials (especially in *Vineyard A*). Several limitations were identified:

- The trial design did not include a positive control (toxic reference), hence the susceptibility of the test system is not confirmed.

- The exact plot size is not reported, but the number of vines per plot (10-14) indicate that the total plot size does not cover the minimum size recommended by Candolfi et al. 2000 for investigating long-term effects (0.2 ha), let alone for addressing of the recovery.

- It is unknown if (and how) the application rate was verified.

- Information on unsprayed area (or other means to avoid contamination of the untreated plots) is reported.

- Information on history and weather conditions is missing. It is reported that one of applications was repeated as a result of partial wash off by rain.

- The application scheme of the study (2 x 20 kg/ha) does not cover the proposed application scheme for the representative use of the product.

B.9.3.2.3/20

Reference	Jaastad et al., 2006 Kaolin as a possible treatment against lepidopteran larvae and mites in organic fruit production Proceedings to the Conference on Cultivation Technique and Phytopathological Problems in Organic Fruit-Growing
Guidelines	-
GLP	No
Previous evaluation	No
Validity/Acceptance	Yes, with limitations

Material and methods

Test substance	kaolin particle film (product: Surround)
Test species	Predatory Mite Populations
Vehicle	Water
Reference item	-
Treatment	3 kg f.p./hl (1-2 applications)
Trial location	Western Norway
Trial design /methodology	Trials were carried out in an organic plum field and in two IPM apple fields in Western Norway in 2003, 2004 and 2005. Varieties in the plum orchard are 'Victoria', 'Reeves', 'Opal', 'Edda' and 'Mallard'. Distance between trees were 4,5 x 2,0 m. Trees were planted in 2000. Apple orchard number one was planted in 1994 and only the variety 'Discovery' was used in this trial. Distance between trees were 4 x 1 m. Apple orchard number two was planted in 2001, distance between trees were 5 x 2 m and only the variety 'Summer red' was used in the trial. Trials with kaolin against early larvae, rust mite, ERM and beneficial mites were carried out in the plum field and in apple field number one in 2003, 2004 and 2005. Three different treatments were tested in this experiment: 1 x kaolin, 2 x kaolin and an untreated control. Kaolin treatments were applied with a tractor-mounted hand-sprayer at a concentration of 3 kg/100 l. Five replicates with three trees in each plot were used in each orchard. Between plots there were two boundary trees. First spray application was just before half inch (56 BBCH), second spray application just before balloon (59 BBCH) in both apple and plum trees in all three years. Effect of kaolin was measured as damage by larvae and number of larvae on leaves and shoot and as number of mites on leaves at the end of blossom (69 BBCH). Dates for spray application and registration varied between years due to varying phenological development.

	Dates also varied between apples and plums as development from half inch to ballon is more rapid in plums. 10 branches were inspected for damage and larvae in each plot. Number of damaged short shoots were counted on each branch. Larvae were collected from each plot and identified. Five leaves from each tree (15 from each plot) were collected and the number of rust mite, ERM and beneficial mites counted.
Statistics	Effect of treatments were analysed by two-way Anova with treatment and block as explanatory variables (SAS Institute Inc., 2005). Differences between mean were tested with Tukey's test.

Findings

The population of beneficial mites were negatively affected by kaolin treatment in both apples and plums in 2004 and 2005. Population of beneficial mites were greatest in these years. The most common species of beneficial mites recorded were *Tydeus* sp., *Typhlodromus* sp. and *Amblyseius* sp. No correlation between number of ERM and beneficial mites were found, neither no correlation between phytophagous mite nor beneficial mites (data not shown).

Table B.9.3.2.3/20-1: Average number of beneficial mites per leaf in plots treated with 1 x kaolin (3 kg/100L), 2 x kaolin (3 kg/100L x 2) and untreated control

	2003		2004		2005	
	apples	plums	apples	plums	apples	plums
Untreated control	0.06 ± 0.3 a	0.7 ± 0.1 a	0.3 ± 0.6 ab	1.8 ± 2.3 a	1.3 ± 1.8 a	2.3 ± 2.9 a
1 x kaolin	0.04 ± 0.2 a	1.0 ± 1.8 a	03. ± 0.7 a	1.4 ± 1.6 a	0.2 ± 0.5 b	1.8 ± 2.6 ab
2 x kaolin	0 a	0.6 ± 1.0 a	0.1 ± 0.5 b	0.6 ± 1.2 b	0.09 ± 0.3 b	1.1 ± 1.5 b

Conclusion

Beneficial mites were negatively affected by kaolin on both apples and plums in 2004 and 2005.

<u>Study limitations:</u>

The study was designed to address adverse effects of kaolin-based particle film on the population density of phytophagous and beneficial mites. Several limitations were identified:

- The trial design did not include a positive control (toxic reference), hence the susceptibility of the test system is not confirmed.

- The exact plot size is not reported, but the number of trees per plot (3) is insufficient.

- It is unknown if (and how) the application rate was verified.

- Information on history and weather conditions is missing.

- The application scheme of the study (2 x 30 kg/hl) does not cover the proposed application scheme for the representative use of the product.

- Insufficient sample size (15 leaves/plot)

B.9.4 EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA

DAR Aluminium Silicate:
No studies of the acute and chronic effects of Aluminium Silicate on earthworms and soil macro-organisms are available in the original DAR. As discussed in the original DAR (Section B.9.6), a low risk can be concluded for soil organisms.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process. The justification provided by the Applicant is considered acceptable. Aluminium Silicate is a natural mineral present in most soils across the world and the use of SOKALCIARBO WP in agriculture will not significantly alter the normal background levels (for more details please refer to Document M-CP 9 for SOKALCIARBO WP). Earthworms and other soil macro- and micro- organisms are constantly exposed to natural clay, including Aluminium Silicate. In addition, it is estimated that earthworms contain about 30% soil. Given that soils typically contain between 5-50% clay, earthworms are being continuously exposed to much higher concentration of Aluminium silicate than any that might arise from the use of Aluminium Silicate as a plant protection product.
A summary of the EU agreed endpoints regarding earthworms, other soil macro-organisms and soil micro-organisms is provided in the **Table B.9.4-1.**

Table B.9.4-1: Endpoints and references for non-target soil macro- and micro-organisms

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

In addition, the Aluminium silicate (Kaolin) in SOKALCIARBO WP is not expected to act any differently from natural clays with which it will be mixed. Furthermore, following the applications of the representative product SOKALCIARBO WP according to the intended uses, the maximum **PECsoil is 140 mg/kg (0.14 g/kg)** (please refer to Document M-CP 8). It can be noted that OECD 222, OECD 232 and OECD 226 guidelines (earthworm, collembolan and predatory mite reproduction tests in soil, respectively) require that the used artificial soil material must contains 20% of Kaolin clay, i.e., 200 g/kg. This is much higher than the Aluminium Silicate (Kaolin) brought by the applications of the representative formulation SOKALCIARBO WP (less than 0.14 g/kg) according to the intended uses. Therefore, it can be concluded that Aluminium Silicate (Kaolin) is not expected to be toxic for all non-target soil microorganisms and the risk for non-target soil microorganisms is considered to be very low.

TASK FORCE TESSENDERLO GROUP N.V.:
No additional data was submitted in the process of the active substance renewal process. The justification provided by the Applicant is considered acceptable. 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)4, it can be

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

noted in the diagram below that a large area of Europe consists of 28 to 98% clay-based soil (**Figure B.9.4-1**). 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. It is a natural mineral substance composed of silicon, aluminium and oxygen, just like a variety of other minerals.

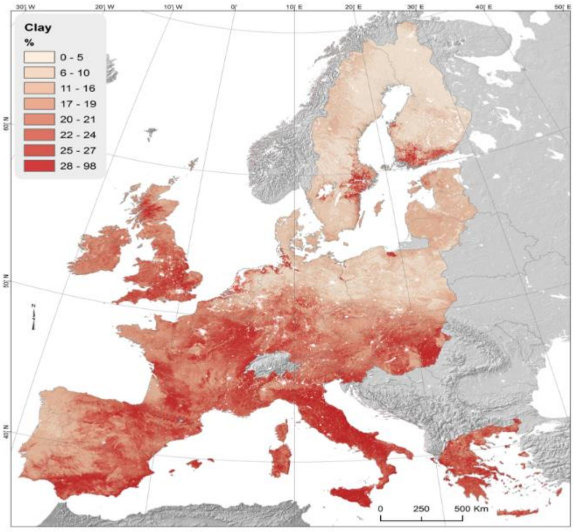


Figure B.9.4-1: Clay concentration in European soils (JRC-ESDAC)

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. When applied to soil, the aluminium silicate particles will readily mix with the other soil components. Some organic materials (e.g. fulvic acids) will adsorb onto the particle surfaces, similarly to the aluminium silicate already existing in the soil. Adsorption and 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. Agricultural soils typically 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.9.4-2**).

Figure B.9.4-1: Soil texture triangle

B.9.4.1 EARTHWORM – ACUTE EFFECTS

No studies on the acute effects of Aluminium Silicate on earthworms were assessed during the EU evaluation of Aluminium Silicate (see DAR 2011).

No new acute studies on earthworms were submitted by SOKA and/or TESSENDERLO GROUP N.V.

Acute studies is no longer a data requirement and therefore in the RAR of the a.s. Aluminium Silicate are not considered necessary.

B.9.4.2 EARTHWORM – SUB-LETHAL EFFECTS

DAR Aluminium Silicate: No studies on reproductive toxicity of Aluminium Silicate for earthworms are available in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process. The justification (see section B.9.4 of the current Document) is considered acceptable.

TASK FORCE TESSENDERLO GROUP N.V.:
A waiver is requested for a chronic earthworm toxicity study with the active substance based on the following information:

- 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 8.4 above). 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.

- Aluminium silicate is a natural component of most soils and is present at concentrations of 5 to 50% in agricultural soils (see Document MCP, Section 9).

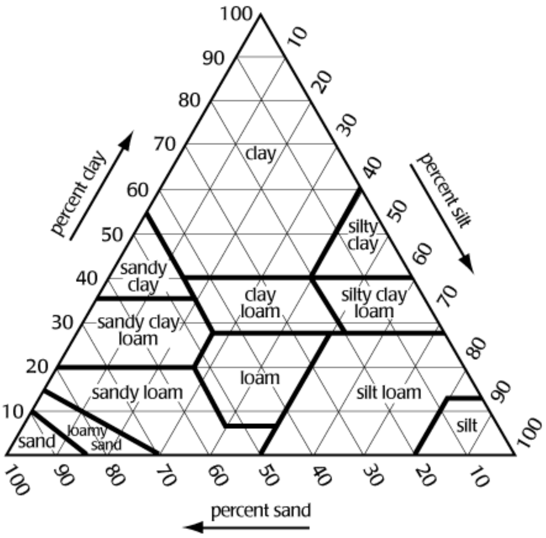
- As detailed in the original DAR (Section B.9.6), it is estimated that earthworms contain about 30% soil (Hoerger & Kenaga, 1972[5]). Given that soils typically contain between 5-40% clay, earthworms are being continuously exposed to much higher concentrations of aluminium silicate (kaolin) than any that might arise from the use of SURROUND® WP CROP PROTECTANT.

- 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, demonstrating the absence of toxicity of kaolin towards earthworms as well as the need for kaolin in soil to support earthworm survival. As a comparison, application of 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).

Conclusion: **In light of these considerations, no toxicity testing with earthworms with the active substance is considered to be necessary for the purposes of renewal and the risk to soil organisms is concluded to be low.**

B.9.4.3 EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA (OTHER THAN EARTHWORMS)

[5] Hoerger, F. and Kenaga, E.E. (1972). Pesticide residues on plants: correlation of representative data as a basis for estimation of their magnitude in the environment. *IN:* F. Coulston and F. Corte, eds., *Environmental Quality and Safety: Chemistry, Toxicology and Technology.* Vol 1. George Theime Publishers, Stuttgart, Germany. pp. 9-28.



B.9.4.3.1 Species level testing

DAR Aluminium Silicate: No studies on reproductive toxicity of Aluminium Silicate were presented for non-target soil meso- and macrofauna (other than earthworms) in the initial DAR.

TASK FORCE SOKA: No additional data was submitted in the process of the active substance renewal process. The justification (see section B.9.4 of the current Document) is considered acceptable.

TASK FORCE TESSENDERLO GROUP N.V.:
No additional data was submitted in the process of the active substance renewal process. A waiver is requested for effects on non-target soil meso- and macrofauna toxicity studies with the active substance based on the following information:

- 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 8.4 above). The agricultural use of SURROUND® WP CROP PROTECTANT therefore is not expected to have any negative effects on soil organisms. 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 is a natural component of most soils and is present at concentrations of 5 to 50% in agricultural soils (see Document MCP, Section 9).

- As detailed in the original DAR (Section B.9.6), it is estimated that earthworms contain about 30% soil (Hoerger & Kenaga, 1972[6]). Given that soils typically contains between 5-40% clay, soil organisms 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.

- 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,

[6] Hoerger, F. and Kenaga, E.E. (1972). Pesticide residues on plants: correlation of representative data as a basis for estimation of their magnitude in the environment. *IN:* F. Coulston and F. Corte, eds., *Environmental Quality and Safety: Chemistry, Toxicology and Technology.*Vol 1. George Theime Publishers, Stuttgart, Germany. pp. 9-28.

demonstrating the absence of toxicity of kaolin towards soil organisms as well as the need for kaolin in soil to support soil organisms' survival.

- 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).

Conclusion: In light of these considerations, no toxicity testing with other soil macro-organisms with the active substance is considered to be necessary for the purposes of renewal and the risk to soil organisms is concluded to be low.

B.9.5 EFFECTS ON SOIL NITROGEN TRANSFORMATION

DAR Aluminium Silicate:
No studies on reproductive toxicity of Aluminium Silicate for nitrogen transformation were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process. The justification (see section B.9.4) is considered acceptable.
A summary of the EU agreed endpoints regarding nitrogen transformation is provided in the table below.

Table B.9.4-1: Endpoints and references on the effects of Aluminium Silicate on nitrogen transformation.

Species	Test substance	Exposure System	End point	Reference
Soil micro-organisms				
-	-	-	Not required, not relevant	Hungary, 2008 Hungary, 2011 EFSA, 2012

TASK FORCE TESSENDERLO GROUP N.V.:
No new data are available or required for effects on nitrogen transformation since the approval of aluminium silicate (kaolin) (EFSA 2012). As discussed in the original DAR (Section B.9.7), a low risk can be concluded for soil organisms.

A waiver is requested for studies on non-target micro-organisms based on the following information:

- 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 8.4 above). The agricultural use of SURROUND® WP CROP PROTECTANT therefore is not expected to have any negative effects on microbial activity. 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 is a natural component of most soils and is present at concentrations of 5 to 50% in agricultural soils (see Document MCP, Section 9).

- Given that soils typically contain between 5-40% clay, soil organisms 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.

Conclusion: In light of these considerations, no study on the effects on nitrogen transformation with the active substance is considered to be necessary for the purpose of renewal and the risk to soil microbial activity is concluded to be low.

B.9.6 EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

DAR Aluminium Silicate:
No studies on reproductive toxicity of Aluminium Silicate for non-target higher plants were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process.
Aluminium Silicate is not intended to be used as an herbicide or a plant growth regulator and is not known to have any herbicidal activities. Aluminium Silicate is used as an insect repellent only, it is a systemic substance, and therefore is not absorbed or metabolized by plants. Furthermore, in this document M-CA 8, it has been shown that:

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

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

TASK FORCE TESSENDERLO GROUP N.V.:
No new data are available or required for effects on non-target terrestrial plants since the approval of aluminium silicate (kaolin) (EFSA 2012). As discussed in the original DAR (Section B.9.8), a low risk can be concluded for non-target terrestrial plants.

B.9.6.1 Summary of screening data

DAR Aluminium Silicate:
No studies on the toxicity of Aluminium Silicate for non-target terrestrial plants were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process. The justification (see section B.9.6 of the current Document) is considered acceptable.

TASK FORCE TESSENDERLO GROUP N.V.:
No new data are available or required for effects on non-target terrestrial plants since the approval of aluminium silicate (kaolin) (EFSA 2012).

B.9.6.2 Testing on non-target plants

DAR Aluminium Silicate:
No studies on the toxicity of Aluminium Silicate for non-target terrestrial plants were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process. The justification (see section B.9.6 of the current Document) is considered acceptable.

TASK FORCE TESSENDERLO GROUP N.V.:
A waiver is requested for non-target terrestrial plant toxicity studies based on the following information:

- 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[7]).

- As detailed in MCA Section 7, clay makes a vital contribution to soil fertility. Loam soil that contains 15-25% clay provides an adequate surface for interaction with water and nutrients, and to have a friable structure beneficial for tillage and root growth.

- 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.

- 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 8.4 above). The agricultural use of SURROUND® WP CROP PROTECTANT therefore is not expected to have any negative effects on non-target terrestrial plants. On the contrary, the use of kaolin as a replacement for conventional pesticides could help to improve soil conditions through the elimination of potentially harmful residues of synthetic compounds within the soil.

- Aluminium silicate is a natural component of most soils and is present at concentrations of 5 to 50% in agricultural soils (see Document MCP, Section 9).

- In a root growth inhibition study by Wang *et al.* (2011[8]), 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).

Conclusion: In light of these considerations, no studies on non-target terrestrial plants with the active substance are considered necessary for the purposes of renewal and adverse effects on terrestrial vascular plants from the application of Aluminium Silicate (kaolin) are not expected.

B.9.7 EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

DAR Aluminium Silicate:
No new study for the purpose of the active substance's renewal has been submitted.

[7] 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

[8] 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.

TASK FORCE SOKA:
Aluminium silicate is present in most natural soils and agricultural soils, and the use of SOKALCIARBO WP in agriculture will not significantly alter the normal background levels (for more details please refer to Document M-CP 9). Aluminium silicate is inert and has no known toxic effects on any organisms. The use of Aluminium silicate as a plant protection product is not expected to have any harmful impact on flora and fauna.

TASK FORCE TESSENDERLO GROUP N.V.:
No additional data are available or required for the purposes of renewal. As detailed in the original DAR (Section B.9.8), aluminium silicate (kaolin) is a common component of the environment. It is inert and has no known toxic mode of action. Aluminium silicate (kaolin) added to the environment through agricultural uses (as with SURROUND® WP CROP PROTECTANT) contributes a negligible amount of aluminium silicate compared with that already present in clays from natural sources (please refer to Document MCP, Section 9 for natural background levels); it therefore has negligible effect upon organisms that might be exposed. Aluminium silicate (kaolin) has already been used for many years as an inert ingredient in numerous pesticide formulations (e.g., WPs, DPs etc.).

B.9.8 EFFECTS ON BIOLOGICAL METHODS FOR SEWAGE TREATMENT

DAR Aluminium Silicate:
No studies on the toxicity of Aluminium Silicate for non-target terrestrial plants were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process.
Aluminium Silicate has been shown to flocculate some toxic waste chemicals and by doing so bring about a marked reduction in toxicity. Any Aluminium Silicate entering sewage works will not affect microbial activity and will be removed with the sludge.

TASK FORCE TESSENDERLO GROUP N.V.:
No new data are available or required for effects on biological methods for sewage treatment (activated sludge study) since the approval of Aluminium Silicate (kaolin) (EFSA 2012).

A waiver is requested for effects on biological methods for sewage–studies based on the following information:

- As detailed in the original DAR (Section B.9.8), kaolin is a common component of the environment.

- As detailed in the original DAR (Section B.9.8), kaolin is inert and has no known toxic effects on any organisms. Kaolin has already been used for many years as an inert ingredient in numerous pesticide formulations (e.g. WPs, DPs etc.).

- As detailed in the original DAR (Section B.9.8), kaolin added to the environment through agricultural uses (as with SURROUND® WP CROP PROTECTANT) contributes a negligible amount of Aluminium Silicate compared with that already present in clays from natural sources. It will therefore have negligible effect upon organisms that might be exposed.

- Suspended clay particles routinely enter water and sewage treatment plants, which are equipped to deal with that type of particulate. If Aluminium Silicate (kaolin) from SURROUND® WP CROP PROTECTANT enters a sewage plant, it is inert and would not interfere with the microbial processes.

- As described above for aquatic organisms (Section 8.2) and soil organisms (Section 8.4), the use of SURROUND® WP CROP PROTECTANT will not significant increase clay concentrations compared to background levels.

Conclusion: In light of these considerations, no studies on biological methods for sewage treatment (activated sludge study) with the active substance are considered necessary for the purposes of renewal and adverse effects from the application of Aluminium Silicate (kaolin) are not expected.

The Applicant provides two publications that demonstrate Aluminium Silicate (kaolin) and can be used as an absorbent to reduce the aquatic toxicity of certain industrial chemicals that might be found in sewage effluent (supporting information). Summaries of these studies are provided below.

B.9.8/01

CA 8.8/01

Task Force	TESSENDERLO GROUP N.V.
Type of study	The study submitted and evaluated for the first inclusion on Annex I.
Study Code:	KCA 8.8/01
Reference:	Cary, G.A., McMahon, J.A., and Kuc W. J. (1987)
Title:	The effect of suspended solids and naturally occurring dissolved organics in reducing the acute toxicities of cationic polyelectrolytes to aquatic organisms
Report No.:	Environmental Toxicology and Chemistry (1987), volume 6, pages 469-474
Guideline(s):	Not reported
Deviation(s):	-
GLP:	No, but study scientifically valid
Validity criteria:	-
Executive Summary	Cationic polyelectrolytes have high acute toxicities to aquatic organisms but react with suspended solids that flocculate them and may therefore be useful for water clarification. This study determines and compares the effects of suspended solids “SS” (bentonite, illite, kaolin and silica) and of dissolved organic carbon compounds “DOC” (humic, fulvic and tannic acids, lignin and lignosite) on the acute toxicities of four cationic water clarification aids to the fathead minnow (*Pimephales promelas*) and a cladoceran (*Daphnia magna*). Compared with standard laboratory water test results, the addition of 50 mg/L of kaolin reduced the acute toxicities of the four cationic polyelectrolytes to *Daphnia magna* and to the fathead minnow by 0.87 to 11x (depending on the type of compound and the test species).
MATERIALS AND METHODS	
Test Material:	Name: Kaolin

	Description: Powder Lot/Batch #: Not specified. Origin: J.T. Baker Purity: Not specified Stability of test component: Stable Particle size: Not specified
Test animals:	Fathead minnow (*Pimephales promelas*) Water flea (*Daphnia magna)*
Testing Facility:	Petrolite Corporation, Environmental Studies Group, St Louis, Missouri 63119

STUDY DESIGN AND METHODS

The fish toxicity tests were conducted in 5-gal glass aquaria containing 15 liters of water. Ten fish per concentration were used in the fathead minnow tests, with a geometric spacing of 1.75 between test concentrations. The test solutions for the daphnids tests were mixed in 500 ml of water and distributed among 250-ml beakers. Twenty daphnids were distributed among three replicates per concentration; a geometric spacing of 1.60 was used between concentrations.

The tests included a water control, polymer control (except for the *D. magna* tests), an SS/DOC control and 5 to 12 test concentrations of each polymer. Tests were initiated by adding the SS/DOC to the test water, followed by the addition of the polymer and finally the test organisms after 15 to 30 minutes. SS materials were added at 50 mg/L in all tests.

The temperature ranged from 19 to 21ºC and the photoperiod was set for 16 h light and 8 h dark. Temperature, pH and dissolved oxygen were determined. All tests were monitored at 24-hours intervals.

48-hour LC_{50} (*Daphnia*) and 96 hours, LC_{50} (Fathead minnow) were determined using the method of Stephan (1977).

RESULTS AND DISCUSSION

Acceptable survival rates were observed in all SS/DOC controls for both species.

Positive polymer controls in the fish studies resulted in 100% mortality within the 96-h test period.

In general, all Suspended Solids (SS)-including kaolin- and Dissolved Organic Carbon (DOC) reduced the acute toxicities of cationic polyelectrolytes to *D. magna* and to fathead minnows. However, kaolin was significantly less effective at reducing toxicity than ether bentonite or all of the DOCs.

Results for the different SS and DOCs are shown in the following tables.

Table 3. Acute toxicities (LC50, mg/L) of selected cationic polyelectrolytes to *Daphnia magna* and to fathead minnows in the presence of suspended solids and dissolved organics[a]

Substrate	Compound A		Compound B		Compound C		Compound D	
	Daphnids	Fatheads	Daphnids	Fatheads	Daphnids	Fatheads	Daphnids	Fatheads
Standard laboratory water	0.21	0.16	0.082	0.17	0.08	0.25	0.20	0.46
Bentonite[b]	20.1	7.3	>8.3	6.2	6.0	6.5	7.1	6.5
Illite[b]	1.0	1.1	3.6	0.27	0.95	0.95	1.2	0.55
Kaolin[b]	0.91	0.41	0.24	0.26	0.90	0.65	1.1	0.40
Silica[b]	0.26	0.35	0.37	0.28	0.12	0.42	0.14	0.39
Tannic acid[c]	17.4	4.6	>8.3	6.2	8.0	6.5	11.9	6.5
Lignin[c]	28.8	3.8	>8.3	3.2	4.0	3.5	>15.4	3.7
Humic acid[c]	10.5	6.4	7.7	6.2	5.0	4.0	7.4	6.5
Lignosite[c]	5.9	2.9	>8.3	3.5	4.7	3.8	7.9	3.7
Fulvic acid[c]	14.6	2.2	4.3	3.3	3.8	3.8	2.2	4.2

[a]See Table 1 for identification of compounds. 48-h LC50 calculated for *D. magna*; 96-h LC50 for fathead minnows.
[b]Test conducted in presence of 50 mg/L of substrate.
[c]Test conducted in presence of 10 mg/L of substrate.

Table 4. Reductions in acute toxicities, relative to standard laboratory water test results, of selected cationic polyelectrolytes[a] to *Daphnia magna* and to fathead minnows in the presence of suspended solids and dissolved organics

	Compound A		Compound B		Compound C		Compound D	
Substrate	Daphnids	Fatheads	Daphnids	Fatheads	Daphnids	Fatheads	Daphnids	Fatheads
Bentonite[b]	96×	46×	>101×	36×	75×	26×	36×	14×
Illite[b]	4.8×	6.9×	44×	1.6×	6.9×	3.8×	6.0×	1.2×
Kaolin[b]	4.3×	2.6×	2.9×	1.5×	11×	2.6×	5.5×	0.87×
Silica[b]	1.2×	2.2×	4.5×	1.6×	1.5×	1.7×	0.70×	0.85×
Tannic acid[c]	83×	29×	>101×	36×	100×	26×	59×	14×
Lignin[c]	137×	24×	>101×	19×	50×	14×	>77×	8×
Humic acid[c]	50×	40×	94×	36×	63×	16×	37×	14×
Lignosite[c]	28×	18×	>101×	21×	59×	15×	39×	8×
Fulvic acid[c]	70×	14×	52×	19×	48×	15×	11×	9×

[a]See Table 1 for identification of compounds.
[b]Test conducted in presence of 50 mg/L of substrate.
[c]Test conducted in presence of 10 mg/L of substrate.

CONCLUSION
Low amounts of kaolin (50 mg/L), can reduce the acute toxicity of some cationic polyelectrolytes to the fish and aquatic species by as much as 11 times.

CA 8.8/02

Task Force	TESSENDERLO GROUP N.V.
Type of study	The study submitted and evaluated for the first inclusion on Annex I.
Study Code:	KCA 8.8/02
Reference:	Maki, W., and Bishop, W.E. 1979
Title:	Acute Toxicity Studies of Surfactants to Daphnia magna and Daphnia pulex
Report No.:	Archives of Environmental Contamination and Toxicology (1979), volume 8, pages 599-612
Guideline(s):	Not reported
Deviation(s):	None
GLP:	No, but study scientifically valid
Executive Summary	This study determines the acute toxicity of linear alkyl benzene sulfonates (LAS) to daphnids. As part of the experiment, reductions in toxicity by adding 50 mg/L of suspended kaolin were examined. Kaolin significantly reduced the toxicity of longer chain length LAS homologs but had no effect on non-ionic surfactant toxicity.
MATERIALS AND METHODS	
Test Material	Name: Kaolin

	Description:White powder Lot/Batch #: Georgia origin, mean particle size 4 µ. Purity: Not specified Stability of test component: Stable
Test animals:	*Daphnia magna*
Testing Facility	The Procter and Gamble Company USA, Ivorydale Technical Centre, Cincinnaty, Ohio, USA.
STUDY DESIGN AND METHODS	
The methods used for culture procedures and acute toxicity tests followed the guidelines established by USEPA (EPA -600/3-75-009, 1975). Details are included only for the part of the experiment that examined the effect of kaolin on surfactant acute toxicity:	
Experimental design	50 mg/L of kaolin clay was added to dilution water up to a total solution volume of 200 mL in 250 mL Pyrex beakers, for each surfactant concentration. All concentrations were tested in triplicate. Five 24-hour-old *Daphnia* per beaker were tested. All Tests lasted 48 hours at a constant temperature of 21 ±1ºC under a 16-hour illumination period.
Observations	Mortality was recorded after 24 and 48 hours. Water hardness, dissolved oxygen, pH, as well as concentrations of nitrate, nitrite, copper, iron, lead, sodium and zinc were measured at the end of the 48-hour test.
Statistical analysis:	LC_{50} values were calculated using a computerized probit analysis program.
RESULTS AND DISCUSSIONS	

Table 5. Effects of a 50 mg/L suspension of kaolin clay on the acute toxicity of a homologous series of anionic surfactants to *Daphnia magna*

		48 hr LC50 and Associated 95% Confidence Limits (ppm)	
Anionic Surfactants		Without Kaolin	With Kaolin
C_{11} LAS		19.3 (14.3 – 23.5)	13.0 (5.1 – 17.4)
C_{14} LAS		1.0 (0.94 – 1.1)	1.4 (1.2 – 1.5)
C_{18} LAS		0.09 (0.07 – 0.11)	0.18 (0.12 – 0.24)
Nonionic Surfactants			
$C_{10}AE_3$		1.9 (1.0 – 2.6)	1.7 (1.1 – 2.3)
$C_{14}AE_3$		0.12 (0.08 – 0.16)	0.12 (0.05 – 0.18)
$C_{18}AE_3$	young adults	5.0 – 20.0 >80.0	<5.0 >80.0

Table 5. Effects of a 50 mg/L suspension of kaolin clay on the acute toxicity of a homologous series of anionic surfactants to *Daphnia magna*

		48 hr LC50 and Associated 95% Confidence Limits (ppm)	
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Nonionic Surfactants			
$C_{10}AE_3$		1.9 (1.0 – 2.6)	1.7 (1.1 – 2.3)
$C_{14}AE_3$		0.12 (0.08 – 0.16)	0.12 (0.05 – 0.18)
$C_{18}AE_3$	young adults	5.0 – 20.0 >80.0	<5.0 >80.0

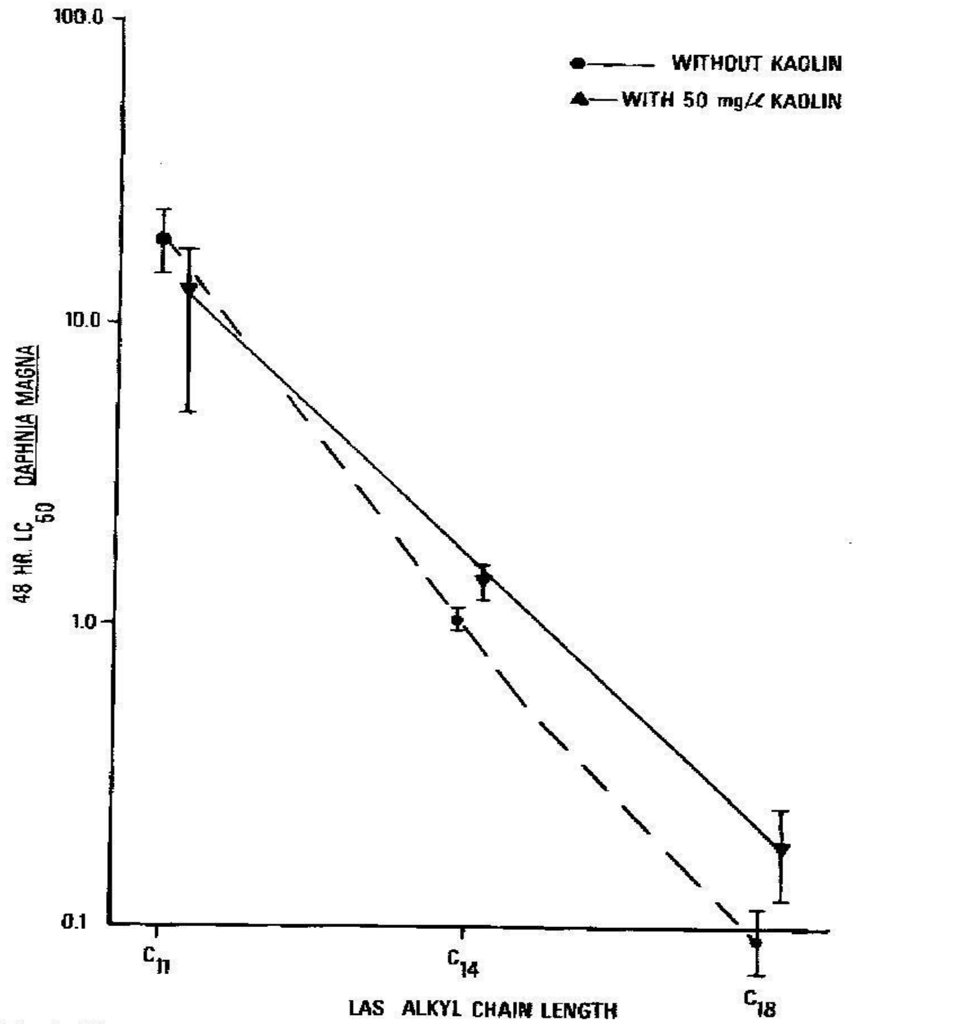


Fig. 3. The influence of suspensions of naturally-occurring Kaolin clay on the acute toxicity of linear alkyl benzene sulfonate to *Daphnia magna*.

The results of the tests with *Daphnia magna* demonstrate variable toxicity, with interactive effects between the 50 mg/L suspension of kaolin clay, the chemical class of surfactant tested, and individual alkyl chain lengths. For the anionic surfactants tested, the 48-hour LC_{50} values were observed at significantly higher concentrations of both the C_{14} and C_{18} homologs, but no significant difference was observed with C_{11} LAS (Figure 3).

CONCLUSIONS

These tests demonstrate that the presence of suspensions of purified, naturally occurring kaolin clay, significantly alters the observed acute toxicity of some long chain surfactants.

CA 8.8/03

Task Force	TESSENDERLO GROUP N.V.
Type of study	The study submitted and evaluated for the first inclusion on Annex I.
Language	Czech (only the English summary is provided)
Reference:	KCA 8.8/03 Valenta, S., and Svobodova, Z. 1980
Title:	An Ichtyotoxicological Evaluation of Electrically Conductive Resins and Coating Mixtures used in the Paper Industry
Report No.:	Buletin VÚRH Vodňany (1980), volume 2
Guideline(s):	Not reported
Deviation(s):	None
GLP:	No, but study scientifically valid

Executive Summary

The electro-conductive resin Alcostat 576, a coating mixture with Alcostat 576, and a coating mixture with ECR 77 were tested for fish toxicity. Species used in the tests were rainbow trout (*Salmo gairdneri*), Guppy (*Poecilia reticulate*) and Common Carp (*Cyprinus carpio*). The test substances were included in a group of chemicals of known high toxicity to fish. After the use of potential deactivating substances (kaolin, sodium carbonate, calcium hypochlorite), the toxicity of these chemicals was reduced, allowing for the group of substances to be classified as just "toxic" to fish.

Out of the deactivating agents used for reducing the toxicity of the electro-conductive resins, kaolin is the most convenient because of its high flocculation effects. Kaolin is present in pulp and paper effluents and once combined with resins it can be removed with the sludge from the sewage-treatment facilities after sedimentation.

B.9.9 MONITORING DATA

DAR Aluminium Silicate:
No studies on the toxicity of Aluminium Silicate for non-target terrestrial plants were presented in the initial DAR.

TASK FORCE SOKA:
No additional data was submitted in the process of the active substance renewal process.
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.

TASK FORCE TESSENDERLO GROUP N.V.:
No additional data was submitted in the process of the active substance renewal process.

B.9.10 BIOLOGICAL ACTIVITY OF METABOLITES POTENTIALLY OCCURRING IN GROUNDWATER

No data required in this section since no ecotoxicologically relevant metabolites have been reported.

B.9.11 REFERENCES RELIED ON

B.9.11.1 Scientific literature review

An open literature search was carried out by both Notifiers. Relevance and reliability of articles found in the search process were appraised in adherence with EFSA guidelines (EFSA Journal 2011;9(2):2092 and EFSA supporting publication 2013:EN-511). A summary of the results of the search are presented below.

Applicant SOKA

Introduction

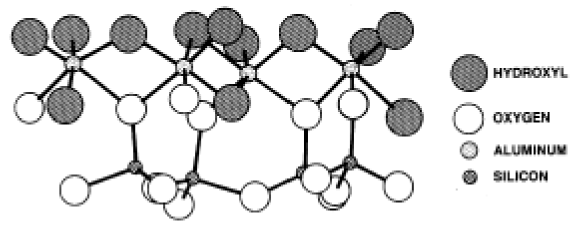
ISO-common name: Kaolin
Synonym: Aluminium Silicate

Chemical name (IUPAC): Not available
Chemical name (CAS): Kaolin

CAS No: 1332-58-7
CIMAP No: 841
EC No: 310-194-1 (E559)

Empirical formula: Hydrous aluminium silicate: $Al_4Si_4O_{10}(OH)_8$
Calcined aluminium silicate: $Al_4Si_4O_{14}$

Structural formula:



Article 8(5) of Regulation (EC) No 1107/2009 requires applicants submitting dossiers for approval and renewal of active substances to provide relevant scientific peer reviewed open literature. This summary of scientific peer reviewed open literature conforms to EFSA guidance "Submission of scientific peer-reviewed open literature under Regulation (EC) No 1107/2009, EFSA Journal 2011; 9(2):2092".

Peer reviewed open literature containing data and analysis dealing with the side effects on health, the environment, and non-target species for common name. The data published within the last ten years before the date of the submission of Aluminium Silicate renewal dossier were reviewed for this document. The document contains the search criteria and results of those searches of "scientific peer-reviewed open literature" performed under Regulation (EC) No 1107/2009 for Aluminium Silicate.

Relevance criteria

Peer reviewed open literature relevant to the dossier may satisfy or partially satisfy data requirements as set out in Regulation (EC) No 1107/2009. The relevance criteria chosen for the selection of peer reviewed scientific open literature is consistent with the OECD guidance and does not restrict the selection of literature (Table 1). The relevance criteria guide the selection of literature dealing with the side effects on health, environment and non-target species for Aluminium Silicate. Non-Good Laboratory Practice studies in open literature may be considered relevant if the design and execution of the study is consistent with generally accepted scientific practice and guidelines. Clearly non-relevant studies are excluded.

Table 1: Criteria for relevance

Data requirement(s) Indicated by the correspondent data point number(s) as identified in Commission Regulation (EU) No 283/2013	**Criteria for relevance**
All data points	1. The test system, target crop, or species are prescribed by regulation (EC) No 1107/2009 or the relevance is explained if not standard.
	2. Well identified test material, including its purity and impurity profile is described
	3. Study design and/or execution are consistent with relevant study guidelines
	4. The endpoint is relevant to an EU data point as prescribed by Commission Regulation (EU) No 283/2013 and No 284/2013
Toxicological and metabolism studies (CA 5)	5. Description of the observations, examinations, analysis performed, or necropsy are well described.
	6. The conditions of exposure should be from legally registered use of the product
Residues in or on treated products, food and feed (CA 6)	7. The application methods complies with Good Agriculture Practice (GAP)
	8. Appropriate in life/processing conditions are used and/or are well described
Fate and behaviour in the environment (CA 7)	9. The model is appropriate for European regulatory requirements
	10. The input parameters selection is appropriate based on European regulatory requirements
	11. The pedoclimatic conditions are appropriate
Ecotoxicological studies (CA 8)	12. A relevant route of exposure is presented

Search criteria

Reasonable effort was taken to locate all sources of relevant peer reviewed open literature concentrated on comprehensive databases containing worldwide coverage of biology, chemistry, biomedical, agricultural and environmental fields. The search ranged up to 10 years and within 6 months of the submission date of the renewal dossier for Aluminium Silicate. The initial search is a single concept search capturing all data points using search terms and synonyms for the active substance. If a large number of search results are returned from the single concept search making assessment for relevance impractical, a separate, focused search is conducted for grouped data points.

Table 2: Details of literature search for Aluminium Silicate and Ecotoxicological studies

Details of the searches: Ecotoxicological studies (CA 8)		
Data requirement(s)	Database	Database 1: PubMed
Ecotoxicological studies (CA 8)	Justification for choosing the source	PubMed is a free search engine accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics.
	Date of the search	January 15th, 2018
	Date span of the search	2008-2018
	Search strategies used for this data requirement	**29. 1-3and mammals toxicity** ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("mammals"[MeSH Terms] OR "mammals"[All Fields]) AND ("toxicity"[Subheading] OR "toxicity"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])
		Total number of records retrieved: 32 After removing duplicate: 13
		30. 1-3 and bees toxicity ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("bees"[MeSH Terms] OR "bees"[All Fields]) AND ("toxicity"[Subheading] OR "toxicity"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])
		Total number of records retrieved: 0
		31. 1-3 and arthropods toxicity ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("arthropods"[MeSH Terms] OR "arthropods"[All Fields]) AND ("toxicity"[Subheading] OR "toxicity"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])
		Total number of records retrieved: 5 After removing duplicate: 2

Details of the searches: Ecotoxicological studies (CA 8) (continued)		
Data requirement(s)	Database	Database 1: PubMed
Ecotoxicological studies (CA 8)	Search strategies used for this data requirement	**32. 1-3 and aquatic organisms toxicity** ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("aquatic organisms"[MeSH Terms] OR ("aquatic"[All Fields] AND "organisms"[All Fields]) OR "aquatic organisms"[All Fields] OR ("aquatic"[All Fields] AND "organism"[All Fields]) OR "aquatic organism"[All Fields]) AND ("toxicity"[Subheading] OR "toxicity"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])
		Total number of records retrieved: 2 After removing duplicate: 0
		30. 1-3 and birds toxicity ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("birds"[MeSH Terms] OR "birds"[All Fields]) AND ("toxicity"[Subheading] OR "toxicity"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])
		Total number of records retrieved: 0
		Total number of summary records retrieved after removing duplicates: 15

Relevant study selection -results of the selection process

Obviously non-relevant studies in open literature search were excluded by applying the relevance criteria previously defined in Table 1 of this document. A total of 269 summary records were reviewed, of these 256 were not relevant. When the summary records did not contain sufficient information to assess relevance, full text documents were reviewed in detail for relevance according to the previously defined criteria. After reviewing full text documents of potentially relevant studies, 13 were excluded from further consideration. No relevant studies has been selected for inclusion in the dossier. The Figure 1 summarized the process for selecting studies to be included in the dossier.

Table 3: Results of the selection process for Ecotoxicological studies (CA 8)

Data requirement(s) captured in the search	Number
Total number of summary records retrieved after all searches of peer-reviewed literature (excluding duplicates)	15
Number of records excluded from the search results after rapid assessment for relevance	13
Total number of full text documents assessed in detail	2
Number of studies excluded from the dossier after detailed assessment for relevance	0
Number of studies not present in the basic search (of which 4 studies came out in the search for another section)	19
Number of studies included in the dossier	21

Literature included in the dossier after detailed assessment

Table 4: Report of all relevant studies included after detailed assessment of full text documents (ordered by author) section CA.8

Authors	Year	Title	Source (journal, volume, pages)	Comment
Bengochea, Budia,	2010	Side effects of kaolin on natural enemies found on olive crops	Iobc Wprs Bulletin, 2010, 55: 61-67	Evaluating the effects of Surround WP on Psyttalia concolor, Chrysoperla carnea, Chilocorus nigritus and Anthocors nemoralis according to IOBC sequential scheme.
Bengochea, Saelicesa, Amora, Adána, Budiaa, Pedro del Estala, Viñuelaa, Medinaa	2014	Non-target effects of kaolin and coppers applied on olive trees for the predatory lacewing Chrysoperla carnea	Biocontrol science and technology, 2014, 24.6: 625-640	In conclusion, this study suggests that both kaolin and copper products appeared to be largely harmless or only slightly harmful to the predator *Chrysoperla carnea*
Bengochea, Amor, Saelices, Hernando, Budia, Adán, Medina	2013	Kaolin and copper-based products applications: Ecotoxicology on four natural enemies	Chemosphere, 2013, 91.8: 1189-1195	Lethal and sublethal effects of kaolin clays and two copper-based products on four natural enemies found in olive orchards Anthocoris nemoralis, Chelonus inanitus Chilocorus nigritus and Scutellysta cyanea Motschulsky were investigates under extended laboratory conditions.
Bengochea, Budia, Vinuela, Medina.	2014	Are kaolin and copper treatments safe to the olive fruit fly parasitoid Psyttalia concolor?	Journal of pest science, 2014, 87.2: 351-359	The aims of this study are to evaluate direct mortality caused by kaolin and copper salts on the parasitoid and the sublethal effects on emergence of adults from treated pupae and on beneficial capacity of females through four different experiments, three at laboratory level and one in semi-field conditions.
Bestete; Torres; Pereira,	2018	Harmonious interaction of kaolin and two insect predator species in plant protection.	International Journal of Pest Management, 2018, 64.2: 166-172	The aim of this article is to evaluated the development and survival of Chrysoperla externa (Hagen) (Neuroptera: Chrysopidae) and Eriopis connexa (Germar) (Coleoptera: Coccinellidae) larvae of different ages treated with kaolin at three different concentrations (ca. 60, 80, and 100 g/L) and prey consumption when treated with kaolin at a field rate of 60 g/L.
Bostanian NJ, Racette G	2008	Particle films for managing arthropod pests of apple	J Econ Entomol. 2008 Feb ;101(1) :145-50	A two-season study showed that a calendar-based spray program to manage arthropod pests with kaolin (60 g/liter) applied at the rate of 450 liters/ha was effective against arthropods.

Authors	**Year**	**Title**	**Source (journal, volume, pages)**	**Comment**
Iannotta N, Belfiore T, Noce ML, Scalercio S, Vizzarri V.	2014	The impact of some compounds utilised in organic olive groves on the non-target arthropod fauna: canopy and soil levels	C. ecological aspects, 2014	The aims of this research were to evaluate the impact of compounds allowed in organic olive farming and searching for more ecocompatible farming strategies. The research was carried out in Southern Italy. Experimental olive grove were untilled, and the grass cover was periodically managed. Six theses composed by 200 plants were randomly chosen and sprayed with rotenone, kaolin, a mixture of copper oxychloride and propolis, and dimethoate
Knight, Christianson, Unruh	2001	Impacts of seasonal kaolin particle films on apple pest management	The Canadian Entomologist, 2001, 133.3: 413-428	The aim of this article is to study the impact of multiple applications of the kaolin-based particle film M96-018 on the population density of selected pests of apple, Malus domestica (Borkh) (Rosaceae), and their natural enemy populations were measured in several Washington State orchards from 1997 to 1999.
Leskey TC, Wright SE, Glenn DM, Puterka GJ.	2010	Effect of Surround WP on behavior and mortality of apple maggot (Diptera: Tephritidae)	J Econ Entomol	The aim of the current study is identified the behavioral and biological effects of this material on apple maggots. Specifically, examine the effect of Surround WP on the visual ecology of adult flies under field conditions, on tactile responses of flies in semifield trials, and on fly mortality in laboratory-based-bioassays
Lo Verde G, Rizzo R, Barraco G, Lombardo A.	2011	Effects of kaolin on Ophelimus maskelli (Hymenoptera: Eulophidae) in laboratory and nursery experiments.	Journal of Economic Entomology	The aim of the current study is to evaluate the effectiveness of the clay kaolin in the laboratory and in the field in reducing the damage caused by the eulophid Ophelimus maskelli (Ashmead) on seedlings of eucalyptus (Eucalyptus L'Hér.) species
Ma r k ó, Blommers , Bo g y a and He l s e n	2006	The effect of kaolin treatments on phytophagous and predatory arthropods in the canopies of apple trees.	Journal of fruit and ornamental plant research, 2006, 14: 79	The effect of a kaolin-based particle film formulation on apple pests and their natural enemies was investigated in an experimental apple orchard in the Netherlands.
Markó; Bogyaa; Kondorosyb; Blommersc	2010	Side effects of kaolin particle films on apple orchard bug, beetle and spider communities	International journal of pest management, 2010, 56.3: 189-199.	The effects of multiple applications of hydrophobic kaolin particle film on apple orchard bug (Heteroptera), beetle (Coleoptera) and spider (Araneae)
Susana Pascual, Guillermo Cobos, Elena Seris, Manuel Gonzalez-Nunez	2010	Effects of processed kaolin on pests and non-target arthropods in a Spanish olive grove	Journal of pest science, 2010, 83.2: 121-133	A 3 years field trials to assess the effects of Surround WP on the arthropod community of olives trees

Authors	Year	Title	Source (journal, volume, pages)	Comment
Pascual, Cobos, Medina, Budia, Viñuela, González-Núñez	2010	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	Pesticides and Beneficial Organisms IOBC/wprs Bulletin Vol 55, 2010 pp11-18	Numbers of predators captured in a one-year field trial in a Spanish olive grove that received different treatments to control the olive fly (Bactrocera oleae (Rossi)) were analysed with two different statistical analysis methods. The treatments were kaolin (Suround WP), trichlorfon bait spray as a positive control (Trichlorfon + protein hydrolysate (Nulure®) and unsprayed control. The aim of this work was to compare results and conclusions obtained from different types of analysis applied to the same dataset and to identify their advantages and disadvantages
Pease, Lopez-Olguın, Perez-Moreno, and Marco-Mancebon	2016	Effects of Kaolin on Lobesia botrana (Lepidoptera: Tortricidae) and Its Compatibility with the Natural Enemy, Trichogramma cacoeciae (Hymenoptera: Trichogrammatidae)	Journal of economic entomology, 2016, 109.2: 740-745	The evaluation of the effect of kaolin treatments on L. botrana oviposition, egg hatch, and neonate larvae mortality is presented in this article.
Porcel; Cotes, Campos	2011	Biological and behavioral effects of kaolin particle film on larvae and adults of Chrysoperla carnea (Neuroptera: Chrysopidae)	Biological Control, 2011, 59.2: 98-105	Laboratory and field experiments reporting the effect of Surround WP on Chrysoperla carnea
Ramos, Marcotegui, Pascual, Fernandez, Cobos, Gonzales-Nunez,	2017	Compatibility of organic farming treatments against Monosteira unicostata with non-target arthropod fauna of almond trees canopy.	Spanish journal of agricultural research, 2017, 15.2: 22.	In this article, the effects of organicfarming-compatible pests control products (kaolin) on nontarget arthropods of almond tree canopy were evaluated, under real field conditions, paying special attention to the community of natural enemies of pests.
Sackett, Buddle and Vincent	2007	Effects of kaolin on the composition of generalist predator assemblages and parasitism of Choristoneura rosaceana (Lep., Tortricidae) in apple orchards	Journal of applied entomology, 2007, 131.7: 478-485	The purpose of this article is to study the effects of a hydrophilic kaolin particle spray on generalist predators and parasitism of the pest species *C. rosaceana* in apple orchards in southern Quebec, Canada.
Scalercio, Iannotta, Belfiore, Noce, Vizzarri	2008	Impact of kaolin and Beauveria bassiana treatments against olive fly on the non-target arthropods of the olive ecosystem	In: Organic Fruit Conference 873. 2008. p. 329-336	The aim of this study was to evaluate the environmental impact of kaolin and of the micoinsecticide on the olive ecosystem, based on the vital spores of *Beauveria bassiana*.
Showler; Satamou	2005	Effects of kaolin particle film on selected arthropod populations in cotton in the lower Rio Grande Valley of Texas.	Southwestern Entomologist, 2005, 29.2: 137-146	Kaolin, a white, nontoxic mineral that can be sprayed onto crops, deters boll weevils and beet armyworm ovipositioning and feeding on cotton squares and foliage. This study assessed the effects of kaolin on other insects common to cotton

Authors	Year	Title	Source (journal, volume, pages)	Comment
Tacoli F, Pavan F, Cargnus E, Tilatti E, Pozzebon A, Zandigiacomo P	2017	Efficacy and Mode of Action of Kaolin in the Control of Empoasca vitis and Zygina rhamni (Hemiptera: Cicadellidae) in Vineyards	J Econ Entomol. 2017 Jun 1 ;110(3) :1164-1178	The influence of kaolin applications and bunch-zone leaf removal on the grapevine leaf hoppers, Empoasca vitis (Go¨ the) and Zygina rhamni Ferrari, and their egg parasitoids (Anagrus spp.) was tested in four vineyards of northeastern Italy. The mode of action of kaolin on E. vitis nymphs was also investigated in the laboratory.

Literature excluded after detailed assessment

No studies / articles were excluded after details assessment

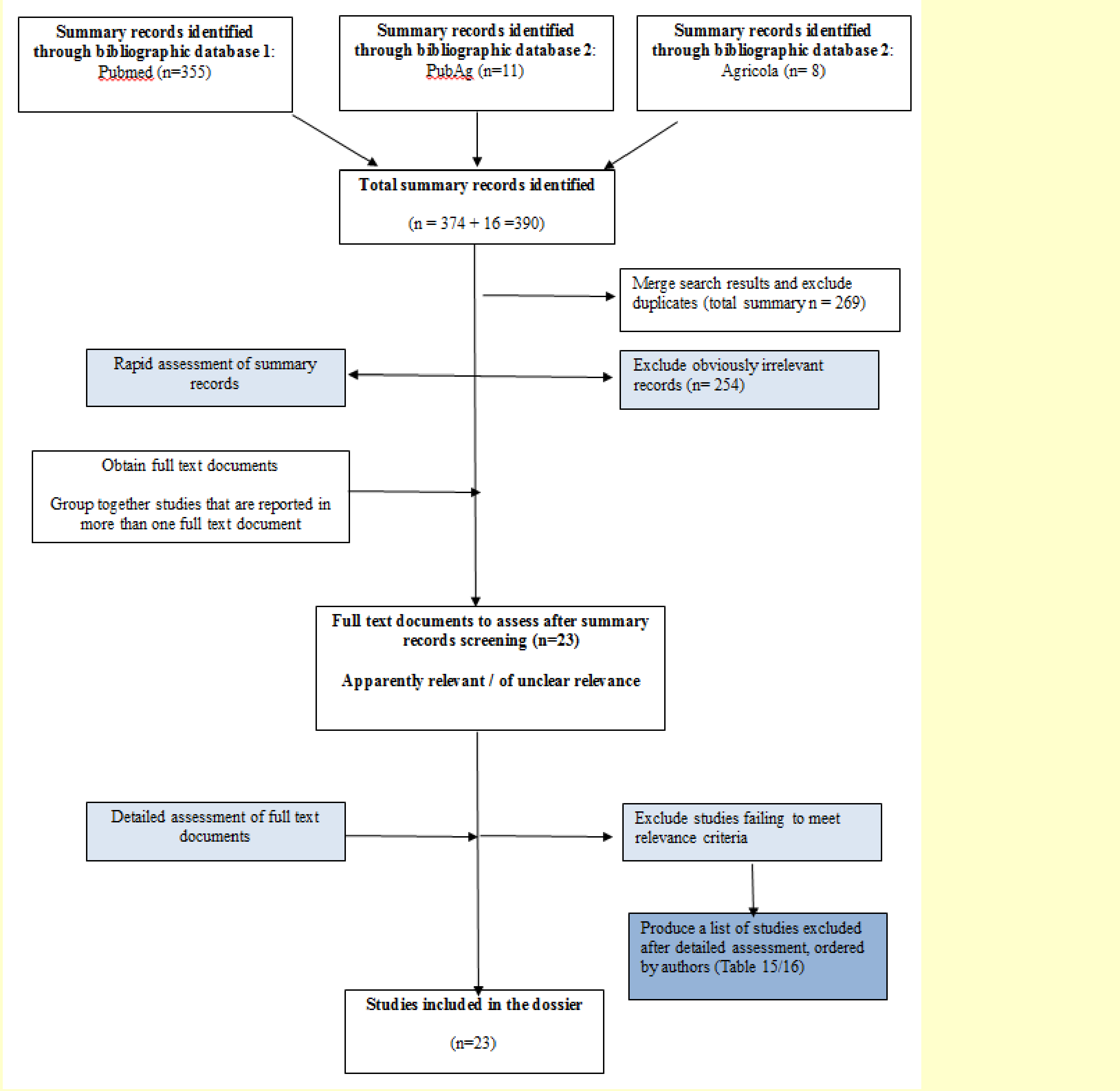
Literature excluded from the first selection stage

Table 5: Report of all non- relevant studies excluded (ordered by author) section CA.8

Authors	Year	Title	Source (journal, volume, pages)	Comment
Garcia CAB, Catalão CHR, Machado HR, Júnior IM, Romeiro TH, Peixoto-Santos JE,Santos MV, da Silva Lopes L	2017	Edaravone reduces astrogliosis and apoptosis in young rats with kaolin-induced hydrocephalus	Childs Nerv Syst. 2017 Mar;33(3):419-428	Not relevant
Jusué-Torres I, Jeon LH, Sankey EW, Lu J, Vivas-Buitrago T, Crawford JA, Pletnikov MV, Xu J, Blitz A, Herzka DA, Crain B, Hulbert A, Guerrero-Cazares H,Gonzalez-Perez O, McAllister JP 2nd, Quiñones-Hinojosa A, Rigamonti D	2016	A Novel Experimental Animal Model of Adult Chronic Hydrocephalus	Neurosurgery. 2016 Nov;79(5):746-756.	Not relevant
Santos MV, Garcia CA, Jardini EO, Romeiro TH, da Silva Lopes L, Machado HR, de Oliveira RS.	2016	Ventricular-subcutaneous shunt for the treatment of experimental hydrocephalus in young rats: technical note	Childs Nerv Syst. 2016 Aug;32(8):1507-11	Not relevant
Yoon JS, Nam TK, Kwon JT, Park SW, Park YS	2015	CSF flow pathways through the ventricle-cistern interfaces in kaolin-induced hydrocephalus rats-laboratory investigation	Childs Nerv Syst. 2015 Dec;31(12):2277-8	Not relevant

Shaolin Z, Zhanxiang W, Hao X, Feifei Z, Caiquan H, Donghan C, Jianfeng B, Feng L, Shanghang S	2015	Hydrocephalus induced via intraventricular kaolin injection in adult rats	Folia Neuropathol. 2015;53(1):60-8	Not relevant
Nakajima S, Katayama T.	2014	Running-based pica in rats. Evidence for the gastrointestinal discomfort hypothesis of running-based taste aversion	Appetite. 2014 Dec;83:178-84	Not relevant
Medina G, Ji G, Grégoire S, Neugebauer V	2014	Nasal application of neuropeptide S inhibits arthritis pain-related behaviors through an action in the amygdala.	Mol Pain. 2014 May 29;10:32	Not relevant
Botfield H, Gonzalez AM, Abdullah O, Skjolding AD, Berry M, McAllister JP2nd, Logan A.	2013	Decorin prevents the development of juvenile communicating hydrocephalus	Brain. 2013 Sep;136(Pt 9):2842-58	Not relevant
Zhang Y, Zhang YP, Shields LB, Zheng Y, Xu XM, Whittemore SR, Shields CB.	2012	Cervical central canal occlusion induces non communicating syringomyelia.	Neurosurgery. 2012 Jul;71(1):126-37.	Not relevant
Lollis SS, Hoopes PJ, Kane S, Paulsen K, Weaver J, Roberts DW.	2009	Low-dose kaolin-induced feline hydrocephalus and feline ventriculostomy: an updated model.	J Neurosurg Pediatr. 2009 Oct;4(4):383-8	Not relevant
Lopes Lda S, Slobodian I, Del Bigio MR	2009	Characterization of juvenile and young adult mice following induction of hydrocephalus with kaolin.	Exp Neurol.2009 Sep;219(1):187-96	Not relevant
Auda SH, Mrestani Y, Fetouh MI, Neubert RH.	2008	Characterization and activity of cephalosporin metal complexes	Pharmazie. 2008 Aug;63(8):555-61	Not relevant
Li J, McAllister JP 2nd, Shen Y, Wagshul ME, Miller JM, Egnor MR, Johnston MG, Haacke EM, Walker ML	2008	Communicating hydrocephalus in adult rats with kaolin obstruction of the basal cisterns or the cortical subarachnoid space.	Exp Neurol. 2008 Jun;211(2):351-61	Not relevant

Table 7: Process for selecting studies to be included in the dossier.


Summary records identified through bibliographic database 1: Pubmed (n=355)
Summary records identified through bibliographic database 2: PubAg (n=11)
Summary records identified through bibliographic database 2: Agricola (n= 8)
Total summary records identified
(n = 374 + 16 =390)
Merge search results and exclude duplicates (total summary n = 269)
Rapid assessment of summary records
Exclude obviously irrelevant records (n= 254)
Obtain full text documents
Group together studies that are reported in more than one full text document
Full text documents to assess after summary records screening (n=23)
Apparently relevant / of unclear relevance
Detailed assessment of full text documents
Exclude studies failing to meet relevance criteria
Produce a list of studies excluded after detailed assessment, ordered by authors (Table 15/16)
Studies included in the dossier
(n=23)

Applicant Tessenderlo

Introduction

Under Article 8(5) of Regulation 1107/2009, a literature review must be submitted as part of the renewal dossier for plant protection products:
"*Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of dossier submission shall be added by the applicant to the dossier*".
In compliance with Article 8.5 of Regulation (EC) No 1107/2009 and Part A of Commission Regulation (EU) No 283/2013, a search of the scientific peer reviewed open literature relative to aluminium silicate (kaolin) was performed and included in the dossier.
The literature search was performed between 1 November 2017 and 15 November 2017.
The search was organised in two parts, with an initial search focusing on identifying literature relative to aluminium silicate, kaolin and derivatives, including trade names, and a final part focusing on identifying literature relevant to each compartment of the dossier. Details of the search term, data mining strategies and results are presented herewith.

Literature search timing

Literature search span: the search was limited to the period spanning from 1 January 2005 (year of submission of the original Aluminium silicate (kaolin) inclusion dossier) until 8 November 2017. The search therefore covered eleven years and ten months of peer-reviewed publications and was performed less than six months before renewal dossier submission deadline (28 February 2018).

Methodology

Search environment

The literature search was performed on the following databases: CAB, PubMed, Toxnet and Science Direct. In addition, relevant documents from Google, Google Scholar, ECHA, ResearchGate and the United States Environmental Protection agency database were downloaded and processed separately.

Identification of peer-reviewed literature pertaining to the Chemical Active aluminium silicate (kaolin)

The reference collections were queried by name, with a typical query string presented below.

Typical name query	Kaolin OR "china clay" OR kaolinite OR "calcined kaolin" OR "hydrous kaolin" OR "Aluminium silicate" OR "Aluminum silicate" OR Aluminosilicate OR "Satintone 5HB" OR "Surround WP" OR "Sokalciarbo WP" OR "Argical Pro" OR "Agri Jardin".

Underlined text refers to trade names of aluminium silicate-containing products.
In addition, the following CAS numbers were included in the search:

Identification number (List)	Identity
1318-74-7 (CAS)	Kaolinite
1332-58-7 (CAS)	Kaolin
296-473-8 (EC)	Kaolin, calcined
310-194-1 (EC)	Kaolin
92704-41-1 (CAS)	Kaolin, calcined

The topics of interest, such as human toxicity, fate, residues, etc., were not included as a key element of the search strategy. Often an event or outcome is not explicitly described by the subject at the title or abstract level and it would be difficult to adequately describe the individual toxic effects one can envisage using key words and/or subject headings in a complex search query. Therefore, a sequential approach was preferred, and once a pool of documents referencing the chemical active had been identified and duplicates removed, a different approach was used to identify relevant literature.

This granular information was captured during the text processing phase using customised gazetteer lists such as the extract given in the table below for toxTestSystem and toxStudyType. In total the gazetteer list of terms describing tox Test Systems contained 81 entries and the tox study type gazetteer contained 97 entries.

Extract from "ToxTestSystem" and "ToxStudyType"

ToxTestSystem list	ToxStudyType list
CHO	Absorbtion
Chromosome aberration test	Acute toxicity
Comet assay	Adverse event
Corrositex®	Endocrine disruption
Corrositex	Endocrine disruptor
Dog	Inhibition
Dogs	Neurotoxicity
Dog	Reproductive toxicity
E. coli WP2 uvrA	Sensitisation
Epidermis	Sublethal
Erythrocyte	Toxicity

Identification of relevant literature in the selected peer-reviewed literature

The search strategy highlighted 14,796 documents of potential interest to this literature review upon execution, including 676 from non-peer-reviewed literature. These were dismissed. The remaining 14120 documents contained a number of duplicates as a result of searching the reference collections separately.

To identify which of these 14,120 records mentioned the aspects of interest to this particular project, a pipeline of processing resources (PR) was applied to each document in turn and only those which specifically mentioned toxic effects, environmental fate and behaviour, etc., of kaolin or its common variants, were identified as a positive result. This granular information was captured during the text processing phase using customised gazetteer lists.

Each PR focused on a specific compartment and performs a different function and in general terms the approach taken was to Tokenise (identify individual words and features) and Sentence-split the documents; use the Gazetteer lists to identify any important key words and phrases such as dietary exposure; identify the Title and Abstract part of the document; look within the Title and Abstract for patterns matching the natural language expressions describing to the toxic effects of each active substance on humans, for example; and index the results. The rules used to identify these passages of text also make a simple allowance for co-referencing where we try to associate a word or phrase (the anaphor) with a previously mentioned entity (the antecedent). This technique was used to assist with the questions on Residue and Human Toxicity at the Sentence level only.

The results of the search were loaded into Microsoft Excel and duplicate records removed using several algorithms.

The entire collection of records was clustered to help with the identification of common themes and the output (network visualisation and density heat map) is provided in Figures 1 and 2

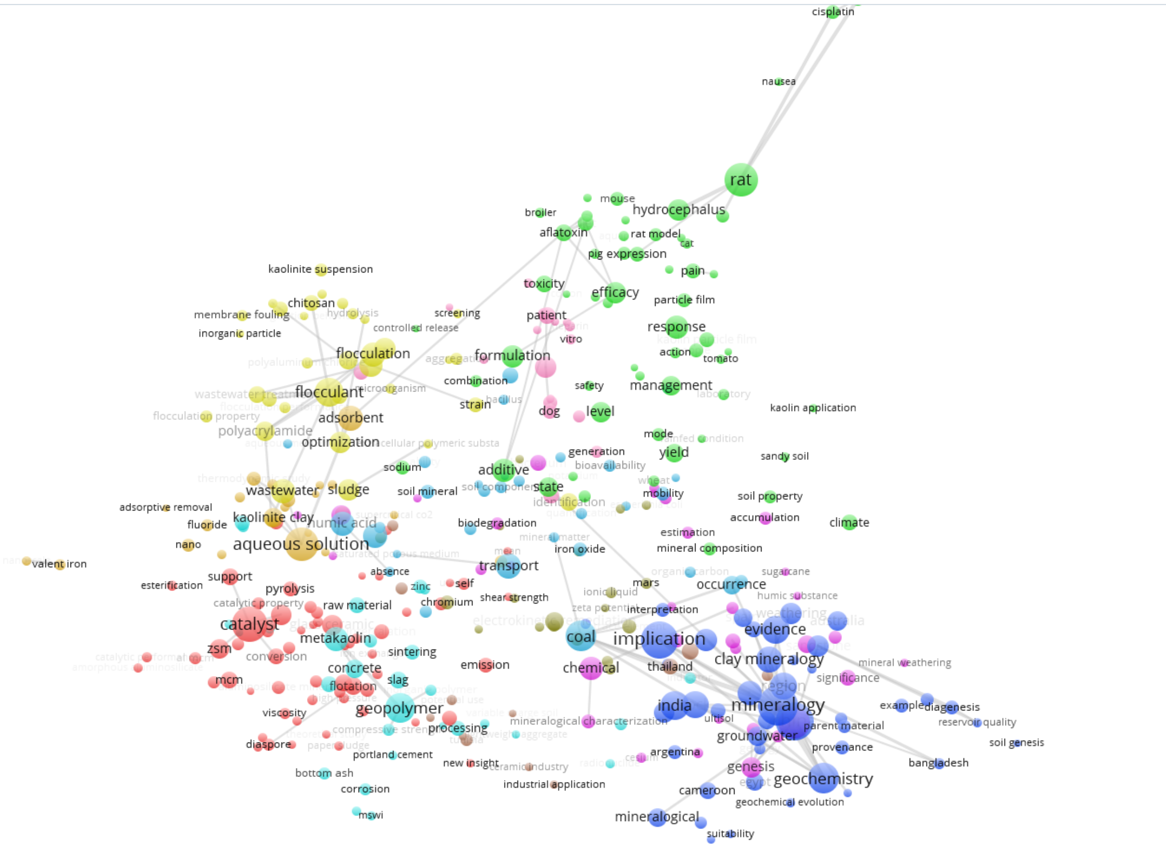


Figure 1: Kaolin network visualisation

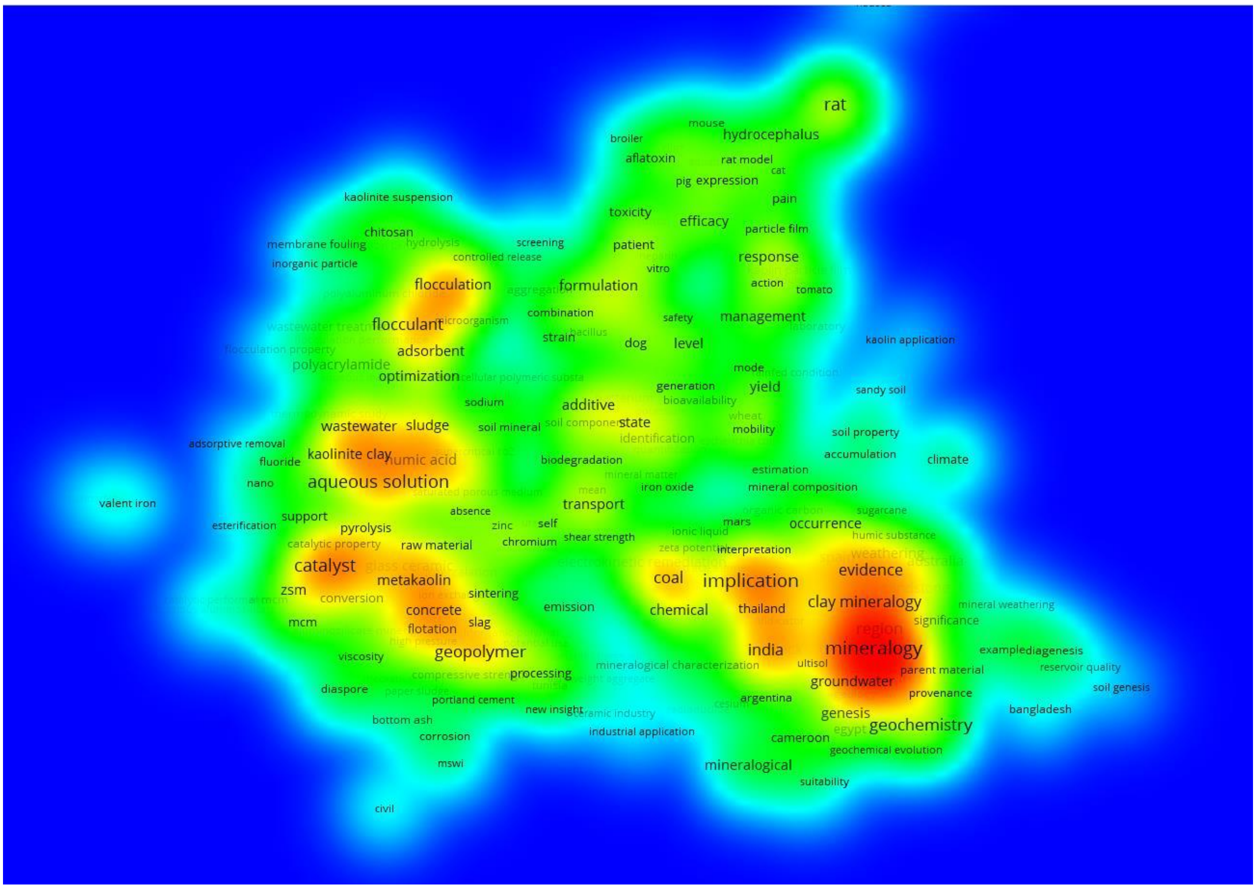


Figure 2: Kaolin density heat map

Results

As a result of applying the text mining pipeline to the document corpus, a number of documents were identified as being of potential relevance to the four questions fundamental to the project, toxicity, ecotoxicology, fate & behaviour, and residues. No potentially relevant documents were identified for the Occupational health and safety category.

The following tables summarise the total number of documents retrieved from each reference collection noting that the total count in Table 2 will include duplicate records found in two or more reference collections. The results presented in Table 3 refer to unique records and show the number of documents identified by text mining as potentially relevant.

Table 1: Number of documents retrieved from each reference location*

Reference Collection	Total Document Retrieved
CAB	4,396
PubMed	2,873
ScienceDirect	6,807
Toxnet	44
Total	14,120

*: includes duplicate documents

Table 2: Number of documents identified as potentially relevant by text mining

Compartment	Unique Documents Identified
Toxicity	301
Residues	52
Environmental Fate	248
Ecotoxicity	241

For each compartment described in Table 2, an excel spreadsheet was provided. Each potentially relevant entry consisted of one line, split into several columns: Database source and record number, date of publication, title, journal reference and author, URL and abstract.

The lists were screened for potential relevance, i.e. references that did not appear to be relevant based on title or abstract only were dismissed.

The remaining references were obtained and screened for relevance again.

Lists of relevant and non-relevant articles by dossier sections

Ecotoxicology evaluation table (relevant articles)

Section	Authors	Year	Title	Reference	Brief summary of the study
CA 8.1.1	Martin, C.D. and Mullens, B.A.	2012	Housing and dustbathing effects on northern fowl mites (*Ornithonyssus sylviarum*) and chicken body lice (*Menacanthus stramineus*) on hens	Medical and Veterinary Entomolgy. Vol 26 (3): 323-333	Supplementary, no data to impact RA Housing and dustbathing effects of fowl mites and chicken body lice
CA 8.1.2.2	Ta, C.A.K, Pebsworth, P.A., Liu, R, Hillier, S., Gray, N., Arnason, J.Y., and Young, S.L.	2017	Soil eaten by chacma baboons absorbs polar plant secondary metabolites representative of those found in their diet	Environ Geochem Health. Springer Netherlands	Supplementary, no data to impact RA Testing this hypothesis of baboon soil preference and why mammals consume clay.
CA 8.2.6.1	Sengo, M.R., and Anderson, D.M.	2004	Controlling Harmful Algal Blooms Through Clay Flocculation	J. Eukaryot. Microbiol. vol 51, no. 2: 169-172	Supplementary, no data to impact RA An evaluation of using clays to control algal blooms.
CA 8.3.2	Gharbi, N., and Abdallah, B.A.	2016	Laboratory Evaluation of Side-Effects of Kaolin on Two Predatory Species Found on Olive Groves	Tunisian Journal of Plant Protection 11: 83-90	Supplementary, no data to impact RA Reporting that the active subdstance, kaolin, applied to olive leaves at 5 kg a.s./hL caused minimal adverse effects to *Anthocoris nemoralis* and *Chrysoperla carnea*.
CA 8.6	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	Supplementary, no data to impact RA Evaluating crop quality from the use of clays.
CP 10.1.2	Ta, C.A.K, Pebsworth, P.A., Liu, R, Hillier, S., Gray, N., Arnason, J.Y., and Young, S.L.	2017	Soil eaten by chacma baboons absorbs polar plant secondary metabolites representative of those found in their diet	Environ Geochem Health. Springer Netherlands	Supplementary, no data to impact RA Testing this hypothesis of baboon soil preference and why mammals consume clay.
CP 10.2	Kefford, B.J., Zalizniak, L., Dunlop, J.E.,	2010	How are macroinvertebrates of slow flowing lotic systems	Environmental Pollution 158: 543-550	Supplementary, no data to impact RA Investigating potential adverse effects from long-term turbidity.

	Nugegoda, D and Choy, S.C.		directly affected by suspended and deposited sediments?		
CP 10.2	Talaat, H.A., *et al*.	2011	Evaluation of Heavy Metals Removal Using Some Egyptian Clay	2011 2nd International Conference on Environmental Science and Technology. IPCBEE vol 6, Singapore	Supplementary, no data to impact RA Reporting how kaolin can be used as an absorbent to reduce the aquatic toxicity of certain chemicals.
CP 10.2	Abu-Safa, A., Abu-Safa, S., Mosa, M., and Gharaibeh, S.	2012	Low Cost Pre-Treatment of Pharmaceutical Wastewater	International Journal of Chemical and Biological Engineering vol 6	Supplementary, no data to impact RA reporting how kaolin can be used as an absorbent to reduce the aquatic toxicity of certain chemicals.
CP 10.3.2	Benhadi-Marin, J., Pereira, J.A., and Santos, S.A.P.	2016	Effects of kaolin particle films on the life span of an orb-weaver spider	Chemosphere 144: 918-924	Supplementary, no guideline data to impact RA. Reference does indicate that orb-weaver spider can be sensitive to based on different routes of exposure.
CP 10.3.2.2/01	Porcel, M., Cotes, B., and Campos, M.	2011	Biological and behavioural effects of kaolin particle film on larvae and adults of *Chrysoperla carnea* (Neuroptera: Chrysopidae)	Biological Control 59: 98-105	Relevant. OECD summary provided. Laboratory and field experiments reporting the effect of Surround WP on *Chrysoperla carnea*
CP 10.3.2.2/02	Bengochea, P., *et al*.	2010	Side effects of kaolin on natural enemies found on olive crops	Pesticides and Beneficial Organisms vol 55: 61-67	Relevant. OECD summary provided. Evaluating the effects of Surround on *Psyttalia concolor*, *Chrysoperla carnea*, *Chilocorus nigritus* and *Anthocoris nemoralis* according to IOBC sequential scheme.
CP 10.3.2.2/03	Bengochea, P., *et al*.	2014	Non-target effects of kaolin and copper applied on olive trees for the predatory lacewing *Chrysoperla carnea*	Biocontrol Science and Technology, vol 24, no 6: 625-640	Relevant. OECD summary provided. Laboratory and field experiments reporting the effect of Surround WP on *Chrysoperla carnea*
CP 10.3.2.2/04	Bengochea, P., *et al*.	2013	Kaolin and copper-based products applications: Ecotoxicology on four natural enemies	Chemosphere 91: 1189-1195	Relevant. OECD summary provided. The effect of kaolin on *Anthocoris nemoralis*, *Chelonus inanitus*, *Chilocorus nigritus* and *Scutellysta cyanea* were investigated under extended laboratory conditions
CP 10.3.2.4/10	Pascual, S., Cobos, G., Seris, E., and Gonzalez-Nunez, M.	2010	Effects of processed kaolin on pests and non-target arthropods in a Spanish olive grove	J Pest Sci 83:121-133	Relevant. OECD summary provided. A 3 year field trisal to assess the effects of Surround WP on the arthropod community of olive trees.
CP 10.3.2.4/11	Marko, V., Bogya, S., Kondorosy, E., and Blommers, L.H.M.	2009	Side effects of kaolin particle films on apple orchard bug, beetle and spider communities	International Journal of Pest Management vol 56: 189-199	Relevant. OECD summary provided. The effects of multiple applications of kaolin particle film on apple orchard bug (Heteroptera), beetle (Coleoptera) and spider (Araneae).
CP 10.6	Wang, M., Chen, L, Chen, S. and Ma, Y.	2011	Alleviation of cadmium-induced root growth inhibition in crop seedlings by nanoparticles	Ecotoxicology and Environmental Safety 79 (2012): 48-54	Supplementary, data not used in guideline RA A root growth inhibition study.

Ecotoxicology evaluation table (non-relevant articles)

Authors	Year	Title	Source (Journal, volume, pages)	Fulfils ecotox data requirement?	Comments	Discussion on relevance
Benhadi-Marin, J., Pereira, J.A., and Santos, S.A.P.	2016	Effects of kaolin particle films on the life span of an orb-weaver spider	Chemosphere 144: 918-924	No	Non-guideline study, focusing on route of exposure.	Not relevant

Authors	**Year**	**Title**	**Source (Journal, volume, pages)**	**Fulfils ecotox data requirement?**	**Comments**	**Discussion on relevance**
Brennan, F.P., Moynihan, E., Griffiths, B.S., Hillier, S., Owen, J, Pendlowski, H., and Avery, L.M.	2014	Clay mineral type effect on bacterial enteropathogen survival in soil	Science of the Total Environment 468-469:302-305	No	The effects of clay on the survival of enteropathogens in the environment.	Not relevant
Dutertre, M., Barille, L., Haure, J., and Cognie, B.	2007	Functional responses associated with pallial organ variations in the Pacific oyster *Crassostrea gigas* (Thunberg, 1793)	Journal of Experimental Marine Biology and Ecology 352: 139-151	No	Non-guideline research on the plasticity and function of the pallial organs in the Pacific oyster.	Not relevant
Karise, R., Muljar, R., Smagghe, G., Kaart, T., Kuusik, A., Dreyersdorff, G., Williams, I.H., and Mand, M.	2016	Sublethal effects of kaolin and the biopesticides Prestop-Mix and BotaniGard on metabolic rate, water loss and longevity in bumble bees (*Bombus terrestria*)	J Pest Sci 89:171-178	No	Non-guideline study. Findings irrelevant for risk assessment	Not relevant
Mahmoud, A.E.M., El-Sebai, O.A., Shahen, A.A., and Marzouk, A.A.	2010	Impact of kaolin-based particle film dusts on *Callosobruchus maculatus* (F.) and *C. chinenesis* (L.) after different storage periods of treated broad bean seeds	Julius-Kuhn Archiv, 425. 10th International Working Conference on Stored Product Protection	No	An efficacy trial to determine in kaolin powder could help in prolonging storage of broad been seeds.	Not relevant
Michel, C, Herzog, S, de Capitani, C, Burkhardt-Holm, P., and Pietsch, C.	2014	Natural mineral particles are cytotoxic to rainbow trout gill epithelial cells *in vitro*	PLOS ONE	No	Non-guideline *in vitro* study on trout gills. Finding no relevant for risk assessment.	Not relevant
Mommaerts, V., Put, K., Vandeven, J., and Smagghe, G	2011	Miniature-dispenser-based bioassay to evaluate the compatibility of powder formulations used in an entomovectoring approach	Pest Management Science	No	Bioassay development	Not relevant
Zhang, X., Guo, P., Huang, J., and Hou, X.	2013	Effects of suspended common-scale and nanoscale particles on the survival, growth and reproduction of *Daphnia magna*	Chemosphere 93: 2644-2649	No	Non-guideline study. Reference focuses more on other compounds other than kaolin.	Not relevant

B.9.11.2 Studies submitted by the applicant

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 8.2.1/01	Goldes, S.A., Ferguson, H.W., Moccia, R.D.and Daoust, P.Y.	1988	Histological effects of the inert suspended clay kaolin on the gills of juvenile rainbow trout, *Salmo gairdneri* GLP not reported Published; Journal of Fish Diseases (1988), volume 11 pages 23-33	Y	N	Not relevant	Public literature
KCA 8.2.1/02	McFarland, V.A., and Peddicord, R.K.	1980	Lethality of a suspended clay to a diverse selection of marine and estuarine macrofauna GLP not reported Published; Archives of Environmental Contamination and Toxicology (1980), volume 9, pages 733-741	Y	N	Not relevant	Public literature
KCA 8.2.1/03	Isono, R.S., Kita, J., and Setoguma, T.	1998	Acute effects of kaolinite suspension on eggs and larvae of some marine teleosts GLP not reported Published; Comparative Biochemistry and Physiology Part C (1998) volume 120, pages 449-455	Y	N	Not relevant	Public literature
KCA 8.2.1/04	Sherk J.A. Jr., O'Connor J.M., Neumann D.A., Prince R.D., and Wood K.V.,	1973	Effects of Suspended and Deposited Sediments on Estuarine Organisms, PHASE II GLP not reported Published; U.S. Department of Commerce, National Technical Information Service	Y	N	Not relevant	Public literature
KCA 8.2.2/02	Redding, J.M., Schreck, C.B., and Everest, F.	1987	Physiological Effects on Coho Salmon and Steelhead of Exposure to Suspended Solids GLP not reported Published; Transactions of the American Fisheries Society (1987), volume 116, pages: 737- 744	Y	N	Not relevant	Public literature
KCA 8.2.2.1/01	Hashimoto, Y., Yamaguchi, M., Itō, T., and Tōi, J.	1986	Effects of Kaolin on Hatching, Growth and Feeding Behaviour of Rainbow Trout, *Salmo gairdneri* GLP not reported Published; Bull. Tokai Reg. Fish. Res. Lab., (1986), volume 120 pages: 39 - 42	Y	N	Not relevant	Public literature

KCA 8.2.4.1/01	Robinson, S.E., Capper, N.A., and Klaine, S.J.	2009	The effects of continuous and pulsed exposures of suspended clay on the survival, growth and reproduction of Daphnia magna GLP not reported Published; Environmental Toxicology and Chemistry Vol 29 (1): 168-175	N	N	Not relevant	Public literature
KCP 10.2.1/01	Goodband, T.J.	2006	Surround WP crop protectant: Acute toxicity to *Daphnia magna* Report number: 2120/0004 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.
KCP 10.2.1/02	Vryenhoef, H.	2006	Surround WP crop protectant: Algal inhibition test Report number: 2120/0003 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.
CA 8.2 CA 8.2.6.1 (refer to K-CP 10.2.1/01)	Vryenhoef H.	2018	SOKALCIARBO WP: Algal Growth Inhibition test ENVIGO, Report No. HM69VD GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 283/2013	SOKA
CA 8.3.1.2 (refer to K-CP 10.3.1.2/01)	Mamet O.	2019	Evaluation of the chronic oral toxicity of Sokalciarbo WP on honey bees (*Apis mellifera* L.). Calculation of Lethal Concentration (LC_{50}) and Lethal Dietary Dose (LDD_{50}). Laboratory conditions. TESTAPI, Report No. 371-2018 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA
K-CP 10.3.1.1.2/1	Mamet O.	2008	«Determination de la DL_{50} de contact sur abeille domestique (*Apis mellifera*) par différentes applications de SOKALCIARBO WP » Testapi, Report N°139-2008 GLP: Yes Published: No	N	Y	Required according to Reg. (EU) no. 284/2013.	SOKA

KCA 8.3.1.1.1/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute Dietary Toxicity Study with the Honey Bee Report no.: 469-102 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCA 8.3.1.1.2/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute ContactToxicity Study with the Honey Bee Report no.: 469-101 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
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.
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	N	N	Data out of protection	Tessenderlo Group N.V.

			SOLEVI GEP: yes Unpublished				
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.
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	N	N	Data out of protection	Tessenderlo Group N.V.

			RSF GEP: yes Unpublished				
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	
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	
KCP 10.3.2.4/18	Showler, A.T, and Sétamou, M.	2004	Effects of kaolin particle film on selected arthropod populations in cotton in the lower Rio Grande Valley of Texas Report number: - GEP: - Published in: Southwestern Entomologist, 29(2): 137-146	N	N	Not relevant	
KCP 10.3.2.4/15	Pascual, S., Cobos, G., Medina, P., Budia, F., Viñuela, E., González-Núñez, M.	2010b	Field assessment of effects of control strategies against the olive fruit fly (*Bactrocera oleae* (Rossi)) on predatory arthropods: comparison of different methods of data analysis Report number: - GEP: - Published in: Pesticides and Beneficial Organisms IOBC/wprs Bulletin vol 55: 11-18	N	N	Not relevant	
	Tacoli, F., Cargnus, E., Pozzebon, A., Duso, C., Tirello, P., & Pavan, F	2019	Side Effects of Kaolin and Bunch-Zone Leaf Removal on Predatory Mite Populations (Acari: Phytoseiidae) Occurring in Vineyards. Report number: - GEP: - Published in: Journal of economic entomology, 112(3), 1292-1298.	N	N	Not relevant	
	Jaastad, G., Røen, D., Hovland, B., & Opedal, O.	2006	Kaolin as a possible treatment against lepidopteran larvae and mites in organic fruit production. In ecofruit-12th International Conference on Cultivation Technique and Phytopathological Problems in Organic Fruit-Growing	N	N	Not relevant	

			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.				