Toxicological profile for

Kaolin, calcined

This ingredient has been assessed to determine potential human health effects for the consumer. It was considered not to increase the inherent toxicity of the product and thus is acceptable under conditions of intended use.

1. Name of substance and physico-chemical properties

1.1. IUPAC systematic name

No data available to us at this time.

1.2. Synonyms

Kaolin, calcined; EINECS 296-473-8; Calcined kaolin clay (PubChem)*1.3. Molecular formula*

1.3. Molecular formula

$Al_4Si_4O_{14}$ (“Note: A single molecule cannot exist”) (European Commission, 2020)

1.4. Structural Formula

No data available to us at this time.

1.5. Molecular weight (g/mol)

258.16 (PPDB, 2023)

1.6. CAS registration number

92704-41-1

1.7. Properties

1.7.1. Melting point

(°C): >1700 (IUCLID, 2000); ”[I]t is considered that the substance does not melt or boil at temperatures below 360 °C” (European Commission, 2020)

1.7.2. Boiling point

(°C): ”[I]t is considered that the substance does not melt or boil at temperatures below 360 °C” (European Commission, 2020); does not boil (APVMA, 2022)

1.7.3. Solubility

<1 g/l at 20°C; 1.15 mg/L at 20°C (PPDB, 2023); “Considered insoluble in water” (European Commission, 2020), insoluble in water and organic media (APVMA)

1.7.4. pKa

”No dissociation constant” (European Commission, 2020)

1.7.5. Flashpoint

(°C): No data available to us at this time.

1.7.6. Flammability limits (vol/vol%)

”Aluminium silicate calcined is not considered flammable, self-heating substance, explosive, or oxidizing” (European Commission, 2020); not flammable (APVMA, 2022)

1.7.7. (Auto)ignition temperature

(ºC): No data available to us at this time.

1.7.8. Decomposition temperature

(°C): No data available to us at this time.

1.7.9. Stability

(in water) $T_{1/2}$ pH4: > 1 year at 25°C.

$T_{1/2}$ pH7: > 1 year at 25°C.

$T_{1/2}$ pH9: > 1 year at 25°C (IUCLID, 2000).

“Temperature has no impact on the stability of the substance” (European Commission, 2020)

1.7.10. Vapor pressure

No data available to us at this time.

1.7.11. log Kow

”No partition coefficient” (European Commission, 2020)

2. General information

2.1. Exposure

The only significant human or environmental exposure route for calcined kaolin is via dust contamination in processing areas. This is strictly contained and monitored by engineering controls. Even worst case scenarios regarding the failure of dust control measures do not generate a significant long or short term effect. (IUCLID, 2000).

Calculated migration of kaolin in water was up to 0.4 mg/kg (EFSA, 2014).

Kaolin, calcined (CAS RN 92704-41-1) is listed as an ingredient (at given concentrations, where specified) in auto (1-13%), home maintenance (10-30%, includes “old” products), and inside the home products by the CPID.

“An AOEC value of 1.4 mg/m^3 (8hrs-TWA) has been set for aluminium silicate (calcined). This value corresponds to 14 mg /day considering an inhalation rate of 1.25 m^3/h (HEEG Opinion No 17, Default human factor values for use in exposure assessments for biocidal products) and a work rate of 8 hrs. (…)

The general population is routinely exposed to kaolin in medicines, cosmetics and industrial applications. No major health effects have been reported from kaolin in the general population. Exposure of the general population to significant levels of kaolin dust, that may be potentially harmful through inhala-tion or eye irritation, is highly unlikely. There are no reported cases on kaolin poisoning in the literature. In such event, no special antidotes or medical treatment are available and symptomatic treatment is recommended."

As taken from European Commission, 2020

2.2. Combustion products

No data available to us at this time.

2.3. Ingredient(s) from which it originates

Calcined kaolin is a phyllosilicate. It is a natural inorganic mineral (aluminium silicate) that has been heated to a temperature just below its fusing point (~450 to 800°C).” As taken from APVMA, 2022.***3. Status in legislation and other official guidance***

3. Status in legislation and other official guidance

Kaolin calcined is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 753). The CEF Panel concluded that the use of kaolin calcined does not raise a safety concern when used in oxygen absorbers in sachets which would prevent the physical release of their contents into the food and placed in the headspace of the packaging or when used in direct contact with dry foods.

As taken from EFSA, 2012.

“The CEF Panel concluded that the use of... calcined kaolin...[in a powdered mixture with iron powder, activated carbon, sodium chloride, polyacrylic acid, sodium salt, crosslinked and calcium chloride] does not raise a safety concern when used in oxygen absorbers in labels, which prevent the physical release of their content into the food. When placed in the headspace of the packaging or when used in direct contact with foods, the labels should not intentionally or unintentionally come into direct contact with liquid foods or foods that have an external aqueous phase on the surface such as sliced fruits.”

As taken from EFSA, 2014.

Kaolin, calcined (CAS RN 92704-41-1) is listed in the US EPA Toxic Substances Control Act (TSCA) inventory and also in the US EPA 2020 CDR list (Chemical Data Reporting Rule).
US EPA 2020 CDR List. US EPA TSCA inventory

There is a REACH dossier on kaolin, calcined (CAS RN 92704-41-1) (ECHA, undated).

Kaolin, calcined (CAS RN 92704-41-1) is included on the US EPA’s list of Safer Chemical Ingredients with functional use: processing aids and additives (US EPA, 2023a).

Kaolin, calcined (CAS RN 92704-41-1) is not classified for packaging and labelling under Regulation (EC) No. 1272/2008 (ECHA, 2023).

Calcined kaolin (CAS RN 92704-41-1) is listed in the US EPA InertFinder Database (2023) as approved for food and non-food use pesticide products. For food use, it is listed (as “kaolinite-type clay”) under 40 CFR 180.910 (Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance) and 180.930 (Inert ingredients applied to animals; exemptions from the requirement of a tolerance) (US EPA, 2023b).

“No ADI has been set for aluminium silicate, since the compound is not systemically bioavailable after oral ingestion. This approach is in line with the EFSA peer review of the DAR (EFSA Journal 2012;10(2):2517) that there is no need to set an acceptable daily intake (ADI) and acute reference dose (ARfD) because consumer exposure is very unlikely.”

European Commission, 2020

4. Metabolism/Pharmacokinetics

4.1. Metabolism/metabolites

“It is not absorbed after ingestion or topical application, it is therefore not bioavailable and there are no metabolites.”

As taken from European Commission, 2020.

“No metabolism data have been provided for calcined kaolin. Calcined kaolin is derived from aluminium silicate, which is ubiquitous within the environment and naturally occurring within soil. It is chemically inert, not metabolised into other compounds, and insoluble in water; therefore, it is not taken up and translocated by plants. On this basis, metabolism data were not required, and a residues definition has not been established.” As taken from APVMA, 2022.

4.2. Absorption, distribution and excretion

“Dermal penetration studies: Negligible” (PPDB, 2023).

“Calcined kaolin is insoluble in both water and organic media, indicating that it cannot be absorbed from the gastrointestinal tract to achieve systemic exposure.”

“As calcined kaolin is not absorbed, and there is no systemic exposure, a mode of action is not relevant.” As taken from APVMA, 2022

“Aluminium silicate calcined is a natural inorganic mineral, it is inert, insoluble in aqueous andorganic solvents and it does not become bioavailable when ingested. Consequently, it is not distributedin tissues and it is not metabolised.” As taken from EFSA, 2022.

4.3. Interactions

"The paper addresses laboratory preparation and antibacterial activity testing of kaolinite/nanoTiO2 composite in respect of the daylight irradiation time. Kaolinite/nanoTiO2 composites with 20 and 40 wt% of TiO2 were laboratory prepared, dried at 105 °C and calcined at 600 °C. The calcination caused transformation of kaolinite to metakaolinite and origination of the metakaolinite/nanoTiO2 composite. X-ray powder diffraction, Raman and FTIR spectroscopic methods revealed titanium dioxide only in the form of anatase in all evaluated samples (non-calcined and calcined) and also transformation of kaolinite to metakaolinite after the calcination treatment. Scanning electron microscopy was used as a method for characterization of morphology and elemental composition of the studied samples. A standard microdilution test was used to determine the antibacterial activity using four human pathogenic bacterial strains (Staphylococcus aureus, Escherichia coli, Enterococcus faecalis, Pseudomonas aeruginosa). A lamp with a wide spectrum bulb simulating daylight was used for induction of photocatalysis. The antibacterial assays found all the KATI samples to have antibacterial potency with different onset of the activity when calcined samples exhibited antibacterial activity earlier than the non-calcined. Significant difference in antibacterial activity of KATI samples for different bacterial strains was not observed." As taken from Dědková K et al. 2014. J. Photochem. Photobiol. B 135, 17-22. PubMed, 2015 available at: http://www.ncbi.nlm.nih.gov/pubmed/24792569

5. Toxicity

5.1. Single dose toxicity

Type: LD50

Species: rat

Sex:

Number of Animals:

Vehicle:

Value: > 2000 mg/kg bw

Method: OECD Guide–line 401 "Acute Oral Toxicity"

Year:

GLP:

Test substance:

Source: Lehmann & Voss & Co. Hamburg

IUCLID, 2000.

“Aluminium silicate calcined (calcined kaolin) was found to be of low toxicity via the oral and the dermal route. The acute inhalation studies performed in rat, indicated an LC50 > 5.07 mg/L/4h (nose-only).”

Summary of acute toxicity studies of aluminium silicate calcined (calcined kaolin):

Test substance	**LD50/LC50** (mg/kg bw or mg/L)	**Species**	**Route**
Satintone 5HB, Lot # 10146, purity: 100 % aluminium silicate calcined	> 5000	Rat / SD	Oral
M-96-018, Lot # 08145, aluminium silicate calcined, polydimethylsiloxane purity: 98.8% calcined kaolin	> 5000	Rat / SD	Oral
hydrous kaolin, Batch 30.03.2015, purity: 100 %	> 2000	Rat / Wistar	Oral
Satintone 5HB, Lot # 10146, purity: 100% aluminium silicate calcined	> 5000	Rat / SD	Dermal
hydrous kaolin, Batch 30.03.2015, purity: 100 %	> 2000	Rat / Wistar	Dermal
M-96-018, purity: 98.8 % aluminium silicate calcined, 1.2% siloxane	> 2.18	Rat / SD	Inhalation
M-97-009, Lot # 09255, 100% aluminium silicate calcined	> 2.07	Rat / SD	Inhalation
hydrous kaolin, Batch 30.03.2015, purity: 100%	> 5.07	Rat / Wistar	Inhalation

A snout-only inhalation study in Han Wistar rats was performed for 6 hours a day, 5 days a week, for 2 weeks at achieved aerosol concentrations of 25.6, 47.6 or 103 µg/L Kaolin or 23.7, 55.0 or 103 µg/L Kaolinitic Clay (nominal concentrations for both compounds: 25, 50 and 110 µg/L) (Robin M., 2019).

Species, Route, Duration	Test item(s)	Concentration	Endpoint	Reference
Rat (Han Wistar), Inhalation (snout only), 2-weeks	Kaolin (92,3% Kaolinite; 0,8% Quartz) Kaolinitic clay (75,3% Kaolinite; 17% Quartz)	*Nominal:* 0, 25, 50, 110 µg/L *Achieved:* Kaolin: 0, 25.6, 47.6 103 µg/L Kaolinitic Clay: 0, 23.7, 55.0, 103	NOAEC = 47.6 µg/L (kaolin) Effects at LOAEC = 103 µg/L: - Nasal turbinates effects (mu-cous cell hyperplas-ia/metaplasia) - Lung effects (changes in dif-ferential white blood cell counts, minimal alveolar macrophage aggregates, in-creased adjusted weight of lungs/bronchi) GLP study. No Guideline.	., 2019 (Study submit-ted for the re-newal)

			Study acceptable.	

Treatment-related observations included minimal alveolar macrophage aggregates in the lungs of animals exposed to Kaolin or Kaolinitic Clay at all concentrations tested. The alveolar macrophage aggregates contained fine refractile granular material which was considered by the study authors likely to be the test item. There was no other morphological change in the lung and there was no mention of inflammation in the study report. Considering the inert and insoluble properties of Kaolin and Kaolinitic clay, minimal alveolar macrophage aggregates could be regarded as adaptive responses to clear the lungs of foreign particulate matter. However, the study did not include a recovery period in order to assess reversibility of the finding.

Analyses of the bronchoalveolar lavage fluid (BALF) revealed statistically significant changes in differential white blood cell counts, with no clear concentration-response pattern. There were no historical control data to assess biological significance. The adjusted weight of lungs/bronchi was statistically significantly increased among females treated with 103 µg/L kaolinitic clay.

Overall, it cannot be clearly demonstrated that the observed lung effects (i.e. increased lung weight, accumulation of macrophages and changes in differential white blood cell counts in the BALF) are adaptive or adverse. It is likely that these findings are adaptive responses and parts of a defence mechanism aimed to clear the lungs of particulate matter and are therefore non-specific findings. On the other hand, the study is of short-duration (14-days) and there are no other studies on short-term or long-term toxicity of kaolin via the inhalation route to assess progression of the lung effects. Thus, progression into fibrosis with lung function changes after longer exposure may not be excluded considering that macrophages play a central role in the pathogenesis of fibrosis.

Other effects at site of contact included increased incidence of mucous cell hyperplasia/metaplasia in the nose of animals exposed to the highest dose of Kaolin or Kaolinitic Clay. This effect was mainly localized to the ventral respiratory epithelium in the caudal aspect of the nose and it was considered secondary to mild irritation caused by the test items.

The study NOAEC was set at 47.6 µg/L for kaolin and 55.0 µg/L for kaolinitic clay based on effects on nasal turbinates (mucous cell hyperplasia/metaplasia) at 103 µg/L. This NOAEC is supported by lung effects including changes in differential white blood cell counts, minimal alveolar macrophage aggregates, increased adjusted weight of lungs/bronchi. Although lung effects were presumed to be adaptive, there is high uncertainty due to short study duration and lack of reversibility period not allowing to assess potential progression to functional lung changes. So, lung effects are considered in NOAEC setting as a conservative approach."

As taken from European Commission, 2020.

"Calcined kaolin has low acute oral, dermal, and inhalational toxicity" As taken from APVMA, 2022.

"Aluminium silicate calcined has a lowacute toxicity after oral, dermal and inhalation administration. It is noted that no inhalation toxicity study has been provided for aluminium silicate calcined, but a study is available with hydrous kaolin (considered as the worst case due to thepresence of crystalline silica, which may be of concern." As taken from EFSA, 2022.

5.2. Repeated dose toxicity

“In the study by Schepers (1971), Kaolin, administered during 12 months *via* intratracheal route to the guinea pig did not induce any epithelialization or neoplasia lesion. (…)

In a 24-month inhalation study (Wagner et al., 1987), Kaolin, administered during 12 months to the rat in an inhalation chamber did not induce any malignant lesion. There were only two incidences of bronchoalveolar hyperplasia in the total of 40 exposed rats which are considered to be reaction to an irritant according to the study author. This study on Kaolin is also included in the REACH dossier3 for consideration in read-across to Kaolin, calcined and it is concluded that: ‘None of 40 rats exposed to Kaolin dust at a concentration of 10 mg/m³ for 6 hours per day with exposure durations ranging from 3 months to 12 months showed tumour formation’. (…)

As taken from European Commission, 2020.

“As regards the toxicological reference values, no ADI and ARfD have been considered necessary forthis compound”

“The only available short-term study is a 2-week nose-only inhalation study in rats performed with kaolin and kaolinitic clay (considered as the worst case due to the presence of crystalline silica whichmight be of concern), where the NOAEC has been set at 47.6 and 55 mg/m3, for kaolin and kaolinitic clay, respectively, on the basis of effects observed at 103mg/m3 in both kaolin and kaolinitic clay treated rats in the nasal turbinates and lungs.Since no concern is expected by the oral route, the same lack of toxicity is expected through dermal exposure taking into consideration the insoluble and inert properties of the active substance.” As taken from EFSA, 2022.

5.3. Reproduction toxicity

“Known to cause a problem” for “reproduction/development effects” (no further details given) (PPDB, 2023).

“There are no GLP or guideline complying studies regarding reproductive toxicity of Aluminium Silicate calcined.
Limited information on reproductive toxicity of clay is provided in literature study by Patterson & Staszak, 1977. In this study, no effects on the development of foetuses (foetal weight, foetal length) are anticipated from exposure of pregnant rats to clay. Moreover, litter size was comparable among control and treated groups suggesting that no substantial effects on fertility are also expected from oral ingestion of clay.

Summary of the reproductive toxicity studies with aluminium silicate:

Species, Route, Duration	Test item	Dose	Endpoint	Reference
Rat, Oral (geophagia), Duration: 37 to 68 days, 69 to 85 days, and 96 to 117 days prior to ferti-lization and during gestation	Kaolin (batch, purity not reported)	0, 20% Kaolin, iron supplemented 20% Kaolin added to the diet	No effects on foetal development. No effects on litter size suggesting that no substantial effects on fertili-ty are also expected from oral in-gestion of clay. No GLP. No Guideline. Study acceptable as supporting information.	Patterson & Staszak, 1977 (DAR, 2008)

As taken from European Commission, 2020.

“No reproductive and developmental toxicity studies are available. One published study performed in the rat and considered as supporting information did not indicate effects of aluminium silicate calcined on reproduction and development.” As taken from EFSA, 2022.

5.4. Mutagenicity

“There are no genotoxicity data with Aluminium silicate calcined. Hydrous Kaolin was negative in a bacterial mutagenicity assay submitted by SOKA (Wisher, 2017).

Summary of the in vitro genotoxicity study with aluminium silicate:

Test / end-point	**Test system**	**Findings**	**Result**	**Reference**
Bacterial mutagenicity	Ames test *Salmonella* strains TA98, TA100, TA1535, TA1537 *E. coli* WP2 (pKM101)	Not mutagenic +/- metabolic activation up to 5000 µg/plate	Negative	Wisher, 2017 (Study submitted for the renewal)

The RMS considers that waiving of genotoxicity data may be acceptable considering that aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested.”

As taken from European Commission, 2020.

“No genotoxicity studies are available for aluminium silicate calcined and a gene mutation test inbacteria is available for hydrous kaolin only, and negative. Aluminium silicate calcined is considered unlikely to be genotoxic.” As taken from EFSA, 2022.

5.5. Cytotoxicity

No data available to us at this time.

5.6. Carcinogenicity

“Known to cause a problem” as a carcinogen (no further details given) (PPDB, 2023).

“Summary of carcinogenicity studies with aluminium silicate:

Species, Route, Duration	Test item	Dose	Endpoint	Reference
Guinea pig, Intratracheal route, 12 months	Kaolin (batch, purity not reported)	Not reported	No epithelialization or neoplastic lesions. No GLP. No Guideline. Study acceptable as supporting information.	Schepers, 1971 (DAR, 2008)
Rat, Inhalation, 12-months (+12 mths obs. period)	Kaolin (batch, purity not reported)	10 mg/m3 (6 h/day, 5 day/week)	No malignant lesions. No GLP. No Guideline. Study acceptable as supporting information.	Wagner *et al.*, 1987 (DAR, 2008)

In the REACH dossier no data on Kaolin, calcined were available. However, a long-term feeding study for synthetic amorphous silica (SAS) by Takizawa et al. (1988) was considered for read-across and was briefly presented as follows:

’Three groups of rats and mice received Syloid 244 at dietary levels of 1.25, 2.5 and 5% for 103 and 93 weeks, respectively. This corresponded to average daily doses of 2000 mg/kg bw/day for the high-dose group of rats and to 4500 to 5800 mg/kg bw/day for the high-dose groups of female and male mice, respectively. The animals were in good condition throughout and showed high survival. The tumour responses in all organs of SAS-treated rats and mice were not statistically significantly different from the controls (Fisher´s exact test and Cochran-Armitage test for trend). Based on the negative results after long-term oral application of SAS, there is no evidence of a carcinogenic potential arising from ingestion of these amorphous minerals.’

The full study report by Takizawa *et al.* (1988) was not available to the RMS for evaluation. Nevertheless, this study has been included in the RAR for Kieselgur (diatomaceous earth) (2019) concluding that SAS was not carcinogenic. The relevance of this study with SAS for the assessment of aluminium sili-cate is not clearly demonstrated.

Overall, the RMS considers that although there are no long-term GLP or guideline studies with Aluminium Silicate calcined, waiving of long-term toxicity/carcinogenicity studies is considered acceptable since aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic sol-vents. It does not become bioavailable when ingested."

As taken from European Commission, 2020.

"No long-term toxicity and carcinogenicity studies are available, a 12-month and a 24-month published studies (by intratracheal route in guinea pigs and by inhalation in rats, respectively) were considered as supporting information and no malignant lesions were observed, thus indicating that aluminium silicate calcined is unlikely to be carcinogenic." As taken from EFSA, 2022.

5.7. Irritation/immunotoxicity

"Known to cause a problem" as a skin sensitiser (no further details given).

"Possible respiratory sensitiser".

As taken from PPDB, 2023.

"According to the available studies, kaolin caused no irritation to rabbit skin and eyes. Finally, the test substance lacks skin sensitisation properties, as indicated in the available LLNA and GPMT tests. Finally, the waivers submitted by both notifiers for phototoxicity are considered acceptable by the RMS, since it is not technically feasible to conduct a phototoxicity study due to the physicochemical properties of aluminium silicate. Aluminium silicate is an inert, insoluble dust and there is no guideline available for the testing of phototoxicity of insoluble substances."

Summary of acute toxicity studies of aluminium silicate calcined (calcined kaolin):

Test substance	**LD50/LC50** (mg/kg bw or mg/L)	**Species**	**Route**
M-96-018, Lot #08145, aluminium silicate calcined, polydimethylsiloxane	Not irritating to skin	Rabbit / NZW	Dermal
M-96-018, Lot #08145, aluminium silicate calcined, polydimethylsiloxane	Not irritating to eyes	Rabbit / NZW	Ocular
Surround WP, Lot #02140, content: 95% kaolin	Not irritating to eyes	Rabbit / NZW	Ocular
hydrous kaolin, Batch 30.03.2015, purity: 100%	Not sensitising	Mouse / CBA/Ca	Dermal
M-99-SPI, aluminium silicate calcined, purity: 99%	Not sensitising	Guinea pig / DunkinHartley	Intradermal and dermal

"The EFSA CONTAM Panel has noted (EFSA Journal 2009; 7(11):1391) that '*Kaolin is not allergenic, although it is known to induce pro-inflammatory responses which have been particularly noticed for the lung following intratracheal administration (Yanagisawa et al., 2007)*'.

The aim of the study by Yanagisawa et al. (2007) was to examine the effects of Asian sand dust parti-cles (ASDPs) on gene expression in the murine lung using microarray analysis and elucidated the com-ponents responsible for lung inflammation. Male ICR mice were intratracheally administrated ASDPs, heat-treated ASDPs (ASDP-F, lipopolysaccharide (LPS), or b-glucan free), or kaolin particles. A micro-array analysis for murine lungs was performed, the results of which were confirmed by quantitative reverse transcription–polymerase chain reaction (RT-PCR). The

protein expression and histologic changes were also assessed. It was concluded that kaolin administration upregulated the expression of several proinflammatory genes (CXCL1/ KC and CXCL2/MIP-2) and proteins (CXCL1/KC, CXCL2/MIP-2, CCL3/MIP-1a, and CXCL10/IP-10). Both ASDP and kaolin induced neutrophil infiltration into the alveolar space, mediated by CXC chemokines. Gene and protein expression of proinflammatory molecules eventually lead to neutrophilic lung inflammation.

Neutrophilic lung inflammation was less severe in the case of kaolin, presumably due to the structure of kaolin being multilayered and highly porous.

Regarding the immunotoxicity endpoint, no additional information is retrieved from the systematic literature search performed by the applicants. Considering all the available data the non-submission of additional data for immunotoxicity has been considered acceptable."

As taken from European Commission, 2020.

"In keeping with its mineral properties, calcined kaolin clay was neither irritating to the skin of rabbits, nor sensitising to the skin in guinea pigs. However, calcined kaolin clay was considered to induce some slight eye irritation, based on its mineral-based abrasive property (i.e. as grit)." As taken from APVMA, 2022.

"It is neither a skin or an eye irritant, nor askin sensitiser. A waiving for phototoxicity testing is considered acceptable on the basis of its physico-chemical properties (insoluble substance, not absorbing UV light)." As taken from EFSA, 2022.

5.8. All other relevant types of toxicity

"May cause toxic responses via inhalation" (PPDB, 2023).

6. Functional effects on

6.1. Broncho/pulmonary system

"Inhalation may cause pneumoconiosis (Kaolinosis)" (PPDB, 2023).

"A large-scale epidemiologic survey on more than 95 % of US workers employed in the mining and pro-cessing of kaolin found no case of primary sensitivity as a result of exposure to kaolin in its solid, liquid or respirable forms (Rawlings, 1997). Some cases of pneumoconiosis were reported in the late 1970's, but, with good dust control practices over the last 25 years, no new cases were found."

As taken from European Commission, 2020.

6.2. Cardiovascular system

No data available to us at this time.

6.3. Nervous system

"No neurotoxicitystudies are available but they are not considered needed given the chemical structure of aluminium silicate calcined (not belonging to organophosphorus compounds and nothaving a neurotoxic mode of pesticidal action)." As taken from EFSA, 2022.*6.4. Other organ systems, dependent on the properties of the substance*

6.4. Other organ systems, dependent on the properties of the substance

"May produce gastrointestinal disturbances as high doses" (PPDB, 2023).

7. Addiction

JTI is not aware of any information that demonstrates that this ingredient has any addictive effect.

8. Burnt ingredient toxicity

No data available to us at this time.

9. Heated/vapor emissions toxicity

Aerosol from heated tobacco stick(s) containing Aluminium Silicate was tested in aerosol chemistry and a battery of in vitro test(s). Under the test conditions and within the sensitivity and specificity of the bioassay(s), the activity of the total particulate matter (TPM) and/or gas vapor phase (GVP) were not increased by the addition of this ingredient when compared to TPM and/or GVP from reference combustible cigarettes. The table below provides the highest tested level(s) and specific endpoint(s):

Endpoint	Tested level (mg/stick)	Reference
Aerosol chemistry	2.41	Labstat International Inc. (2021a)
In vitro genotoxicity	2.41	Labstat International Inc. (2021b)
In vitro cytotoxicity	2.41	Labstat International Inc. (2021b)

10. Ecotoxicity

10.1. Environmental fate

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that kaolin, calcined is persistent in the environment:

Data accessed June 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

10.2. Aquatic toxicity

Type: semistatic

Species: Oncorhynchus mykiss (Fish, fresh water)

Exposure period: 96 hour(s)

Unit: mg/l Analytical monitoring: yes

NOEC: >= 100

LC0: >= 100

LC50: > 100

LC100: > 100

Method: OECD Guide–line 203 "Fish, Acute Toxicity Test"

Year: GLP: yes

Test substance: as prescribed by 1.1 – 1.4

Source: ECC International Europe St Austell

Species: Daphnia magna (Crustacea)

Exposure period: 48 hour(s)

NOEC: >= 1

EC50: > 1

Method: OECD Guide–line 202, part 1 "Daphnia sp., Acute Immobilisation Test"

Test condition: 1.0mg/l was the highest test concentration that could be prepared due to the limited solubility of the test material in water. At concentrations in excess of 1.0mg/l, the test material was observed to settle out at the bottom of the test vessels. It was considered inappropriate to test at concentrations where a visible settlement of the test material was observed as physical effects may give rise to erroneous results.

Species: Scenedesmus subspicatus (Algae)

Endpoint: growth rate

Exposure period: 72 hour(s)

EC50: > 100

Method: OECD Guide–line 201 "Algae, Growth Inhibition Test"

IUCLID, 2000.

The Ecological Categorization Results from the Canadian Domestic Substances List state that kaolin, calcined is not inherently toxic to aquatic organisms:

Pivotal value for iT (mg/l)	0.089
Experimental result iT (mg/l)	0.089
Test species iT (Latin)	Hyallela azteca
Final EndPoint iT	LC50
Exposure duration iT (hours)	168
Comment iT	tested in 10% Lake Ontario water based on measured concentrations of dissolved metal originating from AA standards and complex metal anions.
Reference iT	Unpublished report. NWRI Laboratory. Dr Uwe Borgmann

Data accessed June 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

10.3. Sediment toxicity

No data available to us at this time.

10.4. Terrestrial toxicity

No data available to us at this time.

10.5. All other relevant types of ecotoxicity

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that the bioaccumulative potential of kaolin, calcined in the environment has not been determined.

Data accessed June 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

11. References

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12. Other information

No data available to us at this time.

13. Last audited

June 2023

SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the active substances, activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride for use as active component in food contact materials[1]

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of EFSA deals with the risk assessment of the active substances activated carbon (CAS No 7440-44-0, FCM Substance No 984), water (CAS No 7732-18-5, FCM Substance No 515), iron powder (CAS No 7439-89-6, FCM Substance No 983), kaolin calcined (CAS No 92704-41-1, FCM Substance No 753), sulphur (CAS No 7704-34-9, FCM Substance No 514), sodium chloride (CAS No 7647-14-5, FCM Substance No 985), used in mixtures which are packed into sachets for absorbing oxygen from the food environment. All substances of the oxygen absorber formulations have been evaluated and approved for use as additives in plastic food contact materials and/or as food supplements (sodium chloride). The CEF Panel concluded that the use of the substances activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride, do not raise a safety concern when used in oxygen absorbers in sachets which would prevent the physical release of their contents into the food and placed in the headspace of the packaging or when used in direct contact with dry foods. The sachet should not intentionally or unintentionally come into direct contact with liquid foods or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat. Activated carbon should in addition comply with the same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 10 % (w/w).

[1] On request from from the DGCCRF, France, Question No EFSA-Q-2011-00238; EFSA-Q-2011-00239; EFSA-Q-2011-00242, adopted on 22 March 2012.

[2] Panel members: Ulla Beckman Sundh, Mona-Lise Binderup, Leon Brimer, Laurence Castle, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Iona Pratt, Kettil Svensson, Fidel Toldrá, Detlef Wölfle.
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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Food Contact Materials for the preparation of this opinion: Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Roland Franz, Nathalie Gontard, Eugenia Lampi, Jean-Claude Lhuguenot, Maria Rosaria Milana, Karla Pfaff, Maria de Fátima Poças, Philippe Saillard, Kettil Svensson and Detlef Wölfle for the support provided to this EFSA scientific output.

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KEY WORDS

Activated carbon (CAS No 7440-44-0, FCM Substance No 984), water (CAS No 7732-18-5, FCM Substance No 515), iron powder (CAS No 7439-89-6, FCM Substance No 983), kaolin calcined (CAS No 92704-41-1, FCM Substance No 753), sulphur (CAS No 7704-34-9, FCM Substance No 514), sodium chloride (CAS No 7647-14-5, FCM Substance No 985); Food contact materials; Safety assessment; Evaluation.

SUMMARY

According to the Commission Regulation (EC) No 450/2009 of the Commission of European Communities of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, substances responsible for the active or intelligent function need first to be evaluated by the EFSA before their inclusion into a positive Community list. The procedure of the evaluation and the tasks of EFSA are described in the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

In the context of this evaluation procedure, following a request from DGCCRF, France, the Panel on food contact materials, enzymes and processing aids (CEF) was asked to deliver an opinion on three mixtures comprising activated carbon (CAS No 7440-44-0, FCM Substance No 984), water (CAS No 7732-18-5, FCM Substance No 515), iron powder (CAS No 7439-89-6, FCM Substance No 983), kaolin calcined (CAS No 92704-41-1, FCM Substance No 753), sulphur (CAS No 7704-34-9, FCM Substance No 514), sodium chloride (CAS No 7647-14-5, FCM Substance No 985), for use as oxygen absorbers. The mixtures are packed in 2 types of sachets made on both sides of a perforated polyethylene terephthalate (PET)/cellulosic non-woven (NT)/polypropylene (PP) laminated film or made of a perforated high density polyethylene (non-woven) film on one side and a polyethylene terephthalate (PET)/polyethylene (PE) laminated film on the other side. Dossiers were submitted by the applicant, Atmosphère Contrôle SAS, France.

All ingredients of the oxygen absorber formulations have been evaluated and approved for use as additives in plastic food contact materials and/or as food supplements (sodium chloride). Activated carbon was not evaluated as such, but it meets the specifications for activated charcoal, which is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) i.e. same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with the exception of ash content which may be up to 10%. For iron only there is a restriction of migration of 48 mg /kg food based on a PMTDI of 0.8 /kg bw set by JECFA/WHO (1983) and agreed by the SCF (1990). No migration of iron into water was detected (detection limit 0.032 mg/kg), whilst the migration of sodium chloride was up to 860 mg / kg food.

The CEF Panel, after having considered the above mentioned data, concluded that the use of the substances activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride, do not raise a safety concern when used in oxygen absorbers in sachets which would prevent the physical release of their contents into the food and placed in the headspace of the packaging or when used in direct contact with dry foods. The sachet should not intentionally or unintentionally come into direct contact with liquid foods or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat.

Activated carbon should in addition comply with the same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 10 % (w/w).

For iron an SML of 48 mg/kg food has been set in the EU Regulation No 10/2011 for plastcis in contact with food based on a PMTDI of 0.8 mg/kg bw set by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1983) and the SCF (1990). The EFSA NDA Panel (2004) considered that data available are insufficient to establish a tolerable upper intake level for iron (http://www.efsa.europa.eu/en/efsajournal/doc/125.pdf).

Iron is a natural constituent of foods. Iron compounds are also used as food additives, nutrient sources and for other purposes. The Commission may wish to take note of this if setting a restriction for iron.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE LEGISLATION

Regulation (EC) No 450/2009[4] of the Commission of European Communities is a specific measure that lays down specific rules for active and intelligent materials and articles intended for contact with foodstuffs in addition to the general requirements established in Regulation (EC) No 1935/2004[5] of the European Parliament and of the Council on materials and articles intended to come into contact with food. The substance(s) responsible for the active and/or intelligent function of the material should be included in a positive list by the Commission following a safety evaluation by the EFSA according to the procedure described in the abovementioned regulations.

According to this procedure the industry submits applications to the Member States competent Authorities which in their turn transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the EFSA guidelines on "submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food" (EFSA, 2009).

Active materials and articles are intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. Intelligent materials and articles monitor the condition of packaged food or the environment surrounding the food.

In this case, the DGCCRF, France asked the EFSA to evaluate three mixtures comprising activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride, in 2 types of sachets made on both sides of a perforated polyethylene terephthalate (PET)/cellulosic non-woven (NT)/polypropylene (PP) laminated film or made of a perforated high density polyethylene (non-woven) film on one side and a polyethylene terephthalate (PET)/polyethylene (PE) laminated film on the other side, for use as oxygen absorber.

TERMS OF REFERENCE AS PROVIDED BY THE APPLICANT

The EFSA is required to carry out a risk assessment on the risks originating from the migration into food of the substances activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride, used in oxygen absorbing components in food contact materials, and deliver a scientific opinion, according to the Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

The opinion of the EFSA will be considered by the Commission for adoption of a Community list of authorised substances where according to the Regulation (EC) No 450/2009 there will be specified:

(a) the identity of the substance(s);
(b) the function of the substance(s);
(c) the reference number;
(d) if necessary, the conditions of use of the substance(s) or component;
(e) if necessary, restrictions and/or specifications of use of the substance(s);
(f) if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

[4] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. OJ L 135, 30.5.2009, p. 3–11

[5] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the DGCCRF, France to evaluate the safety of three mixtures comprising activated carbon (CAS No 7440-44-0, FCM Substance No 984), water (CAS No 7732-18-5, FCM Substance No 515), iron powder (CAS No 7439-89-6, FCM Substance No 983), kaolin calcined (CAS No 92704-41-1, FCM Substance No 753), sulphur (CAS No 7704-34-9, FCM Substance No 514), sodium chloride (CAS No 7647-14-5, FCM Substance No 985). The requests have been registered in the EFSA's register of received questions under EFSA-Q-2011-00238; EFSA-Q-2011-00239; and EFSA-Q-2011-00242. Dossiers were submitted by the applicant, Atmosphère Contrôle SAS (ATCO), France, for three different comercial products. .

2. General information

According to the applicant, the substances constituting the oxygen absorber components (activated carbon, water, iron powder, kaolin calcined, sulphur, sodium chloride) are mixed together and the active formulation is a powder. It is introduced into 2 types of sachets. One type of sachets is made of porous polyethylene terephthalate (PET)/cellulosic non-woven (NT)/polypropylene (PP) laminated film on both sides. PET and PP layers are perforated prior to lamination. The other type of sachets on the one side is made of a porous high density polyethylene (non-woven) film and on the other side of a polyethylene terephthalate (PET)/polyethylene (PE) laminated film. PET and PE layer are perforated prior to lamination.

According to the applicant, sealed sachets, containing the active mixture, are placed into the headspace of the food packaging to absorb the residual content of oxygen surrounding the product, to scavenge any oxygen enclosed inside the food, and to scavenge any oxygen that enters the pack by permeation through the packaging material.

These oxygen absorbers are intended to be used in various food industries such as meat, poultry and their related products, precooked dishes, delicatessen, cheese, bakery, cakes, pastry products which are stored at +4°C. Other applications include room temperature storage of products such as cereals, chocolates, sweets, dry food, cakes and bakery products.

According to the applicant, the oxygen absorber components must not be put in direct contact with acid food (pH<4.5) or in contact with a large liquid fraction (liquids or exudates), due to the fact that the oxygen absorption is inhibited under such conditions.

The mixture as such has not been evaluated by the SCF or EFSA in the past. However, the substances constituting the oxygen absorber components (activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride) are authorised either for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) or as food supplement (Regulation EC No 1170/2009) as follows:

- Activated carbon used in these oxygen absorbers, according to the applicant, meets the requirements for activated charcoal, which is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011[6]) with the following restriction: "Only for use in PET at maximum 10 mg/kg of polymer (evaluated by EFSA in 2004[7]). Same

[6] COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food OJ L 12. 15.1.2011, p. 1-89

[7] The EFSA Journal (2004)109, 1-26. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 5th list of substances for food contact materials

purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC[8] with exception of ash content which can be up to 10 % (w/w)", no specific restrictions associated (FCM Substance No 984).

- Water is authorized as additive or monomer for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restrictions. The water specifications must be in compliance with Directive 98/83/EC[9] (FCM Substance No 515) .

- Iron powder is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with a specific restriction of 48 mg iron/kg food based on a Provisional Maximum TDI (PMTDI) of 0.8 mg/kg bw set by JECFA/WHO (1983) and agreed by the SCF (1990). (FCM Substance No 983).

- Kaolin calcined is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 753).

- Sulphur is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 514).

- Sodium chloride is an authorised food supplement (Regulation EC No 1170/2009[10]) with no specific restriction.

3. Data available in the dossier used for this evaluation

The studies submitted for evaluation followed the EFSA guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food (EC, 2009).

Non-toxicity data:

- Data on identity;
- Data on physical and chemical properties;
- Data on manufacturing process;
- Data on function, intended use and authorization;
- Data on overall and specific migrations.

Toxicity data:

- None.

[8] Commission Directive 95/45/EC, of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs, (OJ L 226, 22.9.1995, p. 1)

[9] Council Directive 98/83/ECof 3 November 1998on the quality of water intended for human consumption.

[10] Commission Regulation No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements

4. Evaluation

4.1. Non-toxicological data

The active powder in the oxygen absorbers contains activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride. The exact weight of powder used and the design of each sachet depends on the final application and the target capacity of oxygen absorption.

Overall and specific migration tests were performed on sachets with the highest weight of active formulation per unit of the sachet surface, up to 14.9 g/dm².

Overall and specific migration were measured by total immersion of sachets in 3% acetic acid, water and 95% ethanol (each for 10 days, at 40°C) and into isooctane (2 days at 20°C). Due to the design of the sachet, which is a perforated material, and the foreseeable uses, sachet must not be placed in contact with a liquid fraction. Consequently, experiments by total immersion of sachets are not appropriate but the results were submitted by the applicant and they are summarised here for information.

For the highest surface/weight ratio, foreseen by the applicant to be up to 4 dm^2 of sachet /kg food, the overall migration can reach up to 4555 mg/kg in 3% acetic acid, 987 mg/kg in water, 580 in 95% ethanol and 5 mg/kg in isooctane.

The specific migration of iron into 3% acetic acid was up to 1106 mg/kg, whereas there was no detectable migration (below 0.032 mg/kg) into water.

The migration of silicon into 3% acetic acid was up to 1 mg/kg, which corresponds to a calculated migration of kaolin of up to 4.9 mg/kg.

The migration of sodium into water corresponded to up to 860 mg of sodium chloride per kg food simulant. This represents 87% of the overall migration value into water.

Considering the nature of ingredients and their mode of action, the formation and release of volatile constituents is not expected.
No migration of substances from the sachet is expected under the intended conditions of use.

4.2. Toxicological data

All ingredients of the oxygen absorber formulations have been evaluated and approved for use as additives in plastic food contact materials and/or as food supplements (sodium chloride). Activated carbon was not evaluated as such, but it meets the specifications for activated charcoal, which is authorized as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) i.e. same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with the exception of ash content which may be up to 10%. All these ingredients are expected to be stable in normal storage and handling conditions. Thus no toxicity studies are required.

For iron a PMTDI of 0.8 mg/kg bw was set by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1983) and the SCF (1990). In 2004 the EFSA NDA Panel concluded that the data available are insufficient to establish a tolerable upper intake level for iron (EFSA, 2004).

It is concluded that under the intended conditions of use, which exclude direct contact with liquid acidic food and so the possibility of excessive migration of iron, the oxygen absorber formulations are toxicological

ly acceptable.

CONCLUSIONS

The CEF Panel, after having considered the above mentioned data, concluded that the use of the substances activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride, do not raise a safety concern when used in oxygen absorbers, in sachets which would prevent the physical release of their contents into the food and which are placed in the headspace of the packaging or in direct contact with dry foods. The sachet should not intentionally or unintentionally come into direct contact with liquid foods or foods that have an external aqueous liquid phase on the surface such as sliced fruits and fresh meat.

Activated carbon should in addition comply with the same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 10 % (w/w).

REMARK TO THE COMMISSION

For iron an SML of 48 mg/kg food has been set in the EU Regulation No 10/2011 for plastics in contact with food based on a PMTDI of 0.8 mg/kg bw set by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1983) and the SCF (1990). The EFSA NDA Panel (EFSA) considered that data available are insufficient to establish a tolerable upper intake level for iron (http://www.efsa.europa.eu/en/efsajournal/doc/125.pdf).

Iron is a natural constituent of foods. Iron compounds are also used as food additives, nutrient sources and for other purposes. The Commission may wish to take note of this if setting a restriction for iron.

DOCUMENTATION PROVIDED TO EFSA

Dossiers referenced: EFSA/CEF/FCM/2206 Dated: 18/03/2011. Submitted by DGCCRF, France, on behalf of Atmosphère Control SAS (France).

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EFSA (European Food Safety Authority), 2009. Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food. The EFSA Journal (2009) 1208, 10-1. http://www.efsa.europa.eu/en/efsajournal/doc/1208.pdf.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1983. Evaluation of certain additives and contaminants. 27th report. WHO Techn. Report Series, No 696; http://whqlibdoc.who.int/trs/WHO_TRS_696.pdf.

SCF (Scientific Committee of Food), 1990, First series of food additives of various technological functions, Report 25th Series http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf

EFSA (European Food Safety Authority) Journal (2004) 125, 1-34, Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the

Tolerable Upper Intake Level of Iron http://www.efsa.europa.eu/en/efsajournal/doc/125.pdf

Appendix A

TERMS USED RELEVANT TO MIGRATION:

Overall migration: The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant

Specific migration: The amount of a specific substance released from a food contact material or article into food or food stimulant

ABBREVIATIONS

bw	Body weight
CAS	Chemical Abstracts Service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing aids
EC	European Commission
EU	European Union
DGCCRF	Directioon Générale de la Concurrence, de la Consommation et de la Répression des Fraudes
EFSA	European Food Safety Authority
FCMFood	Contact Msterials
JECFA/WHO	The Joint FAO/WHO Committee on Food Additives
LMWF	Low molecular weight fraction
LOAEL	Low observed adverse effect level
Mn	Number average molecular weight
Mw	Weight average molecular weight
NDA	Dietetic Products, Nutrition and Allergies
PET	Poly(ethylene terephthalate)
PMTDI	Provisional Maximum Tolerable Daily Intake
REF No	Reference Number
SCF	Scientific committee on food
SML	Specific Migration Limit
w/w	Weight by weight

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 92704–41–1
CAS No.	92704–41–1
EINECS Name	Kaolin, calcined
EINECS No.	296–473–8
Molecular Formula	<no data>

Dataset created by: EUROPEAN COMMISSION – European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non–confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

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1.0.2 Location of Production Site

–

1.0.3 Identity of Recipients

–

1.1 General Substance Information

Substance type: inorganic
Physical status: solid

Substance type: natural substance
Physical status: solid

Substance type: organic
Physical status:

1.1.1 Spectra

–

1.2 Synonyms

Alphatex
Source: BASF AG Ludwigshafen

Ansilex 90
Source: BASF AG Ludwigshafen

Ansilex 93
Source: BASF AG Ludwigshafen

Calcined china clay
Remark: Calcination of China Clay can give rise to new minerals/substances. These are, by definition, still calcined china clay but may also have CAS and / or EINECS numbers in their own right. An example is mullite CAS 1302–93–8 / EINECS 215–113–2.
Source: ECC International Europe St Austell

Calcined kaolin
Source: ECC International Europe St Austell
BASF AG Ludwigshafen

China Clay, Kaolin
Source: Lehmann & Voss & Co. Hamburg

Deltatex
Source: BASF AG Ludwigshafen

Kalziniertes Kaolin, AS 45, Kaolinschamotte
Source: AKW Kick GmbH Hirschau

Kaocal
Source: BASF AG Ludwigshafen

Kaolin, calcined
Source: BASF AG Ludwigshafen

M 100
Source: BASF AG Ludwigshafen

M 100 (clay)
Source: BASF AG Ludwigshafen

Nuopaque
Source: BASF AG Ludwigshafen

Pole Star 200R
Source: BASF AG Ludwigshafen

Satintone
Source: BASF AG Ludwigshafen

Satintone 1
Source: BASF AG Ludwigshafen

Satintone 5
Source: BASF AG Ludwigshafen

Satintone SP 33
Source: BASF AG Ludwigshafen

Satintone Special
Source: BASF AG Ludwigshafen

Satintone Whitetex
Source: BASF AG Ludwigshafen

SP 33
Source: BASF AG Ludwigshafen

SP 33 (clay)
Source: BASF AG Ludwigshafen

Tuboryl N
Source: BASF AG Ludwigshafen

1.3 Impurities

-

1.4 Additives

-

1.5 Quantity

Quantity 100 000 - 500 000 tonnes

1.6.1 Labelling

-

1.6.2 Classification

-

1.7 Use Pattern

Type: type
Category: Non dispersive use

Type: type
Category: Use resulting in inclusion into or onto matrix

Type: type
Category: Wide dispersive use

Type: industrial
Category: Agricultural industry

Type: industrial
Category: Paints, lacquers and varnishes industry

Type: industrial
Category: Paper, pulp and board industry

Type: industrial
Category: Personal and domestic use

Type: industrial
Category: Polymers industry

Type: industrial
Category: other: Ceramics industry

Type: industrial
Category: other: Keramische Industrie, Glasuren und Fritten

Type: industrial
Category: other: Kiln car furniture

Type: use
Category: Fillers

Type: use
Category: Pesticides

Type: use
Category: other: Body component

Type: use
Category: other: Investment casting moulds

1.7.1 Technology Production/Use

-

1.8 Occupational Exposure Limit Values

Type of limit: MAK (DE)
Limit value: 6 mg/m3
Source: BASF AG Ludwigshafen

(1)

Type of limit: MAK (DE)
Limit value: 6 mg/m3
Remark: Allgemeiner Staubgrenzwert, Feinstaub < 5 µm; Dieser Wert soll die Beeinträchtigung der Funktion der Atmungsorgane infolge einer allgemeinen Staubwirkung verhindern. Für einen cristobalithaltigen Feinstaubanteil in Kaolinschamotten gilt zusätzlich ein MAK-Wert von 0,15 – 4,0 mg/m³. Ein Feinstaub gilt dann als cristobalithaltig, wenn er 1 Prozent bis zu einer oberen Grenze von 3,75 Prozent dieses Stoffes enthält.
Source: AKW Kick GmbH Hirschau

Type of limit: OES (UK)
Limit value: 2.5 mg/m3
Remark: This is the UK limit for kaolin but it is considered relevant to calcined kaolin as well. This value relates to respirable dust.
Source: ECC International Europe St Austell

(2) (3)

Type of limit: TLV (US)
Limit value: 10 mg/m3
Source: Boero Colori S.r.l. Genova

1.9 Source of Exposure

Remark: The only significant human or environmental exposure route for calcined kaolin is via dust contamination in processing areas. This is strictly contained and monitored by engineering controls. Even worst case scenarios regarding the failure of dust control measures, do not generate a significant long or short term effect.
Source: ECC International Europe St Austell

(4)

Remark: Kaolin wird entwässert, granuliert und anschließend in konventionellen Drehrohröfen kalziniert; gegebenenfalls erfolgt eine eisenfreie Vermahlung des stückigen Rohstoffes.

Die Produktionsanlage befindet sich im Werksteil Schnaittenbach, Oberpfalz/Bayern.
Source: AKW Kick GmbH Hirschau

(5) (6)

1.10.1 Recommendations/Precautionary Measures

-

1.10.2 Emergency Measures

-

1.11 Packaging

-

1.12 Possib. of Rendering Subst. Harmless

-

1.13 Statements Concerning Waste

-

1.14.1 Water Pollution

Classified by: other: Selbsteinstufung AKW
Labelled by:
Class of danger: 0 (generally not water polluting)
Source: BASF AG Ludwigshafen

(7)

1.14.2 Major Accident Hazards

Legislation:
Substance listed:
Remark: kein Stoff der StoerfallVO
Source: BASF AG Ludwigshafen

(8)

1.14.3 Air Pollution

Classified by: TA-Luft (DE)
Labelled by:
Number:
Class of danger:
Remark: Allgemeiner Staubgrenzwert: 50 mg/m3
Source: BASF AG Ludwigshafen

(7)

1.15 Additional Remarks

Remark: wie Bodenaushub, Ziegelsplitt, keramische Scherben
Source: AKW Kick GmbH Hirschau

1.16 Last Literature Search

-

1.17 Reviews

-

1.18 Listings e.g. Chemical Inventories

-

2.1 Melting Point

Value: > 1200 degree C
Decomposition: ambiguous
Sublimation: no
Method: other: General experience
GLP: no data
Source: ECC International Europe St Austell

Value: > 1700 degree C
Decomposition: no
Sublimation: no
Method: other: nicht zutreffend
GLP: no
Source: AKW Kick GmbH Hirschau

Value: ca. 1700 degree C
Source: Lehmann & Voss & Co. Hamburg

2.2 Boiling Point

Value:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Value:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

2.3 Density

Type: density
Value: ca. 2.6 g/cm3 at 20 degree C
Source: Lehmann & Voss & Co. Hamburg

Type: density
Value: = 2.7 g/cm3 at 22 degree C
Method: other: DIN ISO 787 Teil 10
Year: 1981
GLP: no
Source: AKW Kick GmbH Hirschau

Type: relative density
Value: ca. 2.6
Remark: "Density" figure quoted is calcined kaolin's "specific gravity". It does not therefore have units.
Source: ECC International Europe St Austell
Test condition: Principal of measurement is Wa/(Wa-Ww) where Wa is weight ofsubstance sample in air and Ww is weight of water displaced by substance sample.

2.3.1 Granulometry

-

2.4 Vapour Pressure

Value:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Value:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

2.5 Partition Coefficient

log Pow:
Method:
Year:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

log Pow:
Method:
Year:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

2.6.1 Water Solubility

Value: < 1 g/l at 20 degree C
pH: ca. 4 – 6 at 30 g/l and 20 degree C
Source: Lehmann & Voss & Co. Hamburg

Value: < .1 other: Gew.% at 100 degree C
Qualitative: of very low solubility
pH: 6 – 7
Method: other: DIN ISO 787 Teil 3
Year: 1983
GLP: no
Source: AKW Kick GmbH Hirschau

Remark: Work has been undertaken on determining the water soluble salts and soluble ions for the substance and results are available. This is not however the water solubility of the substance.
Source: ECC International Europe St Austell

(9)

2.6.2 Surface Tension

–

2.7 Flash Point

Value:
Type:
Method:
Year:
Remark: Unknown flash point – substance is effectivley inert.
Source: ECC International Europe St Austell

Value:
Type:
Method:
Year:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

2.8 Auto Flammability

Value:
Remark: No data but substance appears to be effectively inert with regard to auto ignition.
Source: ECC International Europe St Austell

Value:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

2.9 Flammability

Result: non flammable
Method: other: General experience
GLP: no data
Source: ECC International Europe St Austell

Result: non flammable
Method: other
GLP: no
Source: AKW Kick GmbH Hirschau

2.10 Explosive Properties

Result: not explosive
Method: other: General experience
GLP: no data
Source: ECC International Europe St Austell

Result: not explosive
Method: other
GLP: no
Source: AKW Kick GmbH Hirschau

2.11 Oxidizing Properties

Result: no oxidizing properties
Method: other: General experience
GLP: no data
Source: ECC International Europe St Austell

Result: no oxidizing properties
Method: other
GLP: no
Source: AKW Kick GmbH Hirschau

2.12 Additional Remarks

Remark: Partikelgröße ca. 1 µm – 30 mm
Source: AKW Kick GmbH Hirschau

3.1.1 Photodegradation

Type: other: nicht zutreffend
Method:
Year: **GLP:**
Test substance:
Source: AKW Kick GmbH Hirschau

Type:
Method:
Year: **GLP:**
Test substance:
Remark: Not determined but may be considered effectively inert with respect to photodegradation.
Source: ECC International Europe St Austell

3.1.2 Stability in Water

Type: abiotic
t1/2 pH4: > 1 year at 25 degree C
t1/2 pH7: > 1 year at 25 degree C
t1/2 pH9: > 1 year at 25 degree C
Method: Directive 84/449/EEC, C.10 "Abiotic degradation: hydrolysis as a function of pH"
Year: 1992 **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Remark: Due to very low solubility, the substance could not be effectively tested under the stated conditions. Less than 10% of the substance had hydrolised in 5 days so no further testing was undertaken (as specified in 1.6.5.1 of L383 A annex to 92/69/EEC). The values stated are also derived from this report.
Source: ECC International Europe St Austell

Type: biotic
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.1.3 Stability in Soil

Type: **Radiolabel:**
Concentration:
Cation exch. capac.
Microbial biomass:
Method:
Year: **GLP:**
Test substance:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Type: **Radiolabel:**
Concentration:
Cation exch. capac.
Microbial biomass:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.2 Monitoring Data (Environment)

Type of measurement:
Medium:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Type of measurement:
Medium:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.3.1 Transport between Environmental Compartments

Type: other
Media: water – soil
Method: other
Year:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

Type:
Media:
Method:
Year:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

3.3.2 Distribution

Media: air – biota – sediment(s) – soil – water
Method:
Year:
Source: AKW Kick GmbH Hirschau

Media:
Method:
Year:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

3.4 Mode of Degradation in Actual Use

Remark: ECC International states that Calcined China Clay is persistant and non–biodegradable but is not likely to have any long term adverse effect on the environment.
Source: ECC International Europe St Austell

Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.5 Biodegradation

Type:
Inoculum:
Method:
Year: **GLP:**
Test substance:
Remark: There is no quantitative information relating to this property for this substance, however general evidence suggests that it is essentially non–biodegradable.
Source: ECC International Europe St Austell

Type:
Inoculum:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.6 BOD5, COD or BOD5/COD Ratio

Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.7 Bioaccumulation

Species:
Exposure period:
Concentration:
BCF:
Elimination:
Method:
Year: **GLP:**
Test substance:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Species:
Exposure period:
Concentration:
BCF:
Elimination:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

3.8 Additional Remarks

Remark: Verhalten in der Umwelt ist vergleichbar mit silikatkeramischen Werkstoffen und Ziegeln.
Source: AKW Kick GmbH Hirschau

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: semistatic
Species: Oncorhynchus mykiss (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: >= 100
LC0: >= 100
LC50: > 100
LC100: > 100
Method: OECD Guide–line 203 "Fish, Acute Toxicity Test"
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Source: ECC International Europe St Austell

(10)

Type:
Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: >= 1
EC50: > 1
Method: OECD Guide–line 202, part 1 "Daphnia sp., Acute Immobilisation Test"
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Source: ECC International Europe St Austell
Test condition: 1.0mg/l was the highest test concentration that could be prepared due to the limited solubility of the test material in water. At concentrations in excess of 1.0mg/l, the test material was observed to settle out at the bottom of the test vessels. It was considered inappropriate to test at concentrations where a visible settlement of the test material was observed as physical effects may give rise to erroneous results.

(10)

Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: >= 100
EC50: > 100
Method: OECD Guide–line 201 "Algae, Growth Inhibition Test"
Year: **GLP:** yes
Test substance: as prescribed by 1.1 – 1.4
Source: ECC International Europe St Austell

(10)

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.4 Toxicity to Microorganisms e.g. Bacteria

Type:
Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: There is no analytical quantitative information relating to this property but it is not recognised as a significant feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: There is no quantitative information relating to this property for the substance under review.
Source: ECC International Europe St Austell

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: There is no quantitative information relating to this property for the substance under review.
Source: ECC International Europe St Austell

Species:
Endpoint:
Exposure period:
Unit: **Analytical monitoring:**
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

Type:
Species:
Endpoint:
Exposure period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: There is no analytical quantitative information relating to this property but it is not recognised as a significant feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species:
Endpoint:
Exposure period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.6.2 Toxicity to Terrestrial Plants

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: There is no analytical quantitative information relating to this property but it is not recognised as a significant feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: There is no analytical quantitative information relating to this property but it is not recognised as a significant feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Species:
Endpoint:
Expos. period:
Unit:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.7 Biological Effects Monitoring

Remark: We have no quantitative information relating to these attributes however in general experience they are not considered to be significant features of China clay.
Source: ECC International Europe St Austell

Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.8 Biotransformation and Kinetics

Type:
Remark: There is no information regarding this property for the substance under review.
Source: ECC International Europe St Austell

Type:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

4.9 Additional Remarks

Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex:
Number of Animals:
Vehicle:
Value: > 2000 mg/kg bw
Method: OECD Guide-line 401 "Acute Oral Toxicity"
Year: **GLP:**
Test substance:
Source: Lehmann & Voss & Co. Hamburg

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.1.2 Acute Inhalation Toxicity

Type: other
Species: human
Sex:
Number of Animals:
Vehicle:
Exposure time:
Value:
Method:
Year: **GLP:**
Test substance:
Source: AKW Kick GmbH Hirschau

(11)

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Exposure time:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: RE1 gives a full citation list of available information on this topic.
Source: ECC International Europe St Austell

(4)

5.1.3 Acute Dermal Toxicity

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.1.4 Acute Toxicity, other Routes

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Route of admin.:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species:
Sex:
Number of Animals:
Vehicle:
Route of admin.:
Value:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: human
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result: not irritating
EC classificat.: not irritating
Method: Estimation
Year: **GLP:** no
Test substance: no data
Source: AKW Kick GmbH Hirschau

Species:
Concentration:

Exposure:
Exposure Time:
Number of Animals:
PDII:
Result:
EC classificat.:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute however, although the substance may be marginally abrasive, in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

5.2.2 Eye Irritation

Species: human
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result: slightly irritating
EC classificat.: not irritating
Method: other: historisch
Year: **GLP:** no
Test substance: no data
Source: AKW Kick GmbH Hirschau

Species:
Concentration:
Dose:
Exposure Time:
Comment:
Number of Animals:
Result:
EC classificat.:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience, beyond physical entry of a foreign body into the eye, it is not a recognisedfeature of Calcined kaolin.
Source: ECC International Europe St Austell

5.3 Sensitization

Type: no data
Species: human
Number of Animals:
Vehicle:
Result: not sensitizing
Classification: not sensitizing
Method: other
Year: **GLP:** no
Test substance: no data
Source: AKW Kick GmbH Hirschau

Type:
Species:
Number of Animals:
Vehicle:
Result:
Classification:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

5.4 Repeated Dose Toxicity

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: RE1 gives a full citation list of available information on this topic.
Source: ECC International Europe St Austell

(12)

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.5 Genetic Toxicity 'in Vitro'

Type:
System of testing:
Concentration:
Metabolic activation:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: RE1 gives a full citation list of available information on this topic.
We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

(4)

Type:
System of testing:
Concentration:
Metabolic activation:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.6 Genetic Toxicity 'in Vivo'

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Doses:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Doses:
Result:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.7 Carcinogenicity

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Result:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Post. obs. period:
Doses:
Result:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.8 Toxicity to Reproduction

Type: other: nicht zutreffend
Species: **Sex:**
Strain:
Route of admin.:
Exposure Period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Source: AKW Kick GmbH Hirschau

Type:
Species: **Sex:**
Strain:
Route of admin.:
Exposure Period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute, however in general experience it is not a recognised feature associated with Calcined kaolin.
Source: ECC International Europe St Austell

5.9 Developmental Toxicity/Teratogenicity

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: We have no quantitative information relating to this attribute for Calcined kaolin.
Source: ECC International Europe St Austell

Species: **Sex:**
Strain:
Route of admin.:
Exposure period:
Frequency of treatment:
Duration of test:
Doses:
Control Group:
Method:
Year: **GLP:**
Test substance:
Remark: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.10 Other Relevant Information

Type: other: nicht zutreffend
Source: AKW Kick GmbH Hirschau

5.11 Experience with Human Exposure

Remark: RE1 gives a full citation list of all available information on this topic.
Source: ECC International Europe St Austell

(4)

Remark: siehe Literaturzitat unter 5.1.2
Source: AKW Kick GmbH Hirschau

(1) TRGS 900 von 4/1995

(2) EH40/94 Occupational exposure limits 1994 – UK Health and Safety Executive ISBN 0-7176-0722-4.

(3) Kaolin criteria document for an exposure limit – UK Health and Safety Executive ISBN 0-7176-0762-3.

(4) Kaolin Criteria Document for an Occupational Exposure Limit – UK Health and Safety Executive ISBN 0-7176-0762-3.

(5) Keramik (Teil 1),
Salmang-Scholze;
6. Auflage, Springer-Verlag, 1982, S. 215-221

(6) Sintervorgänge bei Kaolinen und Tonen,
H. Kromer, K. H. Schüller;
N. Jb. Miner. Abh., 122 (1974), S. 145-185

(7) AKW GmbH, Hirschau, Sicherheitsdatenblatt Hydrite R (04.02.1994)

(8) StoerfallVO vom 20.09.1991

(9) ECC International European Technical Report 9407/1 – Ecotoxicity of ECCI products (1994).

(10) ECC International European Technical Report 9407/1 – Ecotoxicity and ECCI Products (1994)

(11) Konietzko, Dupuis – Handbuch der Arbeitsmedizin
IV – 5.2.4 Kaolinlunge
(ecomed Verlag, Landsberg, Lech)

(12) Kaolin Criteria Document for an Occupational Exposure Limit – UK Health and Safety Executive ISBN 2-7176-0762-3.

7.1 Risk Assessment

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Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public Release Summary

on the evaluation of the new active calcined kaolin in the product Surround WP Crop Protectant

APVMA product number 89894

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This publication is available from the APVMA website.

Contents

List of tables

Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator responsible for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia. Before approving an active constituent and/or registering a product, the APVMA must be satisfied that the statutory criteria, including the safety, efficacy, trade, and labelling criteria, have been met. The information and technical data required by the APVMA to assess the statutory criteria of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined on the APVMA website.

The APVMA has a policy of encouraging transparency in its activities and seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents. This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from advisory agencies, including other Australian Government agencies and State departments of primary industries. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience to encourage public comment.

About this document

This Public Release Summary indicates that the APVMA is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Comment is sought from interested stakeholders on the information contained within this document.

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of the active calcined kaolin and registration of the product Surround WP Crop Protectant should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the application. These matters include aspects of public health, occupational health and safety, chemistry and manufacture, residues in food, environmental safety, trade, and efficacy and target crop or animal safety. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 26 July 2022 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)
- email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Case Management Team – Pesticides

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

Phone: +61 2 6770 2300

Email: casemanagement@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Copies of technical evaluation reports covering chemistry, efficacy and safety, toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request.

Further information on Public Release Summaries can be found on the APVMA website.

Introduction

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Surround WP Crop Protectant, and approval of the new active constituent, calcined kaolin.

Applicant

Tessenderlo Kerley, inc.

Purpose of application

Tessenderlo Kerley, inc has applied to the APVMA for registration of the new product Surround WP Crop Protectant, containing 950 g/kg, as a wettable powder formulation, of the new active constituent, calcined kaolin.

Proposed claims and use pattern

The proposed product Surround WP Crop Protectant is intended for repellency of citrus gall wasp in citrus.

Mode of action

Surround WP Crop Protectant acts by forming a particle film on the crop that repels citrus gall wasp in citrus.

Overseas registrations

The product Surround WP Crop Protectant is currently registered in USA, Canada, Spain, France, Switzerland, and Greece for use as an insect repellent.

Chemistry and manufacture

Active constituent

The active constituent, calcined kaolin, is manufactured overseas. Details of the chemical name, structure, and physicochemical properties of calcined kaolin are listed below (Tables 1 to 2).

Calcined kaolin is a white solid. It is insoluble in water and there are no flammable, explosive, self-igniting, and/or oxidizing properties of safety concern for calcined kaolin.

Table 1: Nomenclature and structural formula of the active constituent calcined kaolin

Common name (ISO):	Calcined kaolin
IUPAC name:	Dialuminium(3+) [(trioxidosilyl)oxy]silanetris(olate)
CAS registry number:	92704-41-1
Empirical formula:	Al2Si2O7
Molecular weight:	N/A due to its 2-dimensional structure and covalent bonding
Structural formula:	N/A

Table 2: Key physicochemical properties of the active constituent calcined kaolin

Physical form:	Powder
Colour:	White
Odour:	Odourless
Melting point:	Does not melt
Boiling point:	Does not boil
Bulk density:	288.3 kg/m3
Safety properties:	Not flammable. Not explosive. Not oxidising.
Solubility in water:	Insoluble
Organic solvent solubility:	Insoluble

Formulated product

The product Surround WP Crop Protectant will be manufactured overseas. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product.

Surround WP Crop Protectant will be available in 12.5 kg 3-ply paper bags.

Table 3: Key aspects of the formulation of the product Surround WP Crop Protectant

Distinguishing name:	Surround WP Crop Protectant
Formulation type:	Wettable powder (WP)
Active constituent concentration:	950 g/kg calcined kaolin

Table 4: Physicochemical properties of the product Surround WP Crop Protectant

Physical form:	White powder
pH (1% dilution):	5.35
Specific gravity/density:	0.32 g/cm3
Wettability:	12 seconds
Persistent foaming:	5 mL at 1 minute
Suspensibility:	39.9% at 2% suspension 62.16% at 3% suspension 82.8% and 90.10% at 5% suspension
Spontaneity of dispersion:	Surround WP Crop Protectant will spontaneously disperse in water due to both the nature of calcined kaolin and the presence of adjuvants
Wet sieve test:	0.0660% retained on a 75 µm sieve
Safety properties:	Not flammable, not explosive, not oxidising, no auto-flammability properties
Storage stability:	There were sufficient data to conclude that the product is expected to remain within specifications for at least 2 years when stored under normal conditions

Recommendations

The APVMA Chemistry section has evaluated the chemistry of the active constituent, calcined kaolin, and associated product Surround WP Crop Protectant including the manufacturing process, quality control procedures, stability, batch analysis results, and analytical methods, and found them to be acceptable. The available storage stability data indicate that the formulated product is expected to remain stable for at least 2 years when stored under normal conditions.

Based on a review of the chemistry and manufacturing details, the registration of Surround WP Crop Protectant and approval of the active constituent calcined kaolin, are supported from a chemistry perspective.

Toxicological assessment

A limited data set was submitted by the applicant to facilitate assessment of the toxicity of kaolin. Calcined kaolin is insoluble in both water and organic media, indicating that it cannot be absorbed from the gastrointestinal tract to achieve systemic exposure. It is therefore expected to represent a low risk to health so studies on absorption, distribution, metabolism and excretion, short-term, sub-chronic, and chronic toxicity (including carcinogenicity), genotoxicity, reproduction, and developmental toxicity were not required.

Evaluation of toxicology

Chemical class

Calcined kaolin is a phyllosilicate. It is a natural inorganic mineral (aluminium silicate) that has been heated to a temperature just below its fusing point (~450 to 800°C).

Pharmacokinetics

No studies were required for assessment, based on the physico-chemical properties of calcined kaolin.

Acute toxicity (active constituent)

Calcined kaolin has low acute oral, dermal, and inhalational toxicity. In keeping with its mineral properties, calcined kaolin clay was neither irritating to the skin of rabbits, nor sensitising to the skin in guinea pigs. However, calcined kaolin clay was considered to induce some slight eye irritation, based on its mineral-based abrasive property (i.e. as grit).

Acute toxicity (product)

The product, Surround WP Crop Protectant, is considered to have low acute oral, dermal, and inhalational toxicity. It is neither irritating nor sensitising to the skin but is a slight eye irritant.

Repeat-dose toxicity

No studies available for assessment.

Chronic toxicity and carcinogenicity

No studies available for assessment.

Reproductive and developmental toxicity

No studies available for assessment.

Genotoxicity

No studies available for assessment.

Neurotoxicity/immunotoxicity

No studies available for assessment.

Mode of action (toxicology)

As calcined kaolin is not absorbed, and there is no systemic exposure, a mode of action is not relevant.

Toxicity of metabolites and/or impurities

No impurities of toxicological concern were identified.

Reports related to human toxicity

Interstitial fibrosis of the lungs has been reported in mine workers involved in kaolin production, and a higher incidence of pneumoconiosis was observed among china clay workers exposed to very dusty working conditions.

Health-based guidance values and poisons scheduling

Poisons Standard

Calcined kaolin is captured by the existing listing for kaolin. Kaolin is included in Appendix B of the SUSMP, as a substance not requiring control by scheduling.

Health-based guidance values

Calcined kaolin is insoluble in all aqueous and organic solvents that are physiologically relevant, indicating that it cannot be absorbed from the gastro-intestinal tract to achieve systemic exposure following oral, dermal, or inhalational exposure. For this reason, no acceptable daily intake (ADI) or acute reference dose (ARfD) have been proposed by the APVMA and the establishment of a maximum residue limit (MRL) is considered to be unnecessary (see next section).

Recommendations

There are no objections on human health grounds to the approval of calcined kaolin.

There are no objections on human health grounds to the registration of the product, Surround WP Crop Protectant, containing 950 g/L of calcined kaolin, when the product is used in accordance with the directions on the label.

Residues assessment

Metabolism

No metabolism data have been provided for calcined kaolin. Calcined kaolin is derived from aluminium silicate, which is ubiquitous within the environment and naturally occurring within soil. It is chemically inert, not metabolised into other compounds, and insoluble in water; therefore, it is not taken up and translocated by plants. On this basis, metabolism data were not required, and a residues definition has not been established.

Analytical methods and storage stability

No analytical methods for determination of calcined kaolin in crops have been provided or are required for this naturally occurring material. Aluminium silicate, the compound from which calcined kaolin is derived, is a natural component of soil and therefore cannot be distinguished from existing clays, either in the soil or as an air born dust. It cannot be analysed by conventional chromatographic techniques.

Residues in food and animal feeds

Calcined kaolin is an inorganic mineral compound and is highly unlikely to be absorbed into foliar surfaces or translocate within plant systems as it is insoluble in water and all organic solvents. Given the nature and properties of calcined kaolin, residue studies were not considered necessary to establish the residue risks in food and animal feeds.

The US FDA has granted kaolin GRAS status (generally recognized as safe) when used in human food. Kaolin is an approved packaging ingredient for dry food, anti-caking agent in foods and also present in toiletries such as toothpaste, antiperspirants and various cosmetics. In addition to being an active ingredient itself, kaolin is also an inert ingredient in other pesticide products.

A study concluded that when Surround WP (57 g ai/L spray) was applied before fruit set on blueberries, no significant residue is left on the fruit. When applied to crops, kaolin leaves a white deposit on the surface that is easily removed by gentle rubbing and washing, a normal procedure before marketing and/or consuming any foodstuff treated with kaolin.

Table 5 of the MRL Standard lists uses of substances where MRLs are not necessary. MRLs are not necessary in situations where residues do not, or should not, occur in foods or animal feeds; where the residues are identical to or indistinguishable from natural food components; or where the residues are otherwise of no toxicological significance. A Table 5 entry in the MRL Standard is appropriate to cover the proposed use of calcined kaolin as its residues are indistinguishable from natural sources and are not of toxicological significance.

Residues in animal commodities

The active constituent of the product is derived from aluminium silicate which is ubiquitous in the environment and occurs naturally within the soil. Calcined kaolin is chemically inert, not bioavailable and not metabolised in mammals. It is not necessary to establish animal commodity MRLs for this constituent.

Dietary risk assessment

Health-based guidance values are considered unnecessary for calcined kaolin. For this reason and because expected residues are indistinguishable from natural sources, the use of this compound on food crops does not introduce a hazard to consumers of food crops treated with the proposed product and it is not necessary to undertake a dietary exposure assessment.

Recommendations

The following amendments are required to be made to the APVMA MRL Standard (Table 5).

Table 5: Amendments to the APVMA MRL Standard

Amendments to Table 5	
Substance	**Use**
Add:	
Calcined kaolin	For use in agricultural situations

Assessment of overseas trade aspects of residues in food

Citrus fruits are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated citrus.

It is recommended that a Table 5 entry be established to cover the proposed use in Australia as MRLs are not considered necessary. This is consistent with the decisions made in the European Union (No MRL required) and the United States of America (exempt from the requirements of an MRL).

Noting that the active constituent is derived from aluminium silicate which is ubiquitous within the environment and occurs naturally within the soil and that residues would be indistinguishable from background amounts of mineral materials, it is deemed that the proposed use is not expected to present a risk to international trade.

Work health and safety assessment

Health hazards

The product, Surround WP Crop Protectant, is considered to have low acute oral, dermal, and inhalational toxicity. It is neither irritating, nor sensitising to the skin, but is a slight eye irritant.

Calcined kaolin is insoluble in both water and organic media, indicating that it cannot be absorbed from the gastro-intestinal tract and achieve systemic exposure.

Occupational exposure

Exposure during use

Surround WP Crop Protectant is a wettable powder preparation containing 950 g/kg kaolin. Following application, the product forms a barrier film that acts as a repellent for citrus gall wasp. It is applied at a rate of 2.5 to 5.0 kg per 100 L water, with thorough coverage required to successfully inhibit gall wasp activity.

No systemic exposure is expected following oral or dermal exposure from the use of the product. Although there is no direct evidence of any inflammatory effects following long-term inhalation of calcined kaolin, it is recommended that inhalation of the spray mist is avoided when using the product.

Exposure during re-entry or rehandling

Post-application exposure is not expected to occur.

Public exposure

Surround WP Crop Protectant is not intended for use by the general public, or in areas accessible by the general public. Due to the physiochemical properties of kaolin, the health risk arising from potential post-application, or bystander exposure is very low.

Recommendations

The following first aid instructions, safety directions, and precautionary (warning) statements are recommended for the product label.

First aid instructions

First aid is not generally required. If in doubt, contact a Poisons Information Centre (phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.

Safety directions

May irritate the eyes. Avoid contact with eyes. Do not inhale spray mist. Wash hands after use.

Precautionary (warning) statements

Restraints/restrictions: DO NOT allow bystanders to come into contact with the spray cloud.

Environmental assessment

Fate and behaviour in the environment

Calcined kaolin is a stable inorganic compound. Its chemical composition is similar to common clay. It is insoluble, known to be inert to mineral acids and bases, and not to be affected by photolytic processes under natural light. Since kaolin is a non-degradable natural component of the environment, no environmental fate data were required.

Effects and associated risks to non-target species

Terrestrial vertebrates

Calcined kaolin has low toxicity to mammals (LD_{50} >5000 mg a.c./kg bw, *Rattus norvegicus*). No observed teratogenic effects were observed in rats fed a diet consisting of 20% kaolin prior to fertilization and during the gestation period. No data are available on toxicity of calcined kaolin to birds.

Calcined kaolin is a natural component of the environment and terrestrial vertebrates have been routinely exposed to kaolin in the soil. Many wild mammals are known to eat soil dwelling earthworms and insects that contain a large amount of soil (including clay) and to take dirt or mud baths for either body cooling or parasite control reasons. Many birds are known to take clay dust baths to help reduce dermal parasites but some birds like the Macaw have even been observed to eat kaolin for the purpose of aiding their digestive systems. Also, terrestrial vertebrates that eat earthworms and other soil dwelling invertebrates, routinely consume large quantities of soil (hence clay) adhering to the prey and present in their digestive tracts.

Based on the available information, risks of the proposed use of Surround WP Crop Protectant to terrestrial vertebrates are considered to be acceptable and no protection statements are required.

Aquatic species

Calcined kaolin has low toxicity to fish (lowest LC_{50} 170 mg a.c./L, *Parapristipoma trilineatum* larvae), aquatic invertebrates (EC_{50} >570 mg a.c./L, *Daphnia magna*), and algae (EC_{50} >570 mg a.c./L, *Scendesmus subspicatus*). Following long-term exposure, reduced survival and growth of fish larvae was observed at concentrations as low as 300 mg a.c./L (NOEC 100 mg a.c./L, *Oncorhynchus mykiss*).

The quantity of kaolin entering surface waters and sediments from the use of Surround WP Crop Protectant are negligible compared with those present from natural sources. Kaolin is present in most water bodies across the world, either as sediment or as suspended particles. Kaolin is insoluble in all organic liquids, water and non-bioavailable to aquatic organisms. Kaolin 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 or reservoirs. However, the amount of kaolin 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 kaolin as an agricultural product.

Based on the available information, risks of the proposed use of Surround WP Crop Protectant to aquatic species are considered to be acceptable. Only the standard protection statement for agricultural products as per the Agricultural Labelling Code is considered to be necessary (DO NOT contaminate wetlands or watercourses with this product or used containers).

Bees and other non-target arthropods

Calcined clay has low toxicity to adult bees following contact exposure (LD_{50} >100 µg a.c./bee, *Apis mellifera*) and oral exposure (LD_{50} >1900 µg a.c./bee, *Apis mellifera*), and has low toxicity to bee larvae (LD_{50} >150 µg a.c./bee, *Apis mellifera*). Following long-term dietary exposure, significant mortality of adult bees was observed at doses as low as 1103 µg a.c./bee/d (NOEL 660 µg a.c./bee/d, *Apis mellifera*), while no adverse effects were observed in bee larvae at the highest tested dose (NOEL 150 µg a.c./bee, *Apis mellifera*).

Because kaolin acts through physical repellence of insects, field studies have been conducted to investigate any effects on the numbers and behaviour of bees foraging treated orchards. These studies in flowering pear and apple orchards demonstrated that the application of a kaolin particle film at 56 kg/ha did not have adverse effects on foraging bee numbers, or their behaviour.

The mode of action of Surround WP Crop Protectant (repellent particle film) renders it unsuitable for conducting meaningful laboratory or semi-field tests on beneficial arthropods. Published laboratory and extended laboratory studies on green lacewing (*Chrysoperla carnea*), predatory bug (*Anthocoris nemoralis*) and Malaysian ladybird beetle (*Chilocorus nigritus*) indicate no adverse effects at the highest rates tested (LR_{50} >48 kg a.c./ha, ER_{50} >48 kg a.c./ha).

Results from 12 field studies conducted in orchards across Europe and North America demonstrate that Surround WP Crop Protectant is not harmful to many groups of beneficials, including lacewings *(chrysoperlids)*, ladybirds *(coccinellids)*, hoverflies *(syrphids)*, some heteropteran bugs (e.g. *mirids*), parasitic hymenopterans and spiders. However, in some trials a reduction in predatory mites (*Amblyseius*) and anthocorid bugs was noted. It is extremely unlikely that these effects are a result of any direct mortality effects, but they are more probably associated with the repellent nature of the particle film causing the predators to avoid the treated areas, and/or the removal of prey in the form of repelled insect pests.

Based on the available information, risks of the proposed use of Surround WP Crop Protectant to bees and other non-target arthropods are considered to be acceptable and no protection statements are required.

Soil organisms

No studies are available on the effects of calcined kaolin on soil organisms. The quantity of kaolin deposited on soil from the use of Surround WP Crop Protectant is negligible compared with that present from natural sources. Kaolin is a natural inert mineral present in most soils across the world. Soil organisms are constantly exposed to natural clay, including kaolin. Surround WP Crop Protectant will mix with, behave in an identical manner to, and immediately become indistinguishable from, naturally present clay. Therefore, risks of the proposed use of Surround WP Crop Protectant to soil organisms are considered to be acceptable and no protection statements are required.

Non-target terrestrial plants

No studies are available on the effects of calcined kaolin on non-target terrestrial plants. Kaolin is a natural, inert mineral present in most soils and water bodies across the world. The crop safety evaluation noted a long history of safe use with no reports of crop safety issues in Australia or overseas. Based on the available information, risks of the proposed use of Surround WP Crop Protectant to non-target terrestrial plants are considered to be acceptable and no protection statements are required.

Recommendations

In considering the environmental safety of the proposed use of Surround WP Crop Protectant, the APVMA had regard to the toxicity of the active constituent in relation to relevant organisms and ecosystems. Based on the available information, the APVMA can be satisfied that the proposed use of the product is unlikely to have an unintended effect that is harmful to animals, plants or things or to the environment.

Efficacy and safety assessment

Proposed product use pattern

Surround WP Crop Protectant containing 950 g/kg calcined kaolin is proposed for use as a repellent to citrus gall wasp (CGW) in citrus crops.

Efficacy and target crop safety

Efficacy

The efficacy data included in this application include Australian and overseas trials to support the registration of Surround WP Crop Protectant for use as a repellent in controlling citrus gall wasp in citrus crops in Australia.

Three Australian replicated field trials were conducted to collect efficacy data for Surround WP Crop Protectant to demonstrate CGW control in oranges (4 sites) and grapefruit (one site). Two applications of Surround WP Crop Protectant were made at a total rate of 7.5 kg/100 L and compared with untreated controls. Surround WP Crop Protectant demonstrated strong repellency against the adult wasps in all 3 trials relative to the untreated controls.

Additionally, Surround WP Crop Protectant treatments were included in pot trials which demonstrated repellency of adult wasps after a double application of 2.5 kg/100 L on the first day of the trial.

Thus, the data provided demonstrated efficacy of Surround WP Crop Protectant in the repellency of CGW in citrus. The label recommendations, such as the first application prior to or during CGW emergence are appropriate and reflect the results of the trials.

Crop safety

Surround WP Crop Protectant has been used by citrus growers in Australia for many years to minimize sunburn and heat stress. The proposed applications of Surround WP Crop Protectant for CGW repellency are at similar rates to current uses. There have been no reports of crop safety issues on citrus trees or on other trees and vines. In addition, no signs of phytotoxicity were observed in the commercial efficacy trials supplied.

Additionally, 2 international research papers were provided that support the crop safety of Surround WP Crop Protectant on citrus trees. Thus, the information provided support the crop safety of Surround WP Crop Protectant when used in citrus trees.

Recommendations

Based on the data provided, Surround WP Crop Protectant will be efficacious and safe when used according to the proposed label recommendations. Thus, the registration of Surround WP Crop Protectant for use as a repellent to citrus gall wasp (CGW) in citrus crops is supported.

Labelling requirements

Surround® WP Crop Protectant

Surround WP forms a barrier film, which acts as a repellent for citrus gall wasp.

Active constituent: 950 g/kg calcined kaolin

Net Contents: 12.5 kg

Directions for use:

Use for repellence of citrus gall wasp:

Crop	Pest	Rate	Comments
Citrus	Citrus Gall Wasp	Initial application: 5.0 kg/100 L Subsequent applications: 2.5 kg/100 L	Apply to new growth prior to emergence of adult citrus gall wasps. Apply initial application at full rate and a subsequent application at half rate at no more than a 7 to 10-day interval, before adult wasp emergence. Further applications should be made immediately if coverage is degraded by rain or other events; such applications may be at half rates provided that water volume is not reduced. A visual inspection of film deposition after spray has dried is crucial to ensure completeness of coverage. Uniformity of coverage is essential and may be improved especially on hard to wet foliage and new growth by the addition of an approved non-ionic adjuvant or silicone-based adjuvant, such as Du-Wett®. Read the adjuvant label thoroughly in order to determine the appropriate adjuvant use rate and volume of water.

Not to be used for any purpose, or in any manner, contrary to this label unless authorised under appropriate legislation.

Withholding period: Not required when used as directed

Protection of wildlife, fish, crustaceans and environment: DO NOT contaminate streams, rivers or watercourses with this product or used containers.

Storage and disposal: Store in a dry, sheltered location. Product is slippery when wet. In case of spill or leak, avoid breathing dust, clean up and dispose of in compliance with relevant local, state or territory government regulations.

Shake and empty contents into spray tank. Do not dispose of undiluted chemicals on site. Break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in

compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

Safety directions: May irritate the eyes. Avoid contact with eyes. Do not inhale spray mist. Wash hands after use.

First aid: If in eyes, hold eyes open and flood gently with water.

First aid is not generally required. If in doubt, contact a Poisons Information Centre (phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.

Precaution: DO NOT allow bystanders to come into contact with the spray cloud.

Acronyms and abbreviations

Shortened term	Full term
a.c.	Active constituent
ADI	Acceptable daily intake (for humans)
a.i.	Active ingredient
ARfD	Acute reference dose
bw	Bodyweight
d	Day
DAT	Days after treatment
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
EC_{50}	Concentration at which 50% of the test population are immobilised
ErC_{50}	Concentration at which the rate of growth of 50% of the test population is impacted
EI	Export interval
EGI	Export grazing interval
ESI	Export slaughter interval
g	Gram
GAP	Good agricultural practice
h	Hour
ha	Hectare
IPM	Integrated pest management
in vitro	Outside the living body and in an artificial environment
in vivo	Inside the living body of a plant or animal
kg	Kilogram
L	Litre
LC_{50}	Concentration that kills 50% of the test population of organisms
LD_{50}	Dosage of chemical that kills 50% of the test population of organisms

Shortened term	Full term
LOD	Limit of detection – level at which residues can be detected
Log K_{OW}	Log to base 10 of octanol water partitioning co-efficient, synonym POW
LOQ	Limit of quantitation – level at which residues can be quantified
mg	Milligram
mL	Millilitre
MRL	Maximum residue limit
MSDS	Material safety data sheet
NEDI	National estimated daily intake
NESTI	National estimated short-term intake
ng	Nanogram
NOEC/NOEL	No observable effect concentration level
NOAEL	No observed adverse effect level
ppb	Parts per billion
PPE	Personal protective equipment
ppm	Parts per million
Q-value	Quotient-value
REI	Re-entry interval
s	Second
SC	Suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
µg	Microgram
WHP	Withholding period

Glossary

Term	Description
Active constituent	The substance that is primarily responsible for the effect produced by a chemical product
Acute	Having rapid onset and of short duration
Carcinogenicity	The ability to cause cancer
Chronic	Of long duration
Codex MRL	Internationally published standard maximum residue limit
Desorption	Removal of a material from or through a surface
Efficacy	Production of the desired effect
Formulation	A combination of both active and inactive constituents to form the end use product
Genotoxicity	The ability to damage genetic material
Hydrophobic	Repels water
Metabolism	The chemical processes that maintain living organisms
Photolysis	Breakdown of chemicals due to the action of light
Toxicology	The study of the nature and effects of poisons

References

Australian Pesticides and Veterinary Medicines Authority, *Spray drift risk assessment tool*, APVMA website, 19 July 2019, accessed 2 May 2022.

Australian Pesticides and Veterinary Medicines Authority, *Data guidelines*, APVMA website, 28 April 2022, accessed 2 May 2022.

World Health Organisation, *Evaluation of certain food additives and contaminants, 80th report of the Joint FAO/WHO Expert Committee on Food Additives*, WHO website, 2016, accessed: 2 May 2022

European Commission

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

Aluminium silicate Calcined (Kaolin Calcined)

Volume 1

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

May 2020

Version History

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

Table of contents

Level 1

Aluminium silicate Calcined

1 Statement of subject matter and purpose for which this report has been prepared and background information on the application

1.1 Context in which the renewal assessment report was prepared

1.1.1 Purpose for which the renewal assessment report was prepared

The Renewal Assessment Report (RAR) has been prepared for the renewal of approval of the active substance "aluminium silicate" renamed to "aluminium silicate calcined", under Reg. (EC) No 1107/2009, in accordance with Commission Regulation (EC) No 844/2012 and Guidance Document SANCO/2012/11251 rev. 4 in order to re-evaluate the dossier submitted by the notifiers Tessenderlo Group N.V. and Société Kaolinière Armoricaine (SOKA).

1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State

For the first Annex I inclusion of aluminium silicate Hungary was the RMS. For the renewal of its approval, RMS is Greece with co-RMS France.

1.1.3 EU Regulatory history for use in plant protection products

The existing chemical active substance Aluminium silicate (kaolin) was included first into Annex I of Directive 91/414/EEC on 1st September 2009 (Directive 2008/127/EC of 18 December 2008).

- With Commission Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances, aluminium silicate (kaolin) was included in the list of approved active substances according to Regulation (EC) No 1107/2009.

- Commission Implementing Regulation (EU) No 571/2012 amended Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance aluminium sili-cate, reporting the following:

PART A: Only uses as repellent may be authorised.

PART B: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium silicate (SANCO/2603/08) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the operator safety; conditions of use shall include the application of adequate personal and respiratory protective equipment, where appropriate.

Conditions of use shall include, where appropriate, risk mitigation measures.

The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards:

(a) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data;

(b) the relevance of the test material used in the toxicity dossier in view of the specification of the technical material. The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 May 2013.'

- In 2014 EFSA published a Technical Report on "Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance aluminium silicate" EFSA supporting publication 2014: EN-625.

- The latest Review report for the active substance aluminium silicate is SANCO/2603/08 – rev. 3, 11 July 2014

- The approval of aluminium silicate is set to expire on 31 August 2020 according to Commission Implementing Regulation (EU) 2017/195 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).

1.1.4 Evaluations carried out under other regulatory contexts

For aluminium silicate calcined CAS No 92704-41-1, referred as Kaolin, calcined, the following are included in the "Substance information" available at the ECHA website (https://echa.europa.eu/substance-information/-/substanceinfo/100.087.663):

Hazard classification & labelling

According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified.

About this substance

This substance is manufactured and/or imported in the European Economic Area in 10 000+ tonnes per year. This substance is used at industrial sites.

Consumer Uses

ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment.

Widespread uses by professional workers

ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the types of manufacture using this substance. ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment.

Uses at industrial sites

This substance is used in the following products: pH regulators and water treatment products and laboratory chemicals.

This substance is used in the following areas: formulation of mixtures and/or re-packaging.

This substance is used for the manufacture of chemicals.

Release to the environment of this substance can occur from industrial use: in processing aids at industrial sites, as an intermediate step in further manufacturing of another substance (use of intermediates) and as processing aid.

In the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation) Registered substances factsheets[1], there are no toxicity studies with the compound itself. Instead, the assessment of selected end-points is based on read-across from "Kaolin clay" that is considered to be a supporting substance (structural analogue or surrogate). It is noted however that the registration dossier concerns a UVCB substance and the relevance of these data for aluminium silicate calcined is considered questionable.

[1] https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/13356/7/2/2

1.2 Applicant(s) information

1.2.1 Name and address of applicant(s) for approval of the active substance

1) Tessenderlo:

Name: Tessenderlo Chemie
Address: Belgium (Details in Vol 3 CP – 1 Tessenderlo)

2) SOKA

Name: Société Kaolinière Armoricaine (SOKA)
Address: France (Details in Vol 3 CP – 1 SOKA)

1.2.2 Producer or producers of the active substance

1) Tessenderlo:

Company: BASF Corporation (USA)

2) SOKA

Company: Société Kaolinière Armoricaine (SOKA) (France)

1.2.3 Information relating to the collective provision of dossiers

Not relevant.

1.3 Identity of the active substance

B.1.1.1.	**Common name proposed or ISO-accepted and synonyms**	Kaolin calcined (aluminium silicate calcined)
B.1.1.2.	**Chemical name (IUPAC and CA nomenclature)**	
	IUPAC	Not available
	CA	Kaolin
B.1.1.3.	**Producer's development code number**	**TESSENDERLO:** M99SP1, M-96-018, M-97-009, **SOKA:** SOKALCIARBO WP, SOKALCIARBO, BAIKAL WP

B.1.1.4. CAS, EC and CIPAC numbers	
CAS	92704-41-1
EC	296-473-8
CIPAC	841
B.1.1.5. Molecular and structural formula, molecular mass	
Molecular formula	$Al_4Si_4O_{14}$ Note: A single molecule cannot exist
Structural formula	Not available
Molecular mass	Not applicable
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	Confidential information. Please refer to Vol. 4
B.1.1.7. Specification of purity of the active substance in g/kg	Tessenderlo: 999.0 g/kg minimum SOKA: Open
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	
B.1.1.8.1. Additives	Confidential information. Please refer to Vol. 4
B.1.1.8.2. Significant impurities	Confidential information. Please refer to Vol. 4
B.1.1.8.3. Relevant impurities	

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

	line silica (< 10 µm)		
B.1.1.9. Analytical profile of batches	Confidential information. Please refer to Vol. 4		

Discussion on CAS and EINECS Numbers by Tessenderlo :
At the request of the RMS (EL), the CAS and EEC numbers of the active substance are being modified to avoid confusion with kaolin (hydrous).
However, the Notifier wishes to indicate that the requested CAS number (92704-41-1, EEC number 296-473-8) does not correctly describe the active substance presented herewith. Moreover, the substance description presented in the ECHA Infocard for CAS number 92704-41-1 is incorrect and misleading as it presents a non-covalent substance susceptible to ionization, which is not the case for calcined kaolin, a covalently bound two-layered phyllosilicate that is insoluble in any solvents and stable over geological timescales (i.e. millions of years).

RMS, EL taking into consideration that the active substance already approved with the name "Aluminium Silicate", and now under consideration for renewal, concerns the calcined aluminium silicate (anhydrous/amorphous aluminium silicate) as declared by both Notifiers (Tessenderlo and SOKA), is of the opinion that the CAS No (1332-58-7) and EC No (310-194-1) used in DAR (2008 & 2011, HU) which refer to the hydrous aluminium silicate should not be maintained in the framework of the renewal.

Molecular formula
It is noted that the molecular formula presented in dRAR for aluminium silicate is $Al_4Si_4O_{14}$ with the note that "A single molecule cannot exist" as it was in DAR as well. In the ECHA Infocard for CAS number 92704-41-1 the molecular formula is $Al_2O_7Si_2$ which uses the half numbers of the individual atoms comparing to the molecular formula used in dRAR. EL considers that the molecular formula is indicative of the kinds of the atoms that constitute the active substance in a specific ratio which is the same in both cases.

1.4 Information on the plant protection product

The representative formulation during the previous EU review of active substance aluminium silicate was "SURROUND® WP CROP PROTECTANT" a wettable powder (WP) formulation containing 950 g/kg aluminium silicate supported by Tessenderlo Chemie NV.
For the renewal of the active substance the same representative formulation "SURROUND® WP CROP PROTECTANT" has been supported by Tessenderlo plus another one "SOKALCIARBO WP" supported by notifier SOKA.

1.4.1 Applicant

TESSENDERLO
Tessenderlo Chemie
Belgium (Details in Vol 3 CP – 1 Tessenderlo)

SOKA
Société Kaolinière Armoricaine (SOKA)
France (Details in Vol 3 CP – 1 SOKA)

1.4.2 Producer of plant protection product

TESSENDERLO
1) Seapac, Inc.
2) Tessenderlo Kerley Inc
(Details in Vol 3 CP – 1 Tessenderlo)

SOKA
Société Kaolinière Armoricaine (SOKA)
(Details in Vol 3 CP – 1 SOKA)

1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product

TESSENDERLO
Trade name: SURROUND® WP CROP PROTECTANT
Company code number: None

SOKA
Code number: SOKALCIARBO WP; SOKALCIARBO; BAIKAL WP

1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product

1.4.4.1 Composition of the plant protection product

1) TESSENDERLO - SURROUND WP

Pure active substance

content of pure active substance:	**950 g / l**	**(95.0 % w / w)**
limits:	925-975 g/kg	92.5-97.5%

Technical active substance

content of technical active substance:	**950.2 g/kg**	**95.0% (w/w)**
limits:	925.2-975.2 g/kg	92.5-97.5%

at a minimum purity of the technical active substance of 99.9 %.

Relevant impurities:

Compound	**maximum limit**
Arsenic:	< 0.95 mg/kg
Lead:	< 4.75 mg/kg
Cadmium	< 0.19 mg/kg
Mercury	< 0.02 mg/kg
TEQ-WHO PCDD/F (sum of congeners)	< 0.19 ng/kg
TEQ-WHO dl-PCB (sum of congeners)	< 0.14 ng/kg
TEQ-WHO PCDD/F/dl-PCB (sum of congeners)	*<0.33 ng/kg*
Sum of ndl-PCB:	< 4.75 µg/kg
Respirable crystalline silica (< 10 µm)	< 0.95 g/kg

2) SOKA - SOKALCIARBO WP

Pure active substance

content of pure active substance:	**open g / kg**	**open (% w / w)**

Technical active substance

content of technical active substance:	**1000 g / kg**	**100 (% w / w)**

Relevant impurities:

Compound	**maximum limit**
Arsenic:	< 12 mg/kg
Lead:	< 15 mg/kg
Cadmium	< 2 mg/kg
Mercury	< 0.1 mg/kg
TEQ-WHO PCDD/F (sum of congeners)	< 0.5 ng/kg
TEQ-WHO dl-PCB (sum of congeners)	< 0.5 ng/kg
TEQ-WHO PCDD/F/dl-PCB	< 0.5 ng/kg
Sum of ndl-PCB:	< 0.5 µg/kg
Respirable crystalline silica (< 10 µm)	(open)

1.4.4.2 Information on the active substances

Type	Name/Code Number
ISO common name	Aluminium silicate calcined (Kaolin calcined)
CAS No	92704-41-1
EC No	296-473-8
CIMAP No	841
Salt, ester anion or cation present	-

1.4.4.3 Information on safeners, synergists and co-formulants

CONFIDENTIAL information – Please refer to Volume 4- Tessenderlo

CONFIDENTIAL information – Please refer to Volume 4 - SOKA.

1.4.5 Type and code of the plant protection product

SURROUND WP	**Type:** Wettable powder [**Code**: WP]
SOKALCIARBO WP	**Type:** Wettable powder [**Code**: WP]

1.4.6 Function

Insect Repellent.

1.4.7 Field of use envisaged

Aluminium Silicate (Kaolin) is intended to be used in agriculture as a physical barrier against insect pests, mainly on fruit trees and vines.

1.4.8 Effects on harmful organisms

Kaolin has contact action and acts as a physical repellent barrier against insect pests and excess sun-light.

The kaolin particles form a physical barrier that acts as a repellent to certain insect pests, e.g. pear psylla.

Kaolin greatly reduces insect damage to crops by creating a particle film that has repellent and irritant effects on pests. It is also thought to camouflage crops from migrating insects by changing the wave-length of light emitted from the crop surface.

Kaolin is totally inert and therefore not absorbed by or translocated in either the crop or the pest.

1.5 Detailed uses of the plant protection products

1.5.1 Details of representative uses

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl) (l)	Water l/ha min max	Kg a.i./ha min max (*) (g/ha) (l)		
Grapevine	All zones	SURROUND WP CROP PROTECTANT	F	*Frankliniella occidentalis*	WP	950 g/kg	Broadcast spraying of entire plant	Up to BBCH 65	a) 1-4 b) 1-4	7	a) 2.85 - 5.70 kg/hl b) 22.80 kg/hl	500 – 1000 L/ha	a) 28.5 kg/ha b) 114 kg/ha	N/A	First spraying at emergence of overwintering females Use sufficient spray volume, apply to near drip but avoid run-off. Re-apply each 7 to 21 days, depending on rainfall and crop development.
Apricot tree	All zones	SOKALCIARBO WP	F	*Brachycaudus schwartzi* and *Hyalopterus*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH	a) 4	7	a) 1st: 5.00-8.33	600-1000 L/ha	a) 1st: 50 2nd-4th:	1	-

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

											b) 23.33				
Walnut tree	All zones	SOKALCIARBO WP	F	*Rhagoletis completa*	WP	1000g/kg	Foliar spray	From the first capture of insect	a) 6 b) 6	10 days after the 1st application and then 20 days	a) 1st: 6.00-10.00 2nd-6th: 3.00-5.00 b) 35.00	600-1000 L/ha	a) 1st: 60 2nd to 6th: 30 b) 210	-	-
Peach tree	All zones	SOKALCIARBO WP	F	*Myzus persicae*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd to 4th: 30 b) 140	1	-
Pome tree (apple, pear, quince, nashi)	All zones	SOKALCIARBO WP	F	*Dysaphis pyri, Aphis pomi* and *Rhopalosiphum insertum*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

Pear tree, quince tree, nashi tree	All zones	SOKALCIARBO WP	F	*Melanaphis pyraria* and *Anuraphis farfarae*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Apple tree	All zones	SOKALCIARBO WP	F	*Dysaphis plantaginea*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-
Apple tree	All zones	SOKALCIARBO WP	F	*Psylla pyrisuga, Psylla mali, Psylla costalis, Cacopsylla pyricola* and *Cacopsylla pyri*	WP	1000g/kg	Foliar spray	1st generation: BBCH 01-59 Following generation: BBCH 69-79	a) 7 b) 7	7	a) 3.00-5.00 b) 35.00	600-1000 L/ha	a) 30 b) 210	1	-
Plum tree	All zones	SOKALCIARBO WP	F	*Brachycaudus schwartzi, Hyalopterus pruni* and *Brachycaudus helichrysi K*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

											b) 23.33				
Citrus tree	All zones	SOKALCIARBO WP	F	*Empoasca vitis*	WP	1000g/kg	Foliar spray	At beginning of fruit ripening and the first capture of insect	a) 6 b) 6	7 days after the 1st application and then 21 days	a) 1st: 5.00-8.33 2nd-6th: 3.00-5.00 b) 33.33	600-1000 L/ha	a) 1st: 50 2nd to 6th: 30 b) 200	-	-
Lavender, lavandin	All zones	SOKALCIARBO WP	F	*Hyalesthes obsoletus*	WP	1000g/kg	Foliar spray	At the first capture of insect (except from the flowering period)	a) 5 b) 5	7	a) 1st: 7.50-10.00 2nd to 5th: 6.00-8.00 b) 42.00	150-200 L/ha	a) 1st: 15 2nd to 5th: 12 b) 63	-	-
Olive tree	All zones	SOKALCIARBO WP	F	*Bactrocera oleae*	WP	1000g/kg	Foliar spray	At the first capture of insect (with olives on the trees)	a) 6 b) 6	10 days after the 1st application and then 20 days	a) 1st: 5.00-8.33 2nd-6th: 3.00-5.00 b) 33.33	600-1000 L/ha	a) 1st: 50 2nd to 6th: 30 b) 200	-	-

Grapevine (wine and table)	All zones	SOKALCIARBO WP	F	*Empoasca vitis*	WP	1000g/kg	Foliar spray	BBCH 69-85	a) 4 b) 4	7	a) 6.66-10.00 b) 40.00	200-300 L/ha	a) 20 b) 80	1	-
Walnut tree	All zones	SOKALCIARBO WP	F	*Panaphis juglandis, Chromaphis juglandicola*	WP	1000g/kg	Foliar spray	1st: BBCH 51-59 2nd-3rd: BBCH 69-79 + Post harvest	a) 4 b) 4	7	a) 1st: 5.00-8.33 2nd-4th: 3.00-5.00 b) 23.33	600-1000 L/ha	a) 1st: 50 2nd-4th: 30 b) 140	1	-

1.5.2 Further information on representative uses

Please see the respective GAP table

1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Not relevant.

1.5.4 Overview on authorisations in EU Member States

The following table summarises the currently approved uses of the Aluminium Silicate formulations within EU Member States.

Product	Crop	Country
SOKALCIARBO WP	Almond Apricot Cherry Citrus Grapevine (wine and table) Hazel Lavender, lavandin Olive Peach Plum Pome trees (apple, pear, quince, nashi) Walnut	France
SURROUND WP CROP PROTECTANT	Pear	Belgium
	Apple (Pear)	France
	Pear	Greece
	Pear	Spain
	Pear	Hungary
	Olive	France
	Olive	Greece
	Olive	Spain
	Apple	France
	Cherry	France
	Peach	France
	Plum	France
	Vine	Greece
	Orange	Spain
	Mandarin	Spain

Level 2

Aluminium silicate calcined

2 Summary of active substance hazard and of product risk assessment

2.1 Identity

2.1.1 Summary of identity

The minimum purity of aluminium silicate approved under Commission Implementing Regulation (EU) No 571/2012 is 999.8 g/kg. Regarding relevant impurities the following was reported in Review Report for the active substance aluminium silicate SANCO/2603/08 – rev. 3, 11 July 2014:

«Considering that for the active substance notified by the main data submitter the manufacturing impurity crystalline silica could be, on the basis of information currently available, of toxicological concern, a maximum level of 0.1% in the technical material must not be exceeded. However, the main properties of aluminium silicate given in Appendix I limit the total impurity content to a maximum level of 0.02% and are thus more restrictive. »

For the purpose of renewal, taking into consideration the particularity of the identity of the active substance, the technical difficulties to quantify the active substance using typical analytical methods and the updated toxicological data, the minimum purity for the active substance aluminium silicate calcined supported by the two Notifiers Tessenderlo Group N.V. and Société Kaolinière Armoricaine (SOKA)Group N.V. are:

Tessenderlo:	999.0 g/kg minimum
SOKA:	Open

Alternatively, a purity of 1000 g/kg is also considered acceptable.

The relevant impurities are reported in Vol 4, Vol 3 B1 and List of endpoints.

Data gap: For data gaps/clarifications please refer to
Volume 4 – Tessenderlo Confidential Section C.1.1.1., C.1.2.1, C.1.2.2, C.1.2.4, C1.3.2
Volume 4 – SOKA Confidential Section C.1.1.1., C.1.2.1, C.1.2.2, C.1.2.4, C.1.2.5.2, C1.3.2

2.2 Physical and chemical properties

2.2.1 Summary of physical and chemical properties of the active substance

Aluminium silicate calcined is an odourless white powder, that is considered insoluble in water and organic solvents. According to bibliography, the melting point of kaolinite is 2123 K (approximately 1850 °C), therefore it is considered that the substance does not melt or boil at temperatures below 360 °C. Aluminium silicate calcined has no dissociation constant and no partition coefficient.

Aluminium silicate calcined is not considered flammable, self-heating substance, explosive, or oxidizing. No classification and labelling according to Regulation (EU) 1272/2008, concerning the safety physicochemical properties is proposed by RMS.

2.2.2 Summary of physical and chemical properties of the plant protection product

The representative formulation during the previous EU review of active substance aluminium silicate was "SURROUND® WP CROP PROTECTANT" a wettable powder (WP) formulation containing 950 g/kg aluminium sili-cate supported by Tessenderlo Chemie NV.
For the renewal of the active substance the same representative formulation "SURROUND® WP CROP PROTECTANT" has been supported by Tessenderlo plus another one "SOKALCIARBO WP" supported by notifier SOKA

TESSENDERLO
Plant Protection Product: SURROUND® WP CROP PROTECTANT

SURROUND® WP CROP PROTECTANT was the representative formulation in the DAR (2008, 2011) for the Annex I inclusion of a.s. aluminium silicate. The composition of SURROUND® WP CROP PROTECTANT has remained identical since the original notification of the active substance and product.

It is an odourless white and wettable powder, not corrosive. Storage under normal warehouse conditions in the original packaging is recommended for two years. The technical properties of Surround® WP Crop Protectant indicate that no particular problems are to be expected when it is used according to recommended use instructions.

The formulation SURROUND® WP CROP PROTECTANT is not anticipated to have neither explosive nor oxidizing properties and it is not anticipated to be self-heating. However according to Reg 284/2013 the self-heating shall be determined and reported. No classification and labelling according to Regulation (EU) 1272/2008, concerning the safety properties is proposed by RMS.

Recommendation: The spray solution should be under continuous agitation

For data requirements please refer to Vol 3 CP B2- SURROUND.

SOKA
Plant Protection Product: SOKALCIARBO WP

SOKALCIARBO WP is a white powder.
The formulation SOKALCIARBO WP is not anticipated to have neither explosive nor oxidizing properties. It is not self-heating. No classification and labelling according to Regulation (EU) 1272/2008, concerning the safety properties is proposed by RMS.

Recommendation: The spray solution should be under continuous agitation

For data requirements please refer to Vol 3 CP B2 - SOKALCIARBO

2.3 Data on application and efficacy

2.3.1 Summary of effectiveness

Aluminium Silicate (Kaolin) is intended to be used in agriculture as a physical barrier against insect pests, mainly on fruit trees and vines.

Kaolin greatly reduces insect damage to crops by creating a particle film that has repellent and irritant effects on pests. It is also thought to camouflage crops from migrating insects by changing the wavelength of light reflected from the crop surface.

Kaolin also provides horticultural benefits for plants by allowing photosynthesis to occur while reflecting harmful IR and UV radiation. Studies have shown that kaolin-treated trees actually increase their rate of carbon fixation.

2.3.2 Summary of information on the development of resistance

Kaolin has no toxic mode of action and therefore cannot induce resistance in pest populations.

Kaolin is not expected to cause resistance like conventional chemical insecticides. Kaolin is not killing the insects through a specific target site so there will be extremely limited selection pressure. Insects are very unlikely to be selected on the basis of modified behaviour and/or morphological attributes that avoid the repellent barrier effects of kaolin. In conclusion, there is very little risk of target pests developing resistance to kaolin.

2.3.3 Summary of adverse effects on treated crops

The registered uses of Aluminium Silicate products have been evaluated under the Uniform Principles based on assessments of relevant selectivity data set. Therefore, no adverse effects on the treated crops are anticipated from the use of pelargonic acid products according to the registerd GAP(s).

2.3.4 Summary of observations on other undesirable or unintended side-effects

The final conclusion will be based on the outcome of the Ecotoxicology Section.

2.4 Further information

2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire

Advice on safe handling

When handling an unopened bag, care should be taken to avoid damaging the packaging in order to avoid spillage. When handling opened bags, care should be taken to avoid prolonged contact or inhalation of the powder. Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment.

Do not to eat, drink and smoke in work areas; wash hands after use; remove contaminated clothing and protective equipment before entering eating areas.

Storage Conditions

The substance should be stored in a dry environment to avoid caking of the powder. Temperature has no impact on the stability of the substance. Minimise airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.

Kaolin, if disposed as received, is a non-hazardous waste. Local disposal laws and regulations will determine the proper waste disposal /recycling /reclamation procedure. Kaolin can be safely disposed of in landfill and packaging can be incinerated.

Transport

Not classified as a dangerous good under transport regulation (USDOT, IMDG, IATA/ICAO).

There are no restrictions concerning transport by land, sea or air.

EU label: symbol: none

Risk phrases: none

Safety phrases: S22 – Do not breathe dust

S24/25 – Avoid contact with skin and eyes

S26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S28 – After contact with skin, wash with plenty of water

S38 – In case of insufficient ventilation wear suitable respiratory equipment

S39 – Wear eye / face protection

Fire

- Kaolin does not burn. When heated above 600ºC, kaolin will evolve water. No further decomposition will occur.
- Extinguishing media: No specific extinguishing media is needed.
- Special hazards arising from the substance or mixture: Non-combustible. No hazardous thermal decomposition.
- Advice for fire-fighters: No specific fire-fighting protection is required.

2.4.2 Summary of procedures for destruction or decontamination

Detailed instructions for safe disposal

Kaolin is a non-toxic, non-hazardous material which can be disposed of following local disposal laws and regulations. Kaolin, if disposed as received, is a non-hazardous waste. Local disposal laws and regulations will determine the proper waste disposal /recycling /reclamation procedure. Kaolin can be safely disposed of in landfill and packaging can be incinerated.

Contaminated packaging and materials may be rinsed with clean water. The nature of kaolin and its absence of solubility in water mean any traces of kaolin will become immediately apparent as suspended particles in rinse water.

Packing Material: Kaolin is packaged in kraft paper bags suitable for disposal in landfill sites.

Spraying Equipment: Wash equipment thoroughly immediately after use. Fill the tank with clean water and spray out before storage or using other products. Traces of product may clog equipment filters if not cleaned thoroughly after use.

2.4.3 Summary of emergency measures in case of an accident

Cover powder spill with plastic sheet or tarpaulin to minimize spreading and dust generation. Scoop up or vacuum the solid into a container for reclamation or disposal. Kaolin is an inert insoluble mineral and no special method of decontamination of water is required other than physical removal of excessive quantities. Kaolin is not hazardous to humans, animals or the environment.

Kaolin is an inert insoluble mineral and no special method of decontamination of water is required other than physical removal of excessive quantities.

First aid measures: No action to avoid, neither special instruction for rescuers.

- Eye contact: Rinse with copious quantities of water and seek medical attention if irritation persists.
- Inhalation: Go to fresh air. If symptoms appear, seek medical attention.
- Ingestion: No special first aid measures necessary.
- Skin contact: No special first aid measures necessary.
- Most important symptoms and effects, both acute and delayed: No acute and delayed symptoms and effects are observed.
- Indication of any immediate medical attention and special treatment needed: No specific actions are required.

2.5 Methods of analysis

2.5.1 Methods used for the generation of pre-authorisation data

a) Analysis of the active substance as manufactured

No common typical analytical method is applicable for the identification and quantification of pure aluminium silicate calcined in the technical material as manufactured.

All methods applied for the determination of different species and/or properties of the active substance as manufactured have been submitted as confidential information by both Notifiers Tessenderlo and SOKA. Details are described in Vol 4 of each notifier in point C.1.2.5.1.

b) Analytical methods applied for the determination of impurities

TESSENDERLO:

For the determination of the relevant impurities in the technical active substance HRGC-HRMS, HR-ICP-MS, AAS - Cold Vapour (CVAAS) and X-ray diffraction (XRD) methods where used.

Data gap : See Vol 4 - TESSENDERLO

SOKA:

For the determination of the relevant impurities in the technical active substance GC-MS/MS, ICP-OES AAS-Graphite, AAS and AAS-Cold vapour methods where used.

Data gap : See Vol 4 - SOKA

c) Formulation analysis

TESSENDERLO: No common typical analytical method is applicable for the identification and quantification of pure aluminium silicate calcined in the plant protection product SURROUND® WP CROP PROTECTANT -Tessenderlo.

All methods applied for the determination of different species and/or properties of the active substance in the plant protection product have been submitted as confidential information by Notifier Tessenderlo. Details are described in Vol 4 Tessenderlo in point C.1.3.4.2.

For the determination of the relevant impurities in the plant protection products notifier Tessenderlo proposes the same methods that are applied for the determination of the relevant impurities in the technical material.

SOKA: No common typical analytical method is applicable for the identification and quantification of pure aluminium silicate calcined in the plant protection product SOKALCIARBO WP – SOKA.

All methods applied for the determination of different species and/or properties of the active substance in the plant protection product have been submitted as confidential information by SOKA. Details are described in Vol 4 SOKA in point C.1.3.4.2.

For the determination of the relevant impurities in the plant protection product notifier SOKA proposes the same methods that are applied for the determination of the relevant impurities in the technical material.
Data gap : See Vol 4 - SOKA

d) Methods for Risk Assessment (CA)

Tessenderlo: No studies submitted
SOKA: No studies submitted

e) Methods for Risk Assessment (CP)

Tessenderlo: Two studies regarding «Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies» were submitted as confidential information. They are presented in Vol 4 -Tessenderlo, point 1.3.5.1**.**

SOKA: No studies submitted

2.5.2 Methods for post control and monitoring purposes

2.5.2.1 Formulation analysis

TESSENDERLO: No common typical analytical method is applicable for the identification and quantification of pure aluminium silicate calcined in the plant protection product SURROUND® WP CROP PROTECTANT -Tessenderlo.

All methods applied for the determination of different species and/or properties of the active substance in the plant protection product have been submitted as confidential information by Notifier Tessenderlo. Details are described in Vol 4 Tessenderlo in point C.1.3.4.2.

For the determination of the relevant impurities in the plant protection products notifier Tessenderlo proposes the same methods that are applied for the determination of the relevant impurities in the technical material.

SOKA: No common typical analytical method is applicable for the identification and quantification of pure aluminium silicate calcined in the plant protection product SOKALCIARBO WP – SOKA.

All methods applied for the determination of different species and/or properties of the active substance in the plant protection product have been submitted as confidential information by SOKA. Details are described in Vol 4 SOKA in point C.1.3.4.2.

For the determination of the relevant impurities in the plant protection product notifier SOKA proposes the same methods that are applied for the determination of the relevant impurities in the technical material.
Data gap : See Vol 4 - SOKA

2.5.2.2 Residue analysis

Food of plant origin

No method is required since no residue definition is set.

Food of animal origin
No method is required since no residue definition is set.

Water

Drinking water
No method is required since no residue definition is set.

Surface water
No method is required since no residue definition is set.

Air
No method is required since no residue definition is set.

Body fluids and tissues
No method is required.

2.6 Effects on human and animal health

A search of the scientific peer reviewed open literature has been carried out by both notifiers for aluminium silicate (kaolin) in compliance with Article 8.5 of Regulation (EC) No 1107/2009 and Part A of Commission Regulation (EU) No 283/2013. The detailed literature search methodology and results for human health effects of aluminium silicate performed by Tessenderlo Group N.V. and SOKA are included in Section B.6 – Appendix III and Appendix IV, respectively.

The RMS has reviewed the literature searches. The approach followed for the systematic literature search was generally in line with the principles described in the EFSA Guidance on *"Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009"* (EFSA Journal 2011; 9(2):2092). Regarding the Literature search performed by Tessendelo Group N.V. the following limitations were noted:

- There is no detailed description of the relevance criteria considered in the selection process.
- Not all 301 documents identified as potentially relevant by text mining are listed in the documents provided by the applicant.

The one article identified as relevant by Tessendelo Group N.V. was a WHO review (2005)[2]. Detailed assessment of this review was not included in the dossier since all studies quoted in this review are old (none post-2003, most pre-1990). Nevertheless, the review itself provides supporting evidence that kaolin is not acutely toxic, not toxic to reproduction, not genotoxic and not carcinogenic when not contaminated with crystalline silica.

Regarding the Literature search performed by SOKA, the following limitations are noted:

- The search was limited to compound aluminium silicate, CAS No. 1332-58-7.
- A limited number of articles was retrieved (Total number of summary records retrieved after all searches of peer-reviewed literature: 74) questioning the adequacy of the relevance criteria considered.

Although limitations have been identified in the literature search by both notifiers, the RMS concludes that overall no information is identified which would impact the outcome of the risk assessment.

[2] https://www.who.int/ipcs/publications/ehc/ehc_231.pdf

2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals

Aluminium silicate as a natural inorganic mineral, it is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested. It is not distributed in the tissues and it is not metabolized.

2.6.2 Summary of acute toxicity

The acute toxicity of aluminium silicate calcined (calcined kaolin) was based on eight studies already reviewed at EU level for the Annex I inclusion and on five studies submitted for the renewal of the active substance. All studies were performed according to GLP principles and are summarized in Vol. 3CA_B-6. Among the five new studies submitted for the renewal of the active substance, only one was performed with aluminium silicate calcined. The other four studies were conducted with hydrous kaolin (crystalline) which is considered worst-case from a toxicological point of view (see Volume 4 – CONFIDENTIAL.

Aluminium silicate calcined (calcined kaolin) was found to be of low toxicity *via* the oral and the dermal route. The acute inhalation studies performed in rat, indicated an LC_{50} > 5.07 mg/L/4h (nose-only). According to the available studies, kaolin caused no irritation to rabbit skin and eyes. Finally, the test substance lacks skin sensitisation properties, as indicated in the available LLNA and GPMT tests. Finally, the waivers submitted by both notifiers for phototoxicity are considered acceptable by the RMS, since it is not technically feasible to conduct a phototoxicity study due to the physicochemical properties of aluminium silicate. Aluminium silicate is an inert, insoluble dust and there is no guideline available for the testing of phototoxicity of insoluble substances.

Table 2.6.2-1: Summary of acute toxicity studies of aluminium silicate calcined (calcined kaolin)

Test substance	**LD_{50}/LC_{50}** (mg/kg bw or mg/L)	Species	Route	Reference
Satintone 5HB, Lot # 10146, purity: 100 % aluminium silicate calcined	> 5000	Rat / SD	Oral	[redacted] 1997a
M-96-018, Lot # 08145, aluminium silicate calcined, polydimethylsiloxane purity: 98.8% calcined kaolin	> 5000	Rat / SD	Oral	[redacted] 1997b
hydrous kaolin, Batch 30.03.2015, purity: 100 %	> 2000	Rat / Wistar	Oral	[redacted], 2016a
Satintone 5HB, Lot # 10146, purity: 100% aluminium silicate calcined	> 5000	Rat / SD	Dermal	[redacted]., 1997c

Test substance	LD_{50}/LC_{50} (mg/kg bw or mg/L)	Species	Route	Reference
hydrous kaolin, Batch 30.03.2015, purity: 100 %	> 2000	Rat / Wistar	Dermal	[redacted], 2016b
M-96-018, purity: 98.8 % aluminium silicate calcined, 1.2% siloxane	> 2.18	Rat / SD	Inhalation	[redacted], 1997d
M-97-009, Lot # 09255, 100% aluminium silicate calcined	> 2.07	Rat / SD	Inhalation	[redacted]., 1997e
hydrous kaolin, Batch 30.03.2015, purity: 100%	> 5.07	Rat / Wistar	Inhalation	[redacted], 2016
M-96-018, Lot #08145, aluminium silicate calcined, polydimethylsiloxane	Not irritating to skin	Rabbit / NZW	Dermal	[redacted] 1997f
M-96-018, Lot #08145, aluminium silicate calcined, polydimethylsiloxane	Not irritating to eyes	Rabbit / NZW	Ocular	[redacted], 1997g
Surround WP, Lot #02140, content: 95% kaolin	Not irritating to eyes	Rabbit / NZW	Ocular	[redacted] 2000
hydrous kaolin, Batch 30.03.2015, purity: 100%	Not sensitising	Mouse / CBA/Ca	Dermal	[redacted], 2016c
M-99-SPI, aluminium silicate calcined, purity: 99%	Not sensitising	Guinea pig / Dunkin-Hartley	Intradermal and dermal	[redacted]., 2017

Overall, based on the available data, no classification is proposed for acute toxicity, irritation or skin sensitisation, according to the Reg. (EC) 1272/2008.

2.6.3 Summary of short-term toxicity

No short-term oral toxicity data with aluminium silicate calcined have been provided to the RMS by either of the notifiers. In the REACH dossier for CAS No. 92704-41-1 no short-term toxicity data were

available on Kaolin, calcined. The RMS considers that waiving of oral short-term toxicity studies is considered acceptable since aluminium silicate is a natural inorganic mineral, it is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested.

A snout-only inhalation study in Han Wistar rats was performed for 6 hours a day, 5 days a week, for 2 weeks at achieved aerosol concentrations of 25.6, 47.6 or 103 µg/L Kaolin or 23.7, 55.0 or 103 µg/L Kaolinitic Clay (nominal concentrations for both compounds: 25, 50 and 110 µg/L) (Robin M., 2019).

Table 2.6.3-1: Summary of the short-term study with aluminium silicate

Species, Route, Duration	**Test item(s)**	**Concentration**	**Endpoint**	**Reference**
Rat (Han Wistar), Inhalation (snout only), 2-weeks	**Kaolin** (92,3% Kaolinite; 0,8% Quartz) **Kaolinitic clay** (75,3% Kaolinite; 17% Quartz)	*Nominal:* 0, 25, 50, 110 µg/L *Achieved:* **Kaolin:** 0, 25.6, 47.6 103 µg/L **Kaolinitic Clay:** 0, 23.7, 55.0, 103	NOAEC = 47.6 µg/L (kaolin) Effects at LOAEC = 103 µg/L: - Nasal turbinates effects (mucous cell hyperplasia/metaplasia) - Lung effects (changes in differential white blood cell counts, minimal alveolar macrophage aggregates, increased adjusted weight of lungs/bronchi) GLP study. No Guideline. **Study acceptable.**	[redacted]., 2019 (Study submitted for the renewal)

Treatment-related observations included minimal alveolar macrophage aggregates in the lungs of animals exposed to Kaolin or Kaolinitic Clay at all concentrations tested. The alveolar macrophage aggregates contained fine refractile granular material which was considered by the study authors likely to be the test item. There was no other morphological change in the lung and there was no mention of inflammation in the study report. Considering the inert and insoluble properties of Kaolin and Kaolinitic clay, minimal alveolar macrophage aggregates could be regarded as adaptive responses to clear the lungs of foreign particulate matter. However, the study did not include a recovery period in order to assess reversibility of the finding.

Analyses of the bronchoalveolar lavage fluid (BALF) revealed statistically significant changes in differential white blood cell counts, with no clear concentration-response pattern. There were no historical control data to assess biological significance. The adjusted weight of lungs/bronchi was statistically significantly increased among females treated with 103 µg/L kaolinitic clay.

Overall, it cannot be clearly demonstrated that the observed lung effects (i.e. increased lung weight, accumulation of macrophages and changes in differential white blood cell counts in the BALF) are adaptive or adverse. It is likely that these findings are adaptive responses and parts of a defence mechanism aimed to clear the lungs of particulate matter and are therefore non-specific findings. On the other hand, the study is of short-duration (14-days) and there are no other studies on short-term or long-term toxicity of kaolin *via* the inhalation route to assess progression of the lung effects. Thus, progression into fibrosis with lung function changes after longer exposure may not be excluded considering that macrophages play a central role in the pathogenesis of fibrosis.

Other effects at site of contact included increased incidence of mucous cell hyperplasia/metaplasia in the nose of animals exposed to the highest dose of Kaolin or Kaolinitic Clay. This effect was mainly

localized to the ventral respiratory epithelium in the caudal aspect of the nose and it was considered secondary to mild irritation caused by the test items.

The study NOAEC was set at 47.6 µg/L for kaolin and 55.0 µg/L for kaolinitic clay based on effects on nasal turbinates (mucous cell hyperplasia/metaplasia) at 103 µg/L. This NOAEC is supported by lung effects including changes in differential white blood cell counts, minimal alveolar macrophage aggregates, increased adjusted weight of lungs/bronchi. Although lung effects were presumed to be adaptive, there is high uncertainty due to short study duration and lack of reversibility period not allowing to assess potential progression to functional lung changes. So, lung effects are considered in NOAEC setting as a conservative approach.

The NOAEC of 47.6 µg/L set for kaolin after treatment *via* the inhalation route is used for AOEC setting for consideration in non-dietary risk assessment.

2.6.4 Summary of genotoxicity

There are no genotoxicity data with Aluminium silicate calcined. Hydrous Kaolin was negative in a bacterial mutagenicity assay submitted by SOKA (Wisher, 2017).

Table 2.6.4-1: Summary of the *in vitro* genotoxicity study with aluminium silicate

Test / end-point	**Test system**	**Findings**	**Result**	**Reference**
Bacterial mutagenicity	Ames test *Salmonella* strains TA98, TA100, TA1535, TA1537 *E. coli* WP2 (pKM101)	Not mutagenic +/- metabolic activation up to 5000 µg/plate	Negative	Wisher, 2017 (Study submitted for the renewal)

The RMS considers that waiving of genotoxicity data may be acceptable considering that aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested.

A similar approach has been described in the RAR (2019) for Kieselgur (diatomaceous earth), another silica compound, where no *in vitro* studies were evaluated, as the potential of Kieselgur to induce genotoxicity was considered irrelevant. Considering *in vivo* data, the results from a Comet assay with Diatomaceous earth did not reveal any genotoxic potential. This approach is further supported considering literature data included in the RAR for Kieselgur (diatomaceous earth), where it is noted that genotoxic effects in alveolar epithelial cells occurred only after crystalline but not amorphous silica exposure (Johnston *et al.*, 2000).

No relevant genotoxicity data on calcined Kaolin were retrieved from the systematic literature search performed by both applicants.

2.6.5 Summary of long-term toxicity and carcinogenicity

There are no GLP or guideline complying studies regarding long-term effects of Aluminium Silicate calcined. However, two published papers were submitted, a 12-month intratracheal study in Guinea pigs (Schepers, 1971), and a 24-month inhalation study in rats with Kaolin (Wagner *et al.*, 1987). These studies were evaluated and regarded as supporting data by the RMS.

In the study by Schepers (1971), Kaolin, administered during 12 months *via* intratracheal route to the guinea pig did not induce any epithelialization or neoplasia lesion. Intratracheal injections create highly artificial local conditions that must necessarily induce pulmonary lesions. To a degree, the intratracheal

method does exaggerate the biological effects of most substances. However, if the material is truly inert, this can be proven by the intratracheal method.

In a 24-month inhalation study (Wagner et al., 1987), Kaolin, administered during 12 months to the rat in an inhalation chamber did not induce any malignant lesion. There were only two incidences of broncho-alveolar hyperplasia in the total of 40 exposed rats which are considered to be reaction to an irritant according to the study author. This study on Kaolin is also included in the REACH dossier3 for consideration in read-across to Kaolin, calcined and it is concluded that: "None of 40 rats exposed to Kaolin dust at a concentration of 10 mg/m³ for 6 hours per day with exposure durations ranging from 3 months to 12 months showed tumour formation".

Table 2.6.5-1: Summary of carcinogenicity studies with aluminium silicate

Species, Route, Duration	**Test item**	**Dose**	**Endpoint**	**Reference**
Guinea pig, Intratracheal route, 12 months	Kaolin (batch, purity not reported)	Not reported	No epithelialization or neoplastic lesions. No GLP. No Guideline. **Study acceptable as supporting information.**	Schepers, 1971 (DAR, 2008)
Rat, Inhalation, 12-months (+12 mths obs. period)	Kaolin (batch, purity not reported)	10 mg/m^3 (6 h/day, 5 day/week)	No malignant lesions. No GLP. No Guideline. **Study acceptable as supporting information.**	Wagner *et al.*, 1987 (DAR, 2008)

In the REACH dossier no data on Kaolin, calcined were available. However, a long-term feeding study for synthetic amorphous silica (SAS) by Takizawa et al. (1988) was considered for read-across and was briefly presented as follows:

"Three groups of rats and mice received Syloid 244 at dietary levels of 1.25, 2.5 and 5% for 103 and 93 weeks, respectively. This corresponded to average daily doses of 2000 mg/kg bw/day for the high-dose group of rats and to 4500 to 5800 mg/kg bw/day for the high-dose groups of female and male mice, respectively. The animals were in good condition throughout and showed high survival. The tumour responses in all organs of SAS-treated rats and mice were not statistically significantly different from the controls (Fisher´s exact test and Cochran-Armitage test for trend). Based on the negative results after long-term oral application of SAS, there is no evidence of a carcinogenic potential arising from ingestion of these amorphous minerals."

The full study report by Takizawa *et al.* (1988) was not available to the RMS for evaluation. Nevertheless, this study has been included in the RAR for Kieselgur (diatomaceous earth) (2019) concluding that SAS was not carcinogenic. The relevance of this study with SAS for the assessment of aluminium silicate is not clearly demonstrated.

Overall, the RMS considers that although there are no long-term GLP or guideline studies with Aluminium Silicate calcined, waiving of long-term toxicity/carcinogenicity studies is considered acceptable since aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic solvents. It does not become bioavailable when ingested.

Limited evidence from literature data on Kaolin administration for 12 months in the guinea pig (tracheal injection) or the rat (inhalation chamber) indicated no increased incidences of malignant lesions. The NOAEC of 47.6 µg/L set for kaolin after a 14-day treatment *via* the inhalation route is used for AOEC setting for consideration in non-dietary risk assessment (see Section 2.6.12).

[3] https://echa.europa.eu/registration-dossier/-/registered-dossier/13356/7/8

2.6.6 Summary of reproductive toxicity

There are no GLP or guideline complying studies regarding reproductive toxicity of Aluminium Silicate calcined.

Limited information on reproductive toxicity of clay is provided in literature study by Patterson & Staszak, 1977. In this study, no effects on the development of foetuses (foetal weight, foetal length) are anticipated from exposure of pregnant rats to clay. Moreover, litter size was comparable among control and treated groups suggesting that no substantial effects on fertility are also expected from oral ingestion of clay.

Table 2.6.6-1: Summary of the reproductive toxicity studies with aluminium silicate

Species, Route, Duration	Test item	Dose	Endpoint	Reference
Rat, Oral (geophagia), Duration: 37 to 68 days, 69 to 85 days, and 96 to 117 days prior to fertilization and during gestation	Kaolin (batch, purity not reported)	0, 20% Kaolin, iron supplemented 20% Kaolin added to the diet	No effects on foetal development. No effects on litter size suggesting that no substantial effects on fertility are also expected from oral ingestion of clay. No GLP. No Guideline. **Study acceptable as supporting information.**	Patterson & Staszak, 1977 (DAR, 2008)

2.6.7 Summary of neurotoxicity

No study was submitted, not required. The RMS considers that waiving of neurotoxicity studies is considered acceptable since aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic solvents. It does not become bioavailable when ingested. Moreover, it does not belong to the chemical class of organophosphorus compounds nor does it have a neurotoxic mode of pesticidal action.

2.6.8 Summary of further toxicological studies on the active substance

2.6.8.1 Toxicity studies of metabolites

No other toxicological studies on aluminium silicate calcined are available. It is not absorbed after ingestion or topical application, it is therefore not bioavailable and there are no metabolites.

2.6.8.2 Supplementary studies on the active substance

Immunotoxicity

The EFSA CONTAM Panel has noted (EFSA Journal 2009; 7(11):1391) that "*Kaolin is not allergenic, although it is known to induce pro-inflammatory responses which have been particularly noticed for the lung following intratracheal administration (Yanagisawa et al., 2007)*". In this context, on the request of the RMS, this study was provided by the notifier and it is evaluated in Section B.6.8.2.

The aim of the study by Yanagisawa et al. (2007) was to examine the effects of Asian sand dust particles (ASDPs) on gene expression in the murine lung using microarray analysis and elucidated the components responsible for lung inflammation. Male ICR mice were intratracheally administrated ASDPs, heat-treated ASDPs (ASDP-F, lipopolysaccaride (LPS), or b-glucan free), or kaolin particles. A microarray analysis for murine lungs was performed, the results of which were confirmed by quantitative reverse transcription–polymerase chain reaction (RT-PCR). The protein expression and histologic changes were also assessed. It was concluded that kaolin administration upregulated the expression of several proinflammatory genes (CXCL1/ KC and CXCL2/MIP-2) and proteins (CXCL1/KC, CXCL2/MIP-2, CCL3/MIP-1a, and CXCL10/IP-10). Both ASDP and kaolin induced neutrophil infiltration into the alveolar space, mediated by CXC chemokines. Gene and protein expression of proinflammatory molecules eventually lead to neutrophilic lung inflammation.

Neutrophilic lung inflammation was less severe in the case of kaolin, presumably due to the structure of kaolin being multilayered and highly porous.

Regarding the immunotoxicity endpoint, no additional information is retrieved from the systematic literature search performed by the applicants. Considering all the available data the non-submission of additional data for immunotoxicity has been considered acceptable.

Endocrine disruption

For the assessment of the endocrine disrupting properties of calcined aluminium silicate, please refer to section 2.10.

sProposal – Low risk substance

Considering the available data, aluminium silicate fulfills the following "Low Risk Criteria" of Regulation (EU) 2017/1432, regarding health effects of an active substance, other than a micro-organism:

(a) it is not classified in accordance with Regulation (EC) No 1272/2008 as any of the following:

- carcinogenic category 1A, 1B or 2,
- mutagenic category 1A, 1B or 2,
- toxic to reproduction category 1A, 1B or 2,
- skin sensitiser category 1,
- serious damage to eye category 1,
- respiratory sensitiser category 1,
- acute toxicity category 1, 2 or 3,
- specific Target Organ Toxicant, category 1 or 2,
- skin corrosive, category 1A, 1B or 1C;

(b) it has not been identified as priority substance under Directive 2000/60/EC;

(c) it is not deemed to be an endocrine disruptor;

(d) it has no neurotoxic or immunotoxic effects.

The above consideration is supported by the evaluation presented in the current RAR for calcined aluminium silicate, as long as the content of the relevant impurity crystalline silica with diameter below 10 μm is lower than 1 g/kg [see RAR Volume 4].

2.6.9 Summary of medical data and information

The notifier SOKA provided a statement regarding employees working over the past nine years on the production site of Aluminium silicate and its representative formulation SOKALCIARBO WP, according to which: "N*o adverse health effects resulting from exposure to Aluminium silicate and its representative formulation SOKALCIARBO WP was reported."*

A large-scale epidemiologic survey on more than 95 % of US workers employed in the mining and processing of kaolin found no case of primary sensitivity as a result of exposure to kaolin in its solid, liquid or respirable forms (Rawlings, 1997). Some cases of pneumoconiosis were reported in the late 1970's, but, with good dust control practices over the last 25 years, no new cases were found.

The general population is routinely exposed to kaolin in medicines, cosmetics and industrial applications. No major health effects have been reported from kaolin in the general population. Exposure of the general population to significant levels of kaolin dust, that may be potentially harmful through inhalation or eye irritation, is highly unlikely. There are no reported cases on kaolin poisoning in the literature. In such event, no special antidotes or medical treatment are available and symptomatic treatment is recommended.

2.6.10 Toxicological end point for assessment of risk following long-term dietary exposure - ADI

No ADI has been set for aluminium silicate, since the compound is not systemically bioavailable after oral ingestion. This approach is in line with the EFSA peer review of the DAR (EFSA Journal 2012;10(2):2517) that there is no need to set an acceptable daily intake (ADI) and acute reference dose (ARfD) because consumer exposure is very unlikely.

2.6.11 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

No ARfD has been set for aluminium silicate, since the compound is not systemically bioavailable after oral ingestion. This approach is in line with the EFSA peer review of the DAR (EFSA Journal 2012;10(2):2517) that there is no need to set an acceptable daily intake (ADI) and acute reference dose (ARfD) because consumer exposure is very unlikely.

2.6.12 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

No short-term oral toxicity data with aluminium silicate calcined have been provided to the RMS by either of the notifiers. The RMS considers that waiving of oral short-term toxicity studies is considered acceptable since aluminium silicate is a natural inorganic mineral, it is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested. So, it is not considered necessary to set an AOEL from the oral route.

The RMS proposes that considering the toxicity profile of the substance by inhalation, an Acceptable Operator Exposure Concentration (AOEC) is needed to perform a non-dietary risk assessment related to inhalation exposure. These conclusions are in agreement with the previous conclusion of the peer review for the active substance aluminium silicate (EFSA Journal 2012;10(2):2517).

In the previous peer review conclusions (EFSA, 2012), the use of the workplace exposure limit (WEL)-time weighted average (TWA) of 2 mg/m^3 established for aluminium silicate for occupational settings, was considered adequate, although it was acknowledged that it probably represents a conservative exposure estimate for an agricultural setting[4]. The TWA of 2 mg/m^3 for a working day of 8 hrs, is equivalent to 20 mg/day considering an inhalation rate of 1.25 m^3/h (HEEG Opinion No 17, Default human factor values for use in exposure assessments for biocidal products). As the TWA refers to an inhalation limit, it cannot be reliably converted to a systemic value, therefore the inhalation exposure estimates have been directly compared to the TWA of 20 mg/day. It is noted that previously considered TWA value of 36.6 mg/day, was estimated considering the same WEL-TWA of 2 mg/m^3 as a starting point, but different values for the inhalation rate (0.04 m^3/h/kg bw) and the duration of the working day (7 hrs), which are not considered acceptable.

[4] EH40/2005 Workplace exposure limits (Fourth Edition 2020), https://www.hse.gov.uk/pubns/priced/eh40.pdf

In the frames of the renewal of the active substance aluminium silicate, a new 2-week inhalation study in rats was included in the dossier and assessed by the RMS (Robin, 2019). The study NOAEC was set at 47.6 µg/L for kaolin and 55.0 µg/L for kaolinitic clay based on effects on nasal turbinates (mucous cell hyperplasia/metaplasia) at 103 µg/L. This NOAEC is supported by lung effects including changes in differential white blood cell counts, minimal alveolar macrophage aggregates, increased adjusted weight of lungs/bronchi. Although lung effects were presumed to be adaptive, there is high uncertainty due to short study duration and lack of reversibility period not allowing to assess potential progression to functional lung changes. So, lung effects are considered in NOAEC setting as a conservative approach.

The RMS proposes to use the NOAEC = 47.6 µg/L (= 47.6 mg/m^3) set for kaolin after treatment *via* the inhalation route as the basis for AOEC setting. It is noted that limited evidence from literature data on Kaolin administration for 12 months in the guinea pig (tracheal injection) or the rat (inhalation chamber) indicated no increased incidences of malignant lesions.

Although a minimum safety margin of 100 should be used according to point 3.6.1 of Annex II to Regulation (EC) No 1107/2009, resulting in an AOEC of 0.476 mg/m^3 based on the NOAEC of 47.6 mg/m^3 from the 2-week toxicity study by inhalation in rats, the RMS is of the opinion that this uncertainty factor does not reflect the specific properties of aluminium silicate i.e. health concerns only upon repeated exposure by inhalation.

In line with the approach followed for the active substance Kieselgur (EFSA, 2020), an overall reduced uncertainty factor of 25 is adopted by the RMS, i.e. 10 to account for intraspecies variability (default) and 2.5 for interspecies variability in toxicodynamics (toxicokinetic not being relevant for local effects in the nose and lungs). Moreover, for AOEC calculation, the NOAEC obtained after 6-hour inhalation exposure of rats in the subacute study is normalised for 8 hours exposure for an occupational setting.

The refined AOEC is estimated as follows:

AOEC = (47.6 mg/m^3 / 25) x 6/8 = 1.4 mg/m^3.

The value of 1.4 mg/m^3 is considered relevant for non-dietary exposure assessment.

For completeness, inhalation exposure estimates have been compared to both the AOEC of 1.4 mg/m^3 estimated in the frames of the renewal and the WEL-TWA of 2 mg/m^3 considered previously (EFSA, 2012).

Please, refer to Volume 4 of the RAR for further considerations regarding the specification of the active substance and the impurity profile.

2.6.13 Toxicological end point for assessment of acute occupational, bystander and residents risks – AAOEL

The RMS for the renewal of approval of aluminium silicate considers that the establishment of an AAOEL is not required given the toxicity profile of aluminium silicate and the lack of acute hazard.
Please, refer to Volume 4 of the RAR for further considerations regarding the specification of the active substance and the impurity profile. See also 2.6.12.

2.6.14 Summary of product exposure and risk assessment

An AOEC value of 1.4 mg/m^3 (8hrs-TWA) has been set for aluminium silicate (calcined). This value corresponds to 14 mg /day considering an inhalation rate of 1.25 m^3/h (HEEG Opinion No 17, Default human factor values for use in exposure assessments for biocidal products) and a work rate of 8 hrs.

In addition, a workplace exposure limit (WEL)-time weighted average (TWA) of 2 mg/m^3 has been established for aluminium silicate for occupational settings[5]. The TWA of 2 mg/m^3 for a working day of 8 hrs, is equivalent to 20 mg/day considering the inhalation rate of 1.25 m^3/h.

For completeness, inhalation exposure estimates have been compared to both reference values.

Tessenderlo

- ***SURROUND WP***

SURROUND WP is a wettable powder (WP) formulation containing 950 g/kg aluminium silicate. The representative use comprises outdoor application by broadcast spraying or manual spraying to grapes. SURROUND WP is foreseen to be applied up to four-times (4) per use with an interval of seven (7) days, at a maximum application rate of 28.5 kg a.s./ha with a water volume of at least 500 L/ha.

As the absorption through the skin is considered negligible, only exposure *via* inhalation is relevant for operators. Estimation of operator exposure towards aluminium silicate has been calculated using the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, [EFSA Journal 2014;12(10):3874[55 pp.]. It has been concluded that inhalation exposure levels are below the AOEC (8hrs-TWA) and the WEL (8hrs-TWA), without the use of any RPE.

For bystanders/residents among the initial four pathways of exposure, only spray drift (at the time of application) and vapour (which may occur after the PPP has been applied) have been considered. Exposure to surface deposits and entry into treated crops are not retained as dermal absorption is negligible. Likewise, hand/object-to-mouth exposure is not a route of exposure for children, as aluminium silicate is not orally absorbed. Bystander and residential exposure towards aluminium silicate has been calculated using the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products [EFSA Journal 2014;12(10):3874[55 pp.]. It has been concluded that bystander/resident inhalation exposure levels are below the AOEC (8hrs-TWA) and the WEL (8hrs-TWA).

For workers as dermal absorption of aluminium silicate is negligible, an exposure assessment is not required.

SOKA

- ***SOKALCIARBO WP***

SOKALCIARBO WP is a wettable powder (WP) formulation containing 1000 g/kg aluminium silicate. The representative uses comprise outdoor application by vehicle mounted spraying or manual spraying to a variety of crops. A summary of the proposed use conditions and selection of the critical GAP used for the non-dietary exposure risk assessment is presented in Table 2.6.14-1.

Table 6.4.14-1: Critical GAP – Application parameters for SOKALCIARBO WP

Use No.	**12***	**13**
Crop	**Citrus**	**Lavender**
Application rate (kg as/ha)	50	15
Number of applications/minium interval	6/7	5/7

[5] EH40/2005 Workplace exposure limits (Fourth Edition 2020), https://www.hse.gov.uk/pubns/priced/eh40.pdf

Crop growth stage (BBCH)	At beginning of fruit ripening and the first capture of insect	At the first capture of insect
Application method	Foliar spray	Foliar spray
Minimum water volume	600	150

As the absorption through the skin is considered negligible, only exposure *via* inhalation is relevant for operators. Estimation of operator exposure towards aluminium silicate has been calculated using the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, [EFSA Journal 2014;12(10):3874[55 pp.]. In case of application to citrus *via* vehicle-mounted sprayer and hand-held equipment a risk has been identified for operators even when RPE/RMM are considered. For the rest of the scenarios assessed, outdoor application of SOKALCIARBO WP poses no risk for operators even without the use of any RPE/RMM.

For bystanders/residents among the initial four pathways of exposure, only spray drift (at the time of application) and vapour (which may occur after the PPP has been applied) have been considered. Exposure to surface deposits and entry into treated crops are not retained as dermal absorption is negligible. Likewise, hand/object-to-mouth exposure is not a route of exposure for children, as aluminium silicate is not orally absorbed. Bystander and residential exposure towards aluminium silicate has been calculated using the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products [EFSA Journal 2014;12(10):3874[55 pp.]. It has been concluded that bystander/resident inhalation exposure levels are below the AOEC (8hrs-TWA) and the WEL (8hrs-TWA).

For workers as dermal absorption of aluminium silicate is negligible, an exposure assessment is not required.

Dermal absorption:

Aluminium silicate is a natural inorganic mineral. It is inert, insoluble in aqueous and organic solvents. Due to its physicochemical properties, dermal penetration of aluminium silicate is negligible.

2.7 Residues

Based on the DAR (2008) and the data submitted in the framework of the renewal, by the criteriria below a waiver from the requirement of residue data and MRL is still suggested:

- Kaolin has no known mode of toxicity, is insoluble in water and does not become bioavailable when ingested.
- No Toxicological Reference Values (ADI and ARfD) have been defined for kaolin.
- When applied to crops it leaves a white deposit on the surface that is easily removed by gentle rubbing and washing. This would be a normal procedure before marketing and/or consuming any foodstuff treated with kaolin.
- Kaolin is naturally present in the environment and is likely to be frequently present on crops contaminated with soil or dust particles.
- Kaolin does not degrade under environmental conditions.
- Kaolin cannot be analysed by conventional spectroscopy techniques. Kaolin is a natural component of soil and therefore cannot be distinguished from existing clays, either in the soil or as an air born dust. It is impossible to differentiate between naturally present kaolin and kaolin from plant protection product.

For all the above reasons, the status of “active substance for which no MRLs are required” and the inclusion of aluminium silicate (kaolin) in the Annex IV of Regulation (EC) No 396/2005 as set in Reg. (EC) No 839/2008 is still supported.

2.7.1 Summary of storage stability of residues

Plant and animal commodities

No data submitted, not required.

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

2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

2.7.2.1 Plants

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

2.7.2.2 Animals

Kaolin is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall. Any livestock metabolism study is therefore not required.

2.7.3 Definition of the residue

Plant commodities/ Animal commodities:

Based on the DAR (2008) and the data submitted in the framework of the renewal, by the criteriria below a waiver from the requirement of residue data and MRL is still suggested:

- Kaolin has no known mode of toxicity, is insoluble in water and does not become bioavailable when ingested.
- No Toxicological Reference Values (ADI and ARfD) have been defined for kaolin.
- When applied to crops it leaves a white deposit on the surface that is easily removed by gentle rubbing and washing. This would be a normal procedure before marketing and/or consuming any foodstuff treated with kaolin.
- Kaolin is naturally present in the environment and is likely to be frequently present on crops contaminated with soil or dust particles.
- Kaolin does not degrade under environmental conditions.
- Kaolin cannot be analysed by conventional spectroscopy techniques. Kaolin is a natural component of soil and therefore cannot be distinguished from existing clays, either in the soil or as an air born dust. It is impossible to differentiate between naturally present kaolin and kaolin from plant protection product.

For all the above reasons, the status of "active substance for which no MRLs are required" and the inclusion of aluminium silicate (kaolin) in the Annex IV of Regulation (EC) No 396/2005 as set in Reg. (EC) No 839/2008 is still supported.

2.7.4 Summary of residue trials in plants and identification of critical GAP

No data submitted, not required.
According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no trial is required regarding the magnitude of residues in plants.

2.7.5 Summary of feeding studies in poultry, ruminants, pigs and fish

No data submitted, not required.
Aluminium silicate is chemically inert, not bioavailable, not metabolised in mammals and not absorbed through the gut wall. Furthermore, according to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no feeding study in poultry is not required.

2.7.6 Summary of effects of processing

Not applicable.
As a solid mineral, aluminium silicate (kaolin) is not readily degraded by typical household / industrial processes. It may only be structurally transformed by extreme temperatures / pressures (diagenesis or metamorphosis, which are two geological processes), or digested under harsh acidic conditions (concentrated nitric acid at reflux, for several hours). Consequently, kaolin will remain stable under the typical processing conditions described within OECD Guideline 507. A hydrolysis study is therefore not deemed to be necessary.
Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds.
Furthermore, according to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. Therefore, no data/information on processing study is required.

2.7.7 Summary of residues in rotational crops

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

2.7.8 Summary of other studies

Not applicable.

2.7.9 Estimation of the potential and actual exposure through diet and other sources

Not applicable.

2.7.10 Proposed MRLs and compliance with existing MRLs

According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005 and no MRLs are necessary (SANCO 11188/2013).

2.7.11 Proposed import tolerances and compliance with existing import tolerances

No import tolerances are proposed.

2.8 Fate and behaviour in the environment

2.8.1 Summary of fate and behaviour in soil

2.8.1.1 Route of degradation in soil

This document has been prepared to evaluate the application of Aluminium Silicate submitted by Société Kaolinière Armoricain (SOKA) and Tessenderlo Group N.V., for EU renewal of the Annex I inclusion. The document supplements and updates the corresponding Annex B section of the Draft Assessment Report produced during the first review of Aluminium Silicate, completed in 2009. In this report new data for the renewal of the approval of Aluminium Silicate has been evaluated. In addition the conclusions of the studies reported in the DAR are presented and have been re-assessed for validity.

This dossier refers to calcined kaolin, registered in 2008 under the term "Aluminium silicate". The regulatory term used throughout this dossier is therefore aluminium silicate, although in geological and mineralogical terms, the substance described therein is known as calcined kaolin.

Aluminium silicate is extremely stable and is a non-degradable natural component of the environment. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate has similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. Aluminium silicate is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the Aluminium silicate already existing in the soil. No increase in compaction, water penetration or aeration is anticipated since the existing clay particles exist in a much larger particle size distribution (already agglomerated) than the narrow fraction that will be added.

Since Aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies.

Representative formulation for SOKA is SOKALCIARBO WP and contains 1000 g/kg anhydrous Aluminium Silicate (Kaolin), formulated as WP (Wettable Powder). Representative formulation for Tessenderlo is SURROUND WP CROP PROTECTANT and contains 950 g/kg calcined aluminium silicate also known as kaolin, formulated as WP (Wettable Powder). Aluminium Silicate is an insect repellent and the representative product (SOKALCIARBO WP) is intended to be used on pome/stone fruits, nuts/walnut trees, citrus, lavender, olive trees and grapevines with the maximum proposed application amount to be 210 kg a.s./ha (60 kg a.s./ha for first application and 30 kg a.s./ha for the next 5 applications; 6 applications in total). Tessenderlo's representative product (SURROUND WP CROP PROTECTANT) is intended to be used on vines with the maximum proposed application amount to be 120 kg a.s./ha (30 kg a.s./ha for four applications in total). Aluminium silicate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as „the Regulation"), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. This active substance is an approved active substance under Regulation (EC) 1107/2009.

Aerobic degradation in soil

Aluminium silicate is ubiquitous in soil and agricultural soils. Aluminium silicate has similar chemical composition to common clay that is found in most soils over the world. Aluminium silicate is extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Very old Aluminium silicate's quarries are found all around the word because Aluminium silicate does not degrade in soil, therefore, it is not appropriated or suitable to perform studies to show the route and rate of degradation in soil of Aluminum silicate as it is not possible.

Anaerobic degradation in soil

No data submitted, nor required.

Photodegradation in soil

No data submitted, nor required.

2.8.1.2 Rate of degradation in soil

No data submitted, nor required.

2.8.1.3 Field dissipation studies

No data submitted, nor required.

Assessment of Persistence (P) in soil

Not applicable.

2.8.1.4 Mobility in soil

Adsorption desorption studies

Active substance

A waiver is requested for adsorption and desorption data on aluminium silicate (kaolin).

Aluminium silicate (kaolin) is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles, as it is a component of said soil particles. Aluminium silicate (kaolin) particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the aluminium silicate (kaolin) already existing in the soil. Adsorption and desorption of aluminium silicate (kaolin) 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.

This is exemplified in OECD Guidance n°106, Adsorption - Desorption Using a Batch Equilibrium Method.

In this guidance, paragraph 7 states: "The soil parameters that are believed most important for adsorption are: organic carbon content [references]; clay content and soil texture [references]; and pH for ionisable compounds [references]."

Paragraph 18 of OECD Guidance n°106 also states: "The soils should be characterised by three parameters considered to be largely responsible for the adsorptive capacity: organic carbon, clay content and soil texture, and pH. As already mentioned in paragraph 7, other physico-chemical properties of the soil may have an impact on the adsorption/desorption of a particular substance and should be considered in such cases."

OECD Guidance n°106 also provides guidance for the selection of soils based on pH range, organic carbon, clay content and soil texture:

Table 1: Guidance for selection of soil samples for adsorption-desorption

Soil type	pH range (in 0.01 M $CaCl_2$)	Organic carbon content (%)	Clay content (%)	Soil texture*
1	4.5-5.5	1.0-2.0	65-80	clay
2	> 7.5	3.5-5.0	20-40	clay loam
3	5.5-7.0	1.5-3.0	15-25	silt loam
4	4.0-5.5	3.0-4.0	15-30	loam
5	< 4.0-6.0§	< 0.5-1.5§‡	< 10-15§	loamy sand
6	> 7.0	< 0.5-1.0§‡	40-65	clay loam/clay
7	< 4.5	> 10	< 10	sand/loamy sand

* According to FAO and the US system (85).
§ The respective variables should preferably show values within the range given. If, however, difficulties in finding appropriate soil material occur, values below the indicated minimum are accepted.
‡ Soils with less than 0.3% organic carbon may disturb correlation between organic content and adsorption. Thus, it is recommended the use of soils with a minimum organic carbon content of 0.3%.

The generic term "clay" is not defined in the guidance; a definition of "clay" is provided in Bergaya et al. (Ed), Handbook of Clay Science, 1st Edition, Development in Clay Science 1, Elsevier Ed. 2006.

Chapter 1, pp. 3-5 states: "There is, as yet, no uniform nomenclature for clay and clay material. Nonetheless, we do not seek a consensus about the meaning of the terms ‘clay’, ‘clays’, and ‘clay minerals’ […]. Georgius Agricola (1494–1555), the founder of geology, was apparently the first to have formalized a definition of clay (Guggenheim and Martin, 1995). The latest effort in this direction was made nearly five centuries later by the joint nomenclature committees (JNCs) of the Association Internationale pour l’Etude des Argiles (AIPEA) and the Clay Minerals Society (CMS). The JNCs have defined ‘clay’ as "…a naturally occurring material composed primarily of fine-grained minerals, which is generally plastic at appropriate water contents and will harden with (sic) dried or fired" (Guggenheim and Martin, 1995). […]Although particle size is a key parameter in all definitions of clay, there is no generally accepted upper limit. Some disciplines and professions, however, have conventionally set a maximum size of clay particles. In pedology, for example, the ‘clay fraction’ refers to a class of materials

whose particles are smaller than 2 µm in equivalent spherical diameter (e.s.d.). In geology, sedimentology, and geoengineering the size limit is commonly set at 0.4 µm e.s.d. (Moore and Reynolds, 1997), while in colloid science the value of 0.1 µm is generally accepted. Indeed, Weaver (1989) has suggested that the term 'clay' should only be used in the textural sense to indicate material that is finer than 4 µm."

Under these criteria the active substance Aluminium silicate (kaolin), which presents a particle size within the range of 0.7 to 11 µm (CP 2.8.5.1, particle size distribution, in Miller 2012 , report number ARC-EX-848-012-P-1) is clearly a clay.

Under those circumstances, adsorption and desorption testing with aluminium silicate (kaolin) is meaningless as the test would involve adding clay to soil, rather than adding an organic substance capable of interacting with the test medium.

Expectations are that by using kaolin instead of another pesticide having toxic residues, the soil biodiversity will improve under aluminium silicate treated fields, since none of the present organisms would be exposed to additional potential toxins.

Adsorption and desorption of metabolites, breakdown and reaction products

No data submitted, nor required. Aluminium silicate does not have any metabolites.

Mobility in soil

Not applicable. Aluminium silicate is not mobile. When applied to soil, aluminium silicate particles will readily mix with other soil components and remain in the topsoil unless physically mixed with the subsoil layer. Therefore, a waiver for mobility studies is requested.
The mobility of clay particles in soil has not been investigated because because clays such as aluminium silicate (kaolin) are known to be insoluble in water, as demonstrated in the presence of an impermeable clay layer in most ponds, lakes or reservoirs. Therefore, aluminium silicate (kaolin) cannot be transported as solute through the soil layer.
Numerous literature sources refer to the clay content expected in soils in general and agricultural soils in particular, such as Newman A.C.D, The significance of clays in agriculture and soils, Phil. Trans. R. Soc. Land. A 311, 375-389 (1984) states (pp. 155-156):
"A soil usually contains at least some clay, and its clay content strongly influences its management and productivity (Davies et al. 1972). Soils with very little clay can be just as difficult to manage, for different reasons, as soils that contain large amounts, and in broad terms loam soils containing 15- 25% clay with particle sizes of under 2 μm and a larger proportion of silt particles sized 2-60 μm are the most productive. Such soils seem to contain enough clay to provide an adequate surface for interaction with water and nutrients, and to have a friable structure beneficial for tillage and root growth. Soils with more than 30-35 % by mass weight of clay tend to take on the properties of the clay itself, with the implications that they waterlog more easily during periods of excess rainfall, stay wet longer, require greater draft in cultivation and form large aggregates (clods) that must be broken down to form a favourable seed bed. In short, they pose more management problems than loamy soils.
Despite these apparently unfavourable properties conferred on soils by an excess of clay, clay makes a vital contribution to soil fertility. In combination with organic matter and sesquioxides, clay contributes coherence and structural stability which enables the soil to resist the mechanically destructive effects of rain and wind. Because clays have a large specific surface that is predominantly negatively charged, they retain cationic nutrients like K+ and NH4+, and also absorb toxic substances. Layer silicate clays may also have plant nutrients present in their structure, and K+ and Mg2+ can be released to soil solution under appropriate conditions."

2.8.2 Summary of fate and behaviour in water and sediment

Aluminium silicate is extremely stable and a non-degradable natural component of the environment. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate has similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies. Apart from a published literature study regarding clay settling in fresh and salt water that actually does not give any useful information regarding degradation of aluminium silicate in soil, no other data were submitted.

Assessment of Persistence (P) in aquatic systems

Not applicable.

2.8.3 Summary of fate and behaviour in air

Aluminium silicate is not vaporized, extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. Therefore it is assumed it does not degrade in air. It is not appropriated or suitable to perform studies to show the fate and behaviour of Aluminum silicate in air as it is not possible. Therefore, the applicant asks for a waiver to perform environmental studies.

2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Aluminium silicate is ubiquitous in soil (including agricultural soils) and aquatic sediments, and applied Aluminium silicate will be indistinguishable from naturally present clay. Therefore, the concept of environmental monitoring does not apply to Aluminium silicate.

2.8.5 Definition of the residues in the environment requiring further assessment

Aluminium silicate is ubiquitous in soil (including agricultural soils) and aquatic sediments, and applied Aluminium silicate will be indistinguishable from naturally present clay. Therefore, the concept of residue in the environment does not apply to Aluminium silicate. For the purpose of risk assessment though, relevant residues in the various compartments were considered as follows:

Soil: Aluminium Silicate

Surface water: Aluminium Silicate

Sediment: Aluminium Silicate

Groundwater: Aluminium Silicate

Air: Aluminium Silicate

2.8.6 Summary of exposure calculations and product assessment

Totally, 2 representative products were submitted. The Predicted Environmental Concentrationswere calculated for the compartments that this was feasible and are presented in detail in Vol. 3 (CP) and reproduced below.

Predicted Environmental Concentrations in soil

SOKALCIARBO WP

Table 2.8.6-1: Input parameters related to application for PECsoil calculations

Use No.	**1, 2, 3, 4, 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Crop interception (%)	60	50	50	80	20	70	60
Depth of soil	5	5	5	5	5	5	5

Table 2.8.6-2: Worst case PECsoil calculations for each concerned crop/use

Use No.	**1, 2, 3, 4, ~~5,~~ 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{soil} for single application (mg/kg)	26.67	40.00	20.00	13.33	16.00	20.00	10.67
Initial PEC_{soil} for multiple applications – cumulated applications (mg/kg)	74.67	140.00	**140.00**	53.33	67.20	80.00	42.67

Moreover, as per the proposal of coRMS the worst case PECsoil for Apples (7*30 kg, 0% crop interception) has been calculated and equals to 40 mg/kg for single application and 280 mg/kg for multiple applications.

SURROUND® WP

Table 2.8.6-3: Application pattern

Crop	Application rate	Max number of Applications	Min Interval	Application period
Vine	30 kg/ha	4	7 days	Up to BBCH 65

Table 2.8.6-4: Worst case PECs for aluminium silicate in soil – use in vines – late treatment

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

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

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

Predicted Environmental Concentrations in groundwater

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

Predicted Environmental Concentrations in surface water

SOKALCIARBO WP

Table 2.8.6-5: Input parameters related to application for PEC_{SW} calculations

Use No.	**1, 2, 3, 4, 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Spray drift for single application*	15.73	15.73	29.20	15.73	2.77	15.73	8.02
Spray drift for multiple applications*	10.12	9.21	22.69	9.21	1.75	9.21	6.71

*Based on Rautmann drift values

Table 2.8.6-6: Worst case PEC_{SW} calculations for each concerned crop/use

Use No.	**1, 2, 3, 4, 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{sw} for single application (mg/l)	2.62	3.14	2.92	2.62	0.14	2.62	0.53

Initial PEC_{sw} for multiple application (mg/l)	4.72	6.45	**15.88**	6.14	0.37	6.14	1.79

Predicted environmental concentrations in sediment (PEC_{SED})

Table 2.8.6-7: Input parameters related to application for PEC_{SED} calculations

Use No.	**1, 2, 3, 4, 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications	4	6/10	7	6	5	6	4
Spray drift for single application*	15.73	15.73	29.20	15.73	2.77	15.73	8.02
Spray drift for multiple applications*	10.12	9.21	22.69	9.21	1.75	9.21	6.71

*Based on Rautmann drift values

Table 2.8.6-8: Worst case PEC_{SED} calculations for each concerned crop/use

Use No.	**1, 2, 3, 4, 6, 7, 8, 9, 11, 16**	**5**	**10**	**12**	**13**	**14**	**15**
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{sed} for single application (mg/kg)	12.10	14.52	13.48	12.10	0.64	12.10	2.47

Initial PEC_{sed} for multiple application (mg/kg)	21.80	29.75	**73.31**	28.34	1.70	28.34	8.26

No FOCUS Step 1-2 calculations were submitted by SOKA.

SURROUND® WP

Table 2.8.6-9: Application pattern

Crop	Application rate	Max number of Applications	Min Interval	Application period
Vine	30 kg/ha	4	7 days	Up to BBCH 65

Two PECsw approaches have been conducted and are presented below.

Approach A

Table 2.8.6-10: Worst case PECsw for kaolin in surface waters with 3 m buffer zone – use in vines – late treatment

	Max single spray	Total season
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Spray drift** (%)	8.02	8.02
Spray deposit (mg/m^2)	240.6	962.4
Water volume (L)	300	300
PEC_{SW} (mg/L)	**0.802**	**3.208**

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

Approach B

Aluminium silicate is not soluble in water. Therefore, aluminium silicate will either settle in a slow-moving water body or be dispersed until settling can take place.
Following a request from the RMS, PEC_{SW} calculations were conducted using the FOCUS STEPS 1-2 model as per co-RMS feedback.
The following input values were used:
All possible scenario combinations were modelled:

- North and South Europe
- Early application (minimal crop cover)
- Late application (full canopy) (repeated by the RMS considering minimal cover as worst case)
- Treatment in October to February, March to May and June to September
- Single application rate: 30 000 g/ha
- 4 applications, 7-day interval
- 0,000001 mg/L water solubility (lowest value accepted by model for an insoluble substance)
- Koc = 1 000 000 L/g (highest value for a natural soil component)
- DT50 = 1000 days in soil, surface water and sediment (default worst case)

Results are presented in Table 2.8.6-11 below.

Table 2.8.6-11: PECSW and PEC_{SED} for SURROUND as calculated by FOCUS STEPS1-2

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

*: Value used for aquatic ecotoxicology risk assessment

Predicted environmental concentrations in sediment (PEC_{SED})

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, we consider 100% of the product entering waterways will transfer to the sediment.

Approach A

Table 2.8.6-12: Worst case PEC_{SED} for kaolin in surface waters with 3 m buffer zone – use in vines – late treatment

	Max single spray	**Total season**
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Spray Drift**	8.02	8.02
Spray deposit (mg/m^2)	240.6	962.4
Sediment weight (1 m^2 x 5 cm depth x 1.3 g/cm^3)	65 kg	65 kg
Transfer to sediment	100 %	100 %
PEC_{SED} (mg/kg)	**3.70**	**14.81**

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

Approach B

For the FOCUS approach, PEC_{SED} have been calculated with the FOCUS STEPS1-2 tool and presented in Table 2.8.6-11 above.

Predicted Environmental Concentrations in air

No PECair estimations were performed nor required.

2.9 Effects on non-target species

2.9.1 Summary of effects on birds and other terrestrial vertebrates

Birds

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

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

Species	Substance	Exposure System	Results	Reference
Gallus gallus domesticus	Kaolin	Dietary,56 d Subchronic	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)

Mammals

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

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.

According to the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

"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."

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).

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.

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).

2.9.2 Summary of 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.

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)

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
Brevoortia tyrannus, Anchoa mitchilli, Fundulus majalis, F.Heteroclitus, Rissola marginata, Menidia menidia, Morone saxatilis, M. Americana, Leiostomus xanthurus, Micropogon undulatus, Cynoscion regalis, Trinectes maculatus, Pomatomus saltatrix, Opsanus tau	24-48h (static)	Aluminium silicate	LC_{50}: >140000 mg/l (nominal)	B.9.2.1/03 Sherk, J. A. Jr., (1973)
Oncorhynchus kisutch & Oncorhynchus mykiss	48 hr (flow-through)	Aluminium silicate	LC_{50}: >4000 mg/l (nominal)*	B.9.2.1/04 Redding, Schreck, & Everest (1987)
Long-term fish				
Oncorhynchus mykiss	64 days (semi-static)	Aluminium silicate	NOEC: 1017 mg/l (nominal)*	B.9.2.2/01 Goldes et al. (1988)
Oncorhynchus mykiss	30 days (ELS) (static)	Aluminium silicate	NOEC: 100 mg/l (nominal)	B.9.2.2.1/01 Hashimoto et al., (1986)
Acute aquatic invertebrates				
Cancer magister	200h (flow through)	Aluminium silicate	LC_{50}: 32000 mg/l (nominal)	B.9.2.4.1/01 McFarland, V. A. and Peddicord, R. K. (1980)
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)

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

2.9.3 Summary of 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.2.8.9-1

Table B.2.9.3-1: 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,

Species	Test item	Time scale/method	Endpoint	Reference
				2012)
	SOKALCIARBO WP	48 h contact toxicity	LD_{50} > 500 µg a.s./bee	Mamet O., 2008
	SURROUND® WP CROP PROTECT-ANT	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 NOEC = 29997 mg a.s./kg diet NOEDD = 882 µg a.s./bee/day	Mamet O., 2019
	SURROUND® WP CROP PROTECT-ANT	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 PROTECT-ANT	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

2.9.4 Summary of effects on non-target arthropods

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.2.9.4-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Laboratory studies				
No GLP-compliant studies were conducted.				
Field or semi-field tests				
Puterka, 1997; Lepine J. 2004; Fraser, H. 2002a,b,c,d,e; G Peusens & P Creemers 2004a,b (EFSA Conclusion 2012; KCP 10.3.2.4/01 to /09) Nine field studies (in many of them several applications of high doses were applied) demonstrated that Surround is not harmful to many groups of beneficials, including lacewings (chrysoperlids), ladybirds (coccinellids), hoverflies (syrphids), some heteropteran bugs (eg mirids), parasitic hymenopterans and spiders. However, in some trials a reduction in predatory mites (*Amblyseius*) and anthocorid bugs was noted. Pascual *et al.*, 2010a A 3-year field experiment was conducted from 2005 to 2007 at Villarejo de Salvanes, Spain to assess the effects of Surround WP (2 x 3 kg/100L) on the arthropod community of olive trees and on natural enemies. The principal response curve (PRC) analysis revealed a significant deleterious effect of Surround WP on the natural enemy arthropod community of the olive grove. Both the abundance and the diversity of arthropods were reduced. The most affected taxa were the following: *Scymnus mediterraneus, Stethorus punctillum, Hyperaspis reppensis, Brachynotocoris ferreri* and different species of *Orius* and the families of Philodromidae, Scelionidae, Pteromalidae, and Aphelinidae, and Chrysopidae. Marko V. et al., 2010 Application of kaolin particle film (10-12 x 45 kg/ha; 10-d intervals) reduced the abundance and species richness of the apple orchard heteropteran, beetle and spider communities, the main guilds and the most common species. It also altered the composition and diversity of communities. The degree of reduction was different in many taxa, causing differences between the composition and diversity of the communities in the kaolin-treated and control				

Species	Substance	Exposure System	Results	Reference
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.				

Species	Substance	Exposure System	Results	Reference
Showler & Sétamou, 2004 Surround at a rate of 42.3 L/ha applied weekly or biweekly from mid-April to the end of June (approximately 7 to 10 applications) in a 2-year field trial in cotton fields. Populations of dipterans, *Orius* spp., and wasps were reduced in the kaolin treatments (specific samplings), but differences were statistically confirmed only in 1 of 20 sampling dates over the two seasons. Pascual *et al.*, 2010b Surround WP (2 x 3 kg/100L) was tested in a olive grove in Madrid in 2006. Both PRC and two-way ANOVA identified the coccinellid *Scymnus mediterraneus* and the spider family Philodromidae as the taxa the most affected by kaolin. Kaolin treatment caused a significant reduction in numbers of predators compared to the untreated control, while trichlorfon treatment had less pronounced effects. Other affected taxa (taxon weight > 0.5) include other Salticidae, *Hyperaspis reppensis*, Chrysopidae, other coccinellidae, *Brachynotocoris ferreri*, *Stethorus punctillum*, *Araniella cucurbitina*, other Thomisidae, *Orius laevigatus* and other Theridiidae. Tacoli *et al*., 2019 Surround WP applied 2 times (20 kg/ha) reduced the abundance of predatory mite populations (Araci: Phytoseiidae) in vineyards located in north-eastern Italy in 2015-2016 (4 field trials). Kaolin caused a gradual decrease in population density levels of *Kampimodromus aberrans* and *Typhlodromus pyri* with the maximum reduction ranging from 49 to 91% and with a complete population recovery in the next spring. Laboratory data showed that kaolin (190-200 kg/ha) reduced the fecundity of *K. aberrans* and *T. pyri* females but not their survival. Jaastad *et al*., 2006 Kaolin particle film (Surround) was applied twice (3 kg/hL) in an organic plum field and in two IPM apple fields in Western Norway in 2003-2005. The population of beneficial mites was negatively affected by kaolin treatment in both apples and plums in 2004 and 2005. The most common species of beneficial mites recorded were *Tydeus* sp., *Typhlodromus* sp. and *Amplyseius* sp.				

2.9.5 Summary of 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 macroorganisms 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 SOKALCI-

ARBO 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 2.9.5-1.**

Table 2.9.5-1: 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)6, it can be noted in the diagram below that a large area of Europe consists of 28 to 98% clay-based soil. 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.

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

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.

Conclusion: **In light of these considerations also presented in details in the Vol. CA and CPs for each Task Force, 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.**

2.9.6 Summary of 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 the considerations provided, 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.

2.9.7 Summary of 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.

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).

Summary of 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).

[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.

Conclusion: In light of the considerations prodived in Vol.3 CA and CPs, 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.

2.9.8 Summary of 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.

TASK FORCE SOKA:
Aluminium silicate is present in most natural soils and agricultural soils, and the use of SOKALCIAR-BO 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.).

2.9.9 Summary of 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.

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 in the Vol 3. CA.

Conclusion: In light of the above 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.

2.9.10 Summary of product exposure and risk assessment

Risk assessment for birds and other terrestrial vertebrates

Birds and Mammals

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

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

Species	Substance	Exposure System	Results	Reference
Gallus gallus domesticus	Kaolin	Dietary,56 d Subchronic	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)

Risk assessment aquatic organisms

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

Toxicity

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

A summary of the available aquatic toxicity endpoints for aluminium silicate is presented below.

Table: Summary of available aquatic toxicity endpoints for aluminium silicate

Test species	Test system	Test substance	Endpoint (mg/L)	Reference
Acute fish				
Larvae of Pagrus major, Oplegnathus fasciatus and Parapristipoma trilineatum	12h (static)	Aluminium silicate	LC_{50}: 494 (geometric mean)*	B.9.2.1/01 Isono et al. (1998)
Cymatogaster aggregata	200h (flow through)	Aluminium silicate	LC_{50}: **3000** mg/l (nominal)	B.9.2.1/02 McFarland, V. A. and Peddicord, R. K. (1980)
Brevoortia tyrannus, Anchoa mitchilli, Fundulus majalis, F.Heteroclitus, Rissola marginata, Menidia menidia, Morone saxatilis, M. Americana, Leiostomus xanthurus, Micropogon undulatus, Cynoscion regalis, Trinectes maculatus, Pomatomus saltatrix, Opsanus tau	24-48h (static)	Aluminium silicate	LC_{50}: >140000 mg/l (nominal)	B.9.2.1/03 Sherk, J. A. Jr., (1973)

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

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

REGULATORY ACCEPTABLE CONCENTRATIONS

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

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

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

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

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

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

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

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

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

Sub-stance	Time span	Species group	Test organism	Selected end-point for use in risk assessment	Assessment factor	RAC (mg/L)
Alumin-ium sili-cate	Acute	Fish	*Cymatogaster aggregata*	LC_{50} = 3000 mg a.s./L	100	30
		Aquatic Inver-tebrates	*Daphnia magna*	EC_{50} = 570 mg a.s./L	100	5.7
	Chronic	Fish	*Oncorhynchus mykiss*	NOEC = 100 mg a.s./L	10	10
		Aquatic Inver-tebrates	*Daphnia magna*	NOEC = 50 mg a.s./L	10	5
		Algae	*Pseudokirchneri-ella subcapitata*	E_rC_{50} = 100 mg a.s./L	10	10

EXPOSURE OF SURROUND WP CROP PROTECTANT

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

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

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

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

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

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

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

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

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

- North and South Europe

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

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

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

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

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

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

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

Overall Conclusion:

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

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

EXPOSURE OF SOKALCIARBO WP

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

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

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

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

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

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
PEC sw (mg/L)						
single application (mg/l)	2.62	0.09	0.26	0.46	0.52	0.26
multiple application (mg/l)	4.72	0.16	0.47	0.83	0.94	0.47

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

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

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

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

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

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

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

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

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

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

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

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

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	0.14	0.005	0.01	0.02	0.03	0.01

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
multiple application (mg/l)	0.37	0.01	0.04	0.06	0.07	0.04

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

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

Group		Fish acute	Fish long-term	Invertebrates acute	Invertebrates Long-term	Algae
Test species		**Cymatogaster aggregata**	**Oncorhynchus mykiss**	**Daphnia magna**	**Daphnia magna**	**Pseudokirchneriella subcapitata**
Endpoint		LC50	NOEC	EC50	NOEC	ErC50
(mg/L)		3000	100	570	50	100
AF		100	10	100	10	10
RAC (mg/L)		30	10	5.7	5	10
PEC sw (mg/L)						
single application (mg/l)	0.53	0.02	0.05	0.09	0.11	0.05
multiple application (mg/l)	1.79	0.06	0.18	0.31	0.36	0.18

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

Overall conclusion for aquatic organisms

Crop	aluminium silicate

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

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

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

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

Risk assessment for bees

SURROUND® WP

The risk assessment for bees has been conducted in line with the current Terrestrial Guidance Document (SANCO/10329/2002). A risk assessment for chronic risk to bees as described in the new EFSA bee guidance will be included for illustration purposes but will not be part of the List of Endpoints. The LDD_{50} 1390 µg a.s./bee/day (worker bee) and the NOED 405 µg a.s./larvae of active substance will be used in the risk assessment.

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

Risk assessment for honeybees according to SANCO/10329/2002

Acute risk to honeybees

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants while bees are foraging on flowers and weeds present in or adjacent to the crop treated. The results of the risk assessment are summarised in the following tables.

Table 2.9.10-: Acute Risk to bees from oral exposure to aluminium silicate

Test substance	Application rate (g a.s./ha)	Oral LD_{50} (µg a.s./bee)	Hazard quotient	Trigger
Aluminium silicate	28500	>100*	<285	**50**
SURROUND® WP		>1900*	15	

* Non-valid study. Risk assessment for illustration purposes

Table 2.9.10-: Acute Risk to bees from contact exposure to aluminium silicate

Test substance	Application rate (g a.s./ha)	Contact LD_{50} (µg a.s./bee)	Hazard quotient	Trigger
Aluminium silicate	28500	>100	<285	**50**

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

Risk assessment for honeybees according to EFSA (2013)

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

Contact exposure

Screening acute contact assessment

A screening assessment has been conducted considering the endpoints from the honeybee studies conducted with the formulated product SURROUND® WP. Acute contact hazard quotients (HQs) for honeybees are presented in the following table. The HQs have been calculated assuming sideward spray application.

Table 2.9.10-: Screening assessment for contact route of exposure for honeybees for the proposed uses of SURROUND® WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	$HQ_{contact}$	Trigger value	Acceptable risk?
Honey bee (adults)	Acute contact	28500	>100	<285	>85	**No**

The hazard quotient (HQ) for contact exposure of bees to SURROUND® WP exceeds the trigger value.

Tier I assessment for contact route of exposure

The risk assessment is conducted for the relevant scenarios.

Table 2.9.10-: Tier I assessment for contact route of exposure for honeybees for the proposed uses of SURROUND® WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	f_{dep}	$HQ_{contact}$	Trigger value	Acceptable risk?
Honey bee (adults)	Acute contact (treated crop)	28500	>100	1*	285	85	**No**
	Acute contact (weeds)			1 (BBCH<10) 0.6 (BBCH 10-19) 0.5 (BBCH 20-39) 0.3 (BBCH >40)	285 171.0 142.5 85.5	42	**No**
	Acute contact (field margin)			0.027 (BBCH <20) 0.08 (BBCH >20)	7.7 22.8	42	Yes

* Honeybees are attracted to the pollen of grapevines

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

Oral exposure

Screening acute oral assessment

Table 2.9.10-:: Screening assessment for oral route of exposure for honeybees for the proposed uses of SURROUND® WP

Test group	Exposure scenario	Appl. rate (kg a.s./ha)	Short-cut value	Endpoint	ETR_{oral}	Trigger value	Acceptable risk?
Honey bee (adults)	Acute oral	28.5	10.6	LD_{50} >100 µg a.s./bee*	3.02	0.2	**No**
	Chronic oral	28.5	10.6	LDD_{50} 1390 µg a.s./bee/d	0.217	0.03	**No**
Honey bee (larvae)	Chronic oral	28.5	6.1	NOED 405 µg a.s./larvae	0.43	0.2	**No**

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

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

Tier I assessment for oral route of exposure

When concern has been raised regarding the potential risk to bees from the consumption of pollen and nectar in the screening assessment, the initial step of the Tier I risk assessment is to refine the exposure estimate used in the above calculations.

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

Table 2.9.10-:: First tier assessment for oral route of exposure

Category	scenario	BBCH	E_f	Short-cut value	twa	Honeybee	
						ETR	trigger
acute	treated crop	< 10	1	0.7	1	0.20	0.2
	treated crop	10 - 19	1	10.6		**3.02**	
	treated crop	20 - 39	1	10.6		**3.02**	
	treated crop	40 - 69	1	10.6		**3.02**	
	weeds	< 10	1	3.7		**1.05**	
	weeds	10 - 19	0.6	3.7		**0.63**	
	weeds	20 - 39	0.5	3.7		**0.53**	
	weeds	40 - 69	0.3	3.7		**0.32**	
	field margin	< 10	0.009	3.7		0.01	

	field margin	10 - 19	0.009	3.7		0.01	
	field margin	20 - 39	0.027	3.7		0.03	
	field margin	40 - 69	0.027	3.7		0.03	
	adjacent crop	< 10	0.0047	7.6		0.01	
	adjacent crop	10 - 19	0.0047	7.6		0.01	
	adjacent crop	20 - 39	0.0143	7.6		0.03	
	adjacent crop	40 - 69	0.0143	7.6		0.03	
	following year	< 10	1	0.7		0.20	
	following year	10 - 19	1	0.7		0.20	
	following year	20 - 39	1	0.7		0.20	
	following year	40 - 69	1	0.7		0.20	
chronic	treated crop	< 10	1	0.54	0.72	0.01	0.03
	treated crop	10 - 19	1	8.2		**0.12**	
	treated crop	20 - 39	1	8.2		**0.12**	
	treated crop	40 - 69	1	8.2		**0.12**	
	weeds	< 10	1	2.9		**0.04**	
	weeds	10 - 19	0.6	2.9		0.03	
	weeds	20 - 39	0.5	2.9		0.02	
	weeds	40 - 69	0.3	2.9		0.01	
	field margin	< 10	0.009	2.9		0.00	
	field margin	10 - 19	0.009	2.9		0.00	
	field margin	20 - 39	0.027	2.9		0.00	
	field margin	40 - 69	0.027	2.9		0.00	
	adjacent crop	< 10	0.0047	5.8		0.00	
	adjacent crop	10 - 19	0.0047	5.8		0.00	
	adjacent crop	20 - 39	0.0143	5.8		0.00	
	adjacent crop	40 - 69	0.0143	5.8		0.00	
	following year	< 10	1	0.54		0.01	
	following year	10 - 19	1	0.54		0.01	
	following year	20 - 39	1	0.54		0.01	
	following year	40 - 69	1	0.54		0.01	
larva	treated crop	< 10	1	0.4	0.85	0.02	0.2
	treated crop	10 - 19	1	6.1		**0.36**	
	treated crop	20 - 39	1	6.1		**0.36**	

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

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

Assessment of risk from exposure to metabolites

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

Risk assessment for accumulative effects

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

Sublethal effects

No specific studies were carried out. Possible sublethal effects on bees from the use of the product SURROUND® WP could not be obtained from the available acute or chronic toxicity studies. No effects on foraging behaviour was recorded in the two non-GLP field studies.

Honey bee exposure via drinking water

Bees may potentially be exposed to the applied product *via* drinking water. Therefore, in line with the EFSA Bee Guidance (2013) the risk to honeybees from this route of exposure has been assessed. Exposure to bees *via* drinking water is based on the maximum PECsw value of 3.208 mg/L (total season).

Since kaolin is practically insoluble to water, the solubility was set to 0. The PEC_{puddle} were not calculated in the fate and behaviour section. The ETR_{oral} values for honeybees *via* exposure from drinking water are presented in the following table.

Table 2.9.10-:: Drinking water assessment for honeybees

Exposure scenario	PEC (µg/µL)	W [a] (µL/bee)	Timescale (life stage)	Toxicity end-point	ETR_{oral}	Trigger value	Acceptable risk?
Surface water	0.0032	11.4	Acute (adult)	LD_{50} >100 a.s./bee*	0.00	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 1390 µg a.s./bee/d	0.00	0.03	Yes
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	0.00	0.2	Yes
Guttation fluid	0	11.4	Acute (adult)	LD_{50} >100 a.s./bee	0	0.2	Yes
		11.4	Chronic (adult)	LDD_{50} 1390 µg a.s./bee/d	0	0.03	Yes
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	0	0.2	Yes
Puddle	-	11.4	Acute (adult)	LD_{50} >100 a.s./bee	-	0.2	-
		11.4	Chronic (adult)	LDD_{50} 1390 µg a.s./bee/d	-	0.03	-
		111	Chronic (larvae)	NOED 405 µg a.s./larvae	-	0.2	-

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

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

Discussion/Overall conclusion

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

A possible risk to worker bees and larva for the treated crop and weeds scenarios is identified at Tier I level when the risk assessment is conducted according to the new EFSA bee GD.

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

The absence of unacceptable effects on bees from the use of the representative formulation SURROUND® WP cannot be excluded. The co-RMS FR is of the opinion that '*the reliability of the risk assessment scheme of the EFSA guidance for natural and inorganic substance as Kaolin could be con-*

sidered questionable. In fact, shortcut values used in the ETR calculations and trigger values are calibrated for substances with toxicities due to a chemical mode of action, since aluminium silicate is an inorganic compound with a physical mode of action, the risk assessment could be considerate as too conservative. Considering the uncertainties on the appropriateness of the risk assessment scheme of the EFSA guidance for aluminium silicate, FR considered that the risk for bees could be refined using a weight of evidence based on the nature of the substance and its mode of action'. The RMS agrees with the opinion that the risk to bees could be refined using a weight-of-evidence approach.

SOKALCIARBO WP

The risk assessment for bees has been conducted in line with the current Terrestrial Guidance Document (SANCO/10329/2002). A risk assessment for chronic risk to bees as described in the new EFSA bee guidance will be included for illustration purposes but will not be part of the List of Endpoints. It should be noted that under the EFSA Technical Report (2015)[9] when data on bumblebees and solitary bees are not available, it cannot be recommended to routinely perform a risk assessment.

A chronic worker bee study with the formulation SOKALCIARBO is available. In the absence of a larvae study conducted for SOKALCIARBO (the notifier stated that it will be available at a later stage) a provisional risk assessment considering the NOED of the active substance (tested as SURROUND® WP) was considered.

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

Risk assessment for honeybees according to SANCO/10329/2002

Acute risk to honeybees

Applications of pesticides can potentially result in exposure of honeybees either through direct overspray, or by contact with residues on plants whilst bees are foraging for food. The results of the risk assessment are summarised in the following tables.

Table 2.9.10-: Acute Risk to bees from oral exposure to aluminium silicate

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

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

[9] EFSA, 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology.

Table 2.9.10-: Acute Risk to bees from contact exposure to aluminium silicate

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

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

Risk assessment for honeybees according to EFSA (2013)

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

Contact exposure

Screening acute contact assessment

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

Table 2.9.10-: Screening assessment for contact route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	$HQ_{contact}$	Trigger value	Acceptable risk?

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

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

Tier I assessment for contact route of exposure

The risk assessment is conducted for the relevant scenarios.

Table 2.9.10-: Tier I assessment for contact route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

Test group	Exposure scenario	Application rate (g a.i./ha)	LD_{50} (µg a.i./bee)	f_{dep}	$HQ_{contact}$	Trigger value	Acceptable risk?
Stone fruits, pome fruits, nuts fruits [1]							
Honey bee (adults)	treated crop	50000	>500	1	<100	85	**No**
	weeds			0.3 (BBCH >40)	<30	42	Yes
	field margin			0.157 (BBCH >40)	<15.7	42	Yes
Citrus, Olive tree [2]							
Honey bee (adults)	treated crop	50000	>500	1	<100	85	**No**
	weeds			0.3 (BBCH >40)	<30	42	Yes
	field margin			0.157 (BBCH >40)	<15.7	42	Yes
Apple tree							
Honey bee (adults)	treated crop	30000	>500	1	<60	85	Yes
	weeds			0.3 (BBCH >40)	<18	42	Yes
	field margin			0.157 (BBCH >40)	<9.4	42	Yes

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

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

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

Oral exposure

Screening acute oral assessment

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

Table 2.9.10-: Screening assessment for oral route of exposure for honeybees for the proposed uses of SOKALCIARBO WP

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

Test group	Exposure scenario	Appl. rate (kg a.s./ha)	Short-cut value	Endpoint	ETR_{oral}	Trigger value	Acceptable risk?
Honey bee (larvae)	Chronic oral		6.1	NOED 405 µg a.s./larvae	0.75	0.2	**No**

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

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

Tier I assessment for oral route of exposure

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

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

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

Table 2.9.10-: First tier assessment for oral route of exposure

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

	treated crop	≥ 70	1	0		0.00	
	weeds	40 - 69	0.3	2.9		0.01	
	weeds	≥ 70	0.3	2.9		0.01	
	field margin	40 - 69	0.052	2.9		0.00	
	field margin	≥ 70	0.052	2.9		0.00	
	adjacent crop	40 - 69	0.031	5.8		0.00	
	adjacent crop	≥ 70	0.031	5.8		0.00	
	next crop	40 - 69	1	0.54		0.01	
	next crop	≥ 70	1	0.54		0.01	
larva	treated crop	40 - 69	1	6.1	0.85	**0.64**	0.2
	treated crop	≥ 70	1	0		0.00	
	weeds	40 - 69	0.3	2.2		0.07	
	weeds	≥ 70	0.3	2.2		0.07	
	field margin	40 - 69	0.052	2.2		0.01	
	field margin	≥ 70	0.052	2.2		0.01	
	adjacent crop	40 - 69	0.031	4.4		0.01	
	adjacent crop	≥ 70	0.031	4.4		0.01	
	next crop	40 - 69	1	0.4		0.04	
	next crop	≥ 70	1	0.4		0.04	
Citrus, Olive tree (6 applications with a maximum of 50000 g a.s./ha) [2]							
acute	treated crop	≥ 70	1	0	1	0.00	0.2
	weeds		0.3	3.7		**0.56**	
	field margin		0.052	3.7		0.10	
	adjacent crop		0.031	7.6		0.12	
	next crop		1	0.7		**0.35**	
chronic	treated crop		1	0	0.72	0.00	0.03
	weeds		0.3	2.9		0.01	
	field margin		0.052	2.9		0.00	
	adjacent crop		0.031	5.8		0.00	
	next crop		1	0.54		0.01	
larva	treated crop		1	0	0.85	0.00	0.2

	weeds		0.3	2.2		0.07	
	field margin		0.052	2.2		0.01	
	adjacent crop		0.031	4.4		0.01	
	next crop		1	0.4		0.04	
Apple tree (7 applications with a maximum of 30000 g a.s./ha)							
	treated crop	< 10	1	0.7		**0.21**	
	treated crop	10 - 19	1	10.6		**3.18**	
	treated crop	20 - 39	1	10.6		**3.18**	
	treated crop	40 - 69	1	10.6		**3.18**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	3.7		**1.11**	
	weeds	10 - 19	0.8	3.7		**0.89**	
	weeds	20 - 39	0.6	3.7		**0.67**	
	weeds	40 - 69	0.3	3.7		**0.33**	
	weeds	≥ 70	0.3	3.7		**0.33**	
	field margin	< 10	0.052	3.7		0.06	
	field margin	10 - 19	0.052	3.7		0.06	
acute	field margin	20 - 39	0.052	3.7	1	0.06	0.2
	field margin	40 - 69	0.052	3.7		0.06	
	field margin	≥ 70	0.052	3.7		0.06	
	adjacent crop	< 10	0.031	7.6		0.07	
	adjacent crop	10 - 19	0.031	7.6		0.07	
	adjacent crop	20 - 39	0.031	7.6		0.07	
	adjacent crop	40 - 69	0.031	7.6		0.07	
	adjacent crop	≥ 70	0.031	7.6		0.07	
	next crop	< 10	1	0.7		**0.21**	
	next crop	10 - 19	1	0.7		**0.21**	
	next crop	20 - 39	1	0.7		**0.21**	
	next crop	40 - 69	1	0.7		**0.21**	
	next crop	≥ 70	1	0.7		**0.21**	
chronic	treated crop	< 10	1	0.54	0.72	0.00	0.03

	treated crop	10 - 19	1	8.2		**0.07**	
	treated crop	20 - 39	1	8.2		**0.07**	
	treated crop	40 - 69	1	8.2		**0.07**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.9		0.02	
	weeds	10 - 19	0.8	2.9		0.02	
	weeds	20 - 39	0.6	2.9		0.01	
	weeds	40 - 69	0.3	2.9		0.01	
	weeds	≥ 70	0.3	2.9		0.01	
	field margin	< 10	0.052	2.9		0.00	
	field margin	10 - 19	0.052	2.9		0.00	
	field margin	20 - 39	0.052	2.9		0.00	
	field margin	40 - 69	0.052	2.9		0.00	
	field margin	≥ 70	0.052	2.9		0.00	
	adjacent crop	< 10	0.031	5.8		0.00	
	adjacent crop	10 - 19	0.031	5.8		0.00	
	adjacent crop	20 - 39	0.031	5.8		0.00	
	adjacent crop	40 - 69	0.031	5.8		0.00	
	adjacent crop	≥ 70	0.031	5.8		0.00	
	next crop	< 10	1	0.54		0.00	
	next crop	10 - 19	1	0.54		0.00	
	next crop	20 - 39	1	0.54		0.00	
	next crop	40 - 69	1	0.54		0.00	
	next crop	≥ 70	1	0.54		0.00	
larva	treated crop	< 10	1	0.4	0.85	0.03	0.2
	treated crop	10 - 19	1	6.1		**0.38**	
	treated crop	20 - 39	1	6.1		**0.38**	
	treated crop	40 - 69	1	6.1		**0.38**	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.2		0.14	
	weeds	10 - 19	0.8	2.2		0.11	

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

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

	weeds	≥ 70	0.3	2.9		0.00	
	field margin	< 10	0.0092	2.9		0.00	
	field margin	10 - 49	0.0092	2.9		0.00	
	field margin	50 - 69	0.0092	2.9		0.00	
	field margin	≥ 70	0.0092	2.9		0.00	
	adjacent crop	< 10	0.0033	5.8		0.00	
	adjacent crop	10 - 49	0.0033	5.8		0.00	
	adjacent crop	50 - 69	0.0033	5.8		0.00	
	adjacent crop	≥ 70	0.0033	5.8		0.00	
	next crop	< 10	1	0.54		0.00	
	next crop	10 - 49	1	0.54		0.00	
	next crop	50 - 69	1	0.54		0.00	
	next crop	≥ 70	1	0.54		0.00	
larva	treated crop	< 10	1	0.4	0.85	0.01	0.2
	treated crop	10 - 49	1	4.4		0.14	
	treated crop	50 - 69	1	4.4		0.14	
	treated crop	≥ 70	1	0		0.00	
	weeds	< 10	1	2.2		0.07	
	weeds	10 - 49	1	2.2		0.07	
	weeds	50 - 69	0.3	2.2		0.02	
	weeds	≥ 70	0.3	2.2		0.02	
	field margin	< 10	0.0092	2.2		0.00	
	field margin	10 - 49	0.0092	2.2		0.00	
	field margin	50 - 69	0.0092	2.2		0.00	
	field margin	≥ 70	0.0092	2.2		0.00	
	adjacent crop	< 10	0.0033	4.4		0.00	
	adjacent crop	10 - 49	0.0033	4.4		0.00	
	adjacent crop	50 - 69	0.0033	4.4		0.00	
	adjacent crop	≥ 70	0.0033	4.4		0.00	
	next crop	< 10	1	0.4		0.01	
	next crop	10 - 49	1	0.4		0.01	

	next crop	50 - 69	1	0.4		0.01	
	next crop	≥ 70	1	0.4		0.01	

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

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

Assessment of risk from exposure to metabolites

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

Risk assessment for accumulative effects

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

Sublethal effects

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

Honey bee exposure via drinking water

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

Table 2.9.10-: Drinking water assessment for honeybees

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

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

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

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

Discussion/Overall conclusion

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

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

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

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

Risk assessment for non-target arthropods

SURROUND® WP

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the SANCO/10329/2002 rev.2, and in consideration of the recommendations of the guidance document ESCORT 2[10].

Risk assessment based on laboratory studies

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

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

Risk assessment based on semi-field and field studies

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

In-field area:

Field studies considered in the previous evaluation of the active substance

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

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

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

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

- no acceptable guideline was followed

Additional open literature studies

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

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

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

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

Overall conclusion

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

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

SOKALCIARBO WP

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the SANCO/10329/2002 rev.2, and in consideration of the recommendations of the guidance document ESCORT 2[11].

Risk assessment based on laboratory studies

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

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

Risk assessment based on semi-field and field studies

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

In-field area:

Field studies considered in the previous evaluation of the active substance

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

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

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

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

Overall conclusion

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

Risk assessment for earthworms and other non-target soil macro- and meso-fauna

TASK FORCE: SOKA // SOKALCIARBO WP

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

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

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

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

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

Risk assessment for soil micro-organisms

TASK FORCE: SOKA // SOKALCIARBO WP

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

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

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

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

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

Risk assessment for non-target terrestrial higher plants

TASK FORCE: SOKA // SOKALCIARBO WP

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

No additional data/study with the representative formulation SOKALCIARBO WP was performed, since it is possible to extrapolate from data obtained with the active substance [due to the composition of the representative formulation SOKALCIARBO WP (please refer to Document J)]. Aluminium silicate is used as an insect repellent only, it is a systemic substance, and therefore is not absorbed or metabolized by plants. Furthermore, in this document, it has been shown that:

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

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

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

TASK FORCE: TESSENDERLO // SURROUND® WP CROP PROTECTANT

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

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

2.10 Endocrine disrupting (ED) properties

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).

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[12] 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).

[12] https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID30107899

2.11 Classification and labelling

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	-	-	-	Conclusive but not sufficient for classification
2.2.	Flammable gases	-	-	-	Not applicable
2.3.	Flammable aerosols	-	-	-	Not applicable
2.4.	Oxidising gases	-	-	-	Not applicable
2.5.	Gases under pressure	-	-	-	Not applicable
2.6.	Flammable liquids	-	-	-	Not applicable
2.7.	Flammable solids	-	-	-	Conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures	-	-	-	Not applicable
2.9.	Pyrophoric liquids	-	-	-	Not applicable
2.10.	Pyrophoric solids	-	-	-	Conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures	-	-	-	Conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	-	Not applicable
2.13.	Oxidising liquids	-	-	-	Not applicable
2.14.	Oxidising solids	-	-	-	Conclusive but not sufficient for classification
2.15.	Organic peroxides	-	-	-	Not applicable
2.16.	Substance and mixtures corrosive to metals	-	-	-	Not applicable
3.1.	Acute toxicity - oral	-	-	-	Conclusive but not sufficient for classification

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
	Acute toxicity - dermal	-	-	-	Conclusive but not sufficient for classification
	Acute toxicity - inhalation	-	-	-	Conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation	-	-	-	Conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation	-	-	-	Conclusive but not sufficient for classification
3.4.	Respiratory sensitisation	-	-	-	data lacking
3.4.	Skin sensitisation	-	-	-	Conclusive but not sufficient for classification
3.5.	Germ cell mutagenicity	-	-	-	Conclusive but not sufficient for classification
3.6.	Carcinogenicity	-	-	-	Conclusive but not sufficient for classification
3.7.	Reproductive toxicity	-	-	-	Conclusive but not sufficient for classification
3.8.	Specific target organ toxicity – single exposure	-	-	-	Conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	-	-	-	Conclusive but not sufficient for classification
3.10.	Aspiration hazard	-	-	-	-
4.1.	Hazardous to the aquatic environment	-	-	-	-
5.1.	Hazardous to the ozone layer	-	-	-	Data lacking

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Scientific justification for the CLH proposal

Human Health Effects CLH proposal for the active substance aluminium silicate:

No classification is concluded based on the available data. Aluminium silicate is a natural inorganic mineral, it is inert, insoluble in aqueous and organic solvents and it does not become bioavailable when ingested.

The effects considered for the setting of the NOAEC in the 2-week inhalation toxicity study, are considered not to support classification as STOT-RE, since it cannot be clearly demonstrated that they constitute adaptive responses or not and changes in organ weights are not sufficient to support classification as STOT-RE.

Limited evidence from literature data on Kaolin administration for 12 months in the guinea pig (tracheal injection) or the rat (inhalation chamber) indicated no increased incidences of malignant lesions and therefore classification for carcinogenicity is not supported. Moreover, limited information on reproductive toxicity of clay suggested no effects on the development of foetuses (foetal weight, foetal length) or on litter size and fertility and classification for reproduction is not supported as well. Aluminium silicate is not genotoxic.

The above considerations are supported as long as the content of the relevant impurity crystalline silica with diameter below 10 μm is lower than 1 g/kg [see RAR Volume 4].

Environmental Effects CLH proposal for the active substance aluminium silicate:

The absence of acute and chronic classification of the active substance is based on the acute lowest endpoint (EC50= 570 mg a.s./L, Daphnia magna) and the chronic lowest endpoint (NOEC= 50 mg a.s./L). Aluminium silicate is non-readily biodegradable.

Classification: -

Labelling: GHS pictogram: -

Signal word: -
Hazard statements: -
Precautionary statements:
P273 – Avoid release to the environment
P501 – Dispose of contents/container in accordance with local regulation

Proposed classification and labelling of the preparations:

Applicant: TESSENDERLO

- ***Surround WP***

According to Regulation (EC) No. 1272/2008 the following classification is proposed for the current represenative preparation Surround WP:

Classification: -

Labelling: GHS pictogram: -

Signal word: -

Hazard statements: -

Precautionary statements: P273 – Avoid release to the environment

P501 – Dispose of contents/container in accordance with local regulation

Scientific justification for the CLH proposal

Human Health Effects CLH proposal Surround WP:

Not relevant.

Environmental Effects CLH proposal of Surround WP: The absence of acute and chronic classification was assigned based on summation method and taken into account that aluminium silicate is non-readily biodegradable.

Applicant: SOKA

- ***Sokalciarbo WP***

According to Regulation (EC) No. 1272/2008 the following classification is proposed for the current represenative preparation Sokalciarbo WP:

Classification: -

Labelling: GHS pictogram: -

Signal word: -

Hazard statements: -

Precautionary statements: P273 – Avoid release to the environment
P501 – Dispose of contents/container in accordance with local regulation

Scientific justification for the CLH proposal

Human Health Effects CLH proposal of Sokalciarbo WP:

Not relevant.

Environmental Effects CLH proposal of Sokalciarbo WP: The absence of acute and chronic classification was assigned based on summation method and taken into account that aluminium silicate is non-readily biodegradable.

2.12 Relevance of metabolites in groundwater

Not applicable.

2.12.1 STEP 1: Exclusion of degradation products of no concern

Not applicable.

2.12.2 STEP 2: Quantification of potential groundwater contamination

Not applicable.

2.12.3 STEP 3: Hazard assessment - identification of relevant metabolites

Not applicable.

2.12.4 STEP 4: Exposure assessment – threshold of concern approach

Not applicable.

2.12.5 STEP 5: Refined risk assessment

Not applicable.

2.12.6 Overall conclusion

Not applicable.

2.13 Consideration of isomeric composition in the risk assessment

2.13.1 Identity and physical chemical properties

Not relevant.

2.13.2 Methods of analysis

Not relevant.

2.13.3 Mammalian toxicity

Not relevant.

2.13.4 Operator, worker, bystander and resident exposure

Not relevant.

2.13.5 Residues and consumer risk assessment

Not relevant.

2.13.6 Environmental fate

Not relevant.

2.13.7 Ecotoxicology

Not relevant.

2.14 Residue definitions

2.14.1 Definition of residues for exposure/risk assessment

Food of plant origin: Not required.
Food of animal origin: Not required.
Soil: -
Groundwater: -

Surface water: -
Sediment: -
Air: -

2.14.2 Definition of residues for monitoring

Body fluids and tissues: Not required.
Food of plant origin: Not required.
Food of animal origin: Not required.
Soil: Not required.
Groundwater: Not required.
Surface water: Not required.
Air: Not required.

Level 3

Aluminium silicate calcined

3. Proposed decision with respect to the application

3.1 Background to the proposed decision

3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X		For the renewal of approval of aluminium silicate, two representative formulations have been submitted: - SOKALCIARBO WP (a WP formulation containing 1000 g/kg aluminium silicate) - SURROUND WP (a WP formulation containing 950 g/kg aluminium silicate) The representative uses assessed are considered to comply with Article 4 of Regulation (EC) No1107/2009.
3.1.1.2. Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	X		
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after	X		All the data requirements concerning Physical/chemical Properties and Methods of Analysis and Toxicology & Metabolism are considered to be confirmatory in nature (see 3.1.4).

	the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			
3.1.1.3 Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	X		The minimum degree of purity of the active substance: Tessenderlo: 999.0 g/kg minimum SOKA: Open The nature and maximum content of certain impurities: Relevant impurities

	Tessenderlo	SOKA
Arsenic:	< 1.0 mg/kg	12 mg/kg
Lead:	< 5.0 mg/kg	15 mg/kg
Cadmium	< 0.20 mg/kg	< 2 mg/kg
Mercury	< 0.02 mg/kg	< 0.1 mg/kg
TEQ-WHO PCDD/F (sum of congeners)	< 0.20 ng/kg	< 0.5 ng/kg
TEQ-WHO dl-PCB (sum of con-geners)	< 0.15 ng/kg	< 0.5 ng/kg
TEQ-WHO PCDD/F/dl-PCB	< 0.35 ng/kg	< 0.5 ng/kg

				(sum of congeners)			
				Sum of ndl-PCB:	< 5.0 µg/kg	< 0.5 µg/kg	
				Respirable crystalline silica (< 10 µm)	< 1.0 g/kg	(open)	

3.1.1.4. Criteria for the approval of an active substance

Dossier

		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the	X		

	commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.			
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection products, when applied in consistence with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		No other efficacy data are deemed necessary at this stage.
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.		X	Not relevant.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impuri-	X		

	ties and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.			Please refer to Volume 1 Section 2.1.1 Please note that there are data required. For more details see 3.1.4.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.		X	No FAO specification is available for Aluminium silicate calcined.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted.		X	No FAO specification is available for Aluminium silicate calcined.
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		Analytical methods and approaches have been provided that are considered acceptable taking into consideration the substance identity and technical difficulties. Please note that data are required. For more details see 3.1.4.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		No residue analytical methods are required since no residue definition is set.

	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcino-		X	

	genicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**			
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not relevant since no classification is proposed as carcinogen category 1A or 1B.
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	
ii)	Linked to above classification proposal.			Not relevant since no classification is proposed.

	It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active sub-		X	Not relevant since no classification is proposed as carcinogenic category 2 and/or toxic for reproduction category 2.

	stance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	Aluminium silicate calcined (kaolin) **cannot** be considered as a POP substance according to the criteria of 1107/2009/EC.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	<u>Persistence</u> The active substance Aluminium silicate calcined (kaolin) does not fulfil the criteria for being classified as a Persistent substance. <u>Bioaccumulation</u> Aluminium silicate calcined (kaolin) is not soluble in water and as a result has a very limited potential to bioaccumulate. No BCF value available. Alumininium silicate calcined is not considered to fulfil the B criterion. <u>Toxicity</u>

				Regarding long-term aquatic toxicity, the lowest NOEC endpoint has been calculated to be 570 mg a.s./L for *Daphnia magna*. As this endpoint is higher than the trigger value of 0.01 mg/L (ECHA Guidance on IR & CSA, Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017)), aluminium silicate is NOT considered to fulfil the T criterion. Regarding human health effects aluminium silicate does not fulfil the T criterion.
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	<u>Persistence</u> The active substance Aluminium silicate calcined (kaolin) does not fulfil the criteria for being classified as a very persistent substance. <u>Bioaccumulation</u> Aluminium silicate calcined (kaolin) is not soluble in water and as a result has a very limited potential to bioaccumulate. No BCF value available. Alumininium silicate calcined is not considered to fulfil the vB criterion.
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant			The risk of aluminium silicate for birds and mammals, earthworms, soil predatory mites, soil microorganisms, non-target terrestrial plants is provided below:

protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

Birds and mammals:

The risk to birds and mammals is acceptable. Due to the nature and properties of the active substance toxicity testing and risk assessment are not necessary.

Bees and other non-target arthropods:

The presented data are insufficient to conclude on the acceptability of the risk to bees and other non-target arthropods.

Aquatic Organism:

Surround WP:

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

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

Sokalciarbo WP:

For the **single application** of the intended uses in stone fruits, pome

				fruits, nuts fruits, walnut tree, apple tree, citrus, lavender, olive and grapevine, the risk to aquatic organisms is **acceptable** without use of any mitigation measures. However, for the **multiple application** of the intended uses, the risk to aquatic organisms is **unacceptable** for: • walnut tree (use no 5) • apple tree (use no 10) • Citrus (use no 12) • olive tree (use no 14) **Soil organisms and non-target plants:** The risk of aluminium silicate is considered acceptable for earthworms, soil predatory mites, soil microorganisms and non-target terrestrial plants.
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	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.
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.			Not applicable, since the interim criteria are not fulfilled (see comment above).

	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.			The available data are not sufficient to conclude.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		The provisional definition of residues is presented under Section 2.7.3 of Vol. 1.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		Not applicable. Due to the nature of the a.s. no PECgw could be calculated.

3.1.2. Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	As aluminium silicate does not fulfil any of the PBT criteria, it should not be considered as a candidate for substitution.

3.1.3 Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**:	X		From an environmental/ecotoxicological point of view, aluminium silicate is NOT classified as Acute 1 (H400) or Chronic 1 (H410), has not a potential for bioaccumulation and it is not persistent. From a toxicological point of view, aluminium silicate is NOT classified for any human health hazards, it is not neurotoxic or immunotoxic and it is not an endocrine disruptor.

	— persistent, — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.			

3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
3.1.4.1 Identity of the active substance or formulation				
Tessenderlo and SOKA Confidential data on the substance identity are requested.	Relevant for all representative uses evaluated	X		
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
Active substance -SOKA: An IR study of the active substance by SOKA is required.	Relevant for all representative uses evaluated.	X		
SURROUND® WP CROP PROTECTANT -Tessenderlo Data requirement regarding Self-heating study (Vol 3 CP B2 SURROUND)	Relevant for all representative uses evaluated.	X		
SURROUND® WP CROP PROTECTANT -Tessenderlo Data requirement regarding Particle size	Relevant for all representative uses evaluated.	X		

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
(Vol 3 CP B2 SURROUND)				
SOKALCIARBO WP – SOKA Data requirement regarding 2-year Shelf life (Vol 3 CP B2-SOKALCIARBO)	Relevant for all representative uses evaluated.		Study anticipated to be submitted in May 2020.	
SOKALCIARBO WP – SOKA Data requirement regarding Accelerated storage stability test (Vol 3 CP B-SOKALCIARBO)	Relevant for all representative uses evaluated.	X		
SOKALCIARBO WP – SOKA Data requirement regarding pH study (Vol 3 CP B-SOKALCIARBO)	Relevant for all representative uses evaluated.	X		

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
3.1.4.3 Data on uses and efficacy				
-	-	-	-	-
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
-	-	-	-	-
3.1.4.5 Methods of analysis				
SOKA: For more details see Volume 4 – Confidential Section SOKA C.1.2.5.2 & C.1.3.4.2. **Tessenderlo** For more details see Volume 4 – Confidential Section Tessenderlo C.1.2.5	Relevant for all representative uses evaluated	X		
3.1.4.6 Toxicology and metabolism				
-				

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.7 Residue data				
-	-	-	-	-
3.1.4.8 Environmental fate and behaviour				
-	-	-	-	-
3.1.4.9 Ecotoxicology				

3.1.5. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	Relevance in relation to representative use(s)
-	-

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	Relevance in relation to representative use(s)
-	-

3.1.7 Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then ‘risk identified’ is not indicated in this table.)

Representative use		Surround WP	Sokalciarbo WP
Consumer risk	Risk identified	-	
	Assessment not finalised	-	
Operator, worker, bystander, resident risk	Risk identified	-	X[2]
	Assessment not finalised	-	-
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	-	
	Assessment not finalised	X[1]	
Risk to aquatic organisms	Risk identified	-	X[1]
	Assessment not finalised	-	-
Groundwater exposure active substance	Legal parametric value breached	n.a.	n.a.
	Assessment not finalised	n.a.	n.a.
Groundwater exposure metabolites	Legal parametric value breached	n.a.	n.a.
	Parametric value of 10µg/L[(a)] breached	n.a.	n.a.
	Assessment not finalised	n.a.	n.a.
Comments/Remarks			

1: Please refer to 3.1.1.4. Criteria for the approval of an active substance, Ecotoxicology
2: Risk identified in case of application to citrus *via* vehicle-mounted sprayer and hand-held equipment

3.1.8 Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification

3.1.9 Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS
Not relevant.		

3.2 Proposed decision

[redacted]

[redacted]

3.3 Rationale for the conditions and restrictions to be associated with the approval or authorisation(s), as appropriate

3.3.1 Particular conditions proposed to be taken into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)
[redacted]	[redacted]
[redacted]	[redacted]

3.4 APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No. 1107/2009, SANCO/10597/2003, rev.10.1

Technical material and preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, section 5) of Directive 91/414, SANCO/3030/99 rev.4.

Guidance document on pesticides residue analytical methods, SANCO/825/00 rev. 8.1

Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev.4.

OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.

WHO/FAO. 2016. Manual on development and use of FAO and WHO specifications for pesticides. Third revision of the first edition. Rome, 2016

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 1997. Soil persistence models and EU registration.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.3 dated December 2014.

European Food Safety Authority, 2009; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA, EFSA Journal 2009; 7(12):1438.

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7):3290.

Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329/2002, rev 2 (final) 17 October 2002.

Candolfi et al. (2001). Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2 workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing), Wageningen, NL, 21-23 March 2000, SETAC Europe. SETAC publication, August 2001.

European Food Safety Authority (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295.

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874. Available online: www.efsa.europa.eu/efsajourna

EFSA Scientific Committee; Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379. [69 pp.], doi:10.2903/j.efsa.2011.2379. Available online: www.efsa.europa.eu/efsajournal.htm

EFSA Technical Report , Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods, doi:10.2903/sp.efsa.2017.EN-12

Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

OECD Test Guideline 203: Fish, Acute Toxicity Test

OECD Test Guideline 202: Daphnia, Acute Immobolisation Test

OECD Test Guideline 201: Algae and Cyanobacteria, Growth Inhibition test

OECD Test Guideline 221: Lemna spp, Growth Inhibition test

OPPTS 850.1035: Mysid Acute Toxicity Test

OECD Test Guideline 219: Sediment-water Chrironomid Toxicity Test Using spiked water

OECD Test Guideline 210: Fish, Early-life stage Toxicity Test

OECD Test Guideline 211: Dapnia magna Reproduction Test

EPA FIFRA guideline 40 CFR 158, subdivision N, section No. 165-4 (in agreement with OCDE n° 305E)

EPA Test Guideline: OCSPP 850.2100: Avian Acute Oral Toxicity Test

EPA Test Guideline: OCSPP 850.2200: Avian Dietary Toxicity Test

EPA Test Guideline: OCSPP 850.2300: Avian Reproduction Test

OECD Guidline 223: Avian Acute Oral Toxicity Test

OECD Guidline 205: Avian Dietary Toxicity Test

OECD Guidline 206: Avian Reproduction Test

EPA FIFRA guideline Series 71: Avian and Mammalian Testing

REFERENCE LIST

See Volume 2.

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 05.10.2016

Revision date: 06.15.2021

KaMin® 70C

SECTION 1: Identification

Product Identifier

Product Name: KaMin® 70C

Synonyms: Calcined Clay, China Clay, Anhydrous Aluminum Silicate

Product code: KaMin 70C

Recommended Use of the Product and Restriction on Use

Relevant Identified Uses: Mineral Pigment or Filler used Speciality Filler Applications including Adhesives, Cosmetics, Coatings, Inks, Ceramics, Plastics, Rubber and Agricultural Applications

Uses Advised Against: Any uses inconsistent with product labeling are advised against

Reasons Why Uses Advised Against: Not determined or not applicable.

Manufacturer or Supplier Details

Manufacturer:

United States

KaMin LLC
822 Huber Road
Macon, GA 31217
+1 478 750 5410
Askus@kaminllc.com

Emergency Telephone Number:

United States

InfoTrac
Within USA: 1-800-535-5053 (24 hours)

SECTION 2: Hazard(s) Identification

GHS Classification: Not a hazardous substance or mixture

Label elements

Hazard Pictograms: None

Signal Word: None

Hazard statements: None

Precautionary Statements: None

Hazards Not Otherwise Classified: None

SECTION 3: Composition/Information on Ingredients

Identification	Name	Weight %

CAS Number: 92704-41-1	Calcined Clay	100

Additional Information:

This product could contain trace levels of crystalline silica at levels below 0.1%. Care is recommended when handling to avoid dust generation.

SECTION 4: First Aid Measures

Description of First Aid Measures

General Notes:

Show this Safety Data Sheet to the doctor in attendance.

After Inhalation:

Remove person to fresh air and place in a position comfortable for breathing. Loosen clothing as necessary and maintain and unobstructed airway. Loosen clothing as necessary and maintain and unobstructed airway.

After Skin Contact:

Wash affected area with soap and water. Seek medical attention if symptoms develop or persist.

After Eye Contact:

Rinse/flush exposed eye(s) gently using water for 15-20 minutes. Check for and remove any contact lenses. Seek medical attention if symptoms develop or persist.

After Swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most Important Symptoms and Effects, Both Acute and Delayed

Acute Symptoms and Effects:

No significant acute effects/symptoms.

Delayed Symptoms and Effects:

No significant delayed effects/symptoms.

Immediate Medical Attention and Special Treatment

Specific Treatment:

Not determined or not applicable.

Notes for the Doctor:

Treat symptomatically.

SECTION 5: Firefighting Measures

Extinguishing Media

Suitable Extinguishing Media:

Use appropriate fire suppression agents for adjacent combustible materials or sources of ignition.

Unsuitable Extinguishing Media:

Not determined or not applicable.

Specific Hazards During Fire-Fighting:

Thermal decomposition may produce irritating and toxic fumes including silicon oxides, aluminum oxides and calcium oxides.

Special Protective Equipment for Firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Move containers from area of fire, if safe to do so. Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

SECTION 6: Accidental Release Measures

Personal Precautions, Protective Equipment, and Emergency Procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Avoid generation and dispersal of dust. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and Material for Containment and Cleaning Up:

Avoid dust generation or stirring up dust. Vacuum or sweep up material and place into covered, sealable containers for future disposal. If appropriate, moisten first to prevent dusting. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to Other Sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and Storage

Precautions for Safe Handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid generation and disperal of dust. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for Safe Storage, Including Any Incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

Occupational Exposure Limit Values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
OSHA	Calcined Clay	92704-41-1	8-Hour TWA-PEL: 15 mg/m³ ((Kaolin Clay, total dust))
	Calcined Clay	92704-41-1	8-Hour TWA-PEL: 5 mg/m³ ((Kaolin Clay, respirable fraction))
NIOSH	Calcined Clay	92704-41-1	TWA: 10 mg/m³ (REL - (Kaolin Clay, total dust) -10 hr)
	Calcined Clay	92704-41-1	TWA: 5 mg/m³ (REL - (Kaolin Clay, Respirable Dust) - 10 hr)

Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Calcined Clay	92704-41-1	8-Hour TWA: 2 mg/m³ ((Kaolin Clay, Respirable Dust) Containing no asbestos and <1% crystalline silica)

Biological Limit Values:

No biological exposure limits noted for the ingredient(s).

Information on Monitoring Procedures:

Monitoring of the concentration of substances in the breathing zone of workers or in the general workplace may be required to confirm compliance with an OEL and adequacy of exposure controls.
Biological monitoring may also be appropriate for some substances.

Appropriate Engineering Controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal Protection Equipment

Eye and Face Protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and Body Protection:

Select glove material impermeable and resistant to the substance. For continuous contact, we recommend gloves with breakthrough time of more than 240 minutes with preference for > 480 minutes where suitable gloves can be identified. Glove thickness should be typically greater than 0.35 mm depending on the glove make and model. Always seek advice from glove suppliers. Wear appropriate clothing to prevent any possibility of skin contact.

Respiratory Protection:

Use a NIOSH/MSHA or European Standard EN149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Comply with the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN149. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

General Hygienic Measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and Chemical Properties

Information on Basic Physical and Chemical Properties

Appearance	White powder
Odor	Odorless
Odor threshold	Not determined or not available.
pH	4.0 - 8.0, 20% water suspension
Melting point/freezing point	>1,700 °C
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.

Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	2.2-2.6 g/cm³
Relative density	Not determined or not available.
Solubilities	Insoluble in water / soluble in strong acid
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

SECTION 10: Stability and Reactivity

Reactivity:
Not reactive under recommended handling and storage conditions.

Chemical Stability:
Stable under recommended handling and storage conditions.

Possibility of Hazardous Reactions:
Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to Avoid:
Generation, dispersal and accumulation of dust

Incompatible Materials:
None Known

Hazardous Decomposition Products:
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological Information

Acute Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data:

Name	Route	Result
Calcined Clay	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rat: >5000 mg/kg

Skin Corrosion/Irritation

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Serious Eye Damage/Irritation

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Respiratory or Skin Sensitization

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens: Not applicable

Germ Cell Mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Reproductive Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Specific Target Organ Toxicity (Single Exposure)

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Specific Target Organ Toxicity (Repeated Exposure)

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:
No data available.

Substance Data: No data available.

Information on Likely Routes of Exposure:
Inhalation; Ingestion; Skin contact; Eye contact

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:
Refer to Section 4 of this SDS.

Other Information:
No data available.

SECTION 12: Ecological Information

Acute (Short-Term) Toxicity
Assessment: Based on available data, the classification criteria are not met.
Product Data: No data available.
Substance Data: No data available.

Chronic (Long-Term) Toxicity
Assessment: Based on available data, the classification criteria are not met.
Product Data: No data available.
Substance Data: No data available.

Persistence and Degradability
Product Data: No data available.
Substance Data: No data available.

Bioaccumulative Potential
Product Data: No data available.
Substance Data: No data available.

Mobility in Soil
Product Data: No data available.
Substance Data: No data available.

Results of PBT and vPvB assessment
Product Data:
PBT assessment: This product does not contain any substances that are assessed to be a PBT.
vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.
Substance Data:
PBT assessment: This product does not contain any substances that are assessed to be a PBT.
vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Other Adverse Effects: No data available.

SECTION 13: Disposal Considerations

Disposal Methods:
It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:
Not determined or not applicable.

SECTION 14: Transport Information

United States Transportation of Dangerous Goods (49 CFR DOT)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None

Special Precautions for User	None

International Maritime Dangerous Goods (IMDG)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

SECTION 15: Regulatory Information

United States Regulations

Inventory Listing (TSCA): All ingredients are listed-active or exempt.
Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.
Export Notification under TSCA Section 12(b): None of the ingredients are listed.
SARA Section 302 Extremely Hazardous Substances: None of the ingredients are listed.
SARA Section 313 Toxic Chemicals: None of the ingredients are listed.
CERCLA: None of the ingredients are listed.
RCRA: None of the ingredients are listed.
Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.
Massachusetts Right to Know: None of the ingredients are listed.
New Jersey Right to Know: None of the ingredients are listed.
New York Right to Know: None of the ingredients are listed.
Pennsylvania Right to Know: None of the ingredients are listed.
California Proposition 65:

⚠**WARNING:** This product can expose you to Silica, crystalline (airborne particles of respirable size); which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov

SECTION 16: Other Information

Abbreviations and Acronyms: None
Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be

considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

NFPA: 0-0-0
HMIS: 0-0-0
Initial Preparation Date: 05.10.2016
Revision date: 06.15.2021

End of Safety Data Sheet

EFSA Journal

CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance aluminium silicate calcined (kaolin calcined)

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Greece and co-rapporteur Member State France for the pesticide active substance aluminium silicate calcined (kaolin calcined) and the considerations as regards the Article 12 MRL review of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of aluminium silicate calcined (kaolin calcined) as an insect repellent via broadcast spray application on grapevine, apricot tree, almond tree, cherry tree, hazel tree, walnut tree, peach tree, apple tree, pear tree, quince tree, nashi tree, plum tree, citrus tree, lavender, lavandin and olive tree, as proposed by the applicants. The reliable endpoints, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

Keywords: Aluminium silicate calcined (kaolin calcined), peer review, risk assessment, pesticide, insect repellent, MRL review

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Requestor: European Commission

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Aluminium silicate calcined is one of the active substances listed in that Regulation. It has to be noted that the European Food Safety Authority (EFSA) issued a previous conclusion for the same substance with the name 'aluminium silicate'. The same name was originally used for the renewal process as well but was changed during the process based on all the available information on the identity of the active substance.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Greece, and co-rapporteur Member State (co-RMS), France, received an application from Société Kaolinière Armoricaine (SOKA) and Tessenderlo Chemie for the renewal of approval of the active substance aluminium silicate calcined (kaolin calcined).

An initial evaluation of the dossier on aluminium silicate calcined was provided by the RMS in the renewal assessment report (RAR) and, subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of aluminium silicate calcined (kaolin calcined) according to the representative uses as an insect repellent via broadcast spray application on grapevine, apricot tree, almond tree, cherry tree, hazel tree, walnut tree, peach tree, apple tree, pear tree, quince tree, nashi tree, plum tree, citrus tree, lavender, lavandin and olive tree, as proposed at EU level result in a sufficient repellent efficacy against the target insects.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to identity, physical and chemical properties, and analytical methods.

In the area of mammalian toxicology, a data gap and issue not finalised have been identified for the batches used in toxicological studies, since no data have been provided.

In the residues section, the consumer dietary risk assessment is provisional for the food crop uses (grapevines, olive, stone fruits, pome fruits, citrus fruits and tree nuts) pending on maximum content of titanium dioxide particles (< 10 μm) and its toxicological evaluation present in kaolin calcined following the representative Good Agricultural Practices (GAPs). No consumer exposure via dietary intake is expected for the representative use in lavender. In addition to the representative uses, an assessment was conducted for authorised uses according to Article 12 of Regulation (EC) No 396/2005, where GAPs were similar. Regarding the five assessment criteria for potential inclusion of aluminium silicate in Annex IV of Regulation (EC) No 396/2005, the overall criteria were either not met or they cannot be currently assessed.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses.

In the area of ecotoxicology low risk was concluded for birds, mammals, soil organisms and biological methods for sewage treatment. For aquatic organisms, a data gap was identified to further address the acute risk for the uses in walnut, apple, citrus, olive trees for multiple applications of SOKALCIABRO WP. For bees, the acute oral risk assessment could not be finalised and the chronic risks to larvae and brood were not indicated as low (data gap). For foliar dwelling non-target arthropods other than bees, the available information was insufficient to indicate low risk (critical area of concern).

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that aluminium silicate is unlikely to be an endocrine disruptor.

Table of contents

Background

Commission Implementing Regulation (EU) No 844/2012[1], as amended by Commission Implementing Regulation (EU) No 2018/1659[2], (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS Greece and co-RMS France received an application from Kaolinière Armoricaine (SOKA) and Tessenderlo Chemie for the renewal of approval of the active substance aluminium silicate calcined (kaolin calcined). Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS France, the European Commission and EFSA about the admissibility.

It has to be noted that EFSA issued a previous conclusion for the same substance with the name 'aluminium silicate'. The same name was originally used for the renewal process as well but was changed during the process based on all the available information on the identity of the active substance.

The RMS provided its initial evaluation of the dossier on aluminium silicate calcined (kaolin calcined) in the RAR, which was received by EFSA on 11 May 2020 (Greece, 2020). Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 5 March 2021 EFSA invited the Member States and the UK[4] to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant(s), Kaolinière Armoricaine (SOKA) and Tessenderlo Chemie, for consultation and comments on 17 February 2021. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 19 April 2021. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant(s) in accordance with Article 13(3) of the Regulation were considered in a telephone

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, pp. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

[4] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.

conference between EFSA and the RMS on 07 June 2021. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant(s) and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 MRL review of Regulation (EC) No 396/2005 took place with Member States via a written procedure in August 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of aluminium silicate calcined (kaolin calcined) as an insect repellent via broadcast spray application on grapevine, apricot tree, almond tree, cherry tree, hazel tree, walnut tree, peach tree, apple tree, pear tree, quince tree, nashi tree, plum tree, citrus tree, lavender, lavandin and olive tree, as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for aluminium silicate calcined (kaolin calcined) according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (21 May 2021);
- the evaluation table (26 September 2022);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Greece, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

The name of this active substance is aluminium silicate calcined (kaolin calcined), there is no ISO common name. The original name used for the active substance was 'aluminium silicate (aka kaolin)'. This name was changed during the renewal evaluation process based on all the available information on the identity of the active substance.

The representative formulated products for the evaluation were 'Surround WP crop protectant' a wettable powder (WP) formulation containing 950 g/kg of aluminium silicate calcined, and 'SOKALCIABRO WP' a wettable powder formulation containing 1,000 g/kg aluminium silicate calcined.

The representative uses evaluated for 'Surround WP crop protectant' comprise outdoor broadcast spraying application as an insect repellent on grapevine, as proposed by applicant (Tessenderlo

Chemie). The representative uses evaluated for 'SOKALCIABRO WP' comprise outdoor broadcast spraying application as an insect repellent on grapevine, apricot tree, almond tree, cherry tree, hazel tree, walnut tree, peach tree, apple tree, pear tree, quince tree, nashi tree, plum tree, citrus tree, lavender, lavandin and olive tree, as proposed by the applicant (SOKA).

Full details of the GAP can be found in the list of end points in Appendix B. Data were submitted to conclude that the uses of aluminium silicate calcined (kaolin calcined) according to the representative uses proposed at EU level result in a sufficient insect repellent efficacy against the target organisms following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: European Commission (2000a,b).

The proposed specification for aluminium silicate calcined (kaolin calcined) is based on batch data from industrial plant production. The RMS did not propose a common reference specification, instead an individual reference specification was proposed for each technical material produced by the applicants. Arsenic, lead, cadmium, mercury; sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) as expressed in World Health Organization (WHO) toxic equivalent[5]; sum of PCDDs, PCDFs and dioxin like polychlorinated biphenyls (dl-PCBs) expressed in WHO toxic equivalent; sum of dl-PCBs expressed in WHO toxic equivalent; sum of non-dioxin like PCBs; respirable crystalline silica (SiO_2) with a diameter < 10 μm and titanium dioxide (TiO_2) particles with diameter < 10 μm were considered as relevant impurities for both technical materials (see Section 2). The maximum content of individual relevant impurities specified in each technical material can be found in the list of end points in Appendix B. Data gaps were identified for 5-batch data for the content of respirable crystalline silica (< 10 μm) and titanium dioxide particles (< 10 μm) in the technical material manufactured by SOKA (see Section 10). In addition, a data gap was identified for 5-batch data for the content of titanium dioxide particles (< 10 μm) in the technical material manufactured by Tessenderlo Chemie (see Section 10). The peer review concluded that the minimum purity of aluminium silicate calcined should be defined as 1,000 g/kg minus the maximum content of the respirable crystalline silica (< 10 μm) and the maximum content of titanium dioxide particles (< 10 μm). The RMS proposed a minimum purity of 999.0 g/kg for the active substance as manufactured by the Tessenderlo Chemie and concluded that a minimum purity cannot be proposed for the active substance as manufactured by SOKA. However, based on the new minimum purity definition and the data gaps identified, EFSA is of the opinion that a minimum purity cannot be concluded for both technical materials. Considering the new definition of minimum purity and the new relevant impurities, it is proposed to update the reference specification to the specifications proposed by the RMS. The analytical profile of the batches used in (eco)toxicological studies does not support the proposed reference specifications for both manufacturing sources (see Sections 2 and 5) and the current reference specification (see Sections 2 and 5). There is no FAO specification available for aluminium silicate calcined (kaolin calcined).

The available data regarding the identity of aluminium silicate calcined (kaolin calcined) and its physical and chemical properties are given in Appendix A.

Data gaps were identified for IR spectrum data of aluminium silicate calcined (kaolin calcined), relevant for SOKA and for self-heating data for the representative formulation 'Surround WP crop protectant', relevant for Tessenderlo Chemie (see Section 10). In addition, label instructions are needed concerning the measures to address the suspensibility of the formulations.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Analytical methods for the determination of aluminium silicate calcined (kaolin calcined) in the technical materials and in the representative formulations were not provided. Considering the manufacturing process of the active substance, the proposed definition of minimum purity and the technical limitations imposed by the physicochemical properties of aluminium silicate calcined (kaolin

[5] Table of TEF (=toxic equivalency factors) for dioxins, furans and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organization (WHO)–International Programme on Chemical Safety (IPCS)expert meeting which was held in Geneva in June 2005 (van den Berg et al., 2006).

calcined) that render the use of conventional analytical methods unfeasible, it was concluded not to set relevant data gaps.

Adequate analytical methods were provided for determination of all relevant impurities, except titanium dioxide (TiO_2) particles with diameter < 10 μm (data gaps relevant for SOKA and Tessenderlo Chemie, see Section 10), in the technical materials and formulations. Data gaps were identified for validation data to demonstrate the applicability, in terms of specificity, of the proposed analytical gas chromatography with tandem mass spectrometry (GC–MS/MS) method for the determination of PCDDs, PCDFs, dioxin like PCBs and non-dioxin like PCBs, in the technical material manufactured by SOKA and in the representative formulation 'SOKALCIABRO WP' (see Section 10). Further data gaps were identified for validation data to demonstrate the applicability, in terms of specificity, of the proposed SOKA analytical methods for the determination of arsenic, lead, cadmium and mercury in the technical material manufactured by SOKA and in the representative formulation 'SOKALCIABRO WP' (see Section 10). A data gap was identified for a validated analytical method for the determination of respirable SiO_2 with a diameter < 10 μm, in the technical material manufactured by SOKA and in the representative formulation 'SOKALCIABRO WP' (see Section 10). Methods for the analysis of residues in food and feed of plant origin, food of animal origin, body fluids and tissues and environmental compartments are not required as no residue definitions were set.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: European Commission (2003, 2012); EFSA (2014); EFSA PPR Panel (2012) and ECHA/EFSA (2018).

Aluminium silicate calcined was discussed at the Pesticide Peer Review Experts' TC 70 in January 2022.

The analytical profile of the batches used in toxicological studies does not support the technical specification (current and proposed) provided (see Section 1), since no data on batches used in toxicological studies have been provided, leading to a data gap and issue not finalised. Relevant impurities such as dioxins, PCBs and heavy metals have been detected in the technical materials manufactured by both SOKA and Tessenderlo Chemie. However, at the levels specified they are of no toxicological concern. Data gaps were identified for the 5-batch data analysis for the content of respirable crystalline silica (with a diameter of < 10 μm) and of titanium dioxide particles (< 10 μm) in the technical material manufactured by SOKA, and for titanium dioxide particles only (< 10 μm) in the technical material manufactured by Tessenderlo Chemie (see also Section 1). Both are considered toxicologically relevant impurities (with particle size < 10 μm) with acceptable levels of 1 g/kg. It is noted that, according to Directive 2017/2398[6] amending Directive 2004/37/EC[7] on the protection of workers from the risks related to exposure to carcinogens or mutagens, as regards that there is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. In addition, titanium dioxide is classified as a suspected carcinogen (Category 2) by inhalation according to Regulation (EC) No 1272/2008[8]. This classification specifically applies to TiO_2 in powder form containing 1% or more particles with aerodynamic diameter ≤ 10 μm. The presence of TiO_2 at a level > 1% might trigger the classification of the active substance as Carcinogen category 2, pending further considerations of the aerodynamic diameter of particles. Additionally, EFSA has recently revised its safety assessment of TiO_2 as a food additive (EFSA, 2021) and has concluded that a genotoxic concern for TiO_2 particles (with unknown relationship to particle size) cannot be ruled out (data gap).

Read-across to other aluminium-containing compounds which commonly dissociate producing ions (e.g. sodium aluminium phosphates, aluminium sulphates, sodium aluminium silicates) is not considered appropriate for aluminium silicate calcined, since aluminium is covalently bonded.

Aluminium silicate calcined is 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 tissues and it is not metabolised. On this basis, the submission of additional oral toxicological studies

[6] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 345, 27.12.2017, pp. 87–95.

[7] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 158, 30.4.2004, pp. 50–76.

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

has been waived, such as Absorption, Distribution, Metabolism, Excretion (ADME) studies (as a consequence, also *in vitro* comparative metabolism studies), short term, genotoxicity, long term toxicity and carcinogenicity, reproductive and developmental toxicity, neurotoxicity, immunotoxicity studies, and studies to assess endocrine disrupting potential. It is noted that a similar approach has been used for Kieselgur, another silica compound.[9]

Aluminium silicate calcined has a low **acute toxicity** after oral, dermal and inhalation administration. It is noted that no inhalation toxicity study has been provided for aluminium silicate calcined, but a study is available with hydrous kaolin (considered as the worst case due to the presence of crystalline silica, which may be of concern). It is neither a skin or an eye irritant, nor a skin sensitiser. A waiving for phototoxicity testing is considered acceptable on the basis of its physico-chemical properties (insoluble substance, not absorbing UV light).

The only available **short term** study is a 2-week nose-only inhalation study in rats performed with kaolin and kaolinitic clay (considered as the worst case due to the presence of crystalline silica which might be of concern), where the NOAEC has been set at 47.6 and 55 mg/m^3, for kaolin and kaolinitic clay, respectively, on the basis of effects observed at 103 μg/m^3 in both kaolin and kaolinitic clay treated rats in the nasal turbinates and lungs.[10] Since no concern is expected by the oral route, the same lack of toxicity is expected through dermal exposure taking into consideration the insoluble and inert properties of the active substance.

No **genotoxicity** studies are available for aluminium silicate calcined and a gene mutation test in bacteria is available for hydrous kaolin only, and negative. Aluminium silicate calcined is considered unlikely to be genotoxic.

No **long-term toxicity and carcinogenicity** studies are available, a 12-month and a 24-month published studies (by intratracheal route in guinea pigs and by inhalation in rats, respectively) were considered as supporting information and no malignant lesions were observed, thus indicating that aluminium silicate calcined is unlikely to be carcinogenic.

No **reproductive and developmental toxicity** studies are available. One published study performed in the rat and considered as supporting information did not indicate effects of aluminium silicate calcined on reproduction and development.

No **neurotoxicity** studies are available but they are not considered needed given the chemical structure of aluminium silicate calcined (not belonging to organophosphorus compounds and not having a neurotoxic mode of pesticidal action).

No **immunotoxicity** studies are available.

With regard to **toxicological reference values**, no acceptable daily intake (ADI), acute reference dose (ARfD) or acute acceptable operator exposure (AAOEL) are considered needed on the basis of the physico-chemical properties and the available toxicological data for aluminium silicate calcined. The acceptable operator exposure concentration (AOEC) is 1.4 mg/m^3 on the basis of the NOAEC of 47.6 mg/m^3 in the 2-week inhalation toxicity study by applying an uncertainty factor (UF) of 25 (10) for intraspecies variability, and 2.5 for interspecies and toxicodynamic variability; a factor accounting for toxicokinetic differences was not considered relevant for the local effects on the nose and lungs; and a correction factor to normalise the 6-h rat subacute inhalation exposure to the 8-h human occupational exposure was applied.

Dermal absorption is considered negligible due to the intrinsic properties of the active substance.

For the **non-dietary exposure**, the estimated operator inhalation exposure did not exceed the AOEC for aluminium silicate calcined in case of application of SOKALCIARBO WP formulation to walnut and similar crops with the use of respiratory protective equipment (RPE) during mixing and loading. For the other uses, including lower application rate and low crops (lavender), no exceedance of AOEC has been observed for operators even without the use of any RPE. Bystander/resident inhalation exposure levels via spray drift and vapour are below the AOEC. For workers, as dermal absorption of aluminium silicate calcined is negligible, an exposure assessment is not required.

Estimated operator inhalation exposure did not exceed the AOEC for aluminium silicate calcined in case of application of Surround WP crop protectant to grapes via broadcast spraying or manual spraying without the use of any RPE. Bystander/resident inhalation exposure levels via spray drift and vapour are below the AOEC. For workers, as dermal absorption of aluminium silicate calcined is negligible, an exposure assessment is not required.

[9] Please refer to Pesticide Peer Review Experts' TC 70 (discussion point 2.2) (EFSA, 2022).
[10] Please refer to Pesticide Peer Review Experts' TC 70 (discussion point 2.1) (EFSA, 2022).

3. Residues

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2011) and JMPR (2004, 2007).

Aluminium silicate calcined (kaolin calcined) is chemically inert, not soluble in water or other solvents, not bioavailable after ingestion and naturally present on the plants surface; a comparison between natural exposure and the representative uses was not provided. Studies to assess the nature of kaolin calcined residues in plants upon foliar and post-harvest treatments were not made available but they are not required, since it is not expected to be translocated to plant tissues.

As regards the toxicological reference values, no ADI and ARfD have been considered necessary for this compound (see Section 2). The proposed uses of kaolin calcined on grapes, olive, fruits (stone, pome, citrus) and tree nuts, via foliar and/or postharvest application are likely to lead to residues in food resulting in a consumer exposure. Although it is expected commodities undergo various processes such as washing and rubbing before they are eaten, the worst-case scenario which is the consumption of commodities without any pre-processes has to be taken into account. It is noted that relevant impurities (see data gaps in Sections 1 and 2) that could have an impact on the consumer risk assessment are present in the technical materials. Thus, the consumer risk assessment via dietary intake for food crops (grapevines, olive, stone fruits, pome fruits, citrus fruits and tree nuts) following foliar and/or postharvest application is provisional, pending the additional information requested in Sections 1 and 2, related to maximum content of titanium dioxide particles (< 10 μm) and its toxicological evaluation. For the use in lavender, no consumer exposure via dietary intake is expected.

As kaolin calcined is not expected to be translocated to plant tissues is unlikely that residues may be found in pollen and bee products.

In the context of Article 12 of Regulation (EC) No 396/2005, the collection of GAPs resulted in additional uses in a variety of crops in Europe; therefore, the assessment covers only the authorised GAPs (see GAP overview file) similar with the representative GAPs.

With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V), the criteria were either not met or not sufficiently addressed for kaolin calcined for the following reasons:

- Criteria I and II are not met,
- Considering criterion III, no ADI and ARfD have been set nevertheless, the toxicological assessment of the relevant impurities is still open,
- Criterion IV cannot be assessed in view of the non-submission data about natural exposure in comparison with the exposure from the representative uses,
- Considering criterion V, consumer exposure to kaolin calcined containing TiO_2 particles via ingestion cannot be excluded.

4. Environmental fate and behaviour

Aluminium silicate calcined, has similar chemical composition to common clay minerals present in most soils and many aquatic sediments, all over the world. Aluminium silicate calcined is an extremely stable, insoluble, photolytically stable and inert material that does not change composition even in contact with mineral acids and bases. The amounts being added to the environment from the uses requested are limited compared to the geologically comparable kaolin clay mineral fractions already present in agricultural soil and aquatic sediments present adjacent to agricultural / horticultural fields. The PEC in soil, surface water and sediment covering the representative uses assessed can be found in Appendix B of this conclusion. Parametric drinking water limits applicable to aluminium silicate calcined are not set. It is not defined as a pesticide in the drinking water directive due to it being an inorganic compound and a repellent.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013a).

It was not sufficiently demonstrated that the batches used in the ecotoxicological studies support the technical specification (current and proposed), as reported in Section 1. For **birds and mammals**, insufficient data were available for a quantitative risk assessment. However, a weight of evidence was submitted considering the following information: (i) aluminium silicate calcined is a widespread clay mineral present in soil and aquatic sediment at higher exposure levels than those resulting from the representative uses; (ii) it is an inert, insoluble compound, used as an insect repellent; (iii) it is unlikely that aluminium silicate calcined will be absorbed from the gut lumen when ingested by birds and mammals; (iv) the available supplementary information suggests that chickens did not experience ecotoxicologically relevant effects up to 2.4 g/kg body weight (bw) per day (30 g a.s./kg); and (vi) other applications of aluminium silicate calcined include uses as food additive (EFSA, 2013b). Therefore, considering the available evidence, the acute and long-term risk for birds and mammals from the representative uses of aluminium silicate calcined is expected to be low. Considering the physical chemical properties of the active substance, a risk assessment for the metabolites was not required.

For **aquatic organisms**, valid acute studies were submitted for invertebrates (Surround WP crop protectant) and algae (SOKALCIABRO WP). Additionally, submitted literature information included studies on fish (acute and chronic) and aquatic invertebrates (chronic), which could only be considered supplementary. For fish, no valid acute endpoint was submitted. However, the available supplementary information indicated low acute hazard in several species.

Aluminium silicate calcined is a repellent. Considering aluminium silicate calcined is inert, insoluble, and stable in the environment, and that the representative uses are expected to result in exposure levels lower than the background in aquatic sediments, the chronic exposure of aquatic organisms from the representative uses is expected to be low. Therefore, low chronic risk to aquatic organisms was concluded. Additionally, considering the physical chemical properties of the active substance, a risk assessment for the metabolites was not required.

For the water column, a quantitative assessment comparing background levels of aluminium silicate to the exposure resulting from the representative uses of the active substance was unavailable. However, an illustrative risk assessment has been provided by the RMS. Considering the above-mentioned information on fish, the acute risk to fish was estimated as low for all representative uses. For aquatic invertebrates and algae, a low acute risk was concluded for the representative use of Surround WP crop protectant. For SOKALCIABRO WP, a low acute risk was indicated for all representative uses for single seasonal applications. Similarly, low acute risk was indicated for multiple applications in stone-, pome- and nut fruits, lavender and grapevine. However, a low risk was not indicated for walnut, citrus and olive trees (i.e., acute risk for invertebrates), and apple (i.e., acute risk for invertebrates and risk to algae), when the SOKALCIABRO WP is used multiple times over the same growing season. This could include refined exposure calculations that account for sedimentation out of the water column to sediment between the applications, such as can be accounted for by using the FOCUS Step 2 calculator (FOCUS, 2001) (data gap, see Section 10).

Valid **honey bee** contact studies were available with the formulation SOKALCIABRO WP and the active substance, while chronic studies on honey bee adults and larvae were submitted for both representative formulations. A study addressing the acute oral toxicity to honey bee adults was submitted and discussed at the peer-review meeting,[11] where it was agreed not to use it in a quantitative risk assessment, due to deviations from the OECD TG 213 (data gap and issue that could not be finalised, see Section 9). The RMS provided a risk assessment for honey bees according to the SANCO guidance (European Commission, 2002a) and the EFSA guidance (2013). Based on the SANCO guidance, high acute contact risk was indicated for all uses except grapevine (SOKALCIABRO WP) and lavender.

Based on the EFSA guidance (2013), the following conclusions were drawn:

- for the use of Surround WP crop protectant in grapevine, a high contact and chronic risk (adults and larvae) was indicated,
- for SOKALCIABRO WP:
  - a high contact risk was indicated at Tier-1 for all uses, except citrus, olive, grapevine and lavender.
  - a high chronic risk (adults and larvae) for bees foraging from the treated crop was indicated at Tier-1 for all representative uses, except for (i) citrus and olive, for which a low risk for larvae and adults was indicated and (ii) lavender, for which the risk to larvae was indicated as low, while the chronic risk for adults was high.

[11] Pesticide Peer Review Experts' TC 72, Expert's consultation 5.1.

The risk assessment for bees was discussed at the peer-review meeting,[9] where it was agreed that the available higher tier field studies were not suitable to address the risks to honeybees, because of their major design flaws. Furthermore, it was acknowledged that available risk assessment schemes were not designed to characterise risks from uses of substances such as aluminium silicate calcined, which is inert and acts as repellent. For this reason, the quantitative risk assessment was considered worst-case. Nonetheless, experts agreed that the available body of evidence was insufficient to conclude low risk (acute contact, chronic and risk to larvae) for honey bees (data gap, see Section 10). A risk assessment for drinking water and metabolites occurring in pollen and nectar was not considered necessary, considering the properties of the active ingredient. A suitable assessment of accumulative effects and sublethal effects (e.g. hypopharyngeal glands (HPGs)) was not available (data gap, see Section 10). In addition, no information was available for bumble bees and solitary bees.

For **non-target arthropods** (NTAs) other than bees, no GLP-compliant laboratory studies on standard indicator species were submitted by the applicant. However, a large body of evidence comprising open-literature laboratory and field studies was available and their use in risk assessment was discussed at the meeting.[12] The available open-literature laboratory studies were not considered suitable to derive a reliable endpoint for the Tier 1 risk assessment for NTAs. Additionally, it was questioned whether standard toxicity designs would actually represent a reasonable worst case for characterising effects of aluminium silicate calcined in NTAs, considering its mode of action and inert nature. The use of the available field studies for a comprehensive in- and off-field risk assessment for NTAs was questioned due to identified uncertainties and limitations (e.g. geographical representativeness and design issues, such and unreported dose verification, sampling methods and absence of a valid toxic reference). However, it was also acknowledged that clear effects on NTA communities were observed across field studies. In addition, data were insufficient to conclude recovery of the affected NTA communities. Therefore, high risk (in and off-field) could not be excluded (data gap and issue not finalised, see Section 9).

The exposure of soil organisms from the representative uses is considered limited compared to the naturally occurring kaolin clay mineral fractions (which are comparable to aluminium silicate calcined) already present in agricultural soil. Therefore, the risk for **soil macro- and microorganisms** are expected to be low.

No data for the active substance are considered necessary for **non-target terrestrial plants**, considering the mode of action of aluminium silicate calcined.

No activated sludge study was submitted. However, considering the inert, insoluble nature of aluminium silicate calcined, its similarity with common clay minerals and taking into account the representative uses, no adverse effects on **biological methods for sewage treatment** are expected.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of aluminium silicate for **humans** and **non-target organisms** in line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018), no (eco)toxicological data were available to assess the endocrine disrupting properties. However, this does not appear scientifically necessary, based on the knowledge on ADME and physico-chemical properties and in particular due to the following justifications:

- Aluminium silicate is an inert natural inorganic mineral;
- It is insoluble in aqueous and organic solvents;
- It does not become bioavailable when ingested. Consequently, it is not distributed in the tissues and it is not metabolised;
- Literature review did not reveal any information on endocrine disrupting properties of aluminium silicate on humans and/or non-target organisms.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that aluminium silicate is unlikely to be an endocrine disruptor.

[12] Pesticide Peer Review Experts' TC 72, Expert's consultation 5.2.

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)[13]

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
None	

Table 2: Groundwater[(a)]

Compound (name and/or code)	> 0.1 μg/L at 1 m depth for the representative uses[(b)] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
None	Not applicable	–	–	–	–

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): As aluminium silicate calcined is inorganic and is a repellent, the parametric drinking water limit of 0.1 μ/L for pesticides and their relevant metabolites as defined by the drinking water directive 98/83/EEC is not applicable.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Aluminium silicate calcined (water only)	Low acute risk to aquatic organisms was not indicated for walnut, apple, citrus and olive trees when the SOKALCIABRO WP is used multiple times over the same growing season

Table 4: Air

Compound (name and/or code)	Toxicology
Aluminium silicate calcined	Rat LC_{50} inhalation > 5.07 mg/m^3, 4 h (nose-only, dust)

LC_{50}: lethal concentration, 50%.

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms (Table 5).

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

[13] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, pp. 32–54.

Table 5: Risk mitigation measures (RMM) proposed for the representative uses assessed

Representative use	SOKALCIARBO WP Walnut (F), other trees (F)	SOKALCIARBO WP Lavender (F), Grapes (F)
	Foliar spray	Foliar spray
Operator risk	Use of PPE is required[(a)]	RMM not required
Worker exposure	RMM not required	RMM not required
Bystander/resident exposure	RMM not required	RMM not required

PPE: personal protective equipment.
(a): For tractor-mounted applications and hand-held equipment: use of RPE during mixing and loading (EFSA, 2014).

9. Concerns and related data gaps

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[14] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

1) The batches used in the (eco)tox studies have not been demonstrated to be representative of the technical specification (see Sections 1, 2 and 5)
   a) Analytical data on composition of batches used in (eco)toxicological studies were not provided (relevant for all representative uses evaluated).
2) The consumer dietary risk assessment is provisional, for the uses in food crops (grapevines, olive, stone fruits, pome fruits, citrus fruits and tree nuts) (see Section 3)
   a) Content of the relevant impurity, TiO_2 particles ($\leq$ 10 μm) in the technical active substance (see Sections 1 and 2).
   b) Genotoxic potential of TiO_2 particles cannot be ruled out (see Section 2).
3) The acute oral risk assessment for honey bees could not be finalised (relevant for all representative uses evaluated, see Section 5)
   a) A valid acute oral toxicity study on honey bees (adults) was not available.
4) The risk assessment for non-target arthropods (in and off-field) could not be finalised (relevant for all representative uses evaluated, see Section 5)
   a) Data were indicative of effects on NTA communities and were insufficient to conclude recovery of the affected NTA communities.

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses,

[14] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, pp. 127–175.

it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

There is no critical area of concern.

9.3. Overview of the concerns identified for each representative use considered (Table 6)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6.)

Table 6: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		**Grapevine**	**Apricot, almond, cherry, hazel, peach, pome fruits, pear, apple, plum, walnut**	**Citrus, olive**	**Walnut**	**Apple**	**Grapevine**	**Lavender**
		4*28.5 kg/ha	**4*(max) 50 kg/ ha**	**6* (max) 50 kg/ ha**	**6*(max) 60 kg/ha**	**7*(max) 30 kg/ha**	**4*20 kg/ha**	**5*(max) 15 kg/ha**
Operator risk	Risk identified							
	Assessment not finalised							
Worker risk	Risk identified							
	Assessment not finalised							
Resident/ bystander risk	Risk identified							
	Assessment not finalised							
Consumer risk	Risk identified							
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	

Representative use		Grapevine	Apricot, almond, cherry, hazel, peach, pome fruits, pear, apple, plum, walnut	Citrus, olive	Walnut	Apple	Grapevine	Lavender
		4*28.5 kg/ha	4*(max) 50 kg/ ha	6* (max) 50 kg/ ha	6*(max) 60 kg/ha	7*(max) 30 kg/ha	4*20 kg/ha	5*(max) 15 kg/ha
Risk to wild non-target terrestrial vertebrates	Risk identified							
	Assessment not finalised							
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[(c),(d)]	X[(c),(d)]	X[(c),(d)]	X[(c),(d)]	X[(c),(d)]	X[(c),(d)]	X[(d)]
	Assessment not finalised	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]
Risk to aquatic organisms	Risk identified							
	Assessment not finalised							
Groundwater exposure to active substance	Legal parametric value breached							
	Assessment not finalised							
Groundwater exposure to metabolites	Legal parametric value breached[(a)]							
	Parametric value of 10 µg/L[(b)] breached							
	Assessment not finalised							

The superscript numbers relate to the numbered points indicated in Sections 9.1. Where there is no superscript number, see Sections 2 to 7 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

(c): High acute oral risk to honey bees, except for lavender, following the SANCO GD and except lavender and grapevine (4*20 kg/ha) following the EFSA guidance (2013).

(d): High chronic risk indicated following the EFSA guidance (2013).

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- Batch data on the content of respirable crystalline silica (SiO_2) with a diameter $\leq$ 10 μm in the technical active substance. Alternatively, applicant to provide an expert signed scientific justification by relevant laboratories justifying why it is not technically possible to supply the requested data (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- Batch data on the content of TiO_2 which is in the form of incorporated in particles with aerodynamic diameter $\leq$ 10 μm in the technical active substance. Alternatively, applicant to provide an expert signed scientific justification by relevant laboratories justifying why it is not technically possible to supply the requested data (relevant for SOKA and Tessenderlo Chemie and for all representative uses, see Section 1).
- Infrared (IR) spectra of the purified aluminium silicate calcined (kaolin calcined) (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- Self-heating data for the representative formulation 'Surround WP crop protectant', (relevant for Tessenderlo Chemie and for representative uses evaluated for 'Surround WP crop protectant', see Section 1).
- A validated analytical method for the determination of the titanium dioxide (TiO_2) particles with diameter $<$ 10 μm, in the technical active substance and the formulation 'SOKALSIABRO WP'. Alternatively, applicant to provide an expert signed scientific justification by the relevant laboratories justifying why it is not technically possible to provide the requested analytical method (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- Data to demonstrate the applicability of method Norm EN 15510: Method DIN EN ISO 11885, modified, in terms of specificity, for the determination of the relevant impurity lead in the technical active substance and the formulation 'SOKALCIABRO WP' (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- Data to demonstrate the applicability of method Norm EN 15550: Method §64 LFGB L00.00–19/3, in terms of specificity, for the determination of the relevant impurities cadmium, arsenic and mercury in the technical active substance and the formulation 'SOKALCIABRO WP' (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- Validation data to demonstrate the applicability, in terms of specificity, of the proposed analytical GC–MS/MS method for the determination of PCDDs, PCDFs, dioxin like PCBs and non-dioxin like PCBs, in the technical material manufactured by SOKA and in the representative formulation 'SOKALCIABRO WP' (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1).
- A validated analytical method for the determination of the relevant impurity respirable crystalline silica with a diameter $<$ 10 μm, in both technical materials, the formulation 'SOKALCIABRO WP' (relevant for SOKA and for representative uses evaluated for 'SOKALCIABRO WP', see Section 1) and the formulation 'Surround WP crop protectant' (relevant for Tessenderlo Chemie and for representative uses evaluated for 'Surround WP crop protectant', see Section 1). Alternatively, applicants to provide an expert signed scientific justification by the relevant laboratories justifying why it is not technically possible to provide the requested analytical method (see Section 1).
- Information to address: (i) the acute contact risk for honey bees for the representative use of 'Surround WP crop protectant' (considering the SANCO guidance), and for all representative uses of 'SOKALCIARBO WP', except grapevine, citrus, olive and lavender (considering the SANCO and EFSA guidance documents); (ii) the chronic risk to honey bee adults and the risk to larvae for the representative use of 'Surround WP crop protectant', considering the EFSA guidance document (2013); (iii) the chronic risks for honey bees (adults and larvae) for all

uses, except citrus and olive considering the EFSA guidance document (2013); (iv) the risks to honeybee adults and larvae from sublethal effects (e.g. effects on hypopharyngeal glands) for all representative use evaluated (see Section 5).

- Information to address the risk to aquatic organisms for the uses on walnut, apple, citrus and olives when the representative product SOKALCIABRO WP is used multiple times over the same growing season. This could include refined exposure calculations that account for sedimentation out of the water column to sediment between the applications, such as can be accounted for by using the FOCUS Step 2 calculator (FOCUS, 2001) (see Section 5).

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
ECHA	European Chemicals Agency
EEC	European Economic Community
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
HPG	hypopharyngeal glands
ISO	International Organization for Standardization
LC_{50}	lethal concentration, median
MS/MS	Tandem mass spectrometry
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PPE	personal protective equipment
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RPE	respiratory protective equipment
WHO	World Health Organization
WP	wettable powder

Appendix A – Consideration of cut-off criteria for aluminium silicate calcined according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Classification criteria not met. Aluminium silicate calcined is not considered to be carcinogenic, mutagenic or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation No 1107/2009.
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine disrupting properties		Aluminium silicate calcined is not considered to meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Aluminium silicate calcined is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Aluminium silicate calcined not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Aluminium silicate calcined not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1,107/2009.
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

Appendix B – List of end points for the active substance and the representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7637

Safety Data Sheet

Anhydrous

Effective 2/1/2023
Expires 2/1/2026

1 - IDENTIFICATION, PRODUCT AND COMPANY

Product name: NO. 50

REACH status: Exempted in accordance with Annex V.7

Other name(s): Calcined Kaolin, Anhydrous Aluminum Silicate, China Clay

Product Use: Mineral pigment used as an extender or filler in paints, coatings, adhesives, sealants, printing inks, rubber and plastic formulations. Also used as a pozzolan in morter and concrete.

Manufacturer: Burgess Pigment Company, 525 Beck Boulevard, P.O. Box 349, Sandersville, Georgia 31082 U.S.A.

Internet: www.burgesspigment.com

Email: technicalcenter@burgesspigment.com

Emergency Number: Burgess Pigment Company, +1 478 552 2544, From 12:30 PM (UTC) to 8:30 PM (UTC), Employees only speak English.

2 - HAZARD IDENTIFICATION

GHS classification: NONE (This product does not meet the criteria for classification as hazardous as defined in the Regulation EC 1272/2008 and in Directive 67/548/ECC)

Signal Word / Pictogram: NONE / NONE

OSHA classification: Not classified as hazardous

WHMIS classification: Non Controlled - contains less than 0.1% crystalline silica

Precautionary statements: Avoid breathing dust, wear approved respiratory protection if exposure is greater than suggested exposure limits (see Section 8)

California Prop 65 hazards: NONE

3 - COMPOSITION, INFORMATION ON INGREDIENTS

Component(s)	CAS Registry No.	EINECS No.	% (Approx.)	EC Hazard Classification	REACH status
Calcined kaolin	92704-41-1	296-473-8	100	Not classified as hazardous	Exempt

4 - FIRST AID MEASURES

Eye / Skin Contact: Direct contact may cause irritation by mechanical abrasion. Hold eyelids apart and flush with a steady stream of water for several minutes. Rinse skin with water.

Inhalation: Dust may irritate the nose, throat, and respiratory tract by mechanical abrasion. Coughing, sneezing, and shortness of breath may occur following unprotected exposure in excess of suggested limits. Move person to fresh air.

Most important symptoms and effects both acute and delayed: Expected to be non-toxic. No acute and delayed symptoms and effects are observed.

Indication of any immediate medical attention and special treatment needed: No specific actions are required

General advice: First-aid responders should wear respiratory protection (e.g. dust mask) in dusty areas. If symptoms persist seek medical attention. Change contaminated clothing.

5 - FIRE FIGHTING MEASURES, FIRE OR EXPLOSION HAZARDS

Extinguishing media: Noncombustible. Use media appropriate for surrounding materials or packaging.

Special hazards arising from the substance: Noncombustible. No hazardous thermal decomposition.

Advice for firefighters: Although inert, product can become slippery when exposed to water. Use caution walking around or handling broken product bags when exposed to water.

Protective measures: Use protective equipment appropriate for surrounding materials or packaging.

Flash point: Noncombustible.

Flammable limits in air: Not flammable.

Autoignition temperature: Not flammable.

Explosion data: Not explosive.

Unusual fire and explosion hazards: None known.

Sensitivity to static discharge: Not applicable.

6 - ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid dust formation. Use approved respirators if dust exposure is greater than recommended limits (refer to Section 8). Water should be used with care as it creates a slipping hazard when mixed with this product.

Environmental precautions: This product is generally non-toxic to aquatic systems but may cause high turbidity in storm water. Product is generally not harmful to water treatment systems.

Clean up methods: Collect by vacuum and mechanical sweeping, avoid dust generation. Remaining residue can be washed to water treatment or storm water systems.

Reference for other sections: See sections 8 and 13

7 - HANDLING AND STORAGE

Precautions for safe handling: Appropriate personal protection should be used when handling (refer to

Section 8). Use care when dispensing to avoid dust generation. Fold and flatten empty bags carefully to reduce dust generation. Wash hands thoroughly after handling. Do not eat, drink or smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for safe storage: Best if kept under dry conditions. Not generally affected by hot or cold storage. Keep unused material in a closed container to avoid contamination and dust exposure. Minimize airborne dust generation and prevent wind dispersal during loading and unloading.

Specific end use(s): Please refer to your customer service, sales or distributor representative for detailed information. Product is considered industry grade material.

8 - EXPOSURE CONTROLS, PERSONAL PROTECTION, PREVENTIVE MEASURES

Exposure limit values: No exposure limits have been published for calcined kaolin products. We recommend using the limits published for Kaolin (CAS# 1332-58-7, EC#310-194-1). Use your local / national occupational exposure limits for kaolin (or 'nuisance dust') if more stringent than the following:

Engineering controls: Dust levels in excess of appropriate exposure limits should be reduced by all feasible engineering controls, including (but not limited to) wet suppression, ventilation, process enclosure, and enclosed employee work stations.

Notes- (-A4) This indicates that kaolin is 'Not Classifiable as a Human Carcinogen' by ACGIH.

Exposure Limits Kaolin CAS# 1332-58-7

Value	Limit	Reference
2 mg/m3 (Respirable dust)	TWA (8 hour)	ACGIH TLV-A4*
15 mg/m3 (Total dust)	TWA (8 hour)	OSHA PEL
5 mg/m3 (Respirable dust)	TWA (8 hour)	OSHA PEL
10 mg/m3 (Total dust)	TWA (10 hour)	NIOSH REL
5 mg/m3 (Respirable dust)	TWA (10 hour)	NIOSH REL

Occupational exposure controls

Eye protection: Approved safety glasses with side shields.

Skin / body protection: Product may have a drying effect on exposed skin. Avoid direct, repeated skin contact. Select protective clothing considering the work environment and exposure risk. Where skin contact is likely use barrier clothing suitable for nuisance dusts.

Hand protection: Any type of glove that reduces or eliminates skin contact is acceptable.

Respiratory protection: Use a compliant particulate respirator when dust levels exceed or are likely to exceed regulatory limits.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practices. Care should be given to avoid dust generation.

Environmental exposure controls: Avoid conditions that would allow wind dispersal.

9 - PHYSICAL AND CHEMICAL PROPERTIES

General information, appearance and odor: Off-white dry powder, soil-like odor.

Important health, safety and environmental information:

pH in water (20% solids suspension): 4.0 - 6.3 (range for all anhydrous products- refer to specific product TDS for exact pH)

Boiling point: N/A (Solid)

Melting point: >1700^{o} C

Flash point: N/A

Flammability: N/A

Explosive properties: N/A

Oxidizing properties: N/A

Vapor pressure (mm Hg): No Vapor

Specific gravity (H2O=1): 2.2 - 2.6 (range for all anhydrous products- refer to specific product TDS for exact specific gravity)

Solubility in water: Insoluble

Vapor density (Air=1): No Vapor

10 - STABILITY AND REACTIVITY

Reactivity: Inert / not reactive

Chemical stability: Chemically stable

Possibility of hazardous reactions: No hazardous reactions.

Conditions to avoid: None known. Stable under normal storage, handling and environmental conditions.

Incompatible materials: None known. This product is stable when used as intended by the manufacturer.

Hazardous decomposition products: None known. This product is stable in water.

11 - TOXICOLOGICAL INFORMATION

Acute toxicity: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

Skin corrosion / irritation: No data available, generally regarded as safe by FDA.

Serious eye damage / irritation: No data available, generally regarded as safe by FDA.

Respiratory or skin sensitization: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

Germ cell mutagenicity: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

Carcinogenicity: Calcined kaolin is not listed as a carcinogen by the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), or the Occupational Safety and Health Administration (OSHA). The American Conference of Governmental Industrial Hygienists (ACGIH) lists kaolin as- Not Classifiable as a Human Carcinogen: Inadequate data on which to classify the agent in terms of its carcinogenicity in humans and/or animals. This product contains less than 0.1% crystalline silica (quartz) based on testing using NIOSH method 7500.

Reproductive toxicity: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

Specific Target Organ Toxicity (STOT)

Single exposure: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

Repeated exposure: Inhalation- Human studies indicate that chronic (15~20 years) exposure to excessive dust levels may lead to pneumoconiosis, a lung disease. Not all individuals with pneumoconiosis will exhibit

symptoms (signs) of the disease. However, pneumoconiosis can be progressive and symptoms can appear at any time, even years after the esposure has ceased. Symptoms of pneumoconiosis may include but are not limited to the following: shorness of breath; difficulty breathing with or without exertion; coughing; diminished work capacity; diminished chest expansion; reduction of lung volume.

Aspiration hazard: Limited animal studies indicate no hazard, generally regarded as safe by FDA.

12 - ECOLOGICAL INFORMATION

Toxicity: N/A. Animal testing indicates no adverse effects.

Persistence and degradability: N/A. This product is made from a naturally occurring, abundant, innocuous mineral.

Bioaccumulative potential: No data available. This product is not expected to accumulate in biota.

Mobility in soil: Negligible. This product is insoluble in water

Results of PBT and vPvB assessment: N/A

Other adverse effects: May affect turbidity of water if discharged in large quantities to lakes or streams.

13 - DISPOSAL CONSIDERATIONS

Waste treatment methods: Improper disposal may create a nuisance dust hazard.

Waste from residues / unused products: Whenever possible pickup and reuse uncontaminated product, avoiding dust generation. Product material is not a hazadous waste. Dispose of in accordance to applicable national and local regulations. Place in closed containers to avoid dust generation.

Packaging: Dust formations from residues in packaging should be avoided and suitable worker protection assured. Empty packaging materials are suitable for recycling. Place in closed containers to avoid dust generation.

14 - TRANSPORTATION INFORMATION

UN or DOT number and proper name: N/A. Not a hazardous material as defined under national / international road, rail, sea and air transport regulations

Transport hazard classes (ADR, IMDG, ICAO / IATA, RID): Not classified

Packaging group: N/A.

Environmental hazards: None

Special precautions for user: No special precautions

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: N/A.

Label required: Use original label including precautionary statement. When disposing of this material in its pure form use a 'Non-Hazardous Waste' label.

15 - REGULATORY INFORMATION

Chemical safety assessment: Not performed on this product. Adverse effects are not expected when product is used according to guidelines presented in this document.

U.S. Federal Regulations

FDA: Kaolin (aluminum silicate, china clay, clay) is acceptable for several specific uses. See 21 CFR 73, 82, 175, 176, 177, 178, 186, 310, 335, 346, 347 and 872.

SARA Title III (EPCRTKA) Section 302: This product does not contain any extremely hazardous substances subject to the reporting requirements of 40 CFR Part 355.

SARA Title III (EPCRTKA) Section 311/312: This product does not contain any hazardous chemicals subject to the reporting requirements of 40 CFR part 370.

SARA Title III (EPCRTKA) Section 313: This product does not contain substances subject to the reporting requirements of 40 CFR Part 372.

TSCA: This product or its components are listed in or exempt from the TSCA inventory requirements. This product does not contain substances subject to export notification under Section 12(b) of TSCA.

North American Regulations

USA: Alaska, Arizona, California, Idaho, Indiana, Massachusetts, Michigan, Minnesota, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, and Washington.

California Prop 65: No substances requiring notification.

Canada: Alberta, British Columbia, Manitoba, New Brunswick, Northwest Territories, Nova Scotia, Nunavut, Ontario, Quebec, Saskatchewan, and Yukon. This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and this MSDS contains all the information required by the Controlled Products Regulations.

WHIMS classification: Noncontrolled (tested, contains less than 0.1% crystalline silica).

Mexico: See national exposure limits.

Several states, provinces and territories specifically list kaolin and regulate dust exposure.

Foreign Regulations

Hazard symbols: None

CAS# 92704-41-1 can be found in the following registries: China Inventory, DSL (Canada), ECL (Korea), EINECS (Europe), ENCS (Japan), NZIoC (New Zealand), PICCS (Philippines). AICS (Australia) lists calcined kaolin under the CAS# 66402-68-4. German Water Classification - Annex 1: Non-Hazardous (ID No. 7926). Product does not require a hazard warning label in accordance with EC Directive 2008/1272/EC.

16 - OTHER INFORMATION

Health = * 0 : (nuisance dust- fine particulate)

Flammability = 0 : (non flammable)

Physical Hazard = 0 : (non reactive)

Personal Protective Equipment = E **:

Revised on 01 February 2023: Minor format changes. Conforms to ANSI Z400.1/Z129.1-2010 Standard, OSHA HCS (2012).

Calcined kaolin is made from a natural mineral which is heated to remove water. Its chemical formula is Al2Si2O7

Hazardous Materials Identification System (HMIS^{R} III) Ratings

* Possible chronic hazard. Review and abide by suggested dust exposure limits. Monitor work area for potential over-exposure to dust.

** Use safety glasses, gloves and appropriate respiratory protection for dusty conditions.