Aluminium silicate (Kaolin)

DOCUMENT N1

OVERALL CONCLUSIONS

Annex to EU Regulation 283/2013 & 284/2013

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Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
February 2018	Initial version	Document N1 – Initial version

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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1 IDENTITY

1.1 Summary of identity

All relevant information on aluminium silicate (kaolin) and of the chemical product SURROUND® WP CROP PROTECTANT have been provided in Documents M-CA Section 1 and M-CP Section 1 except in the case of confidential information which is included in the Document J.

Minimum purity of aluminium silicate is 99.98%. There are no isomers of aluminium silicate (kaolin) and no metabolites. Please refer to Documents N3 and N5 for further details.

2 PHYSICAL AND CHEMICAL PROPERTIES

2.1 Summary of physical and chemical properties of the active substance

Aluminium silicate (kaolin) is a white, odourless powder that is insoluble in water and all organic solvents. Aluminium silicate (kaolin) has no dissociation constant and no partition coefficient. Aluminium silicate (kaolin) is non-explosive and non-oxidizing. Aluminium silicate (kaolin) is not flammable, does not melt and does not boil.

Aluminium silicate (kaolin) is inert and stable.

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

The technical properties of Surround® WP Crop Protectant, containing 95% kaolin active ingredient, indicate that no particular problems are to be expected when it is used according to recommended use instructions. It is a wettable powder and is not corrosive, explosive, oxidizing or flammable. Storage under normal warehouse conditions in the original packaging is recommended – experience with similar products indicates a minimum shelf life of 3 years.

3 DATA ON APPLICATION AND EFFICACY

3.1 Summary of effectiveness

SURROUND® WP CROP PROTECTANT has demonstrated its efficacy against a variety of insect pests as part of its re-evaluation following approval of its chemical active ingredient, aluminium silicate. Efficacy has been demonstrated against *Frankliniella occidentalis*, *Psylla pyri*, *Bractocera oleae*, *Prays oleae*, *Ceratitis* and aphids.

3.2 Summary of information on the development of resistance

Aluminium silicate (kaolin) has no toxic mode of action and therefore cannot induce resistance in pest populations.

Aluminium silicate (kaolin) cannot cause resistance like conventional chemical insecticides. Aluminium silicate (kaolin) is not killing the insects through a specific target site so selection

pressure to counteract the effects of kaolin is of very low probability. 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.

3.3 Summary of adverse effects on treated crops

Aluminium silicate (kaolin) is a purified type of clay naturally present in most agricultural soils. Agricultural soils typically contain 5 to 50% clay. Aluminium silicate is neither absorbed nor translocated by plants. There are no adverse effects of aluminium silicate (kaolin) on treated crops

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

When applied on crops, SURROUND® WP CROP PROTECTANT leaves a white kaolin film that provides an effective barrier against insect pests. This layer of white particles may be difficult to remove from soft, fragile fruits and, although totally non-toxic, may prove unsightly to customers.

4 FURTHER INFORMATION

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

SURROUND® WP CROP PROTECTANT is inert and non-toxic.

Warehouse/user-level storage:

Keep containers tightly closed in a dry, cool and well ventilated place, away from food or feed. Product is slippery when wet.

Transport:

SURROUND® WP CROP PROTECTANT is not classified as dangerous in the meaning of transport regulations.

Fire:

SURROUND® WP CROP PROTECTANT is not classified as flammable. Surround® WP Crop Protectant does not burn. Use extinguishing media appropriate for surrounding fire.

4.2 Summary of procedures for destruction or decontamination

SURROUND® WP CROP PROTECTANT is insoluble, inert and non-toxic. No neutralization procedure is available.

SURROUND® WP CROP PROTECTANT contains 95% kaolin. Kaolin evolves water when heated over 600°C. No further decomposition occurs.

Additives in SURROUND® WP CROP PROTECTANT do not contain halogens. Thus, pyrolysis cannot generate polyhalogenated dibenzo-p-dioxins.

SURROUND® WP CROP PROTECTANT is a solid and does not require adsorbing materials in the event of spillage. Scoop up or vacuum into a container for reclamation or disposal. Dispose of as non-hazardous waste.

4.3 Summary of emergency measures in case of an accident

Fire:

SURROUND® WP CROP PROTECTANT does not burn. Use extinguishing media appropriate for surrounding fire: Firefighters should wear full fire-fighting turn-out gear (full Bunker gear), including NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

Containment of spillage:

Cover powder spill with plastic sheet or tarpaulin to minimize spreading and dust generation. Scoop up or vacuum into a container for reclamation or disposal. Avoid stirring up dust. Dispose of as non-hazardous waste.

SURROUND® WP CROP PROTECTANT is composed of 95% kaolin. Kaolin is an inert insoluble mineral and no special method of decontamination is required other than physical removal of excessive quantities. Kaolin is not hazardous to man or the environment.

5 METHODS OF ANALYSIS

5.1 Methods used for the generation of pre-authorisation data

5.1.1 Analysis of the active substance as manufactured

All methods used to determine the pure active substance in the active substance as manufactured are confidential and described in Document J. Please refer to Document J for further details.

Furthermore, please note that the methods have also been provided in support of the Technical Specifications Dossier submitted on 12 June 2013 to the European Commission. EFSA's conclusions on the Technical Specifications Dossier were published in 2014[1].

5.1.2 Formulation analysis

All methods used to determine the pure active substance in the formulated product as manufactured are confidential and described in Document J. Please refer to Document J for further details.

[1] EFSA (European Food Safety Authority), 2014; Outcome of the consultation with Member States, applicant and EFSA on the pesticide risk assessment of confirmatory data submitted for the active substance aluminium silicate. EFSA supporting publication 2014:EN-625. 10 pp.

5.1.3 Methods for Risk Assessment

Plants and plant products

Not applicable. Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

Food of animal origin

Not applicable. Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

Soil, Water, Air

Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases, except under very harsh conditions. Aluminium silicate has a similar chemical composition to common clay that is found in most soils and aquatic sediments the world over.

Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and cannot be separated from naturally present aluminium silicate clays.

Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies and therefore no analytical methods for quantification in soil, water, sediment, air or any additional matrices is presented.

5.2 Methods for post-authorisation control and monitoring purposes

Plants and plant products

Not applicable. Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

Food of animal origin

Not applicable. Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

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6 IMPACT ON HUMAN AND ANIMAL HEALTH

6.1 Effects Having Relevance to Human and Animal Health

6.1.1 Summary of adsorption, distribution, metabolism and excretion

In view of the inert nature of aluminium silicate (kaolin), its natural occurrence and chronic exposure in everyday life through medicines, toiletries and natural environment, ADME studies are not required.

Aluminium silicate (kaolin) is inert, insoluble in aqueous and organic solvents and non-bioavailable. No oral absorption would be expected because of the molecular size and insolubility in water and organic solvents of the molecule. It would not therefore enter bloodstream and does not distribute in tissues. Kaolin is not metabolized.

The evidence of lack of absorption combined with the chronic exposure to aluminium silicate (kaolin) in daily life through medicines, toiletries and the natural environment, and with the need to avoid unnecessary animal testing[2] has led Tessenderlo Group N.V. to request a waiver for ADME studies.

6.1.2 Summary of acute toxicity

Parameter	Species	Result	Reference
Acute Oral LD_{50}	Rat	> 5000 mg/kg	[redacted]
Acute Oral LD_{50}	Rat	> 5000 mg/kg	[redacted]
Acute Dermal LD_{50}	Rat	> 5000 mg/kg	[redacted]
Acute Inhalation LC_{50}	Rat	> 2.07 mg/l	[redacted]
Acute Inhalation LC_{50}	Rat	> 2.18 mg/l	[redacted]
Acute Skin Irritation	Rabbit	non-irritating	[redacted]
Acute Eye Irritation	Rabbit	non-irritating	[redacted]
Acute Eye Irritation	Rabbit	non-irritating	[redacted]
Skin sensitisation	Guinea pig	non-sensitising	[redacted]

Aluminium silicate (kaolin) is nontoxic via the oral, dermal or inhalation route to rats. Furthermore, it is not irritating to either eyes or skin nor is it a skin sensitiser. Based on the evidence presented aluminium silicate (kaolin) is not toxic and does not warrant classification.

6.1.3 Summary of short-term toxicity

No short-term toxicity studies on aluminium silicate (kaolin) are available. Considering that aluminium silicate (kaolin) has an excellent safety record for continuous use as a food additive, pharmaceutical ingredient, personal hygiene component and in many industrial applications; short-term toxicity endpoints are waived.

[2] Council Directive 86/609/EEC of 24 November 1986

6.1.4 Summary of genotoxicity

No genotoxicity studies on aluminium silicate (kaolin) are available. Considering that aluminium silicate (kaolin) has an excellent safety record for continuous use as a food additive, pharmaceutical ingredient, personal hygiene component and in many industrial applications; genotoxicity toxicity endpoints are waived.

6.1.5 Summary of long-term toxicity and carcinogenicity

No long term-carcinogenicity studies (mice or rat) on aluminium silicate (kaolin) are available. Considering that aluminium silicate (kaolin) has an excellent safety record for continuous use as a food additive, pharmaceutical ingredient, personal hygiene component and in many industrial applications; long term-carcinogenicity toxicity endpoints are waived.

Two publications on aluminium silicate (kaolin) have been presented. The first, a 12-month study, where kaolin was dosed via tracheal injection to guinea pigs, aluminium silicate (kaolin) was not pathogenic and did not induce any epithelialization or neoplastic lesion. The second, in a long-term inhalation study, aluminium silicate (kaolin), administered for 12 months to the rat in an inhalation chamber did not induce any malignant lesion. Neither study presented any evidence for long-term toxicity or neoplasia.

6.1.6 Summary of reproductive toxicity

Although no animal studies, according to international regulatory guidelines, have been performed, extensive contact with and use of aluminium silicate (kaolin) in day-to-day life, be it as a food additive, a pharmaceutical ingredient, an ingredient in cosmetics and toiletry or an industrial chemical, has not led to any reported cases of reproductive toxicity. Given the inert nature of this substance, its lack of oral absorption and therefore bioavailability, conducting new studies on reproductive toxicity may be considered scientifically unjustified.

In a publication on aluminium silicate (kaolin), rats were fed in the short- and long-term on a diet containing 20% kaolin. In that study, significant reductions in haemoglobin, haematocrit, and red blood cell levels were seen, indicating maternal anaemia. An effect of kaolin was to adsorb iron from the gastrointestinal tract. A reduction in the birth weight of the pups was observed. The kaolin fed rats receiving an iron supplement maintained haematocrit, haemoglobin, red blood cell levels, and pup weight were within the normal range. The length of the pups was not affected, and no morphological abnormalities were observed in any of the pups.

6.1.7 Summary of neurotoxicity

No specific neurotoxicity studies on aluminium silicate (kaolin) were available.

Aluminium silicate (kaolin) is a naturally occurring mineral / clay which is ubiquitous within the environment and is widely used within industry and in a variety of consumer products. It is essentially a layered silicate mineral, with an infinite two-dimensional structure. As such, it is not soluble within water or organic solvents.

As a consequence, it is not feasible for aluminium silicate to be uptaken by living organisms and translocate within living tissues. There is no evidence for absorption or bioavailability and

therefore neurotoxicity studies should not be required.Summary of further toxicological studies on the active substance

6.1.8 Summary of further toxicological studies on the active substance

No other toxicological studies on aluminium silicate (kaolin) were available.

6.1.9 Summary of toxicological data on impurities and metabolites

Aluminium silicate (kaolin) is inert, insoluble in aqueous and organic solvents, non-bioavailable or bioactive. No oral absorption would be expected because of the molecular size and insolubility in water and organic solvents of the molecule. It would not therefore enter bloodstream and does not distribute in tissues. Kaolin is not metabolized and therefore there is no requirement for data on metabolites.

6.1.10 Summary of medical data and information

A large scale epidemiological survey on kaolin, in the USA, revealed no cases of primary sensitivity because of exposure to kaolin (solid, liquid or respirable forms). Some cases of pneumoconiosis were reported in the 1970's and 1980's, because of exposure in excess of current ACGIH TLVs (American Conference of Governmental Industrial Hygienists; Threshold Limit Values), some cases dating back to the 1930's. As a result of good dust control practices over the last 25 years no new cases of kaolin associated pneumoconiosis were found. Supportive evidence can also be drawn from studies of English china clay workers[3] where similar conclusion can be drawn.

The general population is routinely exposed to kaolin in foods, medicines, cosmetics and industrial applications. No major toxic health effects have been reported from Kaolin exposure in the general population. Exposure of the general population to significant levels of kaolin dust under everyday circumstances is highly unlikely.

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

No data available – not required

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

No data available – not required

[3] Ogle, CJ, Rundle, EM and Sugar ET (1989). China clay workers in the south west of England: analysis of chest radiograph readings, ventilatory capacity, and respiratory symptoms in relation to type and duration of occupation. British Journal of Industrial Medicine 1989; 46:261-270

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

No suitable data available to set an AOEL.

Inhalation exposure limit (IEL) of 36.6 mg/day derived from the WEL-TWA value of 2 mg/m3 (8 hours) based on a potential for pneumoconiosis after chronic inhalation exposure (EFSA, 2012 [4]).

6.5 Summary of product exposure and risk assessment

One critical use is identified and studied for risk assessment:

- Grapes: max. application rate of 28.5 kg a.s./ha; max. No. of applications = 4 with min. 7 days of interval between applications.

6.5.1 Operators

According to the EFSA calculator, the risk for operators is acceptable (36% of the tolerated dose) even is no PPE are worn during mixing/loading and application on grapes.

6.5.2 Bystander and resident exposure

Pending development of a harmonised approach to the setting of an acute non-dietary reference dose, it is not considered appropriate to undertake acute non-dietary exposure assessments (i.e. those that might be incurred in a single day) using the upper estimates of exposure (i.e. 95th percentile values) as stated in the guidance. Until a method has been described for deriving the Acute Acceptable Operator Exposure Level (AAOEL), this will not be included in the risk assessment. For bystanders, this means that the risk of exposure to substances with the potential for acute effects is not calculated; the risk of long-term exposure to substances for bystanders is included in the assessment of risks for residents.

The risk for residents was assessed using the EFSA calculator. As the exposure scenario in grapes is less than the tolerated dose (i.e. no more than 1.4%), the risk is acceptable.

6.5.3 Workers

Worker exposure can happen during vine hand harvesting. However, during such outdoor task, no inhalation exposure is expected and then the risk to workers is considered negligible.

7 RESIDUES

The metabolism and residues data are not required. A general waiver is deemed acceptable.

7.1 Summary of storage stability of residues

Not relevant.

[4] Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium silicate. EFSA Journal 2012;10(2):2517.

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

Aluminium silicate (kaolin) is a naturally occurring mineral / clay which is ubiquitous within the environment and is widely used within industry and in a variety of consumer products. It is essentially a layered silicate mineral, with an infinite two-dimensional structure. As such, it is not soluble within water or organic solvents.

As a consequence, it is not feasible for aluminium silicate to be uptaken by plants and translocate within plant tissues. It does not degrade, and so is not bioavailable. Based on the intended treatment pattern, fruit produced by treated grapevines are not expected to contain kaolin residues and negligible consumer exposure is anticipated.

Based on the representative use (on grapevines) livestock metabolism / feeding studies are not required, as gapes are not routinely fed to livestock. Furthermore, based on the inherent characteristics of kaolin, the substance will not degrade within the digestive tract of livestock or become bioavailable; any ingested kaolin will be fully excreted and not pose a toxicological concern.

7.3 Definition of the residue

Plants: not applicable

Animals: not applicable

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

Not required.

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

Not required.

7.6 Summary of effects of processing

Not relevant.

7.7 Summary of residues in rotational crops

Not required.

7.8 Summary of other studies

No other study is required.

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

Residues due to use of the product are not considered to be relevant based on the treatment regime and due to the inherent properties of the substance (it cannot be absorbed by plants). Aluminium silicate is naturally occurring in the environment including soil and water. Consumers are potentially exposed to aluminium silicate by consumption of commodities contaminated with residual soil / dust. Furthermore, kaolin is widely used within industry and in consumer products (paper, plastics, rubber, pottery, paint) and is an ingredient in pharmaceutical preparations. The intake of aluminium silicate (kaolin) through use as a plant protection product will be extremely negligible compared with that encountered through everyday exposure.

7.10 Proposed MRLs and compliance with existing MRLs

No MRLs are proposed or required. Aluminium silicate (kaolin) is proposed for the inclusion in Annex IV of Commission Regulation (EC) No 396/2005.

7.11 Proposed import tolerances and compliance with existing import tolerances

Not relevant.

8 FATE AND BEHAVIOUR IN THE ENVIRONMENT

8.1 Summary of fate and behaviour in soil

Aluminium silicate is extremely stable. The kaolin ores that are being mined today to produce aluminium silicate used in the product SURROUND® WP CROP PROTECTANT (the representative chemical product) were formed more than 25 million years ago in what is now the state of Georgia, United States of America.

Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases, except under very harsh conditions. Aluminium silicate has a similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. 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.

8.2 Summary of fate and behaviour in water and sediment

Aluminium silicate is extremely stable. 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 is requested for all environmental fate studies.

8.3 Summary of fate and behaviour in air

Aluminium silicate is extremely stable and non-volatile. As such, it cannot be volatilized and deposited. However, kaolin particles can be suspended in air and re-deposited as fine solids. Extreme storms occurring over non-vegetated areas (arid landscapes) may lift significant concentrations of particles that are later redeposited via rain. However, with an application rate of 30 kg/ha, equivalent to 3 g/m^2, kaolin particles from the use of the plant protection product will be marginal in concentration compared to that of natural soil or sand particles.

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

Not relevant. Kaolin (Aluminium silicate) is a type of clay mineral, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate is stable and inert. It does not degrade and does not react in the environment. There are no metabolites, degradation and reaction products of aluminium silicate.

8.5 Definition of the residues in the environment requiring further assessment

Not applicable. Aluminium silicate is a natural component of all agricultural soils 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.

8.6 Summary of exposure calculations and product assessment

Application pattern:

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

Soil:

Aluminium silicate does not degrade in soil, therefore calculations are presented both for a single application and for a cumulative application without degradation.
(SURROUND® WP CROP PROTECTANT contains 95% calcined aluminium silicate, however an aluminium silicate content of 100% is taken for the calculations).

$$PEC_{SOIL}\ (mg/kg) = \frac{\text{Application rate (g/ha) x [1-crop interception (decimal)]}}{\text{(Soil volume (cm}^3\text{) x soil density (g/cm}^3\text{)) x 10 (conversion factor)}}$$

Table 8.6-1 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 (early season orchard)	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

Agricultural soils normally contain between 5 and 50 % clay; therefore the quantity of kaolin added through the use of SURROUND® WP CROP PROTECTANT will not be sufficient to cause any measurable increase in the clay (aluminium silicate) content of agricultural soils, even after decades of use.

Groundwater:

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

SURROUND® WP CROP PROTECTANT contains 95% kaolin. Kaolin is not soluble in water, but forms suspended particles in water. Therefore, SURROUND® WP CROP PROTECTANT can only reach groundwater via mechanical percolation through soil pores, and not through conventional dissolution in water and leaching through the soil column.

Clay, including kaolin, is present in some natural groundwater reservoirs. Percolation through soil pores or the presence of clay seams allow naturally present clays to form suspensions in these water bodies. It is possible (but highly unlikely) that kaolin from SURROUND® WP CROP PROTECTANT may percolate through soil and reach groundwater, where it will not be possible to be distinguished by analytical means from natural clays.

Surface water and sediment:

The application of aluminium silicate is not expected to increase significantly the natural kaolin content of natural water bodies.

Based on the characteristics of kaolin using standard FOCUS calculations are impossible and meaningless. However, the initial worst-case $PEC_{Surface\ Water}$ for kaolin has been calculated for vines taking into consideration spray drift only, for one application at the maximum dose and also assuming total accumulation of kaolin between applications (Table CP 9.2.5-1). PEC_{SW} are calculated as follows:

$$PEC_{SW}\ (mg/L) = \frac{\text{Application rate (g/ha) x drift (decimal)}}{300\ L/m^2 \text{ x } 10\ \text{(conversion factor)}}$$

Table 8.6-2: Worst case PEC_{SW} 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
PECsw (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

Aluminium silicate is not soluble in water and 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.

PEC_{SED} are calculated as follows:

$$PEC_{SED}\ (mg/kg) = \frac{\text{Application rate (g/ha) x drift (decimal)}}{\text{Sed. volume (cm}^3\text{) x sed. density (g/cm}^3\text{) x 10 (conversion factor)}}$$

Table 8.6-03: 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 %
PECsed (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

Air:

Not applicable. SURROUND® WP CROP PROTECTANT contains 95% calcined aluminium silicate. Aluminium silicate is extremely stable and has no vapour pressure. Therefore, evaporation of aluminium silicate from soil or plant surfaces is not possible.

Aluminium silicate can only be observed in air as particles in suspension, similar to natural dust suspended in air and cannot be distinguished from naturally present dust particles

Other routes of exposure:

Not applicable. Aluminium silicate is a natural form of clay that is present the world over. Exposure to clay particles is ubiquitous in the form of dust, suspended particles in water, sediment or soil. Estimating exposure to one of the most common mineral substances on Earth is meaningless.

9 EFFECTS ON NON-TARGET SPECIES

9.1 Summary of effects on birds and other terrestrial vertebrates

As discussed in the original DAR (2008), considering the nature of the active substance and that it is a widespread element of the environment to which wildlife will often be exposed (i.e., via ingestion and dust bathing); it has been concluded that the risk to birds and mammals from the representative use of aluminium silicate (kaolin) will be low (EFSA Scientific Report (2012) 10(2):2517). Please refer to MCP 10.1.1 and MCP 10.1.2 for complete discussion.

No new avian or mammalian toxicity data are available or required for the renewal of aluminium silicate (kaolin). An acute mammalian toxicity study has been carried out with aluminium silicate (kaolin), and was previously reviewed; LD_{50} > 5000 mg a.s./kg bw/d (refer to KCA 5.2.1/01).

Aluminium silicate (kaolin) is present in most natural water bodies and the use of SURROUND® WP CROP PROTECTANT in agriculture will not significantly alter the normal background levels (see Document MCP 9). Also, the aluminium silicate (kaolin) in SURROUND® WP CROP PROTECTANT is not expected to act any differently from natural clays with which it will be mixed and rapidly become part of the natural sediment. Hence, a drinking water risk assessment is not required and the risk to birds and mammals was concluded to be low.

Aluminium silicate (kaolin) is not soluble in polar or non-polar solvents and thus has no octanol/water partition coefficient. It is considered that there is no potential for bioaccumulation of aluminium silicate (kaolin) in fatty tissues and therefore there is no potential for secondary poisoning. Moreover, aluminium silicate (kaolin) is naturally occurring compound and it is considered that additional exposure from the proposed use on vines will not lead to exposure levels above natural levels.

It was considered that there is an inherent level of safety based on the aquatic and terrestrial risk assessments that will cover the risk to amphibians and reptiles and therefore no additional data are required (please refer to MCP 10.1.3).

9.2 Summary of effects on aquatic organisms

The risk to aquatic organisms was demonstrated to be acceptable for the intended use of SURROUND® WP CROP PROTECTANT in grapevines. There are no relevant surface water metabolites to be considered. During the initial EU evaluation, a data gap for algae (EC_{50} > 570 mg a.s./L) was identified and data are now available with the formulated product and is being submitted to support the submission, along with an acute Daphnia magna study (EC_{50} > 570 mg a.s./L).

Chronic data on aquatic invertebrates are not available. The proposed use should not lead to surface water levels outside normal range (PEC_{SW} = 0.802 mg a.s./L (max single application) and 3.208 mg a.s./L (total season); refer to Document MCP 9) and thus chronic testing is not required. In addition, aquatic organisms are exposed to high levels of clay when floods, storms creating run-off or other natural phenomena, result in high turbidity in natural water bodies. Along with human disturbances such as dredging operations, boating activities or artificial impoundment. Nevertheless, public literature on aluminium silicate (kaolin) and aquatic organisms has been considered. The data are summarised under MCP 10.2 and confirm the very low toxicity of aluminium silicate (kaolin) to aquatic organisms.

The acute fish toxicity endpoint has been re-evaluated, with consideration of all valid studies. The geomean (LC_{50} of 36,577 mg/L) from 16 species was determined to be the most appropriate toxicity endpoint for use in the acute fish risk assessment.

The PEC/RAC ratios were ≤ 0.56 for the most sensitive aquatic organisms exposed to aluminium silicate (kaolin) using total seasonal PEC_{SW} value for use on grapevines. No aquatic risk mitigation was required. Refer to MCP 10.2 for the full risk assessment.

9.3 Summary of effects on arthropods

Bees:

The evaluation of the risk to honey bees from exposure to SURROUND® WP CROP PROTECTANT was performed in accordance with the first tier of the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees) (EFSA Journal 2013;11(7):3295) and is presented in MCP 10.3.1.

Chronic data for adult honey bees are now available for SURROUND® WP CROP PROTECTANT (LDD_{50} = 1390.14 µg a.s./bee/day). For the chronic larvae study, due to the limited optimal seasonal timing in conducting a successful and valid study in the laboratory, the definitive study could not be conducted in time for this submission and the result from the range-finding test (NOED = 150 µg a.s./larvae) was considered in the risk assessment. Once the definitive study in completed in Spring 2018, the chronic risk assessment for larvae will be revised.

The risk to honey bees via contact exposure was not demonstrated to be acceptable based on the screening step assessment with a $HQ_{contact}$ value of < 285 (trigger value of 85). A Tier I assessment was conducted to refine the risk assessment for both early and late applications on grapevines. The acute contact risk to honey bees was demonstrated to be acceptable in the Tier I assessment, except for honey bees forging on weeds in treated field ($HQ_{contact}$ was < 85.5, trigger value of 42). However, the toxicity value is based on a "greater than limit dose value", and it is assuming that blooming weed coverage is 100%. Proper weed management is important for a healthy vineyard, therefore, the potential for blooming weeds to be present during application in grapevines is extremely limited and the acute risk from contact exposure to bees potentially foraging on weeds in treated field can be concluded as acceptable. This is further supported by the field studies which demonstrated that 56 kg kaolin preparation/ha did not have adverse effects on numbers of bees foraging or their behaviour.

The acute oral risk to honey bees was demonstrated to be acceptable based on the screening step assessment with an ETR value of <0.16 (trigger value of 0.2). The oral chronic risk to adult honey

bees and chronic honey bee larvae were not demonstrated to be acceptable at the screening level with ETR values of 0.22 and 1.16, respectively (trigger value of 0.03 and 0.2, respectively). A Tier I assessment was conducted to refine these scenarios for both early and late applications on grapevines.

The chronic Tier 1 risk to adult and larvae honey bees was demonstrated to be acceptable for all scenarios (ETR values ranging from not applicable to 0.107 (based on trigger value of 0.2)). No further consideration was required. These findings are further supported by the low toxicity observed in field studies where multiple applications of 56 kg kaolin preparation/ha in pear and apple orchards did not have adverse effects on numbers of bees foraging or their behaviour. Note that the risk assessment for honey bee larvae will be revised once the definitive study is completed and valid results are available

The risk to honey bees from exposure to potentially contaminated drinking water (surface water or puddle water) was concluded to be acceptable since aluminium silicate (kaolin) is not soluble in water and will not dissipate but settle to the bottom of any water bodies; resulting in minimal exposure.

Based on the overall low risk to bees, exposure via guttation was considered to be minimal, especially in comparison to natural levels of kaolin clay in the environment.

Non-target terrestrial arthropods:

During the initial EU review, it was agreed by EFSA that the product was not suitable for use in standardised laboratory or semi-field tests where indirect effects (e.g., repellency and physical irritation) cannot be accurately evaluated. However, non-target arthropod data from the open literature are available for kaolin and have been considered in a qualitative risk assessment (refer to MCP 10.3.2).

The available data for non-target arthropods suggested that adverse effects are generally noted at rates greater than 50 kg product/ha (47.5 kg a.s./ha). Although the estimated theoretical worst-case in-field PER values were higher at 76.95 kg a.s./ha (foliar) and 96.9 kg a.s./ha (soil) than the maximum tested dose rate, the risk to non-target arthropods was concluded to be acceptable based on the available findings reported from the 12 field studies and 1 semi-field study. Off-field exposure (0.188 to 1.88 kg a.s./ha) PEC values were significantly lower than tested rates reporting no unacceptable adverse effects greater than 50%, hence highly supporting the potential for recovery from off-field arthropod communities. In a 3-year study in olive orchards in Spain (Pascual et al. (2010) KCP 10.3.2.4/10), arthropod community numbers and biodiversity were reported to be reaching levels of that of the control after 2 months following each last application per season; 2 x 30 kg/ha. In another trial (Marko et al. (2009), KCP 10.3.2.4/11), recovery in diversity and abundance on non-target arthropods were noted within the 6-week observation period following 12 x 45 kg product/ha (10 day interval) in apple orchards.

The risk to in-field and off-field non-target arthropods was concluded to be acceptable without the need of additional laboratory data based on the repeated findings of acceptable risk observed in higher tier field trials, and the observed potential for recovery.

9.4 Summary of effects on non-target soil meso- and macrofauna

Macro or micro soil organisms exposure to aluminium silicate (kaolin) resulting from the use of SURROUND® WP CROP PROTECTANT in grapevines will be minimal (PECsoil = 0.24 g/kg per application or 0.096 g/kg total season) compared to its natural presence in the environment (earthworms contain about 30% soil and soils typically contains between 5-50% clay). Therefore, adverse effects on soil organisms were concluded to be low and the request for toxicity studies and conventional EU risk assessments were 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).

9.5 Summary of effects on soil nitrogen transformation

Please refer to Point 9.4, above.

9.6 Summary of effects on terrestrial non-target higher plants

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 (5 to 50% in agricultural soils (see Document MCP, Section 9). Therefore, adverse effects to non-target terrestrial plants were concluded to be low and the request for toxicity studies and conventional EU risk assessments were not considered necessary for a non-toxic and non-bioavailable natural mineral such as kaolin clay as was reported in the EFSA Conclusion for aluminium silicate (2012).

9.7 Summary of effects on other terrestrial organisms (flora and fauna)

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

9.8 Summary of effects on biological methods for sewage treatment

Aluminium silicate (kaolin) is a natural material that is present in soils, sediments and surface water. Any additional concentrations of clay reaching sewage sludge from the proposed use is concluded to be negligible and therefore no adverse effects on biological methods of sewage treatment is expected.

9.9 Summary of product exposure and risk assessment

The risk to terrestrial and aquatic organisms is concluded to be acceptable without the need for mitigation. Aluminium silicate (kaolin) is commonly found in soils, sediments and surface water at significantly higher concentrations than levels potentially added via the proposed foliar use of SURROUND® WP CROP PROTECTANT in grapevines.

10 CLASSIFICATION AND LABELLING

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures:

Labelling: Signal word: None
Hazard statements: None
Precautionary statements:

P261 – Avoid breathing dust

P262 – Do not get in eyes, on skin, or on clothing.

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P350 – IF ON SKIN: Gently wash with plenty of soap and water.

P304+P341 – IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Proposed classification according to Dangerous Substances Directive (Directive 67/548/EEC):

Labelling: Indication of danger: None
R-phrases: None
S-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

11 RELEVANCE OF METABOLITES IN GROUNDWATER

11.1 Summary

Kaolin (aluminium silicate) is a final erosion product of silicate rocks such as basalt and granite. Deposits generally are of two types, in-situ and sedimentary. In-situ, such as the deposits in Cornwall, UK, are caused by in place alteration of feldspar minerals in granite. Sedimentary deposits are formed by weathering alteration of feldspars in rocks such as granite and basalt, subsequent translocation via erosion downstream, and deposition into sedimentary rock deposits.

There are no metabolites of aluminium silicate (kaolin). Short of being metamorphosed by high heat and pressure deep within the Earth, kaolin is stable. It is not broken down into other

substances. Kaolin containing rocks may be eroded liberating the kaolin however as an inert material the kaolin ends up being re-deposited.

11.2 Conclusion

There are no metabolites of aluminium silicate (kaolin).

12 CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT

12.1 Summary

Structural isomerism:

Kaolin is a natural, inorganic silicate mineral**.** Silicate minerals have been extensively studied in geology and are classified based on the structure of their silicate groups, which contain different ratios of silicon and oxygen.

Once dehydrated through calcination, the chemical formula of kaolin is $Al_4Si_4O_{14}$ and there are no structural isomers of calcined kaolin.

Stereoisomerism:

Kaolin is inorganic and does not possess carbon atoms. Therefore Kaolin possesses neither chiral carbon atoms that could give rise to enantiomers, nor carbon-carbon double bonds that could give rise to diastereomers.

Kaolin is a solid of infinite two-dimensional structure without centres of symmetry. Therefore there are no optical isomers of kaolin.

12.2 Conclusion

There are no isomers of aluminium silicate (kaolin) to be considered in the risk assessment.

FURTHER INFORMATION TO BE SUBMITTED

Appendix 1: Metabolites formed from Active Substance and their occurrence

None.

Appendix 2: Proposed Metabolic Pathway

Not applicable. Aluminium silicate is not soluble in polar/non-polar solvents, it is inert and not absorbed by living organisms.