Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Regulatory Decision Document PRDD2003-08

Kaolin/Surround WP Crop Protectant

The active ingredient kaolin and associated end-use biopesticide product Surround WP Crop Protectant to reduce damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot, and plum curculio in apple, pear, crabapple, and quince are proposed for registration under Section 13 of the Pest Control Products (PCP) Regulations.

This Proposed Regulatory Decision Document provides a summary of data reviewed and the rationale for the proposed full registration of these products. The Pest Management Regulatory Agency (PMRA) will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

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Foreword

The submissions for the registration of kaolin and its associated end-use product Surround WP Crop Protectant, a protectant developed by Engelhard Corporation for use on apples, crabapples, quince and pears, has been reviewed by the Pest Management Regulatory Agency (PMRA). Applications of Surround WP may decrease damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio.

The biopesticide Surround WP decreases damage caused by listed pests with a non-toxic mode of action. Kaolin acts as a protectant, and forms a barrier film to protect plants from listed insects. Kaolins are naturally occurring 1:1 layer aluminosilicate clay mineral found predominantly in more weathered soils that occur in Ohio, New York, the southeastern U.S. (e.g., Georgia) and tropical zones. Kaolinite [$Al_2Si_2O_5(OH)_4$] is the layer silicate mineral that typifies the kaolins.

The PMRA has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient pursuant to Section 18(*b*), to allow a determination of the safety, merit and value of the active ingredient kaolin and the end-use product Surround WP Crop Protectant. The Agency has concluded that the use of the active ingredient kaolin and the end-use product Surround WP Crop Protectant in accordance with the label has merit and value consistent with section 18(*c*) of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18(*d*). Therefore, based on the considerations outlined above, the use of the active ingredient kaolin and the end-use product Surround WP Crop Protectant is proposed for full registration, pursuant to Section 13 of the PCP Regulations.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed registration decision for this product.

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1.0 The active substances, its properties and uses

1.1 TGAI Identification

Active substance		Kaolin
Function		Insecticide
Chemical name		
1.	International Union of Pure and Applied Chemistry (IUPAC)	Aluminum silicate hydroxide
2.	Chemical Abstracts Service (CAS)	Aluminum silicate dihydrate
CAS number		1332-58-7
Molecular formula		$Al_4Si_4O_{10}(OH)_8$
Molecular weight		Not established
Structural formula		Not determined
Nominal purity of active		Kaolin (Anhydrous) 100% (Limits 99.985–100%)
Identity of relevant impurities of toxicological, environmental or other significance		The technical grade kaolin does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track-1 substances. Crystalline silica, which may be present in the starting kaolin ore, is destroyed by the calcination process and is not present in the final product.

1.2 Physical and chemical properties

Technical product: Kaolin

Property	Result
Colour and physical state	White powder
Odour	Odourless
Melting point or range	1800°C
Boiling point or range	N/A
Specific gravity	2.5–2.7

Property	Result
Vapour pressure	N/A
Henry's Law constant at 20°C	N/A
Ultraviolet (UV)– visible spectrum	N/A
Solubility in water	Insoluble
Solubility in organic solvents	Insoluble
n-Octanol–water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable

End-use product: Surround WP Crop Protectant

Property	Result
Colour	White
Odour	None
Physical state	Solid
Formulation type	Wettable powder
Nominal guarantee	Kaolin 95% nominal (Limits 94.3–95.7%)
Formulants	The product does not contain any USEPA List 1 or 2 formulants or formulants known to be TSMP Track-1 substances.
Container material and description	Paper bag 25 or 50 lb
Specific gravity	2.4–2.7
pH	6–7
Oxidizing or reducing action	The active ingredient and all formulants are not oxidizers or reducers.
Storage stability	Stable
Explodability	Not explosive

1.3 Details of uses

Applications of Surround WP may decrease damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio on pome fruits (apple, crabapple, pear, quince). Surround WP is applied as a foliar spray using conventional ground application equipment and forms a barrier on the surface of treated plants. Thorough coverage of the foliage and fruit is required, and multiple applications are needed as canopy foliage develops through the season, and the product is removed by weather (e.g., wind, rain). The exact mode of action of kaolin has not been clearly identified, and probably varies from pest to pest.

2.0 Methods of analysis

2.1 Analytical methods for analysis of the active substance as manufactured

No method was provided for the determination of the active ingredient in the technical product. Elemental analysis of the product may be determined using either inductively coupled plasma—atomic emission spectroscopy, inductively coupled plasma—mass spectrometry or a combination of the two. As these analytical techniques are accepted methods, with documented, published validation data, the requirement of submission of the description of the methods and full validation data to support the use of these methods has been waived.

2.2 Analytical methods for formulation analysis

A loss of ignition (LOI) analysis was provided for the analysis of this product. The amount of the active ingredient (a.i.) is measured by the difference between the amount of total product (pre-heating) and the amount of inert (post heating). The accuracy of the method is within 5% of the target values. The precision was ± 2%.

2.3 Analytical methods for residue analysis

Crop residue data were not required to support the use of Surround WP Crop Protectant, containing kaolin, for use on apples, crabapples, quince and pears (Crop Group 11), as kaolin is a mineral found in soil and is not absorbed by the plants. Therefore, methods for residue analysis of plants, plant products and food of animal origin (DACO 7.2) were not required.

3.0 Impact on human and animal health

Humans consume kaolin in a variety of anti-diarrhea medications. A typical use of these medications includes ingestion of 30–60 mL of medication (containing 10–20 g kaolin). The kaolin adsorbs material and fluid from the gastrointestinal tract and forms a protective demulcent coating on the intestinal mucosa. Cholera patients have been fed 600 g of kaolin (plus water) over a 12 h period without ill effects. The acute toxicity of kaolin is limited to its classification as a nuisance dust, which may cause respiratory irritation. Waivers were requested and granted for subchronic, chronic, reproductive, developmental and neurological toxicity based on the long history of use of kaolin without any indications of deleterious effects. Humans are exposed to kaolin on a daily basis in products such as antiperspirants, tooth paste and cosmetics. Kaolin is included in various food products up to a 2.5% concentration as an anti-caking agent. The use of products have resulted in chronic oral and dermal exposure of the general population to kaolin, with no adverse effects reported.

Kaolin clay is not expected to be absorbed in large quantities from the gastrointestinal tract into the systemic circulation. Based on this information and the absence of any systemic toxicity following oral exposure, an acceptable daily intake (ADI) and acute reference dose (ARfD) for kaolin are not being established.

In the series of subchronic and chronic toxicity tests conducted in rodents along with epidemiological information available in industrial workers, the target organ was identified as being the lungs in all species following the inhalation route of exposure. Pneumoconiosis occurs in workers involved in milling, bagging and loading of kaolin. Exposures were expected to be in the range of 2–5 mg/m^3 and workers required 15–20 years of exposure at these concentrations to develop pneumoconiosis with adverse effects on forced vital capacity. For this reason, a threshold limit value of 2 mg/m^3 was adopted to minimize the potential for pneumoconiosis in workers exposed to kaolin. Amorphous kaolin inhalation has not been found to promote tumour formation in animals or humans following chronic exposure.

Although the natural kaolin clay would be expected to pose little risk to workers, the heating of the kaolin during calcination may transform the kaolin into mullite. The company supplied data including electron micrographs and X-ray difraction data to demonstrate the absence of cristobalite or alumino-silicate fibres in the calcined kaolin product. Mullite was noted to be present at a 5% level, but the crystals were small and embedded in the kaolin particles. Thus, the calcination process is not expected to produce particles of toxicological concern. The particles are flat and flake-like in shape and are mainly (>90%) less than 2 µm in diameter. Particles of this size and shape should be adequately cleared from the lung within 40 to 50 days of deposition and as such would not be considered a chronic lung hazard. The final product will be considered a nuisance dust only without the potential for fibrosis development.

3.1 Impact on human and animal health arising from the exposure to the active substance or to impurities contained in it

Due to the absence of toxicological concerns, no quantitative exposure and risk assessments are needed for the present submission of Surround WP Crop Protectant. Risk assessments and a qualitative exposure were conducted to mitigate the nuisance dust exposure to mixer/loader/applicator and for re-entry workers performing tasks involving high foliar contact.

4.0 Residues

4.1 Residue summary

Nature of the residue in plants
A pome fruit metabolism study is not required, as kaolin is an inert naturally occurring mineral with no toxicological endpoints identified and no ADI established. Furthermore, kaolin is not absorbed or translocated in the plant since it does not dissolve in plant fluids. Accordingly, kaolin does not become bioavailable. Therefore, there is no need to define a residue of concern (ROC) in plant matrices.

Nature of the residue in animals
Animal metabolism studies are not required, as kaolin is an inert naturally occurring mineral with no toxicological endpoints identified and no ADI established. Furthermore, kaolin cannot cross the gut membrane in animals and does not dissolve in body fluids. Accordingly, kaolin does not become bioavailable. Therefore, there is no need to define a ROC in animal matrices.

Crop field trials
Supervised crop field trials (DACO 7.4.1) and residue decline studies (DACO 7.4.2) were not required. Kaolin, a mineral found in soil, will not be absorbed by the plants and therefore will not be found in the inner portions of the raw agricultural commodity (RAC) (fruit of apples or pears). Kaolin residues will decline over time on plants and RAC as a result of rain and wind. The protectant effect of kaolin is determined by a smooth even layer of product, therefore to have effective pest control it must be reapplied as weathering occurs. Kaolin is visible on RAC and plants as a hazy, grey or white film and is easily removed with washing.

Kaolin will be recommended for exemption under B.15.002(2) of the *Food and Drugs Act* and Regulations.

Processed food/feed
Processing studies (DACO 7.4.5) were not required as residues of kaolin are only found on the skin of apples and are easily removed with washing. Kaolin cannot transfer into the pulp. Kaolin is insoluble and would therefore not be found in pomace and juice.

Meat/milk/poultry/eggs
The presence of residues of kaolin is not expected to be harmful to livestock as kaolin cannot be absorbed across the gut membrane and would therefore not end up in the meat, milk or eggs.

Dietary risk assessment
Due to the absence of toxicological concerns, no quantitative dietary risk assessment is needed for the present submission of Surround WP Crop Protectant. It is anticipated that the proposed domestic use of kaolin in apples, crabapples, quince and pears (Crop Group 11) will not pose a risk to any segment of the population, including infants, children, adults and seniors when pome fruits are subjected to the normal process of washing/peeling and cooking for human consumption.

5.0 Fate and behaviour in the environment

5.1 Physical and chemical properties relevant to the environment

Kaolins are naturally occurring 1:1 layer aluminosilicate clay minerals found predominantly in more weathered soils that occur in Ohio, New York, the southeastern U.S. (e.g., Georgia) and tropical zones. Kaolinite [$Al_2Si_2O_5(OH)_4$] is the layer silicate mineral that typifies the kaolins.

The traditional physicochemical properties, i.e., solubility in water, vapour pressure, octanol–water partition coefficient, dissociation constant and UV–visible absorption spectrum are not applicable to kaolins and therefore these data are not required.

5.2 Abiotic transformation

Clay minerals may undergo hydrolysis during pedogenesis (i.e., natural soil development). The submission of further information or data on hydrolysis data of kaolins is not required.

5.3 Biotransformation

The determination of phototransformation and biotransformation is not applicable to kaolins and, therefore, these data are not required.

5.4 Mobility

In soil, kaolins exhibit a pH-dependent cation exchange capacity, are relatively weak adsorbents for cations and can form complexes with organic matter and other soil constituents. Clay minerals in general can exhibit some mobility in the soil profile during pedogenesis. The submission of further information or data on the mobility of kaolins is not required.

5.5 Dissipation and accumulation under field conditions

For the reasons given above, field studies of kaolin dissipation are not required.

5.6 Bioaccumulation

The determination of bioaccumulation of kaolins is not applicable and, therefore, these data are not required.

6.0 Effects on non-target species

Kaolins are naturally occurring clay minerals that are expected to be practically non-toxic to non-target terrestrial and aquatic invertebrates (earthworms, insects and molluscs) and plants, fish, birds and mammals. Therefore, toxicity data are not required for the DACOs listed in Table 6.1.

Table 6.1 Toxicity data not required for kaolin

DACO	Study type
9.2.3	Earthworms
9.2.4	Bees/pollinators
9.2.5	Predators
9.2.6	Parasites
9.3	Non-target freshwater invertebrates
9.4	Non-target marine invertebrates
9.5	Fish
9.6	Wild birds
9.7	Wild mammals
9.8	Non-target plants

Nonetheless, the applicant submitted USEPA Data Evaluation Reports (DER) and supporting data for two studies on kaolin toxicity to honeybees. The results of these studies confirmed the non-toxicity of kaolin to bees.

6.1 Effects on terrestrial organisms

6.1.1 Invertebrates

Bees: Two studies were submitted. One study investigated the contact toxicity of kaolin (M-96-018 kaolin, purity 98.8%), while the other investigated oral toxicity. The contact toxicity study was conducted according to the USEPA 141-1 and EPPO 170 guidelines. In the contact toxicity test, groups of 60 worker bees, *Apis mellifera*, were topically treated with 6.25, 12.5, 25, 50 and 100 µg a.i./bee. The number of dead bees in each group was assessed after 24 and 48 hours. Mortality in all groups treated were comparable to controls. The contact LD_{50} was determined to be >100 µg a.i./bee. Therefore, kaolin is categorized as relatively non-toxic (LD_{50}>10.99 µg a.i./bee) to honey bees in accordance with Atkins *et al*. (1981) groups of relative toxicity.

The acute oral toxicity study was reviewed. This study was determined to be deficient, mainly because the amount of treated diet consumed per group was not reported.

Other beneficial arthropods: A predator study was not submitted by the applicant. However, a U.S. DER was submitted with the data package (MRID No. 44356708).

No conclusions could be made regarding the effects of M-96-018 kaolin on predator species (lady beetles, green lacewings and spiders). Predator populations were too low to assess any treatment effects that may have occurred in response to application of kaolin. The USEPA review noted that additional field studies may not provide any new information. Based on lack of adverse effects on honey bees (MRIDs 44356706) following acute contact treatment with M-96-018 kaolin, it is not likely that any adverse effects would occur in predator and prey species following treatment with kaolin.

6.1.2 Summary of effects on terrestrial organisms

Kaolin (M96-018) was not toxic to honey bees after topical contact. The contact LD_{50} was determined to be >100 µg a.i./bee. Therefore, kaolin is categorized as relatively non-toxic (LD_{50}>10.99 µg a.i./bee) to honey bees in accordance with Atkins *et al*. (1981) groups of relative toxicity. The toxicity of kaolin to terrestrial organisms is summarized in Table 6.1.1.

Table 6.1.1 Summary of effects on terrestrial organisms

Organism	Study type	Test substance	Endpoint value	Degree of toxicity
Invertebrates				
Bee	Contact	M-96-016 kaolin 98.8%	LD_{50} >100 µg a.i./bee	Relatively non-toxic

Products that are applied as sprays can be evaluated initially by considering the likely exposure of bees and the toxicity of the product. As kaolin is categorized as relatively non-toxic to honey bees, no restrictions are required for the protection of honeybees for products that fall into this category.

6.2 Effects on aquatic organisms

Kaolins are naturally occurring clay minerals that are expected to be practically non-toxic to non-target aquatic invertebrates, plants and fish. Therefore, toxicity data are not required.

7.0 Efficacy

7.1 Efficacy summary

Applications of Surround WP may decrease damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio on pome fruits (apple, crabapple, pear, quince). Surround WP is applied as a foliar spray using conventional ground application equipment and forms a barrier on the surface of treated plants. Thorough coverage of the foliage and fruit is required, and multiple applications are needed as canopy foliage develops through the season, and the product is removed by weather (e.g., wind, rain). The exact mode of action of kaolin has not been clearly identified, and probably varies from pest to pest.

Eight efficacy trials were conducted in commercial apple orchards in Ontario which compared fruit damage from proposed pests in blocks treated with Surround WP to fruit damage in blocks treated with an integrated pest management program. Nine trials conducted on apple and two conducted on pear in the United States were also provided. Efficacy data showed that multiple applications of Surround WP may decrease damage to pome fruits (apple, crabapple, pear, quince) caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio when applied at an application rate of 25–50 kg product/ha (in 1000 L water/ha). No phytotoxic effects on target plants were observed during efficacy trials.

A potential effect of using Surround WP is that numbers of non-target pests on the treated crop may increase if populations of beneficial insects are affected by application of Surround WP. However, this effect was sporadic, and monitoring should identify this problem so that appropriate measures can be taken. No evidence of development of resistance to kaolin has been established.

Table 7.1 Acceptable uses of Surround WP Crop Protectant on pome fruits

Site	apple, crabapple, pear, quince (USC 14)
Product	Surround WP Crop Protectant (95.0% kaolin)
Rate of application	25–50 kg product/ha (in 1000 L water/ha) Spray volume: Apply to near-drip. Do not apply to run-off to avoid waste and poor coverage. For typical semi-dwarf trees in full foliage, a spray volume of 1000 to 2000 litres per hectare is recommended. Adjust spray volume per Tree Row Volume to achieve near drip for larger or smaller trees. Recommended spray volume is 1000–2000 L water/ha for mature pear trees.
Number of applications	Apply as required at intervals of 7–14 days.
Application timing	Pear psylla: Monitor populations to ensure that applications are needed, and apply prior to oviposition in the spring. Prebloom: Apply up to three pre-bloom applications every 7–10 days. Make the first application as early as the delayed dormant stage of pear development, but no later than green cluster bud. Petal Fall: Apply three applications every 7–14 days starting at first petal fall. Tarnished plant bug: Start application before infestation begins and continue at 7–14 day intervals. Lengthening re-spray interval past 14 days is not recommended. Leafrollers: Apply first two sprays seven days apart starting just prior to green tip stage of host development or at initial emergence of leafroller larvae, as determined by monitoring. Make initial application before larvae roll up into leaves. For subsequent generations, apply at 7–14 day intervals as larvae emerge. Leafhoppers: Apply first spray within three days of first petal fall or at initial infestation, as determined by monitoring. Continue every 7–14 days during infestation period. Apple maggot: Apply two sprays seven days apart before expected oviposition or at first detection of infestation. Continue applications every 7–14 days to keep fruit completely covered during egg laying period. Plum curculio: Apply at first detection. Continue applications every seven days to keep fruit completely covered during egg laying period. Applications at petal fall may disrupt leaf miner parasitism, requiring supplemental control measures.
Target Pests	Application of Surround WP may decrease damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio. Supplemental methods may be needed to enhance the level of performance achieved by applications of Surround WP.
Pre-harvest Interval	May be applied up to day of harvest.

8.0 Toxic Substances Management Policy considerations

During the review of kaolin and Surround WP Crop Protectant, the PMRA has taken into account the federal Toxic Substances Management Policy[1] and has followed its Regulatory Directive DIR99-03[2]. It has been determined that these products do not meet TSMP Track-1 criteria because:

- Kaolin is not bioaccumulative.

- Kaolin (technical grade) does not contain any impurities known to be toxic microcontaminants as identified in Part 2.13.4 of Regulatory Directive DIR98-04 or any TSMP Track-1 substances listed in Appendix II of Regulatory Directive DIR99-03. Impurities of toxicological concern are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

The formulated product is not known to contain any USEPA inert List 1 or 2 formulants or any known TSMP Track-1 substances.

9.0 Proposed regulatory decision

The Pest Management Regulatory Agency (PMRA) has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient, pursuant to Section 18(*b*), to allow a determination of safety, merit and value of kaolin and its end-use product, Surround WP Crop Protectant, manufactured by Engelhard Corporation. The PMRA has concluded that the use of kaolin and Surround WP Crop Protectant in accordance with the label has merit and value consistent with Section 18(*c*) of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18(*d*). Therefore, based on the considerations outlined above, application of Surround WP may decrease damage caused by pear psylla, tarnished plant bug, leafrollers, leafhoppers, apple maggot and plum curculio to apple, crabapple, pear and quince, and the use of Surround WP is proposed for full registration, pursuant to Section 13 of the PCP Regulations.

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1 The federal Toxic Substances Management Policy is available through Environment Canada's Web site at: www.ec.gc.ca/toxics.

2 The PMRA's Strategy for Implementing the Toxic Substances Management Policy, DIR99-03, is available through the Pest Management Information Service: Phone 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); Fax (613) 736-3798; E-Mail pmra_infoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed registration decision for this product.

List of abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
CAS	Chemical Abstracts Service
DACO	data code
DER	data evaluation report
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOI	loss of ignition
MRID	master record identifier
PCP	pest control product
ppm	parts per million
PMRA	Pest Management Regulatory Agency (Canada)
RAC	raw agricultural commodity
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
WP	wettable powder

References

Atkins, E. L., D. Kellum, and K. W. Atkins. 1981. Reducing Pesticide Hazards to Honey Bees: Mortality Prediction Techniques and Integrated Management Strategies. University of California Division of Agricultural Sciences. Leaflet 2883, 22 pp.