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Proposed Re-evaluation Decision

PRVD2021-12

Kaolin and the Associated End-use Product

Consultation Document

(publié aussi en français)

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Proposed re-evaluation decision

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from different sources including from pesticide manufacturers, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Kaolin is a naturally occurring clay mineral and has a long history of use in a variety of consumer and food products. It is a mineral particle used in conjunction with several other integrated pest management practices as a broad-spectrum crop protectant to decrease damage from listed insect pests, sunburn and heat stress on crops. Kaolin is registered for use on pome and stone fruit, tree nuts, carrots, cucurbits, dry beans, grapes, leafy vegetables except *Brassica* vegetables, potatoes, raspberries and strawberries, and onions and shallots. Kaolin can be applied as a spray using air blast, high-pressure hand-held or boom sprayers.

This document presents the proposed regulatory decision for the re-evaluation of kaolin. Kaolin products have value in providing a pest management solution. When the current label directions are followed, potential risks to human health (occupational, dietary, residential and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable. However, label updates are proposed to meet the current labelling standards (Appendix II). Updates to standard label statements related to human health (wording around protective dust masks and avoiding spray drift) and environment (wording to reduce runoff and protect aquatic habitats and drinking water) are proposed.

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing kaolin listed in Appendix I are being proposed for continued registration in Canada.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of kaolin, no further risk mitigation measures for product labels are being proposed. To meet current standards, label updates are proposed in Appendix II.

All products containing kaolin registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,¹ during which written comments and additional information may be submitted to the [PMRA](#). The final re-evaluation decision will be published taking into consideration the comments and information received during consultation.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional scientific information

No additional data are required.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Human health assessment

The toxicology database for kaolin is sufficient to support the currently registered uses and there are no outstanding toxicological concerns for this active ingredient. Refer to Proposed Regulatory Decision Document PRDD2003-08, *Kaolin/Surround WP Crop Protectant* for the assessment of the impact of kaolin on human health.

Kaolin is formulated as a wettable powder and applied as a spray using air blast, high-pressure hand-held or boom sprayers. Due to the absence of toxicological concerns, no reference values were established and qualitative exposure and risk assessments were conducted for kaolin. During the initial registration (refer to PRDD2003-08), a Threshold Limit Value of 2 mg/m³ was adopted to minimize pneumoconiosis in workers and an inhalation exposure assessment was conducted to mitigate the nuisance dust exposure to mixer/loader/applicators and for re-entry workers performing tasks involving high foliar contact. The personal protective equipment (PPE) on the end-use product label includes “coveralls or long-sleeved shirt and long pants, eye protection, and a dust/mist-filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or an NIOSH approved respirator with any N. R. P. or HE filter. Nuisance dust mask is recommended for workers re-entering treated fields to conduct activities involving high foliar contact”. The PPE is proposed to be updated to current standards (Appendix II). The potential exposure to chemical handlers and postapplication re-entry workers is not expected to be of concern when label directions are followed.

There are no domestic class products registered containing kaolin. Therefore, direct residential exposure is not expected. Bystander exposure is expected to be negligible. To further minimize the potential for bystander exposure, a standard spray drift label statement is proposed for the end-use product label (Appendix II).

Based on the current end-use product formulation, use pattern, label directions, and the low toxicity profile of kaolin, occupational and non-occupational exposure and risk is considered to be acceptable when label directions are followed. Refer to Appendix II for the proposed label amendments.

Kaolin residues on plants will decline over time as a result of rain and wind. Kaolin is visible on crops as a hazy, grey or white film and is easily removed with washing. It is anticipated that the use of kaolin will not pose a risk to any segment of the population, when crops are subjected to the normal process of washing/peeling and cooking for human consumption. Refer to PRDD2003-08 for information on the dietary risk assessment.

1.1 Aggregate exposure and risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). As the dietary risks are acceptable, as noted above, and potential residential exposure is expected to be minimal, aggregate risk is considered to be acceptable.

1.2 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA has not identified information indicating that kaolin shares a common mechanism of toxicity with other pest control products. Therefore, a cumulative risk assessment is not required at this time.

2.0 Environmental assessment

Kaolin is a naturally occurring clay mineral. Transformation products are not expected. Kaolin has a non-toxic mode of action, as it forms a barrier film that may reduce insect stress. It is expected to be practically non-toxic to non-target terrestrial and aquatic invertebrates (including pollinators), plants, fish, birds and mammals. Based on the current use pattern and when used according to the current label directions, potential risk to non-target terrestrial and aquatic organisms is considered acceptable. The environmental precautions and use directions are proposed to be updated to current standards (Appendix II). For details on the environmental review, refer to PRDD2003-08.

The PMRA has reached the conclusion that kaolin is not considered a Track 1 substance as it does not meet all the Track 1 criteria as per the Toxic Substances Management Policy (Canada, 2003).

3.0 Value assessment

Kaolin is of value to conventional and organic tree fruit producers as the only available product for increasing the marketability of fruit by preventing plant heat stress and sunburn. Kaolin is of particular value to organic producers for insect control since it is allowed for use in certified organic crop production.

4.0 Incident reports

As of 7 June 2021, one domestic animal incident death (which occurred in the United States) involving kaolin has been submitted to the PMRA. No mitigation measures are required based on the incident report review that concluded the incident is unlikely related to the reported exposure to kaolin. No additional risk mitigation measures are proposed.

Appendix I Registered products containing kaolin

Table 1 Registered products containing kaolin¹

Registration number	Marketing class ²	Registrant	Product name	Formulation type	Guarantee
27468	T	Tessenderlo Kerley, Inc.	Kaolin Technical	Solid	99.985%
27469	C	Tessenderlo Kerley, Inc.	Surround WP Crop Protectant	Wettable Powder	95.0%

¹ as of 1 September 2021, excluding discontinued products or products with a submission for discontinuation

² T – technical grade; C – commercial class

Appendix II – Label amendments

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Human health

- Under PRECAUTIONS remove the Personal Protective Equipment statement:

“Mixer/loader and applicator must wear coveralls or long-sleeved shirt and long pants, eye protection, and a dust/mist-filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N. R. P. or HE filter. Nuisance dust mask is recommended for workers re-entering treated fields to conduct activities involving high foliar contact (e.g., harvesting, thinning, pruning).”

And replace with the following:

“Wear a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested, protective eyewear (goggles or face shield), long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves and protective eyewear are not required during application within a closed cab.

A NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested, is recommended for workers entering treated fields to conduct activities involving high foliar contact (e.g., harvesting, thinning, pruning).”

- Under PRECAUTIONS include the current statement for avoiding spray drift:

“Apply only to agricultural crops when the potential for drift to areas of human habitation and human activity, such as houses, cottages, schools and recreational areas, is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”

Environment

- Under ENVIRONMENTAL PRECAUTIONS remove the following:

“Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.”

- Under ENVIRONMENTAL PRECAUTIONS add the following:

“To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.”

- Under DIRECTIONS FOR USE add the following statements:

“As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT apply by air.”

References

Published information

PMRA number	Reference
655755	Canada, 2003. Proposed Regulatory Decision Document, PRDD2003-08, Kaolin/Surround WP Crop Protectant. December 9, 2003.
715270	Canada, 2004. Regulatory Decision Document, RDD2004-01, Kaolin/Surround WP Crop Protectant. 23 March 2004.