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Re-evaluation Decision

RVD2021-07

Kresoxim-methyl and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation decision for kresoxim-methyl and associated end-use products

Under the authority of 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 meet current health and environmental standards and have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Kresoxim-methyl is a fungicide registered for use on apples, pears and grapes and can be applied by ground application equipment only. Currently registered products containing kresoxim-methyl can be found in the Pesticide Label Search and in Appendix I.

The Proposed Re-evaluation Decision PRVD2020-10, Kresoxim-methyl and Its Associated End-use Products,¹ containing the evaluation of kresoxim-methyl and proposed decision, underwent a 90 day consultation period ending on 14 October 2020. PRVD2020-10 proposed that products containing kresoxim-methyl are acceptable for continued registration in Canada, provided that the additional proposed risk mitigation measures are in place. The proposed risk mitigation measures included additional personal protective equipment (PPE), standard spray drift statements, reduction in number of applications for all crops, environmental hazard statements including terrestrial spray buffer zones, and standard statements regarding runoff, food/feed/water contamination and toxicity to non-target organisms.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2020-10, which lists all information used as the basis for the re-evaluation decision.

This document presents the final re-evaluation decision² for the re-evaluation of kresoxim-methyl, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing kresoxim-methyl that are registered in Canada are subject to this re-evaluation decision.

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

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

Re-evaluation decision for kresoxim-methyl

Health Canada has completed the re-evaluation of kresoxim-methyl. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing kresoxim-methyl is acceptable. An evaluation of available scientific information found that the use of kresoxim-methyl products meets current standards for protection of human health and the environment and has acceptable value when used according to revised conditions of registration, which includes new mitigation measures.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of kresoxim-methyl, are summarized below. Refer to Appendix II for details.

Human health

Risk mitigation:

To protect human health, the following risk-reduction measures are required for continued registration of kresoxim-methyl in Canada:

Occupational Exposure:

- Add standard spray drift statement.
- For mixers/loaders and applicators (M/L/A), update PPE label statements:
 - For application using handheld airblast/mistblower, wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear, and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.
 - For mixing and loading as well as using all other types of application equipment, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, applications, clean-up, and repair. Gloves are not required within a closed cab during application.

Dietary Exposure:

- Reduce the maximum number of applications for the lower application rates (90–120 g a.i./ha) from 4 to 2 applications per year, for all crops (apples, pears, and grapes) and pests.
- Reduce the maximum number of applications for all higher rates (121–225 g a.i./ha) from 4 to 1 application per year, for all crops (apples, pears, and grapes) and pests.
- Update total seasonal rates according to the revised number of applications.

Environment

Risk mitigation:

To protect the environment, the following risk-reduction measures are required:

- Add precautionary label statements to inform users that kresoxim-methyl is toxic to aquatic organisms, birds and certain beneficial arthropods.
- Add statement to inform users that the product demonstrates the properties and characteristics associated with chemicals detected in groundwater.
- Add statements prohibiting the use of kresoxim-methyl products to control aquatic pests, and to reduce the risk of contamination of water, food or feed.
- Add statement prohibiting the use of aerial application equipment.
- Include buffer zones to protect freshwater (≤ 10 m) and estuarine/marine (≤ 2 m) habitats.

Value

Label improvements to meet current standards:

- Update resistance management statements.

Next steps

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry. Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection³ regarding this decision on kresoxim-methyl within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2020-10) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

³ As per subsection 35(1) of the *Pest Control Products Act*

List of Abbreviations

a.i.	active ingredient
g	gram(s)
ha	hectare(s)
m	metre(s)
NIOSH	National Institute for Occupational Safety and Health
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
RVD	Re-evaluation Decision

Appendix I Registered products containing kresoxim-methyl in Canada

Table 1 Registered Kresoxim-methyl products in Canada requiring label amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%)
26926	Technical	BASF Canada Inc.	Kresoxim-methyl Technical Fungicide	Wettable Granules	Kresoxim-methyl (97%)
26257	Commercial		Sovran Fungicide	Wettable Granules	Kresoxim-methyl (50%)

¹ as of 18 November 2020, excluding discontinued products or products with a submission for discontinuation

Appendix II Required label amendments for products containing kresoxim-methyl

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

Label amendments for technical class product

- a) On the primary display panel, replace “GUARANTEE” with “ACTIVE INGREDIENT”
- b) Under the **Environmental Precautions** section, add:
 - a. Toxic to aquatic organisms.
DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.
- c) Under the **Disposal** section, add:
 - a. Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency.

Label amendments for commercial products

Label

1. Replace “GUARANTEE” with “ACTIVE INGREDIENT”
2. Under **PRECAUTIONS**, remove the following statement: Wear protective equipment and clothing, including goggles or face shield, gloves (rubber, PVC, neoprene or nitrile), hat, long-sleeved shirt, trousers and rubber boots.

Booklet

1. Replace “GUARANTEE” with “ACTIVE INGREDIENT”
2. Under DIRECTIONS FOR USE:
 - a. The following statement is required for uses with a handheld airblast/mistblower: “For application using handheld airblast/mistblower, wear chemical-resistant coveralls over long-sleeved shirt, long pants, chemical-resistant hood, socks, chemical-resistant footwear, and a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.”
 - b. For mixing and loading as well as using all other types of application equipment, the following statement is required: “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, applications, clean-up, and repair. Gloves are not required during application within a closed cab.”
3. Under APPLICATIONS INSTRUCTIONS, add the following:
 - a. Apply only when the potential for drift to non-target areas of human habitation or areas of human activity is minimal, taking into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

4. Under AIRBLAST APPLICATIONS, add the following:
 - a. **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.
5. Replace the section heading “BUFFER ZONES” with “SPRAY BUFFER ZONES”
6. Under the SPRAY BUFFER ZONES section, replace all the text with the following:
DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

7. Under SPRAY BUFFER ZONES, add the following:

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Number of Applications	Buffer Zones (metres) Required for the Protection of:			
				Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
				Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Airblast	Apples	Late growth stage	1 at 225 g a.i./ha	10	1	2	1
	Grapes		1 at 150 g a.i./ha	5	1	1	1
	Pears		1 at 180 g a.i./ha	5	1	2	1
	Apples		2 at 120 g a.i./ha	5	0	1	0
	Grapes						
	Pears						

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) spray buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The spray buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Spray Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

8. Under RECOMMENDED APPLICATION RATES AND TIMING TABLES, replace all text and tables with the following:

Table 1 Application rate and timing for apples

DISEASE CONTROLLED	RATE PER HECTARE* (GRAMS PRODUCT)	MAXIMUM NUMBER OF APPLICATIONS PER YEAR
Apple scab (<i>Venturia inaequalis</i>)	180** (preventative rate only)	Apply preventatively at the 1/2 inch green stage, or when environmental conditions become favourable for primary scab development. Maximum of 2 applications per year made 10–14 days apart. During periods of rapid shoot growth, the re-application interval should be shortened to 7 days.
	240 grams (moderate disease pressures – preventative and curative – up to 96 hours post infection)	
	241–360 (curative only, under high*** disease pressure)	Maximum of 1 application per year at this rate. DO NOT apply at this rate if a previous SOVRAN application has already been made.
Powdery mildew (<i>Podosphaera leucotricha</i>)	240 (low to moderate disease pressure)	Maximum 2 applications per year. Apply preventively at the 1/2 inch green stage and re-apply 10–14 days later.
	450 (high*** disease pressure)	Maximum of 1 application per year at this rate. DO NOT apply at this rate if a previous SOVRAN application has already been made.

* **DO NOT** exceed a total seasonal maximum of 480 grams product per crop per ha.

** Use low rate under low disease pressure only.

***High disease pressure = disease is present in your orchard and weather conditions are conducive to the progression of disease.

Table 2 Application rate and timing for grapes

DISEASE CONTROLLED	RATE PER HECTARE* (GRAMS PRODUCT)	MAXIMUM NUMBER OF APPLICATIONS PER YEAR
Powdery mildew (<i>Uncinula necator</i>) Downy mildew (<i>Plasmopara viticola</i>)	240	Maximum of 2 applications per year. Apply during pre and / or post bloom on a 14–21 day re-application interval, depending on disease pressures.
	241–300 **	Maximum of 1 application per year at rates between 241 and 300 g/ha. DO NOT apply at this rate if a previous SOVRAN application has already been made.

Black rot (<i>Guignardia bidwellii</i>)	240	Maximum of 2 applications per year. Apply preventatively. Re-apply once 14 days after initial application if warm, moist environmental conditions persist.
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* **DO NOT** exceed a total seasonal maximum of 480 grams product per crop per ha.

**Use high rate under high disease pressures or when conditions are conducive for disease development.

Table 3 Application rate and timing for pears

DISEASE CONTROLLED	RATE PER HECTARE* (GRAMS PRODUCT)	MAXIMUM NUMBER OF APPLICATIONS PER YEAR
Pear scab (<i>Venturia pirina</i>) Powdery mildew (<i>Podosphaera leucotricha</i>)	240 (low to moderate disease pressure)	Apply preventatively at the 1/2 inch green stage, or when environmental conditions become favourable for primary scab development. Maximum of 2 applications per year made 10–14 days apart. During periods of rapid shoot growth, the re-application interval should be shortened to 7 days.
	360 (high** disease pressure)	Maximum of 1 application per year. DO NOT apply at this rate if a previous SOVRAN application has already been made.

* **DO NOT** exceed a total seasonal maximum of 480 grams product per crop per ha.

** High disease pressure = disease is present in your orchard and environmental conditions are conducive to the progression of disease.

9. Under RESISTANCE MANAGEMENT RECOMMENDATIONS:

- Remove** the statement “Do not make more than a total of 4 applications of SOVRAN fungicide per season” and **replace** with “Do not make more than a total of 2 applications SOVRAN fungicide per crop per season (total management of all diseases).”
- Remove** the statement “BASF recommends making no more than 2 consecutive applications of SOVRAN fungicide. Then, alternate to an effective non-strobilurin fungicide with a different mode of action. Thereafter, SOVRAN fungicide can be sprayed again up to the maximum number of 4 applications per season.” and **replace** with “Do not apply sequential applications of SOVRAN Fungicide, or other fungicides from Group 11 in a season. Where possible, rotate the use of SOVRAN fungicide or other Group 11 fungicides with fungicides from different groups that control the same pathogens”.

10. Change the title from “ENVIRONMENTAL HAZARDS” to “ENVIRONMENTAL PRECAUTIONS”. Under this section, add the following statements:

- TOXIC to aquatic organisms. Observe spray buffer zones specified under DIRECTIONS FOR USE.
- Toxic to birds.

- c. Toxic to certain beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). Minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site such as hedgerows and woodland.
- d. This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.
- e. To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.
- f. Avoid application when heavy rain is forecast.
- g. 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.

11. Under **RESTRICTIONS AND LIMITATIONS**:

- a. The table should be revised as follows:

CROP	TOTAL SEASONAL MAXIMUM PRODUCT/HA	MAXIMUM NUMBER OF APPLICATIONS / SEASON	PRE-HARVEST INTERVAL (PHI)
Apples	480 g	2	30 days
Grapes	480 g	2	14 days
Pears	480 g	2	30 days

- b. The following statement is proposed for all commercial-class labels for products with uses in residential areas: “DO NOT allow people or pets to enter treated areas until sprays have dried.”

- c. 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 using aerial application equipment

12. Under **PRECAUTIONS**, remove the following statement: Wear protective equipment and clothing, including goggles or face shield, gloves (rubber, PVC, neoprene or nitrile), hat, long-sleeved shirt, trousers and rubber boots.

13. Under **DISPOSAL**, remove all the text and add the following:

- a. Store this product away from food or feed.
- b. The following statement would apply to plastic or metal containers that contain agricultural and non-crop land uses (for example, forestry) pesticide products, and that are designed to contain 23 L or less of product:

Disposal of Container

DO NOT reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site.

Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For returnable containers

DO NOT reuse this container for any purpose. For disposal, this empty container may be returned to the point of purchase (distributor/dealer).

For containers that can be refilled for the user by the distributor/dealer

For disposal, this container may be returned to the point of purchase (distributor/dealer). It must be refilled by the distributor/dealer with the same product. Do not reuse this container for any other purpose.

- c. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.