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Re-evaluation Decision

RVD2019-07

Fomesafen and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly 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 pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Fomesafen is an herbicide for weed management in a range of agricultural crops. It provides post-emergence control of a wide spectrum of broadleaf weeds with residual activity in certain pulse crops (dry and succulent beans and peas), soybean, cucumber, strawberry, and potato. The end-use products are applied using ground application equipment only and are registered for use in Eastern Canada, the Red River Valley of Manitoba, or in British Columbia, depending on the specific use. Currently registered products containing fomesafen are listed in Appendix I.

The regulatory approach for the re-evaluation of fomesafen was first presented in the Proposed Re-evaluation Decision PRVD2018-15, *Fomesafen and its Associated End-use Products*¹ which underwent a 90-day consultation period ending on 11 December 2018. PRVD2018-15 proposed that products containing fomesafen are acceptable for continued registration in Canada, provided that the proposed risk mitigation measures are in place.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2018-15, which lists all information used as the basis for the re-evaluation decision.

Outcome of Science Evaluation

With respect to human health, the risks were found to be acceptable. Exposure from the labelled uses is unlikely to affect human health when products containing fomesafen are used according to the proposed updated labels.

Fomesafen enters the environment when used to control specified weeds on various agricultural field crops. Risks to the environment were found to be acceptable when products containing fomesafen are used according to the proposed updated labels.

Fomesafen contributes to weed management in a range of agricultural crops. It provides post-emergence control of a wide spectrum of broadleaf weeds with residual activity in certain pulse crops (dry and succulent beans and peas), soybeans, cucumber, strawberry, and potato. It is the primary and most widely used herbicide on snap beans for which there are limited alternative herbicides.

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

Regulatory Decision for Fomesafen

Health Canada has completed the re-evaluation of fomesafen. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing fomesafen is acceptable. An evaluation of available scientific information found that uses of fomesafen products meet current standards for protection of human health and the environment when used according to the conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix II, are required for all technical and end-use products. No additional data are requested.

Risk Mitigation Measures

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law.

Human Health

Label updates required to meet current standards:

- A label statement prohibiting aerial application.
- A label statement prohibiting application in greenhouses.
- A label statement prohibiting application when there is potential drift to areas of human habitation or areas of human activity.

To protect those entering treated areas from exposure, the following risk-reduction measures are required for continued registration of fomesafen in Canada:

- A 12-hour Restricted-Entry Interval (REI) is required for all crops.

Environment

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

- Standard environmental precaution statements to inform the users of the potential for toxicity to terrestrial vascular plants and aquatic organisms.
- Spray buffer zones to protect sensitive terrestrial habitats from spray drift.
- Precautionary label statements informing users how to reduce the potential for runoff.
- Label statements informing users of the potential for carryover of fomesafen from one season to the next.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing fomesafen that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection² regarding this decision on fomesafen 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 the PMRA's Pest Management Information Service.

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered Fomesafen Products in Canada¹

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24779	Commercial	Syngenta Canada Inc.	Reflex Liquid Herbicide	Solution	240 g/L
28133	Technical	Syngenta Canada Inc.	Fomesafen Technical Active Ingredient Herbicide	Solid	98%
28134	Manufacturing Concentrate	Syngenta Canada Inc.	Fomesafen Sodium Salt Aqueous Concentrate Herbicide	Solution	48%
28827	Manufacturing Concentrate	Syngenta Canada Inc.	Fomesafen Technical Grade Manufacturing Use Product Herbicide	Solution	49.70%
28828	Technical	Syngenta Canada Inc.	Fomesafen Technical Grade Herbicide	Solid	99.80%
30412	Commercial	Syngenta Canada Inc.	Flexstar GT Herbicide	Solution	glyphosate 271 g/L; fomesafen 67 g/L

¹ as of January 2019; excluding discontinued products or products with a submission for discontinuation, based on the PMRA's Electronic Pesticide Regulatory System database (e-PRS)

Appendix II Label Amendments for Products Containing Fomesafen

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Label Amendments for All Products

Front Panel of All Fomesafen Products

On all fomesafen product labels, replace ‘Guarantee’ with ‘Active Ingredient.’

Label Statements to Protect Human Health

Label Amendments for End Use Products

General Label Updates

The following label statements are proposed to be added to the PRECAUTIONS of all commercial end-use product labels, unless already present:

“Apply only when the potential for drift to areas of human habitation or areas of 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.”

Label statements must be amended (or added) to include the following directions to the appropriate labels:

“DO NOT APPLY using aerial application equipment.”

“DO NOT APPLY IN GREENHOUSES.”

Restricted-Entry Interval

Label statements must be amended (or added) to include the following directions to the appropriate labels, unless the current label mitigation is more restrictive:

“DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.”

Label Statements to Protect the Environment

Label Amendments for Technical Grade Active Ingredients and Manufacturing Concentrates (Reg. No. 28828, 28133, 28827, and 28134)

Add the title “ENVIRONMENTAL PRECAUTIONS” and add the following:

“Toxic to aquatic organisms”

Replace all wording under the DISPOSAL heading with the following:

“Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.”

Label Amendments for Commercial Class End-Use Products (Reg. No. 24779 and 30412)

Under PRECAUTIONS, remove the following if it is present:

The entire paragraph starting with: “DO NOT contaminate food and feed...”

The entire paragraph starting with: “For tank mixes...”

Amend the heading ENVIRONMENTAL HAZARDS to ENVIRONMENTAL PRECAUTIONS (if applicable) and add the following:

Toxic to aquatic organisms.

TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

Fomesafen is persistent and may carryover. It is recommended that any products containing fomesafen not be used in areas treated with this product during the previous season.

This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of fomesafen in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

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 is forecast.

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

Amend the heading STORAGE CONDITIONS to “STORAGE” and include the following information in this section:

To prevent contamination store this product away from food or feed.

Replace the DECONTAMINATION AND DISPOSAL heading with DISPOSAL (if applicable). Under DISPOSAL, remove the entire first paragraph starting with:

“For information on disposal...”

Remove the heading CONTAINER DISPOSAL (and OR REFILLING, if applicable).

Replace all the information under “FOR DISPOSAL OF PLASTIC JUGS” with the following:

For disposal of non-recyclable, non-returnable or non-refillable containers:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Follow provincial instruction for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. 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.

Under DIRECTIONS FOR USE, where applicable, remove the paragraphs starting with the following wording:

“Avoid contact with desirable vegetation...”

“Avoid drift or overspray...”

“Do not contaminate water sources...”

The following text must appear in DIRECTIONS FOR USE:

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.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

Buffer zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Buffer Zones Required

Method of Application	Crops	Buffer Zones (metres) Required for the Protection of Terrestrial Habitat:
Field sprayer	Soybean, dry edible beans, snap common beans, lima beans, otebo beans, cucumber, potato, strawberry	4

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) 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 buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

NOTE: For products where one or more other active ingredients are co-formulated with fomesafen, the most restrictive terrestrial and aquatic buffer zones will be required on the label.