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Re-evaluation Decision

RVD2023-04

Zoxamide and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation decision for zoxamide 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.

Zoxamide is a benzamide fungicide registered for use on potatoes, grapes and onions (bulb) for control of various oomycete diseases (for example, late blight and downy mildew). It is registered for application using ground (boom and airblast) and aerial equipment (potato only). Currently registered products containing zoxamide can be found in the [Pesticide Product Information Database](#) and in Appendix I.

This document presents the final re-evaluation decision¹ for the re-evaluation of zoxamide, 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 zoxamide that are registered in Canada are subject to this re-evaluation decision.

Prior to finalizing this decision, Health Canada published the Proposed Re-evaluation Decision, PRVD2022-06, *Zoxamide and Its Associated End-use*,² for a 90-day consultation period ending on 26 June 2022. PRVD2022-06 proposed that products containing zoxamide are acceptable for continued registration in Canada, provided that the additional proposed risk mitigation measures are in place. The proposed risk mitigation measures included environmental precautionary label statements and spray buffer zones, updating the standard statement to minimize human exposure from spray drift, and clarifying the ground application method for bulb onion.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2022-06, which lists all information used as the basis for the re-evaluation decision.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2022-06.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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

Re-evaluation decision for zoxamide

Health Canada has completed the re-evaluation of zoxamide. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing zoxamide is acceptable. An evaluation of available scientific information found that the uses of zoxamide products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes new mitigation measures. Label amendments, as summarized below and listed in Appendix II, are required.

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 zoxamide, are summarized below. Refer to Appendix II for details.

Environment

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

- Precautionary label statements to inform users of the potential toxicity of zoxamide to aquatic organisms.
- Spray buffer zones for the protection of freshwater aquatic habitats such as:
 - 1 to 10 m for field sprayer; 5 to 45 m for airblast; 5 to 350 m for aerial
- To reduce the potential for runoff of zoxamide to adjacent aquatic habitats, precautionary label statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecast.

Other label updates

- An update to the standard statement to minimize human exposure from spray drift.
- Clarify the application method for bulb onion (specify ground application).

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 zoxamide and its associated end-use products 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 PRVD2022-06) 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*.

Appendix I Registered products containing zoxamide in Canada¹

Table 1 Products containing zoxamide requiring (label) amendments

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (% , g/L)
26841	Technical	Gowan Company, L.L.C	Zoxamide Technical Fungicide	Solid	zoxamide: 98%
26840	Commercial		Zoxium 80W	Wettable Powder	zoxamide: 80%
26842			Gavel DF Fungicide	Dry Flowable	zoxamide: 8.3 %; mancozeb 66.7 %
32363			Zing Fungicide	Suspension	zoxamide: 85 g/L; chlorothalonil 500 g/L

¹as of 25 August 2022, excluding discontinued products or products with a submission for discontinuation

Appendix II Label amendments for products containing zoxamide

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

1.0 Label amendments for zoxamide technical products

1.1 Under the title “ENVIRONMENTAL PRECAUTIONS” add the following statements:

TOXIC to aquatic organisms

“DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.”

1.2 Under the title “DISPOSAL”, include the following statements:

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 and the provincial regulatory agency.

2.0 Label Amendments for Zoxamide Commercial End-Use Products

2.1 Under the title “ENVIRONMENTAL PRECAUTIONS” add the following statements:

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

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 filter strip between the treated area and the edge of the water body.

2.2 Under the title “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.

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.

Airblast application: 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.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Reduce drift caused by turbulent wingtip vortices. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Apply only by fixed-wing or rotary aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Spray buffer zones:

A spray buffer zone is NOT required for uses with hand-held application equipment permitted on this label.

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.

Buffer zones for PCP# 26840 (zoxamide only):

Method of application	Crop		Spray buffer zones (metres) required for the protection of:				Terrestrial habitat:
			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	
Field sprayer	Potato		5	1	0	0	0
Airblast	Grape	Early growth stage	45	20	0	0	0
		Late growth stage	35	10	0	0	0
Aerial	Potato	Fixed wing	125	10	0	0	0
		Rotary wing	100	10	0	0	0

When tank mixes are permitted, 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 Pesticides portion of the Canada.ca website.

Buffer zones for PCP# 26842 based on application rates for zoxamide:

Method of application	Crop		Spray buffer zones (metres) required for the protection of:				Terrestrial habitat:
			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	
Field sprayer	Potato		5	1	0	0	0
	Onion		10	1	0	0	0
Airblast	Grape	Early growth stage	40	15	0	0	0
		Late growth stage	30	5	0	0	0

Method of application	Crop		Spray buffer zones (metres) required for the protection of:				
			Freshwater habitat of depths:		Estuarine/Marine habitat of depths:		Terrestrial habitat:
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Aerial	Fixed wing		350	10	0	0	0
	Rotary wing		175	10	0	0	0

When tank mixes are permitted, 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 Pesticides portion of the Canada.ca website.

Buffer zones for PCP# 32363 based on application rates for zoxamide:

Method of application	Crop		Spray buffer zones (metres) required for the protection of:				
			Freshwater habitat of depths:		Estuarine/Marine habitat of depths:		Terrestrial habitat:
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Potato		4	1	0	0	0
Aerial	Fixed wing		200	10	0	0	0
	Rotary wing		125	5	0	0	0

When tank mixes are permitted, 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 Pesticides portion of the Canada.ca website.

3.0 Additional label amendments

3.1 For Reg. No. 26842 add the following statement under Directions for Use for Onion, bulb application:

Ground application only on onion.

3.2 For Reg. Nos. 26840 and 26842 in the “PRECAUTIONS” section replace the following drift statement on the commercial-class product labels

Use good pesticide application practices and apply only when the potential for drift to non-target or sensitive areas is minimal. Take into consideration residential areas, areas of human activities, bodies of water, meteorological conditions including wind speed, wind direction, temperature inversions, application equipment and sprayer settings used for application. Do not spray when the wind is blowing towards adjacent residential areas or areas of human activity, e.g., schools, parks

With the standard drift statement:

Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.