Re-evaluation Decision

Santé

Canada

RVD2023-03

Flucarbazone (present as flucarbazone-sodium) and Its Associated Enduse Products

Final Decision

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Re-evaluation decision for flucarbazone (present as flucarbazonesodium) and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be reevaluated 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.

Flucarbazone (present as flucarbazone-sodium) is a selective herbicide used on wheat (spring, durum and winter) in Alberta, Manitoba, Saskatchewan, and Peace River region of British Columbia. It is used to control certain annual grasses and broadleaf weeds. Flucarbazone products are formulated as wettable granules, suspension or emulsifiable concentrate and can be applied using ground or aerial equipment. Currently registered products containing flucarbazone can be found in the Pesticide Product Information Database and in Appendix I.

This document presents the final re-evaluation decision for the re-evaluation of flucarbazone, including the required risk mitigation measures to protect human health and the environment, as well as label amendments required to bring labels to current standards. All pest control products containing flucarbazone 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, PRVD2022-02, *Flucarbazone* (present as flucarbazone-sodium) and Associated End-Use Products, for a 90-day consultation period which ended 25 April 2022. PRVD2022-02 proposed that products containing flucarbazone are acceptable for continued registration in Canada provided that the additional proposed risk mitigation measures are in place. The proposed risk mitigation measures included updated restricted-entry interval (REI), adding the standard drift mitigation label statement, updating the personal protective equipment (PPE) label statements to reflect current standards, precautionary leaching label statements, and spray buffer zones.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2022-02, which lists all information used as the basis for the re-evaluation decision.

A reference list of data used as the basis for the re-evaluation decision is included in PRVD2022-02.

Re-evaluation decision for flucarbazone

Health Canada has completed the re-evaluation of flucarbazone. Under the authority of the Pest Control Products Act, Health Canada has determined that continued registration of products containing flucarbazone is acceptable. An evaluation of available scientific information found that the uses of flucarbazone products meets 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 label amendments including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of flucarbazone, are summarized below. Refer to Appendix II for details.

Human health

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

- To protect workers during mixing, loading and applying and postapplication exposure:
 - Mixers/loaders and applicators Protective clothing and personal protective equipment (PPE) requirements consisting of a long-sleeved shirt and long pants plus chemical-resistant gloves, socks and shoes.
 - o Re-entry workers A standard restricted-entry interval (REI) of 12 hours.
- To protect bystanders from agriculture application exposure, add standard spray drift statement.

Environment

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

- Precautionary leaching label statements.
- Terrestrial and freshwater aquatic buffer zones to mitigate risk from drift.

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 objection regarding this decision on flucarbazone 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 PRVD2022-02) 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.

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

Appendix I Registered products containing flucarbazone in Canada

Table 1 Products containing flucarbazone requiring label amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee	
26447	Commercial	Arysta LifeScienc e North America,	Everest 70 WDG Herbicide	Wettable granules	66%	
26448			Everest Solupak 70 DF	Wettable granules in water-soluble packets	66%	
29500			Pre-Pare Herbicide	Wettable granules	66%	
30342			Everest 2.0 Herbicide		397.33 g/L	
30580			ARY 0548- 019 Herbicide	Suspension	36.3 g/L (+ 200 g/L fluroxypyr)	
30663		LLC		Wettable granules	45% (+ 23.9% tribenuron methyl)	
32602			Everest 3.0 Herbicide	Suspension	200 g/L	
33258				Everest 3.0 AG Herbicide	Suspension	200 g/L
33273			Inferno Trio Herbicide	Emulsifiable Concentrate or Emulsion	141 g/L (+50 g/L florasulam + 175 g/L carfentrazone-ehtyl)	
33372			Batalium Suspension Concentrat e Herbicide	Suspension	20.4 g/L (+ 241 g/L MCPA ester + 90.5 g/L fluroxypyr + 241 g/L bromoxynil)	
33370		New Agco Inc.	Mpower Himalaya Herbicide	Wettable granules	66%	
32941		Syngenta	Sierra® 3.0 Herbicide	Suspension	200 g/L	
33538		Canada Inc.	Sierra® 3.0 AG Herbicide	Suspension	200 g/L	

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
	Tarkainal	Arysta			
		LifeScienc	Everest		
26446		e North	Technical	Solid	89.20%
		America,	Herbicide		
		LLC			
	Technical Grade Active		Newagco		
33333		New Agco	Flucarbazo	Solid	93.20%
33333		Inc.	ne	Solid	95.20%
	Ingredient		Technical		
			Flucarbazo		
24110		Albaugh	ne	Solid	01.20/
34110		LLC	Technical	Solid	91.2%
			Herbicide		

¹ as of 8 September 2022, excluding discontinued products or products with a submission for discontinuation.

Appendix II Label amendments for products containing flucarbazone

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

Label amendments for technical class products

On the primary display panel, replace "GUARANTEE" with "ACTIVE INGREDIENT".

The following label statements are required under the heading ENVIRONMENTAL PRECAUTIONS for all registered flucarbazone technical grade active ingredients:

"TOXIC to aquatic organisms."

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

Label Amendments for Commercial Class Products

On the primary display panel, replace "GUARANTEE" with "ACTIVE INGREDIENT".

Add to DIRECTIONS FOR USE for Water-Soluble Packages

Using Water-Soluble Packages Dissolved Directly in Spray tanks:

Water-Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs.

"Handling Instructions

Follow these steps when handling pesticide products in WSPs.

- 1. Mix in spray tank only.
- 2. Handle WSP(s) in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on a minimum of coveralls, chemical-resistant gloves, chemical-resistant footwear, and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested and then continue with mixing instructions.
- 3. Keep the WSP(s) in outer packaging until just before use.
- 4. Keep the WSP dry prior to adding to the spray tank.
- 5. Handle with dry gloves and according to the label instructions for PPE.
- 6. Keep WSP intact. Do not cut or puncture WSP.
- 7. Reseal the WSP outer packaging to protect any unused WSP(s).

Mixing Instructions

Follow the steps below when mixing this product, including if tank mixed with other pesticide products. If being tank mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. All other directions for use of all tank mixed products should be followed provided they do not conflict. Do not tank mix this product with products that prohibit tank mixing or have conflicting mixing directions.

- 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.
- 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray.
- 3. Stop adding water and stop any agitation.
- 4. Place intact/unopened WSP(s) into the tank.
- 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP(s).
- 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.
- 7. Dissolving the WSP(s) may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.
- 8. Stop agitation before tank lid is opened.
- 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSPs have fully dissolved and the contents have been thoroughly mixed into the solution.
- 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.
- 11. Once the WSP have fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation.
- 12. Use the spray solution when mixing is complete.
- 13. Maintain agitation of the diluted pesticide mix during transport and application.
- 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label."

Based on the current occupational exposure and risk assessment, the following label statements are required under the **PRECAUTIONS** section, and sub-section **PROTECTIVE CLOTHING** or **PERSONAL PROTECTIVE EQUIPMENT:**

For labels with use directions for ground application only:

"Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab."

For labels with use directions for both ground and aerial application:

"Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab and/or cockpit."

The following label statements are required under the section of **PRECAUTIONS** of all end use products:

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

"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."

Add to **ENVIRONMENTAL PRECAUTIONS**:

"Toxic to aquatic plants and non-target terrestrial plants. Observe spray buffer zones specified under **DIRECTIONS FOR USE**.

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.

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."

Add to **DIRECTIONS FOR USE** (For PCP Numbers: 26447, 26448, 29500, 30342, 30580, 30663, 32602, 29558):

"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.

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) coarse 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."

Add to **DIRECTIONS FOR USE** for all commercial products

"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."

Add to **DIRECTIONS FOR USE** (PCP Number 30430 - Sierra® 2.0 Herbicide):

"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.

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.

Use precautions

Apply only when meteorological conditions at the treatment site allow for complete and even crop coverage. Apply only under conditions of good practice specific to aerial application as outlined in the National Aerial Pesticide Application Manual, developed by the Federal/Provincial/Territorial Committee on Pest Management and Pesticides.

Product specific precautions

Read and understand the entire label before opening this product. If you have questions, call the manufacturer listed on the product label or obtain technical advice from the distributor or your provincial agricultural representative. Application of this specific product must meet and/or conform to the following:

Volume: Apply the recommended rate in a minimum spray volume of 28 litres per hectare."

Spray buffer zones

The spray 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), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Mathad of	Сгор		Spray buffer zones (metres) required for the protection of:			
Method of application			Freshwater hal			
			Less than 1 m	Greater than 1 m	Terrestrial habitat:	
Field sprayer	Spring and winter wheat		2	1	1	
Aerial	Spring and winter wheat	Fixed wing	5	1	20	
(ASABE coarse spray quality		Rotary wing	5	2	25	

	Стор		Spray buffer zones (metres) required for the protection of:			
Method of application			Freshwater hal			
11			Less than 1 m	Greater than 1 m	Terrestrial habitat:	
Aerial		Fixed wing	15	3	40	
(ASABE medium spray quality)	Spring and winter wheat	Rotary wing	15	4	35	

The spray buffer zones presented in this table are for flucarbazone. As spray buffer zones are active specific, for coformulated products care must be taken to ensure the correct spray buffer zones remain on the label. For all non-coformulated products, the spray buffer zones for flucarbazone apply for both aquatic and terrestrial habitats.

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 (ASABE) 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.

Add under STORAGE for all commercial products:

"Store this product away from food or feed."

Add under **DISPOSAL**:

For recyclable Containers:

"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:

"Disposal of Container:

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:

"Disposal of Container:

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."

For all commercial products, add:

"Disposal of unused, unwanted product

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."