



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Re-evaluation Decision

RVD2022-03

Florasulam and Its Associated End-use Products

Final Decision

(publié aussi en français)

7 April 2022

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2022-3E (print version)
H113-28/2022-3E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

Table of Contents

Re-evaluation decision for Florasulam and associated end-use products.....	1
Re-evaluation decision for Florasulam.....	2
Risk mitigation measures.....	2
Next steps	3
Other information	3
Appendix I Registered products containing Florasulam in Canada.....	4
Table 1 Products containing Florasulam requiring (label) amendments ¹	4
Table 2 Products containing Florasulam that do not require (label) amendments.....	6
Appendix II Registered commercial class uses of Florasulam ^{1,2,3}	7
Appendix III Label amendments for products containing florasulam	9

Re-evaluation decision for Florasulam 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.

Florasulam is an herbicide registered for use on oats, spring barley, spring wheat (including durum), winter wheat, grasses grown for seed production, grass pastures, and summerfallow in the Prairie provinces and the interior of British Columbia. It is applied using ground equipment to control or suppress annual and perennial broadleaf weeds and is often used tank mixed or co-formulated with other active ingredients. Currently registered products containing florasulam can be found in the [Pesticide Product Information Database](#) and in Appendix I. The Proposed Re-evaluation Decision PRVD2021-03, *Florasulam and Its Associated End-use Products*¹ containing the evaluation of florasulam and proposed decision, underwent a 90 day consultation period ending on 24 May 2021. PRVD2021-03 proposed that products containing florasulam are acceptable for continued registration in Canada, provided that the additional proposed risk mitigation measures are in place. The proposed risk mitigation measures included personal protective equipment and standard restricted-entry intervals.

The only comment received during the consultation period was from a technical grade active ingredient registrant, supporting the proposal and mitigation measures. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2021-03, which lists all data used as the basis for the re-evaluation decision. However, the PRVD reflected the use pattern as of September 2020 and a minor use (i.e., established alfalfa for forage and hay to PCP No. 31259) was registered in December 2020. While this use expansion was not captured in the PRVD, it has been included in the RVD (under Appendix II). Further information on the evaluation of this use can be found in the Evaluation Report located in the Pesticide Product Information Database under Sub. No. 2020-3054.

This document presents the final re-evaluation decision² for the re-evaluation of florasulam, 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 florasulam 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 Florasulam

Health Canada has completed the re-evaluation of florasulam. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing florasulam is acceptable. An evaluation of available scientific information found that the use of florasulam 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 III, 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 updated label statements and mitigation measures, as a result of the re-evaluation of florasulam, are summarized below. Refer to Appendix III for details.

Human health

Risk mitigation:

To protect workers (mixer/loader/applicator) and those entering treated areas, and bystanders the following risk-reduction measures are required:

- Personal protective equipment (PPE) consisting of a long-sleeved shirt and long pants plus chemical-resistant gloves is required to protect mixers/loaders and applicators.
- A standard restricted-entry interval (REI) of 12 hours is required to protect workers entering treated areas.
- The standard drift mitigation statement is required to minimize the potential for spray drift to bystanders.

Environment

Label improvements to meet current standards:

- Updated discharge of effluent statements.
- Updated disposal statements.
- Updated storage statements.

Risk mitigation:

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

- Standard label statements to minimize potential risks resulting from runoff.
- Label statement to inform users of the potential toxic effects of florasulam to non-target terrestrial and aquatic vascular plants.
- Spray buffer zones (up to 3 metres) to protect terrestrial and aquatic habitats.
- Precaution statements on product labels warning of the potential for leaching and groundwater contamination.

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 florasulam 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 PRVD2021-03) 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 Florasulam in Canada

Table 1 Products containing Florasulam requiring (label) amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type ²	Active ingredient (% , g/L) ³
26888	Technical Grade Active Ingredient	Corteva Agriscience Canada Company	DE-570 Technical Herbicide	SO	FRA: 99.2%
30610		Adama Agricultural Solutions Canada Ltd.	ADAMA Florasulam Technical		FRA: 99.0%
30830		FMC of Canada Ltd.	FMC Florasulam Technical Herbicide		FRA: 99.35%
32664		NewAgco Inc.	NewAgco Florasulam Technical Herbicide		FRA: 98.44%
33121		Zhejiang Zhongshan Chemical Industry Group Co., Ltd.	Zhongshan Florasulam Technical 98%		FRA: 98.43%
33243		Sharda CropChem Ltd.	Sharda Florasulam Technical		FRA: 99.01%
33877		Albaugh, Llc.	ALBAUGH FLORASULAM Technical Herbicide		FRA: 98.34%
34074		Farmer's Business Network Canada, Inc.	FBN Florasulam Technical		FRA: 98.3%
33352		Commercial	Corteva Agriscience Canada Company		GF-1374 Herbicide
32099	Stellar™ XL Herbicide			FRA: 2.5 g/L; FLR: 100 g/L; MAE: 350 g/L	
29286	GF-184 Herbicide			FRA: 2.5 g/L; FLR: 100 g/L	
28804	Frontline™ XL Herbicide			SU	FRA: 4.0 g/L; MAE: 280 g/L
33289	GF-2257 Herbicide				FRA: 5.0 g/L; FLR: 100 g/L
33440	Tridem™ B Herbicide				
33455	Avenza™ A Herbicide				
26891	Florasulam Suspension Concentrate Herbicide				FRA: 50.0 g/L
27031	Spectrum™ A Herbicide				
29651	PrePass™ XC A Herbicide				

Registration number	Marketing class	Registrant	Product name	Formulation type ²	Active ingredient (% , g/L) ³
30060	Commercial		Frontline™ 2,4-D XC A Herbicide	WG	FRA: 20.0%; HXM: 20.0%
31519			ReadySet SC Herbicide		
31547			PREP II Herbicide		
31304			Paradigm™ PRE Herbicide		
33803			Exhilarate™ A Herbicide		
34180			Cirpreme™ A Herbicide		
30162			GF-1352 Herbicide		
30416			PrePass™ 250 WG Herbicide		
31038			Florasulam II Herbicide		
31204			Florasulam WDG Herbicide		
31259			PrePass™ FLEX Herbicide		
31405			Korrex™ A Herbicide		
33936			Syngenta Canada Inc.		
29138		BROADBAND® Herbicide		FRA: 7.73 g/L; PRN: 92.7 g/L	
31646		Adama Agricultural Solutions Canada Ltd.	Outshine	SU	FRA: 2.5 g/L; FLR: 100 g/L
30814			Florasulam 50 SC Herbicide		
30831	PRIORITY® Herbicide				
30857	Florasulam NC				
31252	FMC of Canada Ltd.	SPITFIRE® 50 SC Herbicide	WG	FRA: 20.0; MEX: 30.0%	
32758		CHA 5373 Herbicide			
31325	NewAgco Inc.	MPower Florasulam Herbicide	SU	FRA: 50.0 g/L	
33003		BATTLEFRONT® Herbicide			
31671	Winfield United Canada Ulc.	FirstPass™ Herbicide	SU	FRA: 50.0 g/L	
31687	Loveland Products Canada Inc.	Blitz™ Herbicide			

Registration number	Marketing class	Registrant	Product name	Formulation type ²	Active ingredient (% , g/L) ³
33273	Commercial	Arysta LifeScience North America, Llc.	INFERNO® TRIO Herbicide	EC	FRA: 50 g/L; CAE: 175 g/L; FLS: 141 g/L
33431		Ciech Sarzyna S.A.	Florin Herbicide	SU	FRA: 50.0 g/L
33610		Sharda CropChem Ltd.	Flora Herbicide	SN	FRA: 50.0 g/L
33657		UPL AgroSolutions Canada Inc.	Akito™ Herbicide	EC	FRA: 2.5 g/L; DPI: 80.0 g/L; FLR: 100 g/L
33717		Nufarm Agriculture Inc.	ThunderHawk™ B Herbicide	SU	FRA: 50.0 g/L
34186		Farmer's Business Network Canada, Inc.	FBN Florasulam 50 SC		

¹ As of 4 November 2021, excluding discontinued products or products with a submission for discontinuation.

² EC = emulsifiable concentrate; SN = solution; SO = solid; SU = suspension; WG = wettable granules.

³ FRA = florasulam; CAE = carfentrazone-ethyl; DPI = clopyralid; FLR = fluroxypyr-meptyl; FLS = flucarbazone (present as flucarbazone-sodium); HXM = halauxifen-methyl; MAE = MCPA (present as esters); MEX = tribenuron methyl; PRN = pinoxaden.

Table 2 Products containing Florasulam that do not require (label) amendments

Registration number	Marketing class	Registrant	Product name	Formulation type ²	Active ingredient (% , g/L) ³
26889	Manufacturing Concentrate	Corteva Agriscience Canada Company	EF-1343 Manufacturing Concentrate	SU	FRA: 4.84%
26890			EF-1440 Manufacturing Concentrate		FRA: 45.0%

¹ As of 4 November 2021, excluding discontinued products or products with a submission for discontinuation.

² SU = suspension

³ FRA = florasulam

Appendix II Registered commercial class uses of Florasulam^{1,2,3}

Site ⁴	Listed Weeds ⁵	Application Method and Equipment	Maximum Single Application Rate (g a.i./ha)	Maximum Cumulative Application Rate		Maximum Number of Applications per year	
				per CROP CYCLE (g a.i./ha)	per YEAR (g a.i./ha)		
USC 7, 13, 14 – Terrestrial Non-food and Non-feed Seed and Fibre Crops and Terrestrial Food and Feed Crops							
Spring wheat Prairie Provinces and Interior of BC or Prairie Provinces and Peace River Region only	A	Ground equipment	5	10	10	2	
	B		5	5	5	1	
Winter wheat Prairie Provinces and Interior of BC or Prairie Provinces and Peace River Region only	A		5	10	10	2	
	B		5	5	5	1	
Spring barley Prairie Provinces and Interior of BC or Prairie Provinces and Peace River Region only	A		5	10	10	2	
	B		5	5	5	1	
Oats Prairie Provinces and Interior of BC or Prairie Provinces and Peace River Region only	A		5	5	5	1	
	B		5	10	10	2	
Summerfallow Prairie Provinces and Interior of BC or Prairie Provinces and Peace River Region only	A		5	10	10	2	
	B		5	5	5	1	
Timothy Prairie Provinces and Peace River Region only	B		5	5	5	1	
Grass grown for seed production Prairie Provinces and Interior of BC	B		5	5	5	1	
Established grass pastures Prairie Provinces and Interior of BC	B		4	4	4	1	
Improved pastures containing forage grasses (may contain non-native, tame, or introduced forage grass species)	Prairie Provinces and Peace River Region only		A	5	5	5	1
	Prairie Provinces and Interior of BC		B	2.5	2.5	2.5	1

¹ As of 23 September 2020, excluding discontinued products or products with a submission for discontinuation. Note that since the initiation of this re-evaluation, the following products have been registered, but fall within the currently registered use pattern: Reg. No's. 33003; 33273; 33289; 33352; 33431; 33440; 33455; 33610; 33657; 33717; 33803. Also note that for Reg. No's. 26891 and 31687, the increase to 2 applications per year (to a maximum of 10 g a.i./ha of florasulam) was registered after the initiation of this re-evaluation.

² A user requested minor use for the control or suppression of labelled weeds (refer to weed list A. below) in alfalfa for forage and hay at a maximum application rate (single and per year) of 5 g a.i./ha was added to Reg. No. 31529 on 10 December 2020 and was considered in the re-evaluation decision for florasulam.

³ All information is derived from registered product labels.

⁴ Sites are either as stated on the label or as interpreted by the PMRA.

⁵ The weed list includes:

A. **Florasulam alone:**

Control: buckwheat (wild); shepherd's purse; canola (volunteer); smartweed; chickweed (common); stinkweed; cleavers; mustard (wild); cow cockle; **Suppression:** hemp-nettle; sow thistle (annual, perennial); narrow-leaved hawk's beard, pigweed (redroot).

-
- B. **When it is co-formulated with one or more other active ingredients or required to be used with a tank mix partner:** buckwheat (wild, tartary); shepherd's purse; canola (volunteer); smartweed; chickweed; stinkweed; cleavers; mustard (wild, ball, Indian, Hare's ear, wormseed); burdock; flixweed; hemp-nettle; lamb's quarters; pigweed (redroot, Russian); prickly lettuce; ragweed; sunflower (annual); kochia; dandelion; plantain; sow thistle (annual, perennial); stork's bill; thistle (Canada, Russian); narrow-leaved hawk's beard; bluebur; cocklebur; vetch; wild radish; lady's thumb; flax (volunteer); fleabane (Canada); scentless chamomile; barley (volunteer); wheat (volunteer); brome (downey); foxtail (giant, green, yellow); oats (volunteer, wild); Persian darnel; barnyard grass; canary seed (volunteer); millet (proso); carpetweed; alfalfa (volunteer); American dragonhead; henbit; round-leaved mallow; velvetleaf; night flowering catchfly; white cockle; cow cockle; creeping buttercup; curled dock; sheep sorrel; broadleaved dock.

Appendix III Label amendments for products containing florasulam

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

1.0 Labels of Technical Products

1.1 Under the **ENVIRONMENTAL PRECAUTIONS** section:

Remove the following statement:

Do not contaminate any body of water by direct application, cleaning of equipment or disposal of wastes.

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 **DISPOSAL** section:

Remove the following statement:

Canadian formulators of this technical should dispose of unwanted active and containers in accordance with municipal or provincial regulations. 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 the case of a spill, and for clean-up of spills.

Add the following statement:

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

2.0 Labels for Commercial Class Products

2.1 Under the **PRECAUTIONS** section:

Add the following statement for the Personal Protective Equipment for workers mixing, loading, and applying end-use products:

- 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.

Add the following statement for the restricted entry interval (REI):

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

Add the following statement for the spray drift statement:

- 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.”

2.2 Under the **ENVIRONMENTAL PRECAUTIONS** section:

Remove the following statement:

Do not contaminate any body of water by direct application, cleaning of equipment or disposal of wastes.

Add the following statements:

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

2.3 Under the **GENERAL DIRECTIONS FOR USE** section (after the Mixing Instructions):

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.

2.4 Under the **DIRECTIONS FOR USE** section

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) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: DO NOT apply using aerial application equipment.

Spray Buffer Zones:**Add to ENVIRONMENTAL PRECAUTIONS:**

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

Add to DIRECTIONS FOR USE:**On all commercial end-use products with field sprayer application that require up to 3m buffer zone for terrestrial habitat:**

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.

On all commercial end-use products with field sprayer application that require up to 2m buffer zone for terrestrial habitat:

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) coarse classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply using aerial application equipment.

SPRAY BUFFER ZONES

Spot treatments using hand-held equipment do not require a spray buffer zone.

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

Crop	Method of application	Spray Buffer Zones (metres) Required for the Protection of:		
		Freshwater Habitat of Depths:		Terrestrial Habitat:
		Less than 1 m	Greater than 1 m	
All labelled crops	Field sprayer (coarse)	1	0	2
	Field sprayer (medium)	1	0	3

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

When tank-mixes are permitted, read and observe all label directions, including rates and restrictions for each product used in the tank-mix. Follow the more stringent label precautionary measures for mixing, loading and applying stated on both product labels.

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 that are larger than 1m 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.

2.5 Under the **STORAGE** section:

Add the following statement:

Store this product away from food or feed.

2.6 **Label Improvements:**

- On the PRINCIPAL DISPLAY PANEL of all end-use product labels, replace "... for postemergent control of ..." with "... for postemergent control or suppression of ...".
- Registrants must verify for any specific tank mix claim that the partner pesticide is still registered for that labelled use (crop or site). If not, it must be removed from the product label.
- Tank mix partners must be clearly indicated, by product name, on the product labels. Specific directions regarding use of the tank mix, or a reference to the tank mix partner label, must be included. A general reference that "this product can be tank mixed with other products" is not acceptable. Therefore, any vague or non-specific claims that the product can be tank mixed with another pesticide must be removed.

- For all labels registered for use in the Prairie Provinces (either indicated on the labels as “Prairie Provinces” or as “Manitoba, Saskatchewan, Alberta”) and the Interior of British Columbia (whether the Peace River Region is specified or not), amend geographical description as follows: “FOR SALE FOR USE IN THE PRAIRIE PROVINCES AND THE INTERIOR OF BRITISH COLUMBIA (INCLUDING THE PEACE RIVER REGION) ONLY”. For labels registered for use in the Prairie Provinces and only in the Peace River Region of British Columbia, no amendment is required to the geographical description.
- Update the resistance management statements on each end-use product label as per Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site / Mode of Action*.