Special Review Decision

SRD2019-02

Special Review Decision: Bromoxynil and Its Associated End-use Products

Final Decision Document

(publié aussi en français)

5 July 2019

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

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ISSN: 2561-6269 (online)

Catalogue number: H113-17/2019-2E (print version)

H113-17/2019-2E-PDF (PDF version)

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Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a special review of all registered pest control products containing bromoxynil based on the decision taken by Norway in 2000 to prohibit the use of bromoxynil octanoate due to human health and environmental concerns.

Health Canada evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in Proposed Special Review Decision (PSRD2019-01), *Special Review for Bromoxynil and Its Associated End-use Products*. No comments were received during the consultation period. Health Canada has completed the special review for bromoxynil, and this final special review decision is consistent with the proposed regulatory decision as described in PSRD2019-01.

All pest control products containing bromoxynil that are registered in Canada are subject to this special review decision, and currently registered products containing bromoxynil are listed in Appendix I.

Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing bromoxynil is considered to be acceptable. Following an evaluation of the aspects of concern, Health Canada has determined that the use of bromoxynil continues to be considered acceptable provided that the label amendments, as listed in Appendix II, are implemented.

This document presents the final regulatory decision for the special review of bromoxynil. To comply with this decision, the required label amendments must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document. Registrants of the products containing bromoxynil will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Please refer to the Regulatory Directive DIR2014-01, *Approach to Special Reviews*, for details of the PMRA's special review approach.

Other Information

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Any person may file a notice of objection² regarding this decision on bromoxynil within 60 days from the date of publication of this special review 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.

[&]quot;Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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

Appendix I Registered Products Containing Bromoxynil as of 27 March 2019

Registration No.	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
16164	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BADGE EMULSIFIABLE SELECTIVE WEEDKILLER	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g a.e./L
18001	С	BAYER CROP SCIENCE INC.	PARDNER HERBICIDE	EMULSION	BROMOXYNIL-280 g/L
18022	С	BAYER CROP SCIENCE INC.	BUCTRIL M	EMULSION	MCPA-280 g a.e./L BROMOXYNIL-280 g/L
22659	С	BAYER CROP SCIENCE INC.	THUMPER EMULSIFIABLE SELECTIVE WEEDKILLER	EMULSION	2,4-D-280 g a.e./L BROMOXYNIL-280 g/L
25341	С	NUFARM AGRICULTURE INC.	NUFARM KORIL 235 LIQUID HERBICIDE	EMULSION	BROMOXYNIL-235 g/L
25791	С	BAYER CROP SCIENCE INC.	COMPAS 480 EC HERBICIDE	EMULSION	BROMOXYNIL-480 g/L
26999	С	NUFARM AGRICULTURE INC.	MEXTROL 450 LIQUID HERBICIDE	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g a.e./L
28109	С	INTERPROVINCIAL COOPERATIVE LIMITED	IPCO LOGIC M LIQUID HERBICIDE	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g a.e./L
28123	С	NUFARM AGRICULTURE INC.	APPROVE HERBICIDE	EMULSION	2,4-D-225 g a.e/L BROMOXYNIL-225 g/L
28276	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BROMOTRIL 240 EC	EMULSION	BROMOXYNIL-240 g/L
28519	С	INTERPROVINCIAL COOPERATIVE LIMITED	IPCO BROTEX 240 LIQUID HERBICIDE	EMULSION	BROMOXYNIL-240 g/L
28738	С	BAYER CROP SCIENCE INC.	INFINITY HERBICIDE	EMULSION	PYRASULFOTOLE-37.5 g/L BROMOXYNIL-210 g/L
28779	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	THRASHER	EMULSION	2,4-D-225 g a.e./L BROMOXYNIL-225 g/L
28853	С	INTERPROVINCIAL COOPERATIVE LIMITED	IPCO LEADER LIQUID HERBICIDE	EMULSION	2,4-D-225 g a.e./L BROMOXYNIL-225 g/L
28876	С	NUFARM AGRICULTURE INC.	BENCHMARK B HERBICIDE	EMULSION	BROMOXYNIL-235 g/L
28947	С	INTERPROVINCIAL COOPERATIVE LIMITED	IPCO LEADER 450 LIQUID HERBICIDE	EMULSION	2,4-D-225 g a.e./L BROMOXYNIL-225 g/L
29051	С	BAYER CROP	VELOCITY 2	EMULSION	PYRASULFOTOLE-37.5g/L

Registration No.	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
		SCIENCE INC.	HERBICIDE		BROMOXYNIL-210 g/L
29214	С	BAYER CROP SCIENCE INC.	VELOCITY B HERBICIDE	EMULSION	PYRASULFOTOLE-37.5g/L BROMOXYNIL-210 g/L
29367	С	BAYER CROP SCIENCE INC.	TUNDRA HERBICIDE	EMULSION	PYRASULFOTOLE-15.5 g/L FENOXAPROP-P-ETHYL-46 g/L BROMOXYNIL-87.5 g/L
29510	С	BAYER CROP SCIENCE INC.	BRY-MAE 2 HERBICIDE	EMULSION	MCPA-280 g a.e./L BROMOXYNIL-280 g/L
29513	С	BAYER CROP SCIENCE INC.	THUMPER TOTAL 2 HERBICIDE	EMULSION	2,4-D-280 g a.e./L BROMOXYNIL-280 g/L
29584	С	BAYER CROP SCIENCE INC.	VELOCITY M3 ALL-IN-ONE HERBICIDE	SUSPENSION	THIENCARBAZONE-METHYL- 5 g/L PYRASULFOTOLE-31.3 g/L BROMOXYNIL-175 g/L
30005	С	INTERPROVINCIAL COOPERATIVE LIMITED	WEEDAWAY LEADER HERBICIDE	EMULSION	2,4-D-225 g a.e./L BROMOXYNIL-225 g/L
30007	С	INTERPROVINCIAL COOPERATIVE LIMITED	INT-110 HERBICIDE	EMULSION	MCPA 225 g a.e./L BROMOXYNIL-225 g a.e./L
30008	С	INTERPROVINCIAL COOPERATIVE LIMITED	WEEDAWAY LOGIC M HERBICIDE	EMULSION	MCPA 225 g a.e./L BROMOXYNIL-225 g a.e./L
30009	С	INTERPROVINCIAL COOPERATIVE LIMITED	INT-111 HERBICIDE	EMULSION	BROMOXYNIL-240 g/L
30010	С	INTERPROVINCIAL COOPERATIVE LIMITED	WEEDAWAY BROTEX 240 HERBICIDE	EMULSION	BROMOXYNIL-240 g/L
30370	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BADGE II	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g/L
30371	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BROMOTRIL 11 240 EC	EMULSION	BROMOXYNIL-235 g/L
30372	С	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	THRASHER II	EMULSION	2,4-D-225 g a.e./L BROMOXYNIL-225 g/L
30690	С	NUFARM AGRICULTURE INC.	ENFORCER D HERBICIDE	EMULSION	FLUROXYPYR-80 g a.e./L 2,4-D-240 g a.e./L BROMOXYNIL-190 g/L
30691	С	NUFARM AGRICULTURE INC.	ENFORCER M HERBICIDE	EMULSION	MCPA-200 g a.e./L FLUROXYPYR-80 g a.e./L BROMOXYNIL-200 g/L
31348	С	INTERPROVINCIAL COOPERATIVE LIMITED	IPCO BROTEX 480 LIQUID HERBICIDE	EMULSION	BROMOXYNIL-480 g/L

Registration No.	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31429	С	INTERPROVINCIAL	WEEDAWAY	EMULSION	BROMOXYNIL-480 g/L
		COOPERATIVE LIMITED	BROTEX 480		
31431	С	LOVELAND PRODUCTS	BROMAX TM LIQUID	EMULSION	BROMOXYNIL-480 g/L
		CANADA INC.	HERBICIDE		
31992	С	BAYER CROP SCIENCE INC.	RRRPSABRY HERBICIDE	SUSPENSION	THIENCARBAZONE-METHYL- 5 g/L PYRASULFOTOLE-31.3 g/L BROMOXYNIL-175.0 g/L
32260	С	BAYER CROP SCIENCE INC.	PSABRY HERBICIDE	EMULSION	PYRASULFOTOLE-37.5 g/L BROMOXYNIL-210 g/L
32472	С	ALBAUGH LLC	BROMOXYNIL- MCPA 225-225	EMULSION	MCPA 225 g a.e./L BROMOXYNIL-225 g a.e./L
32528	С	NUFARM AGRICULTURE INC.	CONQUER HERBICIDE	EMULSION	PYRAFLUFEN-ETHYL-15 g/L BROMOXYNIL-467 g/L
32607	С	BAYER CROP SCIENCE INC.	RRRPSABRY-SP HERBICIDE	SUSPENSION	THIENCARBAZONE-METHYL- 5 g/L PYRASULFOTOLE-31.3 g/L BROMOXYNIL-175 g/L
32622	С	ALBAUGH LLC	BROMOXYNIL 240 EC	EMULSION	BROMOXYNIL-240 g/L
32681	С	SYNGENTA CANADA INC.	A19278	EMULSION	BICYCLOPYRONE-37 g/L BROMOXYNIL-175 g/L
32685	С	NEWAGCO INC	MPOWER BUCK M	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g a.e./L
32911	С	NEWAGCO INC	MPOWER BROMOXYNIL	EMULSION	BROMOXYNIL-240 g/L
33248	С	BAYER CROP SCIENCE INC.	INFINITY FX	EMULSION	PYRASULFOTOLE-31.1 g/L FLUROXYPYR-72 g/L BROMOXYNIL-174.3 g/L
33350	С	NUFARM AGRICULTURE INC.	CONQUER II HERBICIDE	EMULSION	PYRAFLUFEN-ETHYL-15 g/L BROMOXYNIL-467 g/L
33372	С	ARYSTA LIFESCIENCE NORTH AMERICA, LLC	BATALIUM	NO_DATA	MCPA- FLUCARBAZONE- FLUROXYPYR- BROMOXYNIL-;
24403	M	BAYER CROP SCIENCE INC.	BROMOXYNIL MIXED ESTER SOLUTION 50% (50% MEO)	SOLUTION	BROMOXYNIL-50%
24404	M	BAYER CROP SCIENCE INC.	BROMOXYNIL MIXED ESTER SOLUTION 60% (60% MEO)	SOLUTION	BROMOXYNIL-60%;
24471	M	BAYER CROP SCIENCE INC.	BROMOXYNIL MIXED ESTER SOLID	SOLID	BROMOXYNIL-66.3%
28696	M	ADAMA AGRICULTURAL SOLUTIONS	BROMOTRIL 240	EMULSION	BROMOXYNIL-240%

Registration	Marketing	Registrant	Product Name	Formulation	Guarantee
No.	Class	Registi ant	1 Toduct Name	Type	Guarantee
		CANADA LTD.		J.F.	
28699	M	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BADGE	EMULSION	MCPA-225 g a.e./L BROMOXYNIL-225 g/L
28864	M	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BROMOTRIL	SOLUTION	BROMOXYNIL-56.2%
29413	M	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL ME 50	SOLUTION	BROMOXYNIL-50%
29414	M	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL ME 60	SOLUTION	BROMOXYNIL-60%
29415	М	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL ME SOLID	SOLID	BROMOXYNIL-66.8%
33190	M	BAYER CROP SCIENCE INC.	INFINITY	EMULSION	PYRASULFOTOLE-37.5 g/L BROMOXYNIL-210 g/L
33229	M	BAYER CROP SCIENCE INC.	PSABRYFPF	EMULSION	PYRASULFOTOLE-15.5 g/L FENOXAPROP-P-ETHYL-46 g/L BROMOXYNIL-87.5 g/L
33239	M	BAYER CROP SCIENCE INC.	RRRPSABRY	SUSPENSION	THIENCARBAZONE-METHYL- 5 g/L PYRASULFOTOLE-31.3 g/L BROMOXYNIL-175 g/L
19693	Т	BAYER CROP SCIENCE INC.	BROMOXYNIL TECHNICAL	SOLID	BROMOXYNIL-92.5%
19700	Т	BAYER CROP SCIENCE INC.	BROMOXYNIL HEPTANOATE TECHNICAL	SOLID	BROMOXYNIL-68.2%
19705	Т	BAYER CROP SCIENCE INC.	BROMOXYNIL OCTANOATE TECHNICAL	SOLID	BROMOXYNIL-65.9%
21926	Т	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL PHENOL	SOLID	BROMOXYNIL-92.5%
21927	Т	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL OCTANOATE TECHNICAL	SOLID	BROMOXYNIL-65.5%
27675	Т	ADAMA AGRICULTURAL SOLUTIONS CANADA LTD.	BROMOTRIL TECHNICAL	SOLID	BROMOXYNIL-66.1%
29412	Т	NUFARM AGRICULTURE INC.	NUFARM BROMOXYNIL HEPTANOATE TECHNICAL	SOLID	BROMOXYNIL-68.2%
31987	Т	NEWAGCO INC	BROMOXYNIL HEP TECHNICAL HERBICIDE	SOLID	BROMOXYNIL-70.85%

Appendix I

Registration No.	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31988	Т	NEWAGCO INC	BROMOXYNIL OCT TECHNICAL HERBICIDE	SOLID	BROMOXYNIL-68.5%
32470	Т	ALBAUGH LLC	ALBAUGH BROMOXYNIL OCTANOATE TECHNICAL	SOLID	BROMOXYNIL-67.2%
32592	Т	BAYER CROP SCIENCE INC.	BROMOXYNIL MIXED ESTER TECHNICAL	SOLID	BROMOXYNIL-67.6%

Appendix II Label Amendments for Products Containing Bromoxynil

The label amendments presented below represent end-use product label requirements for bromoxynil only, and, as such, it does not include all label requirements for individual end-use products (for example, supplementary protective equipment, first aid statements, disposal statements, and precautionary statements). Information on labels of currently registered products should not be removed unless it contradicts the label statements below. Please read each section carefully and make appropriate changes to your product labels.

- I) For consistency and to meet the current labelling standard, the following is to be included in a section entitled **PRECAUTIONS**:
 - "Do not use in residential areas, which are defined as sites where bystanders may be present during or after spraying, including homes, schools, parks, playgrounds, playing fields, and public buildings."
 - "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."
- II) The existing information on personal protective equipment are required to be revised as below in a section entitled **PRECAUTIONS**:
 - "Ground applications: Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up and repair. Wear a long-sleeved shirt and long pants, chemical resistant gloves, and socks plus shoes during applications. Gloves are not required during application within a closed cab."
 - "Aerial applications: the field crew and the mixer/loaders: Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up and repair."
 - "Aerial applicators: Wear a long-sleeved shirt, long pants, socks and shoes during application. Gloves are not required during application within a closed cockpit. Do not allow the pilot to mix chemicals to be loaded onto the aircraft."
- III) The existing information on restricted entry intervals of garlic and sweet corn is required to be revised as below in a section entitled **PRECAUTIONS**:
 - "DO NOT enter or allow worker entry into treated areas during the restricted-entry intervals (REIs) specified in the following table:

CROP	POST- APPLICATION ACTIVITY	REI
Garlic	Irrigation, handset All other activities	2 days 24 hours
Sweet Corn	Irrigation, handset Harvest, hand All other activities	5 days 20 days 24 hours

- IV) For clarity for labels with approved use for two applications at 336 g a.e./ha on CORN (Field & Sweet), the following is required in a section entitled **DIRECTIONS FOR USE**:
 - "Corn may be treated with a broadcast post-emergence application at the recommended rate from the 4-leaf stage onward. To ensure adequate coverage of weeds, drop pipes should be used when corn is beyond the 8-leaf stage or for a second application for later germinating weeds such as cocklebur and velvetleaf. Minimum re-treatment interval for the second application is 21 days. The pre-harvest interval (PHI) is 20 days."
- V) For clarity for labels with approved use for two applications at 336 g a.e./ha on ESTABLISHED ALFALFA (for seed production only, Provinces of Alberta, Saskatchewan, Manitoba only), the following is required in a section entitled **DIRECTIONS FOR USE**:
 - "Established alfalfa may be treated until alfalfa is 25 cm tall. Maximum of 2 applications per year. Minimum re-treatment interval for the second application is 21 days."
- VI) For consistency and to meet the current labelling standard, the following statements are required in a section entitled **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."
- VII) For consistency and to meet the current labelling standard, the following statements are required in a section entitled **ENVIRONMENTAL PRECAUTIONS:**
 - "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 vegetative strip between the treated area and the edge of the water	ced by including a body."

References

Published Information

PMRA	Reference
Document	
Number	
2960394	PSRD2019-01. Proposed Special Review Decision: Special Review for
	Bromoxynil and Its Associated End-use Products, 30 January 2019