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Proposed Maximum Residue Limit

PMRL2024-11

Bromoxynil

(publié aussi en français)

19 June 2024

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

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2024-11E (print version)
H113-24/2024-11E-PDF (PDF version)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide bromoxynil, as part of the following applications for Canadian use under submissions 2016-8092, 2017-4572 and 2017-4583.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested applications to add the new commodities of leeks, green onions and dry bulb shallots to the product label of Pardner Herbicide, containing technical grade bromoxynil, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 18001.

The evaluation of these bromoxynil applications indicated that the end-use products have value, and the human health and environmental risks associated with the new uses are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when bromoxynil is used according to the supported label directions. Therefore, foods containing residues resulting from these uses are safe to eat, and MRLs are being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

Dietary health assessment

In assessing the risk of a pesticide, Health Canada combines information on pesticide toxicity with information on the degree and duration of dietary exposure to the pesticide residue from food. The risk assessment process involves four distinct steps:

- 1) Identifying the toxicology hazards posed by the pesticide;
- 2) Determining the "acceptable dietary level" for Canadians (including all vulnerable populations), which is protective of adverse health effects;
- 3) Estimating human dietary exposure to the pesticide from all applicable sources (domestic and imported commodities); and
- 4) Characterizing health risk by comparing the estimated human dietary exposure to the acceptable dietary level.

Before registering a pesticide for food use in Canada, Health Canada must determine the quantity of residues that could remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health (Steps 3 and 4 above). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to approved label directions is not a health concern. The proposed MRL is then subject to consultation to legally specify it as an MRL.

¹ A maximum residue limit (MRL) is the maximum amount of residue that may remain in or on food when a pesticide is used according to label directions.

An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except for certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for bromoxynil is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for bromoxynil in accordance with the process outlined in the Next steps section of this document.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRLs

The proposed MRLs, to be added to the MRLs already established for bromoxynil, are summarized in Table 1.

Table 1 Proposed maximum residue limits for bromoxynil

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Bromoxynil	3,5-dibromo-4-hydroxybenzotrile	0.02	Green onions, shallot bulbs
		0.01	Leeks

¹ ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International situation and trade implications

Currently, there are no tolerances in the United States (U.S.) for bromoxynil in or on the petitioned commodities listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide; nor are there Codex MRLs² listed for bromoxynil in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

² The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for bromoxynil up to 75 days from the date of publication of this document (by 2 September 2024). Please forward your comments to Publications. Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRLs. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of field trial data used to support the proposed maximum residue limits

Residue data for bromoxynil were submitted to support the use of Pardner Herbicide on leeks.

To support the use of Pardner Herbicide on green onions and shallot bulbs, previously reviewed residue data from field trials conducted on dry bulb onions and garlic, a field rotational crop study, a confined crop rotation study, and the physical and environmental properties of bromoxynil were reassessed.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 9% of the acute reference dose, and therefore there are no health concerns.

Chronic (non-cancer and cancer) dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 60% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for bromoxynil was based upon the field trial data and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for bromoxynil used to calculate the proposed MRLs for green onions, leeks and shallot bulbs.

Table A1 Summary of field trial data used to support the MRLs

Commodity	Application method/ Total application rate (g a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Leeks	Post-emergent foliar/ 270-287	56	<0.01	<0.01
Dry bulb onions	Post-emergent foliar/ 560-582	62–103	<0.02	<0.02
Garlic	Post-emergent foliar/ 1120	60–61	<0.02	<0.02

¹ g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover residues of bromoxynil. Dietary risks from exposure to residues of bromoxynil in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA document number	Citation
2711720	2016, Residue report - Bromoxynil: Magnitude of the Residue on Leek, DACO: 7.4.1,7.4.2