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Proposed Maximum Residue Limit

PMRL2023-21

Clopyralid

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide clopyralid as part of the following applications for Canadian use, under pesticide submission numbers 2018-0878 and 2019-5792.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has approved the requested applications to add the new commodities of Saskatoon berries and dry bulb onions to the product label of Lontrel 360 Herbicide, containing technical grade clopyralid, to control certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 23545.

The evaluation of these clopyralid applications indicated that the end-use product has 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 clopyralid is used according to the supported label directions. Therefore, foods containing residues at these levels 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

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.

consultation to legally specify it as an MRL. 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 clopyralid is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for clopyralid in accordance with the guidance reported 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 replace or be added to the MRLs already established for clopyralid, are summarized in Table 1.

Table 1 Proposed maximum residue limits for clopyralid

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Clopyralid	3,6-dichloro-2-pyridinecarboxylic acid	0.4	Bulb onions (crop subgroup 3-07A)
		0.1	Bushberries (crop subgroup 13-07B) ²

¹ ppm = parts per million

² An MRL of 0.1 ppm is currently established for "blueberries". This MRL will be expired, as the individual commodities of highbush blueberries and lowbush blueberries (both terms reflect current crop terminology) will be covered by the proposed MRL on Bushberries (crop subgroup 13-07B).

The commodities included in the listed crop groups/subgroups can be found on the Residue Chemistry Crop Groups webpage in the Pesticides section of Canada.ca.

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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for clopyralid in Canada with corresponding American tolerances. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for clopyralid in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Table 2 Comparison of proposed Canadian MRLs, American tolerances and Codex MRLs (where different)

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Bulb onions (crop subgroup 3-07A)	0.4	0.4	Not Established
Bushberries (crop subgroup 13-07B)	0.1	0.50	Not Established

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for clopyralid up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). 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 separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

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

Appendix I

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

Residue data for clopyralid were submitted to support the use of Lontrel 360 Herbicide on dry bulb onions. In addition, previously reviewed residue data from field trials conducted in/on highbush blueberries were reassessed in the framework of this petition.

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 13% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 31% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for clopyralid was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for bulb onions (crop subgroup 3-07A) and bushberries (crop subgroup 13-07B).

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)
Highbush blueberries	Foliar application/299	45	<0.05	0.07
Dry bulb onions	Foliar broadcast/199–208	42–49	0.013	0.06
	Foliar broadcast/313–334	50–120	<0.05	0.24

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 to cover residues of clopyralid. Dietary risks from exposure to residues of clopyralid 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#	Citation
3040391	2019, Clopyralid: Magnitude of the Residue on Onion (Dry Bulb), DACO: 7.3, 7.4.1
3040392	2018, Clopyralid: Magnitude of the Residue on Dry Bulb Onion, DACO: 7.2.1,7.4.1,7.4.2.