Proposed Maximum Residue Limit PMRL2022-20

Clomazone

(publié aussi en français)

25 November 2022

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: H113-24/2022-20E (print version)
H113-24/2022-20E-PDF (PDF version)

Purpose of consultation

Maximum residue limits (MRLs)[1] are being proposed for the pesticide clomazone, as part of the following application for Canadian use, under submission number 2020-3018.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add the new commodities of mustard (oilseed and condiment)[brown, Oriental and yellow] and camelina (Gold of Pleasure) to the product label of Command 360 ME Herbicide, containing technical grade clomazone, to control early season cleavers. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 27827.

The evaluation of this clomazone application 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 clomazone is used according to the supported label directions. Therefore, foods containing residues resulting from this use 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 clomazone is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for clomazone 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 clomazone, are summarized in Table 1.

Table 1 Proposed maximum residue limits for clomazone

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Clomazone	2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone	0.05	Gold of Pleasure seeds, mustard seeds (condiment type), mustard seeds (oilseed type)

[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

The MRLs proposed for clomazone in Canada in or on Gold of Pleasure seeds and mustard seeds (oilseed type) are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no American tolerances for clomazone in or on mustard seeds (condiment type) listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide; nor are there Codex MRLs[2] listed for clomazone 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 clomazone 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.

Appendix I

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

Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this petition. In addition, residue data from studies conducted at exaggerated rates in treated canola were reassessed to determine the potential for concentration of residues of clomazone into processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of clomazone is not likely to cause acute health effects in the general population (including infants and children).

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 1% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for clomazone 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 Gold of Pleasure seeds, mustard seeds (condiment type) and mustard seeds (oilseed type).

Table A1 Summary of field trial and processing 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)	Experimental processing factor
Canola seed	Pre-emergent soil application/ 404–436	90–122	<0.02	<0.02	No quantifiable residues observed at exaggerated rates.
	Pre-emergent soil application/2110	122			

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of clomazone. Dietary risks from exposure to residues of clomazone 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

None.