Proposed Maximum Residue Limit PMRL2024-03

Cloquintocet-mexyl

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Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for cloquintocet-mexyl (to cover residues of the safener cloquintocet acid), as part of the following application for Canadian use, under submission number 2022-0479.

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 commodity of rye (belonging to the wheat crop subgroup 15-21A) to the product label of Simplicity GoDRI Herbicide containing technical grade pyroxsulam and safener cloquintocet-acid, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 31916.

The evaluation of this cloquintocet acid application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when cloquintocet acid is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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] An 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 MRL for cloquintocet-mexyl is being conducted via this document. Consultation on the proposed MRL for pyroxsulam is being addressed under a separate action. Health Canada invites the public to submit written comments on the proposed MRL for cloquintocet-mexyl 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 MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to replace the MRL already established for cloquintocet-mexyl, is summarized in Table 1.

Table 1 Proposed maximum residue limit for cloquintocet-mexyl

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Cloquintocet-mexyl	1-methylhexyl[(5-chloro-8-quinolinyl)oxy]acetate, including the metabolite [(5-chloro-8-quinolinyl)oxy]acetic acid (expressed in parent equivalents)	0.01	Wheat (crop subgroup 15-21A)[2]

[1] ppm = parts per million
[2] The MRL is proposed to replace the currently established 0.01 ppm MRL for wheat with an MRL for all food commodities in the crop subgroup at the same MRL value.

The commodities included in the listed crop subgroup 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 geographic locations of the crop field trials used to generate residue chemistry data.

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

Table 2 Comparison of proposed Canadian MRL, American Tolerance and Codex MRL

Food commodity	Proposed Canadian MRL	Established American Tolerance	Established Codex MRL
Wheat (crop subgroup 15-21A)	0.01	0.1 (Wheat, grain)	Not Established

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for cloquintocet-mexyl up to 75 days from the date of publication of this document (by 17 April 2024). 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is 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 limit

Previously reviewed residue data from field trials conducted in/on wheat were reassessed in the framework of this petition for the proposed use on rye. The analytical methods used in these field trial studies can measure both cloquintocet-mexyl and cloquintocet-acid. Cloquintocet-mexyl degrades to cloquintocet acid in vivo. Residues of cloquintocet acid can thus be expressed as cloquintocet-mexyl, which is the form for maximum residue limit (MRL) setting. In addition, processing studies in treated wheat were also reassessed to determine the potential for concentration of residues of cloquintocet-mexyl (which degrades to cloquintocet acid) in processed commodities of rye.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of cloquintocet-mexyl (which degrades to, and is considered toxicologically equivalent to, cloquintocet acid) 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 11% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for MRL for cloquintocet-mexyl was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for cloquintocet-mexyl and cloquintocet acid used to calculate the proposed MRL for wheat crop subgroup (15-21A).

Table A1 Summary of field trial and processing data used to support the MRL

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
Wheat grain	Foliar broadcast/ 45	50–110	<0.01	<0.01	No quantifiable residues observed at exaggerated rate

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

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover residues of cloquintocet-mexyl and cloquintocet acid (expressed as cloquintocet-mexyl). Dietary risks from exposure to residues of cloquintocet-mexyl and cloquintocet acid in these crop commodities at the proposed MRL 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.