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Proposed Maximum Residue Limit

PMRL2023-11

Oxathiapiprolin

(publié aussi en français)

17 February 2023

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: H113-24/2023-11E (print version)
H113-24/2023-11E-PDF (PDF version)

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Purpose of consultation

A maximum residue limit (MRL)¹ for **imported** commodities is being proposed for the pesticide oxathiapiprolin as part of the following application under submission number 2020-5312, in order to permit the import and sale of food in Canada that could contain oxathiapiprolin residues. This import MRL proposal does not result in a change of the current approved conditions of use in Canada.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify a maximum residue limit (MRL) for oxathiapiprolin on imported commodities of crop subgroup 24B (Tropical and subtropical, medium to large fruits, smooth, inedible peel), to control phytophthora root and crown rot.

Oxathiapiprolin is a fungicide currently registered in Canada for use on various commodities.

Health Canada has determined the quantity of residues that may remain in or on the imported commodities when oxathiapiprolin is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the 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.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, 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

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.

above), Health Canada concludes that consuming residues resulting from use according to label directions approved in the foreign country is not a health concern. The proposed MRL is then subject to consultation to legally specify the MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRL for oxathiapiprolin on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for oxathiapiprolin 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 [Canada’s Notification Authority and Enquiry Point](#).

Proposed MRL

The proposed MRL, to be added to the MRLs already established for oxathiapiprolin, is summarized in Table 1.

Table 1 Proposed maximum residue limit for oxathiapiprolin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Oxathiapiprolin	1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone	0.1	Tropical and subtropical, medium to large fruits, smooth, inedible peel (crop subgroup 24B)

¹ ppm = parts per million

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

The MRL proposed for oxathiapiprolin in Canada is the same as corresponding American tolerance as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs² listed for oxathiapiprolin in or on the petitioned commodities on the Codex Alimentarius [Pesticide Index](#) webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for oxathiapiprolin 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 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

Residue data for oxathiapiprolin on avocados and pomegranates were submitted to support the maximum residue limit on imported commodities of crop subgroup 24B. In addition, a processing study in treated pomegranates was reviewed to determine the potential for concentration of residues of oxathiapiprolin in processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of oxathiapiprolin 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 2% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for a maximum residue limit (MRL) for oxathiapiprolin on imported commodities was based upon the residues observed in crop commodities treated according to exaggerated rates in the exporting country, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data used to calculate the proposed MRL for imported commodities in crop subgroup 24B.

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
Avocados	Soil + Foliar/ 352-398	1	<0.01	0.039	Not applicable
Pomegranates	Soil + Foliar/ 351-356	1	0.026	0.036	Juice: <0.5×

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 to cover residues of oxathiapiprolin. Dietary risks from exposure to residues of oxathiapiprolin in these imported 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 imported foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3179227	2018, Oxathiapiprolin - Magnitude of the Residue on Avocado, DACO: 7.4.1,7.4.2
3179228	2018, Oxathiapiprolin - Magnitude of the Residue on Pomegranate, DACO: 7.4.1,7.4.2,7.4.5