## **Proposed Maximum Residue Limit**

Santé

Canada

PMRL2020-31

# Oxathiapiprolin

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Under the authority of the <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish maximum residue limits (MRLs) for oxathiapiprolin on imported citrus fruits (crop group 10) (revised), cacao beans, citrus oil, grapes and raisins to permit the import and sale of foods containing such residues.

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

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when oxathiapiprolin is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an 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 where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for oxathiapiprolin is being conducted via this document (see Next steps). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

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 Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to be added to the MRLs already established for oxathiapiprolin, are as follows.

Table 1 Proposed maximum residue limits for oxathiapiprolin

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Oxathiapiprolin	1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1 <i>H</i> -pyrazol-1-yl]-ethanone	2.0	Citrus oil
		1.3	Raisins
		0.9	Grapes
		0.15	Cacao beans
		0.06	Citrus fruits (crop group 10) (revised)

ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides section of the Canada.ca website.

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**

Table 2 compares the MRLs proposed for oxathiapiprolin in Canada with corresponding American tolerances and Codex MRLs. American tolerances are listed in the <u>Electronic Code of Federal Regulations</u>, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius <u>Pesticide Index</u> webpage, by pesticide or commodity.

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

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Citrus oil	2.0	2.0	3
Dried grapes/raisins	1.3	0.70	1.3
Grapes	0.9	0.70	0.9
Cacao beans	0.15	0.15	Not established
Citrus fruits (crop group	0.06	0.06	0.05
10) (revised)			

#### **Next steps**

The PMRA invites the public to submit written comments on the proposed MRLs 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). The PMRA will consider all comments received before 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 <a href="Maximum Residue Limit Database">Maximum Residue Limit Database</a>.

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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 oxathiapiprolin in oranges, grapefruits, lemons, and grapes were submitted to support the maximum residue limits on imported citrus fruits, cacao beans, and grapes. In addition, processing studies in treated oranges and grapes were reviewed to determine the potential for concentration of residues of oxathiapiprolin into processed commodities.

#### **Maximum residue limits**

The recommendation for maximum residue limits (MRLs) for oxathiapiprolin was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported citrus fruits, cacao beans and grapes.

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

Commodity	Application method/ Total application rate (g a.i./ha) <sup>1</sup>	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Oranges	Postemergent soil and foliar	0	< 0.010	0.024	
Grapefruits			< 0.010	0.018	47× (citrus oil)
Lemons	application/ 301–324	O O	< 0.010	0.033	+/∧ (cittus oii)
Grapes	Postemergent foliar application/ 97.5–125	14	0.021	0.41	1.5× (raisins)

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

#### MRL for cacao beans

Residue data for oxathiapiprolin residues on cacao beans were not provided. As this request pertains to the establishment of an MRL on imported cacao beans, the rationale to waive this data requirement used in the exporting country was found acceptable. The basis of the rationale was that the use of the oxathiapiprolin residue data for citrus fruits would be conservative, considering the surface area to mass ratios of citrus fruits compared to cacao beans and that cacao peel is inedible. In addition, the maximum theoretical concentration factor of 2.5-fold for cacao based on the loss of water during processing was used, which is also conservative. The resulting MRL for cacao beans was calculated by applying this factor to the citrus fruit American tolerance value  $(2.5 \times 0.06 = 0.15)$ .

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of oxathiapiprolin. Residues of oxathiapiprolin in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.