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Proposed Maximum Residue Limit

PMRL2022-12

Oxathiapiprolin

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

Canada 

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Purpose of consultation

A [maximum residue limit](#) (MRL)¹ is being proposed for the pesticide oxathiapiprolin, as part of the following application for Canadian use, under submission number 2019-0144.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested application to add the new commodity of hops to the product label of Orondis Ultra Fungicide, containing technical grade mandipropamid and oxathiapiprolin, to control downy mildew. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [32805](#). PMRA is also proposing acceptability to set MRLs on dry soybeans, sunflower seeds and poultry commodities, for which the uses were previously registered under the oxathiapiprolin-only submissions 2016-0340 (Lumisena Fungicide Seed Treatment), and 2016-0407 (Plenaris 200FS Seed Treatment), but the MRLs were not specified. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers [33001](#) and [33002](#), respectively.

The evaluation of this mandipropamid and oxathiapiprolin 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 oxathiapiprolin 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](#). The currently established 50 ppm MRL for mandipropamid in/on hops (dried cones) is sufficient to cover residues resulting from this new use and is therefore unaffected by this MRL action.

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 human 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

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.

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. 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 oxathiapiprolin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs 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 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 oxathiapiprolin, are summarized in Table 1.

Table 1 Proposed maximum residue limits 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	5.0	Hops, dried cones
		0.01	Dry soybeans; sunflower seeds; eggs; fat, meat and meat byproducts of poultry

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

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. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

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

Table 2 Comparison of proposed Canadian MRLs, American Tolerances and Codex MRLs

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Hops (dried cones)	5.0	5	Not Established
Dry soybeans	0.01	0.01	0.01
Sunflower seeds	0.01	0.01	0.01
Eggs; fat, meat and meat byproducts of poultry	0.01	Not established	0.01

Next steps

Health Canada 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). 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 oxathiapiprolin on hops were submitted to support the use of Orondis Ultra Fungicide on hops. In addition, residue data for oxathiapiprolin on soybean seeds and sunflower seeds were submitted to support the registered uses of Dupont Lumisena Fungicide and Plenaris Fungicide on soybeans and sunflowers.

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 are not a health concern.

Maximum residue limits

The recommendations for the maximum residue limits (MRLs) for oxathiapiprolin were 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 MRL for hops, soybeans, and sunflowers.

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

Commodity	Application method/ Total application rate	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Hops (dried cones)	Soil drench followed by 3 foliar applications/ 388–398 g a.i./ha ¹	6–8	0.33	2.1
Soybean seeds	Seed treatment/ 0.0625 – 0.0841 mg a.i./seed ²	126 – 151	<0.010	<0.010
	Seed treatment/ 0.2515 – 0.2528 mg a.i./seed ²	126 – 151	<0.010	<0.010
Sunflower seeds	Seed treatment/ 0.01877 – 0.0212 mg a.i./seed ²	105 – 148	<0.010	<0.010

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

² mg a.i./seed = milligrams of active ingredient per seed

Based on the dietary burden and residue data, MRLs of 0.01 ppm in eggs; fat, meat, and meat by-products of poultry to cover residues of oxathiapiprolin are also proposed.

Following the review of all available data, the MRLs as proposed in Table 1 are recommended to cover residues of oxathiapiprolin. Dietary risks from exposure to residues of oxathiapiprolin in these crop and animal 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 #	Reference
2600655	2015, Magnitude of residues of oxathiapiprolin and its metabolites in raw and processed soybean commodities of plants grown from seed treated with oxathiapiprolin (DPX-QGU42) 200 G/L SC - USA, 2014, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1,IIIA 8.3.2,IIIA 8.3.3
2600656	2015, Magnitude of residues of oxathiapiprolin and its metabolites in sunflower seed of plants grown from seed treated with oxathiapiprolin (DPX-QGU42) 200G/L SC - USA AND CANADA 2014, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1,IIIA 8.3.2,IIIA 8.3.3
2951332	2018, Oxathiapiprolin: Magnitude of the Residue on Hops, DACO: 7.4.1,7.4.2
3047638	2015, Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Tobacco Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014, DACO: 7.4.1
3047639	2015, Oxathiapiprolin OD (A2094JA) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Cucumber Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations -USA, 2015, DACO: 7.4.1
3047640	2015, Oxathiapiprolin OD (A2094JA) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Brassica Head and Stem Vegetables Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014., DACO: 7.4.1