Proposed Maximum Residue Limit PMRL2018-05

Oxathiapiprolin

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

Internet: pmra.publications@hc-sc.gc.ca

Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product labels of DuPont™ Zorvec™ Epicaltrin™ Fungicide, DuPont™ Zorvec™ Enicade™ Fungicide, Orondis™ 200SC Fungicide, and Orondis™ Fungicide, containing technical grade oxathiapiprolin, is acceptable. The specific uses approved in Canada are detailed on the labels of DuPont™ Zorvec™ Enicade™ Fungicide, DuPont™ Zorvec™ Epicaltrin™ Fungicide, Orondis™ Fungicide, and Orondis™ 200SC Fungicide, Pest Control Products Act Registration Numbers 32101, 32102, 32103, and 32104, respectively.

The PMRA has also concluded that the addition of the new in-furrow use to the product label of Orondis™ Fungicide, containing technical grade oxathiapiprolin, and registration of the new end-use product Orondis™ Gold Fungicide, containing technical grade oxathiapiprolin and metalaxyl-M and S-Isomer, is acceptable. The specific uses approved in Canada are detailed on the labels of Orondis™ Fungicide and Orondis™ Gold Fungicide, Pest Control Products Act Registration Numbers 32103 and 32806, respectively.

The evaluation of these oxathiapiprolin applications indicated that the end-use products have value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to 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. This quantity is then legally established as a maximum residue limit (MRL). 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, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

The currently established 0.5 ppm MRL for metalaxyl in/on potatoes is sufficient to cover residues resulting from this new use and therefore unaffected by this MRL action. Furthermore, the exiting MRLs for metalaxyl are adequate to cover the uses of Orondis Gold Fungicide.

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.

The proposed MRLs, to replace or 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)[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)-1*H*-pyrazol-1-yl]-ethanone	80	Dried basil leaves
		10	*Brassica* leafy greens (crop subgroup 4-13B); fresh basil leaves
		2	Stalk and stem vegetables (crop subgroup 22A)
		0.5	Caneberries (crop subgroup 13-07A)
		0.04	Tuberous and corm vegetables (crop subgroup 1C)[2]

[1] ppm = parts per million
[2] The MRL of 0.04 ppm is proposed to replace the established MRL of 0.01 ppm for all crops in Crop Subgroup 1C.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management 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

The MRLs proposed for oxathiapiprolin in Canada 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 Codex MRLs[1] listed for oxathiapiprolin in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

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

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

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

Residue data for oxathiapiprolin in potatoes, raspberries/blackberries, asparagus, mustard greens and basil (field and greenhouse) were submitted to support the domestic use of Orondis™ Gold Fungicide, DuPont™ Zorvec™ Epicaltrin™ Fungicide, DuPont™ Zorvec™ Enicade™ Fungicide, Orondis™ 200SC Fungicide, and Orondis™ Fungicide on tuberous and corm vegetables (Crop Subgroup 1C), caneberries (Crop Subgroup 13-07A), stalk and stem vegetables (Crop Subgroup 22A), *Brassica* leafy vegetables (Crop Subgroup 4-13B), and basil (field and greenhouse).

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for oxathiapiprolin 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 tuberous and corm vegetables (Crop Subgroup 1C), caneberries (Crop Subgroup 13-07A), stalk and stem vegetables (Crop Subgroup 22A), *Brassica* leafy vegetables (Crop Subgroup 4-13B) and basil (field and greenhouse).

Table A1 Summary of Field Trial and Processing Data Used to Support 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
Potato tubers	In-furrow spray at planting + soil directed spray at-hilling/ 270-293	50-124	<0.01	0.0368	Residues did not concentrate in processed commodities.
Raspberries and Blackberries	Soil directed/ 554 – 578	1 – 6	<0.01	0.223	Not applicable
Asparagus	Soil directed/ 554 – 566	0	0.275	0.745	Not applicable
	Crown soak/ 279 – 789	19 – 43	<0.01	<0.01	
		314 – 383	<0.01	<0.01	
Field and Greenhouse Fresh Basil Leaves	Foliar/ 141 – 148	0	1.8	5.4	Not applicable
Field Dried Basil leaves	Foliar/ 141 – 145	0	24	29	Not applicable
Mustard greens	Foliar/138 – 144	0	1.46	4.29	Not applicable

[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 oxathiapiprolin. Residues of oxathiapiprolin in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.