

Proposed Maximum Residue Limit

Santé

Canada

PMRL2021-01

Difenoconazole

(publié aussi en français)

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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 commodities to the product label of A20259 Fungicide, containing pydiflumetofen and difenoconazole, is acceptable. The specific uses approved in Canada are detailed on the label of A20259 Fungicide, *Pest Control Products Act* Registration Number 33020. Consultation on the maximum residue limits (MRLs) for pydiflumetofen is being conducted under a separate action.

The evaluation of this difenoconazole application indicated that the end-use product has 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 difenoconazole 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 the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for difenoconazole, are as follows.

 Table 1
 Proposed maximum residue limits for difenoconazole

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Difenoconazole	1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1 <i>H</i> -1,2,4-triazole	8.0	Garden beet tops, radish tops
		0.6	Root vegetable (crop subgroup 1A) ²

 $[\]frac{1}{1}$ 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.

² This MRL is proposed to replace the current MRLs for carrot and sugar beet roots.

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 locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for difenoconazole in Canada with corresponding American tolerances and Codex MRLs.¹ 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 Canadian MRLs, American tolerances and codex MRLs (where different)

The PMRA invites the public to submit written comments on the proposed MRLs for

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Root vegetable (Crop subgroup 1A)	0.6	0.6 (Vegetable, root, subgroup 1A, except ginseng)	0.2 (sugar beet) 0.2 (carrot)
Radish tops	8.0	8.0	Not established
Garden beet tops	8.0	(Vegetable, leaves of root and tuber, group 2)	Not established

difenoconazole 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

Next steps

established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

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 difenoconazole on radish (roots and tops) were submitted to support the domestic use of A20259 Fungicide on root vegetables (crop subgroup 1A). Previously reviewed residue data from field trials conducted in/on sugar beets and carrots and a processing study conducted on sugar beet roots were re-assessed in the framework of this petition.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for difenoconazole 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.

Table A1 Summary of field trial and processing data used to support the 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
Radish roots	Foliar broadcast/ 495–510	7	0.025	0.287	Not required
Radish tops	Foliar broadcast/ 495–510	7	0.236	3.830	Not required
Carrot roots	Foliar broadcast/ 528	7	< 0.01	0.181	Not required
Sugar beet roots	Foliar broadcast/	7	<0.01	0.23	Refined sugar: 0.3× Molasses: 0.5×
Sugar beet tops ²	Foliar broadcast/	7	0.150 (minimum)	5.2	Not required

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 difenoconazole. Residues of difenoconazole 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.

² Data from sugar beet tops were extended to garden beet tops.