Proposed Maximum Residue Limit PMRL2015-26

Difenoconazole

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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
healthcanada.gc.ca/pmra
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 new uses on pome fruit commodities for the product label of A20682 Fungicide, containing technical grade difenoconazole, is acceptable. The specific uses approved in Canada are detailed on the label of A20682 Fungicide, *Pest Control Products Act* Registration Number 31564.

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 MRL for difenoconazole 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 MRL can be found in Appendix I.

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 the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for difenoconazole, is as follows.

Table 1 Proposed Maximum Residue Limits for Difenoconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Difenoconazole	1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole	5.0[2]	Pome Fruit (Crop Group 11-09)

[1] ppm = parts per million

[2] This MRL is proposed to replace the established MRL of 1.0 ppm for difenoconazole in pome fruits

This MRL is 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 Health Canada's 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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for difenoconazole in Canada with corresponding American tolerance and Codex MRL.[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 Residues in Food website, 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)
Pome Fruit (Crop Group 11-09)	5.0	5.0	0.5

Next Steps

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

[1] 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 MRL

Residue data from field trials conducted in the United States were submitted to support the domestic use of A20682 Fungicide on pome fruits. Difenoconazole was post-harvest applied to crops at the proposed rates according to label directions.

Maximum Residue Limit(s)

The recommendation for maximum residue limit (MRL) 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 MRL for Crop Group 11-09 (Pome Fruit).

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor
			Min	Max	
Apples	Dip/0.30 g ai/L	0	0.584	1.36	Not applicable
	Drench/0.30-0.32 g ai/L		0.496	2.61	
	Spray/112.5 g ai per 90,000 kg fruit		0.467	1.41	
Pears	Dip/0.30 g ai/L	0	0.592	1.06	
	Drench/0.30-0.32 g ai/L		0.696	1.37	
	Spray/112.5 g ai per 90,000 kg fruit		0.381	1.17	

[1] Residues of difenoconazole.

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