Proposed Maximum Residue Limit PMRL2013-33

Fludioxonil

(publié aussi en français)

20 June 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2013-33E (print version)
H113-24/2013-33E-PDF (PDF version)

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 label of SWITCH® 62.5 WG Fungicide, containing technical grade cyprodinil and fludioxonil, is acceptable. The specific uses approved in Canada are detailed on the label of SWITCH® 62.5 WG Fungicide, Pest Control Products Act Registration Number 28189.

The evaluation of this fludioxonil application indicated that the end-use product has merit and 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 fludioxonil 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. MRL consultation for the cyprodinil present in SWITCH® 62.5 WG Fungicide is being conducted under separate actions.

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 Standards Council of Canada.

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

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	30[a]	Spinach
		0.5[b]	Fruiting Vegetable Group (Crop Group 8-09), except tomatillos and tomatoes

ppm = parts per million

[a] The recommended MRL of 30 ppm will replace the currently established MRL of 0.01 ppm (EMRL2008-02).

[b] The recommended MRL of 0.5 ppm will replace the currently established MRL of 0.01 ppm for bell peppers, eggplants, groundcherries, non-bell peppers, pepinos, and pepper hybrids. A new MRL is not required for tomatillos and tomatoes since there is an established MRL of 0.5 ppm for these two crops (EMRL2012-28).

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 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 pesticide(s) or for food commodity(ies).

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 MRLs proposed for fludioxonil 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 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)
Fruiting Vegetables (Crop Group 8-09), except tomatillos and tomatoes	0.5	0.5 (Vegetable, fruiting, group 8-10, except tomato)	1.0 (Peppers, Sweet (including pimento or pimiento))
Spinach	30	30 (Leafy greens subgroup 4A)	Not Established

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

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil 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 Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data for fludioxonil in spinach, peppers, and non-bell peppers were submitted to support the domestic use of SWITCH® 62.5 WG Fungicide on spinach, field peppers, and greenhouse peppers. In addition, previously reviewed residue data from field trials conducted in/on tomatoes were reassessed in the framework of this petition.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the residues observed in commodities treated at exaggerated rates from submitted field trials, and the guidance provided in the OECD MRL Calculator.

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

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Spinach	Foliar/ 971.8-1021.1	0	1.8	16	Not applicable
Peppers and non-bell peppers	Foliar/ 972.9-1059.2	0	<0.02	0.31	

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