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Proposed Maximum Residue Limit

PMRL2014-72

Fludioxonil

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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 Crop Subgroups 13-07A (Caneberry), 13-07B (Bushberry), 13-07F (Small fruit vine climbing, except fuzzy kiwifruit) and 13-07G (Low growing berry except cranberries) to the product label of Switch 62.5 WG Fungicide, containing technical grade fludioxonil and cyprodinil, 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. Consultation on the proposed MRLs for cyprodinil is being conducted via a separate 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 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) ¹	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 <i>H</i> -pyrrole-3-carbonitrile	7.0 ²	Caneberry subgroup (Crop Subgroup 13-07A)
		3.0 ³	Low growing berry subgroup (Crop Subgroup 13-07G)
		2.0 ⁴	Bushberry subgroup (Crop Subgroup 13-07B), Small fruit vine climbing, except fuzzy kiwifruit subgroup (Crop Subgroup 13-07F)

¹ ppm = parts per million

² This MRL is proposed to replace the established MRL of 4.2 ppm for residues of fludioxonil in/on blackberries, raspberries and loganberries

³ This MRL is proposed to replace the established MRL of 2.0 ppm for residues of fludioxonil in/on strawberries

⁴ The established MRL of 2.0 ppm for residues of fludioxonil in/on blueberries will be extended to all crops in Crop Subgroup 13-07B and the established MRL of 2.0 ppm for residues of fludioxonil in/on grapes will be extended to all crops in Crop Subgroup 13-07F

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 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 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.

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

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

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Caneberry subgroup (Crop Subgroup 13-07A)	7.0	5.0	5 (raspberries, red, black; blackberries; dewberries (including boysenberry and loganberry))
Low growing berry subgroup (Crop Subgroup 13-07G)	3.0	3.0	3 (strawberry)
Bushberry subgroup (Crop Subgroup 13-07B), Small fruit vine climbing, except fuzzy kiwifruit subgroup (Crop Subgroup 13-07F)	2.0	2.0	2 (blueberries, grapes)

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 from field trials conducted in Canada and the United States were reassessed in the framework of this petition to support the domestic use of Switch 62.5 WG Fungicide on Crop Subgroups 13-07A (Caneberry), 13-07B (Bushberry), 13-07F (Small fruit vine climbing, except fuzzy kiwifruit) and 13-07G (Low growing berry except cranberries). Raspberries, highbush blueberries, grapes and strawberries, the representative crops for the Crop Subgroups, respectively, were treated with fludioxonil at the proposed rate and/or at exaggerated rates and harvested according to label directions.

Maximum Residue Limits

The recommendation for the maximum residue limits (MRLs) for fludioxonil was based upon the submitted supervised residue 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 Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	Preharvest Interval (days)	Residues (ppm)	
			Min	Max
Raspberries	Foliar application /0.96-1.00	0	0.81	4.17
Highbush blueberries	Foliar application /0.95-1.01	0	<0.05	0.94
Grapes	Foliar application /0.47-0.52	6-8	0.18	1.10
Strawberries	Foliar application /0.73-1.51	0	0.14	1.32

Following the review of all available data, MRLs of 7 ppm (Crop Subgroup 13-07A), 3 ppm (Crop Subgroup 13-07G) and 2 ppm (Crop Subgroup 13-07B and 13-07F) are recommended to cover residues of fludioxonil. Residues of fludioxonil in Crop Subgroups 13-07A, 13-07B, 13-07F and 13-07G at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.