Agence de réglementation de la lutte antiparasitaire

Proposed Maximum Residue Limit

PMRL2007-10

Fludioxonil

(publié aussi en français)

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> (PCPA), has granted conditional registration to the end-use product Scholar 50WP Fungicide, containing technical grade fludioxonil, for the postharvest control of labelled fungal diseases on pome fruits (Crop Group 11) and stone fruits (Crop Group 12). See Appendix I for a list of crop group commodities. The specific uses that were approved in Canada are detailed on the Scholar 50WP label (PCPA Registration Number 28568).

The evaluation of these fludioxonil applications indicated that the end-use product has merit and value and that the human health and environmental risks associated with the new uses are acceptable. Details on these registrations can be found in Evaluation Report <u>ERC2007-04</u>, *Fludioxonil, Scholar 50WP Fungicide*.

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 the label directions and that such residues will not pose an unacceptable health risk. 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.

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the *Canada Gazette*. Amendments to the *Food and Drugs Act* (FDA), via <u>Bill C-28</u>, anticipated to come into force in 2007, will allow pesticide MRLs to be legally established under the PCPA without having to adopt MRLs by regulation under the FDA, resulting in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed MRLs for fludioxonil is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

MRLs have been legally established in Canada for fludioxonil in or on livestock commodities, grapes, mustard, onions, potatoes, rapeseed (canola) and strawberries in addition to four commodities within the stone fruits crop group for which the MRLs are being amended as a result of this action. Close to 300 MRLs for fludioxonil were also proposed in PMRL2006-01.

The proposed/revised MRLs for fludioxonil in Canada in or on food, to be added to those currently established, are as follows:

Table 1 Proposed Maximum Residue Limits and Revisions to Existing MRLs for Fludioxonil

| Common Chemical Name | Chemical Name of Substance | Food Commodities | Existing MRL (ppm) | Proposed MRL (ppm) |
|----------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------|--------------------------|
| Fludioxonil | 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 <i>H</i> -pyrrole-3-carbonitrile | Pome fruits (Crop Group 11) Stone fruits (Crop Group 12) | | 5.0 |
| | | Apricots | 2.0 | 5.0 |
| | | Nectarines | 2.0 | 5.0 |
| | | Peaches | 2.0 | 5.0 |
| | | Plumcots | | 5.0 |
| | | Plums | 2.0 | 5.0 |
| | | Prune plums | _ | 5.0 |
| | | Sweet cherries | | 5.0 |
| | | Tart cherries | _ | 5.0 |

A complete list of all MRLs established in Canada can be found in <u>Table II</u>, <u>Division 15</u> of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's <u>MRL webpage</u>, which will be updated to include the MRLs listed in this document.

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. The proposed MRLs in Canada are the same as corresponding tolerances established in the United States (listed in 40 CFR 180 by pesticide) for both crop groups. Table 2 identifies differences between Canadian MRLs, American tolerances and Codex MRLs (Codex MRLs searchable by pesticide or commodity).

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Codex 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 Commodities | Canadian MRLs (ppm) | American Tolerances (ppm) | Codex MRLs (ppm) |
|----------------------------------------------------------|---------------------------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pome fruits (Crop Group 11) | 5.0 | 5.0 | |
| Pears | | | 0.7 |
| Apples Crabapples Loquats Mayhaws Oriental pears Quinces | | | No Codex MRL established |
| Stone fruits (Crop Group 12) | 5.0 | 5.0 | 5.0 (interim MRL; 2005–2009) |

Next Steps

The PMRA invites the public to submit written comments on the proposed/revised MRLs for fludioxonil within 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). Health Canada will consider all comments received prior to making a final decision on the proposed MRLs for fludioxonil and before posting an Established Maximum Residue Limit document on the PMRA's website once the amendments to the FDA are in force.

Appendix I

Crop Groups: Numbers and Definitions

| Crop Group Number | Name of the Crop Group | Food Commodities Included in the Crop Group |
|----------------------|---------------------------|-------------------------------------------------------------------------------------|
| 11 | Pome fruits | Apples Crabapples Loquats Mayhaws Oriental pears Pears Quinces |
| 12 | Stone fruits | Apricots Nectarines Peaches Plumcots Plums Prune plums Sweet cherries Tart cherries |