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Proposed Maximum Residue Limit

PMRL2016-15

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 of crop subgroup (CSG) 13-07B (Bushberries), except gooseberries, to the product label of Inspire Super Fungicide, containing technical grade difenoconazole and cyprodinil, is acceptable. The specific uses approved in Canada are detailed on the label of Inspire Super Fungicide, *Pest Control Products Act* Registration Number 30827.

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, 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.

For cyprodinil, the previously established MRLs of 4.0 ppm in/on commodities of CSG 13-07B (Bushberries, including highbush blueberries) and 6.0 ppm in/on commodities of CSG 13-07G (Low growing berries, including lowbush blueberries) are sufficient to cover residues resulting from this new use and are therefore unaffected by this MRL action.

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 | 4.0 | CSG 13-07B (Bushberries), except gooseberries ^{2,3} |

¹ ppm = parts per million

² Gooseberries will remain covered under the MRL of 4.0 ppm which is currently being promulgated for CSG 13-07F (Small fruit vine climbing, except fuzzy kiwifruit) given that the MRL proposed with the current review for CSG 13-07B is also 4.0 ppm.

³ As a result of the current review, the MRL for lowbush blueberries and lingonberries, currently established at 2.5 ppm under CSG 13-07G (Low growing berries), will be replaced by the proposed MRL of 4.0 ppm for CSG 13-07B (except gooseberries).

MRLs are proposed for each commodity included in the listed crop grouping 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

The MRLs proposed for difenoconazole in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs¹ listed for difenoconazole in/on commodities of CSG 13-07B (Bushberries) on the Codex Alimentarius Pesticide Residues in Food webpage.

Next Steps

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

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 Maximum Residue Limits

New residue data for difenoconazole in blueberries from field trials conducted in Canada and the United States were submitted to support the domestic use of Inspire Super Fungicide on commodities of CSG 13-07B (Bushberries). Two formulations of difenoconazole (emulsifiable concentrate (EC) and oil-in-water emulsion (EW)) were applied side-by-side to highbush and lowbush blueberries at the proposed label rate, and fruits were harvested according to label directions. As no processed commodities are associated with any of the commodities included in CSG 13-07B, processing data were not required.

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 for commodities of CSG 13-07B.

Table A1 Summary of Field Trial and Processing Data Used to Support 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 |
|----------------------|---|----------------------------|---|--|--------------------------------|
| Highbush blueberries | Broadcast foliar/ 484 - 544 | 1 | 0.18 | 1.7 | n/a ² |
| Lowbush blueberries | Broadcast foliar/ 500 - 515 | 1 | 0.99 | 1.9 | n/a ² |

¹ g a.i./ha = grams of active ingredient per hectare

² There are no processed commodities associated with blueberries.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of difenoconazole. Residues of difenoconazole in/on 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.