Proposed Maximum Residue Limit

PMRL2013-103

Fluazinam

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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 apples, carrots and ginseng to the product label of Allegro 500F Agricultural Fungicide, containing technical grade fluazinam, is acceptable. The specific uses approved in Canada are detailed on the label of Allegro 500F Agricultural Fungicide, *Pest Control Products Act* Registration Number 27517.

The evaluation of these fluazinam applications 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 fluazinam 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.

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 be added to the MRLs already established for fluazinam, are as follows.

 Table 1
 Proposed Maximum Residue Limits for Fluazinam

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Fluazinam	3-chloro- <i>N</i> -[3-chloro-2,6-dinitro-4- (trifluoromethyl)phenyl]-5-(trifluoromethyl)-2- pyridinamine	4.5	Ginseng roots
		2.0	Apples
		0.7	Carrot roots

ppm = parts per million

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 fluazinam 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 fluazinam in or on any commodity 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 fluazinam 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.

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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 MRLs

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Allegro 500F Agricultural Fungicide on apples, carrots and ginseng. Fluazinam was applied to apples, carrots and ginseng, which were harvested according to label directions. In addition, a processing study in treated apples was reviewed to determine the potential for concentration of residues of fluazinam into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fluazinam in/on apples, carrot roots, and ginseng roots was based upon the field trial data, guidance provided in PRO2005-04, Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data, and the North American Free Trade Agreement calculator as the MRL statistical methodology. Table A1 summarizes the residue data used to calculate the proposed MRLs for apples, carrot roots and ginseng roots.

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

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues (ppm)		Experimental
			Min	Max	Processing Factor
Apples	Foliar/ 4.45–10.1	28–29	<0.01	1.68	<0.4
Carrots	Foliar/ 2.29–3.40	6–8	<0.02	0.56	Not applicable
Ginseng	Foliar broadcast/ 3.64–3.80	28–31	0.071	0.96	Not applicable

PHI = preharvest interval; ppm = parts per million

Following the review of all available data, MRLs of 4.5, 2.0, and 0.7 ppm are recommended to cover residues of fluazinam in/on ginseng roots, apples, and carrot roots, respectively. Residues of fluazinam 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.