Proposed Maximum Residue Limit PMRL2014-73

Prothioconazole

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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 sunflower and safflower to the product label of Proline 480 SC Fungicide, containing technical grade prothioconazole, is acceptable. The specific uses approved in Canada are detailed on the label of Proline 480 SC Fungicide, *Pest Control Products Act* Registration Number 28359.

The evaluation of this prothioconazole 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 prothioconazole 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 prothioconazole, are as follows.

Table 1 Proposed Maximum Residue Limits for Prothioconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Prothioconazole	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-1,2,4-triazole-3-thione, including the metabolite α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl) methyl]-1*H*-1,2,4-triazole-1-ethanol	0.2	Sunflower Subgroup (Crop Subgroup 20B)

[1] ppm = parts per million

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

Currently, there are no American tolerances or Codex MRLs[1] listed for prothioconazole on any commodity in Crop Subgroup 20B in the Electronic Code of Federal Regulations, 40 CFR Part 180 and 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 prothioconazole 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 MRLs

Residue data from field trials conducted in Canada were submitted to support the domestic use of Proline 480 SC Fungicide on sunflower and safflower. Prothioconazole was applied to sunflowers at the proposed rate, and harvested according to label directions. In addition, a processing study in treated sunflower seeds was reviewed to determine the potential for concentration of residues of prothioconazole into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for prothioconazole 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 MRL for crops in the Sunflower Subgroup (Crop Subgroup 20B). Residues of prothioconazole in processed commodities are covered under the recommended MRL for the raw agricultural commodities (RACs).

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

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Sunflower seed	Foliar application/ 197-212	43-53	<0.04	0.17	0.7× for meal 1.2× for oil

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of prothioconazole in/on crops within Crop Subgroup 20B. Residues of prothioconazole 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.