Proposed Maximum Residue Limit PMRL2018-03

Prothioconazole

(publié aussi en français)

21 February 2018

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2018-3E (print version)
H113-24/2018-3E-PDF (PDF version)

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 wheat (spring, winter and durum), barley, oats, rye (spring and fall), triticale and canarygrass seeds to the product label of Prosaro XTR Fungicide, containing technical grade prothioconazole, tebuconazole and the safener mefenpyr-diethyl, and of new uses on rye, triticale and canarygrass seeds to the product label of Prosaro 250 EC Fungicide, containing technical grade prothioconazole and tebuconazole, are acceptable. The specific uses approved in Canada are detailed on the labels of Prosaro XTR Fungicide and Prosaro 250 EC Fungicide, *Pest Control Products Act* Registration Numbers 32824 and 29821, respectively.

The evaluation of this prothioconazole application indicated that the end-use product has value and the human health and environmental risks associated with the new use 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 MRL 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 MRL for prothioconazole can be found in Appendix I. MRL consultations for the other active ingredient (tebuconazole) and the safener (mefenpyr-diethyl), present in the Prosaro XTR Fungicide and/or the Prosaro 250 EC Fungicide are being conducted under separate actions.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for prothioconazole, is as follows.

Table 1 Proposed Maximum Residue Limit 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	0.35	Annual canarygrass seeds

[1] 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

Currently there is no corresponding American tolerance listed for annual canarygrass seeds in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no corresponding Codex MRL[1] listed for annual canarygrass seeds on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL 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 Limit

No new residue data for prothioconazole in/on canarygrass seeds were submitted to support the use of Prosaro XTR Fungicide and Prosaro 250 EC Fungicide on this crop. As such, previously reviewed residue data from field trials conducted in/on barley, wheat and corn were re-assessed in the framework of this petition. In addition, a processing study in treated wheat was also re-assessed to determine the potential for concentration of residues of prothioconazole into processed commodities.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for prothioconazole was based upon the previously reviewed 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 annual canarygrass seeds.

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[2] (ppm)	Highest Average Field Trial Residues[2] (ppm)	Experimental Processing Factor
Barley grain	Foliar application/ 321 – 348	30 – 71	≤ 0.02	0.151	Wheat bran: 2.4x Wheat flour: <0.4x Wheat germ: 2x
Wheat grain	Foliar application/ 315 – 350	10, 30 – 57	≤ 0.02	0.045	
Field corn grain	Foliar application/ 784-821	11 – 14	≤ 0.02	0.062	No concentration of residues observed in field corn edible processed fractions.
Popcorn grain	Foliar application/ 795 – 812	14	≤ 0.02	0.02	Not required
Sweet corn K+CWHR[3]	Foliar application/ 794 – 827	0 and 7	≤0.02	0.02	Not required

[1] g a.i./ha = grams of active ingredient per hectare.
[2] Residues expressed as total prothioconazole (i.e., the sum of prothioconazole and prothioconazole-desthio).
[3] K+CWHR = kernels plus cob with husks removed.

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of prothioconazole in/on annual canarygrass seeds. Residues of prothioconazole in this crop commodity at the proposed MRL will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.