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Proposed Maximum Residue Limit

PMRL2018-04

Tebuconazole

(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 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 labels of Prosaro 250 EC Fungicide, containing technical grade prothioconazole and tebuconazole, and Folicur 250 EW Fungicide, containing technical grade tebuconazole, are acceptable. The specific uses approved in Canada are detailed on the labels of Prosaro XTR Fungicide, Prosaro 250 EC Fungicide and Folicur 250 EW Fungicide, *Pest Control Products Act* Registration Numbers 32824, 29821 and 29820, respectively.

The evaluation of this tebuconazole application indicated that the end-use products have 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 tebuconazole 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 for tebuconazole can be found in Appendix I. MRL consultations for the other active ingredient (prothioconazole) and the safener (mefenpyr-diethyl), present in the Prosaro XTR Fungicide and/or Prosaro 250 EC Fungicide are being conducted under separate actions.

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

Table 1 Proposed Maximum Residue Limits for Tebuconazole

Common Name	Residue Definition	MRL (ppm)¹	Food Commodity
Tebuconazole	α -[2-(4-chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1 <i>H</i> -1,2,4-triazole-1-ethanol	0.15	Annual canarygrass seeds, rye, triticale

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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for tebuconazole in Canada with corresponding American tolerances and Codex MRLs.¹ American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Annual canarygrass seeds	0.15	Not established	Not established
Rye	0.15	Not established	0.15

Next Steps

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

No new residue data for tebuconazole in canarygrass seeds, rye and triticale were submitted to support the use of Prosaro XTR Fungicide, Prosaro 250 EC Fungicide and Folicur 250 EW Fungicide on these crops. As such, previously reviewed residue data from field trials conducted in/on barley, wheat and oats 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 tebuconazole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for tebuconazole 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 MRLs for annual canarygrass seeds, rye and triticale.

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/ 122 – 129 (American data; import)	29 – 31	0.068	0.247	Wheat bran: 1x Wheat flour: 0.25x
	Foliar application/ 100 – 187.5 (Canadian data)	30 – 39	≤ 0.01	0.11	
Wheat grain	Foliar application/ 125-126 (Canadian data)	33 – 48	≤ 0.01	0.08	
Oat grain	Foliar application/ 62.5 – 94 (Canadian data)	35 – 82	≤0.01	0.13	

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

² Residues expressed as tebuconazole (i.e., the parent molecule only).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of tebuconazole in/on annual canarygrass seeds, rye and triticale. Residues of tebuconazole in these crop commodities at the proposed MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.