Proposed Maximum Residue Limit PMRL2018-09

Propiconazole

(publié aussi en français)

27 March 2018

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

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca

Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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

Catalogue number: H113-24/2018-9E (print version)
H113-24/2018-9E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Services and Procurement Canada, Ottawa, Ontario K1A 0S5.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the change in the timing of application on wheat, barley and oats to the product label of Tilt 250E Fungicide, containing technical grade propiconazole, is acceptable. The specific uses approved in Canada are detailed on the label of Tilt 250E Fungicide, *Pest Control Products Act* Registration Number 19346.

The evaluation of this propiconazole 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 propiconazole 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 Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for propiconazole, are as follows.

Table 1 Proposed Maximum Residue Limits for Propiconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole	2.0[2]	Barley
		0.7[3]	Oats
		0.2	Wheat bran, wheat germ
		0.09[4]	Wheat

[1] ppm = parts per million
[2] It is proposed that the existing MRL of 0.05 ppm for barley be revised to 2.0 ppm.
[3] It is proposed that the existing MRL of 0.05 ppm for oats be revised to 0.7 ppm.
[4] It is proposed that the existing MRL of 0.05 ppm for wheat be revised to 0.09 ppm.

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 propiconazole 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)
Wheat	0.09	0.3	0.09
Wheat bran	0.2	0.6	Not Established
Wheat germ	0.2	Not Established	Not Established
Oats	0.7	3.0	0.7
Barley	2.0	3.0	2.0

Next Steps

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

Residue data for propiconazole in wheat, barley and oats were submitted to support the domestic use of Tilt 250E Fungicide on these crops. In addition, a processing study in treated wheat was also reassessed to determine the potential for concentration of residues of propiconazole into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for propiconazole 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 wheat, barley and oats.

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
Barley grain	Foliar application / 248-257	16-49	<0.01	1.12	Wheat bran and Wheat germ: 1.6X
Oat grain	Foliar application / 245-261	25-48	<0.01	0.37	
Wheat grain	Foliar application / 240-259	24-64	<0.01	0.12	Wheat flour: 0.3X

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

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