## **Proposed Maximum Residue Limit**

Santé

Canada

PMRL2021-03

# **Propiconazole**

(publié aussi en français)

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Under the authority of the <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the change in the application timing up to the BBCH 65 growth stage on wheat to the product label of Tilt 250E Fungicide, containing the technical grade propiconazole, is acceptable. The specific uses approved in Canada are detailed on the label of Tilt 250E Fungicide, <u>Pest Control Products Act</u> 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 MRL for propiconazole is being conducted via this document (see Next steps). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

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

The proposed MRL, to replace MRLs already established for propiconazole, is as follows.

 Table 1
 Proposed maximum residue limit for propiconazole

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity	
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1 <i>H</i> -1,2,4-triazole	0.01	Wheat <sup>2,3</sup>	

<sup>&</sup>lt;sup>1</sup> ppm = parts per million

MRLs established in Canada may be found using the <u>Maximum Residue Limit Database</u> on the <u>Maximum Residue Limits for Pesticides</u> webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

<sup>&</sup>lt;sup>2</sup> It is proposed that the existing MRL of 0.09 ppm for wheat be revised to 0.01 ppm.

<sup>&</sup>lt;sup>3</sup> It is proposed that the existing MRL of 0.2 ppm for wheat bran and wheat germ be revoked. Following the revocation of the 0.2 ppm MRL for wheat bran and germ, these wheat commodities will be regulated under the proposed wheat MRL of 0.01 ppm.

#### **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 MRL proposed for propiconazole in Canada with corresponding American tolerances and Codex MRL. American tolerances are listed in the <u>Electronic Code of Federal Regulations</u>, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius <u>Pesticide Index</u> webpage, by pesticide or commodity.

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

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Wheat	0.01	0.3 (Wheat grain) 0.6 (Wheat bran)	0.09

#### **Next steps**

The PMRA invites the public to submit written comments on the proposed propiconazole MRL for wheat, as well as the proposed revocation of MRLs for wheat bran and wheat germ, 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 it is entered into the <a href="Maximum Residue Limit">Maximum Residue Limit</a> 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 maximum residue limit

Residue data for propiconazole in wheat were submitted to support the domestic use of Tilt 250E Fungicide on wheat. Propiconazole was applied to wheat at the registered application rate and up to the BBCH 65 growth stage (the new restriction), and was harvested according to label directions. In addition, a processing study in treated wheat was reassessed to determine the potential for concentration of residues of propiconazole into processed commodities.

#### Maximum residue limit

The recommendation for a maximum residue limit (MRL) 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 MRL for wheat. Based on the new timing of application, no quantifiable propiconazole residues are expected in all wheat commodities including processed fractions. As such, the 0.2 ppm MRL in wheat bran and germ is recommended to be revoked. Residues in all wheat processed commodities will be covered under the proposed revised MRL for the raw agricultural commodity (RAC).

Table A1 Summary of field trial and processing data used to support the MRL

Commodity	Application method/Total application rate (g a.i./ha) <sup>1</sup>	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Wheat	Foliar/250	42–64	<0.01	<0.01	1.6× (wheat bran and germ)

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

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of propiconazole. Residues of propiconazole in wheat commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.