Proposed Maximum Residue Limit

Tebuconazole

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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: 613-736-3799

Information Service:
1-800-267-6315 or 613-736-3799

pmra.infoserv@hc-sc.gc.ca
Under the authority of the *Pest Control Products Act*, Health Canada’s Pest Management Regulatory Agency (PMRA) is proposing to establish maximum residue limits (MRLs) for tebuconazole on imported oranges from Spain (Crop Subgroup 10A - revised) and citrus oil to permit the import and sale of foods containing such residues.

Tebuconazole is a fungicide currently registered in Canada for use on wheat, barley, oats, corn, nuts, cucurbits, and soybeans.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when tebuconazole is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an MRL on the corresponding imported commodity. 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 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 World Trade Organization, as coordinated by 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**

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Residue Definition</th>
<th>MRL (ppm)¹</th>
<th>Food Commodity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tebuconazole</td>
<td>α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol</td>
<td>10</td>
<td>Citrus oil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.0</td>
<td>Oranges (Crop Subgroup 10A revised)</td>
</tr>
</tbody>
</table>

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

The MRLs proposed for tebuconazole in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs\(^1\) listed for tebuconazole in or on orange commodities 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 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.

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\(^1\) 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 tebuconazole in oranges and mandarins were submitted to support the maximum residue limits on imported oranges (Crop Subgroup 10A revised). In addition, processing studies in treated oranges were reviewed to determine the potential for concentration of residues of tebuconazole into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for tebuconazole was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported oranges (Crop Subgroup 10A revised) and citrus oil.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Application Method/ Total Application Rate (g a.i./ha)(^1)</th>
<th>Preharvest Interval (days)</th>
<th>Lowest Average Field Trial Residues (ppm)</th>
<th>Highest Average Field Trial Residues (ppm)</th>
<th>Experimental Processing Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandarins</td>
<td>240</td>
<td>0</td>
<td>0.38</td>
<td>0.48</td>
<td>--</td>
</tr>
<tr>
<td>Oranges</td>
<td>0.20</td>
<td>0</td>
<td>0.20</td>
<td>0.28</td>
<td>24.5 (orange oil)</td>
</tr>
</tbody>
</table>

\(^1\) 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 tebuconazole. Residues of tebuconazole in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.