# **Proposed Maximum Residue Limit**

PMRL2013-63

# **Amitraz**

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has granted conditional registration to technical grade amitraz and the end-use product Apivar<sup>TM</sup> Strips for use in Canada on honey. The specific uses approved in Canada are detailed on the product label of Apivar<sup>TM</sup> Strips, *Pest Control Products Act* Registration Number 29092.

The evaluation of these amitraz applications indicated that the end-use product has merit and 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 amitraz 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 World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRL for amitraz is as follows.

 Table 1
 Proposed Maximum Residue Limit for Amitraz

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Amitraz	N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide and all the metabolites containing the 2,4-dimethylaniline moiety, expressed as parent equivalent <sup>a</sup>	0.1	Honey

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 food commodities.

<sup>&</sup>lt;sup>a</sup> Revised residue definition for plant 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 amitraz in Canada with corresponding American tolerances. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no Codex MRL<sup>1</sup> listed for amitraz in or on honey on the Codex Alimentarius Pesticide Residues in Food website.

 Table 2
 Comparison of Canadian MRLs and American Tolerances

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Honey	0.1	0.2
Honeycomb	Not Established	9

#### **Next Steps**

The PMRA invites the public to submit written comments on the proposed MRL for amitraz 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 MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

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 amitraz in honey were submitted to support the domestic use of Apivar<sup>TM</sup> Strips on honey.

#### **Maximum Residue Limit**

The recommendation for an MRL for amitraz was based upon the residues in honey observed in the submitted field trials when hives were treated according to label directions. An MRL to cover residues of amitraz and all the metabolites containing the 2,4-dimethylaniline moiety, expressed as parent equivalents, in/on honey and processed commodities is proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the recommended MRL for the raw agricultural commodity.

TABLE A1 Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Waximum Residue Limit (WRL)							
Commodity	Application Method/ Total Application Rate	Sampling	Residues (ppb)				
		Total Application (days)	Time (days)	Min	Max		
Honey	2 Apivar strips per hive for 42 days (1993 trials)	21 <sup>a</sup>	< 10	< 10			
		42 <sup>a</sup>	< 10	< 10			
		45 <sup>b</sup>	< 10	< 10			
		49 <sup>b</sup>	< 10	< 10			
	2 Apivar strips per hive for 42 days (1998 trials)	21 <sup>a</sup>	26	138			
		42ª	67	117			
		43 <sup>b</sup>	58	297			
		44 <sup>b</sup>	72	471			
		45 <sup>b</sup>	64	441			
		46 <sup>b</sup>	61	186			
		48 <sup>b</sup>	40	321			
		52 <sup>b</sup>	59	229			
		57 <sup>b</sup>	45	139			

<sup>&</sup>lt;sup>a</sup> Honey samples were collected during treatment of hives with Apivar strips.

No MRLs are proposed for livestock matrices (i.e., milk or eggs, fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep) as honey is not a livestock feed item.

#### **Conclusions**

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover total residues of amitraz. Total residues of amitraz in this food commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

<sup>&</sup>lt;sup>b</sup> Honey samples collected 1–15 days after removal of strips from hives. However, according to label directions. Apivar strips should be removed 14 days prior to placing honey supers in hives.