

Pest Management Regulatory Agency

Agence de réglementation de la lutte antiparasitaire

Proposed Maximum Residue Limit

PMRL2007-11

Thiamethoxam

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca

www.pmra-arla.gc.ca

Information Service:

1-800-267-6315 or 613-736-3799

Facsimile: 613-736-3758



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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> (PCPA), has granted conditional registration to the end-use products Actara 240 SC Insecticide and Actara 25 WG Insecticide, containing technical product thiamethoxam, for use in Canada to control labelled insects on potatoes and pome fruits (Crop Group 11; see Appendix I). The specific uses that were approved in Canada are detailed on the Actara 240 SC and Actara 25 WG labels (PCPA Registration Number 28407 and 28408, respectively).

The evaluation of these thiamethoxam applications indicated that the end-use products have merit and value and that the human health and environmental risks associated with the new uses are acceptable. Details on these registrations can be found in Evaluation Report <u>ERC2007-01</u>, *Thiamethoxam*.

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 the label directions and that such residues will not pose an unacceptable health risk. 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.

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the *Canada Gazette*. Amendments to the *Food and Drugs Act* (FDA), via <u>Bill C-28</u>, anticipated to come into force in 2007, will allow pesticide MRLs to be legally established under the PCPA without having to adopt MRLs by regulation under the FDA, resulting in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed MRLs for thiamethoxam is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

The proposed MRLs for thiamethoxam in Canada in or on food, to be added to those already legally established, are as follows:

 Table 1
 Proposed Maximum Residue Limits for Thiamethoxam

| Common Name | Chemical Name of Substance | MRL (ppm) | Food Commodities |
|----------------|---|-----------|------------------|
| Thiamethoxam | 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro- 5-methyl- <i>N</i> -nitro-4 <i>H</i> -1,3,5-oxadiazin-4- | 0.02* | Pome fruits |
| | imine, including the metabolite (<i>E</i>)— [(2-chloro-5- thiazolyl)methyl]- <i>N</i> '-methyl- | 0.03 | Potatoes |
| | <i>N</i> "-nitroguanidine | 0.04 | Potato, chips |

^{* &}lt;u>Table II, Division 15</u> of the FDR currently includes an MRL for thiamethoxam of 0.02 ppm on or in "All food crops". Therefore, the pome fruits MRL proposed herein is captured under this generic commodity descriptor and does not need to be added. The reference to "All food crops" will be revised to read "All food crops (other than those listed in this item)" given the distinct potato MRLs.

A complete list of all MRLs established in Canada can be found in Table II, Division 15 of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's MRL webpage, which will be updated to include the MRLs listed in this document.

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 field crop trials used to generate residue chemistry data. Table 2 identifies differences among MRLs in Canada, tolerances in the United States and Codex¹ MRLs. The proposed MRLs in Canada differ from corresponding tolerances in the United States (listed in 40 CFR 180 by pesticide). Currently, there are no Codex MRLs for thiamethoxam (Codex MRLs searchable by pesticide or commodity).

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

| Food Commodities | Canadian MRLs (ppm) | American Tolerances (ppm) | Codex MRLs (ppm) | |
|---------------------|------------------------|---------------------------|--|--|
| Pome fruits | 0.02 | 0.20 | No Codex MRLs have been established for thiamethoxam | |
| Potatoes | 0.03 | 0.25 | | |
| Potato, chips | 0.04 | 0.25* | | |

^{*} An American tolerance for processed potato commodities is not specified and is, therefore, covered by the value established for potatoes, the raw agricultural food commodity.

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Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for thiamethoxam within 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). Health Canada will consider all comments received before making a final decision on the proposed MRLs for thiamethoxam and before posting an Established Maximum Residue Limit document on the PMRA's website once the amendments to the FDA are in force.

Appendix I

Crop Groups: Numbers and Definitions

| Crop Group Number | Name of the Crop Group | Food Commodities Included in the Crop Group |
|-------------------------|------------------------|--|
| 11 | Pome fruits | Apples Crabapples Loquats Mayhaws Pears Oriental pears Quinces |