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Proposed Maximum Residue Limit

PMRL2019-27

Spinetoram

(publié aussi en français)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on peppermint and spearmint to the product label of Delegate Insecticide, containing technical grade spinetoram, is acceptable. The specific uses approved in Canada are detailed on the label of Delegate Insecticide, *Pest Control Products Act* Registration Number 28778.

The evaluation of this spinetoram 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 spinetoram is being conducted via this document (see Next Steps). 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 be added to the MRLs already established for spinetoram, are as follows.

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Spinetoram	<p>XDE-175-J: (2<i>R</i>,3<i>aR</i>,5<i>aR</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>,16<i>bR</i>)-2-[(6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranosyl)oxy]-13-[[<i>(2R,5S,6R)</i>-5-(dimethylamino)tetrahydro-6-methyl-2<i>H</i>-pyran-2-yl]oxy]-9-ethyl-2,3,3<i>a</i>,4,5,5<i>a</i>,5<i>b</i>,6,9,10,11,12,13,14,16<i>a</i>,16<i>b</i>-hexadecahydro-14-methyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecin-7,15-dione</p> <p>and</p> <p>XDE-175-L: (2<i>S</i>,3<i>aR</i>,5<i>aS</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>,16<i>bS</i>)-2-[(6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranosyl)oxy]-13-[[<i>(2R,5S,6R)</i>-5-(dimethylamino)tetrahydro-6-methyl-2<i>H</i>-pyran-2-yl]oxy]-9-ethyl-2,3,3<i>a</i>,5<i>a</i>,5<i>b</i>,6,9,10,11,12,13,14,16<i>a</i>,16<i>b</i>-tetradecahydro-4,14-dimethyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecin-7,15-dione</p> <p>including the metabolites</p> <p>N-demethyl-175-J: (2<i>R</i>,3<i>aR</i>,5<i>aR</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>,16<i>bR</i>)-9-ethyl-14-methyl-13-[[<i>(2S,5S,6R)</i>-6-methyl-5-(methylamino)tetrahydro-2<i>H</i>-pyran-2-yl]oxy]-7,15-dioxo-2,3,3<i>a</i>,4,5,5<i>a</i>,5<i>b</i>,6,7,9,10,11,12,13,14,15,16<i>a</i>,16<i>b</i>-octadecahydro-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecin-2-yl 6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranoside</p> <p>and</p> <p>N-formyl-175-J: (2<i>R</i>,3<i>S</i>,6<i>S</i>)-6-({<i>(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)</i>-2-[(6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3<i>a</i>,4,5,5<i>a</i>,5<i>b</i>,6,7,9,10,11,12,13,14,15,16<i>a</i>,16<i>b</i>-octadecahydro-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2<i>H</i>-pyran-3-yl(methyl)formamide</p>	3.5	Peppermint tops, spearmint tops

¹ 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 for food commodities.

International Situation and Trade Implications

The MRLs proposed for spinetoram 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 MRLs¹ listed for spinetoram in or on peppermint tops or spearmint tops on the Codex Alimentarius Pesticide Index webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinetoram 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 spinetoram in mint were submitted to support the domestic use of Delegate Insecticide on mint. In addition, a processing study in treated mint was reviewed to determine the potential for concentration of residues of spinosad into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spinetoram 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 mint.

Table A1 Summary of Field Trial and Processing Data Used to Support the 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
Mint	Foliar/ 520-530	6-7	0.258	3.01	No concentration in processed fractions

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 spinetoram. Residues of spinetoram 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.