Proposed Maximum Residue Limit PMRL2016-55

# Spinosad

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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 various commodities to the product labels of Entrust™ Insecticide and Success™ Insecticide, containing technical grade spinosad, is acceptable. The specific uses approved in Canada are detailed on the labels of Entrust™ Insecticide and Success™ Insecticide, *Pest Control Products Act* Registration Numbers 30382 and 26835, respectively.

The evaluation of this spinosad application indicated that the end-use products have 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 spinosad 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 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 replace or be added to the MRLs already established for spinosad, are as follows.

**Table 1 Proposed Maximum Residue Limits for Spinosad**

| Common Name | Residue Definition | MRL (ppm)[1] | Food Commodity |
|---|---|---|---|
| Spinosad | **Spinosyn A:** (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*, 16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12, 13,14,16a,16b-hexadecahydro-14-methyl-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione and **Spinosyn D:** (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*, 16a*S*,16b*S*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a, 5b,6,9,10,11,12,13,14, 16a,16b-tetradecahydro-4,14-dimethyl-1*H*-as-indaceno[3,2-*d*] oxacyclododecin-7,15-dione | 8.0 | Leafy vegetables (Crop Group 4-13, except leaf lettuce)[a], stalk, stem and leaf petioles (Crop Group 22, except asparagus, kohlrabi)[b] |
| | | 2.0 | *Brassica* head and stem vegetable group (Crop Group 5-13)[c] |
| | | 0.4 | Fruiting vegetables |

| Common Name | Residue Definition | MRL (ppm)[1] | Food Commodity |
|---|---|---|---|
| | | | (Crop Group 8-09)[d] |
| | | 0.2 | Pome fruits (Crop Group 11-09)[e], stone fruits (Crop Group 12-09)[f] |

[1] ppm = parts per million
[a] The MRL is proposed to replace the current established MRL of 7.0 ppm for crop subgroup 4A and include all food commodities in the crop group 4-13, except leaf lettuce.
[b] The MRL is proposed to replace the current established MRL of 7.0 ppm for crop subgroup 4B and include all food commodities in the crop group 22, except asparagus and kohlrabi.
[c] The MRL is proposed to replace the current established MRL of 2.0 ppm for crop subgroup 5A and include all food commodities in the crop group 5-13.
[d] The MRL is proposed to replace the current established MRL of 0.2 ppm for crop group 8 and include all food commodities in the crop group 8-09.
[e] The MRL is proposed to replace the current established MRL of 0.1 ppm for crop group 11 and include all food commodities in the crop group 11-09.
[f] The MRL is proposed to replace the current established MRL of 0.2 ppm for crop group 12 and include all food commodities in the crop group 12-09.

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**

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 spinosad in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

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

| Food Commodity | Canadian MRL (ppm) | American Tolerance (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| Leafy vegetables (Crop Group 4-13, except leaf lettuce) | 8.0 | 8.0 (CG 4) | 10 (leaf and head lettuce)<br>8 (spinach) |
| Stalk, stem and leaf petioles (Crop Group 22, except asparagus and kohlrabi) | 8.0 | 8.0 (CG 4) | 6 (celery) |
| *Brassica* head and stem vegetables (Crop Group 5-13) | 2.0 | 2.0 (CSG 5A) | 0.3 (CG 5) |
| Fruiting vegetables (Crop Group 8-09) | 0.4 | 0.4 (CG 8) | 0.06 (tomato) |
| Stone Fruits (Crop Group 12-09) | 0.2 | 0.2 (CG 12) | 0.3 (peach and nectarine) |
| Pome fruits (Crop Group 11-09) | 0.2 | 0.2 (CG 11) | 0.05 (CG 11) |

## Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinosad 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.

# Appendix I

## Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

No new residue data were submitted for spinosad in support of the amendment to the Entrust™ Insecticide and Success™ Insecticide labels. The approved use pattern on the revised crop groups was determined to be within that of the registered label. Therefore, the previously reviewed residue data was reassessed in the framework of the current submissions.

## Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spinosad was based upon the previously reviewed field trial data. MRLs to cover total residues of spinosad in/on crops are proposed as shown in Table A1.

### Table A1 Summary of Field Trial Data Used to Support Maximum Residue Limits

| 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) |
|---|---|---|---|---|
| Head lettuce (with wrapper leaves) | Foliar / 483-527 | 1 | 0.12 | 3.21 |
| Spinach | Foliar / 483-527 | 1 | 1.48 | 6.57 |
| Mustard greens | Foliar / 500 | 3 | 0.015 | 4.82 |
| Broccoli | Foliar / 500 | 3 | 0.027 | 0.400 |
| Cabbage (with wrapper leaves) | Foliar / 500 | 3 | 0.02 | 0.360 |
| Tomato | Foliar / 494-542 | 1 | 0.018 | 0.123 |
| Bell Peppers | Foliar / 503-524 | 1 | 0.022 | 0.074 |
| Non bell peppers | Foliar / 511-514 | 1 | 0.039 | 0.165 |
| Apples (US) | Foliar / 495-577 | 7 | <0.02 | 0.089 |
| Apples (CDN) | Foliar / 487-510 | 7 | <0.04 | 0.069 |
| Pears | Foliar / 273-952 | 7 | <0.02 | 0.08 |
| Peaches | Foliar / 496-521 | 14 | <0.02 | 0.061 |
| Cherry | Foliar / 489-511 | 7 | <0.02 | 0.135 |
| Plum | Foliar / 501-518 | 7 | <0.02 | <0.02 |
| Celery (untrimmed) | Foliar / 483-527 | 1 | 0.397 | 1.74 |

[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 total residues of spinosad. Residues of spinosad 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.