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Proposed Maximum Residue Limit

PMRL2023-32

Spiromesifen

(publié aussi en français)

19 June 2023

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2023-32E (print version)
H113-24/2023-32E-PDF (PDF version)

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Purpose of consultation

A maximum residue limit (MRL)¹ is being proposed for the pesticide spiromesifen, as part of the following application for Canadian use, under submission number 2019-0995.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested application to add the new commodities of green onions (crop subgroup 3-07B) to the product label of Oberon Flowable Insecticide-Miticide containing technical grade spiromesifen, to control two-spotted spider mites. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [28905](#).

The evaluation of this spiromesifen application indicated that the end-use product has value, and the human health and environmental risks associated with the new uses are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when spiromesifen is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL can be found in [Appendix I](#).

Dietary health assessment

In assessing the risk of a pesticide, Health Canada combines information on pesticide toxicity with information on the degree and duration of dietary exposure to the pesticide residue from food. The risk assessment process involves four distinct steps:

- 1) Identifying the toxicology hazards posed by the pesticide;
- 2) Determining the "acceptable dietary level" for Canadians (including all vulnerable populations), which is protective of adverse health effects;
- 3) Estimating health dietary exposure to the pesticide from all applicable sources (domestic and imported commodities); and
- 4) Characterizing health risk by comparing the estimated human dietary exposure to the acceptable dietary level.

Before registering a pesticide for food use in Canada, Health Canada must determine the quantity of residues that could 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 (Steps 3 and 4 above). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to approved label directions is not a health concern. The proposed MRL is then subject to consultation to legally specify it as an MRL.

¹ A maximum residue limit (MRL) is the maximum amount of residue that may remain in or on food when a pesticide is used according to label directions.

An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except for certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRL for spiromesifen is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for spiromesifen in accordance with the process outlined in the Next steps Section of this document.

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 [Canada's Notification Authority and Enquiry Point](#).

Proposed MRL

The proposed MRL, to be added to the MRLs already established for spiromesifen, is summarized in Table 1.

Table 1 Proposed maximum residue limit for spiromesifen

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Spiromesifen	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolite 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one	1.0	Green onions (crop subgroup 3-07B)

¹ ppm = parts per million

The commodities included in the listed crop subgroup can be found on the [Residue Chemistry Crop Groups](#) webpage in the [Pesticides section](#) of Canada.ca.

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 geographic locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for spiromesifen in Canada with the corresponding American tolerance and Codex MRL². 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 Index](#) webpage, by pesticide or commodity.

Table 2 Comparison of Proposed Canadian MRL, American Tolerance and Codex MRL

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Green onions (crop subgroup 3-07B)	1.0	0.09 (indirect/inadvertent residues in/on rotational crop commodities within Vegetable, bulb, group 3-07)	Not established

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for spiromesifen 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). Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the [Maximum Residue Limit Database](#).

² 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 spiromesifen were submitted to support the use of Oberon Flowable Insecticide-Miticicide on green onions (crop subgroup 3-07B).

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of spiromesifen is not likely to cause acute health effects in the general population (including infants and children).

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 56% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for spiromesifen 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 MRL for green onions (crop subgroup 3-07B).

Table A1 Summary of field trial data used to support the MRL

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)
Green onions	Foliar/ 443-446	6-7	0.107	0.441

¹ g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRL proposed in Table 1 is recommended in order to cover residues of spiromesifen. Dietary risks from exposure to residues of spiromesifen in these crop commodities at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
2970767	2019, Spiromesifen: Magnitude of the Residue on Onion, Green, DACO: 7.4.1,7.4.2.