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Proposed Maximum Residue Limit

PMRL2022-14

# Hexythiazox

*(publié aussi en français)*

**16 June 2022**

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

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**Canada**

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

Catalogue number: H113-24/2022-14E (print version)  
H113-24/2022-14E-PDF (PDF version)

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## Purpose of consultation

A maximum residue limit (MRL)<sup>1</sup> for an **imported** commodity is being proposed for the pesticide hexythiazox as part of the following application under submission number 2019-1377, in order to permit the import and sale of food in Canada that could contain hexythiazox residues.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify a MRL for hexythiazox on the imported commodity of tea (dried leaves), to control or suppress certain insects.

Hexythiazox is an insecticide currently not registered in Canada.

Health Canada has determined the quantity of residues that may remain in or on the imported commodity when hexythiazox is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the food containing residues resulting from this use is safe to consume, 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 human dietary exposure to the pesticide from all applicable sources (domestic and imported commodities); and
- 4) Characterizing human risk by comparing the estimated human dietary exposure to the acceptable dietary level.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, 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 label directions approved in the foreign country is not a health concern. The proposed MRL is then subject to consultation to legally specify the MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed

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<sup>1</sup> 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.

food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRL for hexythiazox on the imported commodity is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for hexythiazox 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 Canada's Notification Authority and Enquiry Point.

## Proposed MRLs

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

**Table 1 Proposed maximum residue limit for hexythiazox**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Hexythiazox	(4 <i>R</i> ,5 <i>R</i> )- <i>rel</i> -5-(4-chlorophenyl)- <i>N</i> -cyclohexyl-4-methyl-2-oxo-3-thiazolidinecarboxamide	15	Tea (dried leaves)

<sup>1</sup> 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 MRL proposed for hexythiazox in Canada is the same as the corresponding American tolerance and Codex MRL.<sup>2</sup> 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 commodity or pesticide.

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<sup>2</sup> The Codex Alimentarius Commission 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 MRL for hexythiazox 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.

## Appendix I

### Summary of field trial data used to support the proposed maximum residue limit

Residue data for hexythiazox in tea were submitted to support the maximum residue limit on imported tea (dried leaves).

### Dietary risk assessment results

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

Chronic non-cancer dietary (food only) intake estimates indicated that the general population and all population subgroups are exposed to less than 4% of the acceptable daily intake, with a cancer risk for the general population of  $2 \times 10^{-7}$ , (less than 1 in a million), and therefore are not a health concern.

### Maximum residue limit

The recommendation for a maximum residue limit (MRL) for hexythiazox was based upon the residues observed in the crop commodity treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for imported tea (dried leaves).

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

Commodity	Application method/ total application rate (g a.i./ha) <sup>1</sup>	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Tea (green)	Foliar/ 50.8–52.7	0	3.06	5.21

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

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of hexythiazox. Dietary risks from exposure to residues of hexythiazox in this imported crop commodity at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus the imported food that contains residues as listed in Table 1 is considered safe to consume.

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**References**

<b>PMRA#</b>	<b>Citation</b>
2978050	<sup>14</sup> C-Hexythiazox – Nature of Residue in the Tea Plants. DACO: 6.3
2978052	Sathiyarayanan. 2009. Studies on the residues of hexythiazox in processed green tea and fermented tea following the double foliar application of hexythiazox 5% w/v EC formulation at the recommended dose 500 mL/ha on tea plant in India, DACO: 7.4.1, 7.4.5
2978053	Sathiyarayanan. 2009. Studies on the residues of hexythiazox in processed green tea and fermented tea following the double foliar application of Hexythiazox 5% w/v EC formulation at the recommended dose 500 mL/ha on tea plant in India – Season II, DACO: 7.4.1, 7.4.5