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Proposed Maximum Residue Limit

PMRL2023-30

# Cyflumetofen

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide cyflumetofen, as part of the following application for Canadian use, under submission numbers 2018-6335 and 2020-3107.

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 stone fruits (crop group 12-09) and hops to the product label of Nealta Miticide containing technical grade cyflumetofen, for control of Two-spotted spider mites, McDaniel spider mites, and European red mites. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [31284](#).

The evaluation of these cyflumetofen applications 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 cyflumetofen is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and MRLs are being proposed as a result of these assessments. A summary of the field trial data used to support the proposed MRLs 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.

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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.

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. 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 MRLs for cyflumetofen is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for cyflumetofen 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 MRLs is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by the [Canada’s Notification Authority and Enquiry Point](#).

## Proposed MRLs

The proposed MRLs, to be added to the MRLs already established for cyflumetofen, are summarized in Table 1.

**Table 1 Proposed maximum residue limits for cyflumetofen**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Cyflumetofen	2-methoxyethyl $\alpha$ -cyano- $\alpha$ -[4-(1,1-dimethylethyl)phenyl]- $\beta$ -oxo-2-(trifluoromethyl)benzenepropanoate	30	Hops (dried cones)
		1.5	Cherries (crop subgroup 12-09A)
		0.4	Peaches (crop subgroup 12-09B)
		0.3	Plums (crop subgroup 12-09C)

<sup>1</sup> ppm = parts per million

The commodities included in the listed crop groups/subgroups 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**

The MRLs proposed for cyflumetofen 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 MRLs<sup>2</sup> listed for cyflumetofen in or on the petitioned commodities on the Codex Alimentarius [Pesticide Index](#) webpage.

## **Next steps**

Health Canada invites the public to submit written comments on the proposed MRLs for cyflumetofen 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 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](#).

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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.

## Appendix I

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

Residue data for cyflumetofen in hops, cherries, peaches and plums were submitted to support the use of Nealta Miticide on stone fruits (crop group 12-09) and hops. In addition, a processing study in treated plums was reviewed to determine the potential for concentration of residues of cyflumetofen in processed commodities.

### Dietary risk assessment results

There were no acute or short-term health effects observed in the cyflumetofen toxicology data for the general population, and therefore an acute reference dose (ARfD) was not necessary for this group. Acute dietary (food plus drinking water) intake estimates indicated that females 13–49 years old are exposed to less than 2% of the acute reference dose, and therefore there are no health concerns.

Chronic (non-cancer and cancer) dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 7% of the acceptable daily intake, and therefore there are no health concerns.

### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for cyflumetofen 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 stone fruits and hops (dried).

**Table A1 Summary of field trial and processing data used to support the MRLs**

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)	Experimental processing factor
Hops, dry cones	Foliar/399–409	14	2.0	7.2	Not required
Cherries (sweet and tart)	Foliar/392–411	6-7	0.085	1.3	Not required
Peaches	Foliar/393–416	6-8	0.024	0.195	Not required
Plums	Foliar/396–410	6-7	<0.01	0.14	Dried prune plums: 1.9×

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

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover residues of cyflumetofen. Dietary risks from exposure to residues of cyflumetofen in these crop commodities at the proposed MRLs 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.

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**References**

<b>PMRA#</b>	<b>Citation</b>
3138663	2020, Cyflumetofen: Magnitude of the Residue on Hops, DACO: 7.4.1,7.4.2
2940831	2018, Cyflumetofen: Magnitude of the Residue on Peach, DACO: 7.4.1,7.4.2
2940832	2018, Cyflumetofen: Magnitude of the Residue on Cherry, DACO: 7.4.1,7.4.2
2940833	2018, Cyflumetofen: Magnitude of the Residue on Plum, DACO: 7.4.1,7.4.2,7.4.5