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Proposed Maximum Residue Limit

PMRL2023-05

# Clethodim

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide clethodim, as part of the following applications for Canadian use under pesticide submission numbers 2018-3304, 2018-3306, 2018-3308, 2018-7026, 2019-2379, 2019-5540 and 2019-5546.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) has approved the requested use expansion applications to add the new commodities of rutabagas, green onions, leeks, celery, celeriac, Napa Chinese cabbages and buckwheat to the product label of Select Emulsifiable Concentrate Post-Emergence Herbicide containing technical grade clethodim to control certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [22625](#).

The evaluation of these clethodim 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 clethodim is used according to the supported label directions. Therefore, foods containing residues resulting from these uses are safe to eat, and MRLs are being proposed as a result of this assessment. 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 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

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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.

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 clethodim is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for clethodim in accordance with the guidance reported 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 clethodim, are summarized in Table 1.

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

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Clethodim	2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, including metabolites containing the 2-cyclohex-1-enone moiety (expressed as parent equivalents)	3.0	Napa Chinese cabbages
		2.0	Green onions (crop subgroup 3-07B) <sup>2</sup>
		0.6	Leaf petioles vegetables (crop subgroup 22B)
		0.3	Buckwheat
		0.09	Celeriac tops <sup>3</sup> , rutabaga tops <sup>3</sup>

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

<sup>2</sup> The current established MRL for “Onions” at 0.2 ppm will be revised to “Dry bulb onions” at the same MRL value to reflect current terminology.

<sup>3</sup> Celeriac and rutabaga roots are excluded from this MRL action as an MRL of 0.3 ppm is already established on these commodities.

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 clethodim in or on green onions (crop subgroup 3-07B), Napa Chinese cabbages and leaf petioles vegetables (crop subgroup 22B) in Canada are the same as the corresponding American tolerance as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. Currently, there are no American tolerances for clethodim in or on rutabaga tops, buckwheat and celeriac tops listed in the Electronic Code of Federal Regulations. Currently, there are no Codex MRLs<sup>2</sup> listed for clethodim 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 clethodim 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 clethodim were submitted to support the use of Select Emulsifiable Concentrate Postemergence Herbicide on green onions, leeks, celery and Napa Chinese cabbages. Previously reviewed residue data from field trials conducted in/on radishes and buckwheat were reassessed in the framework of this petition. In addition, one processing study in treated buckwheat was reviewed and another processing study on treated buckwheat was reassessed to determine the potential for concentration of residues of clethodim in processed commodities.

### Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 8% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 28% of the acceptable daily intake, and therefore there are no health concerns.

### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for clethodim was based upon the submitted and on file 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 rutabaga tops, green onions (crop subgroup 3-07B), leaf petioles vegetables (crop subgroup 22B), celeriac tops, Napa Chinese cabbages and buckwheat.

**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
Radish leaves	Foliar broadcast/ 92.2–95.0	29	<0.09	<0.09	Not required
Green onions	Foliar broadcast/ 549–762	13–15	<0.21	<0.78	Not required
Celery	Foliar broadcast/ 548–639	29–31	<0.4	<0.53	Not required

<b>Commodity</b>	<b>Application method/Total application rate (g a.i./ha)<sup>1</sup></b>	<b>Preharvest interval (days)</b>	<b>Lowest average field trial residues (ppm)</b>	<b>Highest average field trial residues (ppm)</b>	<b>Experimental processing factor</b>
Cabbages	Foliar broadcast/ 560–830	28–31	<0.25	1.24	Not required
Buckwheat	Foliar broadcast/ 45–47	60–74	<0.04	<0.103	No quantifiable residues observed at exaggerated rates

<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 to cover residues of clethodim. Dietary risks from exposure to residues of clethodim 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>
2829327	2000, Clethodim: Magnitude of the Residue on Onion (Green), DACO: 7.4.1
2905765	1999, Clethodim: Magnitude of the Residue on Celery, DACO: 7.4.1
2905780	2000, Clethodim: Magnitude of the Residue on Cabbage, DACO: 7.4.1
2948325	2018, Clethodim: Magnitude of the Residue on Buckwheat, DACO: 7.4.1,7.4.5