# **Proposed Maximum Residue Limit**

Santé

Canada

PMRL2023-13

# Carfentrazone-ethyl

(publié aussi en français)

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# **Purpose of consultation**

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide carfentrazone-ethyl, as part of the following application for Canadian use under submissions number 2020-3919.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add the new commodities of dried and fresh peppermint and spearmint leaves; and add new commodities within the crop groups/subgroups of bulb vegetables (crop group 3-07), leafy vegetables (crop group 4-13), fruiting vegetables (crop group 8-09), pome fruits (crop group 11-09), stone fruits (crop group 12-09), bushberries (crop subgroup 13-07B), rapeseeds (crop subgroup 20A, revised), sunflowers (crop subgroup 20B, revised) and leaf petioles vegetables (crop subgroup 22B) to the product label of Aim EC Herbicide containing technical grade carfentrazone-ethyl, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 28573.

The evaluation of this carfentrazone-ethyl 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 carfentrazone-ethyl 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

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.

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 carfentrazone-ethyl is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for carfentrazone-ethyl 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 <u>World Trade Organization</u>, as coordinated by the <u>Canada's Notification Authority and Enquiry Point</u>.

# **Proposed MRLs**

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

Table 1 Proposed maximum residue limits for carfentrazone-ethyl

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity <sup>2,3</sup>
Carfentrazone- ethyl	ethyl α,2-dichloro-5-[4- (difluoromethyl)-4,5- dihydro-3-methyl-5-oxo- 1 <i>H</i> -1,2,4-triazol-1-yl]-4- fluorobenzenepropanoate, including the metabolite α, 2-dichloro-5-[4- (difluoromethyl)-4,5- dihydro-3-methyl-5-oxo- 1 <i>H</i> -1,2,4-triazol-1-yl]-4- fluorobenzenepropanoic acid	0.1	Bulb vegetables (crop group 3-07); leafy vegetables (crop group 4-13); fruiting vegetables (crop group 8-09); pome fruits (crop group 11-09); stone fruits (crop group 12-09); bushberries (crop subgroup 13-07B); rapeseeds (crop subgroup 20A) (revised); sunflowers (crop subgroup 20B) (revised); leaf petioles vegetables (crop subgroup 22B); fresh peppermint leaves, dried peppermint leaves, fresh spearmint leaves, dried spearmint leaves

 $<sup>\</sup>overline{}^{1}$  ppm = parts per million

<sup>2</sup> The current established MRL of 0.8 ppm for the milling fractions of barley, buckwheat, millet, oat, rye, triticale, and wheat will be expired, as the processed fractions will be covered by the established MRL of 0.1 ppm for the raw agricultural commodities (RAC).

<sup>&</sup>lt;sup>3</sup> The commodities of edible leaved chrysanthemum, Chinese mustard cabbage, mustard spinach and pepper hybrids, all at the established MRL of 0.1 ppm, will be expired to reflect recent changes in crop grouping terminology. The currently established MRLs (all at 0.1 ppm) for the following commodities will be expired and replaced by their relevant proposed crop group/subgroup MRLs: Chinese onions, dry bulb onions, garlic, great headed garlic, green onions, leeks, potato onions, shallots, tree onion tops, Welsh onion tops; amaranth, arugula, bok choy Chinese

cabbages, broccoli rabe, Chinese broccoli, collards, corn salad, dandelion leaves, dock, endives, fresh chervil leaves, fresh parsley leaves, garden cress, garden purslane, garland chrysanthemum, head lettuce, kales, leaf lettuce, Malabar spinach, mustard greens, New Zealand spinach, orach, radicchio, rape leaves, spinach, Swiss chard, upland cress, winter purslane; bell peppers, eggplants, groundcherries, non-bell peppers, pepinos, tomatillos, tomatoes; apples, Asian pears, crabapples, loquats, mayhaws, pears, quinces; apricots, fresh prune plums, nectarines, peaches, plumcots, plums, sweet cherries, tart cherries; blueberries, currants, elderberries, gooseberries, huckleberries; flaxseeds, mustard seeds (oilseed type), rapeseeds (canola); safflower seeds, sunflower seeds; cardoon, celery, Chinese celery and rhubarb.

The commodities included in the listed crop groups/subgroups can be found on the <u>Residue</u> Chemistry Crop Groups webpage in the <u>Pesticides section</u> of Canada.ca.

MRLs established in Canada may be found using the <u>Maximum Residue Limit Database</u> on the <u>Maximum Residue Limits for Pesticides</u> 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 carfentrazone-ethyl in Canada are the same as corresponding American tolerances as listed in the <u>Electronic Code of Federal Regulations</u>, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs<sup>2</sup> listed for carfentrazone-ethyl in or on any commodity on the Codex Alimentarius <u>Pesticide Index</u> webpage.

# **Next steps**

Health Canada invites the public to submit written comments on the proposed MRLs for carfentrazone-ethyl 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 <a href="Maximum Residue Limit Database">Maximum Residue Limit Database</a>.

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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

Previously reviewed residue data from field trials conducted in/on dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, peppers, tomatoes, apples, pears, cherries, peaches, plums, blueberries, canola, sunflowers, celery, mint and wheat were reassessed in the framework of this petition. In addition, processing studies in treated apples, canola, plums, sunflowers, tomatoes and wheat were also reassessed to determine the potential for concentration of residues of carfentrazone-ethyl in processed commodities.

#### Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of carfentrazone-ethyl 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 49% of the acceptable daily intake, and therefore there are no health concerns.

#### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for carfentrazone-ethyl was based upon the submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. Table A1 summarizes the residue data used to calculate the proposed MRLs for bulb vegetables (crop group 3-07), leafy vegetables (crop group 4-13), fruiting vegetables (crop group 8-09), pome fruits (crop group 11-09), stone fruits (crop group 12-09), bushberries (crop subgroup 13-07B), rapeseeds (crop subgroup 20A, revised), sunflowers (crop subgroup 20B, revised), leaf petioles vegetables (crop subgroup 22B), dried and fresh peppermint and spearmint leaves.

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
Dry bulb onions and green onions	Preplant soil followed by hooded spray/ 62.7–107.5	1	<0.1	<0.1	Not required
Head lettuce, leaf lettuce, spinach	Preplant soil followed by hooded spray/ 107.5	1	<0.1	<0.1	Not required

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
Peppers Tomatoes	Preplant soil followed by hooded spray/ 106.4–110.9 Preplant soil followed by hooded spray/ 106.4–217.3	1	<0.1	<0.1	No concentration in processed commodities
Apples and pears	Soil directed or soil and tree trunk directed/ 138.9	3	<0.1	<0.1	No concentration in processed commodities
Cherries (tart and sweet), peaches, plums	Soil directed or a soil and tree trunk directed/ 138.9	3	<0.1	<0.1	No concentration in processed commodities
Blueberries	Post-direct spray to the base of the trunk at the dormant stage followed by a hooded spray/ 42.6–107.5	1	<0.1	<0.1	Not required
Canola	Preplant soil followed by hooded spray/ 62.7–360	1	<0.1	<0.1	No quantifiable residues at exaggerated rates
Sunflowers	Preplant soil followed by hooded spray/ 73.9–280	1	<0.1	<0.1	No quantifiable residues at exaggerated rates
Celery	Preplant soil followed by hooded spray/ 62.7–107.5	1	<0.1	<0.1	Not required

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
Mint	Broadcast application during dormant period/ 16.6–35.6	91–124	<0.1	<0.1	Not required
Wheat grain	Foliar/ 34.7	3–4	< 0.1	< 0.1	No
		46–104	<0.1	<0.1	in processed commodities

<sup>&</sup>lt;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 carfentrazone-ethyl. Dietary risks from exposure to residues of carfentrazone-ethyl 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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None