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Proposed Maximum Residue Limit

PMRL2023-45

Carfentrazone-ethyl

(publié aussi en français)

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Purpose of consultation

A maximum residue limit (MRL)¹ is being proposed for the pesticide carfentrazone-ethyl, as part of the following application for Canadian use, under submission number 2021-3696.

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 mustard seeds (condiment type) to the product label of Authority Strike Herbicide containing technical grade carfentrazone-ethyl and sulfentrazone, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [34867](#).

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 use are acceptable. Dietary risks from the consumption of food listed in Table 1 were shown to be acceptable when carfentrazone-ethyl is used according to the supported label directions. Therefore, food containing residues resulting from this use is 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 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 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 carfentrazone-ethyl is being conducted via this document. The end use product Authority Strike Herbicide also contains sulfentrazone. An MRL is currently established for sulfentrazone on mustard seeds (condiment type) at 0.15 ppm, accordingly, a separate PMRL action is not required. Health Canada invites the public to submit written comments on the proposed MRL 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 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 carfentrazone-ethyl, is summarized in Table 1.

Table 1 Proposed maximum residue limit for Carfentrazone-ethyl

Common name	Residue definition	MRL (ppm) ¹	Food commodity
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	Mustard seeds (condiment type)

¹ 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

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 carfentrazone-ethyl in Canada with the corresponding American tolerance and Codex MRL. American tolerances are listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for carfentrazone-ethyl in or on any commodity on the Codex Alimentarius [Pesticide Index](#) webpage.

Table 2 Comparison of proposed Canadian MRLs, American Tolerances and Codex MRLs

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Mustard seeds (condiment type) ¹	0.1	2.0 (Herbs and spices group 19)	Not Established

¹ Data translated from rapeseeds (canola) to mustard seeds (condiment type).

Next steps

Health Canada invites the public to submit written comments on the proposed MRL 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 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

Previously reviewed residue data from field trials conducted in/on rapeseeds (canola) were reassessed in the framework of this petition. In addition, a processing study in treated rapeseeds (canola) was 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 50% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for a maximum residue limit (MRL) for carfentrazone-ethyl was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data for carfentrazone-ethyl and metabolite carfentrazone-chloropropionic acid used to calculate the proposed MRL for mustard seeds (condiment type).

Table A1 Summary of field trial and processing 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 ² (ppm)	Highest average field trial residues ² (ppm)	Experimental processing factor
Rapeseed (canola) ³	Broadcast soil preplant application + hooded spray application in row middles/62.7–360	1	<0.1	<0.1	No quantifiable residues observed at exaggerated rates

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

² Sum of residues of carfentrazone-ethyl plus metabolite carfentrazone-chloropropionic acid, in parent equivalents.

³ Data translated from rapeseeds (canola) to mustard seeds (condiment type).

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover total residues of carfentrazone-ethyl and metabolite carfentrazone-chloropropionic acid. Dietary risks from exposure to residues of carfentrazone-ethyl and the metabolite in this crop commodity at the proposed MRL was 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

None.