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Proposed Maximum Residue Limit

PMRL2023-14

Benzovindiflupyr

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide benzovindiflupyr, as part of the following application for Canadian use, under submission numbers 2021-1209 and 2019-6247.

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 crop subgroup 1B (root vegetable, except sugar beet) to the product label of Aprovia Top containing technical grade benzovindiflupyr and difenoconazole, to control or suppress certain fungal diseases. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [31526](#).

The evaluation of this benzovindiflupyr 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 foods listed in Table 1 were shown to be acceptable when benzovindiflupyr 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 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 approved label directions is not a health concern. The proposed MRL is then subject to

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.

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 benzovindiflupyr is being conducted via this document. The end-use product Aprovia Top also contains difenoconazole. The currently established MRL for difenoconazole of 0.6 ppm for crops in crop subgroup 1B is sufficient to cover residues resulting from this new co-formulation and is therefore unaffected by this MRL action. Health Canada invites the public to submit written comments on the proposed MRLs for benzovindiflupyr 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 are 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 benzovindiflupyr, are summarized in Table 1.

Table 1 Proposed maximum residue limits for benzovindiflupyr

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Benzovindiflupyr	<i>N</i> -[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1 <i>H</i> -pyrazole-4-carboxamide	3.0	Leaves of root and tuber vegetables (crop group 2)
		0.6	Root vegetable except sugar beet (crop subgroup 1B, except ginseng roots)
		0.3	Ginseng roots

¹ 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

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 MRLs proposed for benzovindiflupyr in Canada with corresponding American tolerances and Codex MRLs.² 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 pesticide or commodity.

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

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Leaves of root and tuber vegetables (crop group 2)	3.0	Not established	Not established
Root vegetable except sugar beet (crop subgroup 1B, except ginseng roots)	0.6	0.6	Not established
Ginseng roots	0.3	0.6 (crop subgroup 1B)	Not established

Next steps

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

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 limits

Residue data for benzovindiflupyr were submitted to support the use of Aprovia Top on crops from crop subgroup 1B (root vegetable, except sugar beet and ginseng roots) and crop group 2 (leaves of root and tuber vegetables).

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 10% 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 3% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for benzovindiflupyr 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 MRL for crop subgroup 1B and crop group 2.

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

Commodity	Application method/Total application rate (g a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Radish roots	Foliar/ 297.7–305.4	7–8	0.032	0.24	Not required
Radish leaves			0.35	1.22	Not required
Carrot roots			0.026	0.13	No concentration in processed fractions
Ginseng roots	Foliar/ 300–311	15–21	0.034	0.15	Not required

¹ 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 benzovindiflupyr. Dietary risks from exposure to residues of benzovindiflupyr 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.

References

PMRA#	Citation
3212813	2020, Benzovindiflupyr EC (A15457K) - Magnitude of the Residues in Carrot and Radish (Crop Group 1B) Raw Agricultural and Processed Commodities USA 2019, DACO: 7.4.1,7.4.2,7.4.5
3051670	2019, Magnitude of the Residue on Ginseng, DACO: 7.4.1,7.4.2