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Protéger la santé
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Proposed Maximum Residue Limit

PMRL2026-01

Sedaxane

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide sedaxane, as part of the following application for Canadian use, submitted by Syngenta Canada Inc. under submission number 2023-3974.

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 bulb onions (crop subgroup 3-07A), edible-podded legume vegetables (crop subgroup 6A), succulent shelled pea and bean (crop subgroup 6B) and cucurbit vegetables (crop group 9) to the product label of VIBRANCE 500FS Seed Treatment containing technical grade sedaxane, to control seed- and soil-borne fungal diseases as a seed treatment use. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 30438.

The evaluation of this sedaxane 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 sedaxane 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 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). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2), 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

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.

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 sedaxane on bulb onions (crop subgroup 3-07A) and cucurbit vegetables (crop group 9) is being conducted via this document. Residues of sedaxane on edible-podded legume vegetables (crop subgroup 6A) and succulent shelled pea and bean (crop subgroup 6B) will be covered by the currently established MRLs of 0.01 ppm on these crop subgroups. Health Canada invites the public to submit written comments on the proposed MRLs for sedaxane in accordance with the process outlined in the [How to get involved](#) 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 sedaxane, are summarized in [Table 1](#).

Table 1 Proposed maximum residue limits for sedaxane

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Sedaxane	<i>N</i> -[2-[1,1'-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1 <i>H</i> -pyrazole-4-carboxamide	0.01	Bulb onions (crop subgroup 3-07A); cucurbit vegetables (crop group 9)

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 and Pest Management section of Canada.ca.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum residue limits, human health, and food safety 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

As reported in [Table 2](#), The MRLs proposed for sedaxane in Canada are the same as corresponding tolerances in the United States (U.S.) as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for sedaxane in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

Table 2 Comparison of proposed Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Bulb onions (crop subgroup 3-07A)	0.01	0.01	Not Established
Cucurbit vegetables (crop group 9)	0.01	0.01	Not Established

ppm = parts per million

How to get involved

Health Canada invites the public to submit written comments on the proposed MRLs for sedaxane up to 75 days from the date of publication of this document (by 5 April 2026). Please forward your comments to Pest Management Regulatory Agency Publications Section. 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 response to comments document found in Pesticides and pest management consultations. 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

No residue data for sedaxane were submitted to support the use of VIBRANCE 500FS Seed Treatment on bulb onions (crop subgroup 3-07A) and cucurbit vegetables (crop group 9) as the seed treatment rates on each of the requested crops are less than or equal to 10 g a.i./100 kg seed, as per SPN2018-01 which states that for human food commodities, no field trial data are required and the MRL is to be set at the LOQ of the enforcement analytical method.

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 1% 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 3% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

As no quantifiable residues of sedaxane are expected as result of the proposed seed treatment uses on bulb onions (crop subgroup 3-07A) and cucurbit vegetables (crop group 9), the recommendation for proposed maximum residue limits (MRLs) for sedaxane was based upon the limit of quantitation for the enforcement method (0.01 ppm), as per SPN2018-01.

Following the review of all available data, the MRLs proposed in [Table 1](#) are recommended, in order to cover residues of sedaxane. Dietary risks from exposure to residues of sedaxane 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

None