Proposed Maximum Residue Limit PMRL2022-03

Mandestrobin

(publié aussi en français)

16 March 2022

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2022-3E (print version)
H113-24/2022-3E-PDF (PDF version)

Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide mandestrobin, as part of the following application for Canadian use, under submission number 2020-0884.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the revised (decreased) MRL for mandestrobin on rapeseed (crop subgroup 20A, revised). This proposed revision results from the change in timing of application of the product, to control or supress certain fungal diseases in these crops that are currently on the registered product label of S-2200 4 SC Fungicide containing technical grade mandestrobin. The specific uses approved in Canada are detailed on the product label, *Pest Control Products Act* Registration Number 32286.

The evaluation of this mandestrobin application indicated that the end-use product has value and the human health and environmental risks associated with the new use is acceptable. Dietary risks from the consumption of food listed in Table 1 were shown to be acceptable when mandestrobin 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 human 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 mandestrobin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for mandestrobin 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 MRLs

The proposed MRL, to replace the MRL already established for mandestrobin, is summarized in Table 1.

Table 1 Proposed maximum residue limit for mandestrobin

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Mandestrobin	2-[(2,5-dimethylphenoxy)methyl]-α-methoxy-*N*-methylbenzeneacetamide	0.2[2]	Rapeseeds (crop subgroup 20A) (revised)

[1] ppm = parts per million
[2] This MRL is proposed to replace the current MRL of 0.5 ppm for rapeseeds (crop subgroup 20A) (revised).

An MRL is proposed for each commodity included in the listed crop grouping in accordance with 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 locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for mandestrobin in Canada with the corresponding American tolerance and Codex MRL (pending the update to the Codex Database). Currently, there are no Codex MRLs[2] listed for mandestrobin in or on any commodity on the Codex

[2] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Alimentarius Pesticide Index webpage. Currently, there are no American tolerances listed for mandestrobin in or on the petitioned commodities on the Electronic Code of Federal Regulations, 40 CFR Part 180.

Table 2 Comparison of proposed Canadian MRL, American Tolerance and proposed Codex MRL

Food commodity	Recommended Canadian MRL	American Tolerance (ppm)	Proposed Codex MRL
Rapeseeds (canola)	0.2	Not Established	0.2[1]

[1] This Codex MRL has been adopted. The update to the Codex Database is pending.

Next steps

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

Appendix I

Summary of field trial data used to support the proposed maximum residue limit

A rationale was submitted requesting that the mandestrobin MRL for rapeseeds (crop subgroup 20A, revised) be amended to harmonize with the proposed Codex MRL. Previously reviewed residue data from field trials conducted on rapeseed were reassessed in the framework of this petition.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of mandestrobin 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 10% of the acceptable daily intake, and therefore are not a health concern.

Maximum residue limit

The recommendation for maximum residue limit (MRL) for mandestrobin 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 revised MRL for rapeseeds (crop subgroup 20A, revised).

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

Commodity	Application method/ Timing / 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
Rapeseeds (canola)	Foliar/BBCH 62-69/ 413–439	34–41	<0.01	0.13	Refined oil: <0.1× Meal: 0.2×

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

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of mandestrobin. Dietary risks from exposure to residues of mandestrobin in these crop commodities at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the food that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3098989	2020, Rationale for Amendment of Maximum Residue Limit for Mandestrobin on Canola, DACO: 7.1