Proposed Maximum Residue Limit PMRL2023-09

S-Metolachlor

(publié aussi en français)

14 February 2023

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

Catalogue number: H113-24/2023-9E (print version)
H113-24/2023-9E-PDF (PDF version)

Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide S-metolachlor, as part of the following application for Canadian use, under pesticide submission number 2018-1220.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has approved the requested use expansion application to add the new commodities of caneberries (crop subgroup 13-07A) to the product label of Dual II Magnum Herbicide containing technical grade S-metolachlor, for the control or suppression of various weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 25729.

The evaluation of this S-metolachlor 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 S-metolachlor is used according to the supported label directions. Therefore, foods containing residues resulting from this use are 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. An MRL applies to the identified raw agricultural

[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.

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 S-metolachlor is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for S-metolachlor in accordance to with the guidance reported 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 S-metolachlor, is summarized in Table 1.

Table 1 Proposed maximum residue limit for S-metolachlor

Common name	Residue definition	MRL (ppm)[1]	Food commodity
S-metolachlor	2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide, including the metabolites 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone	0.1	Caneberries (crop subgroup 13-07A)

[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

The MRL proposed for S-metolachlor in Canada is the same as the corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[2] listed for S-metolachlor in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for S-metolachlor 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

Residue data for S-metolachlor were submitted to support the use of Dual II Magnum Herbicide on caneberries.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of S-metolachlor 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 6% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for S-metolachlor 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 caneberries (crop subgroup 13-07A).

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

Commodity	Application method/ Total application rate (kg a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Raspberries	Directed to soil surface on both sides of cane/ 2.92-4.54	28-30	<0.08	<0.08
Blackberries	Directed to soil surface on both sides of cane/ 2.96 or 4.31	28	<0.08	<0.08

[1] kg a.i./ha = kilograms of active ingredient per hectare

Following the review of all available data, the MRL proposed in Table 1 is recommended to cover residues of S-metolachlor. Dietary risks from exposure to residues of S-metolachlor 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 foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
2864296	2007, S-Metolachlor: Magnitude of the Residue on Caneberry (Blackberry and Raspberry), DACO: 7.3,7.4.1