



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Maximum Residue Limit

PMRL2023-08

Pendimethalin

(publié aussi en français)

14 February 2023

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

Publications
Pest Management Regulatory Agency
Health Canada
2 Consellation Drive
8th Floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada 

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

Catalogue number: H113-24/2023-8E (print version)
H113-24/2023-8E-PDF (PDF version)

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide pendimethalin, as part of the following application for Canadian use, under pesticide submission number 2019-6016.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has approved the requested application to add various pome fruits and stone fruits to the product label of Prowl H₂O Herbicide containing technical grade pendimethalin, to control various weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [29542](#).

The evaluation of this pendimethalin 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 pendimethalin 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.

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.

The proposed MRL is then subject to 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 pendimethalin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for pendimethalin in accordance with the guidance reported in the Next steps 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 pendimethalin, are summarized in Table 1.

Table 1 Proposed maximum residue limits for pendimethalin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Pendimethalin	<i>N</i> -(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, including the metabolite benzenemethanol, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitro-	0.1	Pome fruits (crop group 11-09) ² ; stone fruits (crop group 12-09) ³

¹ ppm = parts per million

² The proposed MRL of 0.1 ppm in/on pome fruits (crop group 11-09) will replace the currently established MRL of 0.1 ppm in/on individual commodities within this crop group.

³ The proposed MRL of 0.1 ppm in/on stone fruits (crop group 12-09) will replace the currently established MRL of 0.1 ppm in/on individual commodities within this crop group.

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 MRLs proposed for pendimethalin in Canada are the same as corresponding American tolerances as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for pendimethalin in or on the petitioned commodities on the Codex Alimentarius [Pesticide Index](#) webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for pendimethalin 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 pendimethalin were submitted to support the use of Prowl H₂O Herbicide on various pome fruits and stone fruits. Previously reviewed residue data from field trials conducted in/on apples, pears, sweet cherries, peaches and plums were also reassessed in the framework of this petition. In addition, processing studies in treated apples and plums were reviewed to determine the potential for concentration of residues of pendimethalin in processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of pendimethalin is not likely to cause acute health effects in the general population (including infants and children).

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 11% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for pendimethalin 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 MRLs for pome fruits (crop group 11-09) and stone fruits (crop group 12-09).

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) ²	Highest average field trial residues (ppm) ²	Experimental processing factor
Apples	Soil-directed spray/ 2000–6400	30–63	<0.1	<0.1	No quantifiable residues observed at exaggerated rates.
Pears	Soil-directed spray/ 2000–4600	29–62	<0.1	<0.1	Not required.
Sweet cherries	Soil-directed spray/ 2000–4550	34–62	<0.1	<0.1	Not required.
Tart cherries	Soil-directed spray/ 4350–4430	60–61	<0.1	<0.1	Not required.

Commodity	Application method/Total application rate (g a.i./ha)¹	Preharvest interval (days)	Lowest average field trial residues (ppm)²	Highest average field trial residues (ppm)²	Experimental processing factor
Peaches	Soil-directed spray/ 2000–6080	32–62	<0.1	<0.1	Not required.
Plums	Soil-directed spray/ 4260–8340	57–60	<0.1	<0.1	No quantifiable residues observed at exaggerated rates.

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

² Total combined residues of pendimethalin and CL 202347

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover total residues of pendimethalin and CL 202347. Dietary risks from exposure to residues of pendimethalin 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
3026843	2002, Pendimethalin: Magnitude of the Residue on Apple, DACO: 7.3,7.4.1,7.4.5
3026844	2002, Pendimethalin: Magnitude of the Residue on Cherry, DACO: 7.4.1
3026845	2002, Pendimethalin: Magnitude of the Residue on Peach, DACO: 7.4.1
3026846	2002, Pendimethalin: Magnitude of the Residue on Plum, DACO: 7.3,7.4.1,7.4.5
3026847	2002, Pendimethalin: Magnitude of the Residue on Pear, DACO: 7.3,7.4.1