



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Maximum Residue Limit

PMRL2018-56

Fenamidone

(publié aussi en français)

29 November 2018

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

Canada 

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

Catalogue number: H113-24/2018-56E (print version)
H113-24/2018-56E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018

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 the Minister of Public Services and Procurement Canada, Ottawa, Ontario K1A 0S5.

Under the authority of the *Pest Control Products Act*, Health Canada’s Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on basil and *Brassica* leafy greens (crop subgroup 4-13B) to the product label of Reason 500SC Fungicide, containing technical grade fenamidone, is acceptable. The specific uses approved in Canada are detailed on the label of Reason 500SC Fungicide, *Pest Control Products Act* Registration Number 27462.

The evaluation of these fenamidone applications indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to 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. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for fenamidone is being conducted via this document (see Next Steps). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

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.

The proposed MRLs, to be added to the MRLs already established for fenamidone, are as follows:

Table 1 Proposed Maximum Residue Limits for Fenamidone

| Common Name | Residue Definition | MRL (ppm) ¹ | Food Commodity |
|-------------|---|------------------------|---|
| Fenamidone | (5 <i>S</i>)-3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4 <i>H</i> -imidazol-4-one | 200 | Dried basil leaves |
| | | 60 | <i>Brassica</i> leafy greens (crop subgroup 4-13B) ² |
| | | 30 | Fresh basil leaves |

¹ ppm = parts per million

² This MRL is proposed to replace the established MRL of 5 ppm in/on Chinese broccoli and the established MRLs of 55 ppm in/on broccoli raab, bok choy Chinese cabbages, collards, kales, mizuna, mustard greens, and rape leaves. The previously established MRL of 55 ppm for “turnip tops” will be replaced by an MRL of 60 ppm for turnip greens to reflect recent changes in crop grouping terminology (DIR2014-02).

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides section of the Canada.ca website.

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 MRLs proposed for fenamidone in Canada with corresponding American tolerances and Codex MRLs.¹ 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 Canadian MRLs, American Tolerances and Codex MRLs (where different)

| Food Commodity | Canadian MRL (ppm) | American Tolerance (ppm) | Codex MRL (ppm) |
|--|--------------------|--------------------------|-----------------------|
| <i>Brassica</i> leafy greens (crop subgroup 4-13B) | 60 | 60 (crop group 4-16) | 4 (broccoli, Chinese) |

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fenamidone 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). The PMRA will consider all comments received before 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.

¹ 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 fenamidone in fresh and dried basil leaves were submitted to support the domestic use of Reason 500SC Fungicide on basil. In addition, previously reviewed residue data from field trials conducted in/on mustard greens were reassessed in the framework of this petition.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fenamidone was based upon the field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial 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) |
|--------------------|--|----------------------------------|--|---|
| Fresh basil leaves | Foliar/ 842–885 | 2 | 1.01 | 10.8 |
| Dried basil leaves | Foliar/ 848–885 | 2 | 10.3 | 84.1 |
| Mustard Greens | Foliar/ 1187–1221 | 2 | 11.31 | 29.09 |

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fenamidone. Residues of fenamidone in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.