



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Maximum Residue Limit

PMRL2023-07

Fluazinam

(publié aussi en français)

2 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 Constellation 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: H113-24/2023-7E (print version)
H113-24/2023-7E-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 fluazinam, as part of the following applications for Canadian use, under submission numbers 2020-1081, 2016-7570 and 2018-3699.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested applications to:

- extend the use on cantaloupes to all commodities of cucurbit vegetables (crop group 9) to the product label of Allegro 500F Agricultural Fungicide, containing technical grade fluazinam, to control or suppress various fungal diseases.
- to add the new commodity of grapes to the product label of Allegro 500F Agricultural Fungicide, containing technical grade fluazinam, for the suppression of anthracnose (*Elsinoe ampelina*) and for the control of dead arm (*Phomopsis viticola*).

The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [27517](#).

The evaluation of these fluazinam applications 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 fluazinam is used according to the supported label directions. Therefore, foods containing residues resulting from these uses 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.

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.

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 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 fluazinam is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for fluazinam 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 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 fluazinam, are summarized in Table 1.

Table 1 Proposed maximum residue limits for fluazinam

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Fluazinam	3-chloro- <i>N</i> -[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine	3.0	Grapes
		0.07	Cucurbit vegetables (crop group 9) ²

¹ ppm = parts per million

² While there are MRLs currently established for commodities within crop subgroup 9A (melon) at 0.07 ppm, the MRLs will be expanded to cover all commodities within crop group 9 (cucurbit vegetables). Hence a crop group MRL for cucurbit vegetables is being proposed, while the current MRLs for individual commodities within crop subgroup 9A will be expired.

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 fluazinam in Canada on grapes and cucurbit vegetables (crop group 9) are the same as the American tolerances on these commodities as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for fluazinam 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 MRLs for fluazinam 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

Submitted residue data for fluazinam on summer squash and cucumber field trials were reviewed to support the use expansion of Allegro 500F Agricultural Fungicide from cantaloupe, which is the representative of crop subgroup 9A, to the entire cucurbit vegetable crop group (crop group 9). Residue data for fluazinam were also submitted to support the use of Allegro 500F Agricultural Fungicide on grapes. In addition, a freezer storage stability study was reviewed for fluazinam on grapes in support of the field trial data.

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 59% of the acute reference dose, and therefore there are no health concerns.

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 32% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for fluazinam 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 cucurbit vegetables (crop group 9) and grapes.

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

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)
Grapes	Foliar broadcast or directed/ 2.33–3.01	19–21	0.08	1.75
Summer squash	1 soil directed + 4 foliar applications / 4.37–4.44	6–7	<0.01	0.027
Cucumbers	1 soil directed + 4 foliar applications / 4.06–4.43	6–7	<0.01	0.013

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

Following the review of all available data, the MRLs as proposed in Table 1 are recommended to cover residues of fluazinam. Dietary risks from exposure to residues of fluazinam 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
2686701	2014, Fluazinam: Magnitude of the Residue on Squash (Summer), DACO: 7.2.1,7.4.1,7.4.2
2686702	2014, Fluazinam: Magnitude of the Residue on Cucumber, DACO: 7.2.1,7.4.1,7.4.2
2704614	2016, Fluazinam: Magnitude of the Residue on Grape, DACO: 7.2.1,7.4.1,7.4.2
2704615	1995, Magnitude of the Residue of Fluazinam and Metabolite AMGT in Grapes from USA and Canada - 1994 (Volume 1), DACO: 7.4.1
2704616	1995, Magnitude of the Residue of Fluazinam and Metabolite AMGT in Grapes from USA and Canada - 1994 (Volume 2), DACO: 7.4.1
2704617	1999, Stability of Fluazinam, AMGT and AMPA in Grapes and Wine after Freezer Storage - Final Report, DACO: 7.3