



Health
Canada Santé
Canada

*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

Proposed Maximum Residue Limit

PMRL2022-21

Sedaxane

(publié aussi en français)

25 November 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: H113-24/2022-21E (print version)
H113-24/2022-21E-PDF (PDF version)

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2022

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 for **imported** commodities are being proposed for the pesticide sedaxane as part of the following application under submission number 2020-1238, in order to permit the import and sale of food in Canada that could contain sedaxane residues. This import MRL proposal does not result in a change of the current approved conditions of use in Canada.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify maximum residue limits (MRLs) for sedaxane on the imported commodities of rice, undelinted cotton seeds and peanuts, to control or suppress certain fungal diseases.

Sedaxane is a fungicide currently registered in Canada for use on various commodities.

Health Canada has determined the quantity of residues that may remain in or on the imported commodities when sedaxane is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the 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.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, 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 label directions approved in the foreign country is not a health concern. The proposed MRL is then

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.

subject to consultation to legally specify the MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for sedaxane on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for sedaxane 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 [Canada’s Notification Authority and Enquiry Point](#).

Proposed MRLs

The proposed MRLs, to be added to the MRLs already established for sedaxane, are summarized in Table 1.

Table 1 Proposed maximum residue limits for sedaxane

Common name	Residue definition	MRL (ppm) ¹	Food commodities
Sedaxane	<i>N</i> -[2-[1,1'-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1 <i>H</i> -pyrazole-4-carboxamide	0.01	Peanuts, rice, undelinted cotton seeds

¹ ppm = parts per million

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 sedaxane in Canada are the same as corresponding American tolerances as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. The MRL proposed for sedaxane in Canada in or on rice is the same as the Codex MRL.² Currently, there are no Codex MRLs listed for sedaxane in or on peanuts and undelinted cotton seeds on the Codex Alimentarius [Pesticide Index](#) webpage.

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

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for sedaxane 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](#).

Appendix I

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

Residue data for sedaxane were submitted to support the maximum residue limits on imported rice, undelinted cotton seeds and peanuts. In addition, processing studies in these commodities were reviewed to determine the potential for concentration of residues of sedaxane into processed commodities.

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 1% 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 3% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for sedaxane on imported commodities was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data used to calculate the proposed MRLs for imported peanuts, rice and undelinted cotton seeds.

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

Commodity	Application method/ Total application rate (g a.i./100 kg seed) ¹	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Cottonseeds	Seed treatment / 15–19	<0.01	<0.01	No quantifiable residues observed at exaggerated rates.
Peanuts	Seed treatment / 15–18	<0.01	<0.01	No quantifiable residues observed at exaggerated rates.
Rice	Seed Treatment / 18–20	<0.01	<0.01	No quantifiable residues observed at exaggerated rates.

¹ g a.i./100 kg seed = grams of active ingredient per 100 kilograms treated seeds

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of sedaxane. Dietary risks from exposure to residues of sedaxane in these imported 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 imported foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3108682	2014, Sedaxane FS (A16148C) - Magnitude of the Residues in or on Cotton USA 2012, DACO: 7.4.1,7.4.5
3108683	2015, Sedaxane FS (A16148C) - Magnitude of the Residues in or on Peanut USA 2013, DACO: 7.4.1,7.4.5
3108684	2015, Sedaxane FS (A16148C) - Magnitude of the Residues in or on Dry Seeded Rice Resulting from Seed Treatment USA 2013, DACO: 7.4.1,7.4.5