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Proposed Maximum Residue Limit

PMRL2025-16

Inpyrfluxam

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide inpyrfluxam, as part of the following application for Canadian use, submitted by Valent Canada Inc. under submission number 2023-6459.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add various commodities (please refer to Table 1) to the product label of S-2399 SC Master Fungicide containing technical grade inpyrfluxam to control or suppress certain fungal diseases from a foliar/in-furrow use. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 34520.

The evaluation of this inpyrfluxam 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 inpyrfluxam 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.

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). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2), 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).

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.

Consultation on the proposed MRLs for inpyrfluxam is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for inpyrfluxam in accordance with the process outlined in the How to get involved 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 inpyrfluxam, are summarized in Table 1.

Table 1 Proposed maximum residue limits for inpyrfluxam

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Inpyrfluxam	3-(difluoromethyl)-N-[(3R)-2,3-dihydro 1,1,3-trimethyl-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide	0.03	Potatoes
		0.01	Asian pears, Chinese quinces, crabapples, Japanese quinces, loquats, medlars, pears, quinces

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

As reported in Table 2, currently there are no tolerances in the United States (U.S.) for inpyrfluxam in or on the petitioned commodities listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide; nor are there Codex MRLs² listed for inpyrfluxam in or on the petitioned commodities 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.

Table 2 Comparison of proposed Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Potatoes	0.03	Not Established	Not Established
Asian pears, Chinese quinces, crabapples, Japanese quinces, loquats, medlars, pears, quinces	0.01	Not Established	Not Established

ppm = parts per million

How to get involved

Health Canada invites the public to submit written comments on the proposed MRLs for inpyrfluxam up to 75 days from the date of publication of this document (by 2 November 2025). Please forward your comments to Publications. 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 response to comments document found in Pesticides and pest management consultations. 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 inpyrfluxam on pears and potatoes were submitted to support the use of S-2399 SC Master Fungicide on Asian pears, Chinese quinces, crabapples, Japanese quinces, loquats, medlars, pears, potatoes and quinces. In addition, a processing study in treated potato was reviewed to determine the potential for concentration of residues of inpyrfluxam in 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 19% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 38% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for inpyrfluxam was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for inpyrfluxam used to calculate the proposed MRLs for Asian pears, Chinese quinces, crabapples, Japanese quinces, loquats, medlars, pears, potatoes and quinces.

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)	Highest average field trial residues (ppm)	Experimental processing factor
Pears	Foliar application/198–206	86–147	<0.01	<0.01	Not required.
Potatoes	In-furrow application/95–113	78–141	<0.01	0.012	No quantifiable residues observed at exaggerated rates.

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

Following the review of all available data, the MRLs proposed in Table 1 are recommended, in order to cover residues of inpyrfluxam. Dietary risks from exposure to residues of inpyrfluxam 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 number	Citation
3524746	2023. Inpyrfluxam: Analyte Selection for the Potato RAC Program. DACO 7.4.1.
3524747	2019, Addendum to S-2399: Freezer Storage Stability of S-2399 and Metabolites in Crops, DACO 7.3 (original report, 2017-10-12; amended report, 2019-08-19)
3524748	2019, Addendum to S-2399: Freezer Storage Stability of S-2399 and Metabolites in Processed Fractions, DACO 7.3
3524702	2021, S-2399: Magnitude of the Residues on Wheat After Application of S-2399 2.84 SC to Wheat Grown from Seed Treated with S-2399 3.2 FS (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524718	2022, S-2399: Magnitude of the Residues on Barley after Application of S-2399 2.84 SC to Barley Grown from Seed Treated with S-2399 3.2 FS (US Trials), DACO: 7.2.1,7.3,7.4.1
3524726	2022, S-2399: Magnitude of the Residues on Barley after Application of S-2399 2.84 SC to Barley Grown from Seed Treated with S-2399 3.2 FS (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524745	2019, S-2399: Magnitude of Residues on Potatoes After Application of S-2399 2.84 SC in-Furrow or to Potato Seed Pieces at Planting (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524744	2023, Magnitude of the Residues of Inpyrfluxam in/on Pear after Two Foliar Applications of Excalia Fungicide (S-2399 2.84 SC), DACO: 7.2.1,7.3,7.4.1,7.4.2
3524698	2023, S-2399: Magnitude of Residues on Potatoes After Application of S-2399 2.84 SC in-Furrow or to Potato Seed Pieces at Planting, DACO: 7.2.1,7.3,7.4.1,7.4.2,7.4.5
3524743	2021, S-2399: Magnitude of the Residues on Wheat After Foliar Application of S-2399 2.84 SC to Wheat Grown from Seed Treated with S-2399 3.2 FS (US Trials) Amended Report #1, DACO: 7.2.1,7.3,7.4.1,7.4.2,7.4.5