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Proposed Maximum Residue Limit

PMRL2025-14

Trinexapac-ethyl

(publié aussi en français)

29 July 2025

This document is published by the Health Canada Pest Management Regulatory Agency.
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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2025-14E (print version)
H113-24/2025-14E-PDF (PDF version)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide trinexapac-ethyl, as part of the following application for Canadian use, submitted by Syngenta Canada Inc. under submission number 2023-6667.

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 the new commodity of rye to the product label of MODDUS containing technical grade trinexapac-ethyl, to aid in the growth and lodging management of plants, as a postemergent foliar use. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 33930.

The evaluation of this trinexapac-ethyl application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of food listed in Table 1 were shown to be acceptable when trinexapac-ethyl is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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. The proposed MRL is then subject to consultation to legally specify it as an MRL.

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.

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 MRL for trinexapac-ethyl is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for trinexapac-ethyl 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 MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to be added to the MRLs already established for trinexapac-ethyl, is summarized in Table 1.

Table 1 Proposed maximum residue limit for trinexapac-ethyl

Common name	Residue definition ¹	MRL (ppm) ²	Food commodity
Trinexapac-ethyl	Metabolite 4-[cyclopropyl(hydroxy)methylidene]-3,5-dioxocyclohexane-1-carboxylic acid	3.0	Rye

¹ The residue definition for trinexapac-ethyl is the metabolite trinexapac acid.

² 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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the geographic locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for trinexapac-ethyl in Canada with the corresponding tolerance in the United States (U.S.) and Codex MRLs.² U.S. 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.

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 the Proposed Canadian MRL, U.S. tolerance and Codex MRL

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. Tolerance (ppm)	Established Codex MRL (ppm)
Rye	3.0	4.0	3

ppm = parts per million

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for trinexapac-ethyl up to 75 days from the date of publication of this document (by 12 October 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 MRL. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

Appendix I

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

Previously reviewed residue data from field trials conducted in/on wheat (as the representative crop for the wheat crop subgroup (crop subgroup 15-21A), which includes rye) were reassessed in the framework of this petition. In addition, a processing study in treated wheat was also reassessed to determine the potential for concentration of residues of trinexapac-ethyl in processed commodities.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that females 13 to 49 years old are exposed to less than 72% of the acute reference dose, and therefore there are no health concerns. Studies in laboratory animals showed no acute health effects relative to dietary exposure in all other population subgroups. Consequently, a single dose of trinexapac-ethyl is not likely to cause acute health effects in the general population and all other population subgroups (except for females 13 to 49 years old).

Chronic dietary (food plus drinking water) intake estimates indicated that females 13 to 49 years old are exposed to less than 47% of the acceptable daily intake, and therefore there are no health concerns. Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all other population subgroups (except for females 13 to 49 years old) are exposed to less than 12% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for trinexapac-ethyl was based upon previously reviewed field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for trinexapac acid used to calculate the proposed MRL for rye.

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

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
Wheat grain	Foliar application/125	56–77	0.074	1.65	Wheat bran ² : 1.9×

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

² Residues of trinexapac acid were observed to concentrate in wheat bran. As such, it is assumed that residues may similarly concentrate in rye bran. However, rye bran is used as an animal feed item only. Since MRLs are not established for feed commodities in Canada, an MRL is not required for rye bran.

ppm = parts per million

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover residues of trinexapac-ethyl. Dietary risks from exposure to residues of trinexapac-ethyl in this crop commodity at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the food that contain residues as listed in Table 1 is considered safe to eat.

References

None.