Proposed Maximum Residue Limit

PMRL2015-15

Myclobutanil

(publié aussi en <u>français</u>)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to specify a maximum residue limit (MRL) for myclobutanil on all commodities of crop subgroup 4A (leafy greens), except spinach, to permit the import and sale of foods containing such residues.

Myclobutanil is a fungicide currently registered in Canada for use on several crops, including greenhouse food crops and terrestrial food crops.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when myclobutanil is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally specified as an 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 where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

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

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 Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for myclobutanil, is as follows.

 Table 1
 Proposed Maximum Residue Limit for Myclobutanil

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Myclobutanil	α-butyl-α-(4-chlorophenyl)-1 H -1,2,4-triazole-1-propanenitrile, including the metabolites α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1 H -1,2,4-triazole-1-propanenitrile and α-(butyl-3-one)-α-(4-chlorophenyl)-1 H -1,2,4-triazole-1-propanenitrile	9.0	Crop subgroup 4A (leafy greens), except spinach

ppm = parts per million.

The MRL is proposed for each commodity included in the listed crop subgroup in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's 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

The MRL proposed for myclobutanil in Canada is the same as the corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no Codex MRL¹ listed for myclobutanil in or on any commodity of Crop Subgroup 4A (Leafy Greens) on the Codex Alimentarius Pesticide Residues in Food webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for myclobutanil 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. 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

Residue data for myclobutanil from field trials conducted with head and leaf lettuce in the United States, including growing regions representative of Canada, were submitted to support the establishment of a maximum residue limit (MRL) on imported commodities of crop subgroup 4A (leafy greens), except spinach. Previously reviewed residue data in plant matrices were also reassessed in the framework of this submission.

Maximum Residue Limit

The recommendation for the MRL for myclobutanil 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 MRL for all imported commodities of crop subgroup 4A (leafy greens), except spinach.

Table A1 Summary of Field Trial Data Used to Support the MRL

Commodity	Application Method/ Total Application Rate (g a.i./ha) ¹	Preharvest Interval (days)	Minimum Residues (ppm)	Maximum Residues (ppm)	Experimental Processing Factor
Head Lettuce (with wrapper leaves)	Foliar applications/ 549–574	2–4	0.04	1.36	n/a²
Leaf Lettuce	Foliar applications/ 559–573	2–4	0.23	4.03	n/a ²

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

Following the review of available data, an MRL of 9.0 ppm as proposed in Table 1 is recommended to cover residues of myclobutanil in/on all imported commodities of crop subgroup 4A (leafy greens), except spinach. Residues of myclobutanil in these imported crop commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

 $^{^{2}}$ n/a = Not applicable since lettuce is not considered to have processed commodities.