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Proposed Maximum Residue Limit

PMRL2013-115

Myclobutanil

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on pears and crops included in the Cucurbit Vegetable Crop Group (Crop Group 9), the Caneberry Subgroup (Crop Subgroup 13-07A), and the Bushberry Subgroup (Crop Subgroup 13-07B) to the product label of NovaTM 40W Agricultural Fungicide, containing technical grade myclobutanil, is acceptable. The specific uses approved in Canada are detailed on the label of NovaTM 40W Agricultural Fungicide, Pest Control Products Act Registration Number 22399.

The evaluation of these myclobutanil applications indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable. Details regarding the registration on pears can be found in the corresponding Evaluation Report available in the Pesticides and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.¹ A summary of the field trial data used to support the proposed MRLs on the remaining commodities can be found in Appendix I.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to 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. This quantity is then legally established as a maximum residue limit (MRL). 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 MRLs for myclobutanil is being conducted via this document (see Next Steps, the last 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 Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for myclobutanil, are as follows.

¹ The relevant report can be accessed by selecting Applications/Minor Use/Historical and requesting the Evaluation Report found under Application Number 2010-1314.

Table 1 Proposed Maximum Residue Limits for Myclobutanil

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Myclobutanil	α -butyl- α -(4-chlorophenyl)-1 <i>H</i> -1,2,4-triazole-1-propanenitrile, including the metabolites α -(3-hydroxybutyl)- α -(4-chlorophenyl)-1 <i>H</i> -1,2,4-triazole-1-propanenitrile and α -(butyl-3-one)- α -(4-chlorophenyl)-1 <i>H</i> -1,2,4-triazole-1-propanenitrile	2.0 ²	Caneberries (Crop Subgroup 13-07A)
		1.5 ³	Bushberries (Crop Subgroup 13-07B), except currants
		0.6	Pears
		0.3	West Indian gherkins, muskmelons (other than those listed)

¹ ppm = parts per million

² Proposed to replace the MRL of 1.2 ppm established for blackberries, loganberries, and raspberries.

³ Proposed to replace the MRL of 0.07 ppm established for Saskatoon berries (juneberries).

MRLs are proposed for each commodity included in the listed crop groupings 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 pesticide(s) or for food commodity(ies).

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 locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for myclobutanil in Canada with corresponding American tolerances and Codex MRLs.² American 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 Residues in Food website, 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 Canadian MRL, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Pears	0.6	Not Established	0.5 (Pome fruits)
Bushberries (Crop Subgroup 13-07B), except currants	1.5	2.0 (Gooseberries)	Not established
West Indian gherkins, muskmelons (other than those listed)	0.3	0.2 (Vegetable, cucurbit, group 9)	Not established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs 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 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 from field trials conducted in Canada were submitted to support the domestic use of Nova™ 40W Agricultural Fungicide on Cucurbit Vegetables, Caneberries, and Bushberries. Myclobutanil was applied to melons, cucumbers, zucchini, raspberries and blueberries, which were harvested according to label directions. In addition, previously reviewed cucurbit residue data on file were re-assessed.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for myclobutanil 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.

Table A1 Summary of Field Trial Data Used to Support Maximum Residue Limits

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)	
			Min	Max
Raspberry	Foliar/409–429	1	<0.35	<0.79
Blueberry	Foliar/400–421	1	<0.03	<0.97
Cucumber	Foliar/139–143	3–4	<0.030	<0.031
Melon	Foliar/142–146	3	<0.038	<0.106
Zucchini	Foliar/139–144	2–3	<0.030	<0.037

Following the review of all available data, MRLs are recommended as indicated in Table 1 to cover residues of myclobutanil. Residues of myclobutanil in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.