Proposed Maximum Residue Limit PMRL2013-95

Bifenazate

(publié aussi en français)

7 November 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2013-95E (print version)
H113-24/2013-95E-PDF (PDF version)

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 Cucurbit Vegetables to the product label of Acramite® 50WS and new uses on greenhouse eggplant to the product label of Floramite® SC Miticide, containing technical grade bifenazate, is acceptable. The specific uses approved in Canada are detailed on the labels of Acramite® 50WS and Floramite® SC Miticide, *Pest Control Products Act* registration numbers 27925 and 27924, respectively.

The evaluation of these bifenazate applications indicated that the end-use products have merit and value and the human health and environmental risks associated with the new uses are acceptable.

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 bifenazate 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 MRLs can be found in Appendix I.

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 bifenazate, are as follows.

Table 1 Proposed Maximum Residue Limits for Bifenazate

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Bifenazate	1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate, including the metabolite diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester	1.1	African eggplants, eggplants, pea eggplants, and Scarlet eggplants
		0.75[a]	Cucurbit Vegetables (Crop Group 9)

ppm = parts per million

[a] Proposed to revise the established 0.25 ppm MRL for residues of bifenazate in/on cucumbers (EMRL2008-02).

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

Table 2 compares the MRLs proposed for bifenazate in Canada with corresponding American tolerances and Codex MRLs.[1] 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.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
African eggplants, eggplants, pea eggplants, and Scarlet eggplants	1.1	2.0 (Vegetable, fruiting, group 8)	Not established
Cucurbit Vegetables (Crop Group 9)	0.75	0.75 (Vegetable, cucurbit, group 9)	0.5 (Fruiting vegetables, Cucurbits)

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for bifenazate 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.

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

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Acramite® 50WS on cucurbit vegetables. Bifenazate was applied at exaggerated rates to cantaloupe, cucumber, and summer squash, which were harvested according to label directions. In addition, residue data from greenhouse trials conducted in Canada were submitted to support the domestic use of Floramite® SC Miticide on greenhouse eggplant. Bifenazate was applied to greenhouse pepper at exaggerated rates, and harvested according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for bifenazate 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 for cucurbit vegetables.

The recommendation for a maximum residue limit (MRL) for bifenazate in/on African eggplants, eggplants, pea eggplants, and Scarlet eggplants was based upon the field trial data, guidance provided in PRO2005-04, *Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data*, and the North American Free Trade Agreement calculator as the MRL statistical methodology. Table A1 summarizes the residue data used to calculate the proposed MRLs for African eggplants, eggplants, pea eggplants, and Scarlet eggplants.

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

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)	
			Min	Max
Cantaloupe	Foliar/538.0–582.8	2–4	0.017	0.163
Cucumber	Foliar/515.6–571.6	2–3	<0.01	0.239
Summer Squash	Foliar/538.0–571.6	2–4	<0.01	0.571
Greenhouse Peppers	Foliar/2250–2310	1	0.49	0.88

PHI = preharvest interval; ppm = parts per million

Following the review of all available data, an MRL of 0.75 ppm is recommended to cover residues of bifenazate in/on Cucurbit Vegetables (Crop Group 9). Following the review of all available data, an MRL of 1.1 ppm is recommended to cover residues of bifenazate in/on African eggplants, eggplants, pea eggplants, and Scarlet eggplants. Residues of bifenazate 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.