Proposed Maximum Residue Limit

PMRL2013-88

Novaluron

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca healthcanada.gc.ca/pmra Facsimile: 613-736-3758 Information Service: 1-800-267-6315 or 613-736-3799

pmra.infoserv@hc-sc.gc.ca



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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 celery and sweet corn to the product label of RIMON 10EC Novaluron Insecticide, containing technical grade novaluron, is acceptable. The specific uses approved in Canada are detailed on the label of RIMON 10EC Novaluron Insecticide, Pest Control Products Act Registration Number 28515.

The evaluation of this novaluron application indicated that the end-use product has 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 novaluron 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 novaluron, are as follows.

Table 1 **Proposed Maximum Residue Limits for Novaluron**

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Novaluron	N-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide	9.0	Celery
		1.0	Milk ^a
		0.05	Sweet corn kernels
			plus cob with husks
			removed

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 (PCPA), both for pesticides or for food commodities.

ppm = parts per million

^a Proposed to replace the established MRL of 0.5 ppm for milk (EMRL2008-06).

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. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for novaluron in Canada with corresponding American tolerances and Codex MRLs. 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)
Milk	1.0	1.0	0.4 (Milks)

Next Steps

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

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 RIMON 10EC Novaluron Insecticide on celery and sweet corn. Novaluron was applied to celery at exaggerated rates, and harvested according to label directions. Novaluron was applied to sweet corn at the proposed rate and harvested according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for novaluron on celery was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. The recommendation for a MRL for novaluron in/on sweet corn was based on guidance provided in PRO2005-04, *Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data*, and the submitted field trial data. Table A1 summarizes the residue data used to calculate the proposed MRLs for celery and sweet corn.

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
Celery	Broadcast foliar/ 269.54–277.2	2–4	1.38	5.4
Sweet corn	Directed or broadcast foliar/ 436–475	1	<0.05	<0.05

PHI = preharvest interval; ppm = parts per million

Based on the dietary burden and the residue data, a MRL of 1.0 ppm in is also proposed to cover novaluron residues in milk.

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