Established Maximum Residue Limit EMRL2012-44

Clothianidin

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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

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has added a new use on potatoes to the product label of Titan ST Insecticide, containing technical grade clothianidin. The specific use approved in Canada is detailed on the label of Titan ST Insecticide, *Pest Control Products Act* Registration Number 27449.

Corresponding maximum residue limits (MRLs) were proposed in the consultation document published on 16 November 2010, Proposed Maximum Residue Limit PMRL2010-54, *Clothianidin*. The PMRA received a number of comments in response to this consultation, although they were essentially unrelated to the proposed MRLs. Appendix I summarizes the comments received and provides the PMRA's response.

The comments received had no impact on the clothianidin MRLs which are established as proposed in PMRL2010-54.

To comply with Canada's international trade obligations, consultation on the proposed MRLs was also conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada. No comments were received as a result of the World Trade Organization consultation.

The following MRLs take legal effect as of the publication date of this document and are in addition to the MRLs already established for clothianidin.

Established Maximum Residue Limits for Clothianidin

Common Name	Residue Definition	MRL (ppm	Food Commodity
Clothianidin	[C(*E*)]-*N*-[(2-chloro-5-thiazolyl)methyl]-*N*'-methyl-*N*''- nitroguanidine	1.5	Potato flakes, potato granules
		0.6	Potato chips
		0.3	Potatoes

ppm = parts per million

A list of pesticide MRLs established in Canada may be requested via the Maximum Residue Limits for Pesticides webpage in the Pesticides and Pest Management section of Health Canada's website.

Appendix I

Comments received via the PMRL consultation;

Numerous comments were received, all referencing the adverse effects of clothianidin on bees, with a few noting concerns with environmental properties including soil persistence and groundwater contamination.

A number of comments received equated the activities of registration and the setting of MRLs, stating that clothianidin should not be considered for registration for use on potatoes.

Another was concerned with the MRLs being proposed for potatoes given that they are significantly higher than the 0.01 ppm established for corn (field, pop and sweet), canola and milk and there was no explanation in the PMRL as to why a higher level of residues could be acceptable for human health in potatoes than in other foods.

Many comments also referenced the banning of clothianidin in a number of European countries, including France, Germany, Italy and Slovenia, and questioned its continuing use in Canada.

PMRA Response

The federal government and Health Canada's Pest Management Regulatory Agency are very aware of the importance of pollinators in the production of food in Canada, as well as the issues regarding the health of bees, including the potential effects of neonicotinoid pesticides. Health Canada scientists have continued to monitor new information related to pesticides and bees, including the growing body of scientific information being generated by experienced researchers. Additionally, Canada is working together with our global regulatory partners and scientists to update the risk assessment framework for pollinators, and ensure that pesticide risk assessments consider and evaluate all potential exposure routes and potential risk to pollinators. Health Canada and the United States Environmental Protection Agency are collaborating on evaluating neonicotinoid pesticides, and are ensuring that appropriate information is being generated to understand the potential risks to pollinators.

The Agency's position in this regard is summarized in Re-evaluation Note REV2012-02, *Re-evaluation of Neonicotinoid Insecticides*, posted to the Health Canada website on 12 June 2012. There will be an opportunity for public comment regarding the use of clothianidin, and other neonicotinoid pesticides, at a later date.

It should be noted that the setting of MRLs is unrelated to pollinator health considerations. While many comments were suggesting not registering clothianidin on potatoes, the seed treatment use for the suppression of wireworms was registered more than 3 years ago.

The purpose of PMRL2010-54 was to propose MRLs corresponding to the registration of Titan ST Insecticide on potatoes. Submitted field trial data supporting the MRLs were reviewed by the Agency and are summarized in the corresponding Evaluation Report as referenced in PMRL2010-54. The Evaluation Report may be requested from the Public Registry under Minor Use application #2008-5310. In addition, concern was expressed that the MRL proposed for potatoes was substantially higher than existing MRLs; however, Canadian clothianidin MRLs are also currently established for pome fruit (0.3 ppm), grapes (0.6 ppm) and stone fruit (0.8 ppm) at levels comparable with that proposed for potatoes. Regardless of the MRL values, all applications with food uses include residue trials conducted in accordance with the product label to support the MRLs and these values are then incorporated into a dietary risk assessment. If acceptable, the product/use is deemed suitable for registration.

With respect to the concerns regarding soil persistence and groundwater contamination, these properties were reviewed by the Agency and conclusions were reported in Evaluation Report ERC2011-01, *Clutch 50 WDG, Arena 50 WDG and Clothianidin Insecticides*. The link leads to a summary of ERC2011-01 and a full copy of the report may be requested via the same web page. The Agency's review and conclusions are found under Section 4.1.1 for terrestrial environment and Section 4.1.2 for aquatic environment.

The MRLs proposed herein are established as proposed in PMRL2010-54.