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Proposed Maximum Residue Limit

PMRL2014-31

Saflufenacil

(publié aussi en français)

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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 canola, mustard and flax to the product label of Heat WG, containing technical grade saflufenacil, is acceptable. The specific uses approved in Canada are detailed on the label of Heat WG, *Pest Control Products Act* Registration Number 29368.

The evaluation of this saflufenacil 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). A 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 saflufenacil 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 be added to the MRLs already established for saflufenacil, are as follows:

Table 1 Proposed Maximum Residue Limits for Saflufenacil

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Saflufenacil	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2 <i>H</i>)-pyrimidinyl]-4-fluoro- <i>N</i> -[[methyl(1-methylethyl)amino]sulfonyl]benzamide, including the metabolites <i>N'</i> -{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl}- <i>N</i> -isopropyl sulfamide and <i>N</i> -[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea	0.5	Crop subgroup 20A (rapeseed, revised)

¹ ppm = parts per million

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 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 saflufenacil 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 Maximum Residue Limits, American Tolerances and Codex MRLs (where different)

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Crop Subgroup 20A (rapeseed, revised)	0.5	0.45	0.6 (rapeseed)

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for saflufenacil 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 Heat WG on canola, mustard and flax. Saflufenacil was applied to canola at label rates, and harvested according to label directions. In addition, a processing study in treated canola was reviewed to determine the potential for concentration of residues of saflufenacil and metabolites M800H11 and M800H35 into processed commodities.

Maximum Residue Limits

The recommendation for MRLs for saflufenacil and metabolites M800H11 and M800H35 was based upon the submitted field trial data, and the guidance provided in the Organisation for Economic Co-operation and Development's MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for Crop Subgroup 20A.

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

Commodity	Application method/ Total application rate (g a.i./ha)	Preharvest Interval (days)	Combined saflufenacil residues ¹ (ppm)		Experimental processing factor
			Min	Max	
Canola	Foliar application as a harvest aid/ 49-52	2-3	0.031	0.37	No concentration observed in canola processed fractions

¹ Combined residues include saflufenacil (parent), M800H11 and M800H35.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of saflufenacil and metabolites M800H11 and M800H35. Residues of saflufenacil in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.