Proposed Maximum Residue Limit

PMRL2014-84

Maleic Hydrazide

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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 dry bulb shallots to the product label of Royal MH-30 Xtra, containing technical grade maleic hydrazide, is acceptable. The specific uses approved in Canada are detailed on the label of Royal MH-30 Xtra, *Pest Control Products Act* Registration Number 29607.

The evaluation of this maleic hydrazide 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 specified 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 maleic hydrazide 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 maleic hydrazide, are as follows.

Table 1 Proposed Maximum Residue Limit for Maleic hydrazide

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Maleic	1,2-dihydro-3,6-pyridazinedione	15	Bulb Onion
hydrazide			Subgroup (Crop
			Subgroup 3-07A)

 $[\]frac{1}{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 for food commodities.

International Situation and Trade Implications

Table 2 compares the MRLs proposed for maleic hydrazide 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.

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

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)	
Shallot bulb	15	Not established	15	
Garlic	15	Not established	15	
Daylilies, fritillaria bulbs, great headed garlic, serpent garlic, lilies, Chinese onions, pearl onions, potato onions	15	Not established	Not established	

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for maleic hydrazide 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 on file for dry bulb onions from field trials conducted in the United States were reassessed in the framework of this petition to support the domestic use of Royal MH-30 Xtra on dry bulb shallots. Maleic hydrazide was applied to dry bulb onions, the representative crop for Crop Subgroup 3-07A, at the proposed rate and the crop was harvested according to label directions.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for maleic hydrazide in/on crops within Crop Subgroup 3-07A was based upon the crop field trial data for dry bulb onions and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for crops in the Bulb Onion Subgroup (Crop Subgroup 3-07A).

Table A1 Summary of Field Trial and Processing Data Used to Support the MRL

Commodity	Application Method/ Total Application Rate (kg a.i./ha) ¹	Preharvest Interval (days)	Minimum Residues (ppm)	Maximum Residues (ppm)
Dry bulb onion	Foliar application using ground equipment / 2.24	10-11	0.48	7.44

¹ kg a.i./ha = kilograms of active ingredient per hectare

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of maleic hydrazide. Residues of maleic hydrazide in/on Crop Subgroup 3-07A at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.