Health Canada Santé Canada

Evaluation Report for Category B Subcategory 5.0 Application

Application Number:	2009-4490
Application:	New MRL for previously assessed TGAI
Product:	Bromoxynil Octanoate Technical
Registration Number:	19705
Active ingredient (a.i.):	Bromoxynil
PMRA Document Number English PDF:	2036336

Purpose of Application

The purpose of this application was to establish maximum residue limits (MRLs) for bromoxynil on barley, bulb onion, cotton, field corn, popcorn, flax, garlic, oat, peppermint, spearmint, rye, sorghum, triticale and wheat.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

Residue data for bromoxynil were submitted to support the establishment of MRLs on imported barley, field corn, popcorn, flax, garlic, oat, bulb onion, peppermint, rye, sorghum, spearmint, triticale, wheat and cotton. In addition, processing studies in treated cereal grains, flax, cotton and mint were also assessed to determine the potential for concentration of residues of bromoxynil into processed commodities.

Based on the maximum residues observed in crops treated according to United States label directions or at exaggerated rates, maximum residue limits (MRLs) to cover residues of bromoxynil in/on crops and processed commodities will be proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodities (RACs). Onions, garlic and flax are covered by previously established MRLs. Residues of bromoxynil in these commodities at the established and/or recommended MRLs will not pose an unacceptable dietary risk to any segment of the population, including infants, children, adults and seniors.

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Table 1 Summary of field trial and processing data used to establish maximum residue limits (MRLs)

Commodity	Application method/ Total rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experiment processing factor	Currently established or proposed MRL (ppm)	Recommended MRL(ppm)
			Min	Max			
Garlic	Foliar spray/ 1.12	60-61	All <0.02		Not applicable	0.1 ppm (EMRL2011-13)	0.1 ppm (EMRL2011-13)
Wheat	Foliar spray/ 0.56	52-71	All <0.02		Concentration of residues only observed in bran at 2.9-fold	none	0.05 ppm* for crop group 15 (cereal grains, except rice)
Barley	Foliar spray/ 0.56	54-71	<0.02	0.03	No concentration of residues in process food commodities	none	
Field corn	Foliar spray/ 0.56	64-97	All <0.02			none	
Sorghum	Foliar spray/ 0.56	65-107	All <0.02			0.1 ppm	
Flax	Foliar spray/ 0.28	53-82	All <0.02		Residues in flax oil were all <0.02 ppm	0.1 ppm (EMRL2011-13)	0.1 ppm (EMRL2011-13)
Mint	Foliar spray/ 1.12-1.68	76-99	All <0.05		Residues in mint oil were all <0.05 ppm	none	0.05 ppm
Cotton	Foliar spray/ 1.68	75	<0.06**	<1.11 **	No concentration of residues in processed food commodities	none	1.5 ppm

* The proposed MRL of 0.05 ppm for cereal grains (except rice) will replace the currently established MRL of 0.1 ppm in pearl millet, proso millet and sorghum

** Combined residues of bromoxynil and the metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid)

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A value assessment was not required for this application.

Conclusions

The PMRA conducted an evaluation of the subject application and determined that MRLs to cover residues of bromoxynil will be proposed as follows:

RAC and/or Processed Commodity	MRL (ppm)
Cereal grains (except rice) – Crop group 15	0.05*
Peppermint tops, spearmint tops	0.05
Undelinted cotton seeds	1.5

* The proposed MRL of 0.05 ppm for cereal grains (except rice) will replace the currently established MRL of 0.1 ppm in pearl millet, proso millet and sorghum.

MRLs were established for bromoxynil in/on garlic and flaxseed at 0.1 ppm on 18 March 2011 under via EMRL2011-13.

While revision was requested for the bromoxynil MRL in/on dry bulb onions from 0.02 ppm to 0.1 ppm, the submitted residue data do not support the proposed revision. The established MRL of 0.02 ppm is considered adequate to cover residues in domestically treated and imported dry bulb onions.

References

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