

Evaluation Report for Category B, Subcategory 3.1, 3.12 Application

Application Number: 2018-1266
Application: Changes to End-Use Product Labels – Application Rate Increase and New Site or Host
Product: Manipulator 620
Registration Number: 31462
Active ingredient (a.i.): Chlormequat Chloride
PMRA Document Number : 3016339

Purpose of Application

The purpose of this application was to amend the label of the end-use product, Manipulator 620, by adding uses on spring and winter barley and spring and winter oats.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

No toxicological data were reviewed for this submission.

The addition of barley and oats to the label of the plant growth regulator Manipulator 620 represents an expansion of the use pattern for the active ingredient chlormequat chloride since these crops are treated at a rate higher than the maximum previously registered rate for wheat. Updated quantitative risk assessments were conducted for mixer/loader/applicator and postapplication worker exposure. No health risks of concern were identified provided that the workers wear the appropriate personal protective equipment and follow all label directions.

New food residue chemistry data for chlormequat chloride were submitted in support of the current application. These data included metabolism studies for plant (wheat) and livestock (goat and hen), residue analytical methods for plant and livestock commodities, freezer storage stability studies for plant and livestock commodities, crop field trial and processing studies for barley, oats and wheat, livestock feeding studies (poultry and dairy cattle) and a confined crop rotation trial study.

The nature of the chlormequat chloride residues in plant (primary and rotational) and livestock commodities is adequately understood. The residue definition (RD) is chlormequat chloride for both enforcement and risk assessment purposes. The data gathering/enforcement analytical methods are valid for the quantitation of chlormequat chloride residues in cereal and livestock matrices. The conditions and intervals under which samples were stored during the magnitude of the residue studies were supported.

Residue data from field trials conducted in Canada and the United States on barley, wheat and oats were submitted to support the domestic use of chlormequat chloride on these crops. Chlormequat chloride was applied to barley, oats and wheat at label rates, and some of the barley field trials were conducted at lower rates but residues were corrected using the concept of proportionality. All samples were harvested at normal commercial maturity, and for some trials samples were harvested before and after normal commercial harvest in order to evaluate residue decline. In addition, processing studies in treated barley, oat and wheat were reviewed to determine the potential for concentration of residues of chlormequat chloride into processed commodities.

Adequate feeding studies were conducted to assess the anticipated residues in livestock matrices resulting from the proposed uses.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for chlormequat chloride was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of chlormequat chloride in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Chlormequat Chloride Residues (ppm) ¹		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAF T	HAF T			
Barley grain	Broadcast foliar/ 1.36-1.5 ²	NCH or later ³	0.161	4.99	3.10x [pearling dust/bran] 0.93x [pot barley] 0.29x [pearled barley] 0.26x [flour]	None	8 [barley] 20 [barley bran]

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)							
Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Chlormequat Chloride Residues (ppm)¹		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
Oat grain	Broadcast foliar/ 1.38-1.48	NCH or later ³	0.021	22.8	3.4x [coarse bran] ⁴ 0.74x [groats/rolle d oats] 0.68x [flour]	None	40 [oats] 80 [oat bran ⁴]
Wheat grain	Broadcast foliar/ 1.05-1.14	NCH	0.339	3.78	5.0x [germ] 3.4x [coarse bran] 0.1x [flour]	1 [wheat]	5 [wheat] 20 [wheat germ] 15 [wheat bran]

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; NCH = normal commercial harvest

¹ Residues in the barley, oat and wheat field trials were expressed as the chlormequat cation. As such, a molecular weight conversion factor (MWCF) of 1.29 was used by PMRA to convert residues to chlormequat chloride equivalents [(158.1 g/mol chlormequat chloride) ÷ (122.6 g/mol chlormequat cation)].

² Chlormequat chloride residue levels from Canadian barley trials were scaled based on the concept of proportionality.

³ Higher residues in samples harvested after normal crop maturity were included in calculation of the MRL as a conservative estimate of exposure.

⁴ Processing factor extended from wheat coarse bran.

Based on the dietary burden and residue data, the following MRLs are also proposed to cover residues of chlormequat chloride in/on livestock commodities:

- 0.7 ppm for the meat byproducts of cattle, goats, horses and sheep
- 0.4 ppm for milk
- 0.09 ppm for eggs; and the meat of cattle, goats, horses and sheep
- 0.08 ppm for the fat of cattle, goats, horses and sheep
- 0.06 ppm for poultry meat byproducts.
- 0.05 ppm for fat, meat and meat byproducts of hogs, and fat and meat of poultry.

Following the review of all available data, MRLs as proposed in Table 1 and above for livestock commodities are recommended to cover residues of chlormequat chloride. Residues in these crop and livestock commodities at the proposed MRLs will not pose unacceptable health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses for chlormequat chloride on spring and winter barley and spring and winter oats are covered by the estimated environmental concentrations (EECs) used during water modelling for the wheat use pattern on the registered label, and the buffer zones required for spring and winter barley and spring and winter oats are identical to the buffer zone required for wheat.

Therefore, the environmental risk associated with the use expansion is not expected to exceed the risk associated with the previously registered uses of Manipulator 620.

Value Assessment

Amending the registration of Manipulator 620 to include spring and winter barley and spring and winter oats as host crops that may be treated for the purpose of improving resistance to lodging will serve as a valuable crop management tool for Canadian barley and oat growers.

Data from field trials conducted on spring and winter barley and spring and winter oats in the United Kingdom between 2001 and 2005 were provided in support of the requested registration amendments to Manipulator 620. Cereal growth parameters and effects measured in the trials included main stem height, lodging incidence and severity, phytotoxicity (chlorosis, necrosis, stunting and crop vigour) and yield. The provided trial data demonstrated that an application of Manipulator 620 as per label directions has the potential to reduce plant height and decrease the amount of lodging of spring and winter barley and spring and winter oats as compared to untreated plants.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the expansion of the label of Manipulator 620 to add uses on spring and winter barley and spring and winter oats.

References

PMRA

Document

Number	Reference
2865596	2017, Research Trials for the Growth Regulator Manipulator 620 in Oats and Barley, DACO: 10.2.3.2(B), 10.2.3.3(B), 10.3.2(A).
2865583	2017, Magnitude of the Residue of Chlormequat Chloride in Barley, DACO: 7.2.1,7.4.1,7.4.2,7.4.5

- 2865584 2017, Magnitude of the Residue of Chlormequat Chloride in Oats, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
- 2865585 2017, Magnitude of the Residue of Chlormequat Chloride in Wheat, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
- 2865586 2016, Magnitude of the Residue of Chlormequat Chloride in Wheat, DACO: 7.4.1,7.4.2
- 2865588 2006, Validation of the Analytical Method 530/0: Method for the Determination of Chlormequat Chloride in Plant Matrices, DACO: 7.2.1
- 2865589 1990, Radioactive Residues and Studies on the Metabolism of ¹⁴C-Chlormequat Chloride (CCC, BAS 062 W) in Spring Wheat, DACO: 6.3
- 2865590 2006, Technical Procedure: Method for the determination of Chlormequat Chloride in Plant Matrices, DACO: 7.2.1
- 2865591 2003, Confined Rotational Crop Study with ¹⁴C-Chlormequat-Chloride., DACO: 7.4.3
- 2865592 2002, Freezer Storage Stability of Chlormequat-Chloride in Cow Meat, Milk and Hen Eggs, DACO: 7.3

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