



Evaluation Report for Category B, Subcategory B4.1, B2.1 and B2.4

Application Number: 2005-4119
Application: Category B, Subcategory B4.1 (Conversion to Full, update the conditions of temporary registration, B2.1 (Change in guarantee), and B2.4 (Proportion of formulants)
Product: Governor 75 WP Insecticide
Registration Number: 24464
Active ingredients (a.i.): Cyromazine
PMRA Document Number: 1388393

Background

Governor 75 WP Insecticide is registered temporarily in Canada, pending submission of certain data/information. Governor 75 WP insecticide is registered under the Use Site Category # 14 and 10 (Terrestrial food crops and Seed treatment, respectively).

Purpose of Application

The purpose of this application was to update the condition of temporary registration. Through the current application some of the required data has been addressed, however, the rest of the required data/information are still pending. Therefore, this product will not convert to full until the remaining of the data gaps be addressed. It is anticipated that the remaining data/information be submitted by December 1, 2008. Meanwhile the % purity (guarantee) of the active ingredient has been changed from 95% to 97% resulting in the minor formulation change of the subject end use product. Therefore, the % w/w of the active in the formulation of Governor 75 WP has decreased from 78.95 to 77.32 and one of the formulants (list 4B mixture) has increased slightly.

Chemistry Assessment

Governor 75 WP is a wettable powder containing the active ingredient cyromazine at a nominal concentration of 75%. This product has a specific gravity of 1.35 at 20°C. The chemistry requirements for Governor 75 WP have been completed.

Health Assessments

A toxicology assessment was not required as there was no change to the product formulation.

The registration of Governor 75 WP Insecticide was previously reinstated after a lapse in registration greater than one year. During this previous application, the uses on potatoes by groundboom to control Colorado potato beetle was assessed as well as the importation of imported treated dry bulb seeds and green onion seeds to control onion maggot. Exposure to both mixer/loader/applicators and post application workers were assessed and found to be acceptable.

Food Residues Exposure Assessment

To support the conversion from conditional to full registration, additional Canadian residue data were reviewed for potatoes. In these trials the crops were treated with two foliar applications of cyromazine formulated as Governor 75WP according to the current label directions, and harvested at the proposed pre-harvest interval. As well, a data gathering method and a freezer storage stability study were provided to validate the methods of analysis and the duration of frozen storage in the residue trial studies. It was determined that the analytical method submitted was adequate for the determination of residues of cyromazine and melamine in potatoes, and that residues of cyromazine and melamine remained stable in potatoes over the duration of frozen storage.

Maximum Residue Limit (MRL)

Following the review of confirmatory data from Canadian supervised residue trials, an MRL of 0.8 ppm is recommended for potatoes and processed commodities to cover residues of cyromazine and the metabolite melamine (see Table 1).

Table 1. Summary of field trial and processing data used to establish maximum residue limits (MRLs)							
Commodity	Application method/ Total app. Rate (g a.i./ha)	PHI (pre-harvest Interval) (days)	Cyromazine (melamine) Residues (ppm)		Experimental Processing Factor	Currently established MRL ¹	Recommended MRL ²
			Min	Max			
Potato	Foliar / 420 g a.i./ha	13-15	0.05* (0.016*)	0.17 (0.016*)	Chip process : 2.44 Granule Process: 3.71	Potato - 0.5 ppm Dry potato products - 1.5 ppm	Potato - 0.8 ppm

* Values of <LOQ are reported at the LOQ for computational purposes.

¹ MRLs currently established in Table II, Division 15 of the FDA&R

² MRLs to be established in Table II, Division 15 of the FDA&R as a result of the current submission.

Environmental Assessment

The Environmental Assessment Division (EAD) will support the full registration of the subject product with the following condition: the full data package to support DACO 8.3.4 (drinking water monitoring studies conducted in Ontario/Quebec and Atlantic Provinces, preferably PEI; as identified during the review of the subject product, must be submitted by December 1, 2008. The minor formulation change is not expected to have significant impact on the environment.

Value Assessment

The proposed use claims and label use direction are identical to that of the approved label for conditional registration. No efficacy/value issues have been identified and associated with the conditions of the conditional registration. The minor formulation change, as a result of small increase in guarantee, is expected to have no significant impact on the product's efficacy performance.

Conclusion

Following the review of all available data, including confirmatory residue data submitted for the purpose of this petition, an MRL of 0.8 ppm is recommended to cover residues of cyromazine and melamine in potatoes treated with Governor 75WP according to current label directions and all processed potato products resulting from treated crops. Residues of cyromazine and the metabolite melamine in these crops and livestock commodities up to the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The minor formulation change is acceptable, and this product has converted from conditional registration to full registration, with conditions. However, the full data package to support DACO 8.3.4 must be submitted by December 1, 2008. Please note that the only outstanding data is DACO 8.3.4 as indicated below.

DACO: 8.3.4

Title: Special Studies Related to Intended Use Pattern

Deficiencies: The data submitted to support DACO 8.3.4 is an interim report of an ongoing study on the drinking water monitoring of cyromazine and melamine conducted in the regions of Ontario and Quebec.

Required DATA: The full data package to support DACO 8.3.4 (drinking water monitoring studies conducted in Ontario/Quebec and Atlantic provinces, preferably PEI; as identified in the correspondence from Parsons to Shaw, February 26, 1996) must be submitted by December 1, 2008.

In the submitted interim study it was reported that "since this study was set up as a residue monitoring study, application of test item was done.", however, no further information in this relation was provided.

The applicant should provide sufficient information on the application rate(s), method of application, number of application(s) and their timing. These information should be reported in the final study report.

References

A. List of studies/information submitted by registrant:

Health Assessment

PMRA Document Number	Reference
1108308	2005, Cyromazine-Residue Levels on Potatoes (tubers) from Trials Conducted with Governor 75WP in Canada During 2004., Syngenta Crop Protection Canada, Inc., DACO: 7.4.1
1181709	2003, Stability of Residues of Cyromazine (CGA 72662) and its Metabolite Melamine © 1803) in Deep Freeze Stored Analytical Specimens of Tomatoes, Potatoes, Beans and Sunflower Seeds., Syngenta Crop Protection AG, 101/01, DACO: 7.3
1335643	2001, Cyromazine (CGA 72662): Determination of Residues of Parent Compound and Its Metabolite Melamine © 1803) by HPLC, Syngenta Crop Protection AG, REM 174.02, DACO: 7.2.2

B. Additional information considered

None.

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