

Evaluation Report for Category B

Application Number: 2006-6941
Application: B.2.3: Identity of Formulants
B.2.5: Formulation Type
Product: Ridomil Gold MZ 68WG Fungicide
Registration Number: 28893
Active ingredients (a.i.): Mancozeb, Metalaxyl-M
PMRA Document Number: 1739378

Purpose of Application

The purpose of this application is to register a new formulated end-use product, Ridomil Gold MZ 68WG. Ridomil Gold MZ 68WG has the same use pattern as the currently registered Ridomil Gold MZ 68WP (Reg No. 25379). Ridomil Gold MZ 68WG and Ridomil Gold MZ 68WP have the same guarantee in terms of active ingredients, however, the end-use products differ in formulation type (wetable powder vs wettable granule) and in the identity of some formulants.

Chemistry Assessment

Ridomil Gold MZ 68WG is a wettable granule formulation type containing the active ingredients mancozeb and metalaxyl-M at nominal concentrations of 64% and 4% respectively. Ridomil Gold MZ 68WG has a density of 0.635 g/mL and pH of 6-8.

The chemistry requirements for Ridomil Gold MZ 68WG have been completed and are acceptable.

Health Assessments

Ridomil Gold MZ 68WG is of low acute toxicity by dermal ($LD_{50} > 5000$ mg/kg bw) and oral routes ($LD_{50} > 5000$ mg/kg bw) in rats. It is of low toxicity via inhalation with an LC_{50} of greater than 5.13 mg/L. Ridomil Gold MZ 68WG is slightly irritating to the skin and mildly irritating to the eyes of rabbits. Ridomil Gold MZ 68WG is a dermal sensitizer in female albino Dunkin Hartley guinea pigs.

Ridomil Gold MZ 68 WG is a wettable granule and Ridomil Gold MZ 68WP is a wettable powder. Unit exposure values for mixing/loading wettable granules is lower than for wettable powders, therefore, the exposure to handlers mixing/loading and applying the Ridomil Gold MZ 68WG (wetable granule) is not expected to increase over Ridomil Gold MZ 68WP (wetable powder). Exposure to workers entering fields and vineyards treated with Ridomil Gold MZ 68WG, is not expected to increase over Ridomil Gold MZ 68WP.

Residue data for metalaxyl-m in potato processed commodities and bridging studies comparing Ridomil Gold MZ 68WG and Ridomil Gold MZ 68WP in grapes and potatoes for residues of metalaxyl-m and mancozeb were submitted.

Previously reviewed residue data from field trials conducted in/on grapes, potato, lettuce and onions were reassessed in the framework of this application. In addition, processing studies in treated grapes and potatoes were also reassessed to determine the potential for concentration of residues of metalaxyl-m and mancozeb into processed commodities.

Following the review of all available data, residues of metalaxyl-m and mancozeb in these crop commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The Ridomil Gold MZ 68WG does not contain any formulants of concern or any formulants that meet TSMP criteria. Therefore, the risk assessment for Ridomil Gold MZ 68WP can be utilized to support Ridomil Gold MZ 68WG.

Value Assessment

Comparative (side-by-side) trials were conducted in Canada and Brazil in 2004 and 2005 to support the registration of Ridomil Gold MZ 68WG. Efficacy of Ridomil Gold MZ 68WG and Ridomil Gold MZ 68WP were evaluated on late blight, early blight and pink rot on potatoes as well as downy mildew of head lettuce and grapes. The results demonstrate the two formulations are equivalent in terms of efficacy for control of late blight and early blight, for suppression of pink rot of potatoes and the control downy mildew of grapes and lettuce.

Trials testing the efficacy of the two formulations for control of onion downy mildew or *Pythium* leak on potatoes were not submitted. However, as the efficacy data provided indicates the two formulations provide equivalent control for the diseases tested, all uses on the currently registered Ridomil Gold MZ 68WP label are acceptable to appear on the Ridomil Gold MZ 68WG label.

Conclusion

The PMRA has completed an evaluation of the information provided with this application and has determined the information to be sufficient to support the full registration of Ridomil Gold MZ 68WG.

References

Studies/Information Provided by Applicant/Registrant

1.0 Chemistry Assessment

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2.0 Impact on Human and Animal Health Assessment

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1311385 2006, Residue levels on potatoes from trials conducted in Canada during 2005, CER05821/05, DACO: 7.4.1,7.4.2

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- 1311367 2005, 4.6.3 - 4-hour acute inhalation toxicity study in rats, T015338-04, DACO: 4.6.3
- 1311368 2006, 4.6.4 - Acute eye irritation study in rats, T002735-05, DACO: 4.6.4
- 1311369 2006, 4.6.5 - Acute dermal irritation study in rabbits, T002736-05, DACO: 4.6.5
- 1311370 1999, 4.6.5 - Acute dermal irritation/corrosion in the rabbit, 993025, DACO: 4.6.5
- 1311371 2005, 4.6.6 - Contact hypersensitivity in albino guinea pigs, Buhler test, 856575, DACO: 4.6.6

3.0 Value Assessment

- 1311354 2006, Data summary tables, DACO: 10.1,10.2.3.1
- 1311355 2006, Efficacy Summary, DACO: 10.2.3.1
- 1311356 2006, Field Trials, DACO: 10.2.3.3,10.3.1,10.3.2

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