



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-5947
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment
Product: Rambler Fungicide
Registration Number: 35048
Active ingredient (a.i.): prothioconazole
PMRA Document Number: 3431182

Purpose of Application

The purpose of this application was to register a new end-use product containing prothioconazole, based on a registered precedent product, for management of various fungal diseases on listed crops.

Chemistry Assessment

Rambler Fungicide is formulated as a suspension containing prothioconazole at a concentration of 480 g/L. This end-use product has a density of 1.1703 g/mL and pH of 6.76. The required chemistry data for Rambler Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Rambler Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Rambler Fungicide is considered to be of low acute toxicity via the oral and dermal routes, and of slight acute toxicity via the inhalation route. It is considered non-irritating to the eyes and slightly irritating to the skin and is not considered a dermal sensitizer.

The use pattern of Rambler Fungicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products containing this active ingredient. No health risks of concern are expected, provided that workers wear the appropriate personal protective equipment and follow all label directions for use.

No new residue data for prothioconazole were submitted or are required to support the registration of Rambler Fungicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Rambler Fungicide label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use product.

Based on this assessment, prothioconazole residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of prothioconazole is not expected to increase with the registration of Rambler Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Rambler Fungicide is within the registered use pattern of the active ingredient prothioconazole, therefore, no additional risk is expected from the use of Rambler Fungicide. The label includes all the required environmental precautions, directions for use and spray buffer zone information which adequately mitigate risks to the environment.

Risk from use of Rambler Fungicide is acceptable from an environmental perspective when used according to label directions.

Value Assessment

A comparison of the formulation of Rambler Fungicide to that of the registered precedent product demonstrated that Rambler Fungicide can be expected to perform similarly in terms of efficacy and crop tolerance. Therefore, all uses and disease claims that are registered for the precedent product are acceptable for Rambler Fungicide. The registration of Rambler Fungicide will provide growers with an alternative tool to manage diseases on labelled crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Rambler Fungicide.

References

PMRA

Document

Number	Reference
3286105	2021, Applicant's Name and Office Address, Formulating Plant and address, Identity for Rambler Fungicide, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.5.13, 3.5.15, 3.5.5
3286106	2021, Certificate of Composition, DACO: 3.2.1 CBI
3286107	2021, Manufacturing Process Steps of Prothioconazole 480 g/L SC, DACO: 3.2,3.2.1,3.2.2 CBI
3286108	2021, Flow Chart of Prothioconazole 480 g/L SC, DACO: 3.2,3.2.1,3.2.2 CBI
3286109	2020, Certificate of Analysis, DACO: 3.7 CBI
3286111	2020, Certificate of Analysis - Reference Standard, DACO: 3.4.1 CBI
3286113	2021, Study on the Physico-chemical Properties of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.4.1, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI

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