

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-6943
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PIIP) policy-Equivalency/Data Compensation Assessment
Product: Shalimar Fungicide
Registration Number: 34357
Active ingredients (a.i.): Prothioconazole and Tebuconazole
PMRA Document Number (English PDF): 3251948

Purpose of Application

The purpose of this application was to register Sharda TebPro Fungicide, a new end-use product for control or suppression of fungal diseases in wheat (spring, durum and winter), barley and oats, based on a registered precedent product.

Chemistry Assessment

Sharda TebPro Fungicide is formulated as an emulsifiable concentrate containing prothioconazole and tebuconazole, both at a concentration of 125 g/L. This end-use product has a specific gravity of 0.9896–1.0067 (20 °C) and pH of 5.83 (1% aqueous solution). The required chemistry data for Sharda TebPro Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Sharda TebPro Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Sharda TebPro Fungicide is considered to be of low acute toxicity by the oral, dermal and inhalation routes, mildly irritating to the skin, and severely irritating to the eyes. Sharda TebPro Fungicide is not considered to be a dermal sensitizer.

The use pattern of Sharda TebPro 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 of these active ingredients. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

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

the precedent end-use product. Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of prothioconazole and tebuconazole is not expected to increase with the registration of Sharda TebPro Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The environmental risks associated with the use of Sharda TebPro Fungicide are acceptable when the product is used according to the label directions.

Value Assessment

Data from three field studies conducted on wheat and a comparison of the product formulation of Sharda TebPro Fungicide to that of a precedent product demonstrated that the performance of Sharda TebPro Fungicide, in terms of both efficacy and crop safety, can be expected to be similar to that of the precedent product. Therefore, the use pattern of the registered precedent product on wheat, barley and oat is supported for Sharda TebPro Fungicide.

Fungal diseases diminish the yield and quality of wheat, barley and oat crops and constitute a perennial problem for cereal growers. The availability of generic products, such as Sharda TebPro Fungicide, will provide cereal growers with an alternative product for management of these diseases.

Conclusion

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

References

PMRA Document Number	Reference
3066964	2018, Value Summary for TebPro Fungicide containing 125g/L of Tebuconazole and 125g/L of Prothioconazole, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.4,10.5
3066965	2017, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd Generic Fungicide on Wheat, DACO: 10.2.3.3(D)
3066966	2017, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd Generic Fungicide on Wheat, DACO: 10.2.3.3(D)
3066972	2018, Description of Process Formulation to Prosaro 250 EC Sharda, DACO: 3.2.1,3.2.2,3.3.1 CBI

3066973	2017, Validation of Analytical Method for Determination of Active Ingredient Content of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.4.1
3066974	2017, Appearance of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.1,3.5.2,3.5.3
3066976	2017, Accelerated Storage Stability and Corrosion Characteristics of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.10,3.5.14
3066977	2017, Determination of Explosive Properties of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.12
3066978	2017, Relative Density of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.6
3066979	2017, Specific Gravity of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.6
3066980	2017, pH of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.7
3066981	2018, Oxidizing Properties of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.8
3066982	2017, Viscosity of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.5.9
3066984	2017, Flash Point of Tebuconazole 125g/L + Prothioconazole 125 g/L EC, DACO: 3.7

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