



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-6941
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: Sharda Prothioconazole 480 SC Fungicide
Registration Number: 35163
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3583062

Purpose of Application

The purpose of this application was to register a new end-use product, Sharda Prothioconazole 480 SC Fungicide, for use as a broadcast foliar treatment to control and suppress fungal diseases on various terrestrial food and feed crops and industrial oil seed and fiber crops, based on a precedent.

Chemistry Assessment

Sharda Prothioconazole 480 SC Fungicide is formulated as a suspension containing prothioconazole at a concentration of 480 g/L. This end-use product has a density of 1.2170–1.2360 g/mL and pH of 6.07 (1% w/v aqueous suspension). The required chemistry data for Sharda Prothioconazole 480 SC Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Sharda Prothioconazole 480 SC Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Sharda Prothioconazole 480 SC 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 to be non-irritating to the eyes and minimally irritating to the skin, and is not considered to be a dermal sensitizer.

The use pattern of Sharda Prothioconazole 480 SC 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 product. 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 were submitted or are required to support the registration of Sharda Prothioconazole 480 SC Fungicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Sharda Prothioconazole 480 SC Fungicide label, including the target crops, method

(ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are similar 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 MRLs. Consequently, dietary exposure to residues of prothioconazole is not expected to increase with the registration of Sharda Prothioconazole 480 SC Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses for Sharda Prothioconazole 480 SC Fungicide are within the currently registered use pattern of the active ingredient, prothioconazole, and therefore, no increase in exposure to the environment is expected when Sharda Prothioconazole 480 SC Fungicide is used according to label directions. The label includes the required environmental precautions and hazards statements.

Value Assessment

Data from six field studies conducted on canola and wheat and a comparison of the product formulation of Sharda Prothioconazole 480 SC Fungicide to that of the cited precedent product demonstrated that the performance of Sharda Prothioconazole 480 SC Fungicide can be expected to be similar to that of the cited precedent product. Therefore, the use pattern registered for the cited precedent product is supported for Sharda Prothioconazole 480 SC Fungicide.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of Sharda Prothioconazole 480 SC Fungicide.

References

PMRA Document Number	References
3066934	2018, Manufacturing Manual - Sharda Prothioconazole 480 SC Fungicide, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3066935	2018, Accelerated Storage Stability Test of Prothioconazole 480g/L SC By Heating At Elevated Temperature of 54+/- 2C for 14 Days, DACO: 3.4.1,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.5,3.5.7,3.7 CBI
3066936	2018, Determination of Explosive Properties of Prothioconazole 480 g/L SC, DACO: 3.5.11,3.5.12
3066937	2018, Determination of Auto Ignition Temperature of Prothioconazole 480 g/L SC, DACO: 3.5.11

- 3066938 2018, Determination of Flash Point of Prothioconazole 480 g/L SC, DACO: 3.5.11,3.7
- 3066939 2018, Determination of Density of Prothioconazole 480 g/L SC, DACO: 3.5.6
- 3066940 2018, Oxidation/Reduction: Chemical Incompatibility of Prothioconazole 480 g/L SC, DACO: 3.5.8
- 3066941 2018, Determination of Viscosity of Prothioconazole 480 g/L SC, DACO: 3.5.9
- 3066921 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Canola, DACO: 10.2.3.3
- 3066922 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Wheat, DACO: 10.2.3.3
- 3066923 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Canola, DACO: 10.2.3.3
- 3066924 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Canola, DACO: 10.2.3.3
- 3066925 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Wheat, DACO: 10.2.3.3
- 3066926 2016, Efficacy, Phytotoxicity and Yield Protocol for Sharda Cropchem Ltd. Generic Fungicide on Wheat, DACO: 10.2.3.3

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