

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-6103
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Protégé Seed Treatment Fungicide
Registration Number: 35230
Active ingredients (a.i.): Metalaxyl-M and S-isomer & Fludioxonil
PMRA Document Number: 3441620

Purpose of Application

The purpose of this application was to register Protégé Seed Treatment Fungicide, an end-use product that controls certain seed- and soil-borne diseases on labelled crops, based on a registered precedent product.

Chemistry Assessment

Protégé Seed Treatment Fungicide is formulated as a suspension containing metalaxyl-M and S-isomer at a concentration of 1.10% and fludioxonil at a concentration of 0.73%. This product has a density of 1.023 g/mL and pH of 6.27. The required chemistry data for this product have been provided, reviewed and found to be acceptable.

Health Assessments

Protégé Seed Treatment Fungicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. It is considered to be of low acute toxicity by the oral, dermal and inhalation routes, non-irritating to the skin, and minimally irritating to the eyes. This product is not considered to be a dermal sensitizer.

The registered use pattern of Protégé Seed Treatment 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 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 metalaxyl-M and S-isomer and fludioxonil were required to support the registration of Protégé Seed Treatment Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Protégé Seed Treatment Fungicide label, including the target crops, method, rates and timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of metalaxyl-M and S-isomer and fludioxonil is not expected to increase with the registration of Protégé Seed Treatment 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 of Protégé Seed Treatment Fungicide falls within the currently registered use pattern of metalaxyl-M and S-isomer and fludioxonil. The registration of this product is acceptable from the perspective of environmental risk when used in accordance with label directions.

Value Assessment

Protégé Seed Treatment Fungicide was concluded to be biologically equivalent to the registered precedent product based on the comparison of their formulations. The differences in the formulations are unlikely to impact on product performance.

In terms of either efficacy or crop tolerance, the use pattern registered for the precedent product was supported for extrapolation to the label of Protégé Seed Treatment Fungicide. The registration of this product provides growers with an additional option in managing various fungal 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 Protégé Seed Treatment Fungicide.

References

PMRA Document Number	Reference
3291598	2021, Applicant Name and Address; Manufacturer Name and Address and Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13,3.5.15,3.5.5
3291599	2021, Certificate of Composition, DACO: 3.2.1 CBI
3291609	2021, Physico-chemical Properties of Metalaxyl-M 1.10% + Fludioxonil 0.73% FS, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3291612	2021, Manufacturing Process of Metalaxyl-M 1.10% + Fludioxonil 0.73% FS, DACO: 3.2.2 CBI
3430980	2023, Revised Formulation Process of Metalaxyl-M 1.10% + Fludioxonil 0.73% FS, DACO: 3.2.2 CBI

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