

Evaluation Report for Category B, Subcategory L.1.2 Application

Application Number: 2020-5242
Application: Application subject to the Protection of Proprietary Interests in Pesticide Data Policy
Product: FBN ProTEB 250 EC
Registration Number: 34868
Active ingredients (a.i.): Tebuconazole and Prothioconazole
PMRA Document Number: 3300389

Purpose of Application

The purpose of this application was to register the fungicide FBN ProTEB 250 EC, for use on wheat, barley, oats and triticale, based on a precedent product.

Chemistry Assessment

FBN ProTEB 250 EC is formulated as an emulsifiable concentrate containing tebuconazole and prothioconazole both at a concentration of 125 g/L. This end-use product has a density of 1.01 g/mL and pH of 5.0-8.0. The required chemistry data for FBN ProTEB 250 EC have been provided, reviewed and found to be acceptable.

Health Assessments

FBN ProTEB 250 EC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN ProTEB 250 EC is considered to be of low acute toxicity via the oral, dermal, and inhalation route. FBN ProTEB 250 EC is considered to be moderately irritating to the eyes and mildly irritating to the skin, and not a potential dermal sensitizer.

The potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products containing prothioconazole and tebuconazole. 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 or tebuconazole were submitted or are required to support the registration of FBN ProTEB 250 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN ProTEB 250 EC label, including the target crops, methods (ground and aerial), rates and timings of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those of 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 or tebuconazole are not expected to increase with the registration of the new end-use product FBN ProTEB 250 EC 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 and application rate on the label of FBN ProTEB 250 EC is within the currently registered use pattern for the actives prothioconazole and tebuconazole. Therefore, no additional risk is expected when FBN ProTEB 250 EC is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

To assess the efficacy of FBN ProTEB 250 EC against a range of important diseases of cereal crops when applied as a foliar spray by ground or aerial equipment, the formulation of FBN ProTEB 250 EC was compared to that of a similar registered precedent product with the same claims. Based on this comparison, it was concluded that these products are expected to perform similarly in terms of efficacy and crop safety. Therefore, all uses and claims included in the registration of the precedent product are acceptable for FBN ProTEB 250 EC.

The availability of FBN ProTEB 250 EC will provide growers with an additional product to manage a range of fungal diseases that affect the yield and quality of wheat, barley, oats and triticale.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register FBN ProTEB 250 EC for use on wheat, barley, oats and triticale.

References

PMRA

Document

Number	Reference
3173098	2020, DER for FBN ProTEB 250 EC, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.3.1, 3.5.15, 3.5.2 CBI
3173101	2020, Manufacturing Process for FBN ProTEB 250 EC, DACO: 3.1.2, 3.2.1, 3.2.2 CBI
3173104	2020, Physico-chemical properties of Tebuconazole 125g/L and Prothioconazole 125g/L Emulsifiable concentrates, 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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