



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-0929
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: FBN Propiconazole 432 EC
Registration Number: 35213
Active ingredient (a.i.): Propiconazole
PMRA Document Number: 3477130

Purpose of Application

The purpose of this application was to register a new fungicide end-use product, FBN Propiconazole 432 EC, for control or suppression of various listed fungal diseases on a wide range of listed terrestrial food and feed crops, based on a registered precedent.

Chemistry Assessment

FBN Propiconazole 432 EC is formulated as an emulsifiable concentrate containing propiconazole at a concentration of 432 g/L. This end-use product has a density of 1.08 g/mL and pH of 5.88. The required chemistry data for FBN Propiconazole 432 EC have been provided, reviewed and found to be acceptable.

Health Assessments

FBN Propiconazole 432 EC is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN Propiconazole 432 EC is considered to be moderately acutely toxic by the oral route. It is considered to be of low acute toxicity by the dermal and inhalation routes. It is considered to be moderately irritating the eye and the skin. It is considered to be a potential skin sensitizer.

The use pattern of FBN Propiconazole 432 EC 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 propiconazole. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for propiconazole were submitted or were required to support the registration of FBN Propiconazole 432 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN Propiconazole 432 EC label, including the target crops, method (ground or aerial), rates and timing of application, geographic restrictions, preharvest intervals, and feeding restrictions are comparable to those on the label of the precedent end-use 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. Consequently, dietary exposure to residues of propiconazole is not expected to increase with the registration of FBN Propiconazole 432 EC and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

A scientific review of the available information has concluded that the environmental risks associated with the use of FBN Propiconazole 432 EC are acceptable when the product is used according to label directions.

Value Assessment

The formulation of FBN Propioconazole 432 EC was compared to that of the precedent product. Based on this comparison, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, all uses and claims included in the registration of the precedent product are acceptable for FBN Propioconazole 432 EC.

The availability of FBN Propioconazole 432 EC will provide Canadian growers with an additional product to manage common and economically important diseases in an assortment of field-grown crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register FBN Propioconazole 432 EC.

References

PMRA

Document

Number	Reference
3326362	2022, Applicant Name and Address;Formulating Plant Name and Address; Product Information, 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
3326366	2022, Physico-chemical Properties of Propiconazole 432g/L EC, 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
3326367	2022, Preparation of Formulation, DACO: 3.2.2 CBI
3354953	2022, Revised Propiconazole 432 EC Composition Recipe, DACO: 3.1 CBI

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