Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-4753
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy - Equivalency/Data Compensation Assessment
Product: FBN Pyraclostrobin 250 EC
Registration Number: 34864
Active ingredient (a.i.): Pyraclostrobin
PMRA Document Number: 3431663

Purpose of Application

The purpose of this application was to register a commercial end-use product, FBN Pyraclostrobin 250 EC, for the control or suppression of fungal diseases on certain grain, oilseed, legume, root/tuber, seed and forage crops, based on a precedent product.

Chemistry Assessment

FBN Pyraclostrobin 250 EC is formulated as an emulsifiable concentrate containing pyraclostrobin at a concentration of 250 g/L. This end-use product has a density of 1.052 g/mL and pH of 5.66. The required chemistry data for FBN Pyraclostrobin 250 EC have been provided, reviewed and found to be acceptable.

Health Assessments

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

The use pattern of FBN Pyraclostrobin 250 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 product of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

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No new residue data for pyraclostrobin were submitted or are required to support the registration of FBN Pyraclostrobin 250 EC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the FBN Pyraclostrobin 250 EC label, including the target crops, method (ground, aerial, and chemigation via pivot or sprinkler), rates and timing of application, geographic restrictions, 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 pyraclostrobin is not expected to increase with the registration of FBN Pyraclostrobin 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 of FBN Pyraclostrobin 250 EC will not pose any additional risks to the environment. The required environmental precautions statements and spray buffer zones to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for FBN Pyraclostrobin 250 EC.

Value Assessment

The efficacy and crop safety of FBN Pyraclostrobin 250 EC was compared to that of the precedent product in field bridging trials. 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 use claims included in the registration of the precedent product are acceptable for extrapolation to the label of FBN Pyraclostrobin 250 EC.

The availability of FBN Pyraclostrobin 250 EC will provide Canadian growers with an additional product to manage common and economically important fungal diseases of certain grain, oilseed, legume, root/tuber, seed and forage crops grown in the field.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register FBN Pyraclostrobin 250 EC.

References

PMRA Document Number	Reference
3267088	2021, Formulation Process for Pyraclostrobin 250 EC, DACO: 3.2,3.2.2 CBI
3267090	2021, Physico-Chemical Properties of Pyraclostrobin 250 EC, DACO: 3.4,3.4.1,3.5.1,3.5.10,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3426914	2023, Statement of Formulation List of Ingredients of FBN Pyraclostrobin 250 EC, DACO: 3.2,3.2.1 CBI
3426915	2023, Formulation Process for Pyraclostrobin 250 EC, DACO: 3.2,3.2.2 CBI
3426916	2021, Formulation CofA from Manufacturer, DACO: 3.3.1 CBI
3426917	2023, Amendment to Final Report - Physico-Chemical Properties of Pyraclostrobin 250 EC, DACO: 3.4,3.5.1,3.5.2,3.5.6,3.5.7 CBI
3338804	2022, FBN Pyraclostrobin Value Summary Final 040122, DACO: 10.1
3338806	2021, FBN Pyraclostrobin 250EC Trial Reports, DACO: 10.2.3.3