Health Canada Santé Canada

Evaluation report for category L, Subcategory 1.2 application

Application Number: 2020-2712
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy (PPIP) – Equivalency/Data Compensation
Product: Foison Pyraclostrobin 250 EC
Registration Number: 34832
Active ingredient (a.i.): Pyraclostrobin
PMRA document number: 3268007

Purpose of application

The purpose of this application was to register Foison Pyraclostrobin 250 EC, a new end-use product for use on various crops to control or suppress certain fungal diseases, based on a registered precedent.

Chemistry assessment

Foison 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 1.0591 - 1.0672 g/mL and pH of 6.08. The required chemistry data for Foison Pyraclostrobin 250 EC have been provided, reviewed and found to be acceptable.

Health assessments

Foison Pyraclostrobin 250 EC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Foison Pyraclostrobin 250 EC is considered to be of high acute toxicity by the oral route and of low acute toxicity by the dermal and inhalation routes. It is considered to be a severe skin irritant and a moderate eye irritant. It is not a skin sensitizer.

The use pattern of Foison 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 Foison Pyraclostrobin 250 EC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Foison Pyraclostrobin 250 EC label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable 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 pyraclostrobin is not expected to increase with the registration of Foison 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

After a scientific review of the available information, it was concluded that the environmental risks associated with the use of Foison Pyraclostrobin 250 EC are acceptable when used according to the label directions.

Value assessment

Based on the available information, the formulation differences between Foison Pyraclostrobin 250 EC and the cited precedent product are unlikely to result in differences in product performance. Therefore, all use claims registered for the precedent product are supported for extrapolation to the Foison Pyraclostrobin 250 EC label from a value standpoint.

The registration of Foison Pyraclostrobin 250 EC provides growers with an additional product in managing listed fungal diseases on labelled crops and plants.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Foison Pyraclostrobin 250 EC.

References

PMRA No.	Reference
3133819	2020, Manufacturing process, DACO: 3.2.2 CBI
3133820	2020, Discussion of the formation of impurities of toxicological concern, DACO: 3.2.3
3133821	2019, Enforcement analytical method, DACO: 3.4.1
3133823	2019, Color, physical state and odour, DACO: 3.5.1,3.5.2,3.5.3
3133825	2020, Container material and description, DACO: 3.5.5
3133826	2019, Density or specific gravity, DACO: 3.5.6
3133827	2019, pH, DACO: 3.5.7
3133828	2019, Oxidizing or reducing action, DACO: 3.5.8
3133829	2019, Viscosity, DACO: 3.5.9
3133830	2019, Storage stability, DACO: 3.5.10
3133831	2019, Flammablity, DACO: 3.5.11
3133832	2019, Explodability, DACO: 3.5.12
3133833	2019, Miscibility, DACO: 3.5.13
3133835	2020, Dielectric breakdown voltage, DACO: 3.5.15
3133836	2020, Nano-material characteristics, DACO: 3.5.16
3261814	2019, Enforcement analytical method for [CBI Removed], DACO: 3.4.1]
3261815	2019, Storage Stability data of [CBI Removed], DACO: 3.5.10