



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2025-0255
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Applicant: Rainbow Cropsciences Inc.
Product: Rainbow Pyraclostrobin 250 EC
Registration Number: 36004
Active ingredient (a.i.): Pyraclostrobin
PMRA Document Number: 3816230

Purpose of Application

The purpose of this application was to register a new end-use product, Rainbow Pyraclostrobin 250 EC, based on a registered precedent product.

Chemistry Assessment

Rainbow 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 1.0586 g/mL and pH of 5.5 – 6.0 (1% solution). The required chemistry data for Rainbow Pyraclostrobin 250 EC have been provided, reviewed and found to be acceptable.

Health Assessments

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

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

No new residue data for pyraclostrobin were submitted or are required to support the registration of Rainbow Pyraclostrobin 250 EC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Rainbow Pyraclostrobin 250 EC label, including the target crops, methods (ground and aerial), 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 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 (MRLs). Consequently, dietary exposure to residues of pyraclostrobin is not expected to increase with the registration of Rainbow 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 Rainbow Pyraclostrobin 250 EC is within the currently registered use pattern for pyraclostrobin. The product formulation was reviewed and no environmental issues were identified that require additional label statements for risk mitigation. Therefore, the environmental risk is acceptable when Rainbow Pyraclostrobin 250 EC is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The formulation of Rainbow Pyraclostrobin 250 EC fungicide was compared to the precedent product with equivalent label claims. Based on this comparison, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the uses on the label of the registered precedent product is acceptable to support comparable claims on the Rainbow Pyraclostrobin 250 EC label by extrapolation.

The registration of Rainbow Pyraclostrobin 250 EC will provide Canadian growers with an additional end-use product option to manage diseases on labelled crops.

Conclusion

Health Canada has completed an assessment of the information provided, and has found the information acceptable to support the registration of Rainbow Pyraclostrobin 250 EC.

References

PMRA Document Number	Reference
3677387	2025, Rainbow Pyraclostrobin 250 EC - Physical and Chemical Properties and Waiver Requests, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.3.1, 3.5.12, 3.5.13, 3.5.15, 3.5.5
3677389	2024, Pyraclostrobin 250G/L EC: Determination of the Physico-chemical Properties, DACO: 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.7, 3.5.8, 3.5.9 CBI
3677390	2024, Pyraclostrobin 250G/L EC: Determination of the Relative Density, DACO: 3.5.6 CBI
3677391	2024, Pyraclostrobin 250G/L EC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
3677392	2024, Pyraclostrobin 250G/L EC: Validation of the Analytical Method for the Determination of Active Ingredient Content, DACO: 3.4.1 CBI
3677393	2024, Manufacturing Process of Rainbow Pyraclostrobin 250 EC, DACO: 3.2.1, 3.2.2 CBI

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