

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-1505
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation
Product: Empire WG Fungicide
Registration Number: 34691
Active ingredients (a.i.): Boscalid and pyraclostrobin
PMRA Document Number: 3370891

Purpose of Application

The purpose of this application was to register Empire WG Fungicide, an end-use product based on precedent, for use on terrestrial food crops, greenhouse food and non-food-crops, and outdoor ornamentals.

Chemistry Assessment

Empire WG Fungicide is formulated as wettable granules containing pyraclostrobin and boscalid at concentrations of 12.8 % and 25.2 %, respectively. This end-use product has a density of 0.670 – 0.674 g/mL and pH of 6.36 (1% solution). The required chemistry data for Empire WG Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Empire WG Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Empire WG Fungicide is considered to be of low acute toxicity via the oral, dermal, and inhalation routes. Empire WG Fungicide is considered to be minimally irritating to the eyes and the skin, and not a potential dermal sensitizer.

The use pattern of Empire WG Fungicide, containing boscalid and pyraclostrobin, 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 these active ingredients. 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 and boscalid were submitted or are required to support the registration of Empire WG Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Empire WG Fungicide label, including the target crops, method, rates and timing of application, preharvest intervals, and crop rotation restrictions are identical to the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those for the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of pyraclostrobin and boscalid is not expected to increase with the registration of Empire WG Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional risk to the environment is expected from the registration of Empire WG Fungicide when label directions are followed.

Value Assessment

Based on a comparison of formulations, Empire WG Fungicide is considered biologically equivalent to a registered precedent product and is expected to perform similarly against labeled diseases when applied as directed. The registration of Empire WG Fungicide will provide growers with an alternative tool to manage diseases on labelled crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of Empire WG Fungicide.

References

PMRA Document Number	References
3219013	2021, Determination of Active Ingredient Content of Pyraclostrobin 12.8% + Boscalid 25.20 % WG, DACO: 3.4.1,3.4.2
3219014	2021, Determination of Accelerated Storage Stability of Pyraclostrobin 12.8 % + Boscalid 25.20 % WG DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.7
3219018	2021, Additional Product Chemistry for Empire WG Fungicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.4,3.5.5
3318348	2022, Manufacturing Process Boscalid 25.2% + Pyraclostrobin 12.8% WG, DACO: 3.2.1,3.2.2,3.2.3,3.3.1, CBI

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