



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1937
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy-Equivalency/Data Compensation Assessment
Product: BUTTON Fungicide
Registration Number: 34439
Active ingredients (a.i.): Cyprodinil and Fludioxonil
PMRA Document Number: 3272380

Purpose of Application

The purpose of this application was to register the new end-use product, Button Fungicide for use on terrestrial crops to control or suppress various fungal diseases, based on a registered precedent product.

Chemistry Assessment

Button Fungicide is formulated as a wettable granule containing cyprodinil at a concentration of 37.5 % and fludioxonil at a concentration of 25 %. This end-use product has a density of 0.611–0.622 g/mL (20 °C) and pH of 9.78 (1% solution). The required chemistry data for Button Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Button Fungicide was considered toxicologically equivalent to the precedent product, therefore no toxicology data were required. Button Fungicide is considered to be of low acute toxicity by the oral, dermal and inhalation routes, slightly irritating to the skin and mildly irritating to the eyes, and is not considered to be a dermal sensitizer.

The requested use pattern of Button Fungicide 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 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 cyprodinil and fludioxonil were submitted or are required to support the registration of Button Fungicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Button Fungicide label, including the target crops, methods (ground), rates, numbers and timing of applications, 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 for the currently registered uses and will be covered by the established maximum residual limits (MRLs) for each active ingredient. Consequently, dietary exposure to residues of cyprodinil and fludioxonil is not expected to increase with the registration of Button Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The environmental risks associated with the use of Button Fungicide are acceptable when the product is used according to the label directions.

Value Assessment

Button Fungicide was concluded to be biologically equivalent to the registered precedent product based on a comparison of their formulations. As differences in the formulations are unlikely to result in any significant impact on product performance, in terms of either efficacy or crop tolerance, the registered use pattern of the precedent product is supported for Button Fungicide.

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 Button Fungicide.

References

PMRA Document Number	Reference
3121826	2020, Manufacturing Process - cyprodinil 25 % + Fludioxonil 37,5 % w/w WG, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3121827	2018, Fludioxonil 25.0 % + Cyprodinil 37.5 % WDG: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure, DACO: 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.11, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8
3121828	2018, Fludioxonil 25.0 % + Cyprodinil 37.5 % WDG: Evaluation of stability of the product after storage in accordance with CropLife - 1 year, DACO: 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.7
3121829	2019, Fludioxonil 25.0 % + Cyprodinil 37.5 % WDG: Evaluation of stability of the product after storage in accordance with CropLife - 1 year, DACO: 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.7
3121830	2018, Fludioxonil 25,0 % + Cyprodinil 37,5 % WDG Determination of explosive properties, DACO: 3.5.12

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