

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-4302
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy-Equivalency/Data Compensation Assessment
Product: Cabil Fungicide
Registration Number: 34638
Active ingredient (a.i.): Boscalid
PMRA Document Number: 3317277

Purpose of Application

The purpose of this application was to register Cabil Fungicide, a new fungicide end-use product for use on terrestrial food and feed crops, based on a precedent product.

Chemistry Assessment

Cabil Fungicide is formulated as wettable granules containing boscalid at a concentration of 70%. This end-use product has a density of 0.57 – 0.59 g/mL and pH of 5.38. The required chemistry data for Cabil Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

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

The requested use pattern Cabil 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 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 boscalid were submitted or are required to support the registration of Cabil Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Cabil Fungicide label, including the target crops, methods, rates and timing of application, 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 boscalid is not expected to increase with the registration of Cabil Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Cabil Fungicide is within the registered use pattern of boscalid, and therefore, no additional risk is expected from the use of Cabil Fungicide. The formulation does not contain any formulants that require environmental risk mitigation measures or management.

The label includes all the required environmental precautions and directions for use statements, as well as spray buffer zones information, which adequately mitigates risks to the environment. Risk from the use of Cabil Fungicide is acceptable from an environmental perspective when used according to the label directions.

Value Assessment

The formulation of Cabil Fungicide was compared to that of the precedent product. 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 uses and claims included in the registration of the precedent product are acceptable for Cabil Fungicide from a value perspective.

The availability of Cabil Fungicide would provide Canadian growers with an additional product to manage common and economically important diseases in labelled crops.

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 Cabil Fungicide.

References

PMRA Document No.	Reference
2851316	2018, Physico-Chemical Characterization of Boscalid 70 WDG, DACO: 3.5.10, 3.5.14, 3.5.6, 3.5.7 CBI
3154514	2017, Manufacturing Process - Boscalid 700WG, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3154515	2016, Boscalid 70% WDG Method development and validation for determination of the content of boscalid in the formulation, DACO: 3.4.1
3154516	2017, Boscalid 70% WDG Part 1: Evaluation of physicochemical properties of the initial preparation and after accelerated storage, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.7
3154517	2016, Boscalid 70% WDG Determination of flammability, relative self-ignition temperature and oxidizing properties, DACO: 3.5.11, 3.5.8
3154518	2017, Boscalid 70% WDG Determination of Explosive Properties, DACO: 3.5.12
3154519	2017, Additional Product Chemistry for Shaft 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, 3.5.9
3205854	2021, Revised Manufacturing Process for Shaft Fungicide (Sub. No. 2020-4300), Cabil Fungicide (Sub. No. 2020-4302) and Pulse Fungicide (Sub. No. 4301), DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3309565	2022, Manufacturing Process Boscalid 700WG, DACO: 3.2.1, 3.2.2 CBI
3309566	2022, Boscalid 700 WG Filler Questioning DACO 3.5, DACO: 3.5.10, 3.5.14, 3.5.6, 3.5.7

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