

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-4300

Application: Submissions Subject to Protection of Proprietary Interests in

Pesticide Data Policy-Equivalency/Data Compensation Assessment

Product: Shaft Fungicide

Registration Number: 34642 **Active ingredient (a.i.):** Boscalid **PMRA Document Number:** 3316069

Purpose of Application

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

Chemistry Assessment

Shaft 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 Shaft Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Shaft Fungicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Shaft Fungicide is considered to be of low acute toxicity via the oral, dermal, and inhalation route. Shaft 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 of Shaft 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 Shaft Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Shaft 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.



The 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 Shaft 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 Shaft Fungicide is within the registered use pattern of boscalid; therefore, no additional environmental risk is expected from the use of Shaft 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 Shaft Fungicide is acceptable from an environmental perspective when used according to the label directions.

Value Assessment

The formulation of Shaft 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 Shaft Fungicide from a value perspective.

The availability of Shaft 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 Shaft Fungicide.

References

PMRA	Reference
Document No.	
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

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.