

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-5239
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: FBN Prothio 480 SC
Registration Number: 34881
Active ingredient (a.i.): Prothioconazole
PMRA Document Number: 3353448

Purpose of Application

The purpose of this application was to register a new commercial fungicide, FBN Prothio 480 SC, for control or suppression of listed diseases in several food, feed and industrial oil seed crops, based on a precedent product.

Chemistry Assessment

FBN Prothio 480 SC is formulated as a suspension containing prothioconazole at a concentration of 480 g/L. This end-use product has a density of 1.1 – 1.2 g/mL and pH of 5.0 – 8.0. The required chemistry data for FBN Prothio 480 SC have been provided, reviewed and found to be acceptable.

Health Assessments

FBN Prothio 480 SC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN Prothio 480 SC is considered to be of low acute toxicity via the oral and dermal routes, and slightly acute toxicity via the inhalation route. FBN Prothio 480 SC is considered to be non-irritating to the eyes, slightly irritating to the skin, and not a potential dermal sensitizer.

The use pattern of FBN Prothio 480 SC 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 prothioconazole were submitted or are required to support the registration of FBN Prothio 480 SC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the FBN Prothio 480 SC label, including the target crops, method, 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 those for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of prothioconazole is not expected to increase with the registration of FBN Prothio 480 SC and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of FBN Prothio 480 SC will not pose any additional risks to the environment. The required environmental precautions statements and required spray buffer zones to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for FBN Prothio 480 SC.

Value Assessment

The formulation of FBN Prothio 480 SC was compared to that of the precedent product. 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 FBN Prothio 480 SC.

The availability of FBN Prothio 480 SC Fungicide will 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 it sufficient to support the registration of FBN Prothio 480 SC.

References

PMRA Document Number	References
3172834	2018, Physico-chemical properties of Prothioconazole 480 g/L Suspension Concentrates, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8 CBI
3172835	2020, Physico-chemical properties of Prothioconazole 480 g/L Suspension Concentrates, DACO: 3.4.1,3.5.11,3.5.6,3.5.9 CBI
3172848	2020, DACO 3.0 for FBN Prothio 480 SC, 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 CBI
3291481	2020, Revised Formulation Process, DACO: 3.2.2 CBI

© 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.