

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-3138
Application: Submissions subject to *Protection of Proprietary Interests in Pesticide Data* policy-Equivalency/Data Compensation Assessment
Product: Tibet 50 SC
Registration Number: 34386
Active ingredient (a.i.): Thiabendazole
PMRA Document Number : 3275580

Purpose of Application

The purpose of this application was to register a new end use fungicide for use as a seed treatment (food and feed), on stored food and feed, and on terrestrial food crops, based on a precedent.

Chemistry Assessment

Tibet 50 SC is formulated as a suspension containing thiabendazole at a concentration of 500 g/L. This end-use product has a density of 1.168 g/mL and pH of 6.58. The required chemistry data for Tibet 50 SC have been provided, reviewed and found to be acceptable.

Health Assessments

Tibet 50 SC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Tibet 50 SC is considered to be of low acute toxicity via the oral, dermal, and inhalation route. Tibet 50 SC is considered to be non-irritating to the eyes and skin, and is not considered to be a dermal sensitizer.

The use pattern of Tibet 50 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 thiabendazole were submitted or are required to support the registration of Tibet 50 SC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Tibet 50 SC label, including the target crops, method, rates, and timing of application, 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 maximum residue limits (MRLs). Consequently, dietary exposure to residues of thiabendazole is not expected to increase with the registration of Tibet 50 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 Tibet 50 SC for the post-harvest control of labelled diseases in labelled crops and seed treatment to control or suppress labelled diseases in soybeans, will not pose any additional risks to the environment. The required environmental precautions and hazards statements to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for Tibet 50 SC.

Value Assessment

To assess the efficacy of Tibet 50 SC against labelled fungal diseases when used as a post-harvest, seed or mushroom casing treatment, the formulation of Tibet 50 SC was compared to that of a registered precedent product. Based on this comparison, it was concluded that these products are expected to perform similarly in terms of efficacy and crop safety. Therefore, all uses and claims included in the registration of the precedent product are acceptable for Tibet 50 SC.

The availability of Tibet 50 SC will provide growers with an additional product to manage a diversity of fungal diseases that affect labelled crops at planting, during production or after harvest.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of Tibet 50 SC.

References

PMRA

Document

Number	Reference
3139425	2020, Description of Process Formulation of Tibet 50 SC (Thiabendazole 500 g/L) SC, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3139427	2018, Physico-Chemical Characterization of Thiabendazole 50% SC - Amendment 1, DACO: 3.4.1, 3.4.2, 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, 3.5.9 CBI
3139410	2020, Additional Product Chemistry for Tibet 50 SC, 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

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

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.