

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2015-3208

Application: Changes to Product Labels - Precautions

Product: ProBlad Plus Fungicide

Registration Number: 31782

Active ingredients (a.i.): BLAD Polypeptide

PMRA Document Number: 2574094

Purpose of Application

The purpose of this application was to amend the product label of ProBlad Plus Fungicide to remove manufacturing date and "use within 12 months of date of manufacture" statements.

Chemistry Assessment

No changes were made to the formulation of ProBlad Plus Fungicide. A 2-year storage stability study was submitted in support of amending the storage instructions present on the product label. In this study, ProBlad Plus Fungicide was assayed for BLAD polypeptide content and potency following storage at ambient temperature (15–38.0 °C) over a period of two years. In this study, BLAD polypeptide content and antifungal activity remained within specification following storage for twenty four months at ambient temperature.

Although the method described for measuring BLAD polypeptide content could not distinguish BLAD polypeptide from any other peptide that may be present in the end-use product, these results combined with observed potency data indicate that the peptides remain in the product and are active since antifungal activity is observed after 24 months. Based on these combined results, the 2-year storage period in a cool dry area away from light is acceptable.

Health, Environmental, and Value Assessments

Health, environmental, and value assessments were not required for this application

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of ProBlad Plus Fungicide, and has found the information sufficient to modify the product label.

References

1.0 Product Characterization and Analysis



2551971	2015, ProBlad DACO: 3.5.10	Plus	Storage	Stability	Study -	24-month	Interim	Report,

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

ISSN: 1911-8082

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.