



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2011-2369

Application: Changes to product label: new site or host

Product: Integral

Registration Number: 29453

Active ingredient (a.i.): *Bacillus subtilis* (strain MBI600)

PMRA Document Number English PDF: 2121979

Background

Integral, containing the active ingredient *Bacillus subtilis* (strain MBI600), was first registered in 2010 as a seed treatment to suppress the seedling disease complex in canola (seed rot, pre and post emergent damping-off, seedling blight and root rots) caused by *Rhizoctonia* spp. and *Fusarium* spp. For a detailed scientific evaluation, please refer to PRD2009-17, *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide and RD2010-04, *Bacillus subtilis* strain MBI 600, Integral™ Liquid Biological Fungicide.

Purpose of Application

The purpose of this application was to add a new claim to the label for protection of soybean against seedling diseases caused by *Rhizoctonia* spp. and *Fusarium* spp..

Chemistry Assessment

The product characterization and analysis database for Integral is complete.

Health and Environmental Assessments

Use expansion to soybeans does not pose any toxicological, occupational/ bystander exposure, food exposure, or environmental concerns. The health and environmental databases for Integral are complete.

Value Assessment

Seven trials conducted in Canada (MB, ON) and the United States (WI) in 2009 and 2010 were submitted for review. Three trials were submitted and reviewed to support claims for diseases caused by *Fusarium solani*. Four trials were submitted and reviewed to support claims for diseases caused by *Rhizoctonia solani*.

The submitted data demonstrated partial suppression to control of seed rot, pre-emergence damping-off, seedling blight and root rot on soybean caused by *Fusarium solani* and *Rhizoctonia solani* when seed was treated with Integral at the labelled rate. Mixing Integral with conventional seed treatments resulted in numerical increases in seedling emergence and the level of efficacy expressed by the conventional products applied alone. Use on canola facilitated extrapolation of the supported claims to include post-emergence damping-off and the inclusion of *Fusarium* spp. and *Rhizoctonia* spp. as the supported pathogens. No phytotoxicity was observed on soybean plants in the trials and treatment with Integral did not negatively affect soybean seed (including germination) when tested in warm or cold storage conditions.

The registration of these claims on the Integral label helps improve efficacy of conventional seed treatments against these pathogens. Integral provides an alternative mode of action as a means to reduce dependency on conventional products and to reduce the risk of resistance development. It was also indicated in a rationale submitted that *B. subtilis* persists longer on the seed than conventional product, extending protection to the elongating root.

Integral is intended for application using commercial and on-farm seed treating equipment; however, many of the registered products that could potentially be tank mixed with Integral are intended for commercial use only. As a result, the label specifies that the most prohibitive use restrictions should be observed when tank mixing.

The submitted data, the use on canola and the existing value of the Integral all support the claim of partial suppression of seed and seedling diseases caused by *Fusarium* spp. and *Rhizoctonia* spp. on soybean at the labelled rate. These diseases can be controlled by mixing Integral with conventional seed treatments registered for the same uses.

Conclusion

The PMRA conducted an evaluation of the subject application and determined that use of the product in accordance with the label has value and will not pose unacceptable health or environmental risk.

References

- | | |
|---------|--|
| 1739531 | 2009, Summary of published research demonstrating increased efficacy of <i>Bacillus subtilis</i> Rhizobacteria compared to fungicides in reducing damage caused by plant pathogens, DACO: M10.2.1, M10.2.2 |
| 2063643 | 2011, Value summary - Information document (Integral), DACO: M10.1 |
| 2063645 | 2011, Field evaluation of integrated biological and chemical management of seedling diseases in soybeans caused by <i>Rhizoctonia solani</i> and <i>Fusarium</i> spp. with Integral (<i>Bacillus subtilis</i> , strain MBI 600), DACO: M10.2.2, M10.3.1, M10.3.2.1, M10.3.2.2 |
| 2063647 | 2011, Integral (<i>Bacillus subtilis</i> , strain MBI 600) seed safety study on 26-10RY soybean 6 month interim report, DACO: M10.3.1 |

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

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.