

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2010-2664
Application: New EP Product Chemistry-New combination of TGIAs
Product: Rancona RS Fungicide
Registration Number: 30217
Active ingredients (a.i.): ipconazole, carbathiin
PMRA Document Number: 2294951

Purpose of Application

The purpose of this application was to register a new end-use seed treatment product containing the active ingredients ipconazole and carboxiin for seed treatment on canola and rapeseed.

Chemistry Assessment

Rancona RS Fungicide is formulated as a suspension containing carbathiin at 87.5 g/L and ipconazole at 9.38 g/L. This end-use product has a density of 1.250-1.330 g/mL and a pH of 6.5-8.5. The chemistry requirements for Rancona RS Fungicide are complete.

Health Assessments

Rancona RS Fungicide was of low acute oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 5000$ mg/kg), and inhalation toxicity ($LC_{50} > 2.56$ mg/L) in rats. It was minimally irritating to the skin and eyes of rabbits. It was not a dermal sensitizer in guinea pigs.

Data on file support the use of ipconazole and carbathiin as seed treatment in/on rapeseed and canola. The proposed use of Rancona RS Fungicide is not expected to increase the magnitude of ipconazole and carbathiin residues in/on rapeseed (canola). Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The proposed use of carbathiin falls within the registered use pattern as a seed treatment on canola seed and rapeseed. Dermal and inhalation exposure assessments for ipconazole were performed for commercial mixer/loader/applicators, planters and on-farm treaters in submission 2010-2979 (Rancona 3.8 FS Fungicide), based on the same surrogate studies submitted for Rancona RS Fungicide. All calculated margins of exposures were above the target, and there were no risks of concern for commercial or on-farm workers treating or planting canola seed or rapeseed with Rancona RS Fungicide when label statements for commercial handlers and personal protective equipment are followed.

Environmental Assessment

Rancona RS Fungicide containing ipconazole and carbathin as a seed treatment on canola and rapeseed does not require any further environmental review, as the on-field application rates for the individual active ingredients in other registered products are higher than to be used for the current end-use product. At this point, no further environmental data are required.

Value Assessment

Twenty Canadian field, greenhouse or laboratory trials were considered in the evaluation of Rancona RS Fungicide seed treatment for use on canola and rapeseed. In all cases, Rancona RS Fungicide provided acceptable control of seed rot/pre-emergent damping off, post-emergent damping off and seedling blight caused by both *Rhizoctonia* and *Fusarium* spp. These claims are fully supported at the proposed rate and application directions. The results were comparable to the commercial standards Helix Xtra and Vitavax RS. Since seed-borne blackleg (*Phoma* spp) was tested in laboratory trials using only culture media, this use is conditionally supported pending confirmatory field or greenhouse trials. Suppression of root rot caused by *Rhizoctonia* and *Fusarium* spp. was also supported based on the results of efficacy trials. Seven canola/rapeseed varieties (Canterra 1818, Rugby, XCEED, DKL 71-45RR, VAR A,B,C) were used in the trials and no significant phytotoxic responses were noted. Rancona RS Fungicide contains the active ingredients carbathiin and ipconazole and the latter is considered as a replacement for thiram in similar products.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support for the product, Rancona RS Fungicide, and has found the information sufficient to support the new end-use product.

References

- 1916582 2010, CBI Reference: Product Identity and Composition, Description of Materials, Method Used to Produce the Product, Description of the Formulation Process, and Discussion of the Formation of Impurities in RANCONA RS Fungicide, DACO: 3.2.1,3.2.2,3.2.3,3.3.
- 1916583 2010, Product Identity and Composition, Description of Materials, Method Used to Produce the Product, Description of the Formulation Process and Discussion of the Formation of Impurities in RANCONA RS Fungicide, DACO: 3.2.1,3.2.2,3.2.3,3.3.2
- 1916584 2010, CBI Reference: Certified Limits of RANCONA RS Fungicide, DACO: 3.3.1 CBI
- 1916585 2010, Certified Limits of RANCONA RS Fungicide, DACO: 3.3.1
- 1916586 2010, Enforcement Analytical Method for Ipconazole and Carboxin in RANCONA RS Fungicide, DACO: 3.4.1
- 1916587 2010, Validation of an Analytical Method for the Determination of Carboxin and Ipconazole in RANCONA RS Fungicide, DACO: 3.4.1
- 1916588 2010, The Physical and Chemical Properties of RANCONA RS Fungicide (UBI 4374-00), DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
- 1916589 2010, Applicants Name and Office Address, DACO: 3.1.1
- 1916590 2010, Name and Address of Formulating Plants, DACO: 3.1.2
- 1916594 2010, Trade Name, DACO: 3.1.3
- 1916595 2010, Other Names, DACO: 3.1.4
- 1916596 2010, Impurities of Toxicological Concern, DACO: 3.4.2
- 1916597 2010, Formulation Type, DACO: 3.5.4
- 1916598 2010, Container Material and Description, DACO: 3.5.5
- 1916599 2010, Storage Stability Data and Corrosion Characteristics, DACO: 3.5.10,3.5.14
- 1916600 2010, Miscibility of RANCONA RS Fungicide, DACO: 3.5.13
- 1916601 2010, Explodability of RANCONA RS Fungicide, DACO: 3.5.12
- 1916602 2010, Flammability of RANCONA RS Fungicide, DACO: 3.5.11

- 1916603 2010, Oxidizing or Reducing Action of RANCONA RS Fungicide, DACO: 3.5.8
- 1916604 2010, Dielectric Breakdown Voltage of RANCONA RS Fungicide, DACO: 3.5.15
- 1973378 2010, Product Identity and Composition, Description of Materials, Method Used to Produce the Product, Description of the Formulation Process and Discussion of the Formation of Impurities in RANCONA RS Fungicide, DACO: 3.2.1,3.2.2 CBI
- 1973379 2010, Memo on Status of Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
- 2013305 2011, DACO 3.1.4_RANCONA RS Fung_31Jan11, DACO: 3.1.4
- 2065346 2011, The Storage Stability and Corrosion Characteristics of RANCONA RS Fungicide in 2.5 Gallon HDPE Packaging over 1 Year, DACO: 3.5.10,3.5.14
- 2065347 2011, The Storage Stability and Corrosion Characteristics of RANCONA RS Fungicide in 250 Gallon IBC Packaging over 1 Year, DACO: 3.5.10,3.5.14

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2013

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.