

Section 12 Notice Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration

Product Name: **Ipconazole 3.8 FS Fungicide**
Registration Number: **29175**
Application Number: **2007-2308**
PMRA Number : **1680707**

During the conditional registration period which has been **granted to December 31, 2010**, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **September 30, 2010** and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 0 INDEX

DACO: 0
Title: Index

Required data: **Please submit an electronic index of the data package submitted in response to this letter. Please refer to Regulatory Directive 2006-05, *Requirements for Submitting Data Index, Documents and Forms*, for additional information.**

PART 5 EXPOSURE (OCCUPATIONAL AND/OR BYSTANDER)

DACO: 5.14
Title: Other Studies/Data/Reports

Details: **A dust off study comparing the dust off potential of Ipconazole 3.8 FS Fungicide on corn to the surrogate used in the risk assessment (Oftanol on canola seeds) may be sufficient as bridging data. However, if the dust off study demonstrates a higher dust off potential for corn treated with Ipconazole 3.8 FS Fungicide than canola treated with Oftanol, further exposure data may be required.**

PART 6

METABOLISM/TOXICOKINETICS STUDIES

DACO: 6.3
Title: Nature of the Residues in Plants

Details: The required clarifications apply to the listed studies below:

PMRA# 1368673. Wang, R. (2001) Ipconazole: Nature of the Residue in Soybean Grain, Soybean Hay and Wheat Grain: Amended Final Report: Lab Project Number: 2000-053. Unpublished study prepared by Uniroyal Chemical Co. 320 p.

PMRA# 1368697. Gay, M. H. 2002. Distribution and Metabolism of [Triazole-3, 5 ¹⁴C]-Ipconazole used as a Seed Treatment for Winter Wheat, Study No: 99226, Unpublished study prepared by Uniroyal Chemical Company. 107 pages. DACO: 6.3

The two winter wheat (PMRA# 1368673 and 1368697) and soybean (PMRA# 1368673) metabolism studies are considered conditionally acceptable pending the submission of acceptable freezer storage stability information. **The applicant must provide the sample analysis dates for all three studies and confirmation of storage temperatures in the winter wheat study only (PMRA#1368697). In addition, evidence should be provided that the identity of residues did not change during the period between collection and final analysis.**

The required clarifications apply to the listed study below:

PMRA# 1368695. Banijamali, A. (2006) Distribution and Metabolism of [(Carbon 14)-Triazolyl]Ipconazole and [(Carbon 14)-Benzylmethylene]Ipconazole Used as a Seed Treatment for Spring Wheat. Project Number: R170501, 2005/002. Unpublished study prepared by Research for Hire. 268 p.

The spring wheat metabolism study (PMRA# 1368695) is considered conditionally acceptable pending the submission of acceptable freezer storage stability information. **The applicant must provide the sample storage conditions for all samples and extracts and provide all sample combustion and analysis dates. The applicant must explain the discrepancy between their statement that all extractions were completed within 84 days of harvest and the reported extraction dates in Appendix IV of the submission, which indicated that extractions were not completed until 286 days after harvest. As specified in DIR98-02 (Section 2.4.7), evidence should be provided that the identity of residues did not change during the period between collection and final analysis. Because the metabolic profiles were**

different for the two radiolabels, supporting storage stability data will be required for each label.

PART 7 **FOOD, FEED AND TOBACCO RESIDUE STUDIES**

DACO: 7.4.1/7.4.2
Title: Crop Field Trial/Residue Decline

Details: The required clarification applies to the listed study below:

PMRA# 1398253. Dzialo, D. (2007) Determination of Residues of Iaconazole and its Metabolites in Barley and Processed Barley (Seed Treatment): Magnitude of the Residue Study: Amended Final Report. Project Number: 2005/020. Unpublished study prepared by Easton Agri-Consulting, Agro-Tech, Inc. and Collins Agricultural Consultants Inc. 530 p

For the sample results reported in the crop field trial for barley (PMRA# 1398253) and wheat (PMRA# 1398245), **the applicant must submit the conditions of extract storage, and must provide storage stability data to support the storage of extracts for durations up to 36 days (barley commodities) and 43 days (wheat commodities). If the applicant can provide data demonstrating that the extracts of spiked untreated samples for concurrent method recovery analyses were stored for the same durations and under the same conditions as the extracts of treated samples, these data will be considered adequate to support the extended extract storage durations.**

PART 10 **VALUE**

DACO: 10.2.3.3
Title: Small-Scale Field or Greenhouse Trials

Details: **The applicant must conduct field trials on each pathogen demonstrating that Vortex FL Fungicide is effective in controlling seed rot, damping-off and seedling blight caused by soil-borne *Fusarium* spp. and seed rot and damping-off caused by *Rhizoctonia solani* on sweet, field and popcorn. The following points must be followed when conducting the trials:**

Crops and Pathogens: Provide efficacy field trials on each pathogen (one on *Fusarium* spp. and two on *R. solani*) on corn according to the proposed use pattern (seed treatment).

Controls: Trials must include both an untreated uninoculated check and an untreated inoculated check. If available, a commercial standard should also be tested for comparison purposes.

Application rate: Proposed rate of 5.6 mL product/100 kg seed should be tested.

Assessment: Emergence counts conducted 7 days after emergence are required to assess seed rot and pre-emergence damping-off. At least 2 stand counts should be made to support post-emergence damping-off. Data should demonstrate good stand counts in the uninoculated check to demonstrate no outside influences on plant health, a decrease in inoculated check stand counts over time to prove presence of disease, and that no or a minimal loss of seedlings over time occurs with treated seeds. Assessment of seedling blight should include at least two emergence/stand counts throughout the growing season, *plus* a third assessment of the visual health of the plant (i.e. to demonstrate no seedling death, but to show that the seedlings are diseased). Disease severity and incidence must both be assessed. Disease severity and incidence must both be assessed. Multiple disease assessments must be made throughout the season every 7 to 14 days.

Disease pressure: Trials must be conducted under moderate to high disease pressures. Trials should be inoculated if necessary to ensure sufficient disease pressures. Trials should be conducted in fields free of natural *Pythium* spp. inoculum.

Data analysis: Statistical analysis must be provided for disease incidence and severity.

Crop phytotoxicity: Any adverse effects of the fungicide application on the plants should be reported.

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2009

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.