

# Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.5 and 3.10 Application

**Application Number:** 2014-5634

**Application:** New End-Use Product Chemistry – Guarantee, Identity of

Formulants, Proportion of Formulants and New Combination of

**TGAIs** 

New End-Use Product Label – Rotational Crops and Tank Mixes

**Product:** PENTRIME

**Registration Number:** #####

Active ingredients (a.i.): Penflufen, Trifloxystrobin, Metalaxyl

PMRA Document Number: 2631248

## **Purpose of Application**

The purpose of this application was to register the fungicide, PENTRIME, containing a new combination of active ingredients, penflufen, trifloxystrobin and metalaxyl, for use as a seed treatment on canola, rapeseed, mustard (oilseed and condiment) for the control of several diseases.

# **Chemistry Assessment**

PENTRIME is formulated as a suspension containing three active ingredients penflufen at a nominal concentration of 15.1 g/L, trifloxystrobin at a nominal concentration of 10.0 g/L, metalaxyl at a nominal concentration of 10.0 g/L. The end-use product has a density of 1.3 g/mL at 20°C and pH of 8.5. The required chemistry data for PENTRIME have been provided, reviewed and found to be acceptable.

#### **Health Assessments**

PENTRIME is of low acute oral, dermal and inhalation toxicity in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits. It did not cause skin sensitization in mice.

The occupational and bystander exposures of PENTRIME fit within the exposures of the registered use patterns of penflufen, trifloxystrobin and metalaxyl. Therefore, the registration of PENTRIME can be supported and no risks of concern are expected when all label precautions and directions are followed.

No residue data were submitted in support of the registration of the end-use product PENTRIME, which contains penflufen, trifloxystrobin and metalaxyl, for use as a seed treatment on canola, rapeseed and mustard (oilseed and condiment type). The use pattern of the end-use product was determined to be within that of the registered product. Therefore, the previously reviewed data



were reassessed in the framework of the current submission and confirmed that the use of PENTRIME, alone or when tank mixed with Poncho 600 FS Seed Treatment Insecticide, which contains clothianidin, and DUPONT Lumiderm Insecticide Seed Treatment, which contains cyantraniliprole, is not expected to result in an increase in the magnitude of penflufen, trifloxystrobin, metalaxyl, clothianidin and cyantraniliprole in/on canola, rapeseed and mustard seed (oilseed and condiment type). Therefore, the use of PENTRIME, used alone and when tank-mixed, will not pose an unacceptable risk to any segment of the population, including infants, children, youth, adults, seniors and females.

## **Environmental Assessment**

No environmental data were submitted in support of the end-use product PENTRIME, nor were any required. The use will not significantly increase environmental exposure to penflufen, trifloxystrobin and metalaxyl. No increased risk to the environment is anticipated from the use of this product. Existing environmental label statements are expected to mitigate known risks.

#### **Value Assessment**

Efficacy data were provided from five bridging trials on canola, where the performance on *Rhizoctonia solani* was assessed, for both PENTRIME and a precedent product. All trials included side-by-side treatments of (i) the precedent product and (ii) PENTRIME +/- an insecticide. Assessments of phytotoxicity were also conducted in seven field trials. In addition, seed safety data from four dedicated laboratory crop tolerance trials on canola were also provided.

The tank mix of PENTRIME with Poncho 600 FS Seed Treatment or Dupont Lumiderm Insecticide seed treatment on canola, rapeseed, and mustard is consistent with the currently registered labels for these products and is not expected to have any adverse effects on the efficacy of the insecticide tank-mix partners.

Based on the similarity of the formulations of PENTRIME and the precedent product, in addition to the confirmatory efficacy data which demonstrated similar performance, the registration of PENTRIME can be supported from a value perspective.

#### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support registration of PENTRIME.

#### References

PMRA Reference Document Number

2478990 2014, PENTRIME Seed treatment Fungicide. Information to Address PMRA DACO Elements 3.1.1 to 3.1.4, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI

2478991 2014, The Characterization of Metalaxyl + Penflufen + Trifloxystrobin FS 35, Batch Number 2014-000748. Final Report., DACO: 3.0, 3.1, 3.1.1, 3.5, 3.5.1, 3.5.2, 3.5.4, 3.5.6, 3.5.7 CBI 2014, Validation of HPLC-method AM024514MF1 - Determination of metalaxyl, 2478992 penflufen and trifloxystrobin in formulations - metalaxyl + penflufen + trifloxystrobin FS 35.1 (10+15.1+10 g/L), DACO: 3.4.1 CBI 2478993 2014, PENTRIME Seed treatment Fungicide. Information to Address PMRA DACO Elements 3.5.1 to 3.5.15, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.7, 3.5.9 CBI 2478994 2014, EPA Confidential Statement of Formula - PENTRIME, DACO: 3.7 CBI 2014, Storage stability at elevated temperature and cold stability of metalaxyl + 2502636 penflufen + trifloxystrobin FS 35.1 (10+15.1+10 g/L), DACO: 3.5.10, 3.5.2, 3.5.7, 3.5.9 CBI 2014, Safety-Relevant Data of metalaxyl + penflufen + trifloxystrobin FS 35.1 2502637 (10+15.1+10 g/L), DACO: 3.5.11, 3.5.12, 3.5.8 CBI 2014, Dielectric Breakdown Voltage of PENTRIME, DACO: 3.5.15 CBI 2502638 2014, Miscibility of PENTRIME, DACO: 3.5.13 CBI 2502639 2014, Formulation Process of PENTRIME, DACO: 3.2.1, 3.2.2 CBI 2502640 2009, Kronos Worldwide Inc. product number change, DACO: 3.2.1 2567810 2015, Clarification request for PENTRIME, Submission number 2014-5634-2567811 September 16, 2015: [CBI Removed], DACO: 3.2.3 2014, The Certified Limits of PENTRIME - Final Report - , DACO: 3.3.1 CBI 2567813 2567814 2014, The Certified Limits of PENTRIME - Final Report - , DACO: 3.3.1 2478995 2014, Final Report MTL+PFL+TFS FS 10+15+10 G Acute Oral Toxicity Study in the Rat (Up and Down Procedure), DACO: 4.6, 4.6.1 2014, Final Report MTL+PFL+TFS FS 10+15+10 G Acute Dermal Toxicity 2478996 Study in Rats, DACO: 4.6, 4.6.2 2478997 2014, Amended Final Report No. 1. metalaxyl+penflufen+trifloxytrobin FS 35 (10+15+10 g/l) - Acute Inhalation Toxicity Study (Nose-only) in the Rat, DACO: 4.6, 4.6.3 2478998 2014, Final Report MTL+PFL+TFS FS 10+15+10 G Acute Eye Irritation Study in Rabbits, DACO: 4.6, 4.6.4 2478999 2014, Final Report MTL+PFL+TFS FS 10+15+10 G Acute Skin Irritation Study in Rabbits, DACO: 4.6, 4.6.5 2014, Final Report Amendment No.1 Metalaxyl + penflufen + trifloxystrobin FS 2479000 35 (10+15+10 g/L) - Local Lymph Node Assay in the Mouse, DACO: 4.6, 4.6.6 2479002 2014, Final Report metalaxyl + penflufen + trifloxystrobin FS 35 (10+15+10 g/l) -In Vitro Eye Irritation Test in Isolated Chicken Eyes Test Item (short name): MTL+PFL+TFS FS 10+15+10 G, DACO: 4.6, 4.6.8 2014, Tier 2 Summary of the Toxicological Studies and Exposure Data and 2502641 Information on the Plant Protection Product for PENTRIME Seed Treatment Fungicide. Final report, DACO: 4.6 1990, Exposures of Workers to Isofenphos during Planting of Oftanol Treated 1039216 Canola Seed, DACO: 5.4 2010, Observational study to determine dermal and inhalation exposure to 1885209 workers in commercial seed treatment facilities: Mixing/treating with a liquid pesticide product and equipment clean-out, DACO: 5.4

2396870	2013, Agricultural Handler Exposure Task Force (AHETF) - Survey Results of
	Commercial and Downstream Seed Treating Facilities, DACO: 5.3, 5.4
2479006	2014, Laboratory Dust-off Study of Canola and Mustard Seed treated with
	PENTRIME seed treatment formulation: Part 5 Exposure (Occupational/
	Bystander), DACO: 5.14
2617850	2016, Dust-off Study, DACO: 5.15
2478987	2014, PENTRIME Seed Treatment Fungicide (penflufen + trifloxystrobin +
	metalaxyl), DACO: 10.1, 10.2, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2, 10.2.3.3,
	10.2.3.3(D), 10.3, 10.3.1, 10.3.2, 10.3.2(B), 10.5.1, 10.5.2, 10.5.3

ISSN: 1911-8082

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

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.