

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2018-2367
Application: New End-Use Product, Product Chemistry – Guarantee, Identity of Formulants and Proportion of Formulants
Product: Orondis Gold Fungicide
Registration Number: 33508
Active ingredients (a.i.): Metalaxyl-M and S-Isomer and oxathiapiprolin
PMRA Document Number : 3014565

Purpose of Application

The purpose of this application was to register the end-use product, Orondis Gold Fungicide, based on a precedent product.

Chemistry Assessment

Orondis Gold Fungicide is formulated as an emulsion containing metalaxyl-M and S-isomer at a concentration of 105 g/L, and oxathiapiprolin at a concentration of 35.0 g/L. This end-use product has a density of 1.063 g/cm³ and pH of 4.4. The required chemistry data for Orondis Gold Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Orondis Gold Fungicide is of low acute oral, dermal and inhalation toxicity in rats. It is severely irritating to the eye and non-irritating to the skin of the rabbit. It is a dermal sensitizer in mice.

The use pattern of Orondis Gold Fungicide on potatoes, ginseng and cucumbers is within the registered use pattern of the active ingredients, metalaxyl-M and S-isomer and oxathiapiprolin. Therefore, potential exposure for mixers, loaders, applicators and postapplication workers is not expected to exceed the current exposure to the registered product of these active ingredients. No health concerns are expected for workers and bystanders when label directions, precautions and restrictions are followed

No residue data for oxathiapiprolin or metalaxyl-M and S-isomer in potato, ginger, or cucumber were submitted to support the registration of Orondis Gold Fungicide. Previously reviewed residue data conducted in/on the above crops were reassessed in the framework of this application. Dietary exposure to residues of oxathiapiprolin and metalaxyl-M and S-isomer will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use sites and seasonal application rates for Orondis Gold Fungicide are the same as for the currently registered precedent product. Additional environmental exposure and risk are therefore not expected.

Value Assessment

A rationale, efficacy trials and the extrapolation of the uses from the precedent product were used to support the registration of Orondis Gold Fungicide for use on potatoes, ginseng, and cucumbers. Based on the sum of the value information provided, the registration of Orondis Gold Fungicide to suppress pink rot and pythium leak on potatoes, control pythium damping off and phytophthora root rot on ginseng, and control pythium damping off and phytophthora root and crown rot on cucumbers is supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information submitted and has found it sufficient to support the registration of Orondis Gold Fungicide.

References

PMRA Document Number	References
2891374	2018, Discussion of the Formation of Impurities of Toxicological Concern, DACO: 2.2, 3.1.1, 3.1.2, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4.2, 4.8 CBI
2891375	2018, Metalaxyl-M/Oxathiapiprolin A22556A- Document MIII, Section 1, DACO: 1.1.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.6, 2.2, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2,3.2.3, 3.3.1, 3.3.2, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7, 5.1, 5.14, 5.2, 8.4.1, 8.6 CBI
2891376	2018, 2018, Description of Starting Materials, DACO: 3.2.1, 3.3.1, 3.3.2 CBI
2891377	2018, A22556A - Document MIII Section 2, DACO: 3.4.1 CBI
2891378	2018, A22556A- Physico-Chemical Studies of the Formulation, DACO: 3.5.1 CBI
2973925	2018, A22556A- SF-957/1- Determination of Metalaxyl-M (incl. its S-enantiomer) and Oxathiapiprolin in A22556A by HPLC - Analytical Method, DACO: 3.4.1 CBI
2973926	2018, A22556A- SFA-1417/1-Determination of Metalaxyl-M isomers, DACO: 3.4.1 CBI
2973927	2018, Metalaxyl-M/Oxathiapiprolin A22556A - Validation of Analytical Method SF-957/1, DACO: 3.4.1 CBI
2973928	2018, A22556A-Validation of Analytical Method SFA-1417/1 - Final Report, DACO: 3.4.1 CBI
2891379	2018, Metalaxyl -M/Oxathiapiprolin DC (A22556A) - Acute Oral Toxicity Study in Rats (Up and Down Procedure), DACO: 4.6.1
2891380	2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - Acute Dermal Toxicity Study in Rats, DACO: 4.6.2

- 2891381 2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
- 2891382 2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
- 2891383 2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - In Vitro Eye Irritation Test in Isolated Chicken Eyes, DACO: 4.6.4
- 2891384 2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
- 2979739 2018, Metalaxyl -M/Oxathiapiprolin DC (A22556A) – In Vitro Skin Irritation Test in the EPISKINTM Model, DACO: 4.6.5
- 2891386 2018, Metalaxyl-M/Oxathiapiprolin DC (A22556A) - Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
- 2648563 2016, Value Summary, DACO:10.1,10.2.1,10.2.2,10.2.3.1,10.3.1,10.3.2
- 2649408 2016, Value Summary, DACO:10.1,10.2.1,10.2.2,10.2.3.1,10.3.1,10.3.2
- 2648567 2014, POT14-03 - Evaluate OXTP+MFX and other products for Oomycete control in potatoes, DACO: 10.2.3.3
- 2648568 2015, POT15-01 - Evaluate soil applications of oxathiapiprolin for control of pink rot in potato, DACO: 10.2.3.3
- 2648569 2015, POT15-02 - Evaluate soil applications of fungicides for control of pink rot in potato, DACO: 10.2.3.3
- 2649410 1999, CUC99-01 - Evaluation of selected fungicides to control Phytophthora blight and fruit rot of cucumber, DACO: 10.2.3.3
- 2649411 2009, FRU09-01 Ridomil Gold 480 SL + Amistar para el efecto de control de enfermedades, DACO: 10.2.3.3
- 2649412 1997, FRU97-01 ensayos para la obtencion del registro de varios formulados del fungicida cga329351 en pimiento, para el control de phytophthora capsici, DACO: 10.2.3.3
- 2649413 1997, FRU97-02 ensayos para la obtencion del registro de varios formulados del fungicida cga329351 en pimiento, para el control de phytophthora capsici, DACO: 10.2.3.3
- 2649414 2000, CUC00-01 Evaluation of selected fungicides to control Phytophthora blight and fruit rot of cucumber, DACO: 10.2.3.3
- 2649415 1996, CUC96-01 - Evaluation of Fungicides for Managing Phytophthora Crown and Fruit Rot in Cucumber, DACO: 10.2.3.3
- 2649416 1997, CUC97-01 Control of Phytophthora Crown and Fruit Rot in Cucumbers, DACO: 10.2.3.3
- 2649417 2015, CUC15-01 - Evaluate oxathiapiprolin for control of P. capsici in zucchini, DACO: 10.2.3.3
- 2649418 1995, FRU96-01 Evaluate Control of Phytophthora Capsici on Pepper in the Field with Ridomil VS 329351, DACO: 10.2.3.3
- 2649419 2006, FRU06-01 - Uniform : Registro en horticolas para control de enfermedades de suelo, DACO: 10.2.3.3
- 2649420 2010, FRU10-01 Uniform (MFX+AZ) A13836B registration trials on glasshouse vegetables in EAME against soilborne diseases (Pythium spp and Phytophthora spp.), DACO: 10.2.3.3
- 2649421 2015, FRU15-01 Evaluate oxathiapiprolin for control of P. capsici in bell pepper (resistant variety), DACO: 10.2.3.3

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2019

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.