Evaluation Report for Category B, Subcategory 2.1, 3.3, 3.12 and 3.14 Application

Application Number: 2014-3285
Application: New End-Use Product Chemistry – Guarantee, New End-Use Product Label – Application number, new site, and classification
Product: Regalia Liquid Fungicide Ready-To-Spray
Registration Number: #####
Active ingredients (a.i.): Extract of *Reynoutria sachalinensis*
PMRA Document Number : 2647625

Purpose of Application

The purpose of this application was to register a domestic fungicide, Regalia Liquid Fungicide Ready-To-Spray, for use on turf and on various food and ornamental crops grown outdoors and in greenhouses.

Chemistry Assessment

Regalia Liquid Fungicide Ready-To-Spray is formulated as a suspension containing extract of *Reynoutria sachalinensis* at a nominal concentration of 5%. This end-use product has a density of 1.05 g/mL and pH of 5.9. The chemistry requirements for Regalia Liquid Fungicide Ready-To-Spray have been fulfilled.

Health Assessments

The submitted toxicology studies indicate that the end-use product is of low acute toxicity by the oral, dermal, and inhalation routes, mildly irritating to the eyes, slightly irritating to the skin, and is not a dermal sensitizer.

Bystander exposure is expected to be low if label directions are followed. Post-application exposure is low with the restricted entry.

The dietary risk due to exposure to extract of *Reynoutria sachalinensis* from the uses of the end-use product is considered to be low. An MRL for extract of *Reynoutria sachalinensis* is not required.

Environmental Assessment

The uses of the end-use product are not expected to increase the environmental exposure relative to other approved products containing the extract *Reynoutria sachalinensis*. Therefore, negligible

risk is expected. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Value information to support the label claims was submitted in the form of greenhouse and field efficacy data along with a scientific rationale based on disease development and the product's putative mode of action as an elicitor of induced systemic resistance in plants. Much of the support for the domestic product claims was obtained from comparable precedent claims on currently registered end-use products.

The value of labeled disease claims was deemed to have been adequately demonstrated. All uses were supported. When evidence of efficacy from trial data or scientific rationale to support claims was limited, consideration of the relative scarcity of non-conventional domestic products and the socio-economic context of their use were important considerations in the comprehensive assessment of their value. Registration of Regalia Liquid Fungicide Ready-To-Spray will provide domestic users with a new product option. Through a unique mode of action that relies on a plant's natural defense mechanisms, the active ingredient in this product will be useful in suppressing or partially suppressing common plant diseases for which relatively few alternatives are currently available for the domestic market.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support registration of Regalia Liquid Fungicide Ready-To-Spray.

References

A. List of Studies/Information Submitted by the Registrant

PMRA Document Number	Reference
2445171	2014, 3.1.1-3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2445172	2013, Regalia: Product Chemistry and Composition, DACO: 3.2.1, 3.2.2, 3.2.3, 3.4.1, 3.4.2, 3.5.1, 3.5.13, 3.5.2, 3.5.3, 3.5.9 CBI
2445173	2014, DACO 3.5.11 Flammability, DACO 3.5.12 Explodability, DACO: 3.5.11, 3.5.12 CBI
2445175	2014, DACO 3.5.15 Dielectric Breakdown Voltage, DACO: 3.5.15 CBI
2445176	2014, DACO 3.5.4 Formulation Type, DACO: 3.5.4 CBI
2445177	2014, DACO 3.5.5 Container Material and Description, DACO: 3.5.5 CBI
2445178	2013, Regalia: Storage Stability and Corrosion Characteristics at 25°C, DACO: 3.5.10, 3.5.14, 3.5.6, 3.5.7, 3.5.9 CBI
2445179	2014, Oxidizing and Reducing Action (Chemical Incompatibility) of Regalia Fungicide Liquid Concentrate, DACO: 3.5.8 CBI

2539172 2015, Description of Starting Materials, DACO: 3.2.1 CBI
2539178 2015, Description of Starting Materials, DACO: 3.2.1 CBI
2539184 2015, Description of Starting Materials, DACO: 3.2.1 CBI
2445180 2014, Toxicology Summary, DACO: 4.1
2445181 2009, Acute Oral Toxicity Up And Down Procedure in Rats of MOI 106-5% Organic Formulation, DACO: 4.6.1
2445182 2008, Acute Dermal Toxicity Study in Rats-Limit Test of MOI 106-5% Organic Formulation, DACO: 4.6.2
2445183 2009, Acute Inhalation Toxicity Study in Rats of MOI 106-5% Organic Formulation, DACO: 4.6.3
2445184 2008, Primary Eye Irritation Study in Rabbits of MOI 106-5% Organic Formulation, DACO: 4.6.4
2445185 2008, Primary Skin Irritation Study in Rabbits of MOI 106-5% Organic Formulation, DACO: 4.6.5
2445186 2009, Dermal Sensitization Study in Guinea Pigs (Buehler Method) of MOI 106-5% Organic Formulation, DACO: 4.6.6
2449049 2014, Use Description / Exposure Scenarios, DACO 5.2
2445120 2014, 10.1 Value Summary for Regalia, DACO: 10.1
2596630 2013, Fungicide Efficacy and Selectivity of MBI 106020, DACO: 10.1, 10.2
2596631 2015, Efficacy of MBI106020 Against *Monilinia* sp. In Apricot Orchards, DACO: 10.1, 10.2
2596632 2011, IR-4 Ornamental Horticulture Program Bacterial Disease Efficacy, DACO: 10.1, 10.2
2596633 2011, Evaluate the efficacy of MBI-106020 Against *Phytophtora infestans* on Tomato (indoor), DACO: 10.1, 10.2
2596634 2011, Evaluate the Efficacy of MBI-106020 Against *Phytophtora infestans* on Tomato (outdoor), DACO: 10.1, 10.2
2596636 2015, Mode of Action of Regalia (*Reynoutria sachalinensis*), DACO: 10.1, 10.2
2596637 2015, Determination of Efficacy of MBI 106020 Against *Monolinia* in Stone Fruit, 2 Sites in EU Southern Zone 2011, DACO: 10.1, 10.2
2596638 2015, Determination of Efficacy of MBI 106020 Against *Monolinia* in Stone Fruit, 2 Sites in EU Southern Zone 2011, DACO: 10.1, 10.2
2596639 2011, Determination of Efficacy of MBI 106020 Against *Phytophthora infestans* in Protected Tomato, 1 Site in EU Central Zone 2011, DACO: 10.1, 10.2
2596640 2011, Determination of Efficacy of MBI 106020 Against Powdery Protected Tomato, 1 Site in EU Central Zone 2011, DACO: 10.1, 10.2
2596641 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Tomato, 4 sites in EU Central Zone 2012, DACO: 10.1, 10.2
2596642 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Tomato, 4 sites in EU Central Zone 2012, DACO: 10.1, 10.2
2596643 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Tomato, 4 sites in EU Central Zone 2012, DACO: 10.1, 10.2
2445123 2013, Raspberry Botrytis Trial, 3 Application Efficacy Screening Trial, DACO: 10.2.3.3

2445124 2010, Efficacy of Regalia Alone and in Tank Mixes to Control Powdery Mildew in Gerbera Daisies (*Gerbera jamesonii L.*), DACO: 10.2.3.3

2445125 2010, Efficacy of Fungicides on *Sphaerotheca pannosa* on Rose, DACO: 10.2.3.3

2445126 2010, Efficacy of Regalia and Regalia Maxx to Prevent Powdery Mildew Infection in Gerbera Daisies (*Gerbera jamesonii L.*), DACO: 10.2.3.3

2445127 2010, Evaluation of Fungicides for the Control of Downy Mildew on Coleus, DACO: 10.2.3.3

2445128 2012, Fungicides for Mummy Berry Control on "Powderblue", "Vernon" and "Ochlockonee" in North Carolina, DACO: 10.2.3.3

2445129 2011, Control of Powdery Mildew and Other Diseases by Experimental Fungicides and Mixed Schedules on Ida Red Apples, DACO: 10.2.3.3

2445130 2009, Evaluation of Compounds for Management of Late Blight in Tomato, Fall DACO: 10.2.3.3

2445131 2010, Evaluation of Compounds for Management of Late Blight in Tomato, Spring DACO: 10.2.3.3

2445132 2011, FSSB Fungicide Field Trial - New England Fruit Consultants, DACO: 10.2.3.3

2445133 2012, Comparison of Fungicides for Management of Cherry Powdery Mildew and Leaf Spot, 2012, DACO: 10.2.3.3

2445134 2012, Evaluate the Efficacy of MBI-10605, for Control of Brown Rot (*Monilinia fructicola*) of Fruit on Peaches Under Field Conditions, DACO: 10.2.3.3

2445135 2011, Fungicide Evaluation for *Phytophthora* Blight of Bell Pepper Percent Dead and Wilted Plants Due to *Phytophthora*, DACO: 10.2.3.3

2445136 2013, Marrone Bio Innovations Canola White Mold Trial, DACO: 10.2.3.3

2445137 2010, Foliar Anthracnose (*Colletotrichum cereale*), DACO: 10.2.3.3, 10.3.2

2445138 2010, Safety of Regalia on Eight Rose Cultivars, DACO: 10.2.3.3, 10.3.2

2445139 2009, IR-4 Ornamental Horticulture Program Research Report Form, DACO: 10.2.3.3, 10.3.2

2445140 2013, Turfgrass Pathology Report, Part 1 Michigan State University, DACO: 10.2.3.3, 10.3.2

2445141 2011, Crown Rot Anthracnose Report, DACO: 10.2.3.3, 10.3.2

2445142 2011, Brown Patch (*Rhizoctonia solani*), DACO: 10.2.3.3, 10.3.2

2445143 2010, Preventive Dollar Spot (*Sclerotinia homoeocarpa*/*Rutstroemia floccosum*), DACO: 10.2.3.3, 10.3.2

2445144 2011, Michigan State University 2010 - 2011 Turfgrass Pathology Report, Part II , DACO: 10.2.3.3,10.3.2

2445146 2010, IR-4 Ornamental Horticulture Program Research Report, Efficacy of Management Tools for Downy Mildew, DACO: 10.2.3.3, 10.3.2

2445147 2008, Effect of Fungicides and Biorational Products on Brown Patch on a Colonial Bentgrass Fairway: Rutgers University, DACO: 10.2.3.3, 10.3.2

2445148 2008, Preventive Control of Dollar Spot with Fungicides and Biorational Products on a Creeping Bentgrass Green: Rutgers University, DACO: 10.2.3.3, 10.3.2

2445149 2008, Effect of Fungicides and Biorational Products on Brown Patch on a Colonial Bentgrass Fairway: Rutgers University, DACO: 10.2.3.3, 10.3.2

2445150 2008, Preventive Control of Dollar Spot with Fungicides and Biorational Products on a Creeping Bentgrass Green: Rutgers University, DACO: 10.2.3.3, 10.3.2

2445151 2008, Effect of Fungicides and Biorational Products on Brown Patch on a Colonial Bentgrass Fairway: Rutgers University, DACO: 10.2.3.3, 10.3.2

2445152 2012, Fungicide Efficacy and Selectivity of MBI 106020 and MBI 106005 on Powdery Mildew (*Sphaerotheca fuliginea*) on Protected Cucurbits (greenhouse) in Spain, DACO: 10.2.3.3,10.3.2

2445153 2013, An Evaluation Of The Efficacy Of MBI-106020 And MBI-106005 Against *Botrytis Cinerea* On Grapevine, DACO: 10.2.3.3, 10.3.2

2445154 2012, An Evaluation Of The Efficacy Of MBI-106020 And MBI-106005 Against *Botrytis Cinerea* On Grapevine, DACO: 10.2.3.3, 10.3.2

2445155 2012, An Evaluation Of The Efficacy Of MBI-106020 And MBI-106005 Against *Botrytis Cinerea* On Grapevine, DACO: 10.2.3.3, 10.3.2

2445156 2013, An Evaluation Of The Efficacy Of MBI-106020 And MBI-106005 Against *Botrytis Cinerea* On Grapevine, DACO: 10.2.3.3, 10.3.2

2445157 2011, Efficacy of Regalia as Compared to Other Organically Certified Products for Control of *Erysiphe necator* in Grape , DACO: 10.2.3.3, 10.3.2

2445158 2012, Evaluation of the Efficacy of MBI-106005 Against *Uncinula necator* on Grapevine, DACO: 10.2.3.3, 10.3.2

2445159 2013, Evaluate the Efficacy of MBI-106020 and MBI-106005 Against *Botrytis cinerea* on Grapevine, DACO: 10.2.3.3,10.3.2

2445160 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Cucurbits, 3 sites in EU Southern Zone 2012, DACO: 10.2.3.3, 10.3.2

2445161 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Cucurbits, 3 sites in EU Southern Zone 2012, DACO: 10.2.3.3, 10.3.2

2445162 2013, MBI 106020: Determination of the Efficacy of MBI 106020 for the Control of Powdery Mildew in Protected Cucurbits, 3 sites in EU Southern Zone 2012, DACO: 10.2.3.3, 10.3.2

2445163 2010, Efficacy of MBI-106050 for Control of *Sphaerotheca macularis* and *Botrytis cinerea* in Strawberry, DACO: 10.2.3.3, 10.3.2

2445165 2012, Control of White Mold in Potatoes, DACO: 10.2.3.3, 10.3.2

2445166 2012, Regalia for Control of White Mold in Canola, DACO: 10.2.3.3, 10.3.2

2445167 2013, Plant Heath on Soybeans 1, DACO: 10.2.3.3, 10.3.2

2445168 2011, Regalia Alone and with Endura for White Mold Control in Potatoes, DACO: 10.2.3.3, 10.3.2

2445169 2013, Evaluate Registered and Candidate Fungicides for the Control of Early Rot in Wisconsin Cranberries - Goodwin Marsh, DACO: 10.2.3.3, 10.3.2

2445170 2013, Evaluate Registered and Candidate Fungicides for the Control of Fruit Rot in Wisconsin Cranberries - Prehn Marsh Marrone, DACO: 10.2.3.3, 10.3.2

B. Additional Information Used

Published Information

Canadian Council of Ministers of the Environment, April 26, 2016, Canadian Water Quality Guidelines for the Protection of Aquatic Life, 1, 4-Dioxane.
http://ceqg-rcqe.ccme.ca/download/en/321

Chemical Substances. Government of Canada, April 26, 2016, (1,4-Dioxane,). http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/summary-sommaire/batch-lot-7/123-91-1-eng.php

Air & Radiation, United States Environmental Protection Agency, April 26, 2016, Technical Fact Sheet, 1,4-Dioxane. http://www3.epa.gov/airtoxics/hlthef/dioxane.html

Scientific Committee on Food, European Commission, April 26, 2016, Opinion of the Scientific Committee on Food on impurities of ethylene oxide in food additives. http://ec.europa.eu/food/fs/sc/scf/out127_en.pdf

ISSN: 1911-8082