

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

Application Number: 2014-3069
Application: New End-Use Product Chemistry – Guarantee,
New End-Use Product Label – Application number, new site, and
classification
Product: Regalia Liquid Fungicide Concentrate
Registration Number: #####
Active ingredients (a.i.): Extract of *Reynoutria sachalinensis*
PMRA Document Number : 2508259

Purpose of Application

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

Chemistry Assessment

Regalia Liquid Fungicide Concentrate 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 Concentrate 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 Concentrate 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 Concentrate.

References

A. List of Studies/Information Submitted by the Registrant

PMRA Document Number	Reference
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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
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B. Additional Information Used

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ISSN: 1911-8082

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