

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

**Application Number:** 2014-3386  
**Application:** New End-Use Product Chemistry – Guarantee,  
New End-Use Product Label – Application number, new site, and  
classification  
**Product:** Regalia RX Biofungicide Liquid Concentrate  
**Registration Number:** #####  
**Active ingredients (a.i.):** Extract of *Reynoutria sachalinensis*  
**PMRA Document Number :** 2647744

### Purpose of Application

The purpose of this application was to register a commercial fungicide, Regalia RX Biofungicide Liquid Concentrate, for use on wheat and soybean.

### Chemistry Assessment

Regalia RX Biofungicide Liquid 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 RX Biofungicide Liquid 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.

There is no occupational concern anticipated from the commercial end-use product because of the adequate exposure mitigation measures present on the end-use product label, which include precautionary (e.g., wearing of personal protective equipment) and hygiene statements. Bystander exposure is expected to be low if label directions are followed. Post-application exposure is low with the restricted entry. There are no toxicological concerns to the domestic-users.

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**

Various foliar fungal disease claims were proposed for cereal grains and soybean at the suppression or partial suppression level of efficacy.

Information used to demonstrate the value of the label claims included field trial data, rationales for extrapolation of evidence from different crops and precedent claims on a similar commercial product currently registered in Canada. The value of all disease claims was deemed to have been adequately demonstrated. The proposed use on cereal crops was limited to wheat due to considerations of host susceptibility and available evidence. Though direct evidence of efficacy was limited for certain disease claims, the inherent socio-economic value of biofungicides and their relative scarcity were important considerations in the comprehensive assessment of the product's value.

### **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 RX Biofungicide Liquid Concentrate.

### **References**

#### **A. List of Studies/Information Submitted by the Registrant**

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## **B. Additional Information Used**

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