

## Evaluation Report for Category B, Subcategory 3.1, 3.11, 3.12 Application

**Application Number:** 2021-3135  
**Application:** Changes to Product Labels-Application Rates, New Pests, and New Site  
**Product:** Regalia Rx Biofungicide Liquid Concentrate  
**Registration Number:** 32350  
**Active ingredients (a.i.):** Extract of *Reynoutria sachalinensis*  
**PMRA Document Number :** 3348948

### Purpose of Application

The purpose of this application was to expand the Regalia Rx Biofungicide Liquid Concentrate label to include several new crops and pests, which includes new rates. In addition an alternate formulating site was added to the registration.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

Regalia Rx Biofungicide Liquid Concentrate is of low acute toxicity by oral, dermal, and inhalation routes, mildly irritating to eyes, slightly irritating to skin, and not a dermal sensitizer.

Occupational risk to individuals is acceptable when the Regalia Rx Biofungicide Liquid Concentrate is used according to label directions. Precautionary, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no food or drinking water concerns when the product is used according to label directions.

### Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally

permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

The specification of an MRL is not required for extract of *Reynoutria sachalinensis*.

### **Environmental Assessment**

The environmental risks associated with the label expansion of Regalia Rx Biofungicide Liquid Concentrate, containing the active ingredient Extract of *Reynoutria sachalinensis*, are acceptable when used according to label directions. Environmental concerns have been mitigated through adequate statements on the product label.

### **Value Assessment**

A bridging rationale and reports of 15 efficacy trials were reviewed to support the label expansion of Regalia Rx Biofungicide Liquid Concentrate. The majority of the new use claims on the Regalia Rx Biofungicide Liquid Concentrate label are supported based on currently registered uses on similar products with the same active ingredient. In addition, results of efficacy trials demonstrated that Regalia Rx Biofungicide Liquid Concentrate suppressed fire blight on apple and pear, or early rot, powdery mildew and cottonball on cranberry.

The addition of these use claims to the Regalia Rx Biofungicide Liquid Concentrate label will provide Canadian growers with a new product to manage those important fungal diseases on labelled crops.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Regalia Rx Biofungicide Liquid Concentrate.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
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3249534	2019, Resistance inducers for apple fire blight suppression, 2019, DACO: 10.2.3.3(D)
3249535	2019, Non-antibiotic materials for control of pear fire blight, 2019, DACO: 10.2.3.3(D)
3249536	2020, Non-antibiotic materials for control of pear fire blight, 2020, DACO: 10.2.3.3(D)
3249537	2017, Cottonball - Marrone, DACO: 10.2.3.3(D),10.3.2(B)
3249538	2017, Cottonball - Amundson (3), DACO: 10.2.3.3(D),10.3.2(B)
3249539	2017, Early Rot - RedRisk Legacy, DACO: 10.2.3.3(D),10.3.2(B)

3249540	2017, Early Rot - Marrone (1), DACO: 10.2.3.3(D),10.3.2(B)
3249541	2017, ExpFungi Cottonball Potter, DACO: 10.2.3.3(D),10.3.2(B)
3249542	2017, ExpFungicides Fru Rot Moodie, DACO: 10.2.3.3(D),10.3.2(B)
3249543	2017, ExpFungicides Fru Rot Prehn, DACO: 10.2.3.3(D),10.3.2(B)
3249544	2017, Fruit Rot - RedRisk Schultz, DACO: 10.2.3.3(D),10.3.2(B)
3249545	2017, Fruit Rot - Marrone (2), DACO: 10.2.3.3(D),10.3.2(B)
3249548	2015, Evaluation of bactericide and chemical regulator programs for the management of fire blight on 'Idared' apples in NY, 2015, DACO: 10.2.3.3(D),10.3.2(B)
3249549	2016, Evaluation of bactericide programs for the management of fire blight on 'Gala' apples in NY, 2016, DACO: 10.2.3.3(D),10.3.2(B)
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3249552	2019, Evaluation of bactericide programs for the management of fire blight on 'Gala' apples in NY, 2019, DACO: 10.2.3.3(D),10.3.2(B)
3249553	2020, Medford - Comice pear, DACO: 10.2.3.3(D),10.3.2(B)
3249531	2021, Use description/scenario (application and post application), DACO 5.2

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