

## Evaluation Report for Category B, Subcategory 3.11, 3.12, 4.6 Application

**Application Number:** 2015-0972  
**Application:** Changes to Product Labels-New Pests  
Changes to Product Labels-New Site or Host  
Submission to fulfill conditions of registration on a product with full registration  
**Product:** Regalia Maxx Biofungicide Liquid Concentrate  
**Registration Number:** 30199  
**Active ingredients (a.i.):** Extract of *Reynoutria sachalinensis*  
**PMRA Document Number :** 2623721

### Purpose of Application

The purpose of this application was to amend the use of the registered end-use product Regalia Maxx Biofungicide Liquid Concentrate, containing the technical grade active Extract of *Reynoutria sachalinensis*, 20%, to include new crops and pests. Confirmatory data was also submitted to address outstanding value information for the strawberry powdery mildew claim.

### Chemistry Assessment

No chemistry assessment was required for this application.

### Health Assessments

No changes to the formulation of Regalia Maxx Biofungicide Liquid Concentrate have been proposed; therefore, toxicological profile of the end-use product is characterized as before.

Since there are no changes to the application methods, rates or frequency, there are no occupational or bystander exposure concerns anticipated from the new uses. The label has adequate exposure mitigation measures, which include precautionary (e.g., wearing of personal protective equipment) and hygiene statements.

There is no dietary or drinking water concern anticipated from the new uses due to the low toxicity of the end-use product and the active ingredient, *Reynoutria sachalinensis*, long history of use as a food item and in medicinal products in other parts of the world with no adverse effects reported.

A Maximum Residue Limit (MRL) has not been specified for the extract of *Reynoutria sachalinensis* and will not be required for the new uses.

The available information is sufficient to support the proposed uses of Regalia Maxx Biofungicide Liquid Concentrate.

## Environmental Assessment

As the new use patterns falls within the currently registered application rate and use pattern, the exposure of non-target organisms to Regalia Maxx Biofungicide Liquid Concentrate is not expected to be increased. The risk to non-target organisms in the environment is acceptable.

## Value Assessment

The application rates and timing for the new disease claims fall within the range of those currently registered on the Regalia Maxx Biofungicide Liquid Concentrate label. Value information was submitted in the form of greenhouse and field data as well as a scientific rationale based on disease development and the product's putative mode of action as an elicitor of induced systemic resistance in plants. Sufficient value information was provided to support all new disease claims. Due to the lack of supportive evidence, two crops (groundcherry and tomatillo) were excluded from the extension of tomato claims to include other fruiting vegetables.

Where for certain claims only limited evidence of efficacy from either trial data or scientific rationale was available, the relative scarcity of non-conventional product options and the social and economic context of their use were important considerations in the comprehensive assessment of their value. Registration of these claims will provide organic producers and other commercial growers, seeking non-conventional alternatives with additional options for disease suppression in high value horticultural crops.

In addition, submitted confirmatory efficacy data was determined to be sufficient in addressing outstanding conditions that had been identified for the strawberry powdery mildew claim following initial registration of Regalia Maxx Biofungicide Liquid Concentrate.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Regalia Maxx Biofungicide Liquid Concentrate, and has found the information sufficient to add new crops and pests to the product label, and to fulfill the outstanding data requirement on strawberries.

## References

PMRA#	Reference
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2510860	2013, Study on the efficacy of the formulation MBI 106020 against powdery mildew ( <i>Podosphaera leucotricha</i> ) on stone fruits (peach) in Spain in 2012, DACO: 10.2.3.3(D)
2510861	2014, Study to determine the efficacy and crop safety of MBI-106020 against <i>Monolinia</i> in Stone fruit (plums/apricot), DACO: 10.2.3.3(D)
2510862	2011, Determination of Efficacy of MBI 106020 against <i>Monilinia</i> in stone fruit, 2 sites in EU Southern Zone 2011, DACO: 10.2.3.3(D)

2510863	2011, Determination of Efficacy of MBI 106020 against powdery mildew in stone fruit, 2 sites in EU Southern Zone 2011, DACO: 10.2.3.3(D)
2510864	2012, Evaluate the efficacy of MBI-106020 against Powdery mildew ( <i>Leveillula taurica</i> ) on tomato (covered), DACO: 10.2.3.3(D)
2510865	2011, Evaluate the efficacy of MBI-106020 against <i>Phytophthora infestans</i> on tomato (indoor), DACO: 10.2.3.3(D)
2510866	2011, Evaluate the efficacy of MBI-106020 against <i>Phytophthora infestans</i> on tomato (outdoor), DACO: 10.2.3.3(D)
2518964	2015, Value Summary for Regalia, Maxx, DACO: 10.1
2518965	2015, Evaluation of fungicides for control of powdery mildew in strawberries grown in a Haygrove tunnel, 2013. , DACO: 10.2.3.3(D),10.3.2(B)
2518966	2014, Determination of Efficacy of MBI 106020 against powdery mildew in protected strawberries, 1 Site in EU South Zone 2013 , DACO: 10.2.3.3(D),10.3.2(B)
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2603689	2015, Value Summary for Regalia Maxx, DACO: 10.1
2603691	2000, 2_induction of phenolic compounds in two cultivars of cucumber by treatment of healthy and powdery mildew-infected plants with extracts of <i>Reynoutria sachalinensis</i> , DACO: 10.2.3.2(D)
2603692	2012, 1_CHR-1_Comparison of fungicides for management of cherry powdery mildew and leaf spot, 2012., DACO: 10.2.3.3(D)
2603693	2013, 6_Induction of defence-related biochemical changes in okra leaves to powdery mildew disease by several plant-derived agents, DACO: 10.2.3.3(D)
2603694	2012, 7_Preventative and Curative Effects of Several Plant Derived Agents Against Powdery Mildew Disease of Okra, DACO: 10.2.3.3(D)
2603695	2010, 8_efficacy of various ir4 recommended products against bacterial leaf spot of tomato and pepper and angular leaf spot of cucumber under greenhouse conditions , DACO: 10.2.3.3(D)
2603696	1994, 9_Differential induction of resistance and enhanced enzyme activities in cucumber and tobacco caused by treatment with various abiotic and biotic inducers, DACO: 10.2.3.3(D)
2603697	1998, 3_Immunological and molecular comparison of polyphenol oxidase in Rosaceae fruit trees, DACO: 10.6
2603698	1999, 4_Host Range of <i>Oidium lycopersicum</i> on Selected Solanaceous Species in Connecticut, DACO: 10.6
2603699	2006, 5_Role of Polyphenols in the Resistance Mechanisms of Plants Against Fungal Pathogens and Insects, DACO: 10.6
2603700	1997, 10_Characteristics and host range of tomato powdery mildew, DACO: 10.6

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