

84059-7

4/2/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 2, 2014

John Fournier
Regulatory Manager
Marrone Bio Innovations
2121 Second Street, Suite B-107
Davis, CA 95618

Subject: Notifications per PRN 98-10 to Add Inert Ingredient Suppliers and
Revise Storage and Disposal, Environmental Hazards, and Warranty Statements
Product Name: Regalia Disease Control Concentrate
EPA Reg. No: 84059-7
Your Submission Dated September 27, 2013

Dear Mr. Fournier:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10, dated above. A screen of these requests has been conducted for applicability under PRN 98-10, and it has been determined that the actions fall within the scope of this document. Our records have been duly noted, and the label and Confidential Statement of Formula (dated 9/27/2013) submitted with this application have been stamped "Notification Accepted" and placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Burnett at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 84059/84059-7	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Marrone Bio Innovations/Reqalia Disease Control Concentra	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Marrone Bio Innovations 2121 Second St., Ste. B-107, Davis, CA 95618 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label and CSF changes per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 24oz,32oz,1gal		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product paper glued		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name John Fournier	Title Regulatory Manager	Telephone No. (include Area Code) 530-750-2800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name John Fournier	5. Date September 27, 2013	

September 27, 2013

Linda Hollis
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Chemical Safety and Pollution Prevention (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Notification of label and CSF changes per PR Notice 98-10 for Regalia Disease Control Concentrate (EPA Reg. No. 84059-7)

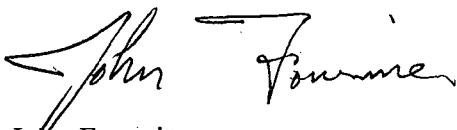
Dear Ms. Hollis:

Please find enclosed a notification of label changes for Regalia Disease Control Concentrate (EPA Reg. No. 84059-7. Storage/Disposal, Environmental Hazards, and Warranty statements have been updated in accordance with PR Notice 98-10. Also in accordance with PR Notice 98-10, additional sources of inert ingredients have been added to the Confidential Statement of Formula (CSF), as well as one production site. A copy of labeling and a CSF bearing these changes have been included with this application.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please contact me at jfournier@marronebio.com or at (530) 750-2800 if you have any questions or comments. Thank you for your assistance.

Sincerely,



John Fournier
Regulatory Manager, Marrone Bio Innovations

Marrone Bio Innovations

Regalia®

Disease Control Concentrate

- Claims: [Boost plants' natural defenses]
- [Strengthens plants' natural immunity]
- [Controls common garden diseases]
- [Controls powdery mildew, leaf spot and rust]
- [For use in organic gardening]:
- [Controls black spot on rose]
- [Use on fruits, vegetables, turf and ornamentals]
- [Fungal and bacterial disease control]
- [Active ingredient made from a plant extract]

Notification Accepted

Date: 4/2/2014

Reviewer: G. Burnett BPPD

Active ingredient: Extract of <i>Reynoutria sachalinensis</i>	5 %
Other ingredients:	95 %
Total	100 %

EPA Reg. No. 84059-7

EPA Est. No. XXXXXX-XX-XXX

KEEP OUT OF REACH OF CHILDREN CAUTION

(See attached labeling for Additional Precautionary Statement and Directions for Use)

First Aid Statement	
IF SWALLOWED:	Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or if going for treatment.	

Net Contents; 24 ounces, 32 ounces, 1 gallon

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Caution: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DIRECTIONS FOR USE

SHAKE WELL PRIOR TO USE

Choose from one of the recommended application methods listed below.

PUMP-UP SPRAYER

1. Fill with required amount of water.
2. **Add 1 fl oz of concentrate per gallon.**
3. Replace sprayer top and shake well before using.
4. Shake occasionally during application.

DIAL-STYLE HOSE-END SPRAYER

1. **Set sprayer to the 1 fl oz per gallon level.**
2. Use only enough product for the area to be treated.
3. Close sprayer, attach to hose and apply.

HANDY CONVERSION: 1 fl oz = 2 Tbsp.

Regalia Disease Control is effective for the prevention and control for various fungal and bacterial diseases including, but not limited to, powdery mildew, downy mildew, Botrytis grey mold, rust, black spot of rose, leaf spots, anthracnose, leaf blights, smut, gummy stem blight, bacterial blight and bacterial spot. Regalia Disease Control also provides suppression of scab and fire blight on fruit trees.

Regalia Disease Control may be used on all roses, flowers, foliage plants, turf and lawns, ornamental trees and shrubs, vegetables, berries and tree fruit.

USE TIPS

Apply Regalia by spraying all green leaves covering both the tops and bottoms as thoroughly as possible. Spray to the point of run-off.

As a preventative, apply every 7 to 14 days until the potential for disease has passed. To control disease that is already present, apply on a 7 day schedule until disease symptoms are gone. Then continue spraying every 14 days to prevent disease recurrence.

When applying on turf, spray water volumes should be at least 2 gallons of water per 1000 sq. ft.

For Scab -When applying for suppression of scab on pome fruit, begin applications at green tip or when environmental conditions favor scab development . Repeat every 7-10 days.

For Fire Blight - When applying for suppression of fire blight, begin applications at bloom and repeat every 3-10 days to protect open, untreated blossoms. After petal fall, continue applications every 7 days.

For Powdery Mildew- Begin application of Regalia at popcorn stage and repeat on a 7 day interval or as needed.

(For Downy Mildew, Botrytis Grey mold, Rust, Black Spot (on Roses), Leaf Spots, Anthracnose, Leaf Blights, Smut, Gummy Stem Blight, Bacterial Blight and Bacterial Spot) For all other diseases – Begin application prior to disease development when environmental conditions and plant stage are conducive to rapid disease development and repeat on a day 7 to 10 day interval or as needed.

NOTE: Regalia Disease Control has been tested successfully on numerous plants. However, not all plant species have been evaluated. When treating tender or sensitive plants, it is recommended to spray a few plants as described in the directions, wait 24 hours, and check for possible injury.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry place. Avoid freezing.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instruction. Never place unused product down any indoor or outdoor drain.

**Marrone Bio Innovations
WARRANTY**

To the extent permitted by applicable law, the seller makes no warranty, expressed or implied, of merchantability, fitness or otherwise concerning use of this product. The user assumes all risks of use, storage or handling that are not in strict accordance with the accompanying directions. [The](Insert Company Name) Guarantee – If for any reason you are not satisfied with this product, send proof of purchase to the address shown and we will gladly refund your purchase price.

Label date: September 27, 2013

US Patents No. 4,863,734 and No. 5,989,429

Regalia® is a registered trademark of Marrone Bio Innovations, Inc.

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Marrone Bio Innovations

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