

1/16/2009

1/9

Keith Pitts  
Vice President, Regulatory Affairs  
Marrone Organic Innovations  
2121 Second Street, suite 107-B  
Davis, CA 95618

JAN 16 2009

Subject: Regalia SC  
EPA Registration No. 84059-2  
Label Amendment  
Letter Dated December 18, 2008

Dear Mr. Pitts:

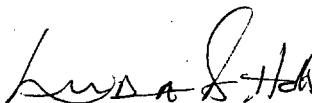
The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact John Fournier at 703-308-0169 or by email at: [fournier.john@epa.gov](mailto:fournier.john@epa.gov). A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosure

Concurrence:

7511.P

Fournier

13 Jan 09

# Regalia<sup>®</sup> SC

A plant extract to boost the plants' natural defense mechanisms against certain fungal and bacterial diseases

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

EPA Reg. No. 84059-2

EPA Est. No. XXXXXXXXX

## KEEP OUT OF REACH OF CHILDREN WARNING

### FIRST AID

<b>IF IN EYES:</b>	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.
<b>IF SWALLOWED:</b>	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.
<b>IF ON SKIN OR CLOTHING:</b>	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.
<b>IF INHALED:</b>	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

### NET CONTENTS:

- 1 gallon
- 2.5 gallons

RECSC-08-02



2121 Second St., Suite B-107, Davis, CA 95618 USA  
Info@marroneorganics.com

# ACCEPTED

JAN 16 2009

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 84059-2

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Waterproof gloves
- Protective eyewear

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, used detergents and hot water. Keep and wash PPE separately from other laundry.

**USER SAFETY RECOMMENDATION**  
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

#### ENVIRONMENTAL HAZARDS

For terrestrial uses. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater, or rinsate.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and the restricted-entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

*(continued)*

**AGRICULTURAL USE REQUIREMENTS** *(continued)*

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

**GENERAL INFORMATION**

Regalia SC is an organic extract from the plant *Reynoutria sachalinensis* for use on ornamental plants and edible crops. Regalia SC applied to actively growing plants (see directions for use) will help make the treated leaf area resistant to certain plant diseases.

Use Regalia SC as a preventative rather than a curative application. Apply prior to disease infestation to protect the growing leaf tissue. The principle diseases controlled in treated plants are Powdery Mildew, Gray Mold, Rust\*, Bacterial Canker\*, Bacterial Blast\*, Bacterial Leaf Spot, Target Spot, and Bacterial Speck\*. See specific information under use recommendations for Ornamental Plants and Edible Crops.

**\*Not for use in California.**

**MODE OF ACTION**

The extract obtained from ground *R. sachalinensis* plant material contains the active chemical substances. These compounds, when applied to the host plant, raise their natural defense system, based on a five-fold increase in phenolics. This induced resistance against some important diseases is not systemic, but there is some translaminar protection. This means that new plant growth needs to be protected, and repeat applications at 7-14 day intervals are recommended. The resistance induction takes place in one to two days. Light is required.

Use Regalia SC therefore as a preventative treatment.

**MIXING INSTRUCTIONS**  
**- SHAKE WELL PRIOR TO USE -**

Regalia SC is a suspension concentrate (SC) consisting of certain natural ingredients. Regalia SC is an extract from Giant Knotweed (REYSA) that contains liquid and solid portions of the plant extract. Both are important for the resistance induction of the treated plants. Some of these ingredients tend to settle out after standing for an extended time in the container. **They need to be shaken vigorously to be re-suspended before using.** Use 50-mesh nozzle screens or larger.

Only the treated green tissues develop resistance, therefore coverage of foliage is important, although there is some translaminar movement. The general use rate recommended is 0.5% v/v of Regalia SC concentrate in 50-100 gallons of water per acre. The larger sized crops and foliage need the larger volume in order to secure thorough coverage.

If mechanical mixing is available when preparing the spray solution, keep the agitators running. Apply with an an ionic wetting agent such as Tween® 20 or Latron B-1956® at 0.02% v/v of the final water volume. Regalia SC can be tank mixed in the spray tank with pesticides and surfactants to enhance disease control. Do not exceed recommended application rates. Regalia SC cannot be mixed with another product with a prohibition against mixing. Use of the tank mix must be in accordance with the more restrictive label limitations and precautions.

**Compatibility:** Do not combine Regalia SC in the spray tank with pesticides, surfactants, or fertilizers if there has been no previous experience or use of the combination to show it is physically compatible, effective and non-injurious under your use conditions.

Regalia SC is compatible with many commonly used pesticides, fertilizers, adjuvants and surfactants but has not been evaluated with all of these. To ensure compatibility of the tank mix combinations they should be evaluated prior to use, as follows: Using a suitable container add the proportional amounts of product to water. Add wettable powders first, then water dispersible granules, then liquid flowables and lastly, emulsifiable concentrates. Mix thoroughly and let stand for at least five minutes. If the combination stays mixed or can be remixed, it is physically compatible. Test the mix on a small portion of the crop to be treated to ensure that a phytotoxic response will not occur as a result of the application.

**ORNAMENTAL PLANTS**

The following plant species have been treated with Regalia SC, either for the purpose of rendering them more vigorous or to prevent disease. The disease most prominently controlled is powdery mildew (*Oidium* spp.), and there are also reports of gray mold (*Botrytis cinerea*) and rust (*Puccinia antirrhini*) control. Plants investigated:

- |              |             |             |
|--------------|-------------|-------------|
| Begonias     | Lisianthus  | Salvias     |
| Crape myrtle | Petunias    | Snapdragons |
| Freesias     | Poinsettias | Zinnias     |
| Gerbera      | Roses       |             |

Since it is not possible to test all ornamental species or varieties grown in the greenhouse, it is recommended that the user first test Regalia SC on a few plants prior to large-scale usage.

**Application Rates and Timing for Ornamental Plants**

Mix Regalia SC with tap water at a concentration of 0.5% v/v (2 qts. Regalia/100 gals. water). Rates for trial purposes should range from 0.25%-1% v/v. Begin applications preventatively (before disease symptoms become visible) at the 4-6 leaf stage and treat at 7-14 day intervals as needed prior to sale or harvest. Spray water volumes should be between 50-100 gallons/acre. Spray until runoff. Make no more than six applications for annual ornamentals.

**EDIBLE CROPS**

Regalia SC used as specified and preventatively will increase the natural defense system of the treated plants listed below towards the diseases specified below.

**LIMITATIONS:**

Do not apply more than six applications per crop.  
Do not apply more than two quarts of Regalia SC per acre seven days prior to harvest.

**Application Rates and Timing for Edible Crops**

**Grapes** – Powdery mildew (*Uncinula necator*), and Gray mold (*Botrytis cinerea*)

Apply Regalia SC preventatively at 0.5% v/v in 50-100 gallons of water on the crop when the first disease symptoms are visible, or when disease pressure is high, and adding 0.02% v/v of a wetting agent. Repeat applications in 7-14 day intervals depending upon crop growth and disease pressure. The shorter interval is recommended for greenhouse cucurbits under high disease conditions.

**Cucurbits: Such as, Cantaloupe, Cucumber, Pumpkin, Zucchini, Watermelon** – Powdery mildew (*Sphaerotheca fuligines*, *Erysiphe cichoracearum*), Downy mildew (*Pseudoperonospora cubensis*), Gummy stem blight (*Didymella bryoniae*)

Apply Regalia SC preventatively at 0.5% v/v in 50-100 gallons of water on the crop when the first symptoms of powdery mildew are visible, or when disease pressure is high, and adding 0.02% v/v of a wetting agent. Repeat applications in 7-14 day intervals depending upon crop growth and disease pressure. The shorter interval is recommended for greenhouse cucurbits under high disease conditions.

**Strawberries** – Powdery mildew (*Sphaerotheca spp.*)

Apply Regalia SC at a concentration of 0.5%-1% v/v in 100 gallons of water at 7-14 day spray intervals as soon as first symptoms appear, adding 0.02% v/v of a wetting agent.

**Walnuts** – Bacterial blight (*Xanthomonas campestris*)

For the preventative control of bacterial blight apply 0.5%-1% v/v Regalia SC in 50-100 gallons of water and add a surfactant such as Nu-Film® P at 0.02% v/v. Repeat applications at 7-10 day intervals.

**Peppers** – Bacterial blight (*Xanthomonas campestris*), Powdery mildew, Bacterial leaf spot, Target spot, Tomato late blight, Early blight of tomato, Bacterial canker\*, Bacterial speck\*, Grey mold\*

For preventative control apply 0.5%-1% v/v Regalia SC in 50-100 gallons of water and add a surfactant such as Nu-Film® P at 0.02% v/v. Repeat applications at 7-10 day intervals.

**Lettuce** – Powdery mildew (*Erysiphe cichoracearum*)

Apply Regalia SC preventatively at 0.5% v/v in 50 gallons of water, adding 0.02% v/v of a wetting agent such as Tween® 20. Repeat applications at 10-14 day intervals.

**Tomato** – Powdery mildew, Bacterial blight, Bacterial leaf spot, Target spot, Grey mold, Tomato late blight, Early blight of tomato, Bacterial canker\*, Bacterial speck\*

For preventative control apply 0.5%-1% v/v Regalia SC in 50-100 gallons of water and add a surfactant such as Nu-Film® P at 0.02% v/v. Repeat applications at 7-10 day intervals.

**Citrus\***: Such as, Orange, Grapefruit, Lemon, Tangerine, Tangelo, Pummelo and other Citrus Crops – Bacterial canker (*Xanthomonas spp.*), Bacterial blast (*Pseudomonas syringae*), Greasy spot (*Mycosphaerella citri*)

Apply 0.5%-1% v/v Regalia SC in 50-100 gallons of water. For improved performance use Regalia SC in a tank mix or rotational program with other registered fungicides. Repeat applications at 7-14 day intervals.

**\*Not for use in California.**

**INTEGRATED PEST MANAGEMENT (IPM)**

Although only some conventional fungicides have been tested in an IPM regime with Regalia SC, results have been very satisfactory. One of the major objectives of IPM has been to reduce the probability of disease resistance development to a particular active ingredient.

The alternate use of Regalia SC (1-2 sprays) followed by a conventional, registered fungicide (1-2 sprays) has been successfully used in many crops. In addition, the uses of tank mixes with a conventional fungicide have been successful.

Follow label instructions of the particular registered product, not to exceed amounts or treatment intervals as recommended on the label.

### LIMITATIONS OF USE

- Do not apply through any type of irrigation equipment.
- Do not apply more than 100 gallons of a 1% spray solution per acre.
- Do not apply more than six applications per year.
- Do not apply with phytotoxic oil.

**Concentrations of 1% Regalia SC or more applied to very small, tender plants may produce plant injury. Do not use on Gerbera and Lisianthus plugs. Wait for two weeks after transplanting.**

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**PESTICIDE STORAGE:** Store in a cool, dry place. Avoid freezing.

**PESTICIDE DISPOSAL:** To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Do not contaminate water when disposing of equipment washwater or rinsate. Pesticide wastes may be toxic. Improper disposal of unused pesticide, washwater or rinse water is a violation of federal law.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances.



9/9

### **WARRANTY**

Other than as indicated on this product label, the seller makes no warranty, express 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, to the extent permitted by applicable law.

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

Regalia® SC is a registered trademark of Marrone Organic Innovations, Inc.  
Tween® 20 is a registered trademark of Mallinckrodt Baker, Inc.  
Latron® B-1956 is a registered trademark of Dow AgroSciences.  
Nu-Film® P is a registered trademark of Miller Chemical.

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