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55638-16

11/21/97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

David L. Olson  
Director, Regulatory Affairs  
Ecogen, Inc.  
2005 Cabot Boulevard West  
P.O. Box 3023  
Langhorne, PA 19047-3023

NOV 21 1997

Dear Mr. Olson:

Subject: AQ10 Biofungicide  
EPA Reg. No. 55638-16  
Application for a label amendment dated October 8, 1997.

On October 8, 1997, you submitted an application to amend the subject label. Revisions are made to

- change the term "Inert" to "Other" in the Ingredient Statement
- change the package size from 2.5 oz. to 0.5 oz.
- add a recommendation for a silicone based surfactant in the Mixing Instructions
- reword the Application Instructions to better reflect commercial practices
- add hand held equipment and aerial application to the Directions for Use
- add statements for Chemigation to the Directions for Use
- reword and expand the tank mix recommendations
- add Application Rate Tables to include a wider variety of vegetable, fruit, and ornamental crops

The labeling amendments referred to above under the Federal Insecticide, Fungicide, and Rodenticide Act are acceptable subject to the comments listed below.

1) Parts of the Directions for Use and the new Application Rate Tables call for up to 1 oz. of product, an amount greater than the revised package size (0.5 oz.). Although not

CONCURRENCES							
SYMBOL	7511W	7511W					
SURNAME	Reynolds	Hutton					
DATE	11/14/97	11/19/97					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

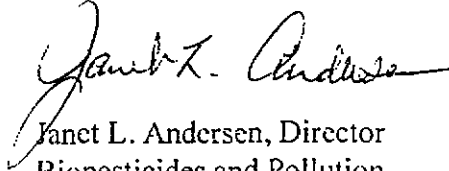
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specifically stated in the regulations (40 CFR 156.10 (d) or (I)), the label must not call for more than the net contents of the package (LP96-07). The application rates on the amended label should be modified so that no more than 0.5 oz. of product is specified.

2) Since the subject product is classified as a Category III eye irritant, the phrase "Causes moderate eye irritation" must be included in the Precautionary Statements. This phrase was also omitted on previously submitted (and approved) labels.

A stamped copy of the draft label for the subject product is enclosed for your records. Please submit (5) copies of your final printed label for AQ10 Biofungicide before release of the product for shipment.

Sincerely,



Janet L. Andersen, Director  
Biopesticides and Pollution  
Prevention Division (7501W)

Enclosure  
A.Reynolds/CS1/605-0515/11-14-97  
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CONCURRENCES							
SYMBOL	7511W						
SURNAME	Reynolds						
DATE	11/14/97						

# AQ10<sup>®</sup>



## Biofungicide

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**AQ10<sup>®</sup>** biofungicide is a selective fungal hyperparasite for control of powdery mildew.

**Active Ingredient:**  
 Ampelomyces quisqualis isolate M-10 . . . . . 58.0%\*

**Other Ingredients** . . . . . 42.0%

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TOTAL . . . . . 100.0%

\*Contains not less than 5.0 x 10<sup>9</sup> viable spores/g

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**STATEMENT OF PRACTICAL TREATMENT**

If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
 Avoid contact with eyes. In case of contact immediately flush eyes with plenty of water. Get medical attention if irritation persists.

**Personal Protective Equipment (PPE):**  
 Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
  - Shoes plus socks
  - Dust/mist filtering respirator (NIOSH/MSHA approval number prefix TC-21C)
- Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

**ENVIRONMENTAL HAZARDS**

For terrestrial uses, do not apply directly to water, or 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 washwaters.

**STORAGE AND DISPOSAL**

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

**Storage:** Store in cool, dry place inaccessible to children. AQ10 contains living spores and care should be taken to properly store the product. The product is best stored at or below room temperature. Do not store in extreme heat or cold.

**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**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.

**ACCEPTED  
 with COMMENTS  
 In EPA Letter Dated  
 11/21/97**

**Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
 55638-16**



Ecogen Inc.  
 2005 Cabot Blvd. West, P.O. Box 3023  
 Langhorne, PA 19047-3023  
 215/757-1590 or 800/220-2135

EPA REG. No. 55638-16  
 EPA EST. No. 36638-MT-01  
 Net Contents: 0.5 Ounces

**S P E C I M E N   L A B E L**

### 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 exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this section only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 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.

### NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to the uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

**Do not enter treated areas without protective clothing until sprays have dried.**

**Preharvest Interval:** AQ10 can be applied up to and including the day of harvest.

**Mode of Action:** AQ10 is a fungus that parasitizes powdery mildew. Following rehydration and application, AQ10 spores germinate into the powdery mildew mycelia and parasitize it.

AQ10 should be used as a preventative treatment for powdery mildew.

### MIXING INSTRUCTIONS

AQ10 should be thoroughly mixed with water. Fill the spray tank one-half full with water; add AQ10 to the tank, then finish filling the tank. The use of a mineral oil or silicone based surfactant is recommended. Continuously agitate the tank mix to maintain suspension. Spray entire contents of mixture within the same day of mixing. AQ10 can lose viability when left in water over 12 hours.

### APPLICATION INSTRUCTIONS

- Initial applications should begin as soon as susceptible plant tissue emerges.
- Foliage and/or fruit should be sprayed thoroughly with sufficient water carrier to ensure complete coverage.
- Applications should be repeated at an interval sufficient to maintain disease control, depending upon plant growth, disease pressure and weather conditions.
- Applications should be made in the early morning or late evening when humidity is at it's highest. This assures maximum germination of AQ10.
- AQ10 can be applied with conventional ground, hand held and aerial application equipment.
- AQ10 may be an effective resistance management tool when used in an IPM spray program with sulfur and sterol inhibitors for control of powdery mildew. It is important to use AQ10 in at least two sequential sprays 7-14 days apart. These sequential applications give AQ10 the opportunity to build up sufficient populations for the most effective long term control.
- Do not use screens smaller than 100 mesh.

### HAND HELD EQUIPMENT

When using hand held equipment, mix 1 ounce per 100 gallons of spray solution. Spray to wet, but not to runoff.

### AERIAL APPLICATION

Do not apply in less than 15 gallons of water per acre.

### TANK-MIX RECOMMENDATIONS

AQ10 can be tank-mixed with other insecticides, fungicides and nutrients that have been tested for compatability. Contact your local sales representative for a complete tank-mix compatability list.

This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rate should be exceeded. Application must be made in accordance with the more restrictive of label limitation and precautions.

The following chemicals cannot be tank mixed with AQ10: sulfur, dithiocarbamates, potassium salts of fatty acids and strobilurins.

## CHEMIGATION

Apply this product only through center pivot, lateral move, end tow, side (wheel) roll, traveler, solid set or hand move sprinkler systems. **Do not apply this product through any other type of irrigation system.** Crop injury or lack of effectiveness can result from nonuniform distribution of treated water.

If you have questions about calibration, contact your State Extension Service Specialist, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

### CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS:

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are

compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

### SPRINKLER CHEMIGATION:

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The pesticide injection pipeline must contain a functional automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

The active ingredient in AQ10 will settle in the tank and injection lines; adequate agitation must be provided before and during the injection period. Use only in systems that apply uniformly and have appropriate check valves. When application is complete, thoroughly flush the injection system and sprinkler lines.

### MIXING RECOMMENDATIONS FOR CHEMIGATION:

Follow general **MIXING INSTRUCTIONS** and provide mild uniform agitation throughout the suspension but do not agitate excessively.

### SPRAY VOLUME:

For chemigation use irrigation levels of 0.15 to 0.5 inches of water per acre.

AQ10 should be injected into no more than the last 30 minutes of the chemigation.

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## APPLICATION RATE TABLE

### I. VEGETABLE CROPS

Crops such as:	Application Rate:	When to Apply:
Artichokes Arugala Beans Carrots Cucurbits Cucumber Eggplant Endive Escarole Leafy Vegetables (Hood, Leaf, Romaine & Specialty) Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.) Peas Peppers Pumpkins Spinach Squash Sugar Beets Sweet Potatoes Tomatoes	0.5 - 1 oz./acre*	Best to apply in the early morning or late evening when humidity is at its highest. This assures maximum germination of AQ10. Repeat applications should be every 7 to 14 days. There should be a minimum of 2 sequential applications in order to maintain the population of the AQ10 organism.

\*Use higher rates when disease pressure is heavy and/or when dense canopies exist.

### II. POME & STONE FRUIT TREES

Crops such as:	Application Rate:	When to Apply:
<b>Pome and Stone Fruit Trees:</b> Apples Apricots Cherries Noctarines Peaches Pears Plums Prunes Quince	1 oz./acre	Best to apply in the early morning or late evening when humidity is at its highest. This assures maximum germination of AQ10. Repeat applications should be every 7 to 14 days. There should be a minimum of 2 sequential applications in order to maintain the population of the AQ10 organism.

**III. OTHER FRUIT & VINE CROPS**

Crops such as:	Application Rate:	When to Apply:
<b>Grapes</b> <b>Hops</b> <b>Small Fruit and Berries:</b> Blackberries Blueberries Boysenberries Cranberries Currants Loganberries Raspberries Strawberries <b>Tropical and Other Fruit:</b> Avocados Bananas Dates Figs Kiwi Mangoes Papayas Persimmons Pineapple Pomegranate Tropical Fruits	0.5 - 1 oz./acre* 0.5 - 1 oz./acre* 0.5 - 1 oz./acre*  0.5 - 1 oz./acre*	Best to apply in the early morning or late evening when humidity is at its highest. This assures maximum germination of AQ10. Repeat applications should be every 7 to 14 days. There should be a minimum of 2 sequential applications in order to maintain the population of the AQ10 organism.

\*Use higher rates when disease pressure is heavy and/or when dense canopies exist.

**IV. HERBS & SPICES**

Crops such as:	Application Rate:	When to Apply:
Basil Chives Cilantro Dill Mint (Scotch, Pepper & Spear) Oregano Parsley Thyme	0.5 - 1 oz./acre*	Best to apply in the early morning or late evening when humidity is at its highest. This assures maximum germination of AQ10. Repeat applications should be every 7 to 14 days. There should be a minimum of 2 sequential applications in order to maintain the population of the AQ10 organism.

\*Use higher rates when disease pressure is heavy and/or when dense canopies exist.

**V. COMMERCIAL, FLOWERS, GREENHOUSE & ORNAMENTAL PLANTS**

Crops such as:	Application Rate:	When to Apply:
Bare Root & Container Stock Bedding & Flowering Plants (Greenhouse & Outdoors) Field Grown Cut Flowers Fruit & Vegetable Transplants Nursery & Landscape Plants Potted Flowering Plants Roses Shade & Flowering Trees Woody Ornamentals	1 oz./100 gallon spray volume	Best to apply in the early morning or late evening when humidity is at its highest. This assures maximum germination of AQ10. Repeat applications should be every 7 to 14 days. There should be a minimum of 2 sequential applications in order to maintain the population of the AQ10 organism.

## **WARRANTY AND CONDITIONS OF SALE**

Ecogen warrants that this product conforms to the description on this label and is reasonably fit for the purposes stated on this label when used in accordance with the directions on this label under normal conditions of use.

**ECOGEN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

If this product is defective, Buyer's exclusive remedy shall be the replacement of the product, or if replacement is impracticable, refund of the purchase price. In no case will Ecogen be liable for incidental, consequential or special damages resulting from the handling, storage or use of this product.