



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division  
(7511C) 401 M St., S.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

69592-4

Date of Issuance:

JUN 20 2000

NOTICE OF PESTICIDE:

  X   Registration  
      Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional  
Time-Limited

Name of Pesticide Product:

Serenade Biofungicide  
Wettable Powder

Name and Address of Registrant (include ZIP Code):

AgraQuest, Inc.  
1530 Drew Avenue  
Davis, CA 95616-6320

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The submitted manufacturing process did not have sufficient quality control required for all fermentation batches. Therefore, the Agency is requiring, as a term and condition of the registration, the following quality control procedure. Batches that do not meet the criteria below must not be used for commercial production.

After fermentation and prior to further processing, each batch must be tested for the following microbial contaminants and have levels below those listed:

E. coli/ Coliform Bacteria	< 10 cfu/g
Salmonella	0 cfu per 25 g
Shigella	0 cfu per 25 g
Staphylococci	< 10 cfu/ g
Vibrio	0 cfu per 25 g
Yeast	< 10 cfu/g
Mold	< 10 cfu/g

Signature of Approving Official:

*JZB* see page 4

Date:

6-20-2000

3. This registration will automatically expire on midnight July 1, 2002. EPA will reevaluate this registration before July 1, 2002 to determine whether to convert the registration to a non-expiring registration.

4. This registration is registered under FIFRA § 3(c)(7)(C) because of the outstanding product chemistry and ecotoxicity data. Submit the following data within the specified time frames:

**TABLE 1: SUMMARY OF CONDITIONAL REGISTRATION DATA REQUIREMENTS**

<b>Product Chemistry Data Required</b>			
<b>Guideline</b>	<b>Title of Study</b>	<b>Data required</b>	<b>Date due</b>
<b>153-9</b> *885.2400	Storage Stability	Data for the 12 month storage stability of the end-use product has not been submitted. This data, along with clarification/justification of the plating technique description described in MRID# 4446517-03 and 446519-03 should be provided.	2 years from date of registration
<b>151-11</b> *885.1200	Manufacturing Process	<p>Additional data described in the December 12, 1999 review and March 8, 2000 letter are required to upgrade submitted process, MRID# 446519-04 to acceptable. This includes:</p> <p>1) A formal submission that clearly describes new quality control steps taken to assure the consistent CFU/g values and limit microbial impurities in the <b>Technical Powder</b>.</p> <p>2) A 5 batch analysis of <b>Technical Powder</b> produced from cell cultures with latest QC</p> <p>3) Raw data for the above mentioned 5 batch analyses.</p>	1 year from date of registration

Guideline	Title of Study	Data required	Date due
151-11 *885.1200	Manufacturing Process	<p>Additional data described in the December 12, 1999 review and March 8, 2000 letter must be provided to address deficiencies noted in MRID# 448923-01 and 448944-01. This includes:</p> <p>1) A formal submission that clearly describes new quality control steps taken to assure the consistent CFU/g values and limit microbial impurities in the <b>whole broth</b>.</p> <p>2) A description of the manufacturing process of the <b>Wettable Powder Basic</b> formula which must include an intermediate quality control step where CFU/g are measured before inerts are added to formula.</p> <p>3) A 5 batch analysis of the latest <b>Wettable Powder Basic</b> formula manufactured from cell cultures produced with the new quality control steps listed above.</p> <p>4) Raw data for the above mentioned 5 batch analyses.</p>	1 year from date of registration
<b>Ecological Effects Data Required</b>			
154-19 *885-4200	Freshwater Fish toxicity/pathogenicity	MRID 448848-01 - did not meet guideline requirements. A new study must be submitted.	1 year from date of registration
154-20 *885-4240	Freshwater aquatic invertebrate toxicity/pathogenicity	A 21 day Freshwater Aquatic Invertebrate Study must be performed. Attenuated and filter sterilized controls should be used in the test. Test lab should attempt to determine cause of death and whether pathogenicity involved.	1 year from date of registration
154-21 *885-4280	30 Day Toxicity/Pathogenicity in <i>Paleomonetes vulgaris</i> (shrimp)	Required due to report of disease in terrestrial amphipod crustacean associated with <i>B. subtilis</i> infection. Protocol must be submitted before initiating study.	1 year from date of registration
154-23 *885-4340	Non-target insect-parasitic Hymenoptera	QST Technical was shown to cause mortality to parasitic Hymenoptera. MRID 446519-14 is graded supplemental. Potential pathogenicity was not investigated. A new 30 day study must be submitted.	1 year from date of registration

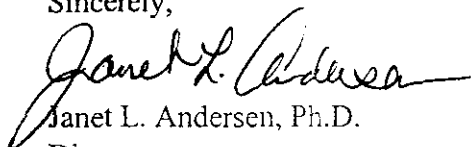
Guideline	Title of Study	Data required	Date due
154-24 *885-4380	Honey bee Dietary toxicity/pathogenicity	All test concentrations showed treatment related mortality. MRID 4456519-17 is supplemental due to the short test duration and the lack of a determination as to whether mortality was due to toxicity only or whether pathogenicity contributed. A 30 day whole hive study is necessary to satisfy this guideline requirement.	1 year from date of registration

\*885-xxxx = OPPTS Microbial Pesticide Test Guideline Numbers.

A stamped copy of the label is enclosed for your records.

5. Submit five(5) copies of the revised final printed labeling before you release the product for shipment.

Sincerely,



Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

# SERENADE

BIOFUNGICIDE



## WETTABLE POWDER

### ACTIVE INGREDIENT

QST 713 strain of dried *Bacillus subtilis* . . . . .10%

INERT INGREDIENT . . . . . 90%

Total . . . . .100%

Contains  $5 \times 10^9$  cfu/g

EPA Reg. No. 69592-4

EPA Est. No.: 1

① ② ③ ④  
069592-CA-001 5905-GA-01 066728-GA-002 37429-GA-2

Superscript corresponds to last digit of lot number stamped on container

U.S. Patent # 6,060,051 on QST 713 strain of *Bacillus subtilis*

Net weight: 24 lbs.

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

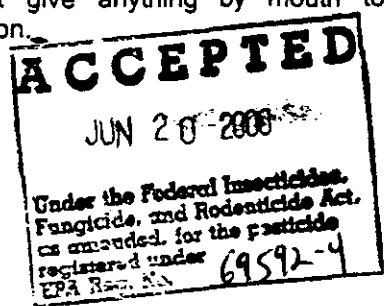
### FIRST AID

**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.

**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 ON SKIN:** Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a 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 by a poison control center or doctor. Do not give anything by mouth to an unconscious person.



### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Gloves
- Shoes plus socks
- Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, P, R, or HE filter.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATIONS

Users should:  
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

#### ENVIRONMENTAL HAZARDS

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. Do not apply when weather conditions favor drift or runoff from treated areas. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

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 emergencies such as leaks or spills, call 24-hour toll-free CHEMTREC hotline at 1.800.424.9300.

**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 box 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.

**STORAGE, DISPOSAL & SPILLS**

**STORAGE:** Store in a dry area inaccessible to children. Store in original containers only. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Do not contaminate water when disposing of equipment rinsate.

**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.

**GENERAL USE INFORMATION**

Serenade® Biofungicide WP is a broad spectrum, preventive product recommended for the control or suppression of many important plant diseases. Serenade Biofungicide WP may be applied as a foliar spray alone, in alternating spray programs or in tank mixes with other registered crop protection products. Serenade Biofungicide WP may be applied with spray equipment commonly used for making ground applications.

**INTEGRATED PEST MANAGEMENT (IPM)**

Integrate Serenade Biofungicide WP into an overall disease and pest management strategy whenever fungicide use is necessary. Follow practices known to reduce disease development. Consult local agricultural authorities for specific IPM strategies developed for your crop(s) and location.

**USE RATE DETERMINATION**

Carefully read and follow all label directions, use rates and restrictions. Serenade Biofungicide WP should be applied prior to or in the early stages of disease development. Use maximum label rates and shortened spray intervals for conditions conducive to threatening or rapid disease development. For proper application, determine the number of acres to be treated, the recommended label use rate and select appropriate gallonage to give good canopy penetration and coverage of plant parts to be protected. Prepare only the amount of spray solution required to treat the measured acreage. Accurate spray equipment calibration is essential prior to use.

**PREHARVEST INTERVAL**

Serenade Biofungicide WP can be applied up to and including the day of harvest.

**APPLICATION INSTRUCTIONS**

**GROUND:** Thorough coverage is essential for optimum disease control. To achieve good coverage use proper spray pressure, gallonage per acre, nozzles, nozzle spacing and ground speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration.

**AERIAL:** Not registered for use by aerial application.

**CHEMIGATION:** Not registered for use through irrigation systems.

**MIXING INSTRUCTIONS**

**MIXING:** Serenade Biofungicide WP is intended for dilution with water for spray application and may be used in spray equipment commonly used for making ground applications. Partially fill the spray tank with clean water and begin agitation. Add the specified amount of Serenade Biofungicide WP to the tank. Finish filling the tank to the desired volume to obtain the proper spray concentration. Maintain agitation continuously while spraying. Do not allow spray mixture to stand overnight or for prolonged periods. Maintain a spray solution pH between 4.5 and 8.5

**COMPATIBILITY:** Do not combine Serenade Biofungicide WP in spray tank with pesticides, surfactants or fertilizers unless prior experience has shown the combination physically compatible, effective and non-injurious under conditions of use. Do not use with penetrant-type adjuvants.

**CONDITIONS FOR SALE AND WARRANTY**

AgraQuest warrants to those persons lawfully acquiring title to this product that at the time of the first sale of this product by Seller that this product conformed to its description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal use conditions. Buyers and users of this product assume the risk of any use contrary to such directions.

EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in the Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.

Serenade® is a registered trademark of AgraQuest.

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**Recommended Application Rates for Selected Crops**  
(Serenade Biofungicide WP has a 0-Day PreHarvest Interval for all crops contained on this label)

Crops	Disease	Rate lb./acre	Use Recommendations
Cherry	Gray Mold <i>Botrytis cinerea</i>	6 - 8	Begin applications when environmental conditions and plant stage are conducive to threatening or rapid disease development. Continue at 7-day intervals.
	Powdery Mildew <i>Podosphaera clandestina</i>	6 - 8	Begin at popcorn and repeat every 7 days as needed.
Cucurbits	Powdery Mildew <i>Erysiphe</i> spp. <i>Sphaerotheca</i> spp.	6 - 8	Begin applications when environmental conditions and plant stage are conducive to threatening or rapid disease development. Continue sprays at 7-day intervals or as needed.
Grape	Gray Mold <i>Botrytis cinerea</i> Sour Rot	4 - 8	Make applications at bloom, before bunch closure, at veraison and preharvest, up to day of harvest if necessary. Apply in sufficient water to provide full coverage.
	Powdery Mildew <i>Uncinula necator</i>	4 - 8	Start application when new shoots are ½- to 1-½ inches long. Repeat when shoots are 3- to 5-inches long, when shoots are 8- to 10-inches long and then at 7- to 10-day intervals until disease conditions no longer exist. Use high rates and shorter intervals when conditions are conducive to threatening or rapid development. Apply in sufficient water to provide thorough coverage.
	Downy Mildew* <i>Plasmopara viticola</i>	5 - 8	For suppression apply at 10-inch shoot then at 7-day intervals until bunch closure (berry touch).
Leafy Vegetables (except Brassica)	Downy Mildew <i>Bremia lactucae</i> <i>Peronospora</i> spp.	3 - 6	Begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue sprays at 7-day intervals or as needed. Apply in sufficient water to ensure full coverage. Under moderate to severe disease pressure Serenade Biofungicide WP must be used in a program with other registered fungicides for downy mildew control.
Pepper*	Gray Mold <i>Botrytis cinerea</i>	4 - 8	Begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue sprays at 7-day intervals or as needed.
	Powdery Mildew <i>Oidiopsis taurica</i>	6 - 8	
Potato	Early Blight <i>Alternaria solani</i>	4 - 6	Begin applications when plants are 4- to 6-inches high. Repeat applications at 5- to 7-day intervals or as needed. Under moderate to severe disease pressure Serenade Biofungicide WP must be used in a program with other registered fungicides for late blight control. Use maximum label rates and shorter spray intervals under conditions conducive to rapid disease development.
	Late Blight - Suppression <i>Phytophthora infestans</i>	6	
Tomato*	Early Blight <i>Alternaria solani</i> Late Blight - Suppression <i>Phytophthora infestans</i>	4 - 8	Begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue applications on 5- to 7-day intervals or as needed. Under moderate to severe disease pressure Serenade Biofungicide WP must be used in a program with other registered fungicides for late blight control. Use maximum label rates under conditions conducive to rapid disease development.
	Powdery Mildew <i>Leveillula taurica</i>	4 - 8	Begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue applications on 5- to 7-day intervals or as needed. Use maximum label rates under conditions conducive to rapid disease development.
	Bacterial Spot - <i>Xanthomonas</i> spp.	4 - 8	For suppression begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue applications on 5- to 7-day intervals or as needed. Under moderate to severe disease pressure Serenade Biofungicide WP must be used in a program with other registered bactericides for bacterial spot control.
Walnut	Walnut Blight <i>Xanthomonas campestris</i>	8 - 10	Apply no later than pistillate bloom and repeat at 7- to 10-day intervals depending on orchard disease history and environmental conditions. Make applications in advance of rain for maximum protection.

\*Not for use in California