



69592-4

6/9/2004

Page 1 of 7

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number AgraQuest, Inc./69592-4	2. EPA Product Manager Dennis Szuhay	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Serenade Biofungicide WP	PM# Branch Chief, BPPD Microbials Div.	
5. Name and Address of Applicant (Include ZIP Code) AgraQuest, Inc. 1530 Drew Avenue Davis, CA 95616 <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. <b>NOTIFICATION</b> Date Reviewed: <u>6-9-04</u> Product Name <u>Serenade</u>	

## Section - II

Reviewed by: \_\_\_\_\_

<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 to master label for Serenade Biofungicide WP (EPA Reg. No. 69592-4) to revise the EPA Establishment Numbers, Patent Numbers, and Net contents/container sizes to match those for Serenade (EPA Reg. No. 69592-7). 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.

## Section - III

1. Material This Product Will Be Packaged In:					
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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Poly bag with liner</u>		
If "Yes" Unit Packaging wgt. _____ No. per container _____		If "Yes" Package wgt. _____ No. per container _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1,2,4,12,18,24,1000lb., 1.5,10 kg		5. Location of Label Directions <input checked="" type="checkbox"/> on label or in attached booklet	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>booklet in pouch on back of bag</u>			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Lesley Palmer Czocho		Title Manager, US Regulatory Affairs	
		Telephone No. (Include Area Code) (610) 558-8703	
<b>Certification</b> 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 (Stamp)
2. Signature <i>Lesley Palmer Czocho</i>		3. Title Manager, US Regulatory Affairs	
4. Typed Name Lesley Palmer Czocho		5. Date March 25, 2004	



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Innovative natural product  
solutions for pest management

March 25, 2004

Ms. Susanne Cerrelli, R.A.L.  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

**Re: Serenade® Biofungicide Wettable Powder (WP), EPA Reg. No. 69592-4:  
Notification of Amendment to Master Label to Revise EPA Establishment  
Numbers, Container Sizes, and Patent Reference Numbers**

Dear Ms. Cerrelli:

Per PR Notice 98-10, AgraQuest, Inc., is hereby notifying US EPA that we are amending the master label for our product, Serenade Biofungicide Wettable Powder (WP), EPA Reg. No. 69592-4, to revise the EPA establishment numbers, container sizes, and patent reference numbers to correspond to those for Serenade (EPA Reg. No. 69592-7).

A completed copy of EPA Application Form 8570-1 is provided in Attachment 1 to this cover letter.

A copy of the revised master label is provided in Attachment 2 in which the revisions are highlighted; all are on page 1. Five unmarked copies of the revised label are also included for your use. The revision date is now 3/25/04.

Except for these revisions, no other changes have been made to the master label, which was previously revised by Notification on 12/14/01 (copy provided in Attachment 3).

If you have any questions about this Notification, please contact me by telephone at (610) 558-8703, fax at (610) 558-8704, or email at [lczochor@agraquest.com](mailto:lczochor@agraquest.com).

Sincerely,

Lesley Palmer Czocho, Ph.D.  
Manager, U.S. Regulatory Affairs

cc: Dr. D. Edgecomb, Mr. R. L. Riggs, Mr. D. Glidewell, AgraQuest, Inc.

c:\Mydocs\Serenade\Serenade WP notification cover letter 032504

BPPD  
APR 7 2004  
sdh

# SERENADE

BIOFUNGICIDE



## WETTABLE POWDER

### ACTIVE INGREDIENT

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

INERT INGREDIENTS . . . . . 90%

Total . . . . . 100%

Contains a minimum of  $5 \times 10^9$  cfu/g

EPA Reg. No. 69592-4

EPA Est. No.:

EPA Reg. No. 69592-4

EPA Est. No.:

	1	2	3	4	5	
* [	69592-	67545-	75582-	37429-	69592-	]*
(	MEX-1	AZ-1	MEX-1	GA-2	CA-1	)

Superscript corresponds to last digit of lot number stamped on container

\* [ U.S. Patent Nos. 6,060,051, 6,103,228, 6,291,426, and 6,417,163 ] \*  
on QST 713 strain of *Bacillus subtilis*

\* [ Net weight: ] \*

**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.

#### 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 CHEMTREC hotline at 1.800.424.9300.

**NOTIFICATION**

Date Reviewed: 6-9-04Reviewed By: [Signature]

**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
Apple, Pear	Fire Blight <i>Erwinia amylovora</i>	6 – 8	For suppression begin applications at 1 – 5% bloom and repeat as necessary to protect open, untreated blossoms when conditions favoring disease development are likely to occur. Application of Serenade Biofungicide WP should be made prior to fire blight infection events. During periods of rapid bloom development and frequent infection periods, spray intervals of 3 – 7 days may be required. For apples and pears after petal fall, continue applications at 7-day intervals while environmental conditions favor rapid disease development. Apply in sufficient water to provide full coverage. Proper orchard cultural practices are essential to eliminate fire blight-infected tissue from the orchard to assure good performance of any crop protection product. Care must be taken to remove and destroy dead and diseased wood from the orchard prior to and during the growing season. Use of Serenade Biofungicide WP alone has not been shown to affect fruit finish. Use caution when selecting spray adjuvants. Select only those adjuvants which through prior experience do not affect fruit finish when combined with Serenade Biofungicide WP.
	Scab <i>Venturia</i> spp.	6 – 8	For suppression begin applications at green tip or when environmental conditions become favorable for primary scab development. Apply Serenade Biofungicide WP in tank mix with another fungicide registered for scab control on a 7- to 10-day schedule.
	Powdery Mildew <i>Podosphaera leucotricha</i>	6 – 8	Begin application at tight cluster, or sooner, if conditions are conducive to onset of disease development. Continue applications through the second cover spray at 7- to 10-day intervals. Additional sprays beyond second cover may be needed on susceptible varieties or when environmental conditions are conducive to threatening or rapid disease development. Use high label rate and shorter spray intervals when conditions are conducive to threatening or rapid disease development.
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 1/2- to 1-1/2- 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 disease 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).

7 8 7

Crops	Disease	Rate lb./acre	Use Recommendations
Hop*	Powdery Mildew <i>Sphaerotheca macularis</i>	6 – 10	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. As plants mature use higher label rates.
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.
Peanut*	Early Leaf Spot <i>Cercospora</i> spp.	4 – 8	Begin applications when environmental conditions are conducive to threatening or rapid disease development. Continue sprays at 7-day intervals or as needed. Peanut hay may be fed to livestock.
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