

85685-1

06/14/2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 14, 2010

Amy Plato Roberts
Regulatory Consultant
Technology Sciences Group Inc.
c/o FourStar Microbial Products LLC
712 Fifth Street, Suite A
Davis, CA 95616

RE: Product Name: FourStar SBG
EPA Reg. No: 85685-1
Application for Notification, dated April 12, 2010 to add optional label claim per
PR Notice 98-10.

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the letter submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Renae Whitaker (703) 347-0136 or email at whitaker.renae@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

NW/7511P/6/14/10

Please read instructions on reverse before completing form.

Form Approval JMB No. 2070-0060, Approval expires 2-28-95



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 85685-1	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FourStar SBG	PM# 92/Microbial Pesticides Br/BPPD	
5. Name and Address of Applicant (Include ZIP Code) FourStar Microbial Products LLC 3330 Noyac Road, Bldg. D-2 Sag Harbor, NY 11963 <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: Notification Accepted EPA Reg. No. _____ Product Name _____ Date: 6/14/10	

Section - II

Reviewer: Whitaker

<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 an optional label claim. See the attached cover letter dated April 12, 2010 for details.
 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 for 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product		<input 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 Amy Plato Roberts / aroberts@tsgusa.com	Title Regulatory Consultant	Telephone No. (Include Area Code) (530) 757-1432
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 Consultant	
4. Typed Name Amy Plato Roberts	5. Date April 12, 2010	



April 12, 2010

WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Sheryl Reilly
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs, EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: FourStar SBG; EPA Reg. No. 85685-1

NOTIFICATION to add an optional label claim

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Dr. Reilly:

With this letter you will find the following in support of a label notification to add an optional label claim per PRN 98-10 to the above referenced product:

- 1) NOTIFICATION form;
- 2) One (1) copy of the label with all changes highlighted in redline.

The optional label claim added (page 8 of the label) is as follows:

- "Single Brood Bti Sand Granule."

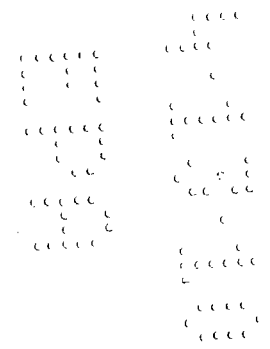
No other changes are made to the label at this time. If you have any questions or comments please let me know directly.

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Sincerely,

Amy Plato Roberts
Regulatory Consultant for FourStar Microbials LLC
Direct dial: (530) 757-1432; E-mail: aroberts@tsgusa.com



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MASTER LABEL

FourStar® SBG

Sublabel A: Commercial Use
Sublabel B: Residential Use
Optional Label Claims

[Alternate Brand Names: FourStar® Single Brood Granule, FourStar® Bti Sand Granule, FourStar® Bti Granule]

ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies *israelensis* Strain BMP 144 solids, spores and insecticidal toxins* 2.15%

OTHER INGREDIENTS: 97.85%

TOTAL: 100.00%

*Equivalent to 150 International Toxic Units (ITU/mg). Note: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

EPA Reg. No.: 85685-1
EPA Establishment No.: XXXXX-XX-XX

Manufactured for:
FourStar Microbial Products LLC
3330 Noyac Road, Bldg. D-2
Sag Harbor, NY 11963

U.S. Patent No. 5,484,600

Notification Accepted

Date: 6/14/10

Reviewer: Whitaker

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Sublabel A: Commercial Use

FourStar[®] SBG

[*Alternate Brand Names: FourStar[®] Single Brood Granule, FourStar[®] Bti Sand Granule, FourStar[®] Bti Granule*]

ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies *israelensis* Strain BMP 144 solids, spores and insecticidal toxins* 2.15%

OTHER INGREDIENTS: 97.85%

TOTAL: 100.00%

*Equivalent to 150 International Toxic Units (ITU/mg). Note: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FIRST AID	
If on skin	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: 85685-1
EPA Establishment No.: XXXXX-XX-XX

Manufactured by:
FourStar Microbial Products LLC
3330 Noyac Road, Bldg. D-2
Sag Harbor, NY 11963

Net Contents: XX

Lot No.: XX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION. Harmful if absorbed through skin or if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Mixers / loaders and applicators not in enclosed cabs or aircraft must wear a dust / mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters or rinsate. Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

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

APPLICATION DIRECTIONS

FourStar SBG is a highly selective single brood microbial insecticide effective against mosquito larvae in a variety of aquatic habitats. **FourStar SBG** releases effective levels of *Bacillus thuringiensis* subspecies *israelensis* to the water surface and throughout the water column. Apply uniformly according to rates listed below by conventional aerial or ground equipment as needed to maintain mosquito control. For permanently flooded habitats, a 7 to 14 day interval between applications should be employed.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential spray drift. The applicator and treatment coordinator are responsible for considering all these factors when making decisions.

APPLICATION SITES

FourStar SBG can be applied to areas that contain aquatic life, fish and plants as well as areas in contact with humans, animals, horses, livestock, pets, birds or wildlife. Examples of application sites include: flood water, standing water, roadside ditches, irrigation ditches, pastures, woodland pools, snow melt pools, tidal water, salt marshes, mangroves, estuaries, catch basins, storm drains, storm water collection areas, retention and detention impoundments, irrigation reservoirs, lakes and ponds, abandoned swimming pools, ornamental fountains and ponds, water gardens, animal drinking troughs, water holding receptacles, rice fields, standing water in agricultural fields.

APPLICATION RATES

To control mosquito larvae, apply 5 to 10 lbs of **FourStar SBG** per acre. Use 10 to 20 lbs of **FourStar SBG** per acre when late 3rd and early 4th instar larvae predominate, larval populations are high, water is heavily polluted and/or algae are abundant.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool [60-80°F (15-27°C)], dry place.

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).

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances.

NOTICE TO USER

To the extent consistent with applicable law, seller makes no warranty express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in strict accordance with label instructions.

U.S. Patent No. 5,484,600

Sublabel B: Residential Use

FourStar[®] SBG

[**Alternate Brand Names:** FourStar[®] Single Brood Granule, FourStar[®] Bti Sand Granule, FourStar[®] Bti Granule]

ACTIVE INGREDIENT:

Bacillus thuringiensis subspecies *israelensis* Strain BMP 144 solids, spores and insecticidal toxins* 2.15%

OTHER INGREDIENTS: 97.85%

TOTAL: 100.00%

*Equivalent to 150 International Toxic Units (ITU/mg). Note: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FIRST AID	
If on skin	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: 85685-1
EPA Establishment No.: XXXXX-XX-XX

Manufactured by:
FourStar Microbial Products LLC
3330 Noyac Road, Bldg. D-2
Sag Harbor, NY 11963

Net Contents: XX
Lot No.: XX

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION: Harmful if absorbed through skin or if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. As a general precaution when exposed to potentially high concentrations of living microbial products such as this, wear a dust particle mask when mixing or applying this product.

ENVIRONMENTAL HAZARDS: Do not apply to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

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

INTRODUCTION

FourStar SBG (is) (are) an easy and effective way to kill developing mosquitoes in standing water before they become biting adults.

DIRECTIONS

FourStar SBG is a highly selective microbial larvicide effective against mosquitoes in a variety of aquatic habitats. Apply **FourStar SBG** to containerized standing water or any private water sites except treated, finished drinking water reservoirs, drinking water receptacles or state waters. **FourStar SBG** can be applied to areas that contain aquatic life, fish and plants as well as areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife.

Apply to any site where standing water accumulates, such as:

- | | | |
|-----------------------|-------------------------|----------------|
| Bird baths | Plastic covers | Rain barrels |
| Fountains | Flower pots | Garbage cans |
| Water gardens | Planters | Buckets |
| Ponds | Urns | Wheelbarrows |
| Ornamental Ponds | Roof gutters | Standing water |
| Unused swimming pools | Old tires | Tree holes |
| Unused spas | Stock tanks | Flood water |
| Pool covers | Animal watering troughs | |

How to Apply:

Uniformly apply **FourStar SBG** in standing water areas where mosquitoes may develop. Use one (1) teaspoon in sites up to 60 square feet of water surface area. For larger areas, apply one (1) cup per 3000 square feet of surface area. Repeat treatments as needed at 7 to 14 day intervals to prevent adult mosquito emergence.

(optional chart)

APPLICATION RATES	
Amount of Product	Treatment Area
¼ tsp.	15 sq. ft.
½ tsp.	30 sq. ft.
1 tsp.	60 sq. ft.
½ tbsp.	90 sq. ft.
1 tbsp.	180 sq. ft.
¼ cup	750 sq. ft.
½ cup	1,500 sq. ft.
1 cup	3,000 sq. ft.
½ lb.	2178 sq. ft.
1 lb.	4356 sq. ft.

Do not use food utensils such as tablespoons or measuring cups for food purposes after use with insecticides.

- (Sprinkle 1 pound to cover 4356 square feet)
- (Sprinkle ½ pound to cover 2178 square feet)
- (Sprinkle 1 cup per 3000 square feet)
- (Sprinkle ¼ cup per 750 square feet)
- (Sprinkle 1 tablespoon per 180 square feet)
- (Sprinkle 1 teaspoon per 60 square feet)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place.

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 partially filled: Call your local solid waste agency or (800) 858-7378 (National Pesticide Information Center) for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE TO USER:

To the extent consistent with applicable law, seller makes no warranty express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in strict accordance with label instructions.

U.S. Patent No. 5,484,600

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OPTIONAL LABEL CLAIMS

- Biolarvicide.
- Biological Mosquito Control.
- (A) Biological Larvicide Granule(s).
- Mosquito Biolarvicide Granule.
- Single Brood Bti Sand Granule.
- Made with microbial active ingredients.
- Highly selective microbial larvicide.
- Concentrated Formula (treats over 8,700 square feet – *claim for Sublabel A only*)
- Controls mosquitoes.
- For use in fish habitats.
- A (highly selective) microbial insecticide effective against mosquitoes in a variety of habitats.
- Easy to use.
- Easy to apply granules.
- Quick, clean and simple to use.
- Nothing to mix or spray.
- Prevents the development of adult mosquitoes.
- Prevents immature mosquitoes from developing into adults.
- Prevents emergence of biting adult mosquitoes.
- Kills developing mosquito larvae.
- Stop 'em before they start!
- Fast acting.
- Made with Bti, a microbial active ingredient.
- "Smart" larvicide specifically targets mosquito larvae.
- Patented formula (technology)

- Controls mosquito larvae (in standing water)(within 24 hours)(in 24 hours).
- Quickly controls mosquito larvae in (within) 24 hours.
- (Use) (Apply) in standing water (where mosquitoes may breed); see label Directions for Use for specific use sites.
- (Use) (Apply) in containerized or private standing water (where mosquitoes may breed); see label Direction for Use for specific use sites.
- Kills mosquito larvae in (stagnant) standing water (before they are able to bite) (where they breed). Apply to standing (stagnant) water in your yard.
- For use in all water-holding receptacles (containers) where mosquitoes may breed including water gardens (and animal (horse) watering troughs); see label Directions for Use for specific use sites.
- When bacteria release by (product name) are ingested by mosquito larvae, mosquitoes are prevented from developing into biting adults.
- When ingested by mosquito larvae, (product name) prevents mosquitoes from becoming [developing into] breeding, biting adults.
- When ingested by mosquito larvae, (product name) prevents the development of adults.
- When bacteria is ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults.
- Kills mosquito larvae upon ingestion by destroying the cellular lining of the insect digestive tract.
- (Product name) is a highly selective microbial insecticide effective against mosquito larvae including those which may (can) transmit (carry) West Nile Virus.
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit (carry) West Nile Virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) before they become breeding, biting adults, including those which may (can) transmit (carry) West Nile Virus (and encephalitis) (and equine encephalitis).
- Kills (mosquitoes) (developing mosquitoes) (mosquito larvae) (before they hatch) including those which may (can) transmit (West Nile Virus and) heartworm disease (to dogs and cats).
- Dual Action Release (logo)