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

MAR 1 4 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Amy Plato Roberts Technology Sciences Group Inc. Regulatory Consultant for Four Star Microbials, LLC 712 Fifth Street, Suite A Davis, CA 95616

Re: March 2010 Amendment to Remove the Expiration Date and Change the Active Ingredient Name to *Bacillus sphaericus* 2362, serotype H5a5b, strain AML614, June 2009 Alternate Formulation Amendment, and Updated Label and Confidential Statements of Formula Dated March 10, 2011 EPA Registration No. 83362-3

Dear Ms. Roberts:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable and subject to the following comments.

1) The expiration date for the subject product has been removed so that it no longer automatically expires.

2) Your revised basic Confidential Statement of Formula and your Alternate Formulation 1 (both dated March 10, 2011) are acceptable and have been placed in your product's file.

Submit five (5) copies of your final printed labeling before you release the amended product for shipment. A stamped copy of the label is enclosed for your records.

Sincerely,

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

Enclosure

FourStar™ Briquets

Alternate Brand Names:

FourStar™ Microbial Briquets FourStar™ Briquets Sustained Release 180 Day Microbial Briquets FourStar™ Briquets Sustained Release 90 Day Microbial Briquets

FourStar™ Briquets Sustained Release 45 Day Microbial Briquets

Sublabel A:Commercial Use – small/medium/large briquetSublabel B:Residential Use – small/medium/large briquetOptional Label Claims

ACTIVE INGREDIENT:

* Bacillus sphaericus 2362, Serotype H5a5b, strain AML614	6.00%
**Bacillus thuringiensis subspecies israelensis, strain BMP 144	1.00%
fermentation solids, spores and insecticidal toxins	
OTHER INGREDIENTS:	<u>93.00%</u>
TOTAL:	100.00%

Equivalent to *60 Bs ITU/mg and **70 ITU/mg respectively. The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

EPA Reg. No.: 83362-3 EPA Establishment No.: XXXXX-XX-XX

Manufactured for:

FourStar Microbials LLC 3330 Noyac Road Sag Harbor, NY 11963

> ACCEPTED with COMMENTS In EPA Letter Dated MAR 14 2011

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

Sublabel A: Commercial Use – small/medium/large briquet

FourStar Briquets

Alternate Brand Names:

FourStar™ Microbial Briquets

FourStar[™] Briquets Sustained Release 180 Day Microbial Briquets FourStar[™] Briquets Sustained Release 90 Day Microbial Briquets FourStar[™] Briquets Sustained Release 45 Day Microbial Briquets

ACTIVE INGREDIENT:

* Bacillus sphaericus 2362, Serotype H5a5b, strain AML614	6.00%
**Bacillus thuringiensis subspecies israelensis, strain BMP 144	1.00%
fermentation solids, spores and insecticidal toxins	
OTHER INGREDIENTS:	
TOTAL:	

Equivalent to *60 Bs ITU/mg and ** 70 ITU/mg respectively. 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		
lf inhaled	 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 poison control center or doctor for treatment advice. 	
lf on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice. 	
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, and then continue rinsing eyes. Call poison control center or doctor for treatment advice. 	
	duct container or label with you when calling a poison control center or doctor, or going for ou may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: 83362-3 EPA Establishment No.: XXXXX-XX-XX

Manufactured for: FourStar Microbials LLC 3330 Noyac Road Sag Harbor, NY 11963

Always read the label before using this product. For product information, call 1-877-264-6655 or visit our web site: <u>www.fourstarmicrobials.com</u>

Net Contents: (10 g = small briquet) (15 g = medium briquet) (30 g = large briquet) (weight varies with hydration +/-15%)

Lot No.: XXXXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION: Harmful if inhaled. Causes moderate eye irritation. 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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.

APPLICATION DIRECTIONS

FourStar Briquets are a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [90 days (for medium briquet)] [180 days (for large briquet)] or more. **FourStar Briquets** release effective levels of *Bacillus sphaericus* and *Bacillus thuringiensis* subspecies *israelensis* to the water surface over time as the briquet dissolves.

APPLICATION SITES

FourStar Briquets 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. Examples of application sites include, but are not limited to: storm drains, catch basins, underground drainage systems, storm water retention areas, retention ponds, abandoned swimming pools, ornamental fountains and ponds, fish ponds, water gardens, animal drinking troughs, standing water, water holding receptacles, man-made and natural sites where mosquitoes may develop.

APPLICATION RATES

For control of mosquito larvae, place one (1) briquet in sites up to 100 square feet of surface area. For large sites, apply 1 additional briquet for each additional 100 square feet of water surface, regardless of water depth. When mosquito populations are high, water is heavily polluted, and/or algae is abundant, double the above application rate.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place.

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

Container Disposal: Nonrefillable container. Do not reuse or refill empty carton or packaging material. Offer for recycling, if available or crush and discard carton in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

NOTICE TO USER - 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. User assumes all risks of use, storage or handling not in strict accordance with label instructions.

FourStar Briquets; EPA Reg. No. 83362-3 Updated ingredient statement MASTER LABEL - Version (11) dated March 10, 2011 Page 3 of 9

Sublabel B: Residential Use – small/medium/large briquet

FourStar Briquets

<u>Alternate Brand Names</u>: FourStar™ Microbial Briguets

FourStar™ Briquets Sustained Release 180 Day Microbial Briquets FourStar™ Briquets Sustained Release 90 Day Microbial Briquets FourStar™ Briquets Sustained Release 45 Day Microbial Briquets

ACTIVE INGREDIENT:

* Bacillus sphaericus 2362, Serotype H5a5b, strain AML614	6.00%
**Bacillus thuringiensis subspecies israelensis, strain BMP 144	1.00%
fermentation solids, spores and insecticidal toxins	
OTHER INGREDIENTS:	
TOTAL:	100.00%

Equivalent to *60 Bs ITU/mg and **70 ITU/mg respectively. 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		
lf inhaled	 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 poison control center or doctor for treatment advice. 	
lf on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice. 	
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, and then continue rinsing eyes. Call poison control center or doctor for treatment advice. 	
	uct container or label with you when calling a poison control center or doctor, or going for ou may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: 83362-3 EPA Establishment No.: XXXXX-XX-XX

Manufactured for:

FourStar Microbials 3330 Noyac Road Sag Harbor, NY 11963

Always read the label before using this product. For product information, call 1-877-264-6655 or visit our web site: <u>www.fourstarmicrobials.com</u>

Net Contents: (10 g = small briquet) (15 g = medium briquet) (30 g = large briquet) (weight varies with hydration +/-15%)

Lot No.: XXXXX

FourStar Briquets; EPA Reg. No. 83362-3 Updated ingredient statement MASTER LABEL - Version (11) dated March 10, 2011 Page 4 of 9

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled. Causes moderate eye irritation. 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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 Briquets are an easy and effective way to kill developing mosquitoes in standing water before they become biting adults. With just one bite, adult mosquitoes may transmit West Nile virus and other viruses that can cause encephalitis in both people and animals. They may also transmit heartworms to dogs and cats. **FourStar Briquets** slowly release bacteria into the water to prevent adult mosquito development for up to [45 days (for small briquet)] [90 days (for medium briquet)] [180 days (for large briquet)]. Mosquito larvae exposed to treated water will die before they reach adulthood.

GENERAL DIRECTIONS

FourStar Briquets are a highly selective biological larvicide effective against mosquitoes in a variety of habitats. Apply **FourStar Briquets** to containerized standing water or any private water sites <u>except</u> treated, finished drinking water reservoirs, drinking water receptacles or state waters. **FourStar Briquets** 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.

Examples of application sites include, but are not limited to:

Bird baths	Plastic covers
Fountains	Flower pots
Water gardens	Planters
Fish ponds	Urns
Ornamental Ponds	Roof gutters
Unused swimming pools	Old tires
Unused spas	Stock tanks
Pool covers	Animal watering troughs

Rain barrels Garbage cans Buckets Wheelbarrows Standing water Flood water Natural depressions Man-made depressions

How to Apply:

Simply place **FourStar Briquets** in standing water where mosquitoes may develop. Use one (1) briquet in sites up to 100 square feet (10 ft X 10 ft) of water surface area. For larger sites, apply 1 additional briquet for each additional 100 square feet of surface area, regardless of water depth. Repeat treatments as needed to prevent adult mosquito emergence.

STORAGE AND DISPOSAL

70411)

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

Storage: Store in a cool, dry place.

If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash and 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:

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. User assumes all risks of use, storage or handling not in strict accordance with label instructions.

OPTIONAL LABEL CLAIMS

- Biolarvicide.
- Biological Mosquito Control.
- (A) Biological Larvicide Briquet(s).
- Mosquito Biolarvicide Briquet.
- Made with microbial active ingredients.
- Highly selective microbial larvicide.
- A (highly selective) microbial insecticide effective against mosquitoes in a variety of habitats.
- Easy to use.
- Easy to apply briquets.
- 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.
- (Use) (Apply) in standing water (where mosquitoes may breed); see label for specific use sites.
- (Use) (Apply) in containerized or private standing water (where mosquitoes may breed); see label 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 for specific use sites.
- Effective year-round when mosquito larvae are present.
- Sustained release biological larvicide for long term control of mosquito larvae.

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SOFIU

- Controlled (Sustained) Release (45 day (for small briquet) (90 day (for medium briquet)) (180 day (for large briquet)) Microbial (Biological) Briquets
- Biological Mosquito Larvicide provides (45 day (for small briquet) (90 day (for medium briquet)) (180 day (for large briquet)) control.
- (45 day (for small briquet) (90 day (for medium briquet)) (180 day (for large briquet)) control.
- Effective [controls] for up to (45 day (for small briquet) (90 day (for medium briquet)) (180 days (for large briquet)).
- A Sustained Release (45 day (for small briquet) (90 day (for medium briquet)) (180-Day (for large briquet)) Mosquito Larvicide Briquet.
- Each briquet treats up to 100 square feet.
- Controls mosquitoes.
- Controls mosquito larvae (in standing water).
- One application controls all season. (for large briquet)
- Season Long Control.
- For use in fish habitats.
- 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 of bacteria.
- 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).

FourStar Briquets; EPA Reg. No. 83362-3 Updated ingredient statement MASTER LABEL - Version (11) dated March 10, 2011 Page 8 of 9

- 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).

- Patent Pending.

- Dual Action Release (Logo).