# PLEASE NOTE

This image contains more than one label approved for this product on this date.

69504-2

9-20-2006

Please read instructions of	reverse before compl	eting form.	Form A	Approved.	OMB No. 20	70-006	O, Approvel expires 2-28-9		
<b>\$EPA</b>	United States  Environmental Protection Agen  Washington, DC 20460				Registrat Amendm Other		OPP Identifier Number		
		Application	ion for Pesticide - Section I						
1. Company/Product Numb 69504-2	Per		2. EPA Product M Dennis Szuhay	•		3. Pr	oposed Classification		
4. Company/Product (Name) Meridian-02			90/Microbial Pesticides Br/BPPD						
5. Name and Address of A	pplicant <i>(Include ZIP C</i>	o <b>d</b> e)	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)						
Meridian LLC 17560 SW Woodhave Sherwood, OR 97140			(b)(i), my product is similar o <b>NGTHAGAN</b> ion and labeling to:  EPA Reg. No						
Check if th	is is a new address		Product Name	Re Re	viewed	By:	AIC		
			Section - II						
Amendment - Explai	Sponse to Agency letter	r dated	Agency I	ted labels in atter dated " Application xplain below	on.	to			
The purpose of this notification is to add an alternate brand name to the product's registration per PR Notice 98-10. This submission is not subject to PRIA. 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 of 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 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.						have been made to the make any false statement to			
	<u></u>		Section - III						
1. Material This Product W	7		The same of the Barbarian		T				
Child-Resistant Peckaging Yes	Unit Packaging		Water Soluble Packaging Yes	2	. Type of Co	Metal			
√ No	√ No		√ No			Plastic Glass			
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container		1 1 0		Paper Other (Specify) corregated box			
3. Location of Net Contents	Information	4. Size(s) Ret	tail Container	5. Locati	ion of Label	Direction	ns		
✓ Label	Container	12.5 g	g briquet or 44 g briquet						
6. Manner in Which Label is Affixed to Product    July   Lithogra   Paper gl   Stencile			graph Other						
			Section - IV						
1. Contact Point (Complete	e items directly below t	for identificatio	n of individual to be contacted	d, if necess	ary, to proc	ess this	application.)		
······			Title Regulatory Consultant			Telephone No. (Include Area Code) (202) 828-8964			
Certificant Continue of the Co			all attachments thereto are tr	ue, accurat fine or imp	te and como prisonment o	iÐ(H.	6. Date Application Received (Stamped)		
2. Signature Lathe Box - for			3. Title Regulatory Consultant						
4. Typed Name Amy Plato Roberts			5. Date March 28, 200	March 28, 2006					





March 29, 2006

#### WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Dennis Szuhay

Chief, Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511C)

Office of Pesticide Programs, EPA

1801 South Bell Street

Arlington, VA 22202

RE: Meridian LLC: Meridian-02 (EPA Reg. No. 69504-2)

Notification to add alternate brand name per PR Notice 98-10

Technology Sciences Group Inc., on behalf of Meridian LLC, hereby submits the enclosed notification to add an alternate brand name to the above referenced

product. Enclosed you will find the following in support of this notification:

#### SACRAMENTO

Dear Mr. Szuhay:

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Notification application form;

- 2) Redline version of revised labeling (1 copy); and
- Three clean copies of the revised product labeling. 3)

Please do not hesitate to contact me directly with any questions.

Sincerely.

1)

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Amy Plato Roberts

Regulatory Consultant for Meridian LLC

Direct dial: (202) 828-8964; E-mail: aroberts@tsgusa.com

# **MERIDIAN - 02**

[Alternate Brand Name: FourStar]

Sublabel A: Commercial Use – small/large briquet

Sublabel B: Commercial Use – small/large briquet (catch basin)

Sublabel C: Residential Use – small/large briquet

**Optional Label Claims** 

#### **ACTIVE INGREDIENT:**

\* Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140 NOTIFICATION

Date Reviewed: 9/20

Reviewed By: \_

Sublabel A:

Commercial Use - small/large briquet

## **MERIDIAN - 02**

[Alternate Brand Name: FourStar]

#### **ACTIVE INGREDIENT:**

Bacillus thuringiensis subspecies israelensis Strain BMP 144 solids, spores and OTHER INGREDIENTS: 93.00% TOTAL: 100.00%

#### KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

	FIRST AID
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
	ct container or label with you when calling a poison control center or doctor, or ent. You may also contact 1-800-222-1222 for emergency medical treatment

information.

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. Note: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

#### **DIRECTIONS FOR USE**

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

**MERIDIAN-02** is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. **MERIDIAN-02** briquets release effective levels of *Bacillus thuringiensis* subspecies *israelensis* (Bti) to the water surface over time as the briquet dissolves.

**MERIDIAN-02** can be applied to areas that contain aquatic life, fish and plants. **MERIDIAN-02** can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply **MERIDIAN-02** to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: Flood water, roadside ditches, irrigation ditches, rice fields, pastures, woodland pools, snowmelt pools, tidal water, salt marshes, storm drains, catch basins, storm water retention areas, detention ponds, lakes, golf course ponds, irrigation ponds, ornamental zoo ponds, abandoned swimming pools, ornamental ponds, fish ponds, water gardens, greenhouses, nurseries, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply **MERIDIAN-02** to known mosquito breeding sites before, or at any time during the mosquito season. Apply **MERIDIAN-02** to known breeding sites when the sites are dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. **MERIDIAN-02** briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

#### **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 are 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:** Do not reuse empty carton or packaging material. Perforate 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

Sublabel B: Commercial Use – small/large briquet (catch basin)

## **MERIDIAN - 02**

## [Alternate Brand Name: FourStar]

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:** 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 or using tobacco. Remove and wash contaminated clothing before reuse.

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

FIRST AID					
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>				
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>				
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>				
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.					

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

#### **DIRECTIONS FOR USE**

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

**MERIDIAN-02** is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. **MERIDIAN-02** briquets release effective levels of *Bacillus thuringiensis* subspecies *israelensis* (Bti) to the water surface over time as the briquet dissolves.

**MERIDIAN-02** can be applied to areas that contain aquatic life, fish and plants. **MERIDIAN-02** can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply **MERIDIAN-02** to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: storm drains, catch basins, underground drainage systems, storm water retention areas, detention ponds, abandoned swimming pools, ornamental fountains and ponds, fish ponds, water gardens, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply MERIDIAN-02 to known mosquito breeding sites before, or at any time during the mosquito season. Apply MERIDIAN-02 to known breeding sites when the sites are dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. MERIDIAN-02 briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

#### **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 are 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:** Do not reuse empty carton or packaging material. Perforate 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)



Sublabel C:

information.

Residential Use - small/large briquet

## **MERIDIAN - 02**

[Alternate Brand Name: FourStar]

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

	FIRST AID
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
	oct container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment

#### **DIRECTIONS FOR USE**

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

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.



#### INTRODUCTION

Mosquitoes are both a nuisance and a serious health threat to people and pets. The recent introduction of mosquito borne West Nile Virus into the United States has made mosquito control more important than ever. In addition to encephalitis, mosquitoes can transmit malaria, dengue, yellow fever and heartworm disease to dogs and cats. **MERIDIAN-02** prevents mosquitoes from completing development into biting adults.

#### **GENERAL DIRECTIONS**

Use **MERIDIAN-02** to treat mosquito breeding sites in early spring, or at any time during the mosquito season. Apply **MERIDIAN-02** to nearby low areas that hold rain or runoff water and produce mosquitoes, even when the sites are dry. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)]. Repeat treatments as needed to prevent adult mosquito emergence. Alternate wetting and drying will not reduce briquet effectiveness, and may extend the control period. **MERIDIAN-02** briquets perform optimally under shaded conditions.

MERIDIAN-02 is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply MERIDIAN-02 to containerized standing water or any private water sites except treated, finished drinking water reservoirs, drinking water receptacles or state waters. MERIDIAN-02 can be applied to areas that contain aquatic life, fish and plants. MERIDIAN-02 can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife.

#### Treatment Areas (For Use In):

Buckets Bird baths Drains Statuary Stock tanks Plastic covers Pool covers Plant travs Old tires Abandoned swimming pools **Planters** Flower pots Tree holes Unused swimming pools or spas Garbage cans Wheelbarrows Other water holding receptacles Water gardens Ornamental fountains Standing water Hollow trees **Fountains** Animal watering troughs Flood water Urns Ponds Roof gutters

Rain barrels Lagoons
Roof gutters Fish ponds

Any location where water collects and remains for periods of time.

#### How to Apply:

To control mosquito larvae, place one (1) briquet in sites up to 100 square feet (10 ft X 10 ft) of surface area. For large sites, apply 1 additional briquet for each additional 100 square feet of surface area, regardless of water depth.

#### STORAGE AND DISPOSAL

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

**Storage:** Store in a cool, dry place.

If empty: Do not reuse 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.: XXXXX-XX-XX** 

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

### **OPTIONAL LABEL CLAIMS**

- Biolarvicide.
- Biological Mosquito Control.
- A Biological Larvicide Briquet.
- Mosquito Biolarvicide Briquet.
- Made with Bti, a microbial active ingredient.
- Concentrated Formula.
- 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.
- Fast acting.
- Prevents the development of adult mosquitoes.
- Prevents immature mosquitoes from developing into adults.
- Prevents emergence of breeding, biting adult mosquitoes.
- Prevents the development of mosquito larvae.
- 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.
- Biological Mosquito Larvicide with (45 day (for small briquette)) (150 day (for large briquette)) control.
- (45 day (for small briquette)) (150 day (for large briquette)) control.
- Effective [controls] for up to (45 days (for small briquette)) (150 days (for large briquette)) .
- A Sustained Release (45-Day (for small briquette)) (150-Day (for large briquette)) Bti Mosquito Larvicide Briquet.
- Each briquet treats up to 100 square feet.
- Controls mosquitoes.
- Controls mosquito larvae (in standing water) (within 48 hours) (in 48 hours).
- Quickly controls mosquito larvae in (within) 48 hours.
- One application controls all season.
- Season Long Control.
- For use in fish habitats.
- 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 ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults.
- Kills mosquito larvae upon ingestion of Bt toxins.
- 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).

	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).
	<b>MERIDIAN-02</b> ; EPA Reg. No. 69504-2 MASTER LABEL <u>Notification Redline</u> Version ( <u>6</u> ) dated March 28, 2006

69504-2

9-20-2006

1/15

Please read instructions on	reverse before compl	eting form.		Form Approve	d. OMB No	. 2070-006	30. Approval expires 2-28-9	
<b>\$EPA</b>	Environmenta	United States 31 Protect nington, DC 20	ion Agency	✓	Registi Amend Other		OPP Identifier Number	
		Applicati	ion for Pestic	de - Sectior	)		<del></del>	
1. Company/Product Number 69504-2	<b>3</b> f			Product Menager is Szuhay		3. P	roposed Classification	
4. Company/Product (Nama Meridian - 02	)		<b>PM#</b> 90/Mi	D L				
5. Name and Address of Ap	plicant <i>(Include ZIP C</i>	ode)	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)					
Meridian LLC 17560 SW Woodhav Sherwood, OR 97140 Check if this			(b)(i), my product is siNGTdFiGATION position and labeling to: EPA Reg. No ate Reviewed: 9/20/06  Product Name eviewed By:					
		<del> </del>	Section -					
Amendment - Explain Resubmission in rest  Notification - Explain	conse to Agency letter	r dated		Finel printed lab- Agency letter de "Me Too" Applie Other - Explain b	ated cation.	se to		
This is a notification to add s This notification is consistent labeling of the Confidential s EPA. I further understand th	Explanation: Use additional page(s) if necessary. (For section I and Section II.)  This is a notification to add several alternate brand names to this product per PR Notice 98-10 and is not subject to PRIA.  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 of 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.						make any false statement to	
			Section - I	<u> </u>				
1. Material This Product Wil	Be Packaged In:							
Child-Resistant Packaging	Unit Packaging		Water Soluble P	ackaging	2. Type of	f Container		
Yes	Yes		Yes		Metal Plastic			
∐ No	No		No			Glass		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per . container	If "Yes" Package wgt				Specify)	
3. Location of Net Contents	Information	4. Size(s) Re	teil Container	5. Le	ocation of La	bel Directio	ens	
rri	ontainer							
6. Manner in Which Label is Affixed to Product Lithogra			ograph Other or glued					
Section - IV								
1. Contact Point (Complete	items directly below f	or identification	on of individual to be	contacted, if nec	essary, to pr	ocess this	application.)	
			1 -			Telephone (202) 828	No. (Include Area Code) -8964	
Certifica I certify that the statements I have made on this form and I acknowledge that any knowlingly false or misleading sta both under applicable law.			nd all attachments thereto are true, accurate and complete.				6. Date Application Received (Stamped)	
2. Signaturo Latha 12. Brownson Laz			3. Title  Regulatory Consultant to Meridian LLC					
4. Typed Name	U		5. Date				Ì	
Amy Plato Roberts			April 12, 2006					



April 12, 2006

#### **WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Dennis Szuhay

Chief, Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511C)

Office of Pesticide Programs, EPA

1801 South Bell Street Arlington, VA 22202

RE: Meridian-02 (EPA Reg. No. 69504-2)

Notification to add alternate brand names per PR Notice 98-10

**SACRAMENTO** 

Dear Mr. Szuhay:

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Doar Ivii. Ozuriay.

Technology Sciences Group Inc., on behalf of Meridian LLC, is submitting the enclosed notification to add five alternate brand names to the above referenced product.

You will find the following in support of this notification:

1) Application form;

2) One (1) copy of the redline label; and

3) Three (3) copies of the product label with the changes incorporated.

Please do not hesitate to contact me directly with any questions.

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 Meridian LLC

Gleather R. Byon to

Direct dial: (202) 828-8964; E-mail: aroberts@tsgusa.com

cc: Dave Sjogren, Meridian LLC

# **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

Sublabel A: Commercial Use – small/large briquet

Sublabel B: Commercial Use – small/large briquet (catch basin)

Sublabel C: Residential Use – small/large briquet

**Optional Label Claims** 

#### **ACTIVE INGREDIENT:**

\* Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140 NOTIFICATION

Date Reviewed: 9/20/06

Reviewed By: \_<



Sublabel A: Commercial Use – small/large briquet

## **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:** 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

	FIRST AID
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
	ict container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment

#### **DIRECTIONS FOR USE**

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

**MERIDIAN-02** is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. **MERIDIAN-02** briquets release effective levels of *Bacillus thuringiensis* subspecies *israelensis* (Bti) to the water surface over time as the briquet dissolves.

**MERIDIAN-02** can be applied to areas that contain aquatic life, fish and plants. **MERIDIAN-02** can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply **MERIDIAN-02** to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: Flood water, roadside ditches, irrigation ditches, rice fields, pastures, woodland pools, snowmelt pools, tidal water, salt marshes, storm drains, catch basins, storm water retention areas, detention ponds, lakes, golf course ponds, irrigation ponds, ornamental zoo ponds, abandoned swimming pools, ornamental ponds, fish ponds, water gardens, greenhouses, nurseries, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply **MERIDIAN-02** to known mosquito breeding sites before, or at any time during the mosquito season. Apply **MERIDIAN-02** to known breeding sites when the sites are dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. **MERIDIAN-02** briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

#### **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 are 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:** Do not reuse empty carton or packaging material. Perforate 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

Sublabel B:

Commercial Use - small/large briquet (catch basin)

## **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

Bacillus thuringiensis subspecies israelensis Strain BMP	144 solids, spores and
insecticidal toxins*	7.00%
OTHER INGREDIENTS:	93.00%
TOTAL:	

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: 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 or using tobacco. Remove and wash contaminated clothing before reuse.

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



	FIRST AID
If 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.
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
	oct container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment

#### **DIRECTIONS FOR USE**

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

**MERIDIAN-02** is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. **MERIDIAN-02** briquets release effective levels of *Bacillus thuringiensis* subspecies *israelensis* (Bti) to the water surface over time as the briquet dissolves.

**MERIDIAN-02** can be applied to areas that contain aquatic life, fish and plants. **MERIDIAN-02** can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply **MERIDIAN-02** to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: storm drains, catch basins, underground drainage systems, storm water retention areas, detention ponds, abandoned swimming pools, ornamental fountains and ponds, fish ponds, water gardens, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply MERIDIAN-02 to known mosquito breeding sites before, or at any time during the mosquito season. Apply MERIDIAN-02 to known breeding sites when the sites are dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. MERIDIAN-02 briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

#### **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 are 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:** Do not reuse empty carton or packaging material. Perforate 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.:** XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

Sublabel C: Residential Use – small/large briquet

## **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

	FIRST AID
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>
	act container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

#### **DIRECTIONS FOR USE**

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

#### INTRODUCTION

Mosquitoes are both a nuisance and a serious health threat to people and pets. The recent introduction of mosquito borne West Nile Virus into the United States has made mosquito control more important than ever. In addition to encephalitis, mosquitoes can transmit malaria, dengue, yellow fever and heartworm disease to dogs and cats. **MERIDIAN-02** prevents mosquitoes from completing development into biting adults.

#### **GENERAL DIRECTIONS**

Use **MERIDIAN-02** to treat mosquito breeding sites in early spring, or at any time during the mosquito season. Apply **MERIDIAN-02** to nearby low areas that hold rain or runoff water and produce mosquitoes, even when the sites are dry. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)]. Repeat treatments as needed to prevent adult mosquito emergence. Alternate wetting and drying will not reduce briquet effectiveness, and may extend the control period. **MERIDIAN-02** briquets perform optimally under shaded conditions.

MERIDIAN-02 is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply MERIDIAN-02 to containerized standing water or any private water sites except treated, finished drinking water reservoirs, drinking water receptacles or state waters. MERIDIAN-02 can be applied to areas that contain aquatic life, fish and plants. MERIDIAN-02 can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife.

#### Treatment Areas (For Use In):

Bird baths Drains **Buckets** Statuary Stock tanks Plastic covers Old tires Pool covers Plant travs Flower pots Abandoned swimming pools Planters Tree holes Unused swimming pools or spas Garbage cans Wheelbarrows Water gardens Other water holding receptacles Ornamental fountains Standing water Hollow trees **Fountains** Animal watering troughs Flood water Ponds Roof gutters Hrns

Rain barrels Lagoons
Roof gutters Fish ponds

Any location where water collects and remains for periods of time.

#### How to Apply:

To control mosquito larvae, place one (1) briquet in sites up to 100 square feet (10 ft X 10 ft) of surface area. For large sites, apply 1 additional briquet for each additional 100 square feet of surface area, regardless of water depth.

#### STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place.

If empty: Do not reuse 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.

**EPA Reg. No.:** 69504-2

**EPA Establishment No.: XXXXX-XX-XX** 

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

## **OPTIONAL LABEL CLAIMS**

- Biolarvicide.
- Biological Mosquito Control.
- A Biological Larvicide Briquet.
- Mosquito Biolarvicide Briquet.
- Made with Bti, a microbial active ingredient.
- Concentrated Formula.
- 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.
- Fast acting.
- Prevents the development of adult mosquitoes.
- Prevents immature mosquitoes from developing into adults.
- Prevents emergence of breeding, biting adult mosquitoes.
- Prevents the development of mosquito larvae.
- 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.
- Biological Mosquito Larvicide with (45 day (for small briquette)) (150 day (for large briquette)) control.
- (45 day (for small briquette)) (150 day (for large briquette)) control.
- Effective [controls] for up to (45 days (for small briquette)) (150 days (for large briquette)).
- A Sustained Release (45-Day (for small briquette)) (150-Day (for large briquette)) Bti Mosquito Larvicide Briquet.
- Each briquet treats up to 100 square feet.
- Controls mosquitoes.
- Controls mosquito larvae (in standing water) (within 48 hours) (in 48 hours).
- Quickly controls mosquito larvae in (within) 48 hours.
- One application controls all season.
- Season Long Control.
- For use in fish habitats.
- 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 ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults.
- Kills mosquito larvae upon ingestion of Bt toxins.
- 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).

# NEXT

# LABEL

69504-2

9-20-2006

1/15

Please read instructions on reven	se <u>before comple</u>	ting form.			Form Appr	roved.	OMB N	. 20	70-0060	D. Approvel expires 2-28-9
SEPA En	vironmental	Inited States  I Protection  Ington, DC 204	_	y			Regist Amen Other			OPP Identifier Number
		Application	n for Pes	sticide	- Secti	on			•	
1. Company/Product Number 69504-2			į.	2. EPA Product Manager Dennis Szuhay  3. Proposed Classification None Restricted					posed Classification	
4. Company/Product (Name) Meridian - 02				PM# 90/Microbial Pesticides Br/BPPD						
5. Name and Address of Applicant (Include ZIP Code)  Meridian LLC  17560 SW Woodhaven Drive  Sherwood, OR 97140  Check if this is a new address			(b) to E	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar product in composition and labeling to:  EPA Reg. No. Date Reviewed: 9/20/06  Product Name Reviewed By:						
			Section	<u>n - II</u>						
Amendment - Explain belo	to Agency letter	dated	<del></del>		al printed ency lette le Too" Ap her - Expla	r date oplica	id tion.	nse to		
This is a notification to add non-FII This notification is consistent with to labeling of the Confidential statements. I further understand that if the	Explanation: Use additional page(s) if necessary. (For section I and Section II.)  This is a notification to add non-FIFRA label claims and to clarify directions for use to this product per PR Notice 98-10 and is not subject to PRIA. 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 of 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.						have been made to the make any false statement to			
			Section	ı - III				_		
1. Material This Product Will Be P	ackaged in:									
Child-Resistant Packaging Unit	t Packaging Yes No		Yes No				Aetal Yastic			
	Yes" t Packaging wgt. 	No. per container	if "Yes" Package w				aper Other (Sp	pecify)		
3. Location of Net Contents Inform		4. Size(s) Reta	ail Container	iner 5. Location of Label Directions					าร	
6. Manner in Which Label is Affixe	ed to Product	Lithogr Paper Stencil	aph glued ed		Other					
Section - IV										
1. Contact Point (Complete items	directly below fo	or identification	n of individual	to be co	ntected, if	nece:	ssary, to	proce	ss this u	application.)
Name Amy Plato Roberts, Technology Sciences Group, Inc.  Title Regulatory Consultan			Telephone No. (Include Area Code y Consultant (202) 828-8954					· ·		
Certification I certify that the statements I have made on this form and all att I acknowledge that any knowlingly false or misleading statemer both under applicable law.				all attachments thereto are true, accurate and complete.					ete.	6. Date Application Received (Stamped)
			3. Title Regulatory Co	le ulatory Consultant to Meridian LLC						
4. Typed Name 5. Date Amy Plato Roberts				May 22, 2006						



May 22, 2006

#### WASHINGTON

1150 18th Street, N.W.

Washington, D.C. 20036

Fax 202 872-0745

Suite 1000

Dennis Szuhay

Chief, Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7504P)

Office of Pesticide Products Telephone 202 223-4392

**US Environmental Protection Agency** 

Room S-4900, One Potomac Yard

2777 South Crystal Drive Arlington, VA 22202-4501

RE:

**SACRAMENTO** 

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Meridian-02 (EPA Reg. No. 69504-2)

Notification to clarify directions for use and to add non-FIFRA related claims per PR Notice 98-10

Dear Mr. Szuhay:

Technology Sciences Group Inc., on behalf of Meridian LLC, is submitting the enclosed notification to add non-FIFRA label claims and to clarify the directions for use for the above referenced product.

You will find the following in support of this notification:

- 1) Application form:
- 2) One (1) copy of the redline label; and
- Three (3) copies of the product label with the changes incorporated. 3)

CANADA

275 Slater Street

Please do not hesitate to contact me directly with any questions.

Ottawa, Ontario

K1P 5H9

Suite 900

Telephone 613 247-6285

Fax 613 236-3754

Sincerely.

Amy Plato Roberts

Regulatory Consultant for Meridian LLC

kathe R. Bjor

Direct dial: (202) 828-8964; E-mail: aroberts@tsgusa.com

cc: Dave Sjogren, Meridian LLC

E-mail tsg@tsgusa.com

http://www.tsgusa.com

## **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

Sublabel A: Commercial Use – small/large briquet

Sublabel B: Commercial Use – small/large briquet (catch basin)

Sublabel C: Residential Use - small/large briquet

**Optional Label Claims** 

#### **ACTIVE INGREDIENT:**

\* Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

EPA Reg. No.: 69504-2

EPA Establishment No.: XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive

Sherwood, OR 97140

U.S. Patent Pending

Always read the label before using product

NOTIFICATION

Date Reviewed: 9/20

Reviewed By:

Sublabel A: Commercial Use - small/large briquet

# **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

Bacillus thuringiensis subspecies israelensis Strain BMP	144 solids, spores and
insecticidal toxins*	7.00%
OTHER INGREDIENTS:	
TOTAL:	100.00%

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

FIRST AID		
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>	
If 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	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>	
	ict container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment	

#### **DIRECTIONS FOR USE**

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

#### INTRODUCTION

MERIDIAN-02 is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. MERIDIAN-02 briquets release effective levels of *Bacillus thuringiensis* subspecies *israelensis* (Bti) to the water surface over time as the briquet dissolves.

MERIDIAN-02 can be applied to areas that contain aquatic life, fish and plants. MERIDIAN-02 can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply MERIDIAN-02 to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: Flood water, roadside ditches, irrigation ditches, rice fields, pastures, woodland pools, snowmelt pools, tidal water, salt marshes, catch basins, storm drains, storm water retention areas, detention ponds, lakes, golf course ponds, irrigation ponds, ornamental zoo ponds, abandoned swimming pools, ornamental ponds, fish ponds, water gardens, greenhouses, nurseries, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply MERIDIAN-02 to known mosquito breeding sites before, or at any time during the mosquito season. Apply MERIDIAN-02 to known breeding sites when the sites are wet or dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. MERIDIAN-02 briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

Deleted: storm drains,

MERIDIAN-02; EPA Reg. No. 69504-2 MASTER LABEL – Notification Version (8) dated May 22, 2006 Page 3 of 13

#### **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 are 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: Do not reuse empty carton or packaging material. Perforate 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.

Always read the label before using product

For product information, call 1-888-846-7233 or visit our web site: www.fourstarbti.com

EPA Reg. No.: 69504-2

EPA Establishment No.: XXXXX-XX-XX

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

Net Contents: (10 g or 12.5 g = small briquet) (32 g or 44 g = large briquet)

Sublabel B: Commercial Use – small/large briquet (catch basin)

#### **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

Bacillus thuringiensis subspecies israelensis Strain BMF	144 solids, spores and
insecticidal toxins*	7.00%
OTHER INGREDIENTS:	93.00%
TOTAL:	

<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### **PRECAUTIONARY STATEMENTS**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: 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 or using tobacco. Remove and wash contaminated clothing before reuse.

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

FIRST AID			
If 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.		
If 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	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>		
	ct container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment		

#### **DIRECTIONS FOR USE**

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

INTRODUCTION MERIDIAN-02 is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats for up to [45 days (for small briquet)] [150 days (for large briquet)] or more. MERIDIAN-02 briquets release effective levels of Bacillus thunngiensis subspecies israelensis (Bti) to the water surface over time as the briquet dissolves.

MERIDIAN-02 can be applied to areas that contain aquatic life, fish and plants. MERIDIAN-02 can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife. Apply MERIDIAN-02 to any water sites except treated, finished water reservoirs or drinking water receptacles.

#### **APPLICATION SITES**

Examples of application sites include, but are not limited to: catch basins, storm drains, underground drainage systems, storm water retention areas, detention ponds, abandoned swimming pools, ornamental fountains and ponds, fish ponds, water gardens, tree holes, animal drinking troughs, standing water, water holding receptacles (old tires, urns, flower pots, cans and other containers), man made and natural sites where mosquitoes may develop.

#### **APPLICATION TIME**

Apply MERIDIAN-02 to known mosquito breeding sites before, or at any time during the mosquito season. Apply MERIDIAN-02 to known breeding sites when the sites are wet or dry and briquets will begin releasing Bti when flooding occurs. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)] or more. Alternate wetting and drying will not reduce briquet effectiveness. MERIDIAN-02 briquets perform optimally under shaded conditions.

The active ingredient Bti has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment. Allow a minimum of 48 hours for control.

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#### **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 are 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: Do not reuse empty carton or packaging material. Perforate 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.

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EPA Reg. No.: 69504-2

**EPA Establishment No.: XXXXX-XX-XX** 

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

**Net Contents:** (12.5 g = small briquet) (44 g = large briquet)

U.S. Patent Pending

Sublabel C: Residential Use – small/large briquet

#### **MERIDIAN - 02**

[Alternate Brand Names: FourStar, FourStar Bti Briquets, FourStar Bti Briquets 45, FourStar Bti Briquets 150, FourStar Bti Catch Basin Briquets 45, FourStar Bti Catch Basin Briquets 150]

#### **ACTIVE INGREDIENT:**

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### 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, or using tobacco. Remove and wash contaminated clothing before reuse.

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

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<sup>\*</sup> Equivalent to 490 International Toxic Units (ITU/mg) Potency units should not be used to adjust rates beyond those specified in the Directions for Use Section. <u>Note</u>: The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

FIRST AID		
If 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.	
If 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	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing eyes.</li> <li>Call poison control center or doctor for treatment advice.</li> </ul>	
	ict container or label with you when calling a poison control center or doctor, or nent. You may also contact 1-800-222-1222 for emergency medical treatment	

#### **DIRECTIONS FOR USE**

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

#### INTRODUCTION

Mosquitoes are both a nuisance and a serious health threat to people and pets. The recent introduction of mosquito borne West Nile Virus into the United States has made mosquito control more important than ever. In addition to encephalitis, mosquitoes can transmit malaria, dengue, yellow fever and heartworm disease to dogs and cats. **MERIDIAN-02** prevents mosquitoes from completing development into biting adults.

#### **GENERAL DIRECTIONS**

Use MERIDIAN-02 to treat mosquito breeding sites in early spring, or at any time during the mosquito season. Apply MERIDIAN-02 to nearby low areas that hold rain or runoff water and produce mosquitoes, even when the sites are dry. Under typical environmental conditions, one (1) application will control for [45 days (for small briquet)] [150 days (for large briquet)]. Repeat treatments as needed to prevent adult mosquito emergence. Alternate wetting and drying will not reduce briquet effectiveness, and may extend the control period. MERIDIAN-02 briquets perform optimally under shaded conditions.

MERIDIAN-02 is a highly selective microbial insecticide effective against mosquitoes in a variety of habitats. Apply MERIDIAN-02 to containerized standing water or any private water sites except treated, finished drinking water reservoirs, drinking water receptacles or state waters. MERIDIAN-02 can be applied to areas that contain aquatic life, fish and plants. MERIDIAN-02 can be applied to areas used by or in contact with humans, animals, horses, livestock, pets, birds or wildlife.

#### Treatment Areas (For Use In):

Bird baths	Fountains	Abandoned swimming pools
Statuary	Urns	Unused swimming pools or spas
Old tires	Rain barrels	Other water holding receptacles
Flower pots	Roof gutters	Standing water
Tree holes	Drains	Animal watering troughs
Water gardens	Stock tanks	Ponds
Ornamental fountains	Pool covers	Lagoons

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Fish ponds

Planters

Flood water Roof gutters

Buckets

Garbage cans Wheelbarrows

Plastic covers
Plant travs

Wheelbarrows

Any location where water collects and remains for periods of time.

#### How to Apply:

To control mosquito larvae, place one (1) briquet in sites up to 100 square feet (10 ft X 10 ft) of surface area. For large sites, apply 1 additional briquet for each additional 100 square feet of surface area, regardless of water depth.

#### STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place.

If empty: Do not reuse 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:

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#### Always read the label before using this product.

For Product information, call 1-888-846-7233 or visit our web site: www.fourstarbti.com

EPA Reg. No.: 69504-2

**EPA Establishment No.: XXXXX-XX-XX** 

Manufactured for: MERIDIAN LLC 17560 SW Woodhaven Drive Sherwood, OR 97140

Net Contents: (12.5 g = small briquet) (44 g = large briquet)

U.S. Patent Pending

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#### **OPTIONAL LABEL CLAIMS**

- Biolarvicide.
- Biological Mosquito Control.
- A Biological Larvicide Briquet.
- Mosquito Biolarvicide Briquet.
- Made with Bti, a microbial active ingredient.
- Concentrated Formula.
- 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.
- Fast acting.
- Prevents the development of adult mosquitoes.
- Prevents immature mosquitoes from developing into adults.
- Prevents emergence of breeding, biting adult mosquitoes.
- Prevents the development of mosquito larvae.
- 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.
- Biological Mosquito Larvicide with (45 day (for small briquette)) (150 day (for large briquette)) control.
- (45 day (for small briquette)) (150 day (for large briquette)) control.
- Effective [controls] for up to (45 days (for small briquette)) (150 days (for large briquette)).
- A Sustained Release (45-Day (for small briquette)) (150-Day (for large briquette)) Bti Mosquito Larvicide Briquet.
- Each briquet treats up to 100 square feet.
- Controls mosquitoes.
- Controls mosquito larvae (in standing water) (within 48 hours) (in 48 hours).
- Quickly controls mosquito larvae in (within) 48 hours.
- One application controls all season.
- Season Long Control.
- For use in fish habitats.
- 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 ingested by mosquito larvae, (product name) prevents emergence of breeding, biting adults.
- Kills mosquito larvae upon ingestion of Bt toxins.
- 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
- (A) Controlled (Sustained) Release [45 day] [150 day] Catch Basin Briquet(s)