

75801-1

9-13-2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 13 2006

Mr. Michael M. Iverson
Turf Science Laboratories, Inc.
2121 Hoover Avenue
National City, CA 91950

Subject: Product Name: Spot-Less Biofungicide
EPA Reg. No: 75801-1
Notification of addition of pest to label
Dated: August 14, 2006

Dear Mr. Iverson:

The Biopesticides and Pollution Prevention Division is in receipt of the above dated application. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action requested falls within the scope of PR 98-10. Our records have been duly noted, and the label submitted with this application has been stamped Notification received, but not reviewed and will be placed accordingly in our records.

Questions concerning this action should be directed to Mr. Andrew Bryceland at 703-305-6928 or email at bryceland@epa.gov.

Sincerely,

Roger Gardner

Roger Gardner, Acting Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division, (7511C)

CONCURRENCES

SYMBOL	7511P						
SURNAME	Pollard						
DATE	9/13/06						

Please read instructions on reverse before completing form.

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 75801-1	2. EPA Product Manager Tessa Milofsky	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spot-Less Biofungicide	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Turf Science Laboratories, Inc. 2121 Hoover Avenue National City, CA 91950 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: NOTIFICATION Received But Not Reviewed EPA Reg. No. _____ Product Name _____ Date: <u>9/13/06</u> Initial: <u>CP</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final product is in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

Revise the label to add the pest Gray Leaf Spot (Pyricularia grisea) to the "effective on" listing. No other changes are required.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1-20 gallons.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael M. Iverson	Title Regulatory Affairs	Telephone No. (Include Area Code) 619 851-4041
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Star. 100)
2. Signature 	3. Title Regulatory Affairs	
4. Typed Name Michael M. Iverson	5. Date 8/11/06	

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2121 Hoover Ave. National City, CA 91950
619.474.5266 619.336.1038

August 14, 2006

Document Processing Desk
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
Washington D.C. 20460

Re: Notification of Label Change
***Spot-LessTM Biofungicide* EPA Reg. No 75801-1**

Dear Sir/Madam:

Attached please find a Notification of a proposed label change to add the pest Gray Leaf Spot (*Pyricularia grisea*). This pest is only on found perennial ryegrass turf. Gray Leaf Spot became a major issue for turf managers in the mid-1990's - about the same time as the original application to the EPA for *Spot-LessTM* (then called *Ping Fungicide*). Our Notification is based on subsequent laboratory research and field observations, especially observations by our customers as they use *Spot-LessTM* against present labeled pests. These factors all support the addition of this pest to our current "Target Pests" listing on pages one and two. There are no other changes required to the label.

Also attached are five copies of the draft label.

Should you have any questions, please contact the undersigned by either email mikeaye@aol.com or cellular 619 861-4041.

Sincerely,

Michael M. Iverson

Attachments

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Spot-Less™ Biofungicide

Manufactured exclusively by Turf Science Laboratories, Inc., for use in the BioJect®

ACTIVE INGREDIENT:		NONPLANT FOOD INGREDIENT
<i>Pseudomonas aureofaciens</i> strain Tx-1*	1.0%	
Inert Ingredients:	99.0%	
Total	100.0%	

*Contains at least 2.9 x 10¹¹ viable cells/fl. oz.

NOTIFICATION
 Received But Not Reviewed
 Date: 9/13/06
 Initial: JPR

KEEP OUT OF REACH OF CHILDREN
CAUTION

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for advice.
If in eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 for emergency medical treatment information.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters.

Directions for Use

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

Spot-Less™ is a liquid biological fungicide for use on turf grass, including golf courses.

Spot-Less™ is effective on the following pests:

- Dollar Spot - (*Sclerotinia homeocarpa*)
- Anthracnose - (*Colletotrichum graminicola*)
- Pythium - (*Pythium aphanadermatium*)
- Microdochium patch (Pink Snow Mold) - (*Microdochium nivale*)
- Gray Leaf Spot - (*Pyricularia grisea*)

Spot-Less™ Biofungicide is the product of a BioJect® fermentation cycle. During periods of high disease pressure, apply **Spot-Less™** 5-7 times per week during evening hours through over-head Chemigation systems. For a conventional sprayer, apply 2-4 pints of **Spot-Less™** using a minimum of 50 gallons of water per acre and treat as necessary to control pests. Treat unoccupied turf preferably when the golf course is closed to the public. Avoid use of treated areas until sprays have dried.

Only trained operators may use the BioJect® system. Refer to the BioJect® Operators Manual for specific operating and handling instructions and Labeling for additional product information.

Manufacturer's Warranty

Turf Science Laboratories, Inc. makes no warranty, expressed or implied; or merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. Users assume all risk of use, storage or handling not in strict accordance with the accompanying directions.



2121 Hoover Avenue National City, CA 91950

1-800-864-4266

EPA Reg No: 75801-1
EPA Est No: 75801-CA-001

11-17 04

Net Contents: 1 gallon (3.79l)

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Spot-Less™ Biofungicide

Directions for Use

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

Application Site:

Spot-Less™ is a liquid biological fungicide for use on turf grass including golf courses. Do not use Spot-Less™ on turf grown for sale or other commercial use, such as, sod, commercial seed production or research purposes.

Target Pests:

- Dollar Spot – (*Sclerotinia homeocarpa*)
- Anthracnose – (*Colletotrichum graminicola*)
- Pythium – (*Pythium aphanadermatium*)
- Microdochium patch (Pink Snow Mold) – (*Microdochium nivale*)
- Gray Leaf Spot – (*Pyricularia grisea*)

Application Using the BioJect® Automatic Fermentation System

Refer to the BioJect® Operators' Manual for specific operating and handling instructions. Only trained operators may use the BioJect® system.

Spot-Less™ Biofungicide is applied using the BioJect® system. During evening hours, treat only unoccupied turf (preferably when the golf course, or other facility, is closed to the public). Avoid use of treated areas until mists have settled and sprays have dried.

A quality control check, using the BioJect® System Quality Control Checklist (page 3), is mandatory for each BioJect® fermentation cycle. If any checklist item does not function properly, the resulting batch must be aborted and appropriately disposed.

NOTE: Use only potable water in the BioJect® system, for operation (fermentation) and disinfection.

Frequency of Application:

Apply during periods of high disease 5-7 times per week through over-head chemigation systems.

Chemigation:

Refer to the section entitled **Chemigation Instructions** (page 4) for directions on chemigation. Do not apply this product through any irrigation system, unless the chemigation labeling is followed.

Conventional Sprayer:

Fill the supply tank with a minimum of 50 gallons of potable water. Check pH of the water and buffer as necessary to a range of 6.0 to 8.0. Add 2-4 pints of Spot-Less™ Biofungicide. Note: Do not add any other products to the tank mixture. Using lowest setting, agitate the mixture for approximately three minutes. For best results, mix and apply during evening twilight.

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BioJect[®] System Quality Control Checklist

A quality control check is mandatory prior to the initiation of each fermentation service cycle for *Spot-Less[™] Biofungicide*. If any checklist item does not function properly, or if procedures are not followed, the resulting batch must be aborted and appropriately disposed.

Item	Quality Control Check
UV light – operating properly.	Visually observe and confirm the UV light is attached to the water input line. Visually observe and confirm the UV light emits a purple glow. Verify, per bulb manufacturer's instructions, the scheduled maintenance and replacements are followed.
Inoculum - properly added to the BioJect [®] fermentation tank.	Visually observe and confirm the inoculum pump's activity during addition.
Disinfecting cycle - occurred immediately after fermentation.	Visually observe and confirm the disinfectant pump is operating during the clean-in-place (CIP) cycle.
Appropriate media - added to the fermentation tank.	Confirm the nutrient medium added to the BioJect [®] is MD-1/2.

Spot-Less[™] Biofungicide Disposal & Storage

Do not contaminate water, feed or food by disposal.

Disposal of Defective Batches:

Prior to disposal, defective batches (including partially used batches) must be disinfected with common household bleach (4-6% Sodium Hypochlorite). Add 1ℓ (0.25 gallons) of bleach per 27 gallon fermentation batch (1% v/v or 10,000 ppm). Allow bleach solution to disinfect for a minimum of five minutes. Dispose of the disinfected batch in the sewer system.

Pesticide Storage: Store in original bags and keep closed. Refrigerate at 40-55°F.

Pesticide Disposal: Disinfect with common household bleach (4-6% Sodium Hypochlorite). Wastes resulting from the use of this product may be disposed of on site or an approved waste disposal facility.

Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Chemigation Instructions

Inject this product into over-head sprinkler. The BioJect[®] automatic fermentation system can be used with this irrigation method. Do not apply this product through any other type of irrigation system. If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system, unless the pesticide label-prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person shall shut the system down and make necessary adjustments should the need arise. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

Over-Head Sprinkler System Requirements:

1. The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline, to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional normally closed, solenoid-operated valve located on the intake side of the injection pump. And connected to prevent fluid from being withdrawn from the supply tank when the irrigation system is automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the pump motor system stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Do not apply when wind speed favors drift beyond the area intended for treatment.
8. The action of the metering pump delivering the *Spot-Less[™] Biofungicide* into the chemigation system will provide all of the necessary mixing. Application of *Spot-Less[™] Biofungicide* can be continuous for the duration of the irrigation schedule.

Testing for *Spot-Less™ Biofungicide* Fermentation Quality:

1. The quality of a *Spot-Less™ Biofungicide* fermentation can be measured on site using a LaMotte Turbidity Test Kit Code #7519. Follow LaMotte's procedure for using the kit and obtain the resulting Jackson Turbidity Unit (JTU) reading. Convert the JTU reading to CFU/ml using the figure below. The minimum reading for *Spot-Less™ Biofungicide* performance on turf is 5E+07 CFU/ml. If your fermentation is below that level, your BioJect® Service Technician will make necessary adjustments to restore BioJect® fermentation quality.

