84545-9

02/07/2011

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

FEB - 7 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

sBioMed, LLC
1272 South 1380 W
Orem, Utah 84058

Attention: Zuhal Tompkins, Technology Sciences Group, Inc.
Regulatory Consultant to sBioMed, LLC

Subject: Steriplex Ultra Part B Notification for label changes
EPA Reg. No. 84545-9
Notification Letter Dated January 21, 2011

This will acknowledge receipt of your notification for the aforementioned product label, submitted under the provisions of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3© (9). Based on a review of the submitted material, the following apply:

- The Agency approves the notification. The Agency has no objection to the following clarifications made to the directions for use:

    - "STERIPLEX Ultra (EPA Reg. No 84545-8): a one gallon bottle (containing 118 oz. of 0.03% silver), and

      STERIPLEX Ultra Activator (Part B) (EPA Reg. No. 84545-9): a smaller bottle (containing 10 oz. of 15.0% peracetic acid and 22.0% hydrogen peroxide)."

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)

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Please read instructions on reverse before completing form. Form Approved. .B No. 2070-0060, Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] **Registration**
- [ ] **Amendment**
- [x] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
84545-9	Marshall Swindell	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Steriplex Ultra Activator Part B	33	

5. Name and Address of Applicant *(Include ZIP Code)*

sBioMed, LLC
1272 South 1380 W
Orem, Utah 84058

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

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

The clarification statement to directions for use has been added pursuant to state registration agency request on the master label per PR Notice 98-10. Please confirm with Zuhal Tompkins: ztompkins@tsgusa.com or via fax (202) 872-0745.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formulation for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[ ] Metal
[x] No	[x] No	[x] No	[x] Plastic
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	4 oz, 12 oz	[x]

6. Manner in Which Label is Affixed to Product

- [x] Lithograph
- [ ] Paper glued
- [ ] Stenciled
- [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Zuhal Tompkins,Technology Sciences Group, Inc.	Regulatory Consultant	(202) 828-8886

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application received (Stamped)

2. Signature	3. Title
Z. Tompkins	Regulatory Consultant to sBioMed, LLC
4. Typed Name	**5. Date**
Zuhal Tompkins	1/21/2011

Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8966
Fax: (202) 872-0745
E-Mail: etesch@TSGUSA.com

January 21, 2011

Marshall Swindell, PM33
Antimicrobial Division
Office of Pesticide Programs (7510C)
U.S. Environmental Protection Agency
Document Processing Desk
Room S4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **sBioMed, LLC: Steriplex Ultra Part B (EPA Reg. No. 84545-9)**
Notification for Label Changes per PR Notice 98-10

Dear Mr. Swindell:

Technology Sciences Group Inc., on behalf of sBioMed, LLC (EPA Company No: 84545), is submitting the enclosed notification to clarify the directions for use by identifying the specific ratio of the mixture. The current directions for use simply indicate to mix the contents of one bottle into another bottle. During the process of seeking state registration, the states have requested the specific amount of product in the bottles be identified on the directions for use. Please find enclosed the following documentation in support of this submission:

(1) Application for Registration (EPA Form 8570-1);
(2) One redline version of the revised label; and
(3) Three clean copies of the revised label.

If you have any questions or need additional information regarding this submission, please contact me at (202) 828-8954 or ztompkins@tsgusa.com.

Sincerely,

Zuhal Tompkins
Regulatory Agent for sBioMed, LLC

For use only by:

- Federal On-Scene Coordinators and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

STERIPLEX Ultra™ Activator (Part B)

SPORICIDAL DECONTAMINANT for INACTIVATION of *Bacillus anthracis* SPORES on DRY, PRECLEANED, HARD NON-POROUS SURFACES

STERIPLEX Ultra™ Activator is a sporicidal decontaminant that inactivates *Bacillus anthracis* spores on dry, precleaned, hard nonporous surfaces at certain sites when used in accordance with all precautions and directions specified on this label and in the attached Training Manual.

STERIPLEX Ultra™ Activator (Part B) is to be used only in the mixture with STERIPLEX Ultra™ (Part A) as a sporicidal decontaminant

Active Ingredients:	Hydrogen Peroxide	22.0%
	Peroxyacetic Acid	15.0%
Inert Ingredients:		63.0%
	Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE (SIDE) (BACK) PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

EPA Reg. No. 84545-9 EPA Est. No. 84545-UT-001

Net Contents: 1 quart 1 gallon 5 gallons 55 gallons

sBioMed™

1272 South 1380 West
Orem, Utah 84058TEL: 801-922-1111 FAX: 801-922-1100

FIRST AID FOR STERIPLEX Ultra™ Activator (Part B)	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN MIXING THIS PRODUCT:

Eyes and Face: Use cup type chemical goggles and a full-face shield when mixing and applying this product to the intended surfaces.

Protective Clothing: Use rubber or neoprene footwear and a rubber or neoprene apron or full-body protective clothing. Completely submerge into water any clothing or other materials contaminated with hydrogen peroxide from contact with the concentrated or mixed products, and then allow clothing to dry. Residual hydrogen peroxide, if allowed to dry on fabrics, cotton, leather, wood, paper or other combustibles, can cause the material to ignite and result in a fire.

Gloves: Rubber or neoprene gloves are required when mixing and applying product. Thoroughly wash the outside of gloves with soap and water prior to removal. Inspect regularly for leaks.

Respiratory: Wear an approved full-face acid/gas cartridge or canister respirator. If concentrations are unknown (e.g., significant spill or other emergencies), or if they are anticipated to be above 5 ppm for hydrogen peroxide or 50 ppm for acetic acid, use a self-contained breathing apparatus (SCBA).

Follow manufacturer's instruction for cleaning/maintaining protective eyewear and respirator users:

The respirator user must be fit tested and fit checked using a program that conforms to OSHA's requirements (29 CFR 1910.134)

The respirator user must be trained using a program that conforms to OSHA's requirements (29 CFR 1910.134)

A qualified medical practitioner to ensure the physical ability of the user to safely wear the type of respirator to be worn must examine the respirator user.

The respirator equipment must be maintained according to a program that conforms to OSHA's requirements (29 CFR 1910.134).

PPE REQUIRED FOR PROTECTION FROM *BACILLUS ANTHRACIS* SPORES:

When applying the product to areas contaminated with *Bacillus anthracis* spores, wear the personal protective equipment (PPE) described in the Training Manual.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the US Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with STERIPLEX Ultra™ (Part A) disinfectant solutions. Product must be diluted in accordance with label directions prior to use. STERIPLEX Ultra™ Activator (Part B) is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

STERIPLEX Ultra™ is a two part sporicidal decontaminant that inactivates *Bacillus anthracis* spores on dry, precleaned, hard, nonporous surfaces, and may be used on sites listed below. This product is for use only by persons listed in the enclosed box above the product name. Read and follow all safety precautions and use directions on the label and in the Training Manual.

For use as a sporicidal decontaminant in Industrial, Commercial, and Institutional settings, including the following sites: Offices, Government and Residential buildings; Educational buildings, Public and Private buildings; Commercial, Government and Private vehicles; Personal Protective Equipment; Hospitals/Healthcare facilities; Military institutions and equipment; Manufacturing facilities; Hotels; Cruise ships; Airports.

Do not use this product on food contact surfaces.

PREPARATION – STERIPLEX Ultra™ is a two-part sporicidal decontaminant system consisting of:

STERIPLEX Ultra™ (Part A) (EPA Reg. No. 84545-8): a one gallon bottle (containing 118 oz. of 0.03% silver), and

STERIPLEX Ultra™ Activator (Part B) (EPA Reg No. 84545-9): a smaller bottle (containing 10 oz. of 15.0% peracetic acid and 22.0% hydrogen peroxide)

1. Wearing specified personal protective equipment (PPE) as described under the PRECAUTIONARY STATEMENTS on this label, find the STERIPLEX Ultra™ Activator (Part B) bottle. Remove the cap from the bottle.
2. On the "Part A" container, remove the cap. Pour the entire contents of the STERIPLEX Ultra™ Activator (Part B) into the opening of the "Part A" container.
3. Discard the spent STERIPLEX Ultra™ Activator (Part B) container in an approved waste disposal receptacle as directed on the STERIPLEX Ultra™ Activator (Part B) label. Replace cap back onto the "Part A" container.
4. Mix the two-part solution by agitating the contents for approximately 15 seconds.
5. Pour the mixed solution into applicator equipment for usage.
6. Mix fresh batch daily. Dispose of unused solution within 24 hours after mixing.

Application Methods – For use on Hard, Non-Porous, Non-Food Contact Surfaces
STERIPLEX Ultra™ can be applied to surfaces by conventional (spray) (mopping) (cloth) or (sponge) method.

To Fill or (refill) empty spray bottle:

1. Remove trigger sprayer (or cap) from empty bottle.

2. Unscrew cap (or open spigot) and pour contents into empty bottle.
3. Replace trigger sprayer (or cap) and use as instructed.

Refill sprayer only with STERIPLEX Ultra™ mixture.

For Use on Dry, Precleaned, Hard Non-Porous Surfaces
For heavily soiled areas, a precleaning step is required. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. Spray or wipe on the mixed STERIPLEX Ultra™ solution by the following means: mop, cloth, sponge, spray bottle or commercial sprayer.

1. Thoroughly apply the solution to the surface using a prescribed method covering the surface with a thin film of product at room temperature.
2. Allow the product to remain on the surface for a minimum of 30 minutes.
3. Rrinse the surfaces with a clean cloth or sponge several times with running water.
4. Larger areas may be treated by applying the product with a spray bottle or commercial sprayer. Allow the product to remain on the contact surface for a minimum of 30 minutes, and then rinse surfaces as prescribed above.
5. Dispose of cleaning utensils as directed in the instructions.

DECONTAMINATION OF EQUIPMENT – For heavily soiled areas, a precleaning step is required. To the extent possible, dismantle equipment and tools. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. All surfaces to be treated must be dry (i.e, not visibly wet) prior to application. Apply the STERIPLEX Ultra™ mixed solution in the following manner:

1. Pour desired amount of solution into a tray or receptacle that will hold the tools and allow for complete immersion in solution.
2. Immerse equipment or tools for a minimum of 30 minutes.
3. Transfer equipment or tools to a rinse bath to remove the solution. Dipping the equipment or tools a couple of times into the rinse bath will thoroughly remove any solution.
4. Allow equipment or tools to air dry prior to reuse.

See Training Manual for additional, detailed instruction on product applications.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Never return STERIPLEX Ultra™ Activator (Part B) to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute STERIPLEX Ultra™ Activator (Part B) with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86 °F. Do not store on wooden pallets.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. STERIPLEX Ultra™ Activator (Part B), which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

CONTAINER DISPOSAL:
Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap and shake for 10 seconds, then uncap and discard rinsate. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times, and then discard container and cap.