



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:
84545-8

Date of Issuance:
APR 02 2010

Term of Issuance:

Name of Pesticide Product:
STERIPLEX Ultra TM
(Part A)

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

sBioMed LLC
1272 So. 1380 West
Orem, Utah 84058

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 84545-8."

Signature of Approving Official:

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

Date:

APR 03 2010

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3. The confidential Statement of Formula dated August 24, 2009, is acceptable.

4. The following additional Terms and Conditions of Registration apply:

a. Sale and Distribution Limitations

The registrant commits not to sell or distribute the product except to:

- Federal On-Scene Coordinators (FOSC), 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;
- Person who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) in each of the topics described under item 2 below.

The registrant commits to verify, prior to sale or distribution, that the recipient falls within one of the above user categories. For the first two user categories listed above (i.e., FOSCs, U.S. Military personnel, their contractors, and other persons under their supervision),, such verification may be accomplished through a critical review of documents, such as a letter on government letterhead, a government purchase order, or a government-issued identification badge.

b. Training and determination of Competency of Applicators

Where a registrant proposes to sell or distribute anthrax-related products to persons other than FOSCs, trained U.S. Military personnel, and contractors and other response personnel under the supervision of FOSC's or trained U.S. Military personnel, the registrant commits to providing training for such persons and to determining their competency through written examination. The registrant may itself perform the training and competency determination, or enter into a contract with a qualified third party to conduct the training and competency determination on the registrant's behalf. The registrant further commits that the training curriculum will provide for refresher training and competency determination at least every two years and, at a minimum, include instruction concerning:

- Characteristics of and human health hazards posed by *B. anthracis* spores;
- Personal Protective Equipment (PPE) appropriate for protection against *B. anthracis* spores and while using the pesticide product;
- Detailed instructions for safe and effective use of the registered pesticide product and any associated equipment;
- Detailed review of the steps involved in the remediation and restoration process as provided in guidance from federal agencies (e.g., National Response Team Technical Assistance for Anthrax Response, Interim Final Draft, July 2005) as well as review of

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applicable federal statutory and regulatory requirements and guidance; and

- As assessment of the trained applicator's competency on the above issues through a written examination.

c. Records and Reporting

The registrant commits to the following, commencing upon the effective date of registration or, if the anthrax-related claim is added to an existing registration by amendment, upon the effective date of that amendment;

- Maintain accurate, up-to-date records of the required activities under these terms and conditions, including:
 - Names of trainers, a listing of their qualifications, and copies of all training materials used.
 - Names and addresses of persons who have been trained and the dates and locations of such training.
 - Names and addresses of persons to whom the pesticide has been sold or distributed as well as the date and location of such sale or distribution and the product and quantity sold or distributed.
- Agree to maintain such records for two years, and to provide copies upon request of any authorized employee of the EPA, or of any state or political subdivision, duly designated by the Administrator.
- Agree that records and reports made or maintained in connection with these Terms and Conditions will not be claimed as confidential business information or trade secrets.

d. Consequence of Non-Compliance with the Terms and Conditions of Registration

The registrant agrees that failure to comply with any terms and conditions of registration specified above, may, at the sole discretion of EPA, result in the issuance of an order canceling the affected registration(s) without a hearing. Before issuing any such order, the Agency will notify the registrant in writing its intention to cancel the registration(s) and specify in such notification the basis for its conclusion that the registrant has failed to comply with the terms and conditions of registration. EPA will allow the registrant ten business days from the receipt of such notification to submit in writing a request of such notification to submit in writing a request to meet with the Director of the Office of Pesticide Programs (Office Director") before a cancellation order is issued. The Agency will not issue a cancellation order before providing the registrant an opportunity to meet with the Office Director to discuss whether cancellation is appropriate. The registrant agrees that the decision of the Office Director will be final.

5. Submit three (3) copies of the final printed label prior to releasing this

A stamped copy of the label is enclosed for your records.

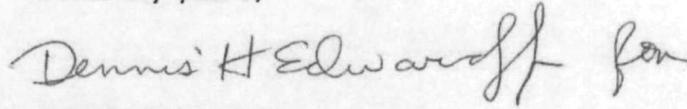
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If these conditions are not complied with, the registration will be subject to cancellations in accordance with FIFRA sec. 6(e) or as may be deemed appropriate by the Agency, as provided for in Condition 1 and/or Condition 4d.

Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely yours,



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

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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™
(Part A)**

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

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

ACTIVE INGREDIENTS:

Silver.....	00.03 %
Other Ingredients.....	99.97%
Total.....	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

EPA Reg. No. 84545-8

EPA Est. No. 84545-UT-001

Net Contents: 1 quart

1 gallon

5 gallons

55 gallons

ACCEPTED
with COMMENTS

EPA Letter Dated:
APR 02 2010

sBioMED™

1272 South 1380 West

Orem, Utah 84058

TEL: 801-922-1111 FAX: 801-922-1100

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. 84545-8

STERIPLEX Ultra™ (Part A)

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FIRST AID FOR STERIPLEX Ultra™ (Part A)

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.
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

CAUTION - Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Harmful if absorbed through skin. Remove and wash contaminated clothing 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).

ACCEPTED
with COMMENTS
EPA Letter Dated:

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STERIPLEX Ultra™ (Part A)

Under the Federal Insecticide,
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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)

The respirator user must be examined by a qualified medical practitioner to ensure the physical ability of the user to safely wear the type of respirator to be worn.

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. 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 Pollution 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 at the EPA.

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, **ACCEPTED** Institutions and equipment; Manufacturing facilities; Hotels; Cruise ships; Airports. **with COMMENTS**

EPA Letter Dated:

Do not use this product on food contact surfaces. ... **APR 0-2-2010**

STERIPLEX Ultra™ (Part A)

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. **84545-8**

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

STERIPLEX Ultra™ (Part A) (EPA Reg. No. 84545-): a one gallon container of 0.03% silver, and

STERIPLEX Ultra™ Activator (Part B) (EPA Reg No. 84545-): a smaller bottle containing 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.

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Refill sprayer only with STERIPLEX Ultra™ mixture.

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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.

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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. Rinse 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.

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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.

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

STORAGE AND DISPOSAL

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

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

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PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water.

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.

CONTAINER DISPOSAL:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

[Container sizes of 1 gal. – 5 gal.] – 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. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

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[Containers with capacities greater than 5 gallons or 50 lbs.] – Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 03 2010

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