

84545-8

12/20/2011

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

sBioMed, LLC  
1272 South 1380 W  
Orem, Utah 84058

DEC 20 2011

Attention: Zuhai Tompkins, Technology Science Group  
Regulatory Consultant

Subject: Steriplex Ultra Part A – Agency Initiated Amended for Stamped Label  
EPA Reg. No. 84545-8  
Amendment Request Letter Dated November 17, 2011

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. On February 7, 2011, the Agency approved a notification for the aforementioned product which clarified the directions for use by identifying the specific ratio of the mixture. As the application to make this change was submitted as a notification, no stamped label was provided. The Company requires a stamped label with those changes included. This Agency Initiate Amendment approves the most up to date version of the label.

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

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

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

**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

Net Contents:

1 quart

1 gallon

EPA Est. No. 84545-UT-001

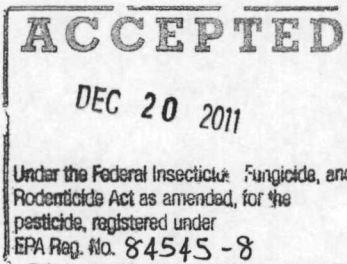
5 gallons

55 gallons

**sBiOMED™**

1272 South 1380 West  
Orem, Utah 84058

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





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## FIRST AID FOR STERIPLEX Ultra™ (Part A)

<b>IF IN EYES</b>	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.
<b>IF ON SKIN OR CLOTHING</b>	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.
<b>IF SWALLOWED</b>	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.	
<b>FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222</b>	

## 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:

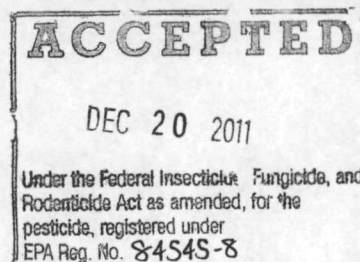
**Eyes and Face:** Use cup type chemical goggles and a full-face shield when mixing and applying this product to the intended surfaces.

**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).

STERIPLEX Ultra™ (Part A)  
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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**

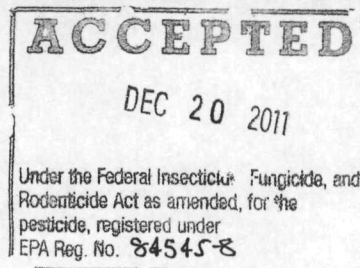
IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT  
IN A MANNER INCONSISTENT WITH ITS LABELING.

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; Military institutions and equipment; Manufacturing facilities; Hotels; Cruise ships; Airports.

*Do not use this product on food contact surfaces.*

STERIPLEX Ultra™ (Part A)  
Notification 1-21-11





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

**STERIPLEX Ultra™ (Part A) (EPA Reg. No. 84545-8): a one gallon container 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:

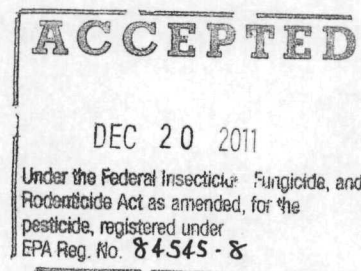
1. Remove trigger sprayer (or cap) from empty bottle.
2. Unscrew cap (or open spigot) and pour contents into empty bottle.
3. Replace trigger sprayer (or cap) and use as instructed.

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. 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.



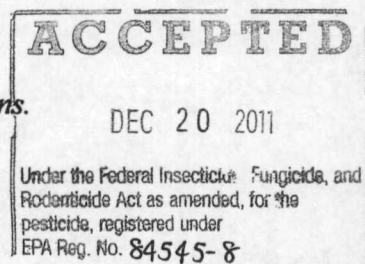
**DECONTAMINATION OF EQUIPMENT** – For heavily soiled areas, a precleaning step is required. To the extent possible, dismantle equipment and tools. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and 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:** 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**  
DEC 20 2011  
Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 84545-8