

84545-4

01/06/2011

1/11



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Technology Sciences Group Inc.
c/o for sBioMed. LLC
1150 18th Street, NW
Suite 1000
Washington, DC 20036

JAN - 6 2011

Attention: Erin Tesch
Regulatory Specialist

Subject: Steriplex HC Solution Part A
EPA Reg. No. 84545-4
Notification Letter Dated December 15, 2010

This will acknowledge receipt of your notification submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

- Clarifying the directions for use by identifying the specific ratio of mixture

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 Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink, appearing to read "Marshall Swindell", with a circled "for" to the left.

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

 Environmental Protection Agency United States Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number _____
---	---	-----------------------------

Application for Pesticide - Section I

1. Company/Product Number 84545-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Steriplex HC Solution Part A	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) sBioMed, LLC 1272 South 1380 W Orem, Utah 84058 <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: EPA Reg. No. _____ Product Name _____	

Section - II

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

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

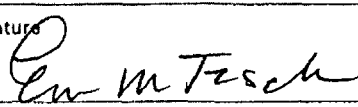
The clarification statement to directions for use has been added pursuant to state registration agency request on the master label per PR Notice 98-10. Please confirm with Erin Tesch: etesch@tsgusa.com or via fax (202) 872-0745.

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Erin M. Tesch, Technology Sciences Group, Inc.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8966
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 (Stamped)
2. Signature 	3. Title Regulatory Consultant to sBioMed, LLC	
4. Typed Name Erin M. Tesch	5. Date 12/15/10	

**WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Mr. Marshall Swindell
 Office of Pesticide Programs
 Antimicrobial Division (7504P)
 Office of Pesticide Products
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202-4501

December 15, 2010

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

**RE: sBioMed, LLC: Steriplex HC Solution Part A
 (EPA Reg. No. 84545-4)
 Notification for Label Changes per PR Notice 98-10**

Dear Mr. Swindell:

Technology Sciences Group Inc., on behalf of sBioMed, LLC, is submitting the enclosed notification to clarify the directions for use by identifying the specific ratio of the mixture (refer to page 4). 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. Therefore, sBioMed have clarified the directions for use to indicate one bottle (containing 2.2 oz of product) should be mixed with the larger bottle (containing one gallon product).

You will find the following included with this submission:

- 1) EPA Application Form,
- 2) One redline version of the revised label, and
- 3) Three clean copies of the revised label.

Please do not hesitate to contact me directly with any questions and/ or concerns at (202) 828-8966 or via e-mail: etesch@tsgusa.com.

Sincerely,

Erin M. Tesch
 Regulatory Agent for sBioMed, LLC

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

4/11

**Steriplex HC™
Solution Part A**

BEFORE USING THIS PRODUCT, READ THIS ENTIRE LABEL CAREFULLY

Steriplex HC™ is a two-part system and, when Part A and Part B are combined, create an effective Sterilant/Sporicide, Tuberculocide, and Bactericide.

ACTIVE INGREDIENTS:

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

CAUTION

**KEEP OUT OF REACH OF CHILDREN
READ ENTIRE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

E.P.A. Reg. No. 84545-4

E.P.A. Est. No. 84545-UT-001

Net Contents: (as indicated on Container)

sBiOMED™

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

(Note to Reviewer: Language in () is optional or interchangeable)

- [New!] (to be used for 6 months after commercial introduction)
- Steriplex HC™ is a two part system, when Part A (Steriplex HC™ Solution Part A) and Part B (Steriplex HC™ Activator Solution Part B) are combined, create an effective Sporicide, (Sterilant) (Disinfectant), (Antibacterial), (Deodorizer).
- Kills, (destroys), (eliminates) 99.999% of the following germs: *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium* (at 20° C), *Pseudomonas aeruginosa*, *Salmonella enterica*, and *Staphylococcus aureus*.
- << Back Panel>> *Kills *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium* (at 20°C), *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*
- When used as directed, Steriplex HC™ is effective against the following pathogens on hard non-porous, non-food contact surfaces:

As a Sporicide: *Bacillus subtilus*
 Clostridium sporogenes

As a Tuberculocide: *Mycobacterium (Tuberculosis)*(at 20°C)

As a Bactericide: *Pseudomonas aeruginosa (Pseudomonas)*
 Salmonella enterica (Salmonella)
 Staphylococcus aureus (Staph)

- Steriplex HC™ is a broad spectrum Sporicide (Disinfectant)(Sterilant) (Antibacterial) (Deodorizer), proven to kill (destroy)(eliminate) (deodorize) *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium* (at 20° C), *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*, on non-porous hard surfaces in (Homes), (Hospitals), (Laboratories), (Nursing Homes), (Day Care Centers), (Medical and Dental Offices), (Animal Shelters), (Kennels), (Hotels), (Motels), (Restaurants), (Offices), (Beauty Salons & Barber Shops), (Subways), (Trains), (Airplanes), (Cruise Lines), (Busses) and (other public transportation vehicles), (Locker Rooms), (Gyms), (Restrooms), (correctional facilities), (funeral homes), (morgues), (spas), (health clubs), (salons), (schools and school medical facilities), and (school buses).
- Steriplex HC™ has been formulated to effectively destroy (kill)(eliminate)(deodorize) *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium* (at 20° C), *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*, on hard, non-porous surfaces (in)(on): Kitchen (Stove Tops), (Sinks), (drain boards), (Cabinets), (Refrigerator exterior surfaces), (floors), and (window sills). Bathroom (counter tops), (tubs), (showers), (glazed tiles), (toilet surfaces), (walls), (floors), (hampers), (diaper pails), (scales), (mirrors), (door knobs), (handles), and (faucet fixtures).

(Note to Reviewer: Language in () is optional or interchangeable)

- Use on (appliances), (telephones), (cell phones), (light switch covers), (computer keyboards), and (remote controls).
- Steriplex HC™ is effective (when used as directed) on (children's toys), (toys), (toy boxes), (diaper changing tables), (cribs), (strollers), (baby car seats), (play pens), (activity centers), (desks), (play table & chairs), (children's play sets), (riding toys), and (bath toys).
- Steriplex HC™ is an effective Sporicide (disinfectant) (sterilant) (antibacterial) (deodorizer) on hard non-porous surfaces within the medical industry including surfaces such as (chairs), (stools), (counter tops), (drawer pulls), (door knobs and handles), (carts), (baskets), (pans), (pails), (IV poles), (tables), (cabinets), (lighting fixtures), (bassinets), (bed rails), (incubators), (physical therapy equipment), (shower stalls), (toilet exteriors and toilet seats), (telephones and other related hard surfaces in hospitals), (operating and surgical rooms), (stretchers), (examination tables), (intensive and critical care units), (emergency units), (dental and veterinary offices), (surgery), (recovery), (anesthesia), (X-Ray), (Cat. Lab), (blood collection and donation centers), (isolation units), (orthopedics), (newborn nursery), (respiratory therapy), (radiology), (pediatrics), (physical therapy), (rehabilitation), (ophthalmology), (optometry), (hospices), (central supply), (emergency medical vehicles), (police and fire vehicles), (correctional facilities), (funeral homes), (morgues), (spas), (health clubs), (salons), (schools and school medical facilities), (school buses), and (day care).
- Steriplex HC™ is effective on these types of surfaces as well: (Formica), (Glazed Ceramic), (Glazed enameled surfaces), (Glazed Porcelain), (Metal), (Plastic), (Sealed Granite), (Sealed Limestone), (Sealed Marble), (Sealed Slate), (Sealed Stone), (Sealed Terra Cotta), (Sealed Terrazzo), (Stainless Steel), (Upholstery), (Vinyl) and (finished Woodwork).

(Note to Reviewer: Language in () is optional or interchangeable)

DIRECTIONS FOR USE

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

General Use Statement

Steriplex HC™ is formulated as Part A of a two-part system and therefore must not be used alone as a disinfectant or as a sterilant. Activate Steriplex HC™ prior to use by, combining Steriplex HC™ Solution Part A, with the Steriplex HC™ Activator Solution Part B (enclosed), into the one-gallon container as instructed below.

Preparation for Steriplex HC™, two-part disinfectant or sterilant system:

Part A (Steriplex HC™ Solution Part A): Main ingredient of one (1) gallon container, and

Part B (Steriplex HC™ Activator Solution Part B): Small 4 oz inside of gallon container.

1. Using appropriate personal protective equipment (PPE), obtain the Steriplex HC™ Activator Solution Part B with protective seal under the large child protective cap. Remove the smaller cap on the main container, as well, to expose the opening with threaded insert.
2. Screw the Steriplex HC™ Activator Solution Part B container fully into the threaded insert, breaking the seal and emptying the contents into the container. **WITH ACTIVATOR BOTTLE STILL ATTACHED**, shake the container to release entire contents.
3. Safely remove and discard the spent Steriplex HC™ Activator Solution Part B container in an approved waste disposal receptacle as directed (see below). Replace both caps back onto the main container.
4. Thoroughly mix the combined solution for approximately 15 seconds.

Application Methods – For use on Hard, Non-Porous, Non-Food Contact Surfaces

Steriplex HC™ 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 HC™ mixture.

Once Part A and Part B are mixed, the mixed solution can only be used as a sporicide for 10 days and as a disinfectant for 40 days. Dispose of any solution that has exceeded these timeframes after activation.

(Note to Reviewer: Language in () is optional or interchangeable)

Cleaning and Deodorization Directions – Pre-clean surfaces prior to application of the activated product.

1. Apply a generous amount of the mixed solution using a cloth, mop or spray device so as to thoroughly wet the surface to be cleaned.
2. Allow surfaces to remain wet for 30 seconds.
3. For clean up, rinse the surface(s) with clean cloth or sponge several times with potable water.
4. Prepare a fresh solution when it becomes visibly dirty or diluted.

General Use Disinfecting Directions

As a Disinfectant – Pre-clean surfaces prior to application of the activated product.

1. Thoroughly apply the solution to the target surface(s) using a prescribed method, covering the surface(s), until wet, of product at room temperature.
2. The product must remain wet on the surface(s) for 5 minutes.
3. For clean up, rinse the surface(s) with a clean cloth or sponge several times with potable water.

As a Tuberculocide – Pre-clean surfaces prior to application of the activated product.

1. Thoroughly apply the solution to the target surface(s) using a prescribed method, covering the surface(s), until wet, of product at room temperature.
2. The product must remain wet on the surface(s) for 15 minutes.
3. For clean up, rinse the surface(s) with a clean cloth or sponge several times with potable water.

Application Methods – For use with non-electrical or non-critical/semi-critical Medical Devices

As a Sporicide (Sterilant) – Pre-clean equipment surfaces prior to immersing equipment. Dismantle devices prior to pre-cleaning, if necessary.

1. Pour desired amount of solution into a tray or receptacle that will hold the targeted items and allow for complete immersion in solution.
2. Immerse equipment or targeted items for a minimum of 180 minutes.
3. Transfer equipment or targeted items to a rinse bath to remove the solution. Dipping them a couple of times into the rinse bath will thoroughly remove any solution.
4. Place on a clean surface to allow items to air dry prior to reuse.

(Note to Reviewer: Language in () is optional or interchangeable)

As a Disinfectant – Pre-clean equipment surfaces prior to immersing equipment.
Dismantle devices prior to pre-cleaning, if necessary.

1. Pour desired amount of solution into a tray or receptacle that will hold the targeted items and allow for complete immersion in solution.
2. Immerse equipment or targeted items for a minimum of 5 minutes.
3. Transfer equipment or targeted items to a rinse bath to remove the solution.
Dipping them a couple of times into the rinse bath will thoroughly remove any solution.
4. Place on a clean surface to allow items to air dry prior to reuse.

As a Tuberculocide – Pre-clean equipment surfaces prior to immersing equipment.
Dismantle devices prior to pre-cleaning, if necessary.

1. Pour desired amount of solution into a tray or receptacle that will hold the targeted items and allow for complete immersion in solution.
2. Immerse equipment or targeted items for a minimum of 15 minutes.
3. Transfer equipment or targeted items to a rinse bath to remove the solution.
Dipping them a couple of times into the rinse bath will thoroughly remove any solution.
4. Place on a clean surface to allow items to air dry prior to reuse.

NOTE: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

(Note to Reviewer: Language in () is optional or interchangeable)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION - Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear protective eyewear. 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.

PHYSICAL OR CHEMICAL EFFECTS

Minimal corrosion effects may occur with natural rubber and soft iron products. Stainless steels, plastics and polymers exhibit no corrosive effects. Never bring mixture in contact with other sanitizers, cleaners or organic substances. This product is not flammable or explosive.

ENVIRONMENTAL EFFECTS

This product is toxic to fish and aquatic organisms. 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID FOR MIXED STERIPLEX HC™ MIXTURE	
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.
Have the product container with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

(Note to Reviewer: Language in () is optional or interchangeable)

STORAGE AND DISPOSAL

Storage

Do not store near reducing agents, fuels or other non-compatible material. Store in a dark, cool, dry, well-ventilated area. For quality purposes, avoid storing in temperatures above 86°F. Do not store in direct sunlight. Do not double stack pallets. Use first in, first out storage system.

Container Disposal and Pesticide Residue Removal

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 caps.

Lot Number:

Not for sale or use after:

sBioMED™

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

(Note to Reviewer: Language in () is optional or interchangeable)