

84545-4

3/4/2010

1/9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Erin Tesch
Regulatory Consultant for,
Technology Sciences Group, Inc.
c/o SBioMed, LLC
1150 18th Street, N W
Suite 1000
Washington, DC 20036

MAR - 4 2010

Subject: Steriplex HC Solution Part A
EPA Registration Number 84545-4
Your Amendment Dated December 4th, 2009
EPA Received Date December 4th, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add an alternate directions for use, is acceptable.

A copy of the stamped labeling is enclosed.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script, which appears to read "M. Swindell", is written over the typed name.

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

2/9

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)

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAR - 4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 84545-4

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

ACCEPTED on hard non-porous, non-food contact surfaces:
with COMMENTS

EPA Letter Dated: As a Sporicide: *Bacillus subtilus*
Clostridium sporogenes

MAR - 4 2010

Under the Federal Insecticide,
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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).

ACCEPTED
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EPA Letter Dated:

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Under the Federal Insecticide,
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registered under EPA Reg. No. 8 4545-4

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DIRECTIONS FOR USE

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

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 a one-gallon container] [, into a 5-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.

OR

{for packaging when Part B container is not physically located inside of Part A container}

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

Part A (Steriplex HC™ Solution Part A): Main ingredient of five (5) gallon container, and

Part B (Steriplex HC™ Activator Solution Part B): 12 oz container.

1. Using appropriate personal protective equipment (PPE), remove the cap on the Steriplex HC™ Solution Part A container to expose the opening.
2. Obtain the Steriplex HC™ Activator Solution Part B and remove the child protective cap. CAREFULLY pour the Steriplex HC™ Activator Solution Part B into the main container and shake small bottle to release entire contents.
3. Replace cap and safely discard the spent Steriplex HC™ Activator Solution Part B container in an approved waste disposal receptacle as directed (see below). Replace the cap on the main container.

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84545-4

- 9/6
4. Thoroughly mix the combined solution for approximately 15 seconds.

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

Steriplex HCTM 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 HCTM 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.

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.

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.

ACCEPTED
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EPA Letter Dated:

MAR - 4 2010

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Steriplex HCTM Solution Part A
Amend directions for use, 12-4-09

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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84545-4

7/9

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.

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.

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Steriplex HCT™ Solution Part A
Amend directions for use, 12-4-09

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EPA Letter Dated:
MAR - 4 2010
Under the Federal Insecticide,
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815

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	

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EPA Letter Dated:
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Under the Federal Insecticide,
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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

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