

84545-4

07-28-2010

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

JUL 28 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

sBioMed, LLC
1272 South 1380 W
Orem, Utah 84058

Attention: Erin Tesch
Regulatory Consultant

Subject: PeraDox HC Activator Solution Part B
EPA Reg. No. 84545-4
Notification Letter Dated July 6, 2010
Application Dated July 6, 2010

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:

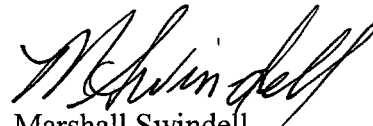
- The Agency rejects the following proposed label changes:
 - Addition of the Alternate Brand Name Steriplex Health Care (Par A). Statements that imply or suggest that the product can or will prevent or control disease or offer health protections are unacceptable.
 - The term "New!" stated to be used for 6 months after commercial introduction must be removed from the label per 40 CFR 156.10 (a)(5)(i). This product was introduced commercially under an alternate name more than 6 months ago and so cannot contain the optional marketing language "New!"
 - The phrase "Achieve FAST, broad-spectrum PATHOGEN KILL*" must be rewritten. The asterisk refers to wording on the back panel and thus it may not be obvious to the consumer which pathogens the product targets. Either the phrase attached to the asterisk must be moved to the same side of the label as the asterisk, or the phrase "Kills pathogens as listed below (or as listed on the label)" must be added to the label.
- The Agency accepts the following proposed label changes:
 - Formatting changes found on page 1.
 - Addition of the following phrases found on page 1 to the label: "Activate prior to use. Read this entire label and attached insert carefully"; See attached insert for additional precautionary statements"; Read attached insert for complete Directions for Use."
 - Addition of 68°F on page 2.

- Addition of the following phrases on pages 3 and 4 are acceptable. "Mixed solution," "General Uses: Steriplex HC mixed solution is effective on non-porous hard surfaces." "Homes Uses: Steriplex HC mixed solution...Laundry Room Surfaces..." "Appliance Uses: (Steriplex HC mixed solution can be used on)... mobile phones...computer mouse..." And "mixed solution" under the subheading Nursery Uses, Medical Industry Uses, and General Surfaces Uses.
- Addition of the statement "Steriplex HC Part A is formulated as one component" under the heading Use Statement on page 5. Also the phrases "Included" and "See attached insert for complete directions for use" under the heading Use Statement.
- Addition of the phrases "mixed solution" under Application Methods on page 6. On page 6, addition of the phrase "Mark the date that the solution was mixed on the container with a permanent marker in the space provided."
- Addition of the term "Mix Date: on page 9.

The Notification is in compliance with PR Notice 2007-4 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 (7510C)



United States
Environmental Protection Agency
Washington, DC 20460

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

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

The alternate brand name of the product has been added as "Steriplex Health Care™ (Part A)" 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:					
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	2. Type of Container <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"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

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 <i>Erin M Tesch</i>		3. Title Regulatory Consultant to sBioMed, LLC	
4. Typed Name Erin M. Tesch		5. Date 07/06/10	



TECHNOLOGY
SCIENCES
GROUP
INC

WASHINGTON

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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

July 6, 2010

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

**RE: sBioMed, LLC: PeraDox 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 add an alternate brand name to “Steriplex Health Care™ (Part A)” as well as reorganize some of the marketing statements. It is important to note that the four marketing statements included on page two of the enclosed label are not new statements, but have been previously approved by EPA in other sections of the current approved label.

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@tsqusa.com.

Sincerely,

Grin MTesch

Erin M. Tesch
Regulatory Agent for sBioMed, LLC

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>

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Steriplex HC™ Solution Part A

Alternate Brand Name: STERIPLEX ~~HEATSTAB-SOL~~™ (PART A)

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BEFORE USING THIS PRODUCT, READ THIS ENTIRE LABEL CAREFULLY

Formatted: Indent: First line:

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**

**[ACTIVATE PRIOR TO USE.] [READ THIS ENTIRE LABEL AND ATTACHED
INSERT CAREFULLY.]**

[SEE ATTACHED INSERT FOR ADDITIONAL PRECAUTIONARY STATEMENTS]

[REFER TO SIDE PANEL FOR COMPLETE ACTIVATION INSTRUCTIONS.]

[READ ATTACHED INSERT FOR COMPLETE DIRECTIONS FOR USE]

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

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

Net Contents: (as indicated on Container)

sBioMED™

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

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

Questions? Comments?
Call 1.888.234.6142
Or visit www.sbiomed.com

- ~~New! (1-1-16) (General Purpose Disinfectant)~~
- BROAD-SPECTRUM STERILANT
- A PROVEN SPORICIDAL DISINFECTANT
- Achieve FAST, broad-spectrum PATHOGEN KILL ✕
- STERIPLEX HC Mixed Solution is an effective sporicide on hard, non-porous surfaces within the medical industry.
- 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 subtilis*, *Clostridium sporogenes*, *Mycobacterium* (at 20° C), *Pseudomonas aeruginosa*, *Salmonella enterica*, and *Staphylococcus aureus*.
- << Back Panel >> Kills *Bacillus subtilis*, *Clostridium sporogenes*, *Mycobacterium* (at 20°C) (at 68°F), *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 subtilis*
 Clostridium sporogenes

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

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

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- Steriplex HC™ mixed solution 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.
- General Uses: Steriplex HC™ mixed solution is effective 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).
- Home uses: Steriplex HC™ mixed solution 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). (Laundry Room Surfaces), Bathroom (counter tops), (tubs), (showers), (glazed tiles), (toilet surfaces), (walls), (floors), (hampers), (diaper pails), (scales), (mirrors), (door knobs), (handles), and (faucet fixtures).
- Appliance Uses: (Steriplex HC™ mixed solution can be used on) Use on (appliances), (telephones), (cell phones), (mobile phones) (light switch covers), (computer keyboards), (computer mouse) and (remote controls).
- Nursery Uses: Steriplex HC™ mixed solution 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).
- Medical Industry Uses: Steriplex HC™ mixed solution 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),

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

(health clubs), (salons), (schools and school medical facilities), (school buses), and (day care).

- General Surface Uses: Steriplex HC™™ mixed solution 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.

Use Statement

Steriplex HC™ ~~Part A~~ is formulated as ~~Part A~~ one component 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-) [included] [, into a one-gallon container] [, into a 5-gallon container] as instructed below. [See attached insert for complete directions for use.]

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.

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

4. Thoroughly mix the combined solution for approximately 15 seconds.

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

Steriplex HCTM mixed solution 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 [mixed solution].

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. [Mark the date that the solution was mixed on the container with a permanent marker in the space provided.]

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.

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

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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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**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)

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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.

[Mix Date:]

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)