

84545-5

10/13/2010

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



Office of Pesticide Programs

OCT 13 2010

sBioMed, LLc
1272 South 1380 W
Orem, Utah
84058

Attention: Erin M. Tesch

Subject: PeraDox HC Activator Solution Part B
EPA Registration No: 84545-5
Notification Dated September 23, 2010

This will acknowledge receipt of your notification for the following additional alternate brand names, submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following comments apply

ADDITIONAL BRAND NAME

“STERIPLEX HC ACTIVATOR (PART B)”

General Comments

The Notification is in compliance with PR Notice 98-10 and is acceptable. A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please feel free to contact Zebora Johnson at (703) 308-7080.

Sincerely

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell
Product Manger (33)
Regulatory Management Branch I
Antimicrobial's Division (7501P)



United States
Environmental Protection Agency
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 84545-5	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PeraDox HC Activator Solution Part B	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. <u>54289-4</u> Product Name <u>Peraclean 15</u>	

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 HC Activator (Part B)" 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 type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 oz, 12 oz		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 	3. Title Regulatory Consultant to sBioMed, LLC	
4. Typed Name Erin M. Tesch	5. Date 09/23/2010	

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Steriplex HC Activator™ (Part B)

(Peroxyacetic Acid Solution)

[Alternate Brand Name: Steriplex HC™ Activator Solution Part B]

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.

OR:

Steriplex HC Activator (Part B) is one component of a two-part system and therefore must not be used alone as a Disinfectant or Sterilant. When combined with Part A, the Steriplex HC Mixed Solution creates an effective Sterilant/Sporicide, Tuberculocide and Bactericide.

ACTIVE INGREDIENTS:

Hydrogen Peroxide.....	22.00 %
Peroxyacetic Acid.....	15.00%
Inert Ingredients.....	63.00%
Total.....	100.00%

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

OCT 13 2010

DANGER

KEEP OUT OF REACH OF CHILDREN

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 84545-5
READ ENTIRE PANEL [AND INSERT] FOR [DIRECTIONS FOR USE AND] ADDITIONAL

PRECAUTIONARY STATEMENTS

[Activate Steriplex HC prior to use by combining Steriplex HC Activator (Part B) with Steriplex HC (PartA) (as instructed in the insert)].

E.P.A. Reg. No. 84545-5

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

Net Contents: (as indicated on Container)

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

ACCEPTED
with COMMENTS
EPA Letter Dated:
OCT 13 2010



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

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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[Note to Reviewer: The following is considered optional marketing language]

- Steriplex HC™ is a two part system, when Part A (Steriplex HC™ (Part A)) and Part B (Steriplex HC Activator™ (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*.
- 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™ mixed solution is a broad spectrum Sporicide (Disinfectant)(Sterilant) (Antibacterial)(and)(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

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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).
- **[Applicance Uses.** Steriplex HC™ mixed solution can be used] [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), (health clubs), (salons), (schools and school medical facilities), (school buses), and (day care).
- **General Surfaces 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).

ACCEPTED
with COMMENTS
EPA Letter Dated:
OCT 13 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
84545-5

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

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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 Activator™ (Part B) is (formulated as) 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™ (Part A), with the Steriplex HC Activator™ (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™ (Part A)): Main portion of one (1) gallon container, and

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

1. Using appropriate personal protective equipment (PPE), obtain the Steriplex HC Activator™ (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™ (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™ (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.

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EPA Letter Dated:

OR

OCT 13 2010

{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™ (Part A)): Main ingredient of five (5) gallon container, and

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 84545-5

1. Using appropriate personal protective equipment (PPE), remove the cap on the Steriplex HC™ (Part A) container to expose the opening.
2. Obtain the Steriplex HC™ Activator (Part B) and remove the child protective cap. CAREFULLY pour the Steriplex HC™ Activator (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 (Part B) container in an approved waste disposal receptacle as directed (see below). Replace the cap on the main container.

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

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

Steriplex HC™ 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 HC™ [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 a clean cloth or sponge several times with potable water.
4. Prepare a fresh solution when it becomes visibly dirty or diluted.

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with COMMENTS
EPA Letter Dated:

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. Allow the product to remain on the surface(s) to dry or for 5 minutes.
3. For clean up, rinse the surface(s) with a clean cloth or sponge several times with potable water.

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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. Allow the product to remain on the surface(s) to dry or 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)

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. 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. Allow the product to remain on the surface(s) to dry or for 15 minutes.
3. For clean up, rinse the surface(s) with a clean cloth or sponge several times with potable water.
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 (1) is introduced directly into the human body, either into or in contact with the human body, 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 FOR STERIPLEX HC ACTIVATOR™ ONLY

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL EFFECTS

STRONG OXIDIZING AGENT. Corrosive. Mix only with Steriplex™ disinfectant solutions. Product must be diluted in accordance with label directions prior to use. STERIPLEX HC ACTIVATOR (Part B) is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

ENVIRONMENTAL EFFECTS

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. 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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the US Environmental Protection Agency.

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

OCT 13 2010

Under the Federal Insecticide,
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FIRST AID FOR STERIPLEX HC ACTIVATOR™ SOLUTION ONLY

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 do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call poison control center or doctor for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	
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	

Personal Protective Equipment (PPE)

User Safety

Some active ingredients of this product can cause eye damage or skin irritation. Prolonged exposure to spray mist or vapor may cause allergic reactions to some individuals. User should wash hands before eating, drinking, or using the toilet. User should be familiar with prescribed safety and usage instructions prior to using this product.

Eyes and Face

Use cup type chemical goggles. Full-face shield should be used when mixing and applying this product to the intended surfaces.

Protective Clothing

Use of rubber or neoprene footwear is recommended. Rubber or neoprene apron and protective clothing should be used. Hydrogen peroxide is an ingredient of this product. Completely submerge hydrogen peroxide contaminated clothing or other materials prior to drying. Residual hydrogen peroxide, if allowed to dry on materials such as fabrics, cotton, leather, wood, paper, or other combustibles can cause the material to ignite and result in a fire.

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84546-5

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Gloves

Rubber or neoprene gloves are recommended when mixing and applying product. Thoroughly wash the outside of gloves with soap and water prior to removal. Inspect regularly for leaks.

Respiratory

For normal use as directed, respiratory protection is not required. However, if exposures are anticipated to be above normal limits or 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, the use of a self-contained breathing apparatus (SCBA) is recommended.

STORAGE AND DISPOSAL

Storage

Never return Steriplex HC™ Activator (Part B) to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute Steriplex HC™ Activator (Part B) with large volumes of water. Avoid damage to container. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86 °F. Do not store on wooden pallets.

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Container Disposal and Pesticide Residue Removal

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

84545-5

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. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. Steriplex Activator, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal

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

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seconds after the flow begins to drip. Repeat this procedure two more times, and then discard container and cap.

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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