| 5-5  | <u></u>  |   |  |  |
|--|--|---|--|--|
| 3 <sup>100</sup> 10 <sup>-5</sup> 14 <sub>16</sub>   | U.S. ENVIRONMENTAL PROTECTION<br>AGENCY  | EPA Reg.<br>Number:   | Date of<br>Issuance:   |  |
| A PROTICING  | Office of Pesticide Programs<br>Antimicrobials Division (7510P)  | 84545-5   | NOV 0 2 200  |  |
|  | 1200 Pennsylvania Avenue NW<br>Washington, D.C. 20460  | Term of Issua   | ince:  |  |
|  |  | Conditional   |  |  |
|  | NOTICE OF PESTICIDE :  | Name of Pesti   | .cide Product:   |  |
|  | x Registration   | PeraDox H   | HC Activator   |  |
|  | Reregistration   | Solution  | Part B   |  |
| (under FIFRA,  | as amended)  |   |  |  |
| Name and Addre   | ss of Registrant (include ZIP Code):   |   |  |  |
| Erin Tesch   |  |   |  |  |
|  | ence Group, Inc.   |   |  |  |
| Agent for SBIO   | MED<br>et, NW Ste. 1000  |   |  |  |
| Washington, DC   | ·  |   |  |  |
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Page 2 EPA Reg. No. 84545-5

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

Marshall Swindell

Product Manager Team-33 Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

# PeraDox HC Activator<sup>™</sup> Solution Part B

(Peroxyacetic Acid Solution)

#### BEFORE USING THIS PRODUCT, READ THIS ENTIRE LABEL CAREFULLY

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

#### **ACTIVE INGREDIENTS:**

| Hydrogen Peroxide | 22.00 % |
|-------------------|---------|
| Peroxyacetic Acid |         |
| Inert Ingredients |         |
| Total             |         |

# DANGER

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

E.P.A. Reg. No. 8454

84545-

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

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#### [Note to Reviewer: The following is considered optional marketing language]

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

| As a Sporicide:     | Bacillus subtillus<br>Clostridium sporogenes  |
|---------------------|---|
| As a Tuberculocide: | Mycobacterium (Tuberculosis) (at NOR) 0 2 2009<br>House the Redenil Insecticide,<br>Received, and Received Access                                   |
| As a Bactericide:   | Pseudomonas aeruginosa (Pseudomonasha pesicide,<br>Salmonella enterica (Salmone Majeured wider SPA Reg. No<br>Staphylococcus aureus (Staph) 84545-5 |

- PeraDox HC<sup>™</sup> is a broad spectrum Sporicide (Disinfectant)(Sterilant) (Antibacterial)(Deodorizer), proven to kill (destroy)(eliminate)(deodorize) Bacillus subtillus, 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).
- PeraDox HC<sup>™</sup> has been formulated to effectively destroy
  (kill)(eliminate)(deodorize) Bacillus subtillus, 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).
- Use on (appliances), (telephones), (cell phones), (light switch covers), (computer keyboards), and (remote controls).

- PeraDox HC<sup>™</sup> 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).
- PeraDox HC<sup>™</sup> 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).
- PeraDox HC<sup>™</sup> 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).

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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

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

#### Preparation for PeraDox HC<sup>TM</sup>, two-part disinfectant or sterilant system:

Part A (PeraDox HC<sup>™</sup> Solution Part A): Main portion of one (1) gallon container, and

Part B (PeraDox HC Activator <sup>™</sup> Solution Part B): Small 4 oz inside of gallon container.

- Using appropriate personal protective equipment (PPE), obtain the PeraDox HC Activator <sup>™</sup> 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.
- Screw the PeraDox HC Activator <sup>™</sup> 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 PeraDox HC Activator <sup>™</sup> 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 PeraDox HC<sup>™</sup> 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 PeraDox HC<sup>TM</sup> mixture.

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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)

PeraDox HC Activator<sup>™</sup> Solution Part B

**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.

#### **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.

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.

# 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 CORRENTS

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

PeraDox HC Activator™ Solution Part B

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 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 FOR PERADOX 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 PeraDox<sup>™</sup> disinfectant solutions. Product must be diluted in accordance with label directions prior to use. PERADOX HC ACTIVATOR Solution 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.

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| FIRST AID FOR<br>PERADOX HC ACTIVATOR™<br>SOLUTION ONLY |  |  |
|---|--|--|
|   |  |  |
| IF ON SKIN OR<br>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<br>vomiting unless told to do so by a poison control center or doctor. Do<br>not give anything by mouth to an unconscious person. Call poison<br>control center or doctor for treatment advice. |  |
| IF INHALED  | Move person to fresh air. If person is not breathing, call 911 or an<br>ambulance, then give artificial respiration, preferably by mouth-to-<br>mouth, if possible. Call a poison control center or doctor for further<br>treatment advice.                        |  |
|   | bable mucosal damage may contraindicate the use of gastric lavage.   |  |
|   | iner with you when calling a poison control center or going for treatment.<br>MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222   |  |

Personal Protective Equipment (PPE)

#### **User Safety**

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Some active ingredients of this product can cause eye damage or skin fritation brother and some active and some individuals placed are exposure to spray mist or vapor may cause allergic reactions to some individuals placed are should wash hands before eating, drinking, or using the toilet. User should be familiar 87545-5 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 aprons or full protective clothing should be used. Hydrogen peroxide is an ingredient of this product. Completely submerge hydrogen peroxide contaminated clothing or other materials in water 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.

#### 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 (CBA) is recommended.

#### STORAGE AND DISPOSAL

#### Storage

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Never return PeraDox HC<sup>TM</sup> Activator Part B to the original container after it has been 84545-5 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 ox PeraDox HC<sup>TM</sup> Activator Part B with large volumes of water. Avoid damage to containers. 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.

#### **Container Disposal and Pesticide Residue Removal**

#### **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. PeraDox 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 <sup>1</sup>/<sub>4</sub> 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 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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(Note to Reviewer: Language in () is optional or interchangeable)

PeraDox HC Activator™ Solution Part B