

84545-4

02/03/2012

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

sBioMed, LLC  
1272 South 1380 W  
Orem, Utah 84058

FEB -3 2012

Attention: Erin Tesch, Regulatory Consultant  
Technology Sciences Group, Inc.

Subject: PeraDox HC Solution Part A  
EPA Reg. No. 84545-4  
Notification Application Dated January 4, 2012

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 accepts the following proposed label change:
  - Clarification of the term "*Mycobacterium*" to read "*Mycobacterium bovis*". This change provides clarification as to the specific *Mycobacterium* species that is supported by the efficacy data submitted and approved by the Agency.

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,

A handwritten signature in black ink that reads "M Swindell".

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



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 84545-4	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.)  
 A clarification to the name of a test organism has been added pursuant to a 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 type="checkbox"/> Metal	<input checked="" 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
<b>Certification</b> 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 <b>(Stamped)</b>
2. Signature 	3. Title Regulatory Consultant to sBioMed, LLC	
4. Typed Name Erin M. Tesch	5. Date 1/4/12	

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**Technology Sciences Group Inc.**

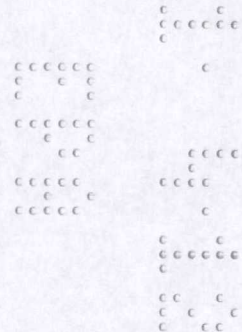
1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, D.C. 20036  
Direct: (202) 828-8966  
Fax: (202) 872-0745  
E-Mail: etesch@tsgusa.com

**Erin M. Tesch**  
Director, Eastern Division

January 4, 2012

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

RE: sBioMed, LLC: PeraDox HC Activator 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 name of the test organism "*Mycobacterium bovis*" on the label. The current label indicates the test organism as "*Mycobacterium*" only. The California Department of Pesticide Registration has requested that "*bovis*" be identified on the label as the specific *Mycobacterium* species that is supported by the efficacy data submitted and approved by the Agency.

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.



# Steriplex HC™ (Part A)

Alternate Brand Name: 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 INGREDIENT:**

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]

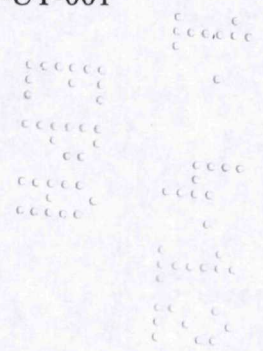
E.P.A. Reg. No. 84545-4

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

Net Contents: (as indicated on Container)

**sBIO MED™**

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



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

**Questions? Comments?**

**Call 1.888.234.6142**

**Or visit [www.sbiomed.com](http://www.sbiomed.com)**

- BROAD-SPECTRUM STERILANT
- A PROVEN SPORICIDAL DISINFECTANT
- 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™ (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 bovis* (at 20° C), *Pseudomonas aeruginosa*, *Salmonella enterica*, and *Staphylococcus aureus*.
- << Back Panel>> Achieve FAST, broad-spectrum PATHOGEN KILL\*
- << Back Panel>> \*Kills *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium bovis* (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 subtilus*  
*Clostridium sporogenes*

As a Tuberculocide: *Mycobacterium bovis* (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) (Deodorizer), proven to kill (destroy)(eliminate) (deodorize) *Bacillus subtilus*, *Clostridium sporogenes*, *Mycobacterium bovis* (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

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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 subtilis*, *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), (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 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) [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™ (Part A)):** Main ingredient of one (1) gallon container, and

**Part B (Steriplex HC™ Activator (Part B)):** Small bottle (containing 2.2 oz of product) 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.

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

**Part B (Steriplex HC™ Activator (Part B)):** Small bottle (containing 11 oz of product).

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.

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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.
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 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.

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

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.

**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.

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This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

**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.

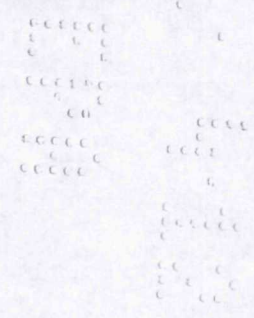
**PHYSICAL OR CHEMICAL EFFECTS**

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.

<b>FIRST AID FOR MIXED STERIPLEX HC™ MIXTURE</b>	
<b>IF IN EYES</b>	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.
<b>IF ON SKIN OR CLOTHING</b>	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.	
<b>FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222</b>	



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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.

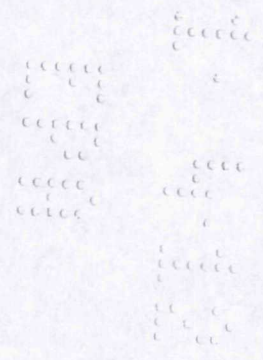
**[Mix Date:]**

**Lot Number:**

**Not for sale or use after:**



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



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