

1043-124

06/29/2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 1043-124

Date of Issuance: JUN 29 2010

Term of Issuance: Conditional

Name of Pesticide Product: HASTe-SSD Component B

NOTICE OF PESTICIDE:

[x] Registration
[ ] Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Steris Corporation
7501 Page Avenue
St Louis, MO 63133

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No." 1-43-124".

Signature of Approving Official:

[Handwritten signature of Marshall Swindell]

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

Date:

JUN 29 2010

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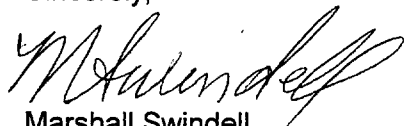
3. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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.

If you have any questions concerning this Notice of Registration, please contact Martha Terry at (703) 308-6217.

Sincerely,



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

Enclosure: (Stamped Label)

# HASTE-SSD-Component B

For Use Only with HASTE-SSD - Component A

Use this product on washable, hard, non-porous environmental surfaces: floors, walls, counters in healthcare facilities, hospitals, medical and dental offices.

One Step Cleaner Disinfectant

Sterilant/Sporicidal, Bactericidal, Tuberculocidal, Fungicidal, \*Virucidal

**Active Ingredients:**

Hydrogen Peroxide 1.00%

**Inert Ingredients:** 99.00%

**Total** 100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

See side panel for precautionary statements

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
IF ON SKIN OR ON CLOTHING	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment.</li> </ul>
IF SWALLOWED	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
<p align="center"><b>HOT LINE NUMBER</b></p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chemtrec at 800-424-9300 for emergency medical treatment information.</p>	

**NET CONTENTS:**

STERIS Corporation  
7501 Page Avenue  
St. Louis, MO 63133 U.S.A.

EPA Reg. No. 1043-<sup>124</sup>~~XXX~~ EPA Est. No.

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amended, for the pesticide,  
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### PRECAUTIONARY STATEMENTS

**Hazard to Humans and Domestic Animals: CAUTION:** Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash hands before reuse.

**For the end use solution,** causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or mist. Use in a well-ventilated area. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash hands before reuse.

#### Physical and Chemical Hazards

This product contains an oxidizing agent.

PRODUCT CLAIMS	
Sterilant/Sporicidal [ <i>B. subtilis</i> (ATCC 19659), <i>C. sporogenes</i> (ATCC 3584)]	1 hour 20°C
Mouse parvovirus (Isolate, Yale University) in the presence of 5% organic soil	10 minutes 20°C
<i>Clostridium difficile</i> spores (ATCC 43599) in the presence of 5% organic soil	5 minutes 20°C
Hospital Disinfectant [ <i>S. aureus</i> (ATCC 6538), <i>S. enterica</i> (ATCC 10708), <i>Ps. aeruginosa</i> (ATCC 15442)] in the presence of 5% organic soil	2 minutes 20°C
The following organisms were all tested in the presence of 5% organic soil: Tuberculocidal ( <i>Mycobacterium bovis</i> BCG) (Clinical Isolate) *HIV-1 (Clinical Isolate) <i>Tricophyton mentagrophytes</i> (ATCC 9533) <i>Candida albicans</i> (ATCC 10231) MRSA (ATCC 33591) VRE (ATCC 51299) ESBL (ATCC ) <i>Klebisella pneumoniae</i> (ATCC ) <i>Acinetobacter baumannii</i> (ATCC 19606)	1 minute 20°C

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**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Store in original closed container.

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site in a sanitary sewer or at an approved waste disposal facility. 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.

Container Disposal

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

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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.

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**Preparation of End-Use Product:** Component A and Component B are mixed together to create an end-use solution containing approximately 0.085% peroxyacetic acid and 1.0% hydrogen peroxide.

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To activate the end-use solution, tear open the protective pouch of Component A and remove the activator dose pack. Open Component B and insert the dose pack into bottle, then recap and seal tightly. Shake thoroughly and let sit for 10 minutes to allow reaction to occur. Apply per directions.

Prepare daily a fresh end-use dilution. As solution becomes dirty, discard and replace with new end-use solution.

**DIRECTIONS FOR STERILIZATION:** This product is not to be used as a terminal sterilant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Immerse the item to be sterilized in a sufficient volume of undiluted product to cover the item and fill all passages requiring sterilization. Hold in the sterilizing solution for a minimum of 1 hour at 20°C temperature (68°F). Remove items after 1 hour and rinse with deionized water.

**Clostridium difficile: Use only on hard, non-porous surfaces.**

**Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

**Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or

sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

**Contact Time:** Leave surfaces wet with undiluted product for a minimum of 5 minutes.

**Mycobacterium tuberculosis BCG:** Remove any obvious debris or organic material from the surface to be treated. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Apply product to hard, non-porous surfaces, thoroughly wetting surfaces with a clean cloth, mop, sponge, or by immersion. Treated surfaces must remain wet for 1 minute. Wipe dry with a cloth, sponge or mop or allow to air dry.

**DIRECTIONS FOR One-Step Cleaner Disinfection, Hospital Disinfection and as a Fungicide:** For disinfection of items such as external surfaces of medical equipment, counters, bathroom fixtures, etc. Remove any obvious debris or organic material from the surface to be treated. Apply product to hard, non-porous surfaces, thoroughly wetting surfaces with a clean cloth, mop, sponge or by immersion. Treated surfaces must remain wet for 2 minutes. Wipe dry with a clean cloth, sponge or mop or allow to air dry. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**USES**

Primarily intended for sterilization, or disinfection of:

High-Touch Hard, Non-porous Surfaces such as bedrails, doorknobs, bathroom fixtures, toilet handle, toilet seat, Floors, and Walls

Can be used on the following materials: Stainless Steel, Plastic Items and surfaces, Glass, Formica, Vinyl

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