

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 4 2005

Steri Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Attention: Michael G. Sarli
Senior Regulatory Specialist

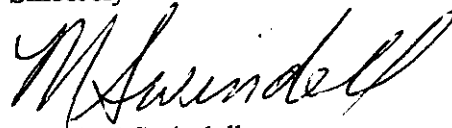
Subject: Steris 20
EPA Registration No. 58779-1
Your Notification Dated July 7, 2005

This will acknowledge receipt of your notification to reflect a change in the brand name to "Steris LW/SW Master", submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10, and is acceptable. This information has been made a part of your file.

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

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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STERIS®



January 28, 2005

Document Processing Desk (RED-RD-PM33)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501
Attn: Mr. Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510C)

**Subject: Peroxy Compounds RED STERIS 20 (EPA Reg. No. 58779-1), Your Letter of 12/8/04
Change in Brand Name to STERIS LW/SW Master**

Dear Mr. Swindell:

Enclosed please find five copies of labeling revised as per your directives of December 8, 2004.

Also enclosed are five copies of labeling reflecting a change in brand name to "STERIS LW/SW Master." The product STERIS 20 is a medical device sterilant and STERIS LW and STERIS SW were additional brand names. Since STERIS 20 as a medical device sterilant is regulated exclusively by the FDA while the STERIS LW and STERIS SW continue to be regulated by the EPA, we request the change in brand name.

If you have any questions, I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Sr. Regulatory Specialist

Enclosures

STERIS® STERIS LW/SW Master

DECONTAMINANT • SANITIZER • GERMICIDE

Catalog Number: Net Contents:

ACTIVE INGREDIENT:
Peroxyacetic acid 35%
INERT INGREDIENTS: 65%
TOTAL: 100%

**KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO**

[Skull & Crossbones]

SEE PRECAUTIONARY STATEMENT ON SIDE
PANEL

FIRST AID	
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, then continue rinsing. Call a 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 mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment.
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 14-20 minutes. Call a poison control center or doctor for treatment.
HOT LINE NUMBER	
For additional information in case of emergency call toll free 800-548-4873. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, or convulsions may be needed.	

Manufactured by:
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 U.S.A.
800-JIT-4-USE (800-548-4873)

This is a single-use chemical decontaminant concentrate validated for use in the EcoCycle 10® Processor. This product is suited to the decontamination of liquid (< 1,000 ml blood content) and dry medical waste such as needles, sharps, glassware, laboratory wastes, specimens, cultures, and other biohazardous materials - recommended for use in hospitals, medical/surgical/dental clinics or offices, laboratories, and biomedical research facilities.

[This product is a single-use chemical decontamination concentrate validated for use in the EcoCycle 10® Processor. This product is suited to the decontamination of dry medical (<100 ml blood content) waste such as needles, sharps, glassware, laboratory wastes, and other biohazardous materials -recommended for use in hospitals, medical/surgical/dental clinics or offices, laboratories, and biomedical research facilities.]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage or skin burns. Fatal if absorbed through skin. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing vapors Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

- Handlers must wear:
- Coveralls over long-sleeved shirt and long pants
- Socks and chemical resistant footwear
- Goggles or face shield
- Chemical-resistant gloves (Such as barrier laminate, butyl rubber, nitrile rubber)

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. IF no such instructions are available, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

User Safety Recommendations

User should wash hands before eating, drinking, chewing gum using tobacco or using the toilet. User should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. User should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly.

Environmental Hazards

Do not discharge effluent containing these products into lakes, streams, ponds, estuaries, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing these products to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency.

Physical or Chemical Hazards

Combustible. Do not use or store near heat or open flames. The dry component must be used only with liquid peroxyacetic acid component of this product.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Use this product only with EcoCycle 10 Processor. Place in a sealed container of this product into the processing chamber prior to cycle start. Follow the operating instructions located in the EcoCycle 10 Operator Manual. Do not attempt to manually open the container.

See the EcoCycle 10 Operator Manual for a comprehensive listing of processing capability.

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 bloodstream or normally sterile areas of the body, or 2) contacts intact mucous membranes but which does not ordinarily 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.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place. Avoid exposure to extreme conditions such as heat, moisture, sunlight, or contaminated substances.

Pesticide Disposal: Dispose of spent container in proper receptacle. Dispose of leaking/damaged containers by submerging the container in a water-filled sink in a well-ventilated area, while wearing goggles or face shield, and rubber gloves. Open container and flush with large quantities of water until container contents have dissolved. Dispose of thoroughly-rinsed container in proper receptacle.

PATENTS

US 5,077,008, 5,0737,623; CA 1,321,137, 1,320,030
EP 0 322 310; DE 689113399.0; JA 1852815

EPA Reg. No. 58779-1

EPA Est. No. 58779-OH-001

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STERIS CORP

STERIS CORP

07/07/2005 14:28 FAX 3147254111

07/07/2005 14:27 FAX 3147254111

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