

58779-1

1/9/2006

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

58779-1

Date of Issuance:

JAN 09 2006

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Steris LW/SW

Name and Address of Registrant (include ZIP Code):

Steris Corporation
P.O. Box 147
St. Louis, MO 63166

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.

Based on your response to the Reregistration Eligibility Document for Peroxy Compound REDs, EPA has reregistered the above name product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

1. Make the following label changes:

a. Revise the EPA Registration Number to read "EPA Reg. No. 58779-1".

Signature of Approving Official:

Marshall Swindell, PM 33
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Date:

JAN 09 2006

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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.

Submit two (2) copies of the final printed labeling for our review. A stamped copy of the label is enclosed for your records.

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
Antimicrobial Division (7510C)

Enclosure

STERIS® STERIS 20

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 P 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 18528

EPA Reg. No. 58779-1

EPA Est. No. 58779-OH-001

ACCEPTED
with COMMENTS
EPA Letter Dated:

JAN 09 2006

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

58779-1

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STERIS CORP

08/04/2005 10:06 FAX 3147254111