



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

EPA Reg. Number:

58779-3

Date of Issuance:

APR 26 2002

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Hydrogen Peroxide Sterilant

Name and Address of Registrant (include ZIP Code):

Steris Corporation  
Company #1043  
CaO. 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 the 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 Compounds RED, 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. 58779-3".
- b. The word "PELIGRO" must be added to the label, following the signal word.

Signature of Approving Official:

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

Date:

APR 26 2002

c. The heading "Statement of Practical Treatment" must be changed to "First Aid" and the statements must be revised as follows:

**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 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:**

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment.

**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.

As per PR Notice 2001-1, the following hotline information must be added to the label:

"Have the product container or label with you when calling a poison control center or doctor or going for treatment"

For additional information in case of emergency call toll free (Telephone Number).

d. As per the acute toxicity review dated 7/5/00, revise the "Precautionary Statements" that appear under the subheading "Hazards to Humans and Domestic Animals" to read:

"Corrosive. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse".

e. As per the acute toxicity review dated 7/5/00, the PPE must be revised to read as follows:

“Personal Protective Equipment (PPE)

Applicators and all other 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, neoprene rubber, polyvinyl chloride, or viton, and
- Respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE prefilter”.

f. As per the RED, the following Environmental Hazards statement must be added to the label:

“Do not discharge effluent containing these products into lakes, streams, ponds, oceans, 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”.

g. The statement “When handling an open container...other protective clothing and boots.”, currently appearing under the Physical or Chemical Hazards should be deleted.

h. Include the following “Note To Physician statement to read:

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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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.

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

# HYDROGEN PEROXIDE STERILANT

Reorder Number: PB001

ACTIVE INGREDIENT:

Hydrogen Peroxide ..... 31%

INERT INGREDIENT: ..... 69%

**KEEP OUT OF REACH OF  
CHILDREN  
DANGER  
OXIDIZER  
CORROSIVE**

SEE BACK PANEL FOR ADDITIONAL  
PRECAUTIONARY STATEMENTS

For use in VHP® Industrial Equipment only.  
Shade from radiant heat. Stow away from powdered  
metals and permanganates.

NET CONTENTS:

STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060 ■ U.S.A.  
440-354-2600  
800-548-4873

## STATEMENT OF PRACTICAL TREATMENT

Do not get in eyes. **IN CASE OF EYE CONTACT:**  
Immediately flush with plenty of water for at least 15  
minutes, lifting upper and lower lids intermittently. Call a  
physician.

**Do not take internally. IF SWALLOWED:** Drink  
plenty of water immediately to dilute. Do not induce  
vomiting. Never give anything by mouth to an  
unconscious person. Call a physician.

**Note to Physician:** Probable mucosal damage may  
contraindicate the use of gastric lavage.

**Avoid breathing vapors. USE ONLY WITH  
ADEQUATE VENTILATION. IF INHALED:**  
Remove to fresh air. If not breathing, give artificial  
respiration. If breathing is difficult, give oxygen. Call a  
physician.

**Avoid contact with skin and clothing. IN CASE OF  
SKIN CONTACT:** Immediately flush skin with plenty  
of water for 15 minutes while removing contaminated  
clothing and shoes. Get medical attention if irritation  
persists. Wash contaminated clothing and shoes  
promptly. Discard contaminated shoes in a fireproof  
container.

## PRECAUTIONARY STATEMENTS

**Hazards to Humans and Domestic Animals**  
**DANGER: Corrosive.** Causes eye and skin damage. Do  
not get in eyes, on skin or clothing. Wear goggles or face  
shield and rubber gloves when handling. Harmful or fatal  
if swallowed. Do not breathe vapor or spray mist. Avoid  
contamination of food. Wash thoroughly with soap and  
water after handling. Remove contaminated clothing and  
wash before reuse.

## Physical or Chemical Hazards

Liquid hydrogen peroxide is a strong oxidant and poses a  
**FIRE, EXPLOSION OR CONTAINER RUPTURE  
HAZARD.** Avoid excessive heat, contamination, or  
contact with combustible materials. Clothing, shoes, or  
other combustible materials that have come in contact  
with hydrogen peroxide must be immediately and  
thoroughly washed with water. If allowed to dry in the  
materials, a fire may result. Discard shoes in a fireproof  
container.

**IN CASE OF FIRE** use water only.

When handling an open container, wear a NIOSH/MSHA  
approved respirator as necessary, chemical splash  
goggles or full face shield, vinyl or neoprene gloves and  
other protective clothing and boots.

**CONTAIN SPILLS** and dilute with 20 parts of water.

After diluting the spill, sodium metabisulfide or sodium  
sulfite (1.9 lbs. of SO<sub>2</sub> equivalent per 500 ml of  
peroxide) may be used to destroy the peroxide.  
**SEE EQUIPMENT MANUAL AND MATERIAL  
SAFETY DATA SHEET FOR ADDITIONAL  
INFORMATION.**

## DIRECTIONS FOR USE

It is a violation of federal law to use this product in a  
manner inconsistent with its labeling.  
This product is intended for use as a non-medical/non-  
healthcare sterilant (i.e., for industrial use only). This  
product is for use in STERIS VHP® industrial equipment  
only, and by trained personnel. For sterilization of empty,  
pre-cleaned, sealed enclosures up to 40 ft<sup>3</sup>, apply 2.2  
grams of product per minute for 90 minutes. See  
Equipment Manual for operating procedures of the  
STERIS VHP industrial equipment.

## STORAGE AND DISPOSAL

Store cartridges upright and refrigerate between 36° -  
46° F. Do not freeze. Do not expose to cyanide,  
hexavalent chromium compounds, other oxidizers,  
reducers, combustible materials, or flammable vapors.

## PESTICIDE DISPOSAL

Rinse cartridges with 20 parts water and then empty into  
sink with running water. Hydrogen Peroxide is classified  
as a DOT oxidizer and a hazardous waste under U.S.  
EPA hazardous waste regulations and it is a violation of  
federal law to improperly dispose of pesticides.

## CONTAINER DISPOSAL

Rinse cartridge with running water and dispose of with  
normal nonincinerated waste.

## LOT NUMBER:

Not for sale or use after:

EPA Reg. No. 58779-3  
EPA Est. No. 58779-OH-003

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 26 2002

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

58779-3

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