

58779-4

12-12-2002

1/3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 12 2002

STERIS Corp.
P.O. Box 147
St. Louis, MO 63166-0647

Attention: Michael G. Sarli
Sr. Regulatory Specialist

Subject: Vaprox Hydrogen Peroxide Sterilant
EPA Registration No. 58779-4
Letter Dated November 22, 2002

This will acknowledge receipt of your notification submitted under the provision of FIFRA Section 3(c)9. Based on a review of submitted material, the following comments apply.

Since you have made changes in addition to those mandated by our last acceptance, this label cannot be considered final printed labeling. Please submit final printed labels revised in accordance with the last acceptance dated May 19, 2000.

The changes you have proposed via notification are acceptable. The Agency has no objection to the labeling revisions in your use directions.

This information has been made a part of your file.

If you have any questions concerning this letter, please contact Solange Garvey at (703) 308-8911.

Sincerely,

S/SG

Marshall Swindell
Product Manger 33
Regulatory Management Branch I
Antimicrobial Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

EPA United States Environmental Protection Agency Washington, DC 20460	Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 58779-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification
4. Company/Product (Name) Vaprox Hydrogen Peroxide Sterilant	PM # 33	<input checked="" type="checkbox"/> None Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corp. P.O. Box 147 St. Louis, MO 63166-0647 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


Amendment -- Explain below.	Final printed labels in response to Agency letter dated "Me Too" Applicaton
Resubmission in response to Agency letter dated	
<input checked="" type="checkbox"/> Notification -- Explain below.	Other -- Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) "Notification of minor label revision per PR Notice 98-10."
 "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 formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make and false statement to EPA. I further understand that if this statement 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:			
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. container No. per	Water Soluble Packaging Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>foil pouch</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 quart	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael G. Sarli	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) 314-290-4704
Certification 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 (Stamped)
2. Signature 	3. Title Sr. Regulatory Specialist	
4. Typed Name Michael G. Sarli	5. Date 11/22/02	

VAPROX™ HYDROGEN PEROXIDE STERILANT

Reorder Number: PB006

ACTIVE INGREDIENT:

Hydrogen Peroxide 35%

INERT INGREDIENT: 65%

**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 SO₂ 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 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. See Equipment Manual
for operating procedures of the STERIS VHP industrial
equipment. Use this product for sterilization in
accordance with procedures defined in the Equipment
Manual.

STORAGE AND DISPOSAL

Store cartridges at or below 77°F or 25°C. 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. 58779-4

EPA Est. No. 58779-OH-003

3/3