

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 17 1995

Pamela C. Tanner  
Steris Corporation  
9450 Pineneedle Drive  
Mentor, Ohio 44060

Subject: Steris 20 Sterilant Concentrate  
EPA Registration Number 58779-1  
Letter Dated December 7, 1994

Dear Ms Tanner:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to include claims for decontamination of biohazardous waste" is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.

a. Move the misuse statement and place immediately below the heading "Directions For Use".

b. Include the heading "Precautionary Statements" and change the statement "Hazards to Humans" to read "Hazards to Humans and Domestic Animals".

c. Include the statement "Harmful If Swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves". Wash thoroughly with soap and water after handling.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2 of 5

2

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely yours,



Walter C. Francis  
Acting Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

Enclosure

STERIS 20<sup>TM</sup> STERILANT CONCENTRATE

Product No. S2000-20  
EPA Reg. No. 58779-1  
MSDS No. 79-21-0

Active Ingredient,  
    Peroxyacetic acid, 35%  
Inert Ingredients,    65%  
    Total    100%

Lot No. *To be assigned*

Contains 0.67 ounces active ingredient per container.

Do Not Use After *To be assigned*

Net Contents 1.91 oz.

DANGER KEEP OUT OF REACH OF CHILDREN

SPORICIDAL - FUNGICIDAL - BACTERICIDAL - VIRUCIDAL - TUBERCULOCIDAL

DECONTAMINANT - SANITIZER - GERMICIDE

STERIS 20 Sterilant Concentrate is a single use chemical sterilant concentrate developed exclusively for use in the STERIS SYSTEM 1 Processor. STERIS 20 Sterilant Concentrate is suited to the sterile processing of immersible articles such as endoscopes and their accessories, dental hand instruments and burrs, and microsurgical instruments. Recommended for use in hospitals, medical, surgical, and dental clinics/offices

STERIS 20 is a single-use chemical decontaminant concentrate validated for use in the STERIS/ECOMED BWD3. STERIS 20 is suited to the decontamination of liquid (<1,000 ml blood) and dry medical (<75 ml blood content) waste materials such as syringes, 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.

DIRECTIONS FOR USE

DIRECTIONS FOR USE

Use STERIS 20 Sterilant Concentrate only in the SYSTEM 1 Processor. For reliable sterile processing, thoroughly clean all articles prior to processing according to manufacturers recommendations. Transfer the sealed container of STERIS 20 Sterilant Concentrate into the SYSTEM 1 sterilant chamber. Follow the operating instructions located in the SYSTEM 1 Operator Manual.

Use only in the STERIS ECOMED BWD3. Place a sealed container into the processing chamber prior to cycle start. Follow the operating instructions located in the BWD3 Operator Manual.

See SYSTEM 1 Operator Manual for a comprehensive listing of materials compatibility.

See the BWD3 Operator Manual for a comprehensive listing of processing capability.

(continued on page 2)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 17 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
58779-1

4 7 5

---

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT  
IN A MANNER INCONSISTENT WITH ITS LABELING.

Do not attempt to manually open the STERIS 20 Sterilant Concentrate container

---

**STORAGE AND DISPOSAL.**

**STORAGE** Store upright in a cool, dry place. Avoid exposure to extreme conditions such as heat, moisture, sunlight, or contaminating substances.

**DISPOSAL** Dispose of spent containers in proper receptacle. Dispose of leaking/damaged containers by placing the container in a sink in a well-ventilated area. Wear 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.

---

**HAZARDS TO HUMANS**

Corrosive. Contact with STERIS 20 Concentrate causes irreversible eye damage including blindness and irreversible destruction of skin tissue. High concentrations of vapor will cause lacrimation and irritate nose, throat, and lungs. Contact may cause an allergic reaction. If reaction occurs avoid further contact.

**STATEMENT OF PRACTICAL TREATMENT**

**IF SWALLOWED** Do not induce vomiting. Drink promptly a large quantity of egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.

**FOR EYE CONTACT** Wash eyes immediately with water for a minimum of 15 minutes, holding eyelids open. Get medical attention.

**FOR SKIN CONTACT** Wash off skin immediately with large amounts of water. Remove and wash contaminated clothing. Get medical attention.

**IF INHALED** Provide good ventilation with fresh air. If not breathing apply artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**NOTE TO PHYSICIAN** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, convulsions may be needed.

**PHYSICAL OR CHEMICAL HAZARDS** Do not use or store near heat or open flames.

---

**MANUFACTURED BY STERIS**

STERIS Corporation  
9450 Pineneedle Drive  
Mentor, Ohio 44060  
USA  
216-354-2600  
Patent Nos. 4,731,222  
Other Patents Pending  
EPA Est No. 58779-011-001

ACCEPTED  
with COMMENTS  
to EPA Letter Dated:

JAN 17 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
and related laws, this pesticide  
is registered under EPA Reg. No.

58779-1

5 4 5

THIS COMPONENTS MUST BE USED ONLY WITH THE PEROXYACETIC ACID COMPONENT OF STERIS 20 STERILANT CONCENTRATE.

ACTIVE INGREDIENT 0%  
INERT INGREDIENTS 100%

NET CONTENTS 4.88 oz.

DANGER - KEEP OUT OF REACH OF CHILDREN

HAZARDS TO HUMANS Corrosive, contact with STERIS 20 Concentrate causes irreversible eye damage including blindness and irreversible destruction of skin tissue. High concentrations of vapor will cause lacrimation and irritate nose, throat, and lungs. Contact may cause an allergic reaction. if reaction occurs avoid further contact.

DISPOSAL Dispose of spent containers in proper receptacle. Dispose of leaking/damaged containers by placing the container in a sink in a well-ventilated area. Wear 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 17 1995

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

58725-1