

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PM 31

58779-5

10-21-99

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OCT 21 1999

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

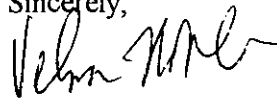
Subject: STERIS - Envirosystems Ethylene Oxide Sterilant
EPA Registration No. 58779-5
Amendment Date: 7/19/99
EPA Receive Date: 7/23/99

Attention: Mr. Micheal G. Sarli,
Regulatory Specialist

The amendment referenced above, submitted in connection with registration under FIFRA, as amended, to update labeling is acceptable. A stamped label is enclosed for your records.

Before you release the product for shipment, you will need to submit one (1) copy of the final printed label to the Agency. If you have any questions regarding this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,




Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510C)


CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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STERIS 		Envirosystems™		ACTIVE INGREDIENT: 100% Ethylene Oxide KEEP OUT OF REACH OF CHILDREN.
		Ethylene Oxide Sterilant		DANGER PELIGRO EXTREMELY FLAMMABLE DO NOT USE NEAR FIRE OR FLAME
				PRECAUTION AL USUARIO
Reorder Number: PB013	Net Contents: 100gms (3.52oz)	Store at room temperature		
<p>STATEMENT OF PRACTICAL TREATMENT IN ALL CASES GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE. IF INHALED, remove exposed person to fresh air, keep warm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed. IN CASE OF CONTACT, immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician. Aerate, wash, or clean contaminated clothing before reuse and discard leather goods. IF SWALLOWED, give at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Call a physician.</p> <p>NOTE TO PHYSICIAN SEE MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION. Material Safety Data Sheets can be obtained by calling 800-JIT-4-USE (800-548-4873).</p>				
<p>DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047.</p> <p>▲ INSERT THIS END This product may be used only in facilities that meet the requirements of 29 CFR 1910.1047 in Amsco 3017 designed for use with Envirosystems containing 100% ethylene oxide. This product may be used only by persons who have been trained in accordance with 29 CFR 1910.1047.</p> <p>For complete use directions (including type of surfaces, objects, or items/products recommended for treatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the Amsco 3017 Sterilizer Operator Manual.</p> <p>▲ This product may be used only to sterilize medical or laboratory items and pharmaceuticals.</p> <p>Instructions for Installing and Operating Ethylene Oxide Canister: Refer to the Amsco 3017 Sterilizer Operator Manual.</p>				
<p>STORAGE AND DISPOSAL Do not contaminate water, food, or feed by storage or disposal. Store at room temperature.</p> <p>PESTICIDE DISPOSAL: Do not puncture unused cartridges. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.</p> <p>CONTAINER DISPOSAL: Aerate empty cartridges according to instructions in the equipment manual. After aeration, dispose of with normal non-incinerated waste.</p> <p>Ethylene oxide cartridges have a shelf life of two (2) years (24 months) from date of manufacture. Do not use after expiration date found on cartridge. The addition of water and/or contamination (grease, oil, dirt, etc.) will cause this product to be less efficacious.</p> <p>SEE OPERATOR MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.</p> <p>Manufactured for STERIS Corporation • 5960 Heisley Road Mentor, OH 44060-1834 • USA • 800-JIT-4-USE (800-548-4873) EPA REG. NO. 58779-5 EPA EST. NO. 3657-WI-2</p>				

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 21 1999
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 58779-5

STERIS 		Envirosystems™		
		Ethylene Oxide Sterilant		
Reorder Number: PB013	Net Contents: 100gms (3.52oz)	Store at room temperature		
<p>PRECAUTIONARY STATEMENTS</p> <p>HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER! CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM DAMAGE. DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.</p> <p>EFFECTS OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, convulsions, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.</p> <p>OTHER POSSIBLE DELAYED HEALTH EFFECTS: May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer. PEL: 1 PPM-TWA Ethylene Oxide (OSHA - 29 CFR 1910.1047) EL: 5 PPM-excursion limit, 15 minutes. ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.</p> <p>PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use adequate ventilation in accordance with 29 CFR 1910.1047.</p> <p>PHYSICAL OR CHEMICAL HAZARDS DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE.</p>				
<p>IF LEAK, evacuate all personnel from area. Wear self-contained breathing apparatus operated in pressure demand mode and protective clothing. Remove sources of ignition and shut off leak if without risk. Reduce vapors with fog or fine water spray. Ventilate leak area or moving leaking assembly to well-ventilated area. DANGER - may form explosive mixtures with air. Flood spills with water spray. Prevent runoff, collect for disposal. Neither pure ethylene oxide nor its aqueous solutions should be discharged into streams or sewers. Flammable vapors may spread from spill. Dilute with 100 volumes of water as an additional safe practice. Before entering exposed area, check atmosphere with appropriate device. Contingency planning is recommended for handling releases, spills, and emergencies.</p> <p>IF FIRE, immediately cool containers with water spray from maximum distance taking care not to extinguish flames. If flames are accidentally extinguished, explosive re-ignition may occur. Wear self-contained breathing apparatus operated in pressure demand mode and protective clothing.</p> <p>ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.</p>				