



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OCT 10 2006

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Michael Sarli
Lead Regulatory Specialist
STERIS Corporation
P.O.Box 147
St.Louis.MO 63166-0647

Subject: EnviroSystems Ethylene Oxide Sterilant
EPA Registration No. 58779-5
Amendment Dated: July 11, 2006
EPA Received Date: July 12, 2006

Dear Mr. Sarli,

The following amendment submitted in connection with registration under section 3(c)(7)(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comments.

Proposed Amendment

- Update the First Aid Statements.

Comments

Make the following revisions to your labeling:

A. Make the following revisions to page one:

1. Revise the following First Aid Statements to read:

If inhaled: Move person to air. If a person is not breathing, call a physician or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

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

CONCURRENCES						
17510C						
P. Keely						
10/10/06						

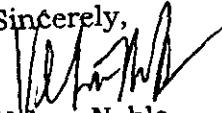
2. Revise the following Note to Physician statement to read:
"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division (7510c)

CONCURRENCES

NAME							

STERIS®



Envirosystems
Ethylene Oxide Sterilant
Active Ingredient: 100% Ethylene Oxide

3 7 4

Reorder Number: Net contents
PB013 100 gms (3.52)

Store at room Temperature

KEEP OUT OF REACH OF CHILDREN

Danger Peligro
Extremely Flammable

Do not use near fire or flame

PRECAUTION AL USERIO

Si usted no entiende la etiqueta busque a alguien para que se la explique a usted en detalle.
Users must follow the requirements of the OSHA occupational exposure standard for ethylene oxide (29 CFR 1910.1047).

ACCEPTED
with COMMENTS
OCT 10 2006

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 58779-5

FIRST AID

If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a physician even if not symptoms are present. Keep under medical observation. Symptoms may be delayed.
If on skin or clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice. <p>Aerate, wash, or clean contaminated clothing before reuse and discard leather goods.</p>
If in eyes	<ul style="list-style-type: none"> •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 the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call 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 do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call STERIS at 314-535-1695 or CHEMTREC at 800-424-9300.

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.

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.

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.

This product may be used only to sterilize medical or laboratory items and pharmaceuticals.

Instructions for installing and Operating Ethylene oxide Canister:
Refer to the Amsco 3017 Sterilizer Operator Manual.

EPA Reg. No. 58779-5

EPA Est. No. 36736-SC-01

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Store at room temperature.

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.

CONTAINER DISPOSAL: Aerate empty cartridges according to instructions in the equipment manual. After aeration, dispose of with normal non-incinerated waste.

Ethylene Oxide cartridges have a shelf life of two (20 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.

SEE OPERATOR MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.

Manufactured for STERIS Corporation · 5960 Hulsley Road
Mentor, OH 44060-1834 · USA · 800-JIT-4-USE (800-548-4873)

STERIS®



EnviroSystems
Ethylene Oxide Sterilant

4 8 4

Reorder Number:
PB013

Net contents
100 gms (3.52 oz.)

PRECAUTIONARY STATEMENTS

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.

EFFECTS OF OVEREXPOSURE: May be fatal 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.

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 90SHA – 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.

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.

PHYSICAL OR CHEMICAL HAZARDS

DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE.

IF LEAK, EVACUATED 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 of 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 sill. Dilute with 100 volumes of water as an additional safe practice. Before entering exposed areas, check atmosphere with appropriate device. Contingency planning is recommended for handling releases, spills and emergencies.

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.

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 of Regional Office of the EPA.

