# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Michael G. Sarli **STERIS** Corporation P.O. Box 147 St. Louis, MO 63166-0147

Subject: Envirosystems Ethylene Oxide Sterilant EPA Registration No.: 58779-5 Amendment Date: November 17, 2009 EPA Receipt Date: November 18, 2009



Dear Mr. Sarli,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

• Label Revisions as per the Reregistration Eligibility Decision for Ethylene Oxide

#### Conditions

Revise the PPE section to include the following statement: "The employer must provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements (see 29 CFR 1910.1047 and 29 CFR 1910.134)."

#### **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 concerning this letter, pléase contact Tracy Lantz at (703) 308-6415.

Sincerely. Veľma Noble

Product Manager (31) Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: stamped la	•		 	<u>.</u>
7510P.1.Lantz:2/9/10.	58779-5accept amend wo	ICURRENCES		
SYMBOL 7510P				
SURNAME ) JUST				
DATE 292010			 	
EPA Form 1320-1A (1/90)	Printed	on Recycled Paper	 OFFICI	AL FILE COPY

ŚTERIŚ

20f3

Envirosystems

Ethylene Oxide Sterilant

Active Ingredient: 100% Ethylene Oxide

Store at room Temperature

Reorder Number: Net contents: 100 gms (3.52 OZ.)

## KEEP OUT OF REACH OF CHILDREN

### Danger Peligro

Extremely Flammable Do not use near fire or flame

ACCEPTED with COMMENTS in EPA Letter Dated; FEB - 9 2010 Under the Federal Insecticide Fungicide, and Redenticide Act as amended, for the pesticide, registered under EPA Reg. No.

58779-5

#### PRECAUTION AL USERIO

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

	FIRS	T AID			
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call a physician or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>				
· · · · · · · · · · · · · · · · · · ·	Call a poison control center or doctor for treatment     Take # application of the second secon	nt aqvice.			
If on skin or	•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes.				
clothing	•Call a poison control center or doctor for treatment advice.				
	•Hold eye open and rinse slowly and gently with water for 15-20 minutes.				
If in eyes	•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.				
ļ	•Call a poison control center or doctor for treatment advice.				
	Call poison control center or doctor immediately for treatment advice.				
If swallowed	•Have person sip a glass of water if able to swallow.				
	•Do not induce vomiting unless told to do so by the poi	son control center or doctor.			
	Do not give anything by mouth to an unconscious personal light to the second seco				
	HOT LINE				
CHEMTREC at 800	-424-9300.	enter or doctor, or going for treatment. Call STERIS at 314-535-1395 or			
	NOTE TO F	PHYSICIAN			
	lamage may contraindicate the use of gastric lavage.				
DIRECTIONS FOR		STORAGE AND DISPOSAL			
	ederal law to use this product in a manner inconsistent	Do not contaminate water, food, or feed by storage or disposal. Store at			
	mployers in facilities that use ETO must comply with all	room temperature.			
of the requirements	for ETO use specified in 29 CFR 1910.1047.				
Not for use in contract sterilization facilities.		<b>PESTICIDE DISPOSAL:</b> 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			
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		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.			
persons who have been trained in accordance with 29 CFR 1910.1047. In hospitals and healthcare facilities, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.		<b>CONTAINER DISPOSAL:</b> Non-refillable container. Aerate empty cartridges according to instructions in the equipment manual. After aeration, dispose of with normal non-incinerated waste.			
After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities		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 confamination (grease, oil, dirt, etc.) will cause this product to be less efficacious.			
For complete use directions (including type of surfaces, objects, or items/products identified 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.		SEE OPERATOR MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.			
This product may be pharmaceuticals.	e used only to sterilize medical or laboratory items and	EPA Reg. No. 58779-5 EPA ဠັຮູ້ຮູ້ ໂດຍເອັດເອັດ ເຊິ່ງ ເ			
Instructions for installing and Operating Ethylene oxide Canister: Refer to the Amsco 3017 Sterilizer Operator Manual.					

# PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMETIC 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 (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.

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.

#### PERSONAL PROTECTION EQUIPMENT (PPE):

A material that is chemical-resistant to this product is butyl rubber. If you want more options, follow the instructions for category B on an EPA chemicalresistant category selection chart.

All handlers must wear at a minimum:

- . Long-sleeved shirt and long plants,
- · Shoes plus socks,

Chemical-resistant gloves, and

• when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,

• when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,

• when the ambient ETO concentration is > 2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full-facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and

• Face-sealing goggles, a full face shield, or a full-face respirator.

#### User Safety Requirements

1. Follow the respirator manufacturer's user's instructions for changing canisters. 2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **User Safety Requirements**

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### PHYSICAL OR CHEMICAL HAZARDS

#### DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE

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 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.

	ιιι ι ι 	
e e	ι	
ι. ι	(, (, <sup>-</sup> (, <sup>-</sup>	
ιc` L	ίζις ζημητικής ζηγουροφορίας ζηγορια ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγοριας ζηγορια ζηγορια ζηγοριας ζηγοριας ζηγοριας ζηγορια ζηγορια ζηγοριας ζηγορια ζηγοριας ζηγορια ζηγορια ζης ζηγορια ζης ζηγορια ζης ζηγορια ζης ζηγορια ζης ζηγορια ζης ζηγορια ζης ζηγορια ζης ζης ζης ζης ζης ζης ζης ζης ζης ζης	
( C	ς ι ιετει ι	
<sup>ズ</sup> . L し	ι. ι	
6.6	۲.	
	ς ς «ξειςς ι	
	6 6 6 6 6 6 6 1	