

58779-5

2/9/2010

1043

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

FEB 9 2010

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, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

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

Enclosure: stamped label

7510P.T.Lantz:2/9/10:58779-5accept amend CONCURRENCES

SYMBOL	7510P						
SURNAME	T. Lantz						
DATE	2/9/2010						

**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 Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.  
**58779-5**

**PRECAUTION AL USUARIO**

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).

<b>FIRST AID</b>	
If inhaled	<ul style="list-style-type: none"> <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> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call STERIS at 314-535-1395 or CHEMTREC at 800-424-9300.	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	
<p><b>DIRECTIONS FOR USE</b></p> <p>It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047.</p> <p><b>Not for use in contract sterilization facilities.</b></p> <p>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. In hospitals and healthcare facilities, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.</p> <p>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</p> <p>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.</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><b>STORAGE AND DISPOSAL</b></p> <p>Do not contaminate water, food, or feed by storage or disposal. Store at room temperature.</p> <p><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 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><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.</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><b>SEE OPERATOR MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.</b></p> <p>Manufactured for STERIS Corporation · 5900 Heisley Road Mentor, OH 44060-1834 · USA · 800-JIT-4-USE (800-543-4873)</p> <p>EPA Reg. No. 58779-5      EPA Est. No. 36736-SC-01</p>

