

US ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (TS-767)  
WASHINGTON, DC 20460

EPA REGISTRATION NO.  
43573-2

DATE OF ISSUANCE  
JUN 23 1994

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION  
(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT  
Ethylene Oxide

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

American Sterilizer Company  
2424 West 23rd Street  
P.O. Box 620  
Erie, PA 16514

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use, if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration No. 43573-2"
- b. A "Note To Physician" Statement must be placed on the product label in close proximity to the "Statement of Practical Treatment."
- c. Revise the "3 Hours at 100° F" exposure time and temperature on your label and in the equipment manual to read "4 and 1/2 Hours at 100° F."
- d. Align the ingredient statement so that it is parallel with and not perpendicular to the label language.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

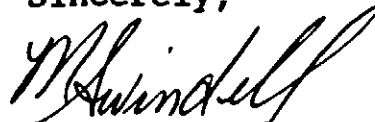
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3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



Marshall Swindell  
Acting Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (H7505C)

Enclosures

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUN 23 1994

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

43573-2

REORDER NO. PB 013  
STORE AT ROOM TEMPERATURE  
NET CONTENTS 100 GALS (1.25 GAL)  
ACTIVE INGREDIENT ETHYLENE OXIDE 100%  
EO-100  
ETHYLENE OXIDE  
AMSCO

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**  
**EXTREMELY FLAMMABLE - DO NOT USE NEAR FIRE OR FLAME**

**STATEMENT OF PRACTICAL TREATMENT:**  
**Do Not Get In Eyes! IN CASE OF EYE CONTACT:** Immediately flush with plenty of water for at least 15 minutes, lifting upper and lower lids intermittently. Get medical attention.  
**Do Not Take Internally! IF SWALLOWED:** Drink egg whites, gelatin solution, or if these are not available, drink large quantities of water. Get medical attention.  
**Avoid Breathing Vapors! Use Only With Adequate Ventilation! IF INHALED:** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.  
**Avoid Contact With Skin Or Clothing! IN CASE OF SKIN CONTACT:** Immediately flush skin with plenty of water for at least 15 minutes. Remove and wash all contaminated clothing before reuse.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

Ethylene Oxide (EO) is toxic. Exposure to EO may cause serious adverse health effects. Possible hazards may include carcinogenic, mutagenic, neurologic and reproductive effects. Liquid EO causes eye damage, burns to the skin, and is harmful if swallowed. Exposure to EO vapor causes irritative effects. Inhalation may cause neurologic effects and may be fatal. Chronic exposure may cause carcinogenic, mutagenic and reproductive effects.

**PHYSICAL OR CHEMICAL HAZARDS:**

Ethylene Oxide gas is extremely flammable. Do not use near flame, electrical sparks or hot surfaces. Ground all equipment to prevent static sparks. Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130° may cause bursting.

**DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling. This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization of medical devices in healthcare facilities. See the Eagle 3017 Sterilizer Equipment Manual for detailed Instructions For Use and types of items intended to be sterilized. Exposure time at 130°F is 1 Hour and at 100°F is ~~1 hour~~ 4 and 1/2 hours

**STORAGE AND DISPOSAL:**

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

**PESTICIDE DISPOSAL:**

Do not puncture or incinerate 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.

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

Manufactured for  
AMERICAN STERILIZER CO., APD, NC 27562 EPA REG NO.  
400077-603 05/11/94 EPA EST NO 138124-001

INSERT THIS END

### Canister Labeling

AMSCO Corporate Design Artwork		CDA	Date	6-10-94
Part No.	400077-603	Art No	XAC-132	Rev
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