

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 1992

Union Carbide Industrial Gases  
39 Old Ridgebury Road  
Danbury, CT 06817

Attn: Algirdas G. Vilkas

Subject: Ethylene Oxide  
EPA Registration No. 10330-13  
Amendment dated October 31, 1991

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, and Rodenticide Act, as amended, to make revision to product labeling and directions for use tag, is acceptable, provided that you:

1. Make the following changes listed below before you release the product for shipment bearing the amended labeling:

a. Under the section "Effects of Overexposure", delete the phrase "in high concentrations" from the statement "May be fatal if inhaled."

b. Delete the word "overexposure" under the section "Statement of Practical Treatment".

c. In the "Environmental Hazards" section, delete the statement beginning with "Ethylene oxide is a nonpersistent chemical...aquatic systems". and replace it with the following statement to read:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

d. Include the heading "Precautionary Statements" above the statement "Hazards to Humans".

e. Revise the statement "Hazards to Humans" to "Hazards to Humans and Domestic Animals".

f. Delete the words "First Aid:".

d. In your instruction manual, delete the "Formulation of Sterilizing Gas Mixtures" section. The combination of formulating use and end-use for instructions is not permitted for the same registration.

2. The revised Confidential Statement of Formula reflects the reduction in the active ingredient, agrees with the label and is acceptable.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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 bearing the amended labeling constitutes acceptable of these conditions.

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

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,



John H. Lee  
Product Manager 31  
Antimicrobial Program Branch  
Registration Division H7505C

Enclosure

# ETHYLENE OXIDE

CAS: 75-21-8

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT.

DANGER PELIGRO

**PRECAUTION AL USARIO:** Si usted no lee Ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

## HAZARDS TO HUMANS

**DANGER! EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE. MAY CAUSE EXPLOSIVE MIXTURES WITH AIR. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE. DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.**

**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 reaction.

**OTHER POSSIBLE DELAYED HEALTH EFFECTS:** May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

PEL: 1PPM-TWA Ethylene Oxide (OSHA-29CFR1910.104 )

EL: 5PPM-excursion limit, 15 minutes.

ODOR: Ether-like at 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, on clothing. Store and use with adequate ventilation.

## PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide, is extremely flammable and reactive Contents under pressure. Keep away from heat, flame, sparks or hot surfaces. Do not allow sources of ignition near the sterilization/fumigation area Use only in a closed system. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty. Use in accordance with tag attached to valve. Ground all equipment, including containers, to avoid static sparks.

## ENVIRONMENTAL HAZARDS

Ethylene oxide, is not intended for outdoor use. Ethylene

oxide is a nonpersistent chemical structure which would not be expected to accumulate in the environment. Its moderate level of aquatic toxicity coupled with this nonpersistence should prevent any long-term toxic effects on aquatic systems.

## STATEMENT OF PRACTICAL TREATMENT

**IN ALL CASES OF OVEREXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.**

## FIRST AID:

**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.

**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 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.

**NOTE TO PHYSICIAN:** REFER TO SECTION IV, HEALTH HAZARD DATA, LINDE MATERIAL SAFETY DATA SHEET FORM L-4798

**LEAK:** Evacuate area and keep personnel upwind. Shut off all sources of ignition Use self-contained breathing apparatus and protective clothing, and shut off leak if without risk.

**FIRE:** Do not extinguish burning gas if flow cannot be shut off immediately Move container away from fire if without risk Use water spray or fog nozzle to keep container cool

## IN CASE OF EMERGENCY IN USA:

Call 1-800-UCC-HELP (1-800-822-4357)

**BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND LINDE MATERIAL SAFETY DATA SHEET FORM L-4798.**

**FOR INDUSTRIAL USE ONLY, NOT FOR USE IN HOSPITALS OR IN HEALTH CARE FACILITIES.**

DOT/IMO Shipping Name: Ethylene Oxide UN1040

**INHALATION HAZARD**

EPA Registration No. 10330-13

EPA Establishment No. 10330-

BATCH-

Union Carbide Industrial Gases Inc.

Linde Division

Danbury, CT 06817-0001

ACCEPTED  
with COMMENTS  
to EPA Letter Dated

AUG 31 1992

**LINDE STERILANT GASES**

DO NOT REMOVE THIS LABEL

MADE IN USA

STB-0100 (7/91)

Under the Federal Insecticide,  
Fungicide and Rodenticide Act  
as amended, for use possible  
Registered under EPA Reg. No.  
10330-13

**ETHYLENE OXIDE**  
UN 1040  
INHALATION HAZARD  
STN-510 (7/91)  
CGA-510  
STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT 100% BY WEIGHT  
NET CONTENTS 4LBS. (1.8 Kg)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER  
STERILANT GASES

**ETHYLENE OXIDE**  
UN 1040  
INHALATION HAZARD  
RQ  
STN-510 (7/91)  
CGA-510  
STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT  
NET CONTENTS 15LBS. (6.8 Kg)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER  
STERILANT GASES

**ETHYLENE OXIDE**  
UN 1040  
INHALATION HAZARD  
RQ  
STN-510 (7/91)  
CGA-510  
STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT  
NET CONTENTS 175LBS. (79.4 Kg)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER  
STERILANT GASES

**ETHYLENE OXIDE**  
UN 1040  
INHALATION HAZARD  
RQ  
STN-510 (7/91)  
CGA-510  
STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT  
NET CONTENTS 400LBS. (181.4 Kg)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER  
STERILANT GASES

ACCEPTED  
with COMMENTS  
by EPA Letter Dated:  
**AUG 31 1992**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
**12330-13**

5 7 8

**DO NOT REMOVE THIS TAG**

**ETHYLENE OXIDE  
STERILANT-FUMIGANT GAS  
DANGER! EXTREMELY FLAMMABLE AND EXPLOSIVE  
HARMFUL IF INHALED**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

**AUG 31 1992**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
10330-1.3

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. When used in the workplace, it is the employer's responsibility to ensure that all personnel are familiar with and adhere to 29 CFR 1910.1047. Ethylene Oxide is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Ethylene Oxide must have knowledge of the hazards of this chemical and must be trained in the proper use of required respirator equipment, monitoring and detection devices, and in the implementation of emergency procedures.

To be used only by persons experienced in ethylene oxide sterilization and fumigation, or by persons under direct supervision of persons who are experienced in ethylene oxide sterilization and fumigation. Use only in accordance with the directions and safety precautions listed on the label and this tag. See current Union Carbide Industrial Gases Inc. Material Safety Data Sheet Form L-4798, Condensed Safety Information, Compressed Gases and Cryogenic Liquids, Form L-12-237, and Guidelines for Handling Compressed Gas Cylinders and Cryogenic Liquid Containers, Form L-14-153. Also see Ethylene Oxide Brochure F-7618.

**GENERAL INSTRUCTIONS**

1. Always check container valves and plugs for leaks before moving container into your facility.
2. This container is equipped with an eductor tube for liquid delivery. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 psig (3.52 kg/cm<sup>2</sup>) at 70°F (21.1°C). Pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C). Contact supplier if, upon receipt, container pressure is below 50psig (3.52 kg/cm<sup>2</sup>) at 70°F (21.1°C).
4. Container must be in an upright position when discharging. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve outlet (marked "Liquid") is provided with a CGA 510 connection which has lefthand threads.

- 6. EOX style cylinders and DOT 5P drums are also provided with a CGA 580 inert pressurizing valve (marked "Vent") which has righthand threads. Do not discharge product from the CGA 580 inert pressurizing valve.
- 7. Remove protective valve plugs and make sure valve threads are undamaged. Do not attach an ordinary pipe fitting to these valves. The connections to the container valves should be brass CGA 510 and CGA 580 connectors. Use of other metals could cause damage to the brass container valves.
- 8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressures to be encountered. Do not use rubber, plastics, or copper materials. Install relief devices where liquid can be trapped between valves.
- 9. Ground all equipment including containers, to avoid static sparks.
- 10. Use only spark-proof tools.
- 11. Use only explosion proof electrical equipment where ethylene oxide may be present.
- 12. Install check valves in the discharge line from this container to processing equipment to prevent back-flow into container.
- 13. Connect the CGA 580 inert pressurizing valve (marked "Vent") to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve and check valve. The source of nitrogen should be used exclusively for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum.
- 14. To open container valves, turn handwheel counter clockwise. The liquid discharge valve is equipped with a handwheel. Do not use a wrench or other leverage device on handwheel. Use a "T" wrench to open the inert pressurizing valve on EOX cylinders and 5P drums.
- 15. Use with adequate general and local ventilation. Vapors form from this product and may travel or be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters, electrical equipment, static discharges or other ignition sources at locations distant from product handling point.
- 16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:  
**AUG 31 1992**  
 U.S. Environmental Protection Agency  
 Office of Air Quality Planning and Standards  
 Research Triangle Park, North Carolina 27711  
 Registered under EPA Reg. No.  
10330-13

1.) STERILIZATION AND FUMIGATION

Ethylene oxide may be safely used to reduce microbial load and/or sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, whole and ground spices and other processed natural seasoning materials except mixtures to which salt has been added, (see 21CFR 193.200), cosmetics, and other inanimate objects.

Items to be sterilized should be thoroughly cleaned of soil before being placed in any type of sterilizer.

A. Sterilization/fumigation with ethylene oxide must be performed only in vacuum or gas tight chambers designed for use with ethylene oxide and in accordance with directions supplied by the chamber manufacturer.

B. Ethylene oxide sterilization cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air or inert gas concentration; ethylene oxide concentration; chamber temperature; humidity level; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized/fumigated product and package.

C. The following is a list of ranges for the critical variables which must be in proper relationship for ethylene oxide to be an effective sterilizing/fumigating agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

Temperatures - 70°F to 150°F

Pre-Vacuum - typically 25 to 28 inches of mercury. Use vacuums and/or inert gas purges compatible with the products and packages to be sterilized/fumigated, and such that explosive atmospheres are never present in the chamber.

Moisture - Relative humidity of 33% to 80%

Gas Concentration - 250 mg/L to 1500 mg/L (mg/L means milligrams of ethylene oxide per liter of chamber volume)

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Ethylene oxide is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

Aeration - aerate sterilized/fumigated materials before use. Do not allow any person to enter the chamber or aeration area if such entry will result in exposures to ethylene oxide above the levels established in 29 CFR 1910.1047.

Cycle parameters and post cycle aeration parameters (temperature, time, air flow-rate) can affect residue levels. The user must determine that the parameters chosen result in goods which comply with applicable Federal and State residue requirements.

For residual limits of ethylene oxide on drug products and medical products see 21 CFR 211.70 and 21 CFR 821.100 or subsequent revisions. For residual limits on agricultural commodities see 40 CFR 180.151 and 21 CFR 193.200 or subsequent revisions.

D. The sterilization/fumigation cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user. NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

2. FORMULATION OF STERILIZING GAS MIXTURES:

ACCEPTED  
with COMMENTS  
to EPA Letter Dated:

AUG 31 1992

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the products registered under EPA Reg. No. 10330-13

Ethylene oxide may be used in the repacking of sterilizing gas and in the formulation of sterilizing gas mixtures.

STORAGE AND DISPOSAL

Store according to instructions provided on label and this tag. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out basis. A good rule of thumb is to use ethylene oxide within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, ethylene oxide should not be stored in any place where the temperature consistently exceeds 100°F. See Linde Publication "Sterilizer Maintenance and Ethylene Oxide Polymer", L-6848.

STORE IN AN AREA WITH ADEQUATE VENTILATION

RETURN CONTAINER TO SUPPLIER FOR REUSE. BEFORE RETURNING CONTAINER TO SUPPLIER:

- A. PRESSURIZE CONTAINER WITH NITROGEN TO 50 PSIG TOTAL PRESSURE AT 70°F AND BE SURE CONTAINER VALVES ARE CLOSED.
- B. REPLACE VALVE PLUGS TIGHTLY IN VALVE OUTLETS. IF VALVE PLUGS ARE NOT AVAILABLE, CONTACT SUPPLIER.
- C. CHECK CONTAINER VALVES AND PLUGS FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.

ACCEPTED  
 with COMMENTS  
 to EPA Letter Dated:  
**AUG 31 1992**  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act  
 as amended, for the pesticide  
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10330-13