

PM31 10-30-14

10-8

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (1-5-767) WASHINGTON, DC 20460 NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	EPA REGISTRATION NO. 10330-14	DATE OF ISSUANCE JAN 06 1993
	TERM OF ISSUANCE	
	NAME OF PESTICIDE PRODUCT Ethylene Oxide 100 R	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Praxair, Inc
 39 Old Ridgebury Road
 Danbury, CT 06810

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: (master label)
 - a. Add the phrase "EPA Registration No. 10330-14".
 - b. Add the appropriate EPA Establishment No.
 - c. It is preferred that you delete the phrase: "By Weight"
 - d. Move the entire paragraph: "Do not discharge effluent containing this product into lakes, streams, ..." to appear directly under the heading: ENVIRONMENTAL HAZARDS

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
---------------------------------	------

2 of 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

e. It is preferred that the signal word: Danger, (Center panel only) be placed directly under the heading: KEEP OUT OF REACH OF CHILDREN

f. Add the following statements and headings:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use by manufacturers only in formulating and/or repackaging sterilants and/or fumigants. Formulators/Repackagers using this product are responsible for EPA registrations which may include for providing data of their formulated/repackage product.

See tag for complete use directions and Storage/Disposal instructions.

g. Revise "Keep away from heat, flame, sparks or hot surfaces" to read:

Do not use near flame, electrical sparks, or hot surfaces. Do not puncture or incinerate container.

3. Make the labeling changes listed below before you release the product for shipment: (collar label)

a. Delete the phrase: "by weight"

b. Revise "...read warning label on side..." to read "...read label on side..." or "... read the main label on side..."

4. Make the labeling changes listed below before you release the product for shipment: (tag label)

a. In the storage and disposal section, include the following subheadings:

Pesticide Disposal
Container Disposal

b. Include the product name at the top of the tag.

c. Include the phrase "EPA Registration No. 10330-14".

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Box 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 3 -

d. Revise the statement: "Repacking, Mixing and Formulation of Sterilant-Fumigant. This product is intended for use only in manufacturing..." to read:

FORMULATION/REPACKAGING OF STERILANTS/FUMIGANTS

For use by manufacturers only in formulating and/or repackaging sterilants and/or fumigants. Formulators/Repackagers using this product are responsible for EPA registrations which may include for providing data of their formulated/repackage product.

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,



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

Enclosures

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

PH 31 10330-14

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 06 1993

ETHYLENE OXIDE

100 R

CAS: 75-21-8

ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT.

DANGER PELIGRO

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 10330-14

RECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS
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-29CFR1910.1047)
EL: SPPM-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 classification/demarcation 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.

~~oxide is a non-flammable gas which should not be exposed to high concentrations. Do not breathe the vapor. Do not get in eyes, on skin, on clothing. Store and use with adequate ventilation.~~

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

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 1-800-800-HELP (1-800-800-4357)
645-4633

FORMULA / REPACKING

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

EPA Registration No. 10330-28
EPA Establishment No. 10330-BATCH-

INHALATION HAZARD

Praxair, Inc.
Union Carbide Industrial Gases Inc.
Linde Division
Danbury, CT 06817-0001

LINDE STERILANT GASES

MADE IN USA

STB-0100 (7/91)

DO NOT REMOVE THIS LABEL

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.

JAN 06 1993

10330-14

ETHYLENE OXIDE 100R

UN 1040
INHALATION HAZARD
RQ

STW-9119 (7/91)

ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT
NET CONTENTS 15LBS. (6.8 Kg)

CGA-510

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

STERILANT GASES

ETHYLENE OXIDE 100R

UN 1040
INHALATION HAZARD
RQ

STW-9120 (7/91)

ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT
NET CONTENTS 175LBS. (79.4 Kg)

CGA-510

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

STERILANT GASES

ETHYLENE OXIDE 100R

UN 1040
INHALATION HAZARD
RQ

STW-9120 (7/91)

ACTIVE INGREDIENT-ETHYLENE OXIDE 100% BY WEIGHT
NET CONTENTS 400LBS. (181.4 Kg)

CGA-510

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

STERILANT GASES

6078

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1993

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

10330-14

DO NOT REMOVE THIS TAG

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

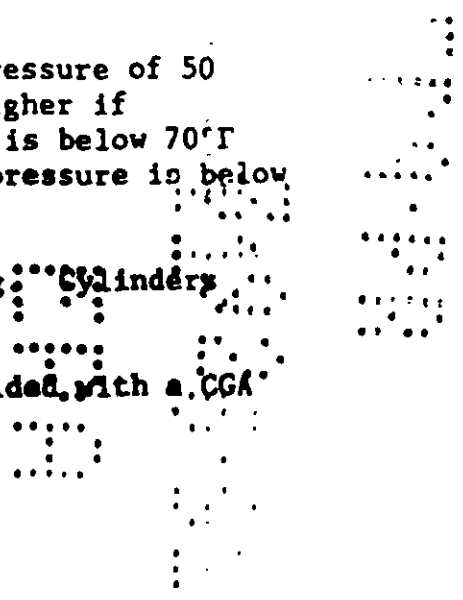
DIRECTIONS FOR USE

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.

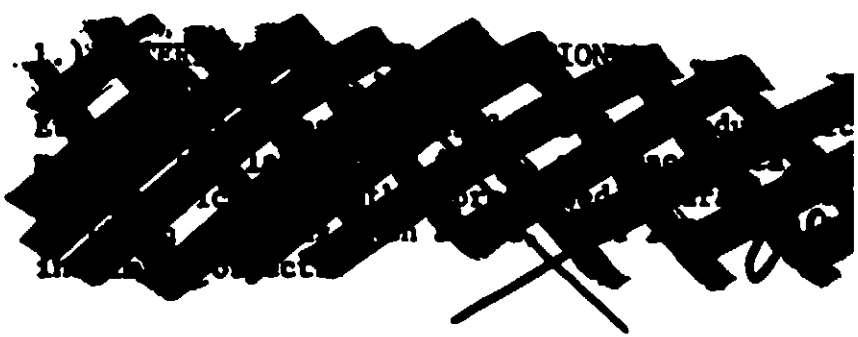
To be used only by persons experienced in ^{using} ethylene oxide sterilization and ^{for manufacturing, formulating, mixing, or} fumigation, or by persons under direct supervision of persons who are ^{repacking for} experienced in ^{use as a} ethylene oxide sterilization and fumigation. Use only in 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/cm²) 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/cm²) 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:

JAN 06 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
10330-14

STERILANT-FUMIGANT
FORMULATION OF ~~STERILANT~~ GAS MIXTURES:

REPACKING, MIXING AND

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.

This product is intended for use only in manufacturing, formulating, mixing or repacking for use as a pesticide.

- A. Ethylene Oxide may be repacked for use as a sterilant-fumigant gas.
- B. Ethylene oxide may be used in the formulation of sterilant-fumigant gas mixtures.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 10 1971
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
10330-14