US ENVIRONMENTAL PROTECTION AGENCY 10330-15 OFFICE OF PESTICIDES PROGRAMS TERM OF ISSUANCE REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: REGISTRATION Oxyfume 2000 (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) Praxair, Inc. 39 Old Ridgebury Road Danbury, CT 06810-5113 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: 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. 10330-15" b. Delete the CAS numbers from the ingredient statement. Properly align the percentages of your ingredients, and include the total percentage of 100%. Also delete the phrase "by weight" from the ingredient statement. c. Change "explicado" to "explicada". d. Delete the words "First Aid", the precautions in this section are considered to be the Statement of Practical Treatment. 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,

John H. Lee

Product Manager (31)

Antimicrobial Program Branch Registration Division (H7505C)

Enclosures

# THIS LABEL TO APPEAR ON CYLINDER SHOULDER

COMPRESSED GAS N.O.S.
(CHLOROTETRAFLUOROETHANE and ETHYLENE OXIDE)
UN 1956
RQ



ACCEPTED
with COMMENTS
in EPA Letter Dates:

APR 15 1993

Under the Federal Inverticide, Functicide, and Redemands had as amended, for the past of registrated under First New Value 10330-15

CGA 510

**OXYFUME 2000** 

STERILANT FUNIGANT GAS

Active Ingredient: ETHYLENE OXIDE 8.6% by weight

Inert Ingredient: CHLOROTETRAFLUOROETHANE 91.4% by weight

Net Contents: 135 lbs (61.2 kg)

LINDE STERILANT GASES

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER.

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# THIS LABEL TO APPEAR ON CYLINDER SIDE WALL

with COMMENTS in EPA Lotter Dated:

APK 1.5 1963

Under the Federal Insecticide, Fungicide, and Rodanticide Act amended, for the posteride symmetric under EPA Reg. No. 10330-15

OXYFUNE 2000

STERILANT FUNIGANT GAS

Active Ingredient: ETHYLENE OXIDE (CAS:75-21-8) 8.6% by weight

Inert Ingredient: CHLOROTETRAFILIOROETHANE (CAS:2837-89-8) 91.4% by weight

DANGER

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PELIGRO

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

#### HAZARDS TO HUMANS

DANGER! Nonflammable liquid and gas under pressure. Harmful if inhaled. Harmful if swallowed. May cause respiratory and nervous sytem 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, lightheaded 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 HEALT EFFECTS: May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29CFR1910.1047)

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

Contents under pressure. 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.

#### ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Oxyfume 2000, 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.

BEST AVAILABLE COPY

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.

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: 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.

FOR HEALTH CARE FACILITY AND INDUSTRIAL USE ONLY.

DOT/INO SHIPPING NAME: Compressed Gas, N.O.S. (Chlorotetrafluoroethane and Ethylene Oxide) UN1956

EPA Registration No. EPA Establishment No. 10330 Union Carbide Industrial Gases Inc. 39 Old Ridgebury Road Danbury, CT 06817

DO NOT REMOVE THIS LABEL

STB-XXXX (M/YR)

ACCEPTED
with COMMENTS
in EPA Lotter Dated:

APR 15 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide regulered under EPA Rev. No. 10320-15

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## DO NOT REMOVE THIS TAG

ACCEPTED
with COLDENTS
in EPA Lotter Dated:

OXYFUME . 2000 STERILANT-FUNIGANT GAS DANGER! NON-FLAMMABLE LIQUID AND GAS UNDER PRESSURE HARMFUL IF INHALED

APR 15 1993

Under the Federal insecticide, Fungicide, and Ecdenticide Act as amended, for the posticide repatiesed under ERA Reg. No. 10330-15

## 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. Oxyfume 2000 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Oxyfume 2000 must have knowledge of the hazards of this chemical mixture 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 Oxyfume 2000 sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxyfume 2000 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, 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.

## GENERAL INSTRUCTIONS

- 1. Always check cylinder valves and relief valves for leaks before moving cylinder into your facility.
- 2. This cylinder is equipped with an eductor tube for liquid delivery. Use vaporizing equipment to convert the liquid into a gas.
- 3. The approximate yapor pressure exerted by this gas mixture will be 26 psig (2.86 kg/cm²) at 70° (21.1°C) while liquid is present. Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70° (21.1°).
- 4. Cylinder must be in an upright position when discharging. Cylinders must be secured to prevent falling over.
- Discharge valve outlet is provided with a CGA 510 connection which has lefthand threads.
- 6. 1/2 ton style cylinders are also provided with a vapor phase CGA 510 connection which has lefthand threads. This vapor valve is for UCIG maintenance use only. Do not attempt to remove the locking plug from this vapor valve.

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- 7. Remove protective valve plug and make sure valve threads are undamaged. The connection to this cylinder valve should be a brass CGA 510 connector. Use of other metals could cause damage to the brass valve. Do not attach an ordinary pipe fitting to this valve.
- 8. All other piping and fittings should be steel or stainless steel, capable of withstanding the pressure to be encountered. Do not use rubber or plastic materials. Install relief devices where liquid can be trapped between valves.
- 9. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
- 10. To open cylinder valve, turn handwheel counter clockwise. Do not use a wrench or other leverage device to open or close cylinder valve.

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- 11. Use with adequate general and local ventilation.

with COMMENTS to EPA Lietter Dated:

12. Determine the quantity of product withdrawn from this cylinder by using an appropriate scale. APR 15 1993

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## 1.) STERILIZATION AND FUMIGATION

Oxyfume 2000 may be safely used to reduce microbial load and/or sterilize 10330-15 medical and laboratory items, pharmaceuticals, aseptic packaging,

inanimate objects.

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

A. Sterilization/fumigation with Oxyfume 2000 must be performed only in vacuum or gas tight chambers designed for use with 8.6% ethylene oxide by weight and 91.4% chlorotetrafluoroethane by weight, and in accordance with directions supplied by the chamber manufacturer.

NOTE: It is a violation of Federal Law to use Oxyfume 2000 Sterilant/Fumigant Gas for the fumigation of airplanes, trains, buses, ships, trucks, trailers, warehouses or other similar spaces.

- B. Oxyfume 2000 cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air 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 Oxyfume 2000 to be an effective sterilizing/
  fumigating agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

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Temperatures - 70° to 150°F

<u>Pre-Vacuum</u> typically 10 to 25 inches of mercury. Use vacuums compatible with the products and packages to be sterilized/fumigated.

Moisture - Relative humidity of 33% to 80%

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

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Oxyfume 2000 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

<u>Aeration</u> - 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.

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.

## 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 Oxyfume 2000 within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Oxyfume 2000 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.

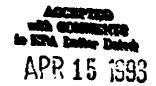
STORE IN AN AREA WITH ADEQUATE VENTILATION.

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

- A. REPLACE VALVE PLUG TIGHTLY IN VALVE CUTLET. IF VALVE PLUG IS NOT AVAILABLE, CONTACT SUPPLIER.
- B. CHECK CONTAINER VALVES FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER."

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