

AUG 31 1992

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

Attn: Algirdas G. Vilkas

Subject: Oxyfume 80
 EPA Registration No. 10330-3
 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:".

2. 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 acceptance 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

OXYFUME[®] 80

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT-ETHYLENE OXIDE (CAS: 75-21-8) 80% BY WEIGHT.

INERT INGREDIENT-CARBON DIOXIDE (CAS: 124-38-9) 20% 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 FORM 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 (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

Oxyfume 80 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, the active ingredient in Oxyfume 80, 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-4800.

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-4800.

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

DOT/IMO Shipping Name: Carbon Dioxide and Ethylene Oxide Mixtures, UN1041

INHALATION HAZARD

EPA Registration No. 10330-3
EPA Establishment No. 10330-
BATCH-

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

DO NOT REMOVE THIS LABEL

ACCREDITED
with COMMENTS
in EPA Letter
LINDE STERILANT GASES
MADE IN USA

STR-0500 (7/91)

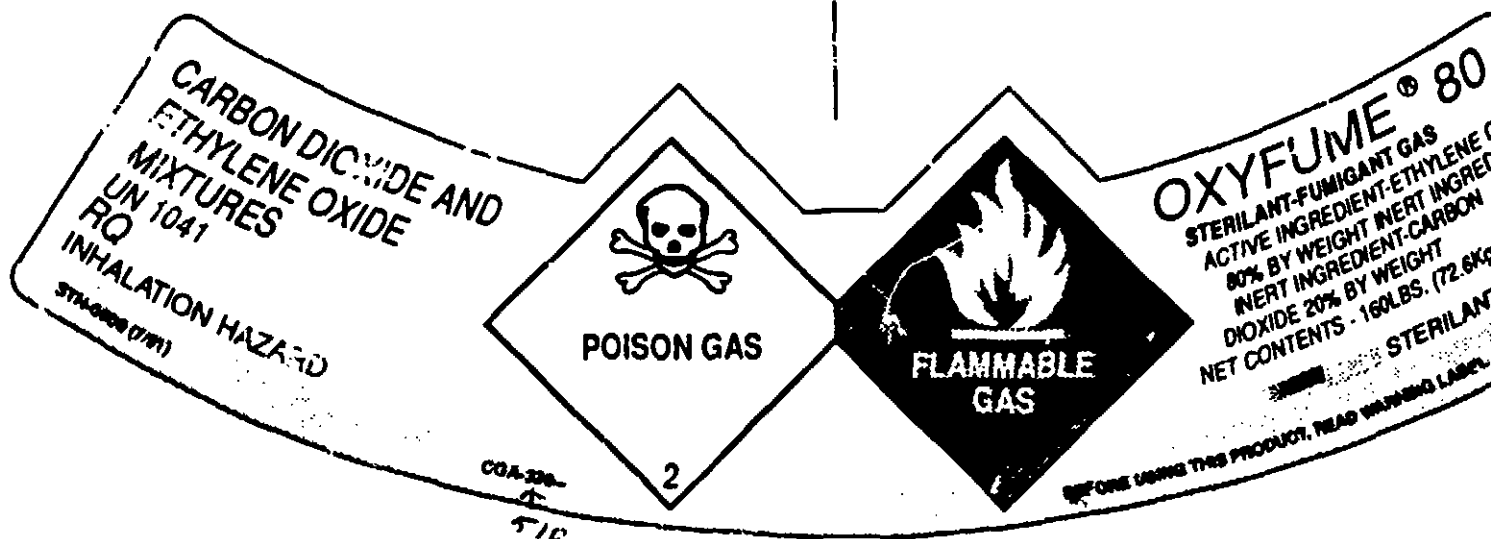
AUG 31 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
It is ordered, for the pesticide
registered under EPA Reg. No.
10330-3

BEST AVAILABLE COPY

STN-0500

ALL COPY BLACK
FLAMMABLE D.O.T. DIAMOND GREEN
BAR ACROSS BOTTOM PMS 466
LINDE LOGO-BLUE PMS 273 & GREEN 354
EDUCATORE CIRCLE PMS 354
THIS LABEL HAS BEEN CHANGED FROM DIE 128 TO G-25



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ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 31 1992
Under the Federal Insecticide,
Fungicide, and Rodenticide
Act, amended, for the purpose
of registration under EPA Reg.
10330-3

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. Oxyfume 80 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Oxyfume 80 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 80% EO 20% CO₂ sterilization or by persons under direct supervision of persons who are experienced in 80% EO 20% CO₂ sterilization. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current Union Carbide Industrial Gases Inc. Material Safety Data Sheet Form L-4800, 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 valve and plug 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 vapor pressure exerted by this gas mixture will be 175 psig (13.33 kg/cm²) at 70°F (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°F (21.1°C).
4. Cylinder must be in an upright position when discharging. Cylinder must be secured to prevent falling over.
5. Discharge valve outlet is provided with a CGA 510 connection which has lefthand threads.
6. Remove the protective valve plug and make sure the valve threads are not damaged. The connection to the cylinder valve should be a brass CGA 510 connector. Use of other metals could cause damage to the brass cylinder valve. Do not attach an ordinary pipe fitting to this valve.

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7. All other piping and fittings should be steel or stainless steel, capable of withstanding the pressure to be encountered. Do not use rubber, plastics, or copper materials. Install relief devices where liquid can be trapped between valves.
8. Ground all equipment including containers, to avoid static sparks.
9. Use only spark-proof tools.
10. Use only explosion proof electrical equipment where Oxyfume 80 may be present.
11. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
12. To open cylinder valve, turn handwheel counter clockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
13. 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.
14. Determine the quantity of product withdrawn from this cylinder by using an appropriate scale.

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registered for the pesticide
registered under EPA Reg. No.

10320-3

1.) STERILIZATION

Oxyfume 80 may be safely used to reduce microbial load and/or sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, 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 with Oxyfume 80 must be performed only in vacuum or gas tight chambers designed for use with 80% ethylene oxide by weight and 20% carbon dioxide by weight, and in accordance with directions supplied by the chamber manufacturer.

B. Oxyfume 80 cycle parameters depend on several sterilizing 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, packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized product and package.

C. The following is a list of ranges for the critical variables which must be in proper relationship for Oxyfume 80 to be an effective sterilizing 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 180°F

Pre-Vacuum - typically 25 to 29 inches of mercury. Use vacuums and/or inert gas purges compatible with the products and packages to be sterilized, 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 (milligrams of ethylene oxide per liter of chamber volume)

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Oxyfume 80 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

Aeration - aerate sterilized 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 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 OXYFUME 80 AND AIR TO ENTER THE CHAMBER.

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 80 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 80 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 OUTLET. IF VALVE PLUG IS NOT AVAILABLE, CONTACT SUPPLIER.
- B. CHECK CONTAINER VALVE AND PLUG FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.

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in EPA Letter Dated

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