

MAY 01 1987

Union Carbide Corporation
 Linde Division
 39 Old Ridgebury Road
 Danbury, CT 06817-0001

Attention: Algirdas G. Vilkas

Gentlemen:

Subject: Oxyfume 80
 EPA Registration No. 10330-3
 Your Submission Dated February 19, 1987

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable 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.
2. Make the labeling change listed below before you release the product for shipment bearing the amended labeling:
 - Add the following misuse statement under the heading DIRECTIONS FOR USE:

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

3. Submit an updated Confidential Statement of Formula.
4. Submit five (5) copies of your final printed labeling before you release the product for shipment.

BEST AVAILABLE COPY

93120: Lee: L-15: KENCO: 3/31/87: 4/10/87: TAR: VO: EK: TAR

CONCURRENCES							
SYMBOL	ORIGINATOR						
SURNAME							
DATE							

OFFICIAL FILE COPY

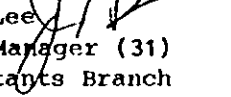
2/5

2

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

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

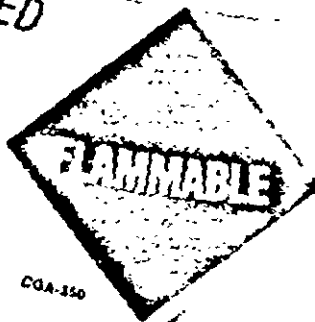
Sincerely yours,


John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

COMPRESSED
GAS N.O.S.
UN1954

OXYFUME® 80
CGA-350 (N/A2)
(2/87)



STERILANT - FUMIGANT GAS
ACTIVE INGREDIENT - ETHYLENE OXIDE
80% BY WEIGHT
INERT INGREDIENT - CARBON DIOXIDE
20% BY WEIGHT
NET CONTENTS - 150 LBS (72.5Kg)

RQ

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

LINDE SPECIALTY GASES

ACCEPTED
with COMMENTS
by EPA Label Desk

MAY 01 1987

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

10330-3

BEST AVAILABLE COPY

STERILIZATION

1. Use Oxyfume® 80 only in sterilizers designed for use with 80% by weight Ethylene Oxide and 20% by weight Carbon Dioxide.
2. Use Oxyfume® 80 in accordance with directions supplied by the sterilizer manufacturer.
3. Sterilizer temperature and pressure influence both exposure time and Ethylene Oxide concentration. The variation of type and quantity of material to be sterilized, how packed, size of sterilizer, types of bacteria to be killed, and chamber relative humidity also effect the exposure required for sterilization. Gas sterilizer cycle parameters should be those prescribed by the sterilizer manufacturer, if applicable. If other cycle parameters are used, the efficacy of the alternate cycle must be validated and is the responsibility of the user.
4. Aerate sterilized materials before use.

Union Carbide Corporation—Linde Division, Danbury, CT 06817

UNDE SPECIALTY GASES

STT-0500 (2/87)

STORAGE AND DISPOSAL

Return cylinder to supplier.
Store according to instructions
provided on label and tag.

ACCEPTED
with COMMENTS
in EPA Label Book

MAY 01 1987

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

10330-5

OXYFUME® 80 STERILANT GAS

ACTIVE INGREDIENT - ETHYLENE OXIDE 80% BY WEIGHT
INERT INGREDIENT - CARBON DIOXIDE 20% BY WEIGHT

DIRECTIONS FOR USE

DANGER - EXTREMELY FLAMMABLE

To be used only by persons experienced in Oxyfume® 80 gas sterilization, or by persons under direct supervision of persons who are experienced in Oxyfume® 80 gas sterilization. Use only in accordance with directions given on this tag and the precautions listed on the body label. See Union Carbide Corporation, Linde Division, Material Safety Data Sheet, Form L-480f and safe practices booklet L-3499 for additional safety information.

GENERAL INFORMATION

1. This cylinder is equipped with an eductor tube and is designed to discharge liquid.
2. The approximate vapor pressure exerted by this gas mixture will be 175 psig (1210 kPa) at 70°F (21°C) while liquid is present. Vapor pressure will be lower if temperature is below 70°F (21°C), higher if temperature is above 70°F (21°C).
3. Cylinder must be in an upright position when discharging. Cylinder must be secured to prevent falling over.
4. Discharge valve outlet is provided with a CGA 510 valve connection which has left hand threads. Make sure valve threads are undamaged. Do not attach ordinary pipe fittings to this valve.
5. Use metal (except aluminum) fittings and piping or Teflon-lined tubing capable of withstanding the pressures to be encountered. Install pressure relief device where liquid can be trapped between valves. Ethylene-propylene rubber and Teflon are suitable materials for gaskets. Ground all equipment, including cylinder, to avoid static sparks.
6. Install check valves in the discharge line from this cylinder to processing equipment to prevent back flow into cylinder.
7. Open cylinder valve by turning handwheel counterclockwise. Never use a wrench or other leverage device to open or close cylinder valve.

BEST AVAILABLE COPY

OXYFUME® 80**STERILANT GAS****ACTIVE INGREDIENT - ETHYLENE OXIDE 80% BY WEIGHT.****INERT INGREDIENT - CARBON DIOXIDE 20% BY WEIGHT.****DANGER! EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE. MAY FORM EXPLOSIVE MIXTURES WITH AIR. HARMFUL IF INHALED. CAUSES EYE AND SKIN BURNS.**

- **DANGER: CANCER HAZARD AND REPRODUCTIVE HAZARD**

- **OTHER POSSIBLE DELAYED HEALTH EFFECTS** may be nervous system injury, chromosomal changes, and cataracts.

- **EFFECTS OF OVEREXPOSURE** may be nausea, vomiting, diarrhea, numbness, weakness, loss of muscle coordination, dizziness, drowsiness, convulsions, loss of consciousness, irritation of lungs, delayed lung injury (fluid in lungs), breathing difficulties, blisters on skin, allergic skin reaction.

PEL: 1PPM-TWA (ETHYLENE OXIDE)
(OSHA-29CFR1910.1047)

ODOR: Ether-like at high concentrations.

Keep away from heat, flame and sparks. Do not breathe vapor. Do not get in eyes, on skin or clothing. Use only in a closed system. Store and use with adequate ventilation. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty. Use in accord with tag attached to valve.

FIRST AID: If inhaled, remove to fresh air. 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.

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 EMERGENCY: Call CHEMTREC 800-424-9300.

BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND LINDE SAFETY PRECAUTIONS BOOKLET FORM L-3499 AND MSDS FORM L-4800.

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

Union Carbide Corporation — Linde Division, Danbury, CT 06817

DOT Shipping Name: Compressed Gas N.O.S. UN1854

IMO Shipping Name: Carbon Dioxide and Ethylene Oxide Mixture, UN 1941

CAS: 75-21-8 (Ethylene Oxide).

CAS: 124-38-9 (Carbon Dioxide).

EPA Reg. No. 10330-3

EPA Est. No. 10330

878-0500 B/B

LATCH

LINDE SPECIALTY GASES

MADE IN USA

DO NOT REMOVE THIS LABEL

ACCEPTED
with COMMENTS
in EPA 10330-3

MAY 01 1987

This is a copy of the original
label for the product. It
must be used for the product
and must comply with EPA Reg. No. 10330-3

10330-3