

1/10 10330-5 PM 31

FEB 03 1987

Union Carbide Corporation  
Linde Division  
39 Old Ridgebury Road (R-4678)  
Danbury, CT 06817

Attention: Algirdas G. Vilkas

Gentlemen:

Subject: Oxyfume 12  
EPA Registration No. 10330-5  
Your Amendment Application Dated October 28, 1986

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:
  - Delete the term "GENERAL CLASSIFICATION."
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

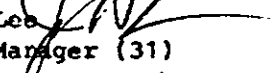
90198:Lee:L-4:KENCO:1/21/87:1/31/87:de:lf

| CONCURRENCES |  |  |  |  |  |  |  |
|--------------|--|--|--|--|--|--|--|
| SYMBOL ▶     |  |  |  |  |  |  |  |
| SURNAME ▶    |  |  |  |  |  |  |  |
| DATE ▶       |  |  |  |  |  |  |  |

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

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

Sincerely yours,

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

Enclosure

)

)

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
STN-0200 (6/85)

CGA-819



STERILANT  
ACTIVE INGREDIENT - 12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 25 LBS (11.3kg)

BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER  
LINDE SPECIALTY GAS

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
STN-0210 (7/85)

CGA-819



STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT - ETHYLENE OXIDE  
12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 55 LBS (24.9kg)

CAS: (75-71-8)(75-21-8)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

LINDE SPECIALTY GAS

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
STN-0220 (6/85)

CGA-810



STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT - ETHYLENE OXIDE  
12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 135 LBS (61.2kg)

CAS: (75-71-8)(75-21-8)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

LINDE SPECIALTY GAS

ACCEPTED  
with  
in

FEB 03 1985

Tested  
Fumigant  
as intended  
registered under EPA  
10330-5

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
STN-0230 (7/85)

CGA-819



STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT - ETHYLENE OXIDE  
12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 229 LBS (122.4kg)

CAS: (75-71-8)(75-21-8)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

1/6

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
8 (14-0230) (7/80)



CGA 418

STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT - ETHYLENE OXIDE  
12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 1130 LBS (512Kg)



LINDE SPECIALTY GASES  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

CAS (75-71-8)(75-21-8)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

COMPRESSED  
GAS N.O.S.  
UN1956

OXYFUME® 12  
8 (14-0230) (7/80)



CGA 418

STERILANT - FUMIGANT GAS  
ACTIVE INGREDIENT - ETHYLENE OXIDE  
12% BY WEIGHT  
INERT INGREDIENT - DICHLORODIFLUORO-  
METHANE 88% BY WEIGHT  
NET CONTENTS - 1620 LBS (735Kg)

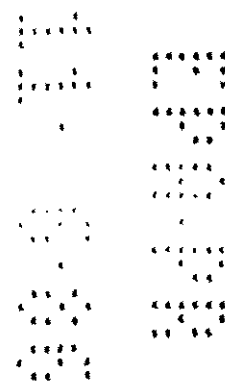


LINDE SPECIALTY GASES  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

CAS (75-71-8)(75-21-8)  
BEFORE USING PRODUCT, READ WARNING LABEL ON SIDE OF CYLINDER

ACCEPTED  
FEB 03 1987

1030-5



## FUMIGATION

1. Fumigation with Oxyfume® 12 should be performed in vacuum or gaslight chambers designed for use with 12% by weight Ethylene Oxide and 88% by weight Dichlorodifluoromethane (Refrigerant 12). If vacuum or gaslight chambers are not used, precautions must be taken to assure the safety of all potentially exposed personnel.
2. If Oxyfume® 12 is not used in a fumigation chamber, provisions must be made to assure complete vaporization of the liquefied compressed gas by using an appropriately designed heat exchanger or vaporizing nozzle (Linde P/N 201-4080).
3. Place warning signs around areas where material is being fumigated. Ventilate adjacent areas.
4. Use self-contained breathing apparatus and protective clothing if personnel are required in an enclosed area during the initial gassing of that area.
5. Ventilate fumigated area before entering. Aerate fumigated materials before use.
6. Dosage:
  - A. For chamber fumigation at 70°F (21.1°C) or higher, materials such as furs, clothing, furniture, spices, and natural seasonings, are typically treated with 15 pounds (6.8 Kg) by weight of Oxyfume® 12 per 1000 cubic feet (28.3m³) of chamber space for 16 hours. Treatment may not be effective if material is densely packed.
  - B. For transportation equipment, such as planes, railcars, passenger cars, and buses, at 70°F (21.1°C) or higher, 10 pounds (4.5 Kg) by weight of Oxyfume® 12 is typically used for every 1000 cubic feet (28.3m³) of vehicle space for 5 to 6 hours.

## JD TREATMENT: 21 CFR 193.200

"Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices and other processed natural seasoning materials, except mixtures to which salt has been added . . ."

"Ethylene oxide, either alone or admixed with carbon dioxide or dichlorodifluoromethane, shall be used in amounts not to exceed that required to accomplish the intended technical effects."

Union Carbide Corporation - Linde Division, Danbury, CT 06817

## LINDE SPECIALTY GASES

STT-0200 (3/83)

## GENERAL CLASSIFICATION

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

## STORAGE AND DISPOSAL

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

## OXYFUME® 12 STERILANT-FUMIGANT GAS

ACTIVE INGREDIENT-ETHYLENE OXIDE 12% BY WEIGHT  
INERT INGREDIENT-DICHLORODIFLUOROMETHANE  
88% BY WEIGHT

## DIRECTIONS FOR USE

To be used only by persons experienced in Oxyfume® 12 gas sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxyfume® 12 gas sterilization and fumigation. Use only in accordance with directions given on this tag and the safety precautions listed on the body label. See current Union Carbide Corporation, Linde Division, Material Safety Data Sheet, Form L-4799, 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 60 psig (414 kPa) at 70°F (21.1°C) while liquid is present. Vapor pressure will be lower if temperature is below 70°F (21.1°C); higher if temperature is above 70°F (21.1°C).
3. Cylinder must be in upright position when discharging. Cylinder must be secured to prevent falling over.
4. Discharge valve outlet is provided with a CGA 510 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 pressure to be encountered. Install pressure relief device where liquid can be trapped between valves. Ethylene-propylene rubber and Teflon are suitable materials for gaskets.
6. Open cylinder valve by turning handwheel counterclockwise. Never use a wrench or other leverage device to open or close cylinder valve.

## STERILIZATION

1. Use Oxyfume® 12 only in sterilizers designed for use with 12% by weight Ethylene Oxide and 88% by weight Dichlorodifluoromethane (Refrigerant 12).
2. Use Oxyfume® 12 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 affect the exposure time 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.

ACCEPTED  
with [unclear]  
in [unclear]

FEB 03 1987

10330-5

# OXYFUME® 12

STERILANT - FUMIGANT GAS.

ACTIVE INGREDIENT - ETHYLENE OXIDE 12% BY WEIGHT.  
INERT INGREDIENT -

DICHLORODIFLUOROMETHANE 88% BY WEIGHT.

**DANGER! NONFLAMMABLE LIQUID AND GAS  
UNDER PRESSURE. 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.

Do not breathe gas. Do not get in eyes, on skin, or clothing. Store and  
use with adequate ventilation. No part of the cylinder 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, imme-  
diately 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 contam-  
inated clothing and discard leather goods.

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

**FIRE:** Use water spray or fog nozzle to keep cylinder cool. Move  
cylinder away from fire if without risk.  
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-4799.**

## FOR HOSPITAL AND INDUSTRIAL USE ONLY.

This product contains Chlorofluorocarbon-12.  
Classified by Underwriters' Laboratories, Inc. as to fire hazard only.  
Oxyluma® 12 Sterilant - Fumigant: The product supplied liquefied  
under pressure is non-flammable at ordinary temperatures, but at  
higher temperatures (ignition temperature 483°C, 865°F), is capable  
of forming weakly combustible mixtures with air, which do not pro-  
pagate flame throughout the mixture. Control No. 898P,  
Union Carbide Corporation—Linde Division, Danbury, CT 06817

DOT Shipping Name: Compressed Gas N.O.S. UN1956.

IMO Shipping Name: Liquefied Gas, Toxic, N.O.S. UN1956

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

CAS: 75-71-8 (Dichlorodifluoromethane).

EPA Reg. No. 10330-5

EPA Est. No. 00000

ST2-0200 8/86

BATCH:-

**LINDE SPECIALTY GASES**

MADE IN U.S.A.

DO NOT REMOVE THIS LABEL

BEST AVAILABLE COPY