

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460  <b>NOTICE OF PESTICIDE:</b> <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION  <i>(Under the Federal Insecticide, Fungicide,          and Rodenticide Act, as amended)</i>	EPA REGISTRATION NO. <b>67470-9</b>  TERM OF ISSUANCE  NAME OF PESTICIDE PRODUCT  <b>Oxyfume 2002</b>	DATE OF ISSUANCE <b>OCT 12 1994</b>
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)  <div style="border: 1px solid black; padding: 10px; width: fit-content; margin: auto;"> <p>AlliedSignal Inc              PO BOX 1139              Morristown, NJ 07962</p> </div>		
<b>NOTE:</b> 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.		
<p>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.</p> <p>A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.</p> <p>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.</p> <p style="text-align: center;"><b>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</b></p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Make the labeling changes listed below before you release the product for shipment:       <ol style="list-style-type: none"> <li>a. Add the phrase "EPA Registration No. 67470-9".</li> <li>b. Add the appropriate EPA Establishment No.</li> <li>c. It is preferred that the signal word: Danger, (Center panel only) be placed directly under the heading: KEEP OUT OF REACH OF CHILDREN</li> <li>d. Revise the statement: Hazards to Humans to read: Hazards to Humans and Domestic Animals</li> </ol> </li> </ol>		
<input type="checkbox"/> ATTACHMENT IS APPLICABLE		
SIGNATURE OF APPROVING OFFICIAL	DATE	

1076

e. Include the heading: Precautionary Statements. This statement must be placed directly above the subheading: Hazards to Humans and Domestic Animals.

f. Delete the word: Warning

g. Add a referral statement: Refer to tag for complete use directions.

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

a. Add a referral statement to the main label for use directions and precautionary statements.

b. Include the EPA Registration No.

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 phrase "EPA Registration No. ".

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,



Marshall Swindell  
Acting Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (H7505C)

# OXYFUME® 2002

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT: ETHYLENE OXIDE

10.0%

INERT INGREDIENT: CHLORODIFLUOROMETHANE

27.0%

INERT INGREDIENT: CHLOROTETRAFLUOROETHANE

63.0%

100.0%

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

**WARNING:** Contains HCFC-22 and HCFC-124, substances which harm public health and environment by destroying ozone in the upper atmosphere.

## ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Oxyfume 2002, is not intended for outdoor use. 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.

### STATEMENT OF PRACTICAL TREATMENT

IN ALL CASES OF 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, FIRST AID MEASURES, ALLIEDSIGNAL MATERIAL SAFETY DATA SHEET.

LEAK: Evacuate area and keep personnel upwind. 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 1-201-455-2000

BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND THE ALLIEDSIGNAL MATERIAL SAFETY DATA SHEET FOR THIS PRODUCT.

FOR HEALTH CARE FACILITY AND INDUSTRIAL USE ONLY.

DOT-E 10184

DOT/IMO Shipping Name: Compressed Gas, N.O.S. (Ethylene oxide, Chlorodifluoromethane and Chlorotetrafluoroethane) UN1956 Ethylene Oxide CAS: 75-21-8

Chlorodifluoromethane CAS: 75-45-6

Chlorotetrafluoroethane CAS: 2837-89-0

EPA Registration No.

EPA Establishment No.

BATCH-

AlliedSignal Inc.  
101 Columbia Road  
Morristown, NJ 07962-1139

**AlliedSignal**  
CHEMICALS

DO NOT REMOVE THIS LABEL

MADE IN USA

STB-2002 (2/94)

OCT 12 1994

BEST AVAILABLE COPY

67470-9

STN-2002 (2/94)  
DIE# G-114  
ALL COPY BLACK  
DIAMOND-DOT GREEN pick up from STN-0200  
EDUCTOR CIRCLE-DOT GREEN pick up from STN-0200  
BAR ACROSS LOWER EDGE-BEIGE pick up from STN-0200

BEST AVAILABLE COPY

DOT GREEN

COMPRESSED GAS, N.O.S.  
(ETHYLENE OXIDE,  
CHLORODIFLUOROMETHANE  
AND CHLOROTETRAFLUOROETHANE)  
UN 1956  
RQ

NON-FLAMMABLE  
GAS  
2

NET CONTENTS - 135 LBS. (61.2 Kg)

**OXYFUME® 2002**  
STERILANT-FUMIGANT GAS

ACTIVE INGREDIENT:	
ETHYLENE OXIDE	10.0%
INERT INGREDIENTS:	
CHLORODIFLUOROMETHANE	27.0%
CHLOROTETRAFLUOROETHANE	63.0%
	100.0%

EDUCTOR TUBE

**AlliedSignal**  
CHEMICALS

BC11-6

OCT 12 1994

APPROVED  
WITH COMMENTS  
by EPA Est. No. 1000000000

617470-4

**STERILIZANT/ FUMIGANT GAS**

**DANGER! NON-FLAMMABLE LIQUID AND GAS UNDER PRESSURE.  
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. Oxyfume 2002 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Oxyfume 2002 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 2002 sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxyfume 2002 sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current AlliedSignal Material Safety Data Sheet

**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 vapor pressure exerted by this gas mixture will be 50 psig (5.50 kg/cm<sup>2</sup>) 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 left-hand threads.
6. Remove protective valve plug and make sure valve threads are undamaged. The connection to the cylinder valve should be brass a 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.
7. 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.
8. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
9. To open cylinder valve, turn handwheel counterclockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
10. Use with adequate general and local ventilation.
11. Determine the quantity of product withdrawn from this cylinder by using an appropriate scale.

**STERILIZATION AND FUMIGATION**

Oxyfume 2002 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/fumigation with Oxyfume 2002 must be performed only in vacuum or gas tight chambers designed for use with 10% ethylene oxide by weight, 27.0% Chlorodifluoromethane by weight and 63.0% chlorotetrafluoroethane by weight, and in accordance with directions supplied by the chamber manufacturer.

NOTE: It is a violation of Federal Law to use Oxyfume 2002 Sterilant/Fumigant Gas for the fumigation of airplanes, trains, buses, ships, trucks, trailers, warehouses or other similar spaces.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 12 1994

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

67470-9

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B. Oxyfume 2002 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 2002 to be an effective sterilizing/fumigating agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

TEMPERATURES - 70°F to 150°F

PRE-VACUUM - 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 oxide per liter of chamber volume)

EXPOSURE TIME - 45 minutes to 20 hours

POST-VACUUMS - Oxyfume 2002 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

AERATION - 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 2002 within 6 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Oxyfume 2002 should not be stored in any place where the temperature consistently exceeds 100°F. See AlliedSignal Publication "Sterilizer Maintenance and Ethylene Oxide Polymer."

**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 FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.

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