

OXYFUME® 2000

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT: ETHYLENE OXIDE

8.6%

INERT INGREDIENT: CHLOROTETRAFLUOROETHANE

91.4%

KEEP OUT OF REACH OF CHILDREN

100.0%

DANGER PELIGRO

PRECAUCION AL USUARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta la haya sido explicada ampliamente. Users must follow the requirements of the OSHA occupational exposure standard for ethylene oxide (29 CFR 1910.1047).

AlliedSignal
CHEMICALS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! LIQUID AND GAS UNDER PRESSURE.
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 Ethylene Oxide (OSHA-
29CFR1910.1047)

EL: 5PPM-exposure 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 in accordance with 29 CFR
1910.1047.

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Use only in 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-124, a substance which
harmful public health and environment by destroying
ozone in the upper atmosphere.

ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Oxyfume 2000, 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 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 even if no
symptoms are present. Keep under medical observation.
Symptoms may be delayed.

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, OXYF-0003. To obtain MSDS,
call 1-201-455-4157.

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 CALL: 1-201-455-2000

REFER TO TAG FOR COMPLETE USE DIRECTIONS.

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: Ethylene Oxide and Chlorotetrafluoroethane Mixture

US DOT Hazard Class: 2.2 US DOT ID Number: UN 3297

Ethylene Oxide CAS: 75-21-8

Chlorotetrafluoroethane CAS: 2837-89-0

EPA Registration No. 67470-8

EPA Establishment No. 67470-AZ-001

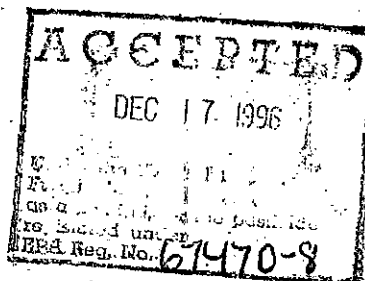
AlliedSignal Inc.
101 Columbia Rd., Morristown, NJ 07962-1053

BATCH-

DO NOT REMOVE THIS LABEL

MADE IN USA

STB-0900 (4/96)



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PM3) 67470-8

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DO NOT REMOVE TAG

OXYFUME 2000
STERILANT/FUMIGANT GAS
DANGER! 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 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 the safety precautions listed on the label and this tag. See current AlliedSignal Material Safety Data Sheet, OXYF-0003.

STERILIZATION AND FUMIGATION

Oxyfume 2000 may be safely used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and reduce microbial load on cosmetics. Items to be sterilized should be thoroughly cleaned of soil before being placed in any type of sterilizer.

- A. Oxyfume 2000 may be used only in facilities that meet the requirements of 29 CFR 1910.1047 in non-portable vacuum or gas-tight chambers designed for use with 8.5% ethylene oxide, and 91.4% chlorotetrafluoroethane. Oxyfume 2000 may be used only by persons who have been trained in accordance with 29 CFR 1910.1047. When used by healthcare providers to sterilize health care items, Oxyfume 2000 must be used in non-portable ethylene oxide gas sterilizers that meet FDA regulatory requirements, and in accordance with directions supplied by the sterilizer manufacturer.

NOTE: It is a violation of Federal Law to use Oxyfume 2000 Sterilant/Fumigant Gas for the fumigation of beehives, 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.

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.)

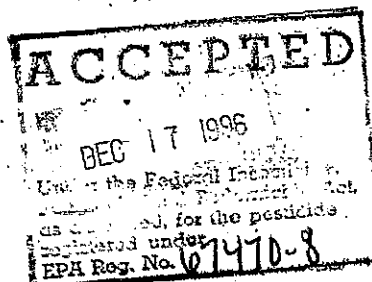
EXPOSURE TIME - 45 minutes to 20 hours

POST-VACUUMS - Oxyfume 2000 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 201.1 sub-section (d).

- D. The sterilization/fumigation cycle parameters should be those prescribed by the sterilizer 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.



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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 28 psig (2.86 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 left-hand threads.
6. Remove protective valve plug and make sure valve threads are undamaged. The connection to the cylinder valve should be 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.
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.

STORAGE AND DISPOSAL

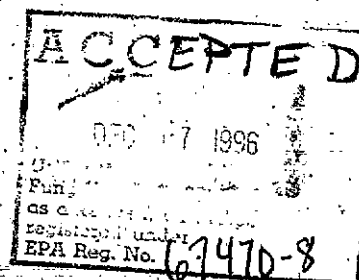
Store according to instructions provided on label and this tag. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out basis. A good rule of thumb is to use Oxyfume 2000 within 6 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Oxyfume 2000 should not be stored in any place where the temperature consistently exceeds 100°F. See AlliedSignal Publication "Sterilizer Maintenance and Ethylene Oxide Polymer."

STORE IN AN AREA WITH ADEQUATE VENTILATION**PESTICIDE DISPOSAL:
CONTAINER DISPOSAL**

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.

PATENT INFORMATION This product and its use for sterilization are protected by US Patent #5376333. The purchase of this product gives you a license under the patent for single use only, and subsequent use constitutes patent infringement. Any re-use of this product, or unauthorized reconditioning (which may not meet stringent requirements), is potentially unsafe and a violation of the license terms granted to you upon sale of this product.



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