

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AlliedSignal Inc  
101 Columbia Rd  
Morristown, NJ 07962-1139

Attention R Greg Watson  
Supervisor, Product Safety

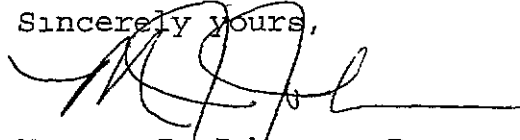
Subject Oxyfume 12  
EPA Registration Number 67470-3  
Your Submission June 28, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release this product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact Velma Noble at (703) 305-7441

Sincerely yours,



Marion J. Johnson, Jr  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

## CONCURRENCES

SYMBOL								
SURNAME								
DATE								

# OXYFUME® 12

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT: ETHYLENE OXIDE 12.0%

INERT INGREDIENT: DICHLORODIFLUOROMETHANE 88.0%

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).



## 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 CFC-12, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

## ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Oxyfume 12, 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. Aspirate, 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-0002. 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 Dichlorodifluoromethane Mixture

US DOT Hazard Class: 2.2

US DOT ID Number: UN 3070

Ethylene Oxide CAS: 75-21-8

Dichlorodifluoromethane CAS: 75-71-8

EPA Registration No. 67470-3

EPA Establishment No. 67470-AZ-001

AlliedSignal Inc.

101 Columbia Rd., Morristown, NJ 07962-1053

BATCH-

DO NOT REMOVE THIS LABEL

MADE IN USA

8TB-0200 (4/86)

BEST AVAILABLE COPY

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**OXYFUME® 12**  
**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. Oxyfluene 12 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Oxyfluene 12 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 Oxytyme 12 sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxytyme 12 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-0002.

## STERILIZATION AND FUMIGATION

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

- A. Oxifume 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 10.0% ethylene oxide, and 89.0% dichlorodifluoromethane. Oxifume 12 may be used only by persons who have been trained in accordance with 29 CFR 1910.1047. When used by health care providers to sterilize health care items, Oxifume 12 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 12 Sterilant/Fumigant Gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.

8. Orytime 12 cycle parameters depend on several sterilizing/tumigating 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/tumigated; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized/tumigated product and package.

- C. The following is a list of ranges for the critical variables which must be in proper relationship for Oxymune 12 to be an effective sterilizing/tunigating 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 12 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 sanitation 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). For residual limits on agricultural commodities see 40 CFR 180.151 and 40 CFR 185.2850. The sterilization/functional cycle parameters should be those prescribed by the sterilizer equipment

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The above information is for informational purposes only and does not constitute a recommendation for use. The user should consult the product label for complete instructions and safety information.

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.

#### 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 60 psig (5.25 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 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 Oxytume 12 within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Oxytume 12 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.



CHIMICALS  
AlliedSignal Inc.  
101 Columbia Road  
Morristown, NJ 07962-1053

EPA Registration No. 67470-3

STT-0200 (4/96)