

ETHYLENE OXIDE

STERILANT-FUMIGANT GAS.
ACTIVE INGREDIENT: ETHYLENE OXIDE 100.0%
KEEP OUT OF REACH OF CHILDREN

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.
DANGEROUSLY EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE. MAY CAUSE EXPLOSIVE MIXTURES WITH AIR. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE.
DANGEROUS! 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

Ethylene oxide is extremely flammable and reactive. Contents under pressure. Keep away from heat, flame, sparks or hot surfaces. Do not allow sources of ignition near the sterilization/fumigation area. 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. Ground all equipment, including containers, to avoid static sparks.

ENVIRONMENTAL HAZARDS

Ethylene oxide 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. Breathe,

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-0001. 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: 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 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 INDUSTRIAL USE ONLY. NOT FOR USE IN HOSPITALS OR HEALTH CARE FACILITIES.
DOT/IMO Shipping Name: Ethylene Oxide **INHALATION HAZARD**

US DOT Hazard Class: 2.3 **US DOT ID Number: UN 1040**

Ethylene Oxide CAS: 75-21-8

EPA Registration No. 67470-6 **EPA Establishment No. 67470-AZ-001**

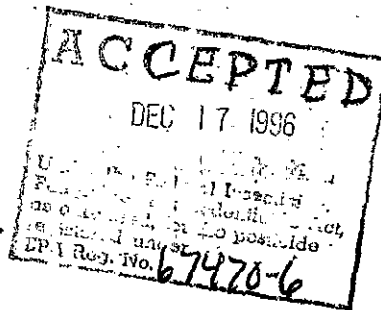
BATCH:

DO NOT REMOVE THIS LABEL

MADE IN USA

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

STB-0100 (4/96)



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PM 31 67470-6

DO NOT REMOVE TAG

**ETHYLENE OXIDE
STERILANT-FUMIGANT GAS
DANGER! EXTREMELY FLAMMABLE AND EXPLOSIVE
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. Ethylene oxide is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Ethylene oxide 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 ethylene oxide sterilization and fumigation, or by persons under direct supervision of persons who are experienced in ethylene oxide 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-0001.

STERILIZATION AND FUMIGATION

Ethylene oxide may be safely used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and to 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. Ethylene oxide 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 100.0% ethylene oxide. Ethylene oxide 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, ethylene oxide 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 ethylene oxide sterilant/fumigant gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.

B. Ethylene oxide 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 ethylene oxide 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 25 to 28 inches of mercury. Use vacuums compatible with the products and packages to be sterilized/fumigated, and such that explosive atmospheres are never present in the chamber.

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 - Ethylene oxide is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

AERATION - Breathe 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). For residual limits on agricultural commodities see 40 CFR 180.151 and 40 CFR 185.2850.

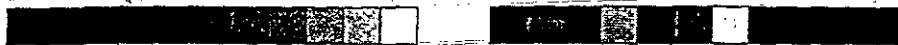
D. The sterilization/fumigation cycle parameters should be those prescribed by the sterilizer equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user.

NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

ACCEPTED
DEC 17 1996
This is the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under
EPA Reg. No. 64410-6

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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. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 psig (3.52 kg/cm²) at 70°F (21.1°C). Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C). Contact supplier if, upon receipt, container pressure is below 50 psig (3.52 kg/cm²) at 70°F (21.1°C).
4. Container must be in an upright position when discharging. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve (marked "Liquid") is provided with a CGA 510 connection which has left-hand threads.
6. EOX and SS55 style cylinders and DOT 5P drums are also provided with a CGA 580 inert pressurizing valve (marked "Vent") which has right-hand threads. Do not discharge product from the CGA 580 inert pressurizing valve.
7. Remove protective valve plugs and make sure valve threads are undamaged. Do not attach an ordinary pipe fitting to these valves. The connections to the container valves should be brass CGA 510 and CGA 580 connectors. Use of other metals could cause damage to the brass container valves.
8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressure to be encountered. Do not use rubber, plastics, or copper materials. Install relief devices where liquid can be trapped between valves.
9. Ground all equipment, including containers, to avoid static sparks.
10. Use only spark-proof tools.
11. Use only explosion-proof electrical equipment where ethylene oxide may be present.
12. Install check valves in the discharge line from this container to processing equipment to prevent back-flow into the container.
13. Connect the CGA 580 inert pressurizing valve (marked "Vent") to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve and check valve. The source of nitrogen should be used exclusively for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum.
14. To open container valves, turn counterclockwise. The liquid discharge valve is equipped with a handwheel. Do not use a wrench or other leverage device on handwheel. Use a "T" wrench to open the inert pressurizing valve on the EOX and SS55 cylinders and SP drums.
15. Use with adequate general and local ventilation. Vapors form from this product and may travel or be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters electrical equipment, static discharges or other ignition sources at location distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using and appropriate scale.

STORAGE AND DISPOSAL

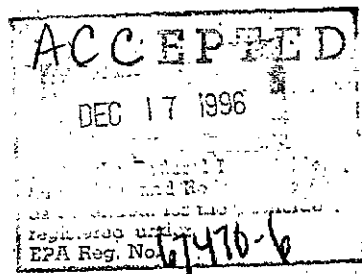
Store according to instructions provided on label and this tag. To control ethylene oxide polymer growth, use all inert gas on a first-in, first-out basis. A good rule of thumb is to use ethylene oxide within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, ethylene oxide 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. Pressure container with nitrogen to 50 psig total pressure at 70°F (21.1°C) and be sure container valves are closed.
 - B. Replace valve plugs tightly in valve outlets. If valve plugs are not available, contact supplier.
 - C. Check container valves and plugs for leaks prior to shipment. If leaks are detected contact supplier.



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EPA Registration No. 67470-3

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