

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.

NOTE TO USER: 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 must 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. Also see current Honeywell Material Safety Data Sheet for Oxyfume 2000.

STERILIZATION AND FUMIGATION

Oxyfume 2000 must be used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and reduce microbial load on cosmetics, artifacts, archival material or library objects. Items to be sterilized must be thoroughly cleaned of soil before being placed in any type of sterilizer.

- A. Oxyfume 2000 must be used only in facilities that meet the requirements of 29 CFR 1910.1047 in non-portable (commercial) vacuum or gas-tight chambers designed for use with 8.6% ethylene oxide, and 91.4% chlorotetrafluoroethane. Oxyfume 2000 must be used only by persons who have been trained in accordance with 29 CFR 1910.1047. In hospitals and healthcare facilities, sterilization/fumigation with Oxyfume 2000 must be performed only in vacuum or gas-tight chambers designed for use with Oxyfume 2000 that have FDA clearance and in accordance with directions supplied by the sterilizer manufacturer. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

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.

In contract sterilization facilities, including facilities treating medical equipment and supplies, library/museum artifacts and cosmetics, the following requirements must be followed: Sterilization/fumigation with Oxyfume 2000 must be performed only in vacuum or gas-tight chambers designed for use with Oxyfume 2000.

Safety and awareness training is required for all employees including office staff. Information must be provided to all employees in the facility at the time of initial assignment and annually thereafter.

The safety training must include, at a minimum, the following information:

1. the most recent monitored ambient levels of ethylene oxide in the facility;
2. the potential health effects from the levels of ethylene oxide in the facility;
3. the emergency response plan and how to respond in an emergency;
4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ethylene oxide.

In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. It greatly reduces potential long-term risks to employees not directly involved in the ethylene oxide applications.

- B. Oxyfume 2000 cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (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.
- E. Employers in facilities that use Oxyfume 2000 must comply with all of the requirements for ethylene oxide use specified in 29CFR 1910.1047.

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 26 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

Do not contaminate food, feed, or water by storage and disposal.

PESTICIDE STORAGE

Store according to instructions provided on label and this tag. Store away from heat in an area with adequate ventilation. Do not store in direct sunlight. To minimize polymer growth, Oxyfume 2000 must not be stored in any place where the temperature consistently exceeds 100°F. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out basis.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Refillable container. Refill this container only with a non-flammable ethylene oxide mix. Do not reuse this container for any other purpose. Return container to supplier for reuse. Before returning container to supplier:

- A. Replace valve plugs tightly in valve outlets. If valve plugs are not available, contact supplier.
- B. Check container valves and plugs 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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