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DO NOT REMOVE THIS TAG

ACCEPTED

OCT 3 1995

Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 36736-7

STERILIZING GAS 8

STERILANT-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. Sterilizing Gas 8 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Sterilizing Gas 8 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.

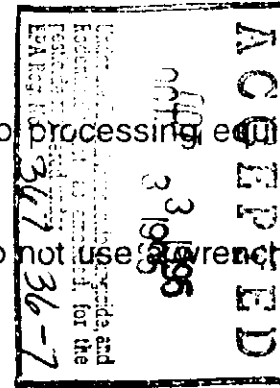
To be used only by persons experienced in 8.5% EO 91.5% CO₂ (or 10% EO 90% CO₂) sterilization and fumigation, or by persons under direct supervision of persons who are experienced in 8.5% EO 91.5% CO₂ (or 10% EO 90% CO₂) sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current MG Industries Material Safety Data Sheet for Sterilizing Gas 8.

GENERAL INSTRUCTIONS

1. Always check cylinder valve 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 750 psig (53.76 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 350 connection which has lefthand threads.
6. Remove protective valve plug and make sure valve threads are undamaged. The connection to the cylinder valve should be a brass CGA 350 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, plastics, or copper 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 counter clockwise. Do not use wrench or other leverage device to open or close cylinder valve.
10. Use with adequate general and local ventilation.
11. Always open the cylinder valve wide open when discharging contents. Do not restrict flow of gas from cylinder valve or use pressure regulators because the ratio of carbon dioxide to ethylene oxide in the gas mixture will be changed.



STERILIZATION AND FUMIGATION

Sterilizing Gas 8 may be safely used to reduce microbial load and/or sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, whole and ground spices and other processed natural seasoning materials except mixtures to which salt has been added (see 21 CFR 193.200), 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 Sterilizing Gas 8 must be performed only in vacuum or gas tight chambers designed for use with 8.5% ethylene oxide by weight and 91.5% carbon dioxide by weight, and in accordance with directions supplied by the chamber manufacturer.

NOTE: It is a violation of Federal Law to use Sterilizing Gas 8 for the fumigation of airplanes, trains, buses, ships, trucks, trailers, warehouses or other similar spaces.

- B. Sterilizing Gas 8 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 Sterilizing Gas 8 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° to 150°F

Pre-Vacuum - Typically 20 to 28 inches of mercury. Use vacuum and/or inert gas purges compatible with the products and packages to be sterilized/fumigated.

Moisture - Relative humidity of 33% to 80%

Gas Concentration - 150 mg/L to 800 mg/L (milligrams of ethylene oxide per liter of chamber volume).

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Sterilizing Gas 8 should be 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 exposure 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. For residual limits on agricultural commodities, see 40 CFR 180.151 and 21 CFR 193.200 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 Sterilizing Gas 8 within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Sterilizing Gas 8 should not be stored in any place where the temperature consistently exceeds 100°F.

STORE IN AN AREA WITH ADEQUATE VENTILATION.

RETURN CONTAINER TO SUPPLIER. 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 AND PLUG FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.

