

RECEIVED
DEC 17 1986
EPA Reg. No. 107470-1

STB-0300 (4/96)

BATCH-

DO NOT REMOVE THIS LABEL

MADE IN USA

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 675 psig (48.49 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 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 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 or plastic materials. Install relief devices where liquid can be trapped between valves.
8. Ground all equipment, including containers, to avoid static sparks.
9. Use only spark-proof tools.
10. Use only explosion-proof electrical equipment where Oxyfume 20 may be present.
11. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
12. To open cylinder valve, turn handwheel counterclockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
13. Use with adequate general and local ventilation. Vapors 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.
14. Determine the quantity of product withdrawn from this container by using and appropriate scale.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 sterilant gas on a first-in, first-out basis. A good rule of thumb is to use Oxyfume 20 within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Oxyfume 20 should not be stored in any place where the temperature constantly exceeds 100°F. See AlliedSignal Publication "Sterilizor Maintenance and Ethylene Oxide Polymer."

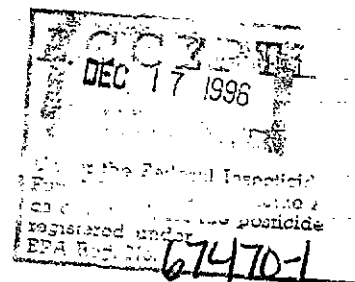
STORE IN AN AREA WITH ADEQUATE VENTILATION

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.



BEST AVAILABLE COPY



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

EPA Registration No. 67470-4

STT-0300 (4/96)

DO NOT REMOVE TAG

OXYFUME 20
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. Oxyfume 20 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Oxyfume 20 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 20 sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxyfume 20 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-0004.

STERILIZATION AND FUMIGATION

Oxyfume 20 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. Oxyfume 20 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 20.5% ethylene oxide, and 80.0% carbon dioxide. Oxyfume 20 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 20 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 20 Sterilant-Fumigant Gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.
- B. Oxyfume 20 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 20 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.

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

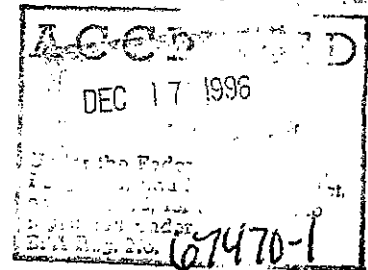
POST-VACUUMS - Oxyfume 20 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

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). For residual amounts 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 OXYFUME 20 AND AIR TO ENTER THE CHAMBER.



BEST AVAILABLE COPY