'STERETHOX'

Gaseous Sterilant

For use by experienced personnel only in hospital and industrial applications. Use only in accordance with directions attached to cylinder valve.

Active ingredient: ethylene oxide 12%
Inert ingredient: dichlorodifluoromethane 88%

KEEP OUT OF REACH OF CHILDREN.

WARNING: HARMFUL VAPORS.
CAUSES EYE INJURY AND SKIN IRRITATION.
CONTENTS MAY BECOME DANGEROUS IF EXPOSED TO FLAMES OR HOT GLOWING SURFACES.

STATEMENT OF PRACTICAL TREATMENT

SKIN: Liquid splashes or concentrated vapor. Flush skin with plenty of water while removing contaminated clothing and shoes.

EYES: Liquid splashes or concentrated vapor. Immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INHALATION: Concentrated vapor. Remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Call a physician. In case of spillage, flush spill area with plenty of water.

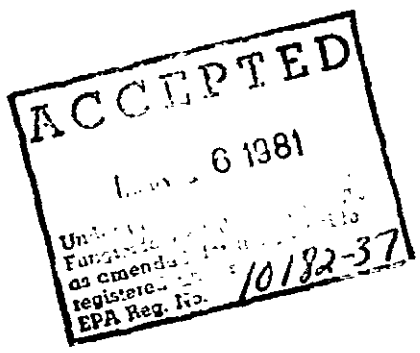
STORAGE AND DISPOSAL

Store in a cool, well ventilated place away from fire risk. Do not expose to sun or other sources of heat which might cause a dangerous increase in pressure. Empty containers should be returned to ICI Ltd. Valve cover nuts and protection domes should be replaced before returning empty containers.

Net Contents - Cylinders 62 kg (NET)
Drums 832 kg (NET)

STERETHOX

Handling and Use



Sold By:

ICI Americas Inc.

Wilmington, Delaware 19897

Manufactured by: Imperial Chemical Industries Limited
Mond Division
London, England

KEEP OUT OF REACH OF CHILDREN

WARNING

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HARMFUL VAPORS. CAUSES EYE INJURY AND SKIN IRRITATION.
CONTENTS MAY BECOME DANGEROUS IF EXPOSED TO FLAMES
OR HOT GLOWING SURFACES.

STATEMENT OF PRACTICAL TREATMENT:

Skin - Liquid splashes or concentrated vapor. Flush skin with plenty of water while removing contaminated clothing and shoes.

Eyes - Liquid splashes or concentrated vapor. Immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

Inhalation - Concentrated vapor. Remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Call a physician.

In case of spillage, flush spill area with plenty of water.

STERETHOX

Gaseous Stericant

Active Ingredient: Ethylene oxide 12%

Inert Ingredient: Dichlorodifluoromethane 88%

Approximate pressure when filled: 60 psig at 70°F

DIRECTIONS FOR USE
GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is limited to use by medical professionals or appropriately trained technical personnel in medical and industrial use areas.

1. For industrial and medical use only in commercial gas sterilizers.
2. Follow the sterilization procedure specified in the gas sterilizer manual.
3. Use within three months of receipt.

Preconditioning: Ethylene oxide will not kill dehydrated spores. Medical instruments must be precleaned to remove adhering tissues and serious exudates. Cleaned instruments or articles must be air-dried or towel-dried; never use dry heat for drying. Instruments and articles must be soaked in water a minimum of one hour immediately prior to exposure with ethylene oxide or be sterilized in an ethylene oxide sterilizer with a built-in automatic moisture-vapor pretreatment rehydration system.

STERETHOX may be used in all sizes of equipment, but the economics of sterilizing processes are such that its use is generally confined to small and medium-size sterilizers up to 500 cubic feet in volume.

In order to obtain effective concentrations of ethylene oxide, the sterilizer should normally be operated at pressures between 5 and 10 psig. Operation at atmospheric pressure is possible as is operation at higher pressures.

Some materials will absorb ethylene oxide vapor and it is therefore necessary to desorb this vapor by applying a vacuum for an extended time at the end of the sterilizing cycle, or by storage of product at 104°F to 140°F under well ventilated conditions.

Monitor sterilization can be accomplished using a product control sterility test for each batch or a commercially available bacterial test strip with Bacillis subtillis NCTC 10073 using 10^6 organisms per strip. Strips should be distributed through the load, and incubated 7 days after sterilization. Strip preparation should be made according to method of Beeby and Whitehouse, J Appl Bact 1965 Vol 28(3) 349-360

TYPICAL STERILIZING CYCLE

1. Heat the sterilizing chamber to the desired temp This may vary from ambient to 140°F (60°C) depending on the nature of the material lzed. Sterilization is more effective at higher temperatures, giving shorter cycle ti. or heat sensitive materials, a lower temperature with a longer cycle may be necessa
2. Heat the vaporizer to the operating temperature.
3. Load the sterilizer.
4. Evacuate the sterilizer to 26 in./30 in. mercury to remove air from the chamber and from the packages.
5. Introduce water vapor to produce a relative humidity of 40% to 60%. Approximately 60% relative humidity will be required for packaging materials which are less permeable to moisture, and lower humidities for those materials through which moisture will defuse readily. Theoretical studies indicate an optimum relative humidity of 30-40% but if this humidity is to be achieved inside the package, higher humidities will be required in the vapor space of the chamber so that defusion of moisture through the packaging material takes place at a rate which yields a practical cycle time.
6. Introduce STERETHOX vapor to give the required chamber pressure. The concentration of ethylene oxide present will be controlled by selection of the appropriate pressure and temperature of the chamber. It is desirable to obtain effective sterilization in the shortest time with minimum usage of sterilant. This is achieved in practice by control of the pressure and temperature of the sterilizing chamber. However, no general recommendation can be given since the time taken to achieve effective sterilization is also governed by the rate of defusion of ethylene oxide through both the packing material and through the articles being sterilized.
7. Maintain the desired pressure for at least 3 hours. For large loads, for complex articles and for those materials through which ethylene oxide and moisture do not readily defuse, longer exposure times may be required.
8. Release the pressure on the chamber. This must be done slowly when sealed packages are being sterilized to avoid burst packages.
9. Evacuate the chamber to 28 in./30 in. mercury. Materials which absorb ethylene oxide may require a longer period of time under vacuum to allow desorption to take place.
10. Allow filtered sterile air to enter the chamber until one atmosphere is reached.
11. Remove the load and store in a well-ventilated area for 24 hours.

EMPTYING OF CONTAINERS

All cylinders containing STERETHOX are fitted with dip pipes. This is indicated by the words "dip pipe fitted" painted on the cylinders and also by means of a metal disc, similarly marked, fitted under the valve stem. Liquid may be withdrawn from these cylinders when standing in the vertical position with the valve at the top.

Drums are fitted with two valves which are protected by a metal dome which must be removed. The valves are fitted with dip pipes and in the correct working position, the drum is laid on its side with the two valves in line one above the other. The dip pipe attached to the upper valve extends into the vapor space of the drum, and the dip pipe of the lower valve is submerged in the liquid. Connection should be made to the lower valve to withdraw liquid. Drums should be securely blocked to prevent movement.

The pressure within a container gives no indication of the quantity of liquified gas held by the container. The only satisfactory way of checking the contents of cylinders and drums is by weighing and this method should be used to determine whether a container is empty.

Valve cover nuts and protection domes should be replaced before returning empty containers.

SAFETY

Flammability

Gaseous STERETHOX is non-flammable with any proportion of air at temperatures up to 140°F (60°C) and pressure up to 10 psig, but mixtures containing more than 15% ethylene oxide and less than 85% dichlorodifluoromethane are flammable in air at ambient temperature and pressure, the flammability limits increasing with increasing proportions of ethylene oxide and with increasing temperature and pressure.

It is important that STERETHOX is withdrawn as liquid from the containers and that the liquid is completely vaporized prior to introduction of the vapor into the sterilizing chamber. The mixture fed into the sterilizing chamber will then have an ethylene oxide content of not more than 12% and the dangers associated with flammable vapors will be avoided. Withdrawal of vapor can result in fractionation of the two components so that initially the vapor will be low in ethylene oxide content, increasing in concentration to above 15% so that it is flammable. Most sterilizers are fitted with vaporizers designed to be fed liquid, thereby preventing the problem.

Toxicity

Information available on the toxicity of ethylene oxide indicates that a concentration of 50 ppm v/v is the maximum allowable concentration in the atmosphere of any working space for continuous exposure. The available data also indicates that for exposures of up to 1 hour duration, the probable safe limit is a concentration of 250 ppm v/v. (See MCA Chemical Safety Data Sheet SD 38, 1971).

Dichlorodifluoromethane is virtually non-toxic other than in high concentrations, at which levels the ethylene oxide content of STERETHOX would then far exceed the TLV of 50 parts per million given above.

The mixture of 12% ethylene oxide and 88% dichlorodifluoromethane can therefore be considered to be less toxic than ethylene oxide alone but only when considered with regard to the total quantity of mixture present. If the vaporized product is released into an unventilated room, e.g., at the end of a sterilizing cycle, then unsatisfactory conditions will exist for continuous working if the ethylene oxide concentration exceeds 50 ppm, regardless of the concentration of dichlorodifluoromethane. Each 1 pound of product when vaporized will produce approximately 4.0 cubic feet of vapor at atmospheric pressure at 20°C. This will be made up of 1 cubic foot of ethylene oxide and 3.0 cubic feet of dichlorodifluoromethane. Thus, for every 1 pound of product used, a room of 20,000 cubic feet would be required if it is assumed that the sterilized contents are discharged into an unventilated room, and a concentration in excess of 50 ppm is to be avoided.

It is recommended that sterilizers be installed in well-ventilated rooms and that the gaseous contents of the sterilizers be evacuated to a safe point outside the building. Alternatively, the ethylene oxide content of the gaseous ethylene may be absorbed in a water scrubber.

The inhalation of low concentrations of ethylene oxide vapor may produce delayed nausea and vomiting. High concentrations may produce edema of the lung and irritation of the eyes and mucous membranes. The vapor may also cause blistering of the skin due to absorption in perspiration and moisture. Liquid ethylene oxide may cause burns on the eyes or skin. Skin irritation may not be felt immediately after exposure to liquid.

Contact with liquid dichlorodifluoromethane should be avoided since this may result in freezing of the skin tissue, eye fluids, etc