

3502 W. 11th HOUSTON, TEXAS  
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ACTIVE INGREDIENT:  
ETHYLENE OXIDE 20 BY WEIGHT  
INERT INGREDIENT:  
CARBON DIOXIDE 80 BY WEIGHT  
TOTAL CONTENTS \_\_\_\_\_ LBS. NET  
E.P.A. REG. NO. 34782-4

CYLINDER NO. \_\_\_\_\_

3502 W. 11th HOUSTON, TEXAS

**DANGER: CONTENTS UNDER PRESSURE:**

- 1 Do not use or store near heat or open flame
- 2 Do not puncture cylinder
- 3 Exposure to temperature of 130 F may cause cylinder failure
- 4 Never incinerate
- 5 Do not use oil or grease on valve regulator or fittings
- 6 Do not refill without written consent of Big Three Industries

**• DANGER •**

**KEEP OUT OF REACH OF CHILDREN**

Breathing of vapors harmful. Exposure to eyes and skin may cause severe irritation. Avoid contact with eyes, skin or clothing. In case of contact remove all clothing and shoes. Flush skin or eyes with plenty of water for at least 15 minutes. Get medical attention immediately.



**MEDICAL DIVISION BIG THREE INDUSTRIES (NON LIFE SUPPORTING)**

**ETHYLENE OXIDE AND  
CARBON DIOXIDE STERILIZING  
GAS MIXTURE**

**CYLINDER NO.** \_\_\_\_\_



**ACTIVE INGREDIENT:**  
ETHYLENE OXIDE 20% BY WEIGHT  
**INERT INGREDIENT:**  
CARBON DIOXIDE 80% BY WEIGHT  
**TOTAL CONTENTS** \_\_\_\_\_ **LBS. NET**  
**E.P.A. REG. NO.** 34782-4

3602 W. 11th HOUSTON, TEXAS

- (1) "FOR INDUSTRIAL & MEDICAL USE ONLY IN COMMERCIAL GAS STERILIZERS." AND  
(2) "FOLLOW THE STERILIZATION PROCEDURES SPECIFIED IN THE GAS STERILIZER MANUAL."

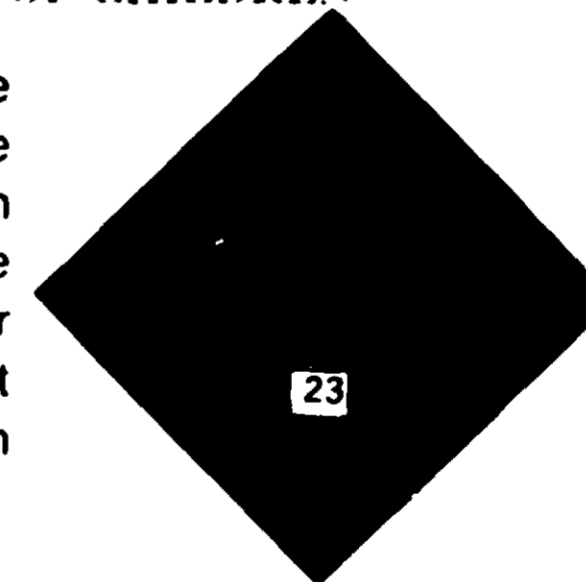
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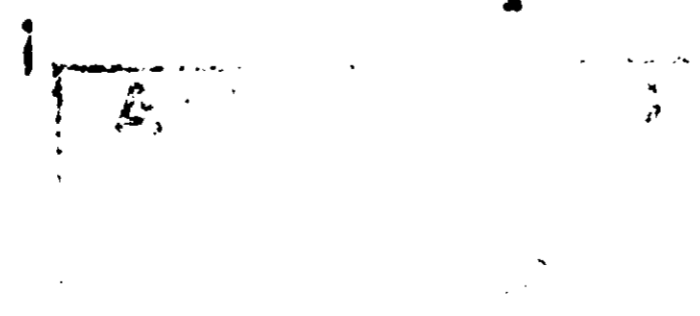
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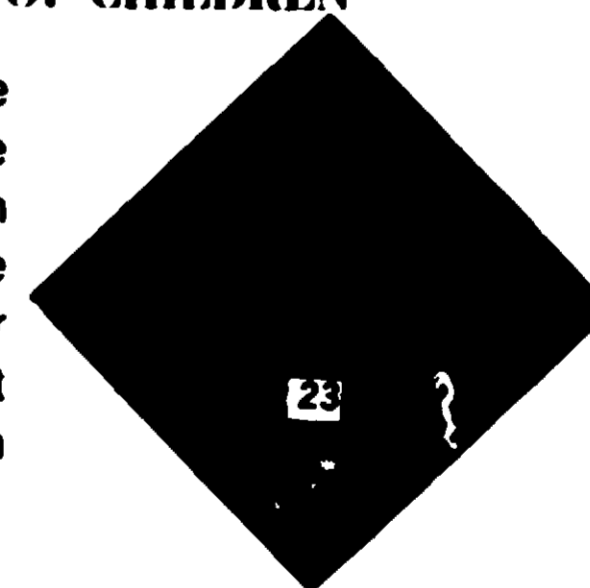
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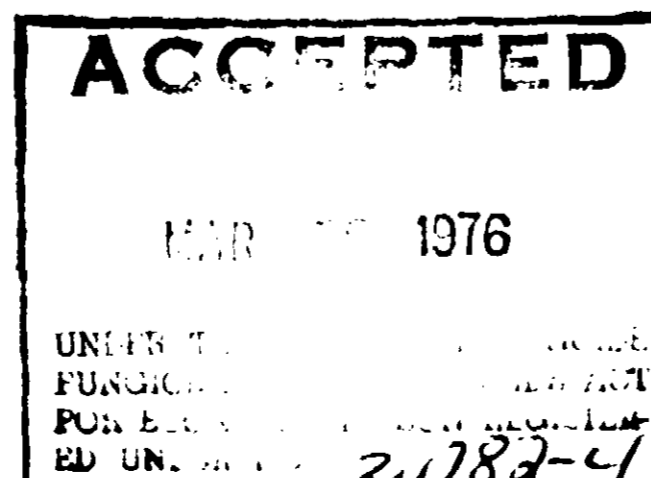
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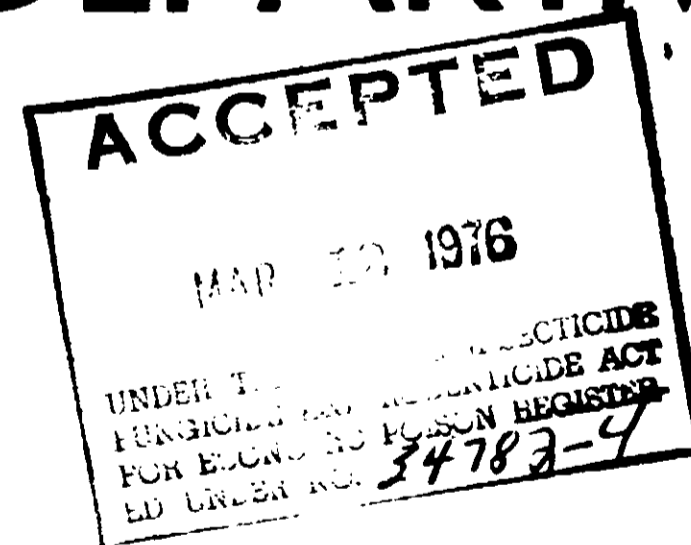


**MEDICAL DIVISION BIG THREE INDUSTRIES (NON LIFE SUPPORTING)**



# STERILIZATION GAS MIXTURES

## SPECIALTY GASES DEPARTMENT



**BIG THREE INDUSTRIES, INC.**



# STERILIZATION GAS MIXTURES

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### INTRODUCTION

Big Three Industries, Inc. intent is to provide some guidelines on the safe handling of sterilization mixtures and their end uses, namely:

- (1) 10% Ethylene Oxide - 90% Carbon Dioxide
- (2) 20% Ethylene Oxide - 80% Carbon Dioxide
- (3) 12% Ethylene Oxide - 88% Dichlorodifluoromethane

Autoclaving (steam pressure) has been used for many years to sterilize materials in hospitals. However, in recent years, with the increased use of various types of plastics, pressurized steam in some cases has become impractical. Hence, it has increased the usage of other methods for sterilization.

In addition ethylene oxide mixtures have found utility in the fumigation of many heat sensitive food and other miscellaneous products where other types of fumigants were prohibitive.

## PROPERTIES OF ETHYLENE OXIDE

Ethylene Oxide is a cyclic ether compound  $(\text{C}_2\text{H}_4\text{O})_n$  and has a molecular weight of 44.05. The liquid freezes at  $-111.3^\circ\text{C}$  ( $-168.3^\circ\text{F}$ ) and boils at  $10.73^\circ\text{C}$  ( $51.3^\circ\text{F}$ ) at one atmosphere. Its vapor pressure is 7.3 psig at  $70^\circ\text{F}$  ( $21.1^\circ\text{C}$ ). Ethylene Oxide readily reacts with water in the presence of anhydrous chlorides, iron, tin and aluminum to form polyethylene glycol. It is soluble in alcohol, ether and many organic solvents. It is also absorbed by such solid materials as rubber, plastics and leather products.

While liquid ethylene oxide is relatively stable to detonating agents, gaseous ethylene oxide is highly explosive and flammable in the presence of air with a source of ignition which can be either an electric spark, static electricity, heat or open flame.

Ethylene oxide is toxic in both its liquid and gaseous state. Liquid acts as a skin irritant or vesicant and causes serious delayed burns from clothing, gloves and shoes when exposed to the liquid and not immediately removed.

The gas is moderately toxic when inhaled. It can cause irritation to eyes and mucous membranes.

A maximum tolerance of 50 ppm during an 8 hour period is permissible. We also suggest that protective clothing be worn when handling ethylene oxide.

## STERILIZATION MIXTURES

Since pure ethylene oxide in the gas phase is highly explosive and flammable for routine sterilization and fumigation, the following mixtures are offered to reduce the flammable and explosive range or eliminate it.

- (1) Mixtures containing the following percentages are considered non-flammable:
  - (a) 10% Ethylene Oxide - 90% Carbon Dioxide by weight
  - (b) 12% Ethylene Oxide - 88% Dichlorodifluoromethane

While mixtures containing 20% Ethylene Oxide - 80% Carbon Dioxide are considered flammable by definition, the hazard is considerably reduced as compared to pure ethylene oxide.

## EFFECTIVENESS

While there are several opinions as to the chemical reactions that occur to make ethylene oxide effective, the most accepted theory is

based on the process of alkylation, eg., the replacement of hydro-ethyl radicals of available hydrogen atoms within a protein molecule such as amino carbonyl and hydroxyl groups.

The rate of reaction which destroys various organisms appears to be related to the rate of diffusion of the gas through the cell wall. This is a function of cell wall porosity whether vegetated or in the spore state with concentration and time.

## MATERIAL DISADVANTAGES TO STERILIZATION MIXTURES

Ethylene Oxide is considered an excellent sterilant. It does have some disadvantages which require caution in its usage.

- (1) Deleterious effect on plastics and rubber products.
- (2) Solvent action on acrylic plastics and plasticizers.
- (3) Water solution will hemolyze red blood cells.
- (4) Various culture media sterilized with ethylene oxide has been regarded unsuitable for cultures.
- (5) Animal diets exposed to ethylene oxide also have adverse effects.

## STABILITY OF STERILIZATION MIXTURES

While mixtures of ethylene oxide, carbon dioxide or dichlorodifluoromethane are highly effective, there are some problems of storage life and proper handling due to decomposition of the ethylene oxide molecules called polymerization.

Usually the degradation of ethylene oxide forms a compound of a lower molecular weight polymer. This product is usually referred to as NVR-nonvolatile residue. This NVR forms in pure ethylene oxide and the various mixtures also.

NVR can be removed from containers and transfer lines by hot water of approximately  $180-200^\circ\text{F}$ . Steam cleaning is not preferred as it hardens the polymers. NVR is catalyzed by acids and bases, thus, cleaners of this type should not be used in lines or containers. Temperature also affects the formation of NVR. The higher the temperature, the higher the rate of formation of NVR. It is necessary that caution be used in storage of sterilization mixtures. They should be kept in cool areas away from the direct sources of heat, especially sunlight.

It is recommended that all transfer lines be of stainless steel and all general piping. At present Big Three uses 510 cadmium plated valves with

stainless steel fittings and stainless steel educator tubes (siphon tube).

**Summary :**

- (1) Check ethylene oxide for nonvolatile residue (NVR) and viscosity which would indicate polymer present before using.
- (2) Do not allow ethylene oxide or sterilization mixture to be subjected to a temperature of more than 130°F.
- (3) Keep in dry, cool place out of direct source of heat.
- (4) Use dry nitrogen for purging all lines.
- (5) Avoid the use of all acids, bases and moisture in lines and cylinders.
- (6) Avoid excessive inventory time.
- (7) Use hot water, not steam for cleaning.

**STERILIZATION EQUIPMENT**

It is recommended that before purchase of any of the aforementioned sterilization mixtures, that you contact your sterilizer manufacture service man for proper instructions on the use of their equipment.

**EXPOSURE TIME OF ETHYLENE OXIDE**

- (1) Dosages at 70°F or higher atmospheric conditions:
  - (a) Clothes, furniture, spices or natural seasonings and furs:  
1.8 # Ethylene Oxide per 1000 cubic ft. - 16 hours
  - (b) Vehicles, airplanes, railroad cars and buses:  
1.2 # Ethylene Oxide per 1000 cubic ft. - 5-6 hours

**(2) Evacuated Systems:**

- (a) Temperature 120 - 140°F (49c - 60c)
- (b) Gas 500 - 1000 mg Ethylene Oxide / liter
- (c) Humidity 35% - 50%
- (d) Exposure 2 - 6 hours

While the above dosage rates using Ethylene Oxide in carbon dioxide or dichlorodifluoromethane will give an adequate gas concentration to insure sterilization it must be kept in mind that these are optimum dosages and conditions. Dehydrated spores under these conditions will not be killed by ethylene oxide.

It is again suggested that you contact your sterilizer manufacture service man for proper cleaning, operating instructions and articles that can safely be sterilized.

Should you be using these mixtures on other than hospital applications, we strongly recommend that you contact the National Association of Pest Control operators for qualified personnel and competent instructions for use in this type of fumigation.

The above information is intended as a guideline for the use of our product with general types of equipment and conditions. It is not a recommendation for any specific type of condition or equipment.

**LITERATURE SOURCES**

- (1) Ethylene Oxide Data Sheet SD-38, Mfg. Chem. Assoc., Inc.
- (2) Phillips, C.R., American Journal Hyg. 50, 280-288(49)
- (3) Kaye & Phillips Am. Jr. Hyg. 50, 296-306(49)
- (4) Ethylene Oxide Sterilant Residues  
Wilson, John E., Bulletin Parential Drug Association 24(5) 226-234(70)
- (5) Residual Ethylene Oxide and Reaction Products Wallace, L.G., Bulletin Parential Drug Association 24(2) 68-75 (1970)

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