Form No
51V-1-82

Matheson
A SEALED COMPANY

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STERILIZING GAS MIXTURE

FOR INDUSTRIAL AND MEDICAL USE ONLY IN COMMERCIAL GAS STERILIZER BY MEDICAL PROFESSIONALS OR APPROPRIATELY TRAINED TECHNICIANS.

ACTIVE INGREDIENT 20%
ETHYLENE OXIDE

INERT INGREDIENT 80%
CARBON DIOXIDE

EPA REG. NO. 7256-2

Gross Wt. _____ Lbs.

Tare Wt. _____ Lbs.

Net Wt. _____ Lbs.

Filling Date _____

DANGER
GAS AND LIQUID
UNDER PRESSURE

DANGER

STORAGE AND DISPOSAL

Use and store in cool, dry, well ventilated place. Keep cylinder temperature from exceeding 125°F. Close valve when not in use. Never refill cylinder. Handle cylinder with care. Discharge in normal vertical position. After discharge close cylinder valve to prevent suck-back of contaminants. Ethylene Oxide is subject to polymerization, use within 2 months after receipt.

Avoid breathing vapors. Avoid contact with skin & eyes. In case of contact, flush thoroughly with water for at least 15 minutes. For eyes, get medical attention. Avoid contact with oxidizing materials.

Do not reuse empty cylinder. Return cylinder to originating shipping point.

READ MATHESONS STERILIZING GAS MIXTURE BROCHURE BEFORE USING

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7256-2

STERILIZING GAS MIXTURES

For Industrial And Medical Use
Only In Commercial Gas Sterilizer

From

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STERILIZING GAS MIXTURES

DESCRIPTION — Sterilizing gas mixtures as provided by Matheson are compressed liquefied gases which is the active sterilizing agent diluted with an inert gas such as Carbon Dioxide, or a halogenated hydrocarbon or combination of halogenated hydrocarbons.

Ethylene Oxide is a true bactericidal agent. It acts as a germicide on both bacterial and fungal spores. The addition of proper diluents acts to decrease the volatility of the sterilizing gas and decrease the flammable hazard associated with the handling of Ethylene Oxide.

Penetrative Properties

Sterilizing gases containing Ethylene Oxide have high penetrative qualities. They are capable of readily diffusing through paper, clothing and plastic sheets. Penetration of powders, dried drugs, certain fabrics depends on the method of packaging and the density of the material itself. Sterilization of prepacked material is possible through proper use of packaging materials. The gas is known to penetrate polyethylene and phenolic.

Types of Sterilizing Gases Available

The following typical Ethylene Oxide mixtures are available from all branches of Matheson:

a. 10% Ethylene Oxide — 90% Carbon Dioxide

b. 20% Ethylene Oxide — 80% Carbon Dioxide

12% Ethylene Oxide — 88% Freon-12®

Mixtures containing 20% by weight or less of Ethylene Oxide in Carbon Dioxide or 12% by weight or less of Ethylene Oxide in Freon-12® are considered non-flammable at atmospheric conditions when tested in accordance with the Bureau of Mines test procedure. The use of mixtures containing more than 20% Ethylene Oxide in Carbon Dioxide or more than 12% Ethylene Oxide in Freon-12® requires special hazardous procedures and equipment design.

The cylinder pressures of sterilizing mixtures will vary with the concentration of the various constituents. At higher proportions of diluents, lower vapor pressures will cause the product to have a higher vapor pressure. The vapor pressures at 70°F. (cylinder pressures) of the above mixtures are as follows:

MIXTURE	VAPOR PRESSURE (p.s.i.g.)
10% Ethylene Oxide — 90% Carbon Dioxide	720
20% Ethylene Oxide — 80% Carbon Dioxide	640
12% Ethylene Oxide — 88% Freon-12®	52

Vapor pressure or cylinder pressure should not be confused with sterilizer pressure. Sterilizer pressure is dependent on the amount of sterilizing mixture that appears solely in the gas phase in the sterilizer; however, cylinder pressure is of value in determining whether or not enough liquid product is available to force the gas out of the cylinder at the sterilizer, or a specified sterilizer equipment.

ADVANTAGES OF STERILIZING GAS MIXTURES

These mixtures have been used to sterilize heat and moisture sensitive materials. Gas sterilization can substantially reduce the time of exposure normally subjected to steam or low temperature sterilization processes.

Among the materials sterilized and tested by Ethylene Oxide mixtures are the following:

PHARMACEUTICAL

Plastic ware for packaging and dropping
Antibiotics and powder
suitable drugs
Rubber stoppers

MEDICAL

Catheters
Syringes
Surgical instruments
Respiratory equipment
Surgical dressings
Gloves
Cultured cells

OTHER

Soil
Straw
Books
Leather
Paper
Electrical equipment
Motor oil
Vaseline

STERILIZING GAS MIXTURES

Below are [illegible] *of sterilization. The information* [illegible] *tions and* [illegible] *carefully prior to their adoption.*

GAS STERILIZATION — Sterilization with Ethylene Oxide mixtures has been used for some time. Because of its effectiveness and its advantages it is now commonly used by the surgical dressing and pharmaceutical [illegible] important advantages are as follows:

1. They are not harmful to most materials.
2. They have [illegible] properties.
3. They are readily removed by aeration.
4. They destroy all forms of microorganisms.
5. They are readily available.
6. They are convenient to store and handle.
7. They reduce the flammability hazard inherent in the use of pure Ethylene Oxide.

Conditions of Sterilization

Sterilization by Ethylene Oxide mixtures is essentially a function of time of exposure, concentration of Ethylene Oxide in the sterilizer space, temperature and humidity. Other conditions affecting sterilization are the moisture content of the microbial cell at the time of exposure and the type of organism to be destroyed.

A. TIME OF EXPOSURE

In general, non-spore forming cells are killed with relative ease, while a longer exposure is required for a 100% kill of spore-forming bacteria. Generally, exposure time is a function of the Ethylene Oxide concentration in the sterilizer [illegible]. The following table illustrates relative exposure times to kill various types of organisms:

SPECIES OF BACTERIA	RELATIVE TIME (X = UNIT TIME)
Bacillus globig[illegible]	5X
Staphylococcus aureus	3X
Mycobacterium [illegible]	3X
Gaffka tetragena	3X
Serratia [illegible]	2X
Eberthella [illegible]	X
Klebsiella [illegible]	X
Escherichia coli	X
Clostridium [illegible]	0.5X
Bacillus subtilis	0.5X

B. CONCENTRATION

For sterilization purposes Ethylene Oxide concentrations of 450 to 1000 mg/L or cc/L of sterilizer space are required to effect a 100% kill. [illegible] 1 oz/1000 cu ft. Biologically the concentration of Ethylene Oxide, the shorter the time of exposure required for sterilization, usually doubling the concentration reduces the exposure time by one half. The "Freon" mixtures have the added advantage of giving a by-volume percent of Ethylene Oxide in the gas phase which still remains non-flammable, compared with Carbon Dioxide mixtures of similar weight percent thus offering more rapid sterilization at low chamber pressures.

Fig. 1 shows the variation of chamber pressure for three typical gas mixtures at a few commonly used temperatures, as a function of Ethylene Oxide concentration in the sterilizer space. These curves have been developed assuming the mixtures behave as ideal gases. This graph assumes complete evacuation of the sterilizer before addition of the sterilizing gas. Initial sterilizer absolute pressure should be added to the graph value to determine final sterilizer pressure. The use of the chart is shown by the following example.

What sterilizer pressure is required to utilize a 20% Ethylene Oxide – 80% Carbon Dioxide mixture at a concentration of 600 mg/L or Ethylene Oxide and 130°F, assuming initial sterilizer pressure of 2 p.s.i.a?

Follow vertically from 600 on the horizontal scale to the line representing 130°F in the group of lines representing 20% Ethylene Oxide – 80% Carbon Dioxide mixture. At this intersection, follow horizontally to the left to the pressure scale reading the pressure of approximately 27 p.s.i.a. Add to this the initial pressure of 2 p.s.i.a. = total of 29 p.s.i.a. Subtracting 14.7 p.s.i. gives the sterilizer final gauge pressure of 14.3 p.s.i.g.

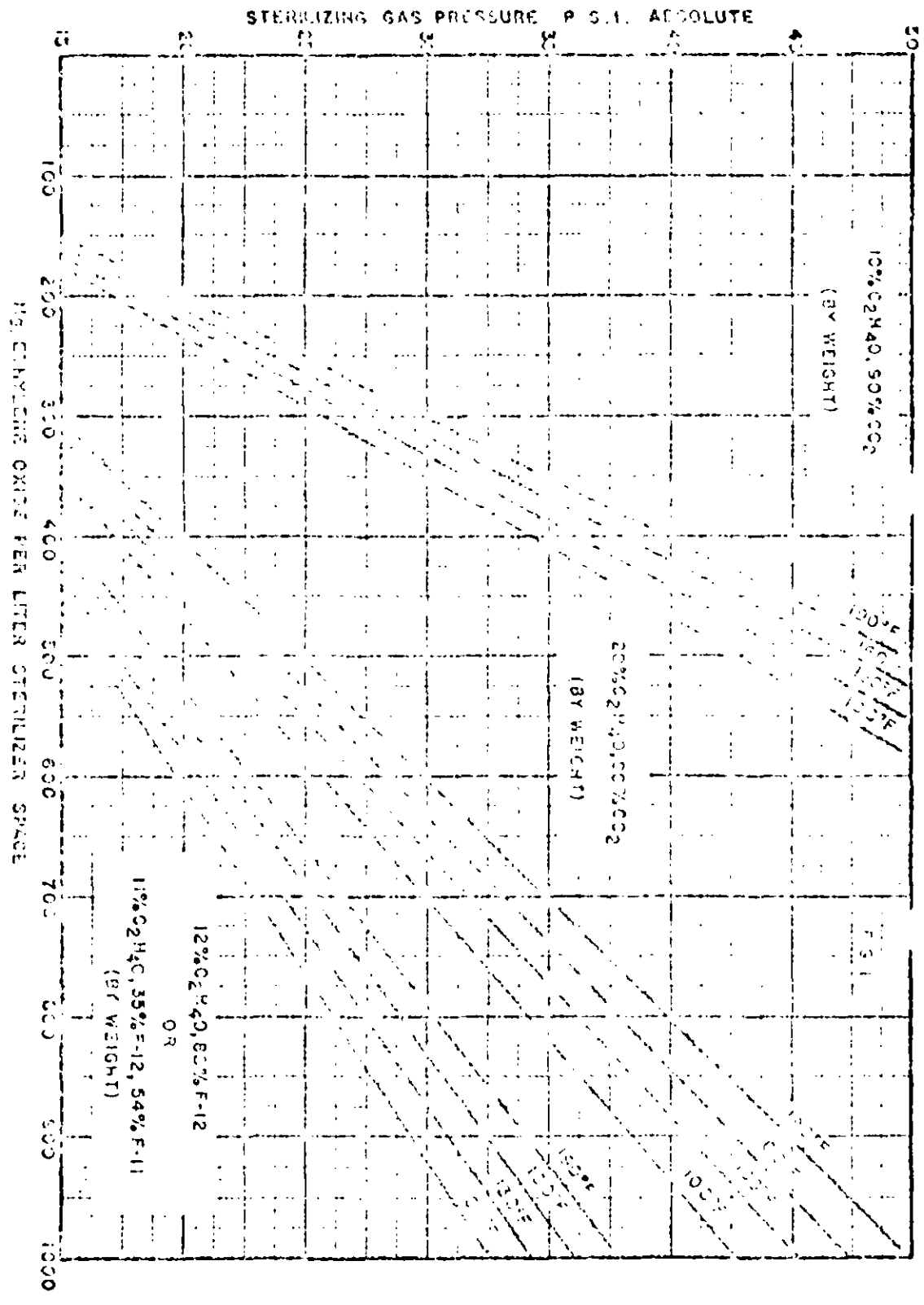
The following equation can be used to calculate the lbs. of sterilizing gas mixture needed for a sterilizer.

$$\text{lbs. mixture needed} = \frac{0.0062 \times C \times V}{L}$$

C = Concentration of Ethylene Oxide in Sterilizer space, mg/L.

L = Percent Ethylene Oxide concentration in sterilizing mixture.

V = Sterilizer volume, cu ft.



STERILIZING GAS MIXTURES

For example: How many pounds of [illegible] Ethylene Oxide in [illegible] mixture [illegible] are required for a 10 cubic foot sterilizer [illegible] cycle, assuming a [illegible] Ethylene Oxide concentration of 800 mg/l in the sterilizer space?

$$\text{lbs. mixture need} = \frac{0.0624 \times 800 \times 10}{11} = 4.53 \text{ lbs}$$

This assumes neither leakage loss nor absorption. From a practical standpoint some excess should be used.

C. TEMPERATURE

While sterilization can be effected with Ethylene Oxide at 70°F, rather long exposure periods are required. As temperature is raised, the rate of sterilization is increased. Generally, for every 30°F rise in temperature, the time required for sterilization is halved. Phillips has demonstrated the temperature effect in his studies on the sterilization of [illegible] spores at 50°C, 25°C and 37°C in which the increase in temperature afforded a considerable reduction of exposure time. He showed that the time required for Ethylene Oxide to sterilize is [illegible] by a factor of 2.74 for each 10°C rise in temperature [illegible] complete kill of the bacterial spores. Temperatures in the range of 130-150°F are usually employed.

D. HUMIDITY

Humidity is [illegible] to the sterilizing efficiency for Ethylene Oxide [illegible] relative humidity in the range of 30 [illegible] for maximum [illegible] during the gas exposure [illegible] in itself to render the gas mixtures effective [illegible] dry spores [illegible] exposure to very high [illegible] sure intervals [illegible] assured sterilization [illegible] cycle should be a minimum of one hour.

E. RESIDUAL GAS

All materials should be [illegible] release of residual Ethylene Oxide [illegible] number of factors, [illegible] packaging [illegible] Ethylene Oxide [illegible] conf[illegible] temperature and relative [illegible] tion will reduce the [illegible] more rapidly as compared [illegible]

room conditions. A complete [illegible] analysis of the [illegible] Ethylene Oxide [illegible] In [illegible] the user should verify that his procedure reduces residual [illegible] to [illegible] level.

A number of [illegible] for the analysis of Ethylene Oxide residues are available and [illegible] directed to the literature for the method most suited to individual needs.

The establishment of maximum acceptable limits for Ethylene Oxide [illegible] and [illegible] federal regulations.

See Section on Toxicity for more detailed information regarding the effects of Ethylene Oxide.

Dispensing of [illegible] Gas for Sterilization

In dispensing [illegible] either a complete [illegible] charge [illegible] quantities are removed may be used. [illegible] are available in [illegible] the cylinder as a [illegible] small [illegible] cylinders [illegible] with the [illegible] discharge into the sterilizer [illegible] warm [illegible] residual [illegible] The gas [illegible] sterilizer, usually [illegible] desired sterilizer

[illegible]

HANDLING AND STORAGE OF CYLINDERS -

The following general practices should apply to the handling and storage of sterilizing gas mixtures:

1. Never drop cylinders or permit them to strike each other violently.

2. Cylinders should be stored in a dry, cool, well-ventilated and preferably separate spot. Keep cylinders away from excessive heat, open flames, sparks, electric circuits from radiators or other sources of heat. Storage conditions should comply with local and state regulations.

3. The valve protection cap should be in place until the cylinder has been secured against a wall or bench, or placed in a cylinder stand and is ready to be used.

4. Avoid dragging, rolling or sliding cylinders, even for a short distance. They should be moved by using a suitable hand truck.

5. Never tamper with safety devices on valves or cylinders.

6. As soon as a cylinder has been discharged close the cylinder valve. Replace any valve outlet or protective cap which was removed from the cylinder. Mark or label the cylinder EMPTY.

7. No part of the cylinder should be subjected to a temperature higher than 125°F. Temperatures in excess of this figure may cause the safety devices to function in full resulting in excessive loss of gas or cylinder rupture. Never permit a flame to come in contact with any part of a compressed gas cylinder.

8. Contact the gas supplier when it is necessary to move cylinders over long distances. Be sure cylinder is properly secured in vehicle and valve protection cap is in place to prevent leakage through valve packing.

9. Federal law prohibits the transportation of compressed gas cylinders unless they bear proper identification and are in proper condition. Return empty cylinders promptly to original supplier.

TOXICITY - The toxic effects of sterilizing mixtures stem mainly from the Ethylene Oxide component. Ethylene Oxide is used elsewhere in the world as a fumigant and is considered as simply a physical hazard. Exposure to it can present a large amount of risk to the health of personnel. The Occupational Safety Administration has recently established the maximum allowable concentration of Ethylene Oxide for days of 8 hours each. Several states have set lower limits of exposure or higher concentrations of Ethylene Oxide vapors.

Liquid Ethylene Oxide can cause severe burns.

Protective clothing should be worn when working with Ethylene Oxide or its mixtures. Such clothing should be worn by persons who are exposed to the liquid as skin contact can cause burns. Contact only as a last resort. When using the gas in the gaseous state, no special precautions are required other than to insure adequate ventilation.

FIRE AID - The combustible nature and use of Ethylene Oxide necessitate a discussion of the possibility of being exposed to excessive heat or to the vapors of the mixture under fire conditions. However, the following first aid suggestions are also applicable to several exposure hazards other than fire and those recommended for Ethylene Oxide.

Eye irritations have been believed to be common problems. Eye irritation does not always be the case. Eye irritation is a common symptom of exposure to Ethylene Oxide vapors. Contact with the eyes with liquid Ethylene Oxide can cause severe damage to the eyes. Immediately flush the eyes with large amounts of water for at least 15 minutes. Do not attempt to neutralize with chemicals. Call a physician immediately.

STERILIZING GAS MIXTURES

Inhalation

In case breathing has stopped, artificial respiration should be started at once. After severe exposure, pure Oxygen should be administered as soon as possible by trained personnel. The patient should breathe pure Oxygen under positive pressure for one to one-half hour periods every hour for at least the first 8 hours. If there are no spontaneous respirations at the end of this period, artificial breathing should be continued. If the skin and mucous membranes is good, Oxygen inhalation may be discontinued. The patient should be kept adequately warm, but not hot.

Skin Contact

All clothing contaminated with liquid Ethylene Oxide or exposed to high concentrations of Ethylene Oxide vapors should be removed at once. Clothing, including shoes, should not be worn again before thoroughly aerated. Shoes cannot be adequately decontaminated, and it is suggested that they be not worn again. All affected areas of skin should be thoroughly washed with soap and water.

Eyes

Ethylene Oxide - liquid or vapor is capable of causing eye damage. Should a liquid or vapor exposure occur, the eyes should be immediately washed with water for fifteen minutes.

The eyelids should be held apart to assure thorough contact between the eyeball and the water. Medical attention must be obtained promptly. If available, a local anesthetic solution should be used to relieve pain. A physician should be consulted in attendance.

Precautions

Once the presence of Ethylene Oxide is established by the methods mentioned above, the following precautions should be observed:

(1) All those engaged in the operation of the generators or any standard operating procedures established for any standard gas mixtures, as well as those persons and processes in the immediate vicinity of the operation, should be instructed in the hazards involved.

All Matheson lecture bottles are equipped to accept all types of [illegible] valves and will be very helpful [illegible] mixtures involving toxic or corrosive gases.

Matheson provides researchers and industry with their specialty gas requirements.

We take pride in our capability to provide gases of high purity, specialty mixtures, chemicals and rare gases to a tube trailer. We maintain extensive inventories in two convenient locations for fast delivery of up to 20 component mixtures prepared on state-of-the-art blending equipment.

We carry in stock a full line of high quality equipment for regulating, measuring, monitoring and controlling gases.

Our catalog is yours for the asking at any of our branch plants.

Matheson

STERILIZING GAS MIXTURE

FOR INDUSTRIAL AND MEDICAL USE ONLY IN COMMERCIAL GAS STERILIZER BY MEDICAL PROFESSIONALS OR APPROPRIATELY TRAINED TECHNICIANS

ACTIVE INGREDIENT ETHYLENE OXIDE 20%
INERT INGREDIENT CARBON DIOXIDE 80%

DANGER

Flammable compressed gas can form explosive mixture with air. Keep away from fire, heat and open flames. See other precautions on the back of this tag and small cylinder valve tag.

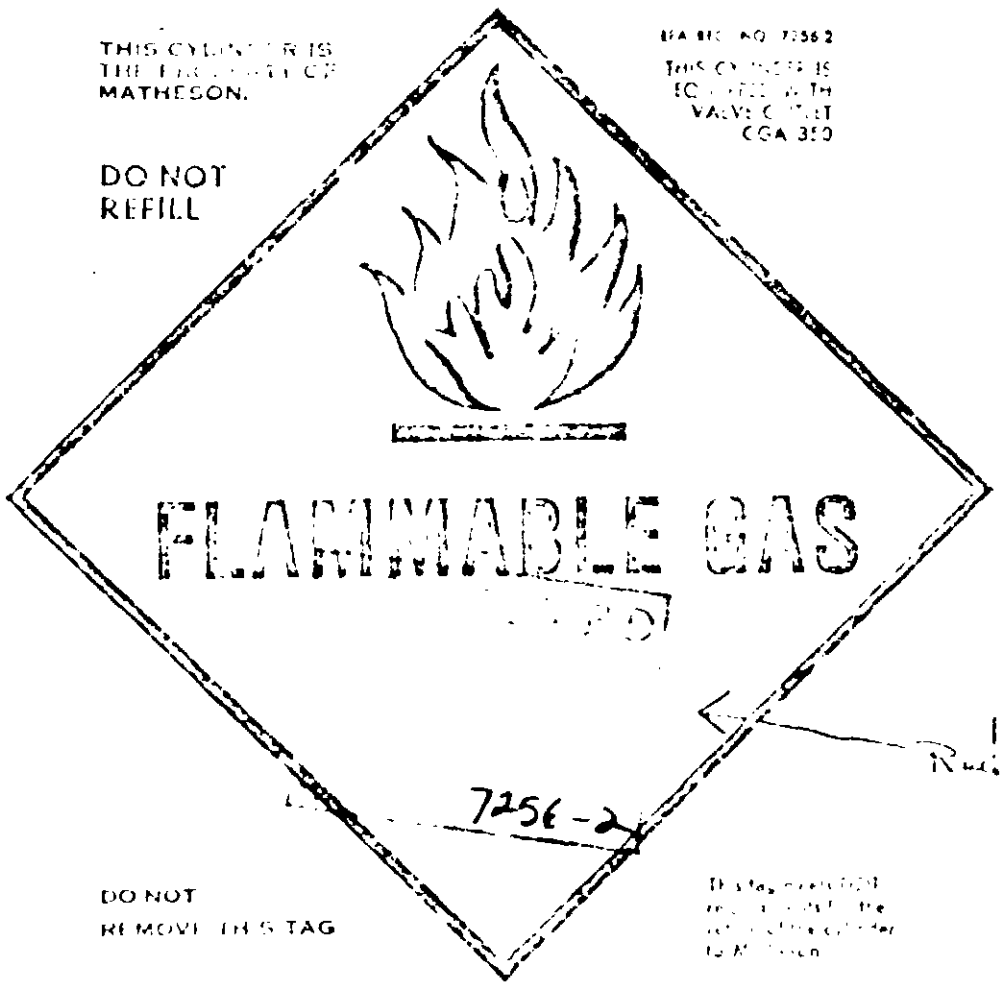
DOT EST 7256 CA-1, -2 GA-1 IL-1 MA-1 NJ-1, TX-1

THIS CYLINDER IS THE PROPERTY OF MATHESON.

DO NOT REFILL

DOT RIC NO 7256.2

THIS CYLINDER IS EQUIPPED WITH VALVE OUTLET CGA 350



DO NOT REMOVE THIS TAG

BEST COPY AVAILABLE

STERILIZING GAS MIXTURE

FOR INDUSTRIAL AND MEDICAL USE ONLY IN COMMERCIAL GAS STERILIZER BY MEDICAL PROFESSIONALS OR APPROPRIATELY TRAINED TECHNICIANS.

DANGER: GAS AND LIQUID UNDER PRESSURE

EPA REG. NO. 7256-2

STORAGE AND DISPOSAL

Use and store in cool, dry, well ventilated place. Keep cylinder temperature below 125°F. Close valve when not in use. Never refill cylinder. Handle cylinder with care. Discharge in safe, controlled manner. After discharge close cylinder valve to prevent back up of contaminants. If cylinder contents is subject to polymerization, use within 2 months of receipt.

DO NOT REUSE EMPTY CYLINDERS
RETURN TO ORIGINATING SHIPPING POINT.

READ MATHESON'S STERILIZING GAS MIXTURES BROCHURE BEFORE USING.

SHIP TO:

7256-2

RETURN TO MATHESON