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Steri-Gas

3M

Cartridge 4-100
Active Ingredient: Ethylene Oxide 100% • Net Wt. 100 g

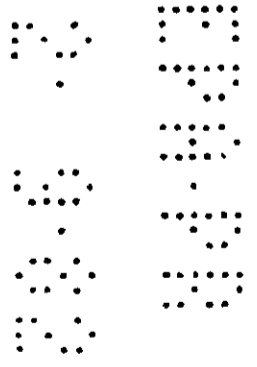
Store at Room Temperature • Do Not Incubate • Avoid Puncturing

DANGER — EXTREMELY FLAMMABLE
DO NOT USE NEAR FIRE OR FLAME
N.F.D.C. (F.A. No. 933)
USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERIVAC MODEL 4001.
KEEP CONTAINER CLOSED — AVOID BREATHING VAPOR

Medical Products Division 3M

E.P.A. Reg. No. 7182-1
E.P.A. Est. No. 3657-WI-2

ACCEPTED
1982



DANGER: ETHYLENE OXIDE

FLAMMABILITY:

Ethylene oxide is flammable in air when present in concentrations from 3% (30,000 ppm) to 100%. Keep matches, lighted cigarettes and other potential sources of ignition away from the sterilizer.

TOXICITY

Acute Inhalation may cause nausea, vomiting (either immediate or delayed), dizziness, weakness, chest pain, irritation of the respiratory tract and neurotoxic effects. Repeated overexposure may result in olfactory fatigue and reduced tolerance to the vapor.

Chronic Inhalation.

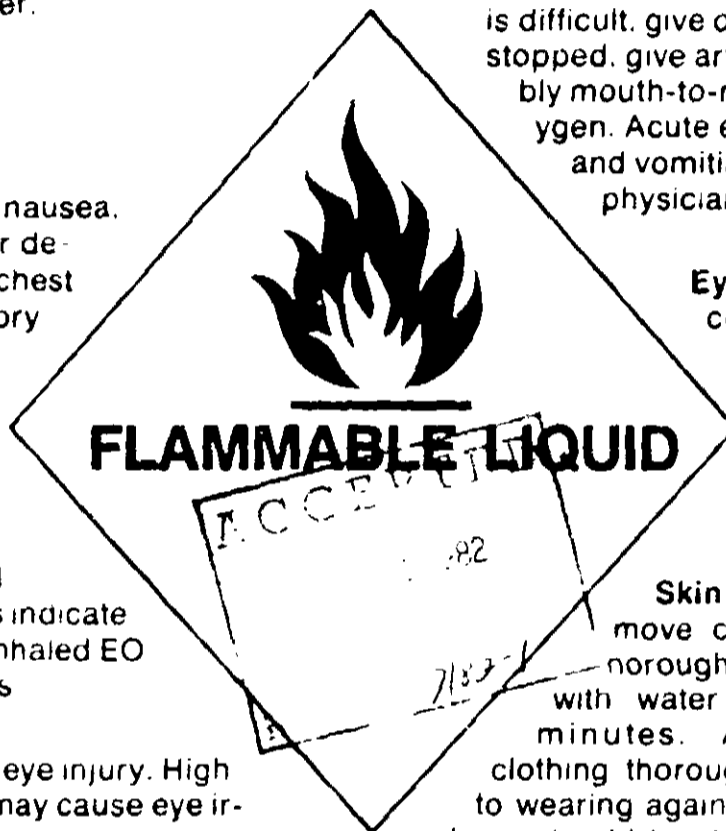
Results of animal toxicity and human epidemiology studies indicate that long-term exposure to inhaled EO may be hazardous to humans.

Liquid EO/Eye Contact.

Liquid EO may cause severe eye injury. High concentrations of EO vapor may cause eye irritation.

Liquid EO/Skin Contact.

Liquid EO may cause delayed chemical burns taking the form of blisters.



STATEMENT OF PRACTICAL TREATMENT

Inhalation. Go at once to fresh air. If nausea and vomiting occur, keep person quiet and warm and call a physician. If breathing is difficult, give oxygen. If breathing has stopped, give artificial respiration, preferably mouth-to-mouth, then administer oxygen. Acute exposure causing nausea and vomiting should be treated by a physician.

Eyes. If liquid EO or a high concentration of vapor contacts the eyes, immediately flush eyes with water for a minimum of 15 minutes, then contact a physician.

Skin Contact. Immediately remove contaminated clothing and thoroughly flush the area of contact with water for a minimum of 10 minutes. Aerate contaminated clothing thoroughly and launder prior to wearing again. Contaminated leather shoes should be discarded because EO residue cannot be removed.

Steri-Gas[®] Cartridge Selection

It is essential to use the correct cartridge/gas sterilizer combination. The chart below will guide you in the proper selection of the correct cartridge.

Steri Gas Cartridge No.	Gas Sterilizer
1-30	Steri-Vac Gas Sterilizer Model 100
G10	ACMI Gas Sterilizer Model GS 10
2-67	Steri-Vac Gas Sterilizer Models 200 202A & 202B
4-100	Steri-Vac Gas Sterilizer Model 400C
4-134	Steri-Vac Gas Sterilizer Models 400 and 400B

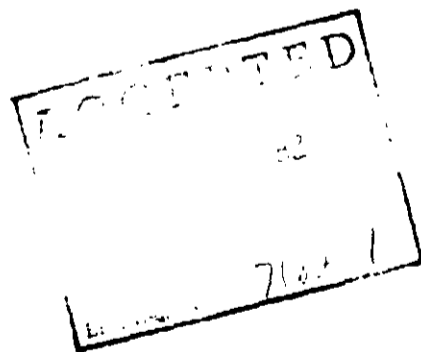
Note: This product is limited to use by medical professionals or appropriately-trained personnel in medical and industrial use areas. It is a violation of Federal Law (USA) to use this product in a manner inconsistent with its labeling.

Manufactured for
Medical Products Division 3M
 St. Paul, Minnesota 55144

EPA Reg. No. 7182-1
 EPA EST. No. 3457-W-2

Consumer Product Profile

Steri-Gas Cartridges



3M

A. Introduction

The Steri-Gas cartridge system is a very efficient means of delivering ethylene oxide gas. The Steri-Gas cartridge is made of a special material which allows ethylene oxide gas to pass through it and sterilize the contents of the container. The use of Steri-Gas cartridges is the most efficient method of delivering ethylene oxide gas to the sterilization chamber.

B. Advantages of the Steri-Gas System

When compared to alternative methods for EO delivery, Steri-Gas cartridges offer the following advantages:

1. Controlled delivery of the proper amount of ethylene oxide per cycle.
2. A stable product with a minimum shelf life of 24 months.
3. A cost-effective and efficient method for reprocessing small sterilization loads.
4. Elimination of the lines and polymer filters required with large tanks of EO mixtures.
5. Elimination of the need for the chlorofluorocarbon drier which is known to accelerate corrosion of certain plastics.
6. Only small amounts of EO are handled via the cartridge system.

C. Steri-Gas Applications

Steri-Gas Cartridge No.	*Steri-Vac Sterilizer
1-30	Model 100
G-10 (ACMI)	ACMI GS-10 Sterilizer
2-67	Models 200, 202 and 202B
4-100	Model 400C
4-134	Model 400 and 400B

*Model 400B is not available in the United States.

D. Product Specifications

1. Shelf Life:

Steri-Gas cartridges have a minimum shelf life of 24 months. Cartridges older than 24 months should be weighed. Cartridge weight should be compared to the gross weight printed on the cartridge and accepted if the cartridge weight is between the gross weight and the net weight. If the cartridge weight is less than the net weight, the cartridge should be discarded.

For more information, see page 147.

2. Cartridge weights

Net weight (grams) Minimum Gross Weight (grams)

Steri-Gas Cartridge No.	Minimum Gross Weight (grams)
1-30	47
G-10 (ACMI)	78
2-67	88
4-100	132
4-134	163

3. Cartridge contents

Pure ethylene oxide in liquid form. Pure EO has the following chemical characteristics:

boiling point	10.7°C (51.3°F)
color	colorless
flammable limits—lower	3% (30,000 ppm)
upper	100%
odor is detectable at	500 ppm

4. Cartridge construction

Seamless aluminum 0.065 cm (0.02 in) thick with a valveless cap of tin plated steel 0.028 cm (0.011 in) thick.

5. Cartridge approvals

a. EPA registration:

Manufacturers of chemical pesticides such as EO are required to register their product label claims with the Environmental Protection Agency (EPA). Based on these claims, the EPA requires the manufacturer to show that the product meets certain performance standards prior to issuance of a registration number. The EPA registration number for Steri-Gas cartridges is 7182-1. This number appears on all Steri-Gas cartridges.

b. Factory Mutual approval

Steri-Gas No. 4-134 and 4-100 cartridges are approved by Factory Mutual Systems when used in conjunction with Steri-Vac Model 400B and 400C gas sterilizers respectively.

Factory Mutual Systems is a well known independent laboratory organization. The Factory Mutual label is located near the top of the Steri-Vac Model 400B and 400C gas sterilizers.

b. Decontaminating

When a Steri-Gas cartridge is used, it will be contaminated with ethylene oxide. This waste should be treated as a hazardous waste and disposed of accordingly.

The Steri-Gas cartridges are stored in the Steri-Gas cabinet. They are not to be used as a means of disposal of the Steri-Gas.

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E. Storage of Steri-Gas Cartridges

1. National Fire Protection Association (NFPA) Codes

NFPA Article No. 30, Section 4450 deals with storage of Class I flammable liquids (such as 100% EO in Steri-Gas cartridges) inside Office Education and Institutional Occupancies. Subparagraph (b) of this section states: "Not more than 10 gallons of Class I and Class II liquids combined shall be stored outside of a storage cabinet or storage room, except in safety cans. Ten (10) gallons of pure EO is approximately equivalent to 245 of the largest Steri-Gas cartridges (i.e. No. 4134).

2. Recommendations for optimum storage

It is felt that Steri-Gas users should not store such a large number of cartridges outside of a storage cabinet. Therefore, we recommend the following storage procedures:

- For an average department one day's requirement or no more than 12 cartridges should be kept in the immediate sterilizer area.
- Any amount in excess of 50 Steri-Gas cartridges should be stored in an approved flammable liquid storage cabinet or in an area suitable for storage of flammable liquids.
- Store cartridges at room temperature.

*Please note that this recommendation is significantly more stringent than the national code (i.e., NFPA Article 30, sub-paragraph 4450(b)).

F. Cartridge Shipping

Steri-Gas cartridges must be stored and transported in the original shipping case or intermediate packaging, both of which are Department of Transportation (DOT) approved shipping containers.

G. Handling and Disposal Instructions

1. Used cartridges

- The empty, used Steri-Gas cartridge should be aerated under the water conditions as sterilized medical items. The procedure will safely eliminate the residual amount of vaporous EO which may remain in the cartridge at the completion of a sterilization cycle.
- After aeration, Steri-Gas cartridges should be disposed of along with normal nonincinerated hospital waste.
- Dispose of aerated cartridges immediately. The practice of returning empty cartridges to the box containing full ones is not advisable. This practice may lead to accidental disposal of full cartridges. Discard each empty individual cartridge after it is used and aerated.

2. Disposition of unused cartridges

Should it become necessary to dispose of unused, outdated or underweight cartridges, contact a local hazardous waste disposal company. Ethylene oxide (100%) is classified by NFPA as a Class I flammable liquid. As such, disposal must be carried out by individuals knowledgeable in such matters. If further information is required, contact your local 3M Medical Systems representative.

H. Ethylene Oxide Spills

Ethylene oxide is both flammable and toxic. Under normal circumstances these characteristics will be adequately controlled by the cartridge and sterilizer system. However, in the event of an accidental spill associated with the cartridge, users should be trained in the proper action needed.

We strongly recommend that an accidental spill policy be developed by every facility and department using ethylene oxide. We endorse the "Action Team" concept as described in the following reference:

Good Hospital Practice: Ethylene Oxide Gas - Ventilation Recommendations and Safe Use

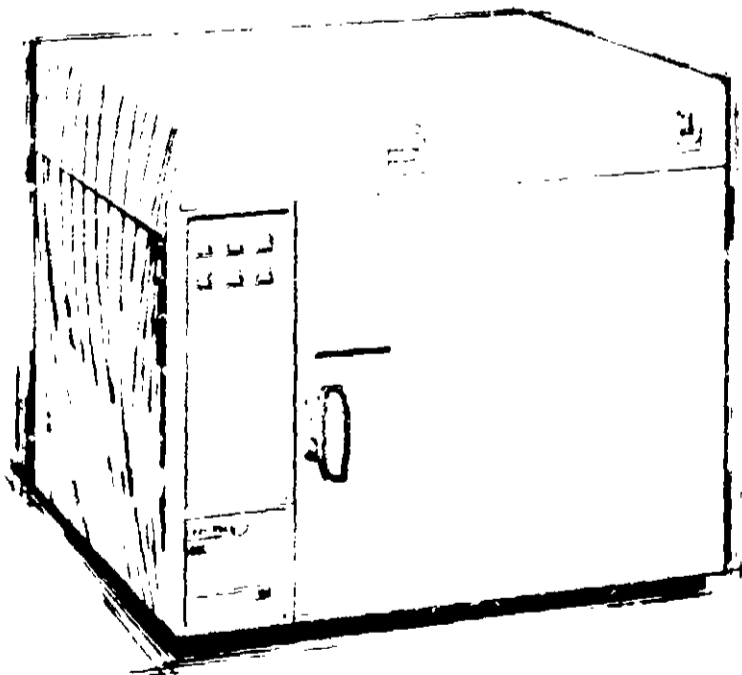
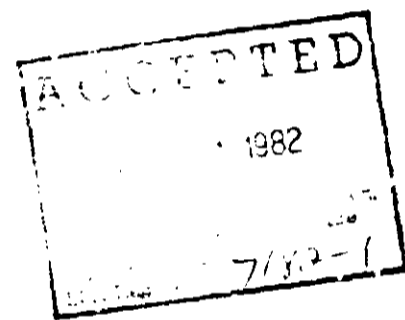
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Association for the Advancement of Medical Instrumentation (AAMI)
1901 N. Ft. Myer Drive, Suite 602
Arlington, VA 22209
Phone: 703-526-4800

Steri-Vac™

3M

Operator's Manual



Model 400C Gas Sterilizer

Medical Products Division 3M
3M Center St Paul MN 55144