3M™ Steri-Gas™ EO Gas Cartridges

Product Profile

3M

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3M™ Steri-Gas™ EO Gas Cartridges are single-use cartridges containing 100% ethylene oxide intended for use in 3M™ Steri-Vac™ Sterilizer/Aerators (ethylene oxide sterilizers). When used in the appropriate 3M™ Steri-Vac™ Sterilizer/Aerator, the cartridges deliver the predetermined amount of ethylene oxide for each sterilization cycle. Before a sterilization cycle is started, an operator secures a cartridge in the cartridge bay located inside the sterilizer chamber. The product load is placed in the sterilizer chamber; the sterilizer door is closed and automatically locks when the sterilization cycle is started. Inside the locked sterilization chamber, when conditioning parameters are obtained, the cartridge is punctured under a vacuum and the entire amount of ethylene oxide contained in the cartridge is delivered to the sterilization chamber. The used cartridge is aerated along with sterilized items during the aeration phase of the cycle. After sterilization and aeration are complete, the used cartridges can be recycled or disposed of with non-incinerated waste per facility policy.

3M™ Steri-Gas™ EO Gas Cartridges were developed and designed with the safety of operators and patients in mind.

- Only small amounts of ethylene oxide (EO) are contained in the cartridges (nominal net fill weights of 100 – 170 grams).
- The cartridges deliver the proper amount of EO for each sterilization cycle. The cartridges are placed inside the sterilizer chamber and punctured only after the chamber door is securely locked, the chamber is in a vacuum, and process parameters are at predetermined values.
- The cartridges allow for a sterilization process that is performed completely under a vacuum. If the system integrity is compromised during EO gas exposure, room air will enter the chamber. In this situation, the system will detect a rise in pressure and will safely cancel the cycle when the system cannot maintain a vacuum. The system will flush the sterilizer chamber with room air and exhaust it though the sterilizer system vent.
- There are no bulky sterilant tanks to store, change and transport.
- There are no external valves requiring time-consuming maintenance. External valves can be a source of gas leaks.
- There are no gas line filters that can plug and require periodic changing. Gas line filters can also be sources of EO exposure.
- The cartridges do not contain chlorofluorocarbon or other diluents banned and implicated in the destruction of the earth's ozone layer.
- The cartridges have a scanable 2D barcode individualized for each cartridge. The 2D barcode is encrypted with the 3M™ Steri-Gas™ EO Gas Cartridge's catalogue number, lot code (expiration date) and nominal fill weight. The barcode is unique to each individual cartridge, reducing the risk that the wrong cartridge may be used in a specific cycle or sterilizer.
- 3M recommends that inventories greater than 12 full cartridges be stored in a ventilated flammable liquid storage cabinet exhausted to the outside.

Product Use

3M™ Steri-Gas™ EO Gas Cartridges are used as a sterilant in 3M™ Steri-Vac™ Sterilizer/Aerators by trained personnel in health care facilities, life science or other settings for the sterilization of products and medical devices. Reference Table 1 to determine the appropriate 3M™ Steri-Gas™ EO Gas Cartridge for each model of 3M™ Steri-Vac™ Sterilizer/Aerator.

Table 1. Use Settings for 3M™ Steri-Gas™ EO Gas Cartridges

Cartridge Selection for 3M™ Steri-Vac™ Sterilizer/Aerator – **Health Care Setting**

Cartridge Catalog Number	3M™ Steri-Vac™ Sterilizer/Aerator Series	EO Net Fill Weight [1]
8-170	8XL, GS8, GS8X [2]	170 g (5.99 oz)
4-100	4XL, 5XL, GS5, GS5X [2]	100 g (3.52 oz)

Cartridge Selection for 3M™ Steri-Vac™ Sterilizer/Aerator – **Life Science Setting**

Cartridge Catalog Number	3M™ Steri-Vac™ Sterilizer/Aerator Series	EO Net Fill Weight [1]
8-170	8XL, GS8, GS8X	170 g (5.99 oz)
4-134 [3]	5XL, GS5, GS5X, 8XL, GS8, GS8X	127 g (4.47 oz)
4-100 [3]	4XL, 5XL, GS5, GS5X, 8XL, GS8, GS8X	100 g (3.52 oz)
4-60 [3]	4XL, 5XL, GS5, GS5X, 8XL, GS8, GS8X	Custom EO net wt.

1. Nominal manufacturing net fill weight of ethylene oxide in 3M™ Steri-Gas™ EO Gas Cartridges
2. National Regulations may determine the use of GSX Series sterilizer/aerators in health care facilities. For more information, contact your local 3M office. Global office locations are available at: www.3M.com
3. The use of catalog numbers 4-60, 4-100 and 4-134 cartridges in the 8XL, GS8, or GS8X sterilizer requires a special adaptor. For more information, contact your local 3M office. Global office locations are available at: www.3M.com

Regulatory Status

Always consult your national, regional, and local regulatory requirements before the use of 100% ethylene oxide Chemical Abstract Society (CAS) number 75-21-8. Listed below are the 3M™ Steri-Gas™ EO Gas Cartridges classifications/registration for several global regions.

- U.S. EPA Registration Number 7182-1
- Canada Health Canada Drug Identification Number (DIN) 02154900
- European Union REACH registration European Union (EU) as an accessory to a medical device; CE marked as a Class 1 medical device (non-sterile, non-measuring) with European Union REACH registration
- Japanese Ministry of Health, Labor, and Welfare (MHLW) (Koseirodosho) classified and regulated as a pharmaceutical

Safety

DANGER: Indicates a hazardous situation which, if not avoided, will result in death or serious injury.

Dangers

DANGER: Potential health effects of ethylene oxide

3M™ Steri-Gas™ EO Gas Cartridges are limited to use by appropriately trained personnel in health care and life science use areas. Users in the United States must follow the requirements of the United States Occupational Exposure Standard for Ethylene Oxide OSHA (29 CFR 1910.1047). 100% ethylene oxide (EO) CAS number 75-21-8 is a colorless gas at ambient conditions. Do not rely on sense of smell for the detection of ethylene oxide. EO has a high odor threshold and can only be detected by sense of smell when it exceeds 500–750 parts per million (ppm). EO has a characteristic ether-like odor (i.e. a sweet and irritating solvent smell).

Consult the 3M™ Steri-Gas™ EO Gas Cartridge Safety Data Sheet (SDS) for additional information (www.3M.com/MSDS).

Directions for Use

This product may only be used in facilities that follow 3M recommended practices for storage and use of 3M™ Steri-Gas™ EO Gas Cartridges. Always use 3M™ Steri-Gas™ EO Gas Cartridges in accordance with the supplied instructions for use (IFUs) and 3M™ Steri-Vac™ Sterilizer/Aerator Operator's Manual.

In addition, local requirements for ethylene oxide use must be followed. Users should determine personal exposure limits per local regulations. Attention is drawn to the possible existence in some countries of regulations giving safety requirements for handling EO and for the premises in which it is used. Regulations may include but are not limited to:

1. Routine training for personnel using and handling EO.
2. Use only in regulated or restricted areas.
3. Special signage and labeling of regulated or restricted EO use areas.
4. Personnel exposure monitoring for ethylene oxide may be indicated by local or national regulation.
5. Area monitoring for ethylene oxide may be necessary by local or national regulation.

Performance Concentrations and Application

Chamber gas concentration is based on nominal manufacturing net fill weights and the respective sterilizer series internal chamber volume. Table 2 provides calculations of the empty chamber gas concentrations (mg/L) and the calculated minimum pressure increases (mBar and kPa) for process temperatures ranging from 34 – 60°C for each 3M™ Steri-Vac™ Sterilizer/Aerator model. The calculated minimum pressure increase (mBar and kPa) is the expected minimum pressure based on the following parameters:

1. Estimated rise in pressure approximately 70 seconds into the EO injection stage.
2. Range of process temperatures.
3. The internal chamber volume of the respective sterilizer(s).

Table 2. Performance Concentrations and Application

Models GS5, GS5X, 5XL

Catalog Number	Nominal Weight of EO (grams)	Calculated Empty Chamber Gas Concentration (mg / L)	Process Temperature Range (°C)	Calculated Minimum Pressure Increase (mBar & kPa)
4-100*	100	735	34 – 60°C	427 – 463 mBar 42.7 – 46.3 kPa
4-134*	127	934	34 – 60°C	542 – 582 mBar 54.2 – 58.2 kPa
8-170	N/A	N/A	N/A	N/A
4-60**	Custom Fill	Custom Fill	34 – 60°C	Custom Fill

Models GS8, GS8X, 8XL

Catalog Number	Nominal Weight of EO (grams)	Calculated Empty Chamber Gas Concentration (mg / L)	Process Temperature Range (°C)	Calculated Minimum Pressure Increase (mBar & kPa)
4-100	100	446	34 – 60°C	259 – 281 mBar 25.9 – 28.1 kPa
4-134	127	567	34 – 60°C	329 – 357 mBar 32.9 – 35.7 kPa
8-170	170	759	34 – 60°C	440 – 478 mBar 44.0 – 47.8 kPa
4-60**	Custom Fill	Custom Fill	34 – 60°C	Custom Fill

*Requires an adaptor for the GS8X Series sterilizer.
**Available for Life Science customers only.

Customer Certification Net Weights

3M™ Steri-Gas™ EO Gas Cartridges are classified as a Gas Under Pressure: Liquefied Gas[1]

Liquefied gases are gases which can become liquids at normal (ambient or room) temperatures when they are under pressure inside cylinders. They exist inside the cylinder in a liquid-vapor balance or equilibrium. Initially the cylinder is almost full of liquid, and gas fills the space above the liquid. As gas is released from the cylinder, enough liquid evaporates to replace it, keeping the pressure in the cylinder constant. 3M™ Steri-Gas™ EO Gas Cartridges are cylinders with liquefied gases and may emit at very low levels; however, when stored to 3M recommendations, they meet or exceed occupational safety requirements. At manufacturing 3M™ Steri-Gas™ EO Gas Cartridges are certified and released at the nominal net fill weights. At the customer site and during the shelf-life, 3M™ Steri-Gas™ EO Gas Cartridges are certified to the net weights as documented in Table 3.

Table 3. Customer Certification Net Weights

Catalog Number	Nominal Customer Net Weight (g)	Customer Certification Net Weight Range (g)	Tolerance from Nominal for Customer Certification Net Weight (g)
4-100	100	95 – 104	(-) 5 to (+) 4
4-134	127	122 – 131	(-) 5 to (+) 4
8-170	170	163 – 176	(-) 7 to (+) 6

1. The gas cylinder pictogram applies to Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. The gas cylinder is not applicable and will not appear on product where the European Union (EU) Classification Labeling and Packaging (CLP) Regulation applies.

Cartridge Barcode

A 2D barcode is imprinted on each 3M™ Steri-Gas™ EO Gas Cartridge (Figures 1 and 2). 3M™ Steri-Gas™ EO Gas Cartridges with the 2D barcode can be used in both the 3M™ Steri-Vac™ Sterilizer/Aerators XL Series, GS Series, and GSX Series; however, the XL Series sterilizers do not have the feature to read the barcode.

The 2D barcode is encrypted with the 3M™ Steri-Gas™ EO Gas Cartridge's catalogue number, lot code (expiration date), nominal fill weight of EO, and is unique to each individual cartridge. The 2D barcode may be applied to the cartridge in one of two methods: (1) with a laser etch or (2) an adhesive label. Figure 1 illustrates a laser etch 2D barcode and Figure 2 illustrates the 2D barcode on an adhesive label. The expiration date and lot code is also printed on the label of the cartridge box.

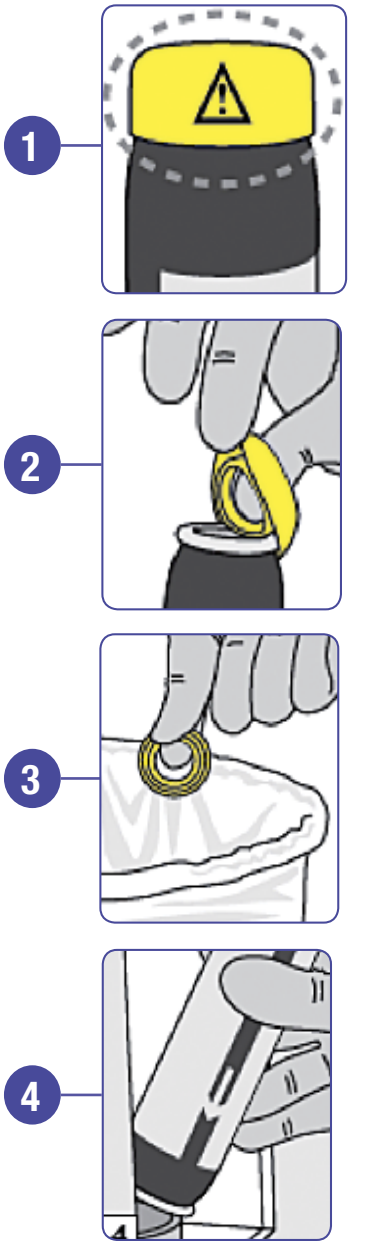
Figure 1. Laser Etch 2D Barcode

Figure 2. 2D Barcode Adhesive Label

Protective Yellow Over-cap

To help prevent inadvertent damage to the 3M™ Steri-Gas™ EO Gas Cartridge seal, each cartridge includes a flexible over-cap to provide additional protection during shipping and handling. The over-cap must be removed by hand and discarded prior to use of the cartridge (Figure 3). Do not use a tool to remove the over-cap. If the 3M™ Steri-Gas™ EO Gas Cartridge is weighed upon incoming receipt, the over-cap must be removed before weighing and then replaced prior to product storage.

Figure 3. Yellow Over-cap



Storage and Shelf Life

3M™ Steri-Gas™ EO Gas Cartridges are designed for structural safety during transport and storage and meet DOT (U.S. Department of Transportation) 2Q specifications (DOT-2Q). DOT-2Q is a classification for certain aerosol cans that adhere to specific dimensional, material, manufacture, wall thickness, testing, and marking requirements. The DOT-2Q certification is the strongest among the three classifications: non-specification, DOT-2P and DOT-2Q. All DOT-2Q cans are required to withstand a minimum of 180 psig (1337 kPa) without buckle and 270 psig (1889 kPa) without burst.

Transportation of 3M™ Steri-Gas™ EO Gas Cartridges in the U.S. requires a special permit and authorization by the U.S. Department of Transportation. End users are not permitted to transport 3M™ Steri-Gas™ EO Gas Cartridges without special permits and authorizations.

Storage per National Fire Protection Association (NFPA)® Codes

NFPA® 30 Flammable and Combustible Liquids Code 2015 edition defines a Class 1A flammable liquid as any liquid that has a flash point below 73°F (22.8°C) and a boiling point below 100°F (37.8°C).

NFPA® 30 defines the Maximum Allowable Quantity (MAQ) as the quantity of flammable and combustible liquid permitted in a control area. A control area is a building or portion of a building within which flammable and combustible liquids are allowed to be stored, dispensed, and used or handled in quantities that do not exceed the maximum allowable quantity.

NFPA® 30 identifies health care facilities as special occupancies and the MAQs for special occupancies and a Class 1 flammable and combustible liquid shall not exceed 10 gallons (38 L) per control area.

Ten (10) gallons (38 L) of 3M™ Steri-Gas™ EO Gas Cartridge is approximately equivalent to the quantities contained in Table 4.

Table 4. Equivalent Quantity of Cartridges and Cases Equaling 10 Gallons

Cartridge Catalog Number	Number of Individual Cartridges	Number of Cases
4-100	363	30
4-134	286	23
8-170	213	17

The maximum quantity of Class IA liquid in a flammable liquids storage cabinet in a building with automatic sprinklers designed in accordance with NFPA® 13 is 120 gallons (see Table 9.6.1 in NFPA® 30, not contained in this document).

3M Recommended Storage

3M's recommendations for storing 3M™ Steri-Gas™ EO Gas Cartridges outside a flammable liquid storage cabinet are more stringent than those in the NFPA® Codes and are intended to minimize the potential for workplace exposure to ethylene oxide (EO).

NOTICE: Always check your local fire protection codes for additional requirements.

Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the cartridges. Store the cartridges in an upright position.

Quantities greater than one (1) box of twelve (12) 3M™ Steri-Gas™ EO Gas Cartridges must be stored in a flammable storage cabinet vented to the outside, through a non-recirculating, continuously operating, dedicated exhaust system, or in an area suitable for storage of flammable liquids appropriately vented to the outside. 3M does NOT recommend the use of unventilated flammable storage cabinets.

NFPA® 30 Flammable and Combustible Liquids Code 2015 edition defines the requirements for acceptable flammable liquid storage cabinets for Class I flammable liquids. The volume of Class I flammable liquids stored in an individual storage cabinet shall not exceed 120 gal (460 L).

One (1) box of twelve (12) 3M™ Steri-Gas™ EO Gas Cartridges can be stored in a room (Central Supply Department or the sterilizer room) **that is designed and verified with equal to or greater than (≥) 10 air exchanges per hour**. Cartridges must be stored at least 2 meters (6 feet) away from the operator desk or work station.

If an individual cartridge is ever dropped, it should be used immediately or disposed of as described in the disposal instructions for a full cartridge in the 3M™ Steri-Vac™ Sterilizer/Aerator Operator's Manual.

Shelf Life

The shelf life of 3M™ Steri-Gas™ EO Gas Cartridges is 5 years from the date of manufacture. The expiration date and lot code for each cartridge is applied to the cartridge in one of two methods, as shown on the previous page: (1) with a laser etch, as in Figure 1 or (2) an adhesive label, as in Figure 2. The expiration date and lot code are also printed on the label of the cartridge box.

The expiration date and lot code are printed in the following format: year (YYYY), dash (-) , month (MM), and a two-character alpha-code (e.g. 2020-11AJ). The product expires on the last day of the month provided in the expiry date code (e.g. November 30, 2020).

Japan's regional regulatory requirements for 3M™ Steri-Gas™ EO Gas Cartridges currently requires labeling with a 3 year shelf life from the date of manufacture for 3M™ Steri-Gas™ EO Gas Cartridges.

U.S. Occupational exposure to ethylene oxide, final standard (29 CFR 1910.1047)

The following sections are duplicated from U.S. OSHA 29 CFR 1910.1047 Ethylene Oxide and 29 CFR 1910.38 Emergency Action Plans. U.S. facilities must have a written plan in place for emergency situations and must have a means of alerting employees of the possibility of employee exposure to EO because of an emergency.

OSHA 29 CFR 1910.1047 Ethylene oxide

h) Emergency situations

1) Written plan

i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

iii) The plan shall include the elements prescribed in 29 CFR 1910.38, "Employee emergency plans and fire prevention plans."

2) Alerting employees

Where there is the possibility of employee exposure to EO because of an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.

Examples of suitable communication methods include a public address announcement, alarm lights, or warning sounds. OSHA also requires these systems to be tested on a periodic basis.

j) Communication of EO hazards to employees

1) Signs and labels

i) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER

ETHYLENE OXIDE

CANCER HAZARD AND REPRODUCTIVE HAZARD

AUTHORIZED PERSONNEL ONLY

RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

OSHA 29 CFR 1910.38 Emergency Action Plans Sections b) through f).

Written and oral emergency action plans. An emergency action plan must be in writing, kept in the workplace, and available to employees for review. However, an employer with 10 or fewer employees may communicate the plan orally to employees.

Minimum elements of an emergency action plan.
An emergency action plan must include at a minimum:

- Procedures for reporting a fire or other emergency;
- Procedures for emergency evacuation, including type of evacuation and exit route assignments
- Procedures to be followed by employees who remain to operate critical plant operations before they evacuate;
- Procedures to account for all employees after evacuation;
- Procedures to be followed by employees performing rescue or medical duties; and
- The name or job title of every employee who may be contacted by employees who need more information about the plan or an explanation of their duties under the plan.
- Employee alarm system. An employer must have and maintain an employee alarm system. The employee alarm system must use a distinctive signal for each purpose and comply with the requirements in 29 CFR 1910.165.
- Training. An employer must designate and train employees to assist in a safe and orderly evacuation of other employees.
- Review of emergency action plan. An employer must review the emergency action plan with each employee covered by the plan:
  - When the plan is developed or the employee is assigned initially to a job;
  - When the employee's responsibilities under the plan change; and
  - When the plan is changed.

For general product information or to find your local U.S. 3M representative:

3M Health Care Customer Helpline
1 800 228 3957

Outside of the U.S. contact your local 3M office. Global office locations are available on our website: visit **www.3M.com** and select the specific country for access to your local 3M contacts.

Contact Information

Product Technical Information

3M Sterilization Tech Line (U.S. only)
1-800-441-1922, option 2

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Issued 6/15. 10266HB
70-2011-5685-1

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