



INSTRUCTIONS FOR USE EFELAB STERILIZING GAS CARTRIDGES



Nro. Rev. 02

INSTRUCTIONS FOR USE

To perform a sterilization cycle with a sterilizer machine.

When the cartridges or ampoules are used with a sterilizer machine it always has to be following the indications of the sterilizer manufacturer. Please note that the cartridges, ampoules and the different machine models correspond to each other.

DANGER!
KEEP OUT OF REACH OF CHILDREN
EXTREMELY FLAMMABLE – DO NOT USE NEAR FLAME
CAUSES EYE AND SKIN BURNS. MAY CAUSE NERVOUS SYSTEM DAMAGE
CANCER HAZARD AND REPRODUCTIVE HAZARD
 Use Only in Accordance With Manufacturer's instructions in Ethylene Oxide Gas Sterilizers
 Users must follow the requirements of National or Local Occupational Exposure Standard for Ethylene Oxide

FIRST AID: IN ALL CASES GET MEDICAL ATTENTION IMMEDIATELY. TAKE THE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. If breathing is difficult, give oxygen. Call a poison control center for doctor immediately for further treatment advice. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN OR CLOTHING: Immediately flush skin with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call a poison control center for doctor immediately for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center for doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Persons exposed to ethylene oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously. Prolonged or high vapor concentration exposure may result in respiratory tract irritation and the development of pulmonary edema after a latent phase of several hours. Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation, which may be delayed. At high concentrations, severe conjunctivitis can occur. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER! CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED.
MAY CAUSE NERVOUS SYSTEM DAMAGE.
DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD
EFFECTS OF OVER EXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, convulsions, coma, delayed lung injury (fluid in the lungs), immediate or delayed skin irritation or blisters, allergic skin reaction.

OTHER POSSIBLE DELAYED HEALTH EFFECTS: May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes and cancer.
PEL: 1 PPM TWA
STEL: 5 PPM – excursion limit 15 minutes
ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin or on clothing. Store and use with adequate ventilation in accordance with National or Local regulations
Personal Protection Equipment (PPE): A material that is chemical-resistant to this product is butyl rubber.
 All handlers must wear at a minimum: Long sleeved shirt and long pants, Shoes plus socks, Chemical-resistant gloves and when the ambient ETO concentration is 1 to 50 ppm, full-face piece respirator with ETO approved canister, front or back mounted, when the ambient ETO concentration is > 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-face piece, hood or helmet; or (2) continuous-flow supplied-air respirator (positive pressure) equipped with hood, helmet or suit, when the ambient ETO concentration is > 2,000 ppm or unknown (e.g. emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-face pieces; or (2) positive-pressure full-face piece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.
 When handlers could have eye or skin contact with ETO or ETO solutions, such as during Maintenance and repair, vessel cleaning, or cleaning up spills, they must wear: Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and face-sealing goggles, a full face shield or a full-face respirator. When wearing respirators: Follow the respirator manufacturer's user's instructions for changing canisters.
 Respirators must be fit-tested and fit-checked using a program that conforms to National or Local requirements.
 Respirator users must be trained using a program that conforms to National or Local requirements.

Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change.
 Follow manufacturer's instructions for cleaning/maintaining PPE. If no such Instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations
 Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
 Users should remove clothing/PPE immediately if ethylene oxide gets inside. Then wash thoroughly and put on clean clothing.
 Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing

PHYSICAL AND CHEMICAL HAZARDS: DANGER! FLAMMABLE LIQUID AND GAS UNDER PRESSURE. Contents under pressure. Do not use near flame, electrical sparks or hot surfaces, or allow sources of ignition near the sterilization / fumigation area. Ethylene Oxide is extremely flammable and reactive.

Ground all equipment to prevent static sparks. Do not puncture or incinerate container. Exposure to temperatures above 65°C may cause bursting.

LEAK: In case of leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use self-contained breathing apparatus and protective clothing and shut off leak if without risk.

FIRE: In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

SHELF LIFE: Shelf life is printed on the Cartridges or Ampoules' container box.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the National or local regulations. Do not discharge effluent containing this product to sewer systems without previously checking out local regulations or notifying the local sewage treatment plant authority For guidance contact your National or Local Authorities.

DIRECTIONS FOR USE: It may be a violation of National or Local law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in National or Local regulations. This product may be used only in facilities that meet requirements of National or Local regulations in Ethylene Oxide Gas Sterilizers designed for use with EO Gas Cartridges or ampoules containing ethylene oxide.
 This product may be used only by people who have been trained in accordance with National or Local regulations. In hospitals and healthcare facilities, sterilization with ETO may be performed only in vacuum or gas tight chambers designed for use with ETO.
 A single chamber process may be required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities. In contract sterilization facilities, including facilities treating medical equipment and supplies, musical instruments, library/museum artifacts and cosmetics. The Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.
 Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter.

The safety training must include, at a minimum, the following information:

The most recent monitored ambient levels of ETO in the facility;
 The potential health effects from the levels of ETO in the facility;
 The emergency response plan and how to respond in an emergency;
 The availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO
 In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. For complete use directions (including type of surfaces, objects or items/products recommended for treatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the ethylene oxide gas sterilizer manufacturers.

Operators Manual.
 This product may be used only to sterilize medical or laboratory items, pharmaceuticals and aseptic packaging or to reduce microbial load on cosmetics materials and artifacts, archival material or library objects.
 Sterilization /fumigation with Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.
 Ethylene Oxide cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (if any); exposure time; temperature, chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired degree of disinfection and the desired performance of the sterilized/fumigated product and package.

The sterilization cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user. NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE.

MIXTURES OF ETHYLENE OXIDE AND AIR, STORAGE AND DISPOSAL: Do not contaminate food, feed or water by storage and disposal.

Product Storage: Store cartridges and ampoules in an upright position. Have established handling and emergency response procedures in place prior to use. Protect containers from physical damage and regularly inspect them for cracks or leaks. Store Ethylene oxide in a dry, cool and well ventilated area away from incompatible sources of ignition like Aqueous Alkalines; Amines; Mineral Acids; Metal Chlorides; and Metal Oxides. Store away from acids; Keep away from heat, sparks, lighted cigarettes, matches, open flame, pilot lights and all sources of ignition.
DO NOT STORE IN DIRECT SUNLIGHT.
 Store in accordance with local or National regulations.

National or Local regulations:
Product Disposal: EO gas wastes are acutely hazardous. Improper disposal of excess EO, spray or mixture of rinsate may be a violation of National or Local Law. If these wastes cannot be disposed of by use according to label instructions, contact your National or Local authorities for guidance.

Container Disposal: Do not puncture or incinerate unused cartridges. Aerate empty cartridges according to instructions in equipment manual. After aeration offer for recycling or dispose of with non-incinerated waste.

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	EFELAB S.R.L. Costa Rica 449/1043 B1714CC Ituzaingo Buenos Aires - Argentina		TOXIC GAS
	xxxx-xxxx		HANDLE WITH CARE
	DD/MM/YYYY		

