

EO 101

Background and History

1. Ethylene Oxide has been registered by the Environmental Protection Agency (EPA) for use as an antimicrobial pesticide since the 1940's¹.
2. EO is a colorless gas at room temperature. Its vapors are highly flammable and explosive above a 3% concentration (30,000 ppm).²
3. EO remains the only proven and universally accepted method for sterilizing such heat and moisture sensitive devices as delicate surgical instruments, optics, electrical devices and plastics.
4. EO has historically demonstrated its effectiveness against a wide spectrum of microorganisms including yeast, mold, bacterial spores, and viruses.
5. The specific mechanism whereby EO renders a microbe inactive is called alkylation, i.e., the replacement of a hydrogen atom in a molecule by an alkyl group. This process severely impairs the normal metabolic and reproductive processes of microorganisms, resulting in cell death.³

Ethylene Oxide Usage Facts

1. EO is found in the production of solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam and pharmaceuticals.⁴
2. World consumption of ethylene oxide is 14 million tons per year and continues to grow at a rate of approximately 3% per year.⁵
3. The USA is the largest producer, of ethylene oxide.⁵
4. 98% of the EO produced in the US is used for industrial purposes. Less than 2% is used in medical facilities and for device sterilization.
5. Over half of all medical devices sterilized by device manufacturers are sterilized by EO.³
6. The average hospital uses less than 500 pounds pure EO sterilant per year.³

Traditional EO Chamber Systems.

1. Traditional EO sterilizers use a system where the product is loaded into a chamber. A vacuum is pulled in the chamber, steam is injected and allowed to dwell for a period of time, after which sterilant gas is injected. At the end of the sterilization cycle, the chamber is purged and the product removed to an aeration chamber. The product is then aerated for the amount of time determined appropriate for that particular item.
2. Another type of commercially available chamber, produced by 3M, employs a 100% ethylene oxide cartridge which is activated when the sterilizer door is closed. The actual sterilization time varies from model to model and additional aeration time is necessary for most items sterilized in this type of system. This type of system allows for only one load to be processed at a time and requires a separate aeration chamber.

Environmental Issues.

1. Ethylene oxide is not a green house gas; it does not persist nor accure in the atmosphere. EO is non-persistent due to washout by rain and chemical degradation.⁶
2. In the past, traditional chambers have used chlorinated fluorocarbons, (or CFC's) mixed with ethylene oxide (commonly referred to as mixture systems such as "12/88") as a means of reducing the potential explosion/flammability danger posed by the large quantity of EO required for chamber sterilization. Due to the recent belief that links CFC's and other "greenhouse gases" with ozone layer depletion, a ban on CFC's., including EO mixture systems, was instituted in December, 1995.
3. CFCs have been replaced with HCFCs which were thought to have a less detrimental effect of the environment. HCFCs however do have some ozone depleting properties and under the Clean Air Act are to be phased out by 2030. Hospitals may only continue to buy new sterilizers using these materials until the year 2015.³
4. EOGas and Anprolene use 100% EO and have never contained CFC's nor HCFC's. There has never been a ban proposed for 100% EO.

5. The Andersen delivery systems consists of a glass ampoule filled with ethylene oxide liquid which is housed in a plastic cartridge. Instead of a metal chamber the system uses plastic sterilization bags. This design eliminates the need for fixed chambers, external EO supply tanks and supply lines, external compressors, water supply lines or costly metal exhaust piping.
6. With EOGas and Anprolene, each cycle can be tailored to your sterilization load needs. EOGas and Anprolene bags and ampoules are available in several sizes, thus a small load of just a few items can be processed just as easily and cost-effectively as a large load consisting of several large, bulky items.

Limitations and Incompatibilities

1. Certain food components, including vitamins and amino acids, are chemically altered by EO. Drugs and antibiotics are also affected. Other limitations include all liquid substances and materials which are completely sealed in glass vials or in non-vented devices.
2. Because EO is gaseous during sterilization, it can not penetrate through liquids to sterilize them. It also can not penetrate sealed glass, metal, or certain plastic (nylon, mylar, etc) containers.

Operator Exposure Issues

OSHA Regulations

1. Employers must tightly control the amount of EO that employees are exposed to. Below are facts involving exposure monitoring of employees:⁷
 - a. Ethylene oxide exposure is measure in parts per million (PPM); that is parts of ethylene oxide per 1,000,000 parts of air.
 - b. TWA (Time Weighted Average): An 8 hour monitoring period during which OSHA limits allow an average of 1 ppm worker exposure,
 - c. STEL (Short Term Exposure Limit): a 15 minute period during which the worker may not be exposed to an average of more than 5 ppm. This is also referred to as the Excursion Limit.

2. Overexposure to ethylene oxide can result in respiratory irritation, nausea, vomiting and diarrhea. Skin contact with EO can result in eye irritation frostbite.⁷

Ethylene Oxide Worker Exposure Studies

1. A study of mortality among workers exposed to ethylene oxide was published in the New England Journal of Medicine in 1991. This study followed over 18,000 U.S. workers exposed to levels of ethylene oxide which exceed current guidelines. Overall, the results of this study demonstrated that there was no significant increase in mortality from any cause in the study group.⁸
2. A follow up study performed by NIOSH in 2002 also concluded that there was little evidence of any excess cancer mortality for the group as a whole (with the exception of bone cancer based on small numbers).⁹
3. Another follow up NIOSH study in 2003 yielded a similar conclusion: “Our data suggest that ETO is associated with breast cancer, but a causal interpretation is weakened due to some inconsistencies in exposure–response trends and possible biases due to non–response and incomplete cancer ascertainment.”¹⁰

References:

1. Environmental Protection Agency
2. Agency for Toxic Substances and Disease Registry: Division of Toxicology
3. Infection Control Today 6/2000: The future of Ethylene Oxide Sterilization.
4. Occupational Safety and Health Administration Fact Sheet
5. Gobi International Chemical Company Website
6. Conway R, Waggy G, Spiegel M, Berglund R. Environmental Fate and Effects of Ethylene Oxide. Environ. Sci Technol 1983; 17:107–112.
7. Code of Federal Regulations Title 29 part 1910
8. National Institute for Occupational Safety and Health May 1991
9. National Institute for Occupational Safety and Health October 2002
10. National Institute for Occupational Safety and Health February 2003