

Exerpts from Factsheet: Ethylene Oxide Sterilant Alternatives

Board of Public Works
HTM Office
City of Los Angeles

Background

Ethylene oxide (EtO) is widely used by health care institutions as a sterilant because of its potency in destroying pathogens. A few facilities use pure EtO, but the vast majority employ a "12/88" mixture of EtO and Chloroflourocarbon (CFC1), primarily to improve safety. Use of EtO sterilizers is of regulatory concern because:

- EtO is flammable and explosive
- EtO is a probable human carcinogen
- EtO is a toxic air contaminant
- CFC is an ozone depleter

Pure EtO is a colorless gas at room temperature. It has an extremely wide explosive range of 3 to 100 volume percent in air. The Flash point is - 4oF (Sax, 1984).

California classifies EtO as a toxic air contaminant, and regulates emissions sterilizers accordingly. At present, EPA does not regulate EtO sterilizers. However, the phase-out of CFCs affects a majority of the users. Switching from 12/88 to pure EtO would permit continued usage of this chemical, but would greatly increase the safety hazard.

This fact sheet presents some of the environmental issues with EtO sterilizers and presents some alternatives to the use of EtO as a sterilant.

Process Description

The EtO sterilization process usually employs five steps:

- 1.Pesterilization conditioning
- 2.Serilization
- 3.Eacuation
- 4.Air wash
- 5.Aeration

Conditioning includes sealing and evacuating the loaded chamber, then adjusting temperature and pressure. The sterilization step involves adding the sterilant, establishing the correct operating pressure and temperature and holding the chamber for a soaking period of 4 to 24 hours. The chamber pressure should be slightly below atmospheric for pure EtO or two atmospheres for 12/88 mixtures. After soaking, the chamber is evacuated, then given a series of air washes to finish removing EtO. Any residual EtO in

the sterilized product is removed by aeration, which may be done either in the sterilizer chamber or in a specially-designed aeration chamber (SCAQMD, 1990).

EtO emissions can be controlled by any of the following technologies:

1. Thermal oxidation
2. Catalytic oxidation
3. Acid-catalyzed scrubbers
4. Solid reactant beds.

Regulatory Issues

OSHA standards for EtO specify a permissible exposure limit (PEL) of 1ppm, time-weighted over 8 hours, and a short-term exposure limit (STEL) of 5 ppm, time-weighted over 15 minutes.

OSHA also requires

1. Monitoring employees to determine actual exposure to EtO during work shift
2. Restricting access to EtO areas authorized personnel
3. Implementing a system to provide emergency warning in the event of a release.

In order to meet the exposure limits, the ventilation of the sterilizer and EtO storage rooms should provide a minimum of 10 air changes per hour, according to recommendations of the 1974 Hill-Burton Standard and the American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE). Local exhaust ventilation is recommended at the following points; above the supply cylinders, and at the overpressure relief valve.

EtO air emissions are currently unregulated by EPA.

EtO Source Reduction

Source Reduction possibilities for EtO sterilizers are especially important, since between the phase-out of CFCs and the regulations on EtO will make these sterilizers increasingly difficult to operate in coming years. Alternative methods of sterilization are available, but many lack the wide material compatibility of EtO. Some possibilities are (SCAQMD, 1990):

Steam:

Steam sterilization has the advantage of being an established, effective and well-understood technology. However, steam is incompatible with plastics and rubber-substances that comprise a large fraction of the materials used in modern medical care. This option may warrant examination for metal instruments and materials as the regulatory restrictions on both EtO and incinerators become more strict.

Ozone:

Ozone produced by passing oxygen through an electric discharge oxidizes microorganisms very effectively. Unfortunately it also oxidizes many metals, rubber and plastics, shortening the useful life of the product. EtO sterilizers can be converted to ozone sterilization.

Radiation:

Both gamma and electron-beam radiation processes are used commercially for sterilization. Gamma rays emitted by cobalt-60 destroy microorganisms by attacking the DNA molecule. Electron- beam radiation sterilization compared to ozone are: no harmful emissions; the entire volume of the product is sterilized; and gas-permeable packaging is not needed. A disadvantage is that radiation degrades some plastic gels.

Vapor-Phase Hydrogen Peroxide (VPHP):

This is a technology currently being developed as an alternative method of sterilization. Early test indicate reduced processing time, no atmospheric emissions, and reduction of harmful residues on sterilized items. However, VPHP is incompatible with iron and some plastics (which are susceptible to the oxidation by hydrogen peroxide), and cannot sterilize highly absorptive products, such as those made from cellulose.

Plasma:

Another new technology, this employs a plasma (a cloud of ions, electrons, and free radicals). The free radicals react with cell membranes, enzymes and nucleic acids to destroy microorganisms. There are no harmful emissions, but this process cannot be used for cellulose like linen and paper.

Microwave Radiation:

Microwaves can destroy the proteins of microorganisms. The application of microwave technology to sterilization is still in the R & D phase.

Thus, of the six alternatives listed, three are commercially used now and three are still under development.

One way to reduce the use of sterilant is to increase the use of disposal items. However, this increases the quantity of material that must be managed as a medical waste.

Recovery and recycling EtO returns to a main storage tank. There is a possibility that recovered EtO could become contaminated by a material that would cause a spontaneous reaction, resulting in explosion or fire.

References

ECRI, 1990a. "EtO Phone Home: The Future of Sterilization in Hospitals" Healthcare Hazardous Materials Management, Vol. 3, No. 10, July 1990.

ECRI, 1990b. "Ethylene Oxide Control Technology I: Occupational Exposure". Healthcare Hazardous Materials Management, Vol. 3, No. 12, September 1990.

ECRI, 1990c. "Ethylene Oxide Control Technology I: Occupation Exposure". Healthcare Hazardous Materials Management, Vol. 4, No. 1, October 1990.

ECRI, 1990d. "Waste Minimization Healthcare Facilities". Healthcare Hazardous Materials Management, Vol. 4, No. 3, December 1990.

Sax, N. Irving (ed.) 1984. Dangerous Properties of Industrial Materials, 6th Ed. Van Nostrand Reinhold, Co., pp. 1347-8.

SCAQMD, 1990. "Control of Ethylene Oxide and Chlorofluorocarbon emissions for Sterilization or Fumigation Process". rule 1405 November 1990. South Coast Air Quality Management District.

US EPA, 1990a. "Medical Waste Management in the United States: EPA/530 SW-90-051B, May 1990. US. EPA, 1990B. "Guide to Pollution Prevention for Selected Hospital Waste Streams, EPA/625/7-90/009, June 1990.