THE MASSACHUSETTS TOXICS USE REDUCTION INSTITUTE

Massachusetts Chemical Fact Sheet

Ethylene Oxide

Ethylene oxide poses serious hazards to human health; it was recently upgraded to a known human carcinogen by the National Toxicology Program. In 1996, United States manufacturers consumed over 8.8 billion pounds of ethylene oxide, primarily as an intermediary chemical in the manufacture of ethylene glycols, glycol ethers, ethanolamines, and surface-active agents (surfactants). Some businesses and hospitals use ethylene oxide directly as a sterilant or fumigant as it effectively kills microbial organisms. In Massachusetts, only one facility uses ethylene oxide in large quantities to sterilize disposable medical equipment.

FACTS	
Other Names:	1,2-Epoxyethane, Oxirane, Dimethylene Oxide
Chemical formula:	C_2H_4O
CAS Number:	75-21-8
Vapor Pressure:	1,095 mm Hg at 20°C (gas at room temperature, liquid at 12°C)
Water Solubility:	Miscible
Flammability:	High

Hazards

Acute (Short-Term) Health Effects

- Inhaling ethylene oxide can cause nausea, vomiting, and neurological disorders. At concentrations of 800 parts per million (ppm), ethylene oxide can be lethal.

- Contact with ethylene oxide in solution can cause severe irritation and burns of the eyes, skin, and lungs.

- Ethylene oxide is an extremely flammable and reactive gas or liquid. Even static can cause ethylene oxide to ignite.

Chronic (Long-Term) Health Effects

- Ethylene oxide is a "known" or " probable" human carcinogen, depending on the classifying body. The National Toxicology Program recently upgraded it to a known human carcinogen. The U.S. Environmental Protection Agency (EPA) classifies it as a Group B1 (probable) carcinogen and the International Agency for Research on Cancer (IARC) classifies it as a Group 2A (probable) carcinogen.

- Ethylene oxide is a potential reproductive hazard (teratogen). Both chronic and acute exposures may cause miscarriages. Animal studies indicate the potential for lower testicular weight and sperm concentration, and testicular degeneration.

- Ethylene oxide may also damage the central nervous system, liver, and kidneys, or cause cataracts.

Hazards of Ethylene Oxide-based Chemical Products

- The ethylene oxide-based glycol ethers are potential teratogens. Animal studies have documented increased rates of infertility, birth defects, and decreased fetal weight from glycol ether exposure.

- The degradation products of ethylene oxide-based nonylphenol ethoxylates, nonylphenol and short-chained nonylphenol ethoxylates, are acutely toxic to

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marine organisms and have the potential to bioaccumulate.

(For section references, see endnote #1.)

Exposure Routes

Worker Health

Facilities using ethylene oxide (EtO) must minimize worker exposure.

- Use ethylene oxide in closed systems. If a closed production system is infeasible, enclose operations and use local exhaust ventilation. If ethylene oxide exposure may exceed 0.1 ppm, use a Mine Safety and Health Administration/National Institute for Occupational Safety and Health-approved supplied-air respirator with a full facepiece.

- Take precautions to avoid ethylene oxide contact with skin and eyes. If ethylene oxide contacts skin, wash immediately.

- For an in-depth discussion of the hazards associated with ethylene oxide as well as lessons learned from previous industrial accidents involving EtO, refer to a publication by Shell Chemical Company, Dow Chemical Company, Sunoco, Celanese Ltd., and Equistar Chemicals, "Ethylene Oxide User's Guide," second edition, August 1999.

Public Health

Air emissions are the principal source of public exposure to ethylene oxide.

- Manufacturing facilities and hospitals are the primary sources of ethylene oxide emissions.

- Other airborne sources include auto exhaust, releases from commodity-fumigated materials, and tobacco smoke.

(For section references, see endnote #1.)

Use Nationally and in Massachusetts

Eleven corporations, all located in Louisiana and Texas, had the capacity to manufacture 8.8 billion pounds of ethylene oxide in 1996. U.S. manufacturers primarily use ethylene oxide as an intermediary to produce other chemicals. The major end-uses for ethylene oxide are ethylene glycol (58%), other glycols (10%), glycol ethers (6%), ethanolamines (10%), surface-active agents or surfactants (11%), and other uses (5%).

Common products made using ethylene glycol as an intermediary chemical include the following: polyethylene terephthalate (PET; a prominent example of PET is 2-liter soda bottles), antifreeze, lubricants, natural gas, polyurethane, polyvinyl chloride (glycols act as a plasticizer), brake fluids, printed circuit boards, and detergents.

Direct uses of EtO include its use as a fumigant and sterilant; it effectively kills microbial organisms. Approximately 8-9 million pounds were used to sterilize or fumigate disposable and reusable medical items, scientific equipment, clothing, furniture, spices, books, packaging materials, and museum artifacts.

Ethylene oxide consumption in Massachusetts is low because the state lacks manufacturers of ethylene glycols, glycol ethers, or ethylene oxide-based surfactants where EtO would be used as an intermediary. While only 3 firms have ever reported EtO use in Massachusetts, it is likely used widely as a sterilant in quantities below the 10,000

Table 1. Ethylene Oxide Consumption by Use Category in Massachusetts (1990 and 1997)

Use Category	Facility Name	Use by Facility (pounds) 1990	1997	Percent Change
Sterilization of Medical Products	Bard CR Inc	13,900	0 [1]	-100%
	Isomedix Inc	0	337,200	n/a [2]
	Total	13,900	337,200	2326%

[1] "0" indicates either that the facility is not using the chemical or has dropped below the reportable threshold; [2] n/a = not applicable; Source: Massachusetts Toxics Use Reduction Act data, 1999.

pound threshold for reporting under MA TURA (Massachusetts Toxics Use Reduction Act) and U.S. TRI (Toxics Release Inventory).

- In 1997, one Massachusetts' facility, Isomedix, used 337,200 pounds of ethylene oxide in the "terminal sterilization" of disposable medical instruments and supplies (see Table 1).

- CR Bard reported on its use of EtO for a few years beginning in 1990 and then either ceased using EtO or dropped below threshold.

Table 2 includes two sources of "output" data: MA TURA and U.S. Environmental Protection Agency (EPA), Toxics Release Inventory (TRI) data. The MA TURA database includes all non-product material created by a process line prior to release, on-site treatment, or transfer ("byproduct") and the amount of toxic chemical incorporated into a product ("shipped in or as product"). The U.S. EPA, TRI database includes information on the waste materials generated by a facility after on-site treatment including: releases to air, land, and water ("environmental releases") and transfers off-site for treatment or disposal ("off-site transfers").

- In its use as a sterilant, EtO ends up as a byproduct of production.

- In 1990, Bard, Inc. reported 10,400 pounds of fugitive and point air emissions. In 1997, Isomedix reported only 709 pounds of fugitive and point air emissions.

(For section references, see endnote #2.)

Alternatives

Sterilization is defined as a process intended to remove or destroy all viable forms of microbial life, including bacterial spores. Effective sterilization of medical instruments is essential for manufacturers of medical products and for hospitals. While several methods of sterilization exist, each have their own advantages and disadvantages. Ultimately the choice of a sterilization process must be made with the specific product or circumstance and the potential process hazards in mind. Table 3 offers technical, environmental, worker health and safety advantages and limitations of common sterilization alternatives. Costs of the various technologies are not discussed as they are dependent on the types and amounts of materials being processed.

(For section references, see endnote #3.)

Table 2. Ethylene Oxide: Use and Output Data for Massachusetts 1990 and 1997 (pounds)

Use Data -- MA TURA	1990	1997	Change	% Change
Manufactured or Processed	0 [1]	0	0	n/a [2]
Otherwise Used	13,900	337,200	323,300	2326%
Total TURA Inputs	13,900	337,200	323,300	2326%
Output Data -- MA TURA	**1990**	**1997**	**Change**	**% Change**
Generated as Byproduct	13,900	337,200	323,300	2326%
Shipped In or As Product	0	0	0	n/a
Total TURA Outputs	13,900	337,200	323,300	2326%
Releases and Transfers -- US EPA, TRI	**1990**	**1997**	**Change**	**% Change**
Environmental Releases	10,380	709	-9,671	-93%
Off-site Transfers	0	0	0	n/a
Total TRI R&T	10,380	709	-9,671	-93%

[1] "0" indicates that no facility is reporting use of the chemical. Facilities may be using the chemical below threshold quantities; [2] n/a = not applicable; Sources: MA TURA -- Massachusetts Toxics Use Reduction Act data, 1999; and US EPA, TRI -- US Environmental Protection Agency, Toxics Release Inventory data, 1999.

Regulatory Context

A well-known hazard to human and environmental health, both the U.S. Occupational Safety and Health Administration (OSHA) and EPA regulate ethylene oxide.

- The OSHA permissible exposure limit (PEL) for an eight-hour workshift for ethylene oxide is 1 ppm and the short-term exposure limit (STEL) — it should not be exceeded during any 15-minute work period — is 5 ppm.

The U.S. EPA regulates ethylene oxide under the authority of six environmental statutes. Under the:

- Clean Air Act, EtO is both a "hazardous air pollutant" and a "regulated toxic, explosive, or flammable substance."
- Comprehensive Environmental Responsibility, Compensation and Liability Act (popularly known as "Superfund"), EtO is an "extremely hazardous substance."
- Emergency Planning and Community Right-to-Know Act, TRI program, all large quantity users of ethylene oxide must submit data on environmental releases and off-site transfers.
- Federal Insecticide, Fungicide, and Rodenticide Act, ethylene oxide is a "registered pesticide."
- Resource Conservation and Recovery Act, ethylene oxide is a "hazardous constituent."

The U.S. Food and Drug Administration has regulatory jurisdiction over liquid chemical sterilants

Table 3. Advantages and Limitations of Sterilization Alternatives			
	Alternatives	**Advantages**	**Limitations**
High Temperature	Steam/Autoclave	established process; relatively short cycle times; no gas residuals	some materials cannot withstand high temperatures and pressures, (i.e, plastics, rubber); efficient heat transfer is difficult for large volumes; may require rust inhibitors
	Dry Heat	established process; no rust or corrosion problems; no gas residuals	requires higher temperature than autoclave; long cycle time
Radiation	Microwave	suitable for plastics; relatively short cycle time; no gas residuals	new application of this technology
	Gamma-Cobalt 60	entire volume of product is sterilized	potential worker exposure to radioactive material; creation of radioactive waste; degrades some plastic gels; long cycle time; only suitable for high volumes
	E-beam	suitable for most products and devices; relatively short cycle time; no gas residuals	new application of this technology
Plasma	Mixed chemical plasma device using peracetic acid	no toxic byproducts, low temperature	relatively long cycle time; chemical has worker health and safety concerns; not suitable for liquids
	Hydrogen peroxide plasma	relatively short cycle time; low temperature; no toxic byproducts	limited use on instruments having lumens; not suitable for cellulose-based products, powders or liquids
Liquid Chemical	Peracetic acid Formaldehyde Propylene oxide Hydrogen peroxide Chlorine dioxide Glutaraldehyde	convenient, low temperature, relatively short cycle time	chemicals may have worker health and safety and environmental concerns; difficult to prove success of sterilization process; only appropriate for immersible materials; may be more appropriate for high level disinfection, not sterilization; limited FDA approvals
Vapor Chemical	Ethylene oxide gas (100% and with carrier gases)	established process; low temperature; used for materials that heat and moisture may damage; effective on most medical materials	carcinogenic chemical; environmentally toxic and flammable chemical; long cycle time (hours to days); products must be in breathable packaging; cost of use is increasing due to regulations
	Ozone	existing EtO sterilizers can often be converted to the ozone process; no toxic byproducts; low temperature; relatively short cycle time	oxidizes many metals, rubbers and plastics, shortening their useful life; complex process
	Vapor phase hydrogen peroxide	relatively short cycle time; low temperature	incompatible with iron and some plastics; not suitable for cellulose-based products; polypropylene/polyester packaging requires post-sterilization aeration
Note: Specific clearances for the technologies must be investigated with the U.S. Food and Drug Administration.			

and/or high level disinfectants used to process reusable critical and semicritical medical devices.

At the international level, Sweden has phased-out most uses of nonylphenol ethoxylate. An ethylene oxide-based surfactant used in detergents, nonylphenol ethoxylates degrade easily into products toxic to marine organisms. Acknowledging the marine toxicity of nonylphenol ethoxylate byproducts, U.S. manufacturers voluntarily ceased using nonylphenol ethoxylates in household detergents.

(For section references, see endnote #4.)

Endnotes

1 The data for this section were collected from the following sources: Environmental Defense Fund, 1999, "Chemical Profile for Ethylene Oxide" (New York: EDF; see webpage: http:/www.scorecard.org/chemical profiles/html/ethylene_oxide.html); Richard J. Lewis, Sr. (ed.), 1993, *Hazardous Chemicals Desk Reference* (New York: Van Nostrand Reinhold); New Jersey Department of Health and Senior Services, 1994, "Hazardous Substance Fact Sheet: Ethylene Oxide" (Trenton, New Jersey; see webpage: http:// www.state.nj.us/health/eoh/rtkweb/rtkhsfs.htm); Ted Schettler, Gina Solomon, Paul Burns, and Maria Valenti, 1996, *Generations at Risk: How Environmental Toxins May Affect Reproductive Health in Massachusetts* (Cambridge, Massachusetts: Greater Boston Physicians for Social Responsibility and Massachusetts Public Interest Research Group); Swedish National Chemicals Inspectorate (KemI), 1991, *Risk Reduction of Chemicals: A Government Commission Report*, Report No. 1/91 (Solna, Sweden: KemI); and U.S. EPA, Office of Air Quality Planning and Standards, 1998, "Ethylene Oxide" (Washington, D.C.: U.S. EPA; see webpage: http://www.epa.gov/ ttn.uatw/hlthef/ethylene.html); Shell Chemical et al, "Ethylene Oxide User's Guide," second edition, August 1999, (see webpage: http://www.ethyleneoxide.com/); U.S. Department of Health and Human Services, National Toxicology Program, 2000, "9th Report on Carcinogens."

2 The national chemical use data are from Stanford Research Institute (SRI) International, 1997, *Chemical Economics Handbook,* "Ethylene Oxide " (Palo Alto, California: SRI). The Massachusetts chemical use data are from the Massachusetts Department of Environmental Protection (MA DEP), 1998, "Massachusetts Toxics Use Reduction Act Chemical Reporting Data" (Boston: MA DEP).

3 References for the alternatives section are as follows: Los Angeles Board of Public Works, 1995, "Factsheet: Ethylene Oxide Sterilant Alternatives;" Advanced Sterilization Products, 1996, "The Future of Low-Temperature Sterilization Technology," (Newport Beach, CA: Communicore); The Titan Corporation, "Electron Beam Technology," (see webpage: http:// www.scan.titan.com); Centers for Disease Control and Prevention, "Sterilization or Disinfection of Medical Devices: General Principles," (see webpage: http:// www.cdc.gov/ncidod/hip/sterile/sterilgp.htm).

4 The data in this section are from the following sources: EDF, 1999; New Jersey Department of Health and Senior Services, 1996; and Swedish National Chemicals Inspectorate, 1991 (see endnote #1 for full citations).