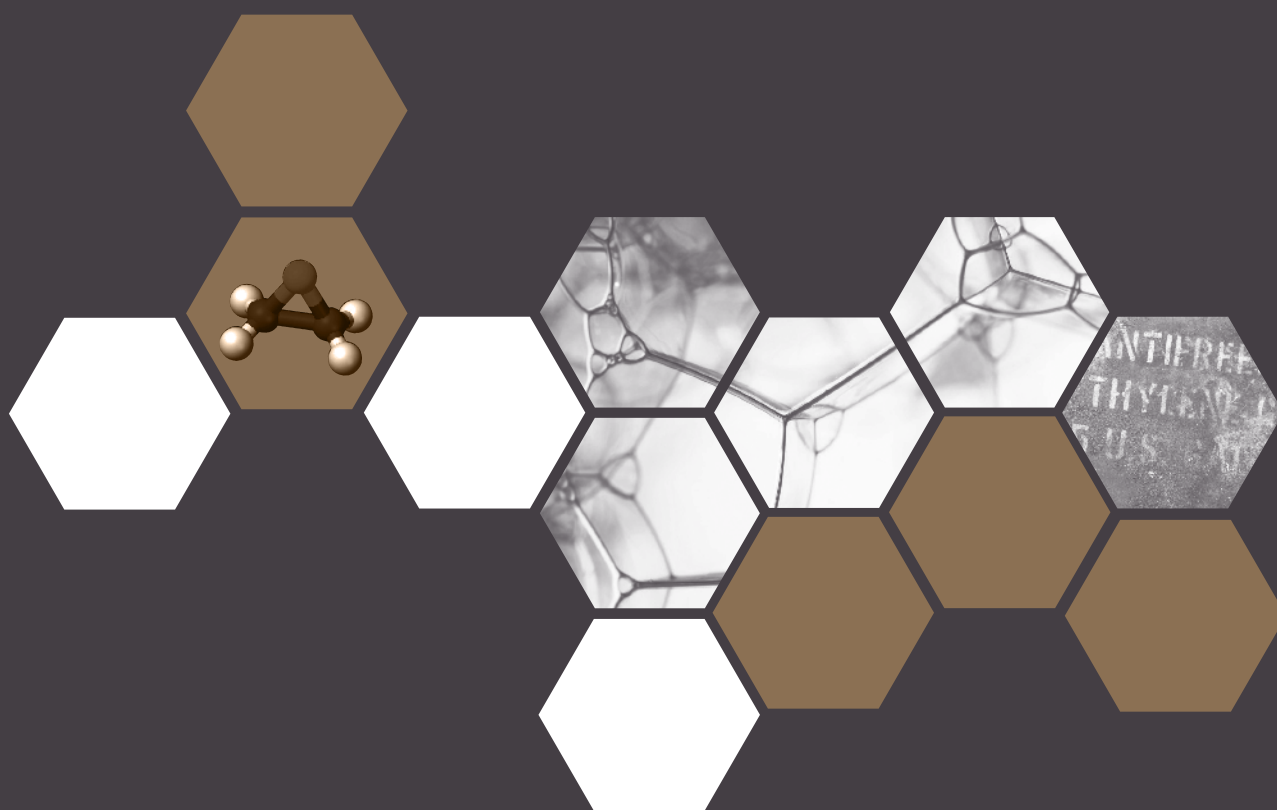


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To the Reader

Manual Preparation

As members and affiliated companies of the American Chemistry Council, we support efforts to improve the industry's responsible management of chemicals. To assist in this effort, the American Chemistry Council's Ethylene Oxide/Ethylene Glycols Panel supported the creation and publication of this manual. The Panel is comprised of the following companies:

Balchem Corporation/ARC Specialty Products

BASF Corporation

Bayer Material Science LLC

Celanese Ltd.

Champion Technologies

Croda, Inc.

The Dow Chemical Company

Eastman Chemical Company

Honeywell

Shell Chemical LP

The development of this manual was led by the Panel's Ethylene Oxide Safety Task Group (EOSTG), a group comprised of producers and users of ethylene oxide. The EOSTG functions to generate, collect, evaluate and share information to support product stewardship with regard to ethylene oxide. The EOSTG formed a manual work group, chaired by Keith Vogel of Lyondell Chemical Company, to lead the development of this document. The following work group members provided significant contributions:

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Table of Contents

1.0	Introduction	1	6.0	Design of Facilities	39
1.1	Purpose and Use of Manual ...	1	6.1	Introduction.....	39
2.0	Properties of Ethylene Oxide ..	2	6.2	Plant Layout and Siting	39
2.1	Introduction.....	2	6.3	Materials of Construction ...	40
2.2	Physical Properties	3	6.4	Unloading Facilities – Bulk Receipt of EO	46
2.3	Reactive and Combustive Properties	5	6.5	EO Storage	49
2.4	Commercial Chemistry	14	6.6	Reaction Systems	54
2.5	Uses of Ethylene Oxide	15	6.7	Piping and Pumps	57
3.0	Health Effects of Ethylene Oxide	16	6.8	Handling of Vents and Effluent.....	63
3.1	Introduction.....	16	6.9	Miscellaneous.....	66
3.2	Acute Inhalation Exposure ...	16	7.0	Personnel Exposure	68
3.3	Skin and Eye Contact	16	7.1	Introduction.....	68
3.4	Chronic Exposure Hazards ..	16	7.2	OSHA Standard for Ethylene Oxide	68
4.0	Environmental Effects of Ethylene Oxide	18	7.3	Other Exposure Standards/ Recommendations for Ethylene Oxide	68
4.1	Introduction.....	18	7.4	Measuring Exposure	70
4.2	Properties in the Environment	18	7.5	Personal Protective Equipment.....	70
4.3	Ecotoxicological Effects	21	8.0	Equipment Preparation and Maintenance	82
4.4	Environmental Evaluation of Ethylene Oxide Spills.....	21	8.1	Introduction.....	82
4.5	Fugitive Emissions	22	8.2	Preparation for Inspection or Maintenance	82
5.0	Hazards of Ethylene Oxide ...	23	8.3	Preparation of Internal Surfaces	83
5.1	Introduction.....	23	8.4	Leak Repair Clamps.....	83
5.2	Contamination Incidents.....	23	8.5	Preventive Maintenance	84
5.3	Formation of Ethylene Oxide Vapor Clouds.....	27	8.6	Equipment Commissioning...	84
5.4	Ethylene Oxide Decomposition Incidents	27	9.0	Transportation and Unloading Operations	85
5.5	Ethylene Oxide Transportation Incidents	35	9.1	Introduction	85
5.6	Runaway Ethylene Oxide Polymerization Incidents ...	36	9.2	Emergency Response Telephone Numbers.....	85
5.7	Runaway Reactions in Ethoxylation Units.....	36	9.3	Ethylene Oxide Classification.	85
5.8	Incidents in Ethylene Oxide Abatement Devices	37			

9.4	Railcars	85	11.0	Selected Regulations	105
9.5	IM Portable Tanks (Intermodal/Iso-Containers) ..	94	11.1	Introduction.....	105
9.6	Non-Bulk Packaging for High Purity Ethylene Oxide ...	94	11.2	Regulations — Numerical with Subject Listed	105
9.7	Ethylene Oxide Shipping Data	98	Appendix A Figures and Tables		118
9.8	Shipments of Ethylene Oxide between the U.S. and Canada.....	98	Appendix B Laboratory Compatibility Testing of Elastomers with Ethylene Oxide.....		137
10.0	Emergency Response.....	100	Appendix C Railcar Repressurization		141
10.1	Introduction	100	Appendix D References		145
10.2	Potential Hazards	100	Appendix E Glossary of Selected Terms, Abbreviations and Organizations.....		151
10.3	Fire Response.....	101			
10.4	Spill Response	102			
10.5	Emergency Response to Temperature Rise.....	102			
10.6	Emergency Response Plan to Temperature Rise	103			
10.7	Use of Water in Emergencies.....	104			

Figures

Figure 2.1	The Ethylene Oxide Molecule	2	Figure 5.9	Remnants of Railcar (after EO explosion caused by contamination with ammonia)	26
Figure 2.2	Flammable Region of Ethylene Oxide/Nitrogen/Air Mixtures	7	Figure 5.10	High Speed Centrifugal Pump “Launched” by Decomposition of 0.6 Pounds of Ethylene Oxide	29
Figure 2.3	Flammable Region of Ethylene Oxide/Carbon Dioxide/Air Mixtures	7	Figure 5.11	Motor Landed on Operating Ethylene Oxide Pump Discharge Line	29
Figure 2.4	Effects of Pressure on Flammable Region of Ethylene Oxide/Nitrogen/Air Mixtures	8	Figure 5.12	Ethylene Oxide Distillation Column Reboiler after Explosion	30
Figure 2.5	Ethylene Oxide Polymer Instantaneous Drop-Out Temperatures	13	Figure 5.13	Aerial View of Ethylene Oxide Plant after Explosion. . .	31
Figure 2.6	Ethylene Oxide Polymer Drop-Out Temperatures after 4 Days	14	Figure 5.14	Remnants of Base of Ethylene Oxide Distillation Column after Explosion	31
Figure 4.1	Neutral EO/Water/Glycol Kinetics - Isothermal Case, Initially EO/Water mixture . .	19	Figure 5.15	Piece of Ethylene Oxide Distillation Column Wall Turned Inside Out by Explosion	32
Figure 4.2	Neutral EO/Water/Glycol Kinetics - Adiabatic Case, Initially EO/Water	19	Figure 5.16	Aerial View of EO Unit After Explosion.	33
Figure 5.1	Older View of Plant Before Explosion Showing EO Tanks in Foreground	23	Figure 5.17	EO Plant Burning after Explosion.	33
Figure 5.2	Blast Center after Explosion – EO Vessels No Longer Visible	23	Figure 5.18	EO Purification After Explosion – Two Towers are Missing.	34
Figure 5.3	Aerial View of the Plant Showing Overall Damage. . .	24	Figure 5.19	Ethylene Oxide Re-distillation Tower Explosion.	34
Figure 5.4	EO Tank Blown Into Process Structure 400 Feet Away . . .	24	Figure 5.20	Resulting Damage to the Plant.	34
Figure 5.5	Plant Laboratory After EO Vapor Cloud Explosion, 300 Feet Away from Explosion Center	25	Figure 5.21	Filter Case after Runaway Polymerization	36
Figure 5.6	Remnants of Railcar	25	Figure 5.22	Filter Case after Runaway Polymerization	36
Figure 5.7	Remnants of Railcar	25	Figure 5.23	Filter Case after Runaway Polymerization	36
Figure 5.8	Damage to Other Railcars from Ethylene Oxide Railcar Explosion	25	Figure 5.24	Diagram of Sterilizer Explosion	37
			Figure 5.25	Sterilizer Explosion Damage.	38

Figure 5.26	Sterilization Chamber Damage.	38	Figure 6.11	Example of Severely Degraded O-ring in High Temperature EO-water Service (Chemraz® 505). . . .	44
Figure 5.27	Damage to the building wall from impact of sterilizer door	38	Figure 6.12	Example of Flange Seal Band with Leak Detection Drip Tube	45
Figure 6.1	Degradation of Compressed Asbestos Valve Bonnet Gaskets by Ethylene Oxide. . .	41	Figure 6.13	EO Unloading Facilities.	46
Figure 6.2	PTFE Gasket Failures in EO Service Due to Cold Flow. . .	41	Figure 6.14	Representative layout of Ethylene Oxide unloading facilities – Pressurized transfer	47
Figure 6.3	Glass Filled PTFE Gasket Failure Due to EO Polymerization in PTFE-Glass Matrix	42	Figure 6.15	Representative layout of Ethylene Oxide unloading facilities – Pump transfer. . .	48
Figure 6.4a	Deformation of a Spiral Wound Stainless Steel-PTFE Gasket Due to EO Permeation and Polymerization	42	Figure 6.16	Total pressure required to inert vapor above Ethylene Oxide with nitrogen diluent .	51
Figure 6.4b	Deformation of a Spiral Wound Stainless Steel-PTFE Gasket.	42	Figure 6.17	EO Decomposable Limits versus Molar Nitrogen Concentration	56
Figure 6.5	Spiral Wound Gasket with Stainless Steel Windings, Flexible Compressed Graphite Filler, and Inner and Outer Retaining Rings	43	Figure 6.18	Decomposition Limit of Mole % EO versus Total System Pressure	57
Figure 6.6	Gasket Test Showing Failure of Compressed Graphite Gasket, Laminated on Flat Stainless Steel Sheet with an Adhesive	43	Figure 6.19	Ethylene Oxide Vent Scrubber System.	63
Figure 6.7	Laminated Gasket Made of Polycarbon Sigriflex™ BTCSS Flexible Compressed Graphite – Laminated on Stainless Steel Tang Sheet .	43	Figure 6.20	Schematic of Typical Flaring System.	65
Figure 6.8	Laminated Gasket Made of UCAR Grafoil GH™ E Flexible Compressed Graphite – Laminated on Stainless Steel Tang Sheet	43	Figure 6.21	EO Sampling System	67
Figure 6.9	Butyl Rubber O-Ring Before and After Exposure to EO for 30 days	44	Figure 7.1	OSHA Warning for EO Regulated Areas	69
Figure 6.10	Example of Degraded O-ring Attacked by EO	44	Figure 7.2	Chemical Burn Resulting from Low Concentration of EO in Water	70
			Figure 9.1	DOT 105-J railcar for transporting Ethylene Oxide	86
			Figure 9.2	Dome Arrangement of a DOT 105-J Railcar for Ethylene Oxide Service	87
			Figure 9.3	DOT “Stop—Tank Car Connected” Sign	88
			Figure 9.4	Canister Mask with Ethylene Oxide-Specific Canister	90

Figure 9.5	Positive Pressure “Hoseline” Type Respirator	90	Figure 16	Flammability Data on EO-Air Mixtures at Subatmospheric Pressures	128
Figure 9.6	Commonly Used Non-bulk Containers	95	Figure 17	Vapor/Liquid Equilibria of Ethylene Oxide/Water Systems	129
Figure 9.7	Typical Drum Connections . .	96	Figure 18	Density vs. Composition of Ethylene Oxide/Water Systems	130
Figure 10.1	Ethylene Oxide / Water (Neutral) Reaction Temperature Profile	103	Figure 19	Boiling points of aqueous EO concentrations.	131
Figure 1	Ethylene Oxide Liquid Density	118	Figure 20	Decomposition Data	132
Figure 2	Ethylene Oxide Vapor Pressure	118	Figure 21	Vapor Compressibility vs. Pressure as a Function of Temperature.	133
Figure 3	Ethylene Oxide Liquid Heat Capacity	119	Figure B1	Weight Change of O-rings Exposed to EO at 27°C	138
Figure 4	Ethylene Oxide Liquid Viscosity	119	Figure B2	Volume Change of O-rings Exposed to EO at 27°C	138
Figure 5	Ethylene Oxide Liquid Thermal Conductivity	120	Figure B3	Tensile Strength of O-rings Exposed to EO at 27°C	140
Figure 6	Ethylene Oxide Heat of Vaporization	120	Figure B4	Maximum Deformation of O-rings Exposed to EO at 27°C	140
Figure 7	Ethylene Oxide Vapor Heat Capacity	121	Figure C1	Unloaded Railcar Repressuring — Nitrogen — Less than 50 Gallon EO Heel	142
Figure 8	Ethylene Oxide Vapor Viscosity	121	Figure C2	Unloaded Railcar Repressuring — Vapor Balancing — Less than 50 Gallon Heel	144
Figure 9	Ethylene Oxide Vapor Thermal Conductivity	122			
Figure 10	Freezing Points Ethylene Oxide/Water Mixtures	122			
Figure 11	C_p/C_v For Saturated Ethylene Oxide Vapor	123			
Figure 12	Ethylene Oxide Vapor Density	123			
Figure 13	Ethylene Oxide Coefficient of Cubic Expansion	124			
Figure 14	Raoult’s Law Deviation Factors for Ethylene Oxide/ Water Mixtures.	126			
Figure 15	Raoult’s Law Deviation Factors for Ethylene Oxide/ Water Mixtures.	127			

Tables

Table 2.1	Physical Properties of Ethylene Oxide	3	Table 7.2	OSHA Minimum Standards for Respiratory Protection for Airborne Ethylene Oxide.	72
Table 2.2	Physical Properties of Aqueous Ethylene Oxide Solutions.	5	Table 7.3	Ethylene Oxide Permeation Data for Clothing	73
Table 2.3	Heat of Reaction of Various Ethylene Oxide Reactions at 25°C.	6	Table 7.4	Ethylene Oxide Permeation Data for Gloves	79
Table 2.4	Physical Properties of Ethylene Oxide Polymer	12	Table 7.5	Ethylene Oxide Permeation Data for Boots	81
Table 2.5	Solubility* of Ethylene Oxide Polymer in Various Solvents	13	Table 9.1	Illustration – Pressuring Unloaded Railcars with Pure Nitrogen (Assuming 50 Gallon Ethylene Oxide Liquid Heel)	93
Table 3.1	Carcinogenicity Classifications of Ethylene Oxide.	17	Table 9.2	Illustration – Repressuring Unloaded Railcars – Vapor Balancing (50 Gallon Ethylene Oxide Liquid Heel).	94
Table 3.2	Findings of the NIOSH Ethylene Oxide Studies	17	Table 9.3	Temperature/Density/Vapor Pressure for Shipping Ethylene Oxide.	98
Table 4.1	Environmentally Relevant Parameters of Ethylene Oxide	18	Table A1	Physical Property Equations	134
Table 4.2	Biological Degradation Data for Ethylene Oxide	20	Table A2	Conversion Factors.	134
Table 4.3	Aquatic Toxicity Data for Ethylene Oxide*	21	Table A3	Henry’s Law Constants (Atm/mole fraction)	135
Table 6.1	EO Pump Shutdown and Alarm Considerations.	62	Table A4	Henry’s Law Constants (MPa/mole fraction).	135
Table 7.1	AEGL Values for Ethylene Oxide [ppm (mg/m ³)]	69	Table B1	O-Rings Selected for Compatibility Testing	137

3.0 Health Effects of Ethylene Oxide

3.1 Introduction

This Chapter provides a brief overview of information pertaining to potential health hazards associated with exposure to EO. A comprehensive discussion of health information pertaining to EO is beyond the scope of this manual. For more information, you may want to contact your supplier. Additional health effects information, including first aid information, also may be found in your supplier's Material Safety Data Sheet (MSDS).

The government and other organizations have established standards and recommendations for personnel exposure to EO [1]. These include the National Institute for Occupational Safety and Health (NIOSH), the American Industrial Hygiene Association (AIHA), the National Academy of Sciences (NAS) in conjunction with the U.S. Environmental Protection Agency (EPA), and the Occupational Health and Safety Administration (OSHA). The OSHA standard for EO is located at 29 CFR 1910.1047. It is important to be familiar with these standards and recommendations because they set exposure levels that are designed to be protective of human health. See Chapter 7.0, Personnel Exposure, for a more detailed discussion of these topics and contact your supplier for additional information.

For general information about this topic, users may wish to consult the Concise International Chemical Assessment Document (CICAD #54) on EO published in 2003 [2]. This document, prepared by the World Health Organization's International Programme on Chemical Safety, summarizes sources of EO exposure and potential effects on humans and the environment. The CICAD notes inhalation to be the route of likely greatest exposure for human health effects from EO. The CICAD designates cancer as the critical end-point for risk characterization of EO.

3.2 Acute Inhalation Exposure

EO has a high odor threshold (>250 ppm). Its odor threshold is too high to provide an adequate warning of hazardous concentrations. The effects of inhalation exposure to EO are concentration and time dependent. Concentrations of several hundred ppm may be tolerated for a few minutes

without significant immediate health effects; however, similar concentrations may cause severe injury, especially if inhaled for longer periods.

Short-term exposures to EO vapors may cause irritation of exposed surfaces, including eyes, skin, nose, throat and lungs. Irritation of the lungs can lead to secondary infections, which may lead to pneumonia. Short-term exposures may also affect the central nervous system, leading to symptoms such as drowsiness, disorientation, nausea and vomiting. Convulsions and limb weakness may also occur. These symptoms may be expected to reverse within a few days after cessation of acute exposure.

See reference [4] for proposed Acute Exposure Guidance Levels for EO issued by the National Academy of Sciences committee in September 2006; also see discussion in Section 7.3 regarding IDLH, ERPG, and AEGL values and proposed values for EO.

3.3 Skin and Eye Contact

Liquid EO can cause freezing of the skin by evaporative cooling. It is also highly irritating to the eyes and skin and even dilute solutions can cause blistering or severe damage to the skin or eyes. EO liquid and solutions easily and rapidly penetrate cloth, leather and some types of rubber, and can produce blistering if clothing or footwear contaminated with EO is not removed. See Figure 7.2 in Chapter 7.0 for a photograph of a chemical burn to feet which resulted from a dilute EO-water mixture permeating leather work boots.

3.4 Chronic Exposure Hazards

Repeated dermal exposure to EO, or materials treated with EO, may lead to skin sensitization (allergic) reactions. Repeated exposure to high inhalation concentrations may result in respiratory sensitization (asthmatic) symptoms [5]. A possible association with long term exposure to EO and cataract formation has also been reported [3].

Long-term exposure to EO may also result in neurological effects similar to those observed in cases of acute short-term exposure. Many of the effects may be non-specific, including headaches, nausea, lethargy, numbness and memory loss. There may also be a reduced sense of smell and/or taste, and muscle weakness particularly in the legs. The

potential short-term and long-term effects of EO on the nervous system are regarded as reversible.

There have been a few epidemiological reports of increased spontaneous abortions in pregnant hospital or dental sterilizer workers exposed for short times to relatively high EO concentrations [6]. However, methodological questions have raised doubts about the conclusions drawn in these studies [7]. Experimental animal studies have shown reproductive effects in rodents exposed to EO. Effects include a decrease in the number and weight of offspring in rats exposed to high levels of EO. The potential effects of EO on male and female reproduction and development have been the subject of research for many years [6-14] and research into this area continues. Contact your supplier for additional information.

Because EO is reactive, it is capable of directly combining with proteins and DNA when absorbed into the body. EO can react with DNA in tissues to form various DNA adducts [5, 15, 16]. Ongoing research is focused on the repair of these DNA adducts and the possible existence of an exposure threshold associated with the formation of DNA adducts and associated repair mechanisms. Contact your supplier for additional information.

The potential for EO to cause cancer, reproductive, developmental or genetic effects has been examined in experiments using laboratory animals and also by studying exposed human worker populations in epidemiological studies [17-23]. Based primarily on animal data and on cytogenetic changes in exposed workers, the International Agency for Research in Cancer (IARC) classified EO as a known human carcinogen [17]. In 2002, the U.S. National Toxicology Program classified EO as “known to be a human carcinogen” based on “sufficient evidence of carcinogenicity from studies in humans [18]. In April 2004, NIOSH issued a worker notification bulletin summarizing the results of several recent human studies [24]. Ongoing research is being conducted by numerous investigators, including some sponsored by the American Chemistry Council’s Ethylene Oxide/Ethylene Glycols Panel, to explore the potential for EO to cause cancer. For more information concerning potential chronic hazards from exposure to EO, contact your supplier.

Examples of cancer classifications established by various governmental entities as of the date of publication of this manual are listed in Table 3.1.

Table 3.1 Carcinogenicity Classifications of Ethylene Oxide

Organization	Classification
International Agency for Research on Cancer (IARC)	Known Human Carcinogen
Environmental Protection Agency (EPA)	Probable Human Carcinogen
National Toxicology Program (NTP)	Known Human Carcinogen
National Institute for Occupational Safety and Health (NIOSH)	Potential Occupational Carcinogen
American Conference on Governmental Industrial Hygienists (ACGIH)	Suspected Human Carcinogen

Table 3.2 Findings of the NIOSH Ethylene Oxide Studies [24]

Summary of the Recent NIOSH Ethylene Oxide Studies	
Purpose	To determine if exposure to EO is related to cancer or other diseases.
Subjects	18,235 men and women exposed to EO from 14 sterilizer plants around the country. Most of these workers used EO to sterilize medical supplies and treat spices. These were the largest studies ever conducted on EO exposure and the risk of disease.
Findings	No overall elevated risk for any type of cancer or other diseases as compared to the general U.S. population. However, among those workers with very high EO exposures, (combination of exposure levels and years worked); there was evidence of an elevated risk for blood cancers among men and breast cancers among women.
Conclusions	Persons exposed to very high levels of EO may be at an increased risk of developing blood cancers among men and breast cancers among women.