

MATERIAL SAFETY DATA SHEET

ETHYLENE OXIDE

Section 1 Chemical Product & Company Identification

Product: ANPROLENE®

Manufactured by:

Andersen Sterilizers, Inc.
Health Science Park
3154 Caroline Drive
Haw River, NC 27258 USA

Information Telephone Number: (336) 376-8622

**Emergency Telephone Number
(24 HRS, 7 DAYS PER WEEK)
CHEM-TEL (800)-255-3924**

Section 2 Composition/ Information on Ingredients

Chemical Name: Ethylene Oxide
Weight By %: 84 to 97%
Chemical Family: Epoxide
Formula: (CH₂)₂O
Molecular Weight: 44.06 gms/mole
CAS Number: 75-21-8
CAS Name: Oxirane
Synonyms: EO, EtO, Dihydroxirene, 1-2 Epoxyethane, Dimethylene Oxide, Oxane, Oxirane, Alkene Oxide, Alpha/Beta-Oxidoethane, Oxacyclopropane.
Product Uses: Chemical intermediate for production of anti-freeze, polyester resins, non-ionic surfactants and specialty solvents; sterilizing agent for controlling microorganisms in health care applications; fumigant for controlling insect infestation in whole and ground spices and cosmetics.

Section 3 Hazard Identification

EMERGENCY OVERVIEW

Colorless liquid or heavier-than-air gas with a sweet, ether-like odor. Extremely flammable liquefied gas which burns in the absence of oxygen and can explode when exposed to elevated temperatures. Toxic when inhaled. Causes severe skin and eye irritation or burns and respiratory tract irritation; effects may be delayed. Harmful if swallowed or absorbed through the skin. Contact with liquid may cause frostbite.

Statement of Hazards:

DANGER!

Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly reactive. May be harmful if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.

HAZARD RATINGS: (0 = minimum; 4 = maximum)

HMIS RATING: Health = 3
Flammability = 4
Reactivity = 3
Personal Protection Code = x (Consult your supervisor or standard operating procedures for special handling directions.)

NFPA RATING: Health = 3
Flammability = 4
Reactivity = 3

Exposure Limits:

	<u>TWA (8 hr)</u>	<u>STEL (15-min)</u>
OSHA	1 ppm	5 ppm
ACGIH	1 ppm	n/a

PRIMARY ROUTES OF EXPOSURE: Inhalation; eye contact, skin contact/absorption

SIGNS AND SYMPTOMS OF OVEREXPOSURE: Effects include skin, eye and respiratory tract irritation or burns. Central nervous system effects initially cause headache, dizziness and nausea and in extreme cases, unconsciousness and death. Peripheral nerve damage may result in muscular weakness, giddiness, irrational behavior and loss of sensation in the extremities. Dulling of the sense of smell may occur.

ACUTE HEALTH EFFECTS:

INHALATION: Inhaling concentrated vapor may cause serious health effects. Inhalation may progressively cause mucous membrane and respiratory irritation, headache, vomiting, cyanosis, drowsiness, weakness, incoordination, CNS depression, lachrymation, nasal discharge and salivation, gasping, and labored breathing. Delayed effects may include nausea, diarrhea, edema of the lungs, paralysis and convulsions. NOTE: Ethylene oxide has a high odor threshold (>250 ppm) and the sense of smell does not provide adequate protection against its toxic effects.

EYE CONTACT: Liquid ethylene oxide is severely irritating and corrosive to the eyes and contact can cause swelling of the conjunctive and irreversible corneal injury. Contact with liquid ethylene oxide can cause frostbite. Vapors may cause eye irritation, tearing, redness and swelling of the conjunctive.

SKIN CONTACT: Prolonged contact with liquid ethylene oxide can cause a local erythema, edema, and formation of blisters. Response is more severe on damp skin. There may be a latency period of several hours prior to the onset of symptoms. Ethylene oxide may be absorbed by the skin, and sustained contact may produce adverse effects such as headache, dizziness, nausea, and vomiting. Ethylene Oxide is a skin sensitizer and some individuals may suffer an allergic skin reaction. Skin contact may also cause allergic contact dermatitis in some exposed individuals. Liquid Ethylene oxide evaporates rapidly and may chill the skin causing frostbite.

INGESTION: This relatively unlikely route of exposure is expected to cause severe irritation and burns of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma. Aspiration may occur during swallowing or vomiting, resulting in lung damage.

CHRONIC HEALTH EFFECTS:

SKIN CONTACT: Long term effects are unknown but are expected to be similar to acute effects of skin exposure.

EYE CONTACT: Some cases of cataract formation have been reported.

INHALATION: Respiratory irritation which can result in permanent, lung injury, chromosomal aberrations and peripheral neurotoxic effects with a numbing of the sense of smell. Cognitive and CNS impairment may result from long term exposures.

INGESTION: May cause anemia, gastrointestinal irritation, effects on liver, kidneys, and adrenal glands.

CARCINOGENICITY:

OSHA classifies ethylene oxide as a cancer/ reproductive hazard and considers that, at excessive levels, ethylene oxide may present reproductive, mutagenic, genotoxic, neurologic and skin sensitization hazards.

ACGIH classifies ethylene oxide as "A2"- suspected human carcinogen.

NTP classifies ethylene oxide as a known human carcinogen.

IARC classifies ethylene oxide in Group 1 (carcinogenic to humans).

NIOSH classifies ethylene oxide as a potential human carcinogen.

Section 4 First Aid Measures

EYE CONTACT: Immediately flush eyes, including the entire surface of the eyes and under the eyelids, gently but thoroughly with plenty of running water for at least 15 minutes. Obtain medical attention immediately. **NOTE: Never wear contact lenses when working with ethylene oxide.**

SKIN CONTACT: Immediately flush skin thoroughly with water for at least 15 minutes while removing contaminated clothing and shoes. Obtain medical attention immediately. Wash clothing before reuse and discard contaminated leather articles such as shoes and belts.

INHALATION: Remove exposed person to fresh air. If breathing has stopped, give artificial respiration then have qualified personnel administer oxygen, if needed. Get immediate medical attention.

INGESTION: If patient is conscious give plenty of water (minimum of two glasses) but **DO NOT INDUCE VOMITTING**. This material is corrosive. Keep head lower than hips to avoid aspiration, should vomiting occur. Get medical attention immediately.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Preexisting skin, eye and respiratory disorders; lung, blood, nervous system and peripheral nerve disorders.

NOTE TO PHYSICIANS: Respiratory symptoms include nausea, vomiting and irritation of the nose and throat. Pulmonary edema may occur. Respiratory effects may be delayed. Consider oxygen administration. If a chemical burn is present decontaminate skin and treat as any thermal burn. No specific antidote is known, however consider gastric lavage and administration of a charcoal slurry.

Section 5 Fire Fighting Measures

FLASH POINT (TEST METHOD):

Tag Closed Cup: -4F (-20C)

FLAMMABLE LIMITS IN AIR (% BY VOLUME):

Upper flammable limit: 100%

Lower flammable limit: 3.0% (30,000 ppm)

NEFA HAZARD RATING:

Health: 3 Flammability: 4 Reactivity: 3

AUTOIGNITION TEMPERATURE:

804 F (429C); burns in the absence of air

EXTINGUISHING MEDIA: Carbon dioxide, dry chemical or water spray for small fires. Water spray, polymer or alcohol resistant foams for large fires. Dilution of liquid ethylene oxide with 23 volumes of water should render it non-flammable. Dilution with 100 parts water to one part of ethylene oxide vapor may be required to control build up of flammable vapors in closed systems. Water spray can be used to reduce intensity of flames to cool fire-exposed containers and to dilute spills to render non-flammable.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide and carbon dioxide.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Ethylene oxide is dangerously explosive under fire condition; it is flammable over an extremely large range of concentrations in air and burns in the absence of oxygen. Liquid ethylene oxide is lighter than water (floats) and vapors are heavier than air and may travel along ground long distances to sources of ignition and then flash back. Containers should not be subject to temperatures hotter than 127F (52 C). Vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 3%.

Section 6 Accidental Release Measures

PRECAUTIONS: Treat any ethylene oxide leak as an emergency. Evacuate all personnel from the area except those directly engaged in stopping the leak or in cleaning up. If an Anprolene ampoule is inadvertently dropped and activated before it is sealed inside of the sterilization liner bag, it will still take time for the ethylene oxide to

to diffuse out of the gas release bag and into the room. At one full minute after activation there is less than 1ppm measured at a distance of 18 inches from the gas release bag. In the case of a premature activation the operator should immediately:

- Place the Anprolene ampoule inside the sterilizer
- Close the sterilizer door
- Turn the power on; and
- Press the button to the right of PURGE.

This will cause the purge and ventilation pumps to turn on and evacuate the ethylene oxide from the sterilizer and exhaust it from the workspace. Allow a full 14 hour cycle before you open the door and remove the used Anprolene ampoule and dispose of it.

Section 7 Handling and Storage

HANDLING AND STORAGE PRECAUTIONS: Have established handling and emergency response procedures in place prior to use. Make sure that the sterilizer is properly grounded. Protect containers from physical damage and regularly inspect them for cracks or leaks.

ENGINEERING CONTROLS: Ethylene oxide, a major fire hazard, can burn in the absence of oxygen. All electrical devices used in areas processing or handling ethylene oxide must be engineered and designed to the applicable local electrical/fire codes. Safeguards can include designing electrical devices as explosion proof and/or intrinsically safe. **ATTENTION:** Ethylene oxide vapors are colorless and odorless above OSHA'S permissible exposure level. An air monitoring system and/or AirScan® badges are recommended to determine airborne exposure levels.

STORAGE SEGREGATION: Store ethylene oxide in a cool, dry, well-ventilated area away from incompatible chemicals and sources of ignition. Store Anprolene® refill kits upright; do not drop and move in a carefully supervised manner. **DO NOT STORE IN DIRECT SUNLIGHT.**

SHIPPING AND STORAGE CONTAINERS: (See 49 CFR 173.4) All Anprolene® refill kits containing ethylene oxide are packaged and shipped in accordance with the small quantities exemption under 49 CFR 173.4(c) and DOT approval CA 9803005 issued April 9, 1998.

Section 8 Exposure Controls/Personal Protection

EX-

POSURE LIMITS:

OSHA ACTION LEVEL (8 HR. TWA)	0.5 ppm
OSHA PEL (8 HR TWA)	1 ppm
OSHA 15 MINUTE EXCURSION LIMIT	5 ppm; 9 mg/m ³
ACGIH TLV/TWA	1 ppm; 1.8 mg/m ³
IDLH:	800 ppm

EYE PROTECTION: NEVER WEAR CONTACT LENSES when working with ethylene oxide.

VENTILATION: Install and operate general and local exhaust ventilation systems powerful enough to maintain airborne levels of ethylene oxide below the OSHA PEL in the worker's breathing area.

AAMI / ANSI ST41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance Guidelines, Section 3.4 recommends a minimum of 10 room makeup air changes per hour. Emission controls must be in compliance with Federal State and local regulations.

OTHER PROTECTION: Sterilizer must be electrically grounded/bonded. Practice good personal hygiene; always wash thoroughly after using this material. Do not eat drink or smoke in work area.

Section 9 Stability and Reactivity

Boiling Point:	50.9°F (10.5°C)
Freezing Point	-169° F (-111.7°C)
Specific Gravity:	0.871 at 20°C
Vapor Pressure:	1094 mm Hg @ 20°C
Vapor Density (Air =1)	1.5
Solubility in Water:	100%
Molecular Weight:	44.06 gms/mole
Percent Volatile by Volume	100%
Evaporation rate (Butyl Acetate = 1)	Not applicable
PH:	7, neutral (100 grams/liter in water)
Appearance and Odor:	Colorless liquid or gas with sweet ether-like odor. Odor threshold: 261 ppm (detectable); 600-700 ppm recognizable).
Log Octanol/Water Partition Coefficient (log Kow):	-0.3

STABILITY: Material is stable for extended periods in closed airtight, pressurized containers at room temperature, under normal storage and handling conditions. Vapors may explode when exposed to common ignition sources.

CONDITIONS TO AVOID: Storage at warm temperatures or any exposure of storage or shipping containers to hot temperatures. Prevent exposure to all sources of ignition such as heat, flame, lighted tobacco products, or electrical or mechanical sparks.

HAZARDOUS DECOMPOSITION PRODUCTS: Ethylene oxide undergoes thermal decomposition to form carbon dioxide and carbon monoxide gases.

Section 10 Toxicological Information

TOXICOLOGICAL- ACUTE INHALATION: LC₅₀ (1 hr. exposure)

5748 ppm (male rat)
4439 ppm (female rat)
5029 ppm (rat – combined sexes)

Various mammalian species exposed to lethal concentrations of ethylene oxide had symptoms of mucous membrane irritation, central nervous system depression, lacrimation, nasal discharge, salivation, nausea, vomiting, diarrhea, respiratory irritation, incoordination, and convulsions.

TOXICOLOGICAL-CHRONIC INHALATION: Symptoms of chronic exposure are similar to those observed in acute studies, including lung, kidney and liver damage and testicular tubule degeneration in some species. Studies demonstrated neuromuscular effects as the most sensitive indicator of ethylene oxide over exposure.

TOXICOLOGICAL-ACUTE DERMAL: No dermal LD₅₀ information is available on this product. It is expected to be corrosive to rabbit skin.

TOXICOLOGICAL – CHRONIC DERMAL: No chronic dermal toxicity data are available on this product.

TOXICOLOGICAL- EYE: No eye irritation animal data are available on this product; however, it is expected to extremely irritating to rabbit eyes.

TOXICOLOGICAL-ACUTE INGESTION: The acute oral LD₅₀ for This product is; 72 mg/kg, rat

TOXICOLOGICAL-CHRONIC INGESTION: The effects of chronic ingestion of this product are unknown

CARCINOGENICITY: A recent assessment of available epidemiology studies related to ethylene oxide concluded that the evidence indicates that ethylene oxide does not cause heart disease, an excess of cancers overall, or brain, stomach or pancreatic cancers which were seen in some animal and isolated human studies. The findings with respect to leukemia and non-Hodgkins lymphoma are less definitive. While the majority of the evidence does not indicate that ethylene oxide causes these cancers, there are some suggestive trends. Longer follow-up of ethylene oxide workers is needed to better clarify these relationships. Two inhalation studies with rats demonstrated carcinogenic responses consisting of increased incidences of mono-nuclear cell leukemia, peritoneal mesotheliomas, and primary brain tumors. In 2-year inhalation studies with mice there was evidence of carcinogenic activity as indicated by dose-related incidences of benign or malignant neoplasms of the uterus, mammary gland, and hematopoietic system (lymphoma).

MUTAGENICITY: While ethylene oxide has demonstrated, in epidemiological studies with exposed workers, an increased incidence of chromosomal aberrations and sister chromatid exchanges, the relevance of such effects to human health hazard evaluation is currently uncertain. In rodent studies, dose related exposure to ethylene oxide induces increases in numbers of adducts in DNA and hemoglobin. Laboratory studies with mice have shown that acute exposure to ethylene oxide at 300 ppm and above caused testicular injury as evidenced by concentration-related increased embryonic deaths following mating of exposed males to non-exposed females (Dominant-Lethal Test).

NEUROTOXICITY: Effects are similar to those of acute (short term) exposure, namely headaches, nausea, diarrhea, lethargy, and irrational behavior. Muscle weakness, loss of sensation in the extremities and a reduction in the sense of smell and/or taste may also result. Studies on workers indicate that CNS and cognitive impairment may result from chronic exposures to ethylene oxide.

REPRODUCTIVE EFFECTS: Some limited epidemiological data suggests that women exposed to ethylene oxide have a greater incidence of miscarriages. A one-generation reproduction study in rats showed decreased number of pups at 100 ppm, but not at 33 ppm. In a two-generation reproduction study involving exposure of rats to ethylene oxide vapor for 5 hrs/day, 5 days/week, there was parental toxicity at 33 ppm and 100 ppm. The no-observable effect concentration for adult toxicity, offspring effect and reproductive effect was 10 ppm.

TERATOLOGY: Inhalation development toxicity studies with rats exposed to ethylene oxide vapor at concentrations of 50 ppm, 125 ppm and 225 ppm showed that maternal toxicity occurred at 125 and 225 ppm. Fetotoxicity, evidenced by reduced fetal body weight, occurred at all concentrations. At 225 ppm and to a lesser extent at 125 ppm an increased incidence of skeletal variants was found. There was no evidence of embryotoxicity or malformations.

TARGET ORGANS: Overexposure to this product may affect the skin, eyes, respiratory system, liver, kidneys, brain, blood, reproductive system, and central nervous system.

Section 11 Ecological Information

ECOTOXICOLOGICAL DATA: Ethylene oxide hydrolyzes to ethylene glycol. Biodegradation of ethylene oxide occurs at a moderate rate after acclimation (3-5% degradation after 5 days; 52% after 20 days). Biodegradation is expected in a wastewater treatment plant. Ethylene oxide has an estimated half-life in the atmosphere of 211 days. A high adsorptivity in soil is expected.

Section 12 Disposal Consideration

WASTE MANAGEMENT/DISPOSAL: Dispose **used** Anprolene ampoules, sterilization liner bags, indicators and accessories as you would ordinary trash.

However, **unused** Anprolene ampoules containing ethylene oxide are a RCRA hazardous waste with waste code U115 (Commercial chemical product - listed for toxicity and ignitability). **Unused** Anprolene ampoules containing ethylene oxide may be incinerated in an approved hazardous waste incinerator or can be biologically treated in an approved facility. **Unused** Anprolene ampoules containing ethylene oxide are banned from land disposal.

Dispose of waste materials in accordance with all applicable Federal, State and local laws and regulations.

Section 13 Transport Information

TRANSPORTATION DATA:

DOT Proper shipping Name:	Ethylene Oxide
DOT Class or Division:	2.3 (Poison Gas)
Identification Number	UN 1040
Packing Group:	n/a
DOT Label:	"This package conforms to 49 CFR 173.4"
DOT Packaging	See section 7, "Handling and storage"
DOT Approval:	CA-9803005

Section 14
Regulatory Information

U.S. REGULATIONS:

TSCA status: Listed
CERCLA Section 103 (40 CFR 302.4): listed
10 lb. Reportable Quantity
SARA Section 304 (40 CFR 356.40): Listed
1 lb Reportable Quantity
SARA Section 311/312 (40 CFR 370.21) Hazard categories met:
Acute, Chronic, Fire, Reactive, Sudden Release
SARA Section 313 (40 CFR 372.65): Listed
OSHA (29 CFR 1910. 1200): Meets criteria as a hazardous material
OSHA (29 CFR 1910. 1047): Ethylene Oxide Standard
EPA list of Hazardous Air Contaminants: Listed
EPA Organic Hazardous Air Pollutant (HAP) list: Listed
EPA list of Pesticide Chemicals (40 CFR 180.151): Listed
EPA NESHAPS (40 CFR 63.360)
VOC Rule: 100% VOC

STATE RIGHT-TO-KNOW REGULATIONS:

California Proposition 65: Listed; cancer hazard; reproductive hazard
California Director's List: Listed
Florida Hazardous Substance List: Listed
Massachusetts Extraordinarily Hazardous Substance List: Listed
Minnesota Hazardous Substance List: Listed
New Jersey Hazardous Substance List: Listed on 0882
(Special Hazardous Substance: Environmental
Hazardous Substance)
Pennsylvania Right-to-know List: Listed

Section 15
Other Information

GLOSSARY OF TERMS AND ABBREVIATIONS:

ACGIH- American Conference of Governmental Industrial Hygienists
CERCLA- Comprehensive Environmental Response, Compensation
and Liability Act.
CAS- Chemical Abstract Service
CFR- Code of Federal Regulations
CNS- Central Nervous System
DOT- U.S. Department of Transportation
EPA- U. S. Environmental Protection Agency
HMIS- Hazardous Materials information Sheet
IARC- International Agency for Research on Cancer
IDL- ingredient Disclosure List
IDLH- Immediately dangerous to life and health
HAP- Hazardous Air Pollutant
LC₅₀ - Median lethal dose that kills 50% of an exposed population by
the inhalation route
LD₅₀- Median lethal dose that kills 50% of an exposed population by
the oral (or dermal) route
NESHAPS- National Emission Standards for Hazardous Air Pollut-
ants
NFPA- National Fire Protection Association
NIOSH- National Institute of Occupational Safety and Health
NTP- National Toxicology Program

OSHA- Occupational Safety and Health Administration
p/p- parts per part
PEL- Permissible exposure Limit
PVC- Polyvinyl chloride
ppm- Parts per million
p.s.i.g- Pounds per square inch (gauge pressure)
RCRA- Resource, Conservation and Recovery Act
SARA- Superfund Amendment and Reauthorization Act of 1990
STEL- Short-term exposure Limit
TDG-Transportation of Dangerous Goods
TLV- Threshold Limit Value
TSCA- Toxic Substance Control Act
TWA- Time Weighted Average
VOC- Volatile organic compound
WHMIS-Workplace Hazardous Material Information System

MSDS Revision Date: 10/23/02

Disclaimer

It is imperative that the user/reader be familiar with and adhere to OSHA regulations which are specific to ethylene oxide (29CFR1910.1047) as well as any other applicable Federal, State, or local government regulations. Regulations listed in Section 14 of this document may not be all inclusive and are subject to change. The data in this MSDS is furnished gratuitously independent of any sale of the product only for your investigation and independent verification. While the information is believed to be correct, Andersen makes no representation as to the accuracy of the information contained herein. Andersen shall in no event be responsible for any damages of whatsoever nature directly or indirectly resulting from publication or use of, or negligence upon data contained herein. No Warranty (either expressed or implied) of merchantability or of fitness for any purpose with respect to the product or to the data herein is made hereunder