Ethylene Oxide SDS

Effective Date: 2022-05-23	Revision 0	Andersen Sterilizers, Inc.	Language: EN

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER		
1.1. GHS product identifier.	Ethylene Oxide	
1.2. Other means of identification	Anprolene® Refill Kits AN7514.00, AN7916.00 EOGas® Refill Kits AN 1006.00, AN 2011.00, AN 2014.00, AN2018.00, AN1004.16	
1.3. Intended use and restrictions on use.	Intended: for use by health care professionals as a sterilizing agent in an Andersen Sterilizers, Inc. sterilizer for controlling microorganisms in health care applications. Advised Against: Consumer use or applications other than those described above.	
1.4. Supplier's details.	Name: Address: Telephone Number:	Andersen Sterilizers, Inc. 3154 Caroline Drive Haw River, NC 27258 USA +1 336-376-8622
1.5. Emergency phone number.	**EMERGENCY TELEPHONE NUMBER** **(24 hrs. / 7 days per week)** **In US and Canada: CHEM-TEL (800)255-3924** **Outside US and Canada: CHEM-TEL +1-813-248-0585**	

2. HAZARDS IDENTIFICATION	
2.1. GHS classification of the substance or mixture and any national or regional information.	Flammable Gas 1 Pressurized Gas (Liquefied Gas) Carcinogen Category 1B Mutagen Category 1B Acute Toxicity Category 3 (Inhalation); Category 4(oral) Eye Irritant Category 2A Specific Target Organ Toxicity – Single Exposure 3 Skin Irritant 2 Reproductive Toxicity (Fertility) 1A
2.2. GHS label elements, including precautionary statements. The labels shown to the right must be affixed to the exterior of the product by any entity introducing the product into interstate commerce in final packaging configurations that are either: non-compliant with the requirements of 49 CFR 173.4(c) and DOT CA-9803005 or, are offered for transportation outside of the United States.	Product Label Name: ETHYLENE OXIDE Signal Word: DANGER 

For final packaging configurations that are compliant with the requirements of both 49 CFR 173.4(c) and DOT CA-9803005 and are shipped to destinations within the United States.	This package conforms to 49 CFR 173.4 for domestic highway or rail transport only.

Hazard statement:	
H220: H280: H302: H315: H319: H331: H335: H340: H350:	Extremely flammable gas Contains gas under pressure; may explode if heated Harmful if swallowed Causes skin irritation Causes serious eye irritation Toxic if inhaled May cause respiratory irritation May cause genetic defects May cause cancer
Precautionary statement:	
P201:	Obtain special instructions before use.
P202:	Do not handle until all safety precautions have been read and understood.
P210:	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P261:	Avoid breathing gas/vapors.
P264:	Wash hands thoroughly after handling.
P270:	Do not eat, drink, or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P280:	Wear protective gloves / protective clothing / eye protection / face protection.
P281:	Use personal protective equipment as required.
P301: P312:	IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell.
P330:	Rinse mouth.
P302: P352:	IF ON SKIN: Wash with plenty of soap and water.
P362:	Take off contaminated clothing and wash before reuse.
P332: P313:	If skin irritation occurs: Get medical advice/attention.

	P304: P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305: P351: P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337: P313:	If eye irritation persists: Get medical advice/attention.
	P312:	Call a POISON CENTER or doctor / physician if you feel unwell.
	P308: P313:	IF exposed or concerned: Get medical advice / attention.
	P321:	Specific treatment: See first aid section of SDS.
	P377:	Leaking gas fire: Do not extinguish, unless leak can be stopped safely.
	P381:	Eliminate all ignition sources if safe to do so.
	P403: P233:	Store in a well-ventilated place. Keep container tightly closed.
	P405:	Store locked up.
	P410: P403:	Protect from sunlight. Store in a well-ventilated place.
	501:	Dispose of contents / container in accordance with local / regional / national / international regulation.
2.3. Other hazards which do not result in classification or are not covered by the GHS.	EUH006:	Explosive with or without contact with air.

3. COMPOSITION / INFORMATION ON INGREDIENTS	
3.1. Substance:	
Chemical identity.	Ethylene Oxide
Common name, synonyms, etc.	EOGas, Anprolene, Oxirane, EO, Dihydroxirene, 1-2 Epoxyethane, DimEthylene Oxide, Oxane, Oxirane, Alpha/Beta-Oxidoethane, Oxacyclopropane
Weight by %	96% -99% Ethylene Oxide
CAS number, EC number, etc.	CAS#: 75-21-8; EC#: 200-849-9 (from EINECS) Chemical Family: Epoxide Formula: (CH2)2O Molecular Weight: 44.053 g/mol

Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.	Contains no other components or impurities which will influence the classification of the product.

3.2. Mixture:

The chemical identity and concentration or concentration ranges of all ingredients, which are hazardous within the meaning of the GHS and are present above their cutoff levels.	Chemical Identity:	Concentration:	CAS No.:
	No applicable information found.		

4. FIRST AID MEASURES	
4.1. Description of 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. Treat for possible cryogenic injury, if needed by warming affected areas with tepid water (wrap with a blanket if lukewarm water is not available). 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 VOMITING**. 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.
4.2. Most important symptoms/effects.	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.

4.3. Indication of immediate medical attention and special treatment needed, if necessary.	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.

5. FIREFIGHTING MEASURES		
5.1. Suitable (and unsuitable) extinguishing media.	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 22 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 buildup of flammable vapors in closed systems. Water spray can be used to reduce flame intensity, cool fire-exposed containers and dilute spills to render non-flammable.	
5.2. Specific hazards arising from the chemical.	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. Harmful or fatal 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
	UNUSUAL FIRE AND EXPLOSION HAZARDS: Ethylene oxide is dangerously explosive under fire conditions; 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 long distances along ground to sources of ignition, and then flash back. Avoid storage at warm temperatures [around 100 °F (38 ºC)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 ºC) under any circumstances. Vapors are extremely flammable and are readily ignited by static charge, sparks, and flames at concentrations above 2.6%.	

5.3. Special protective equipment and precautions for firefighters.	SPECIAL FIRE-FIGHTING PROCEDURES: Wear NIOSH-approved self-contained breathing apparatus (SCBA) operated in the pressure-demand mode and full chemical-resistant protective clothing. Evacuate all personnel from danger area. Immediately cool containers with water spray from maximum safe distance. Remove containers from fire area, if without risk.

6. ACCIDENTAL RELEASE MEASURES	
6.1. Personal precautions, protective equipment, and emergency procedures.	PRECAUTIONS: Treat any ethylene oxide leak as an emergency. Evacuate all personnel from the area except those directly engaged in containing the leak. If an Ethylene Oxide ampoule or cartridge is inadvertently activated before it is sealed inside of the sterilization bag, there are three options. Options 1 and 2 must be completed within thirty (30) seconds of cartridge activation[1] and the operator must then exit the room until it is confirmed that air quality levels are below the permissible levels set forth in Section 8.1. 1. If the sterilizer is on, but not running a cycle, place the cartridge inside the sterilizer cabinet, close the door, and press the START button, which will turn on the ventilation pump. Tag the sterilizer as out of service and leave the cartridge inside the cabinet for a minimum of 12 hours. 2. If the sterilizer is on and already running a cycle, place the cartridge inside the included Zip-Lock bag, seal the bag closed, and attach the male quick connect fitting to the Accidental Release Connection Mechanism female port located on the left side of the top cabinet. Leave it connected to cabinet for a minimum of 12 hours with the pumps running. 3. If option 1 or 2 is not possible, immediately evacuate the room for a minimum of 12 hours. Tag the room as out of service and do not reenter the room until it is confirmed that air quality levels are below the permissible levels set forth in Section 8.1.

7. HANDLING AND STORAGE	
7.1. Precautions for safe handling.	HANDLING AND STORAGE PRECAUTIONS: Wear all recommended protective clothing and devices (e.g. safety glasses) when handling this material. Have established handling and emergency response procedures in place prior to use. Make sure that the sterilizer is properly grounded. Protect cartridges from physical damage and inspect them for cracks or leaks.
7.2. Conditions for safe storage, including any incompatibilities.	STORAGE SEGREGATION: Store ethylene oxide in a cool, dry, well-ventilated area away from incompatible chemicals and sources of ignition. Store refill kits upright; move in a carefully supervised manner being careful not to drop. DO NOT STORE IN DIRECT SUNLIGHT

[1] Based upon an Andersen Scientific study conducted in August of 2005, in a 6,645 ft^3 room at 70-72°F with 6 fresh air exchanges per hour. A simulated 17.6 gram EO cartridge dropped onto the floor and broken resulted in a fifteen minute STEL in the breathing zone, at the point where the cartridge dropped of 3.4 ppm with a standard deviation of 0.71.

	SHIPPING AND STORAGE CONTAINERS: (See 49 CFR 173.4) Individual refill kits containing ethylene oxide are packaged in accordance with the small quantities exemption under 49 CFR 173.4(c) and DOT approval CA 9803005 issued April 9, 1998.
	ATTENTION: Ethylene oxide vapors are colorless and odorless above OSHA'S permissible exposure level. An air monitoring system and / or personnel breathing zone monitoring badges are recommended to determine airborne exposure levels.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters.

Exposure Limits			
SOURCE	TWA (8-hr)	STEL (15-min)	OTHER
OSHA	1 ppm	5 ppm (9 mg/m3)	0.5 ppm action level (8-hr TWA)
ACGIH	1 ppm (1.8 mg/m3)	No applicable information found	800 ppm IDLH

8.2. Appropriate engineering controls.

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. When considering engineering controls, users of ethylene oxide should consult the current edition of NFPA 55 (Compressed Gases and Cryogenic Fluids Code, Section 14: Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation). Sterilization facilities should consult NIOSH Publication NO. 2007-164 (Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities).

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 comply with Federal, State and local regulations.

WASHING STATIONS: Have eyewash stations and washing facilities available in all work areas.

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.

8.3. Individual protection measures, such as personal protective equipment.	RESPIRATORY PROTECTION: Refer to OSHA respirator regulations cited at 29 CFR 1910.134 and 29 CFR 1910.1047. Wear a NIOSH-approved full facepiece respirator in situations where atmosphere is at or above OSHA's Action Level. Do not exceed the maximum use conditions of the respirator. For emergency or non-routine uses where concentrations are unknown, wear an SCBA with a full facepiece operated in the pressure-demand or positive pressure mode.
	EYE PROTECTION: Always wear chemical safety glasses. NEVER WEAR CONTACT LENSES when working with ethylene oxide.
	SKIN PROTECTION: Wear long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves to prevent the possibility of skin contact. Launder contaminated clothing and discard contaminated leather shoes, belts, etc.

9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1. Information on basic physical and chemical properties.	
Appearance (physical state, color, etc.).	Colorless liquid or gas
Corrosivity	Not Corrosive
Odor.	Sweet ether-like
Odor threshold.	261 ppm – detectable 500 to 700 ppm - recognizable
pH.	7, neutral (100 g/L in water)
Melting point/freezing point.	-169 ºF (-112 ºC)
Initial boiling point and boiling range.	50.7 ºF (10.4 ºC)
Flash point.	Tag Closed Cup: < 0 ºF (< -18 ºC)
Evaporation rate.	100% volatile by volume
Flammability (solid, gas).	Flammable
Upper/lower flammability or explosive limits.	Upper flammable limit: 100% vol/vol Lower flammable limit: 2.6% vol/vol
Vapor pressure.	1095 mmHg @ 20 ºC
Vapor density.	1.5 (Air = 1)
Relative density.	0.875 at 20 ºC
Solubility (ies).	100% in water
Partition coefficient: n-octanol/water.	-0.3
Autoignition temperature.	833 ºF (445 ºC); Burns in the absence of air

Decomposition temperature.	~932 °F (~773 °K)
Viscosity.	0.255 centipoise at 80° F
Oxidizing properties.	Not an oxidizer

10. STABILITY AND REACTIVITY	
10.1. Reactivity.	Not reactive under normal conditions. Under abnormal conditions (for example external heating), thermal decomposition, and runaway polymerization can occur and may lead to explosion.
10.2. Chemical stability.	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.
10.3. Conditions to avoid (e.g., static discharge, shock or vibration).	CONDITIONS TO AVOID: Avoid storage at warm temperatures [around 100 °F (38 ºC)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 ºC) under any circumstances. Prevent exposure to all sources of ignition such as heat, flame, lighted tobacco products, or electrical or mechanical sparks.
10.4. Hazardous decomposition products.	HAZARDOUS DECOMPOSITION PRODUCTS: Ethylene oxide undergoes thermal decomposition to form carbon dioxide and carbon monoxide gases.

11. TOXICOLOGICAL INFORMATION	
11.1. Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);	PRIMARY ROUTES OF EXPOSURE: Inhalation; eye contact; skin contact/absorption.
11.2. Symptoms related to the physical, chemical and toxicological characteristics;	INHALATION: Inhaling concentrated vapor may cause serious health effects, possibly death. Inhalation may progressively cause mucous membrane and respiratory irritation, headache, vomiting, cyanosis, drowsiness, weakness, loss of coordination, CNS depression, lachrymation, nasal discharge, and salivation, gasping, and labored breathing. Delayed effects may include nausea, diarrhea, edema of the lungs, paralysis, convulsions, and possibly death. 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 conjunctiva and irreversible corneal injury. Contact with liquid ethylene oxide can cause frostbite. Vapors may cause eye irritation, tearing, redness, and swelling of the conjunctiva.

	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.
11.3. Delayed and immediate effects and also chronic effects from short- and long-term exposure;	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 I (carcinogenic to humans). **NIOSH** classifies ethylene oxide as a potential human carcinogen.
11.4. Numerical measures of toxicity (such as acute toxicity estimates).	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, loss of coordination 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 overexposure.
	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 be extremely irritating to rabbit eyes.
	TOXICOLOGICAL - ACUTE INGESTION: The acute oral LD50 for this product is: 330 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-Hodgkin's lymphoma are less definitive. While the majority of the evidence does not indicate that ethylene oxide causes these cancers, there are some suggestive trends. A longer follow-up of ethylene oxide was completed in 2004 to better clarify these relationships. NIOSH reported no overall elevated risk for any type of cancer or other diseases as compared to the general population, however, among those workers with very high ethylene oxide exposure (combination of exposure level and years worked); there was evidence of an elevated risk for blood cancers among men and breast cancer among women. Two inhalation studies with rats demonstrated carcinogenic responses consisting of increased incidences of mononuclear 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 miscarriage. A one-generation reproduction study in rats showed decreased numbers 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 6 hrs/day, 5 days/week, there was parental toxicity at 33 ppm and 100 ppm. Post implantation losses with reduction in litter size and offspring body weight were found 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.

12. ECOLOGICAL INFORMATION	
12.1. Ecotoxicity (aquatic and terrestrial, where available).	AQUATIC TOXICITY: Acute 96-hr. LC50 data: 57-84 mg/L, fathead minnow (Pimephales promelas) 90 mg/L, goldfish (Carassius auratus) 137-300 mg/L, water flea (Daphnia magna) Material is slightly toxic to marine invertebrates. 48 hr. LC50 in brine shrimp: 490 mg/L
12.2. Persistence and degradability.	CHEMICAL FATE INFORMATION: BOD5: 0.35 p/p. BOD10: 1.1 p/p. BOD20: 1.3 p/p.

12.3. Bioaccumulative potential.	Bioconcentration is not expected to occur due to high water solubility and a low log Kow. Ethylene oxide hydrolyzes to ethylene glycol. Biodegradation of ethylene oxide occurs at a moderate rate after acclimation (3-20% degradation after 5 days; 70% after 20 days). Biodegradation is expected in a wastewater treatment plant. Ethylene oxide has an estimated half life in the atmosphere of 105 days. EO does not readily absorb into sediments or soils and does not persist in soils; if absorbed, soil organisms will over time convert EO to glycols eliminating any persistence in the soil.
12.4. Mobility in soil.	EO does not readily absorb into sediments or soils.

13. DISPOSAL CONSIDERATIONS	
13.1. Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.	WASTE MANAGEMENT / DISPOSAL: Dispose of **used** Ethylene Oxide ampoules/cartridges, sterilization bags, indicators, and accessories as you would ordinary trash.
	Unused Ethylene Oxide ampoules/cartridges are a RCRA hazardous waste with waste code U115 (Commercial chemical product - listed for toxicity and ignitability). **Unused** Ethylene Oxide ampoules/cartridges may be incinerated in an approved hazardous waste incinerator or can be biologically treated in an approved facility. **DO NOT INCINERATE ANY UNUSED** Ethylene Oxide ampoules/cartridges. Unused Ethylene Oxide ampoules/cartridges are banned from land disposal. Dispose of unused Ethylene Oxide ampoules/cartridges in accordance with all applicable Federal, State and local laws and regulations.

14. TRANSPORT INFORMATION	
14.1. UN number.	UN 1040
14.2. UN / DOT proper shipping name.	Ethylene Oxide
14.3. DOT Approval	CA-9803005, approval for small quantity packaging pursuant to 49 CFR § 173.4(c).
14.4. DOT Label	This package conforms to 49 CFR 173.4 for domestic highway or rail transport only.
14.5. IATA Regulation	IATA SO A131 and UN SP 342
14.6. Packaging	See Section 7.2
14.7. Transport hazard class (es).	DOT Primary: 2.3 (Poison Gas); Secondary: 2.1 (Flammable Gas) Poison-Inhalation Hazard Zone D Reportable Quantity 10 lb (4.54 kg)

	IMO Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)
	TDG (from or within Canada) Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)
14.8. Packing group, if applicable.	Not applicable
14.9. Marine pollutant (Yes/No).	No
14.10. Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.	See Section 7.2
14.11. Transportation in bulk according to Annex II of MARPOL 73/78 and the IBC Code.	Product is not supplied in bulk

15. REGULATORY INFORMATION		
15.1. Safety, health, and environmental regulations specific for the product in question.		
US Federal:	CERCLA:	Section 103: Reportable Quantity – 10 lb (40 CFR 302.4)
	CWA:	Release into a waterway may require reporting to the National Response Center @ 800-424-8802 (40 CFR 116.4).
	FIFRA	If this chemical is a pesticide product registered by the United States Environmental Protection Agency, it is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.
		EPA Establishment Registration No. 69340-NC-01 DANGER: Causes irreversible eye damage and skin burns. Harmful if inhaled. Do not breath vapor. Do not get on eyes, skin, or clothing. Do not swallow. Cancer Hazard and Reproductive Hazard. May cause nervous system damage. Store and use with adequate ventilation in accordance with 29 CFR1910.1047.
	RCRA:	If discarded in purchased form, this product is a listed and characteristic hazardous waste. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a hazardous waste (40 CFR 261.20-24).

	Other EPA	EPA list of Hazardous Air Contaminants: Listed EPA Organic Hazardous Air Pollutant (HAP) list (40 CFR 61.01): Listed EPA list of Pesticide Chemicals (40 CFR 180.151): Listed EPA NESHAPS (40 CFR 63.360) VOC Rule: 100% VOC
	FDA/USDA:	Not applicable.
	OSHA:	This product is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. Ethylene Oxide Standard 29 CFR 1910.1047
US State:	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 sn 0882 (Special Hazardous Substance; Environmental Hazardous Substance)	
	Pennsylvania Right-to-know List: Listed	
Canadian:	DSL:	Not Listed
	WHMIS:	Ingredient Disclosure List: Listed 0.1%, item 725 (1310) Classification: A; B1; D1A; D2A; D2B; F This MSDS complies with the Canadian Controlled Product Regulations.
EU:	CLP:	See Section 2
	EINECS:	See Section 3
	REACH:	Not applicable.

16. OTHER INFORMATION INCLUDING INFORMATION ON PREPARATION AND REVISION		
Last Revision Date:	See top of each page under 'Effective Date'	
	Rev 0	Original
Risk Phrases Used:	See Section 2	
Hazard Ratings:	See Section 5.2	
THE FOLLOWING ABBREVIATIONS MAY BE USED IN THIS DOCUMENT:		

ACGIH	American Council of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
BOD 5, 10, 20	Biochemical Oxygen Demand, 5, 10 or 20 day
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CLP	Classification, Labeling and Packaging
CNS	Central nervous system
CWA	Clean Water Act
D.O.T. or DOT	Department of Transportation
DSL	Domestic Substance List (Canada)
EC50	Effective concentration, which induces a response halfway between the baseline and maximum.
EC	European Community
ECL	Existing Chemicals List (Korea)
EINECS	European Inventory of Existing Commercial Substances
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GHS	Globally Harmonized System
HAP	Hazardous Air Pollutant
HMIS	Hazardous Materials Information System
IARC	International Agency for Research on Cancer
IBC	International Bulk Chemical Code
IDL	Ingredient disclosure list
IDLH	Immediately Dangerous to Life and Health
IMO	International Maritime Organization
KSt	Deflagration Index
LC50	Median lethal concentration for 50% mortality of subject species by the inhalation route
LD50	Median lethal dose for 50% mortality of subject species by the oral or dermal route

LDLO	Median lethal dose low; the lowest dose of a substance introduced by any route other than inhalation reported to have caused death in humans or animals.
LEL / LFL	Lower Explosive Limit / Lower Flammable Limit
MARPOL	International Convention for the Prevention of Pollution from Ships
MSHA	Mine Safety Health Administration
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PBT	Persistent Bioaccumulative Toxic
PEL	Permissible Exposure Limit (default 8 hour day, 40 hour week TWA)
p/p	Parts per part
Ppm	Parts per million
p.s.i.g. or psig	Pounds per square inch (gauge pressure)
PSM	Process Safety Management
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Substances
REL	Recommended Exposure Limit (default 10 hour day, 40 hour week TWA)
RMP	Risk Management Plan
SARA	Superfund Amendment and Reauthorization Act of 1990
SCBA	Self-contained breathing apparatus
STEL	Short Term Exposure Limit (default 15 minute TWA)
TDLO	Lowest dose to which humans or animals have been exposed and reported to produce a toxic effect other than cancer
TDG	Transportation of Dangerous Goods
TLV	Threshold limit value
TSCA	Toxic Substance Control Act
TWA	Time Weighted Average
UFL	Upper Flammable Limit

USDA	United States Department of Agriculture
VOC	Volatile organic chemical
vPvB	Very Persistent, Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System Regulations

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