

Product Stewardship Summary

Effective date: 1 September 2019

Supersedes: 15 December 2018

Ethylene Oxide

General Statement

Ethylene oxide is an extremely flammable gas with a sweetish odor. It is mainly used as an intermediate in the creation of antifreeze and polymers. A small fraction of ethylene oxide production is used for sterilization of medical equipment and controlling insect spoilage of stored foods and spices. Ethylene oxide used to make polymers becomes part of the polymer and only trace amounts remain as ethylene oxide. Thus, there will not be a significant exposure to ethylene oxide from polymers made with ethylene oxide.

Exposure to ethylene oxide at low levels in dried foods and spices is expected to be safe. Exposure to concentrated ethylene oxide such as from sterilized bandages or leaky equipment can cause severe burns. Ethylene oxide also presents an explosion hazard even at low temperatures. Long term exposure to elevated levels of ethylene oxide such as from poorly maintained sterilization equipment, has been linked to respiratory and nervous system damage as well as cancer.

Chemical Identity

Name: Ethylene Oxide

Brand Names: Ethylene Oxide is used in and is consumed during the production of Hydroxyethylcellulose and Methylhydroxethylcellulose product lines, including Natrosol™, Natrosol™ Plus, Dextrol™, and Culminal™. Chemical name (IUPAC): Oxirane

CAS number(s): 75-21-8

EC number: 200-849-9

Molecular formula: C₂H₄O

Structure:



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Uses and Applications

Ethylene oxide is a manufactured chemical primarily used in the production of ethylene glycol (a key ingredient in antifreeze) and various polymers including polyester. A small portion of ethylene oxide production is used as a sterilizing agent for medical products, as well as insect control in stored foods and spices.

Physical/Chemical Properties

Phys/Chem Safety Assessment

Property	Value
Form	Colorless Gas
Physical state	Gas
Color	Colorless
Odor	Sweet, ethereal
Density	0.88 g/cm ³ @10°C
Melting / boiling point	-111/10.7 °C
Flammability	H220: Extremely flammable gas
Explosive properties	Not classified
Self-ignition temperature	429°C
Vapor pressure	1752 hPa @25 °C
Mol weight	44.05256
Water solubility	Miscible with water
Flash point	-18 °C
Octanol-water partition coefficient (Log _{k_{ow}})	-0.3

Exposure, Hazard and Safety Assessment

The following section describes possible exposures scenarios and hazards associated with acetic acid. The exposure assessment describes both the amount of and the frequency with which a chemical substance reaches a person, a population of people, or the environment. Hazard refers to the inherent properties of a substance that make it capable of causing harm to human health or the environment. The safety assessment reports the possibility of a harmful event arising from exposure to a chemical or physical agent under specific conditions. Just because a substance may possess potentially harmful properties does not mean that it automatically poses a risk. It is not possible to make that determination without understanding the exposure.

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Human Health Effects

Human Exposure Assessment

Consumer: Most people are exposed only to very low levels of ethylene oxide in foods and spices, and from medical equipment sterilized with ethylene oxide.

Worker:

Workers in facilities using ethylene oxide sterilization may be exposed by inhaling vapors from leaky machinery. It is important to remember that the toxic effects of ethylene oxide may occur at airborne concentrations which cannot be smelled. Individuals touching ethylene oxide-sterilized medical equipment without protective gloves may also be exposed. INEOS plants require strict engineering controls and proper training to prevent worker exposure to ethylene oxide.

Human Hazard Assessment

Effect Assessment	Result
Acute Toxicity Oral / inhalation / dermal	H302: Harmful if swallowed. H331: Toxic if inhaled
Irritation / corrosion Skin / eye / respiratory test	H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation
Sensitization	Not classified
Toxicity after repeated exposure Oral / inhalation / dermal	Not classified
Genotoxicity / Mutagenicity	H340: May cause genetic defects
Carcinogenicity	H350: May cause cancer
Reproductive / Developmental Toxicity	Not classified
Aspiration hazard	Not applicable

Human Health Safety Assessment

Consumer and worker: Ethylene oxide is irritating to mucous membranes such as eyes, nose, and lungs. Inhalation of air containing high concentrations of ethylene oxide for brief periods can result in bronchitis, pulmonary edema, and emphysema. Dermal exposure to ethylene oxide, such as from sterilized gauze, may lead to redness, blister formation, scaling, crusted ulcerations, and burns. Long term exposure to ethylene oxide has been shown to increase the risks of several types of cancer in humans. Increased risks of stomach cancer and leukemia have been reported in workers exposed to ethylene oxide over long periods of time. Other forms of cancer have been observed in animals. Reproductive functionality may also be impaired by long term ethylene oxide exposure, but evidence for this effect is not sufficient for classification.

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Environmental Effects

Environmental Exposures

Ethylene oxide is highly reactive and will not persist in the environment. Ethylene oxide in water will rapidly evaporate. Toxic exposure to the environment is unlikely except in cases of spills and other accidental releases.

Environmental Hazard Assessment:

Effect Assessment	Result
Aquatic toxicity	Not classified

Fate and behavior	Result
Biodegradation	Readily biodegradable
Bioaccumulation potential	Not bioaccumulative
PBT / vPvB conclusion	Not PBT or vPvB

Environmental Safety Assessment

Ethylene oxide is highly reactive and will not persist in the environment. Ethylene oxide in water will rapidly evaporate. Environmental toxicity due to ethylene oxide exposure is unlikely.

Risk Management Recommendations

Exposure to ethylene oxide in the workplace is covered by established exposure limits. For example, the US Occupational Safety and Health Administration (OSHA) established an airborne PEL of 1 ppm as an 8-hour time-weighted average. OSHA has further established a short-term excursion limit of 5 ppm for no more than 15 minutes. If employees are exposed to ethylene oxide at concentrations above 0.5 ppm for more than 30 days per year, they must be monitored by a medical surveillance program. Any work in areas containing ethylene oxide concentrations above OSHA PEL's must ensure the use of respirators to control worker exposure. Workers at risk of exposure to liquid ethylene oxide must wear goggles and appropriate skin protection. Most EU member states have also adopted the 1ppm time weighted average for ethylene oxide exposures. Other geographies have similar protection programs in place for workers dealing with ethylene oxide.

Exposure to ethylene oxide in the workplace is covered by established exposure limits. A partial list of references follows:

- US OSHA PEL: 1 ppm (8h TWA)
- ACGIH TLV: 1 ppm (8h TWA)

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- EU and member states: <http://osha.europa.eu/en/topics/ds/oel/index.stm/members.stm>
- China: 2 mg/m³ (8h TWA)

Regulatory Agency Review

Epichlorohydrin is listed in:

- the list of REACH registered substances (EC) 1907/2006
- the US TSCA inventory
- Canada's DSL list
- The Australia Index of Chemical Substances
- the China Inventory of Existing Chemical Substances
- the Japan Inventory of Existing and New Chemical Substances
- the Korea Existing Chemicals Inventory
- the New Zealand Inventory of Chemicals
- the Philippines Inventory of Chemicals and Chemical Substances
- the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen
- the US National Toxicology Program (NTP) as a known human carcinogen

Regulatory Information / Classification and Labeling

Under the Globally Harmonized System for classification and labeling (GHS), substances are classified according to their physical, health, and environmental hazards. The hazards are communicated via specific labels, Safety Data Sheets (SDS) and accessory documentation required by local hazard communication standards. GHS provides standardized hazard classification and communication elements designed for global applications so that the intended audience (workers, consumers, transport workers, and emergency responders) can better understand the hazards of the chemicals in use.

GHS Classification:

Flammable gases and chemically unstable gases: Category 1 (Flam. Gas); Category A (Chem. Unst. Gas.)

Acute toxicity (oral): Category 4

Acute toxicity (inhalation): Category 3

Skin corrosion/irritation: Category 2

Serious eye damage/eye irritation: Category 2

Germ cell mutagenicity: Category 1B (inhalation)

Carcinogenicity: Category 1B (inhalation)

Specific target organ toxicity (single): Category 3 (respiratory system)

Specific target organ toxicity (repeated): Category 1 (nervous system)

Hazard Statements:

H220: Extremely flammable gas

H302: Harmful if swallowed

H315: Causes skin irritation

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H319: Causes serious eye irritation

H331: Toxic if inhaled

H340: May cause genetic defects

H350: May cause cancer

Signal Word:

Danger

Precautionary Statements:

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 dust/fume/gas/mist/vapours/spray

P280: Wear protective gloves/protective clothing/eye protection/face protection

P377: Leaking gas fire: Do not extinguish, unless leak can be stopped safely

P332+P313: If skin irritation occurs: Get medical advice/attention

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

P501: Dispose of contents and container to appropriate waste site or reclaimer in accordance with local and national regulations.

Hazard Pictograms:



Conclusion

Ethylene oxide is an essential chemical. It is used in the creation of many polymers, as well as for its own properties. While exposure to concentrated ethylene oxide is very hazardous, it is quite possible to work safely with this chemical.

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Additional Information

For more information on Product Stewardship at INEOS Composites, visit our website's Safety, Health and Environment (SHE) page: www.ineos.com/composites-she

For more information on GHS, visit <http://www.osha.gov/dsg/hazcom/ghsguideoct05.pdf> or http://live.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

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REACH registration is specific to Importers/Manufacturers that place the chemical on the EU market and is specific to registered uses. Inclusion on the list of REACH Registered Substances does not automatically imply registration by INEOS Composites.

Inclusion on the New Zealand Inventory of Chemicals applies only to the pure substance listed. The importer of record must determine whether their substances comply.