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Ethylene Oxide (EtO) is an organic compound with the chemical formula C2H4O. At room temperature, EtO is a colorless, soluble gas with a faintly sweet, ether-like odor. At room temperature it is flammable and dangerously reactive. This reactivity is responsible for many of EtO's uses as well as its hazards. It is potentially carcinogenic, mutagenic, and can have reproductive toxicity.

Ethylene Oxide

EtO is primarily used as an intermediate in the production of other industrial chemicals, the most notable of which is ethylene glycol. EtO and intermediate chemicals are used to make many consumer and non-consumer chemicals including detergents, thickeners, solvents, textiles, plastics, and various organic chemicals. It is also used to sterilize medical devices, as a disinfecting agent, and as a fumigant.

Background of EtO

Commercial production of EtO began 1914 when BASF built the first production facility using the chlorohydrin process. A more efficient process was developed by Shell Oil Co. in 1958 which involved the direct oxidation of ethylene with oxygen at elevated temperature and pressure. After 1975, this method completely replaced previous production methods. Today, almost all EtO is produced by direct oxidation of ethylene with either air or oxygen in the presence of a catalyst.

Use of EtO for insecticidal use gained popularity in the 1930s. By the 1940s, EtO was registered as an antimicrobial pesticide and early use in hospitals began. Use of EtO as a sterilant was developed in the 1940s by the US military. Its use as a sterilant for medical devices dates to the late 1950s, when the McDonald process was patented. By the late 1960s, EtO became the dominant chemical sterilant used in major healthcare facilities. By the 2000s, 75% of hospitals were using EtO to sterilize medical devices.

Production of EtO

EtO is industrially produced by the oxidation of ethylene in the presence of catalysts at a temperature of 200° to 300°C. The production of EtO accounts for about 11% of worldwide ethylene demand. The world production of ethylene oxide was 22.45 million tons in 2020, making it the 14th most produced organic chemical (the 2nd most produced was ethylene with 150 million tons).

The world's largest producers of and players for EtO include Dow Chemical, ABIC, Glycols Limited, DowDuPont Inc., Indorama Ventures Public Company Limited, Saudi Basic Industries, Royal Dutch Shell, BASF, China Petrochemical Corporation, Formosa Plastics USA, Indian Oil Corporation, Huntsmann International, LOTTE Chemical, and Akzo Nobel N.V.

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Raw material in chemical production

EtO is one of the most important raw materials used in large-scale production of various industrial chemicals.
The majority of EtO is used for the synthesis of ethylene glycols, including diethylene glycol and triethylene glycol, which accounts for up to 75% of its global consumption. EtO is also used in the production of ethylene glycol ethers, ethanolamines, and ethoxylates.

- Ethylene glycol is used as antifreeze, in the production of polyester textiles, in the production of plastic such as polyethylene terephthalate (PET, a raw material for plastic bottles), liquid coolants, and solvents.
- Polyethylene glycols are used in perfumes, cosmetics, pharmaceuticals, lubricants, paint thinners and plasticizers.
- Ethylene glycol ethers are used in brake fluids, detergents, solvents, lacquers and paints.
- Ethanolamines are used in soap and detergents and for purification of natural gas.
- Ethoxylates which are reaction products of EtO with higher alcohols, acids or amines. Ethoxyllates are used in the manufacture of detergents, surfactants, emulsifiers and dispersants.

> EtO is one of the most commonly used sterilization methods in the healthcare industry because of its non-damaging effects for delicate instruments and devices.

Uses of EtO

The direct use of EtO accounts for less than 1% of its global production. Direct uses of EtO include sterilization, disinfection, and fumigations. EtO is used for gas-phase sterilization of medical equipment and instruments, packaging materials and clothing, surgical and scientific equipment. It is also used to fumigate the storage of tobacco, grain, rice, etc.

Use as a healthcare sterilant

EtO is one of the most commonly used sterilization methods in the healthcare industry because of its non-damaging effects for delicate instruments and devices and for its wide range of material compatibility. It replaces steam in the sterilization of heat-and moisture-sensitive tool and medical products, such as disposable plastic syringes.

EtO is capable of destroying most viruses, bacteria, and fungi, including bacterial spores. EtO is highly effective as a sterilant gas because it is highly potent and can penetrate packaging (such as cardboard, shrink wrap, paper, and other wrappings).

Examples of medical devices sterilized using EtO include gowns and drapes, surgical kits, syringes, feeding tubes, cardiac stents, pacemakers, ventilators, IV sets, heart valves, and sutures. EtO is also used to sterilize instruments that cannot tolerate heat, moisture or abrasive chemicals, such as electronics, optical equipment, paper, rubber and plastics. According to the FDA, approximately 50% of sterile medical devices (about 20 billion per year) are treated with EtO. For some devices, EtO is the only effective sterilization method that is currently available.

It is estimated that there are more than 10,000 EtO sterilizers in use in U.S. health care facilities. Large sterilizers are found in central supply areas of most hospitals, and smaller sterilizers are found in clinics, operating rooms, tissue banks and research facilities. There are large-scale also commercial/ contract EtO sterilization facilities (e.g., Sterigenics).

Use as a food sterilant

EtO is used to sterilize some food products such as cocoa, flour, dried egg powder, coconut, spices, dried herbs, dried fruits and vegetables, sesame seeds and walnuts.

Use as a fumigant

EtO is used as a fumigant to remove pests and microorganisms from spices and seasonings, furs, furniture, nut meats, tobacco, books, drugs, leather, motor oil, paper, soil, animal bedding, clothing and transport vehicles. EtO is also used for treating bulk grain by recirculation in grain silos.

Niche uses

Niche uses of EtO include as a fungicide and as an accelerator of maturation of tobacco leaves. It is also used as a sterilant of cosmetics and dental devices. EtO is also used as a main component of thermobaric weapons (fuel-air explosives).

> The primary way people are exposed to EtO is through breathing air containing EtO. Certain occupational groups may be exposed in the workplace.

Sources of EtO in the environment

The primary way that EtO enters the environment is through releases into the air. Industrial sources of EtO emissions include uncontrolled emissions, venting with other gases, and fugitive emissions. Other sources of EtO air emissions include its use of EtO as a sterilizer of medical equipment and its release from fumigated materials.

In a 1985 study of U.S. emissions of EtO, sterilization and fumigation sites accounted for 57% of total emissions while production and captive use accounted for 31%, medical facilities for 8%, and ethoxylation plants for 4%. Most emissions from production and ethoxylation sites are due to equipment leaks.

Less than 0.1% of the ethylene oxide produced in the U.S. is used in medical sterilizer and fumigator processes, but nearly all of the ethylene oxide used for this purpose is released into the atmosphere or mixed with water and routed to a sewer system. EtO has also been detected in both urban and rural areas far from known industrial sources.

Human exposure

The primary way people are exposed to EtO is through breathing air containing EtO. Certain occupational groups (e.g., workers in EtO manufacturing or processing plants, sterilization technicians, hospital workers, workers involved in fumigations, and workers in certain chemical industries) may be exposed in the workplace.

People who live near facilities that release EtO to the air may also be exposed to EtO depending on how much EtO is released and how close they live to the facility. Based on sampling data, the EPA does not expect EtO levels in the outdoor air to be high enough to cause acute, immediate health effects.

Acute (short-term) toxicity

Short-term exposure to EtO can have irritating, sensitizing and narcotic effects.

Chronic (long-term) toxicity

EtO is a carcinogen, mutagen (meaning that it can cause DNA and genetic damage), and reproductive hazard known to cause reduced fertility.

The following is a partial list of agencies that have classified EtO as a carcinogen:

- The International Agency for Research on Cancer (IARC): Group 1 (human carcinogen).
- German Senate Commision for the Investigation of health Hazards of Chemical Compounds in the Work Area (MAK commission): Class 2 carcinogen.
- ACGIH: A2 suspected human carcinogen.
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)—a 2006 European Union regulation: EtO is "presumed to have carcinogenic potential for humans."

Recent controversy related to EtO use is related to a study published in December 2016 by the US EPA's Integrated Risk Information System program (IRIS). IRIS assessments are a source of information used by EPA, state and local health agencies, other federal agencies, and international health organizations. It is not a safety limit and is not intended to be a regulatory standard. In 2016, EPA's IRIS group completed a review and reclassified EtO from "Probably Carcinogenic" to "Carcinogenic" and updated its inhalation unit risk estimate. The IRIS update gained attention in 2018, when the EPA used it to evaluate nationwide cancer risks as part of its National Air Toxics Assessment (NATA). NATA's computer-simulated assessment combined the IRIS inhalation unit risk estimate with 2014 public emissions data from facilities across the country. This analysis implied that 106 census tracts across the country were identified as having an elevated risk of cancer due to EtO. The IRIS value of 0.1 parts per trillion of EtO is an inhalation unit risk estimate, which assumes that inhaling EtO 24 hours per day, 7 days per week for 70 years might increase the risk that 1 additional person in 1 million will get cancer.

EPA's study that showed that EtO emissions from some commercial sterilization facilities contribute to elevated cancer risk for people living in nearby communities. The EPA completed a risk assessment for communities near the approximately 100 commercial sterilizers operating in the U.S. Exposure to EtO over a lifetime (24 hours a day for 70 years) at concentrations found near some commercial sterilizers can increase the risk of developing cancer.

Regulatory Status

Clean Air Act

EtO has been regulated as a hazardous air pollutant under the Clean Air Act (CAA) since 1990. However, USEPA's December 2016 EtO cancer risk assessment update concluded that EtO is considerably more dangerous than previously believed and that inhalation of EtO is associated with increased risk of various cancers. Beginning in 2018 the USEPA initiated a review of CAA regulations related to EtO for certain industry sectors, including the following:

- Commercial sterilizers (review to be completed in 2022)
- Hospital sterilizers (review to be completed in 2023)
- Group 1 polymers and resins (neoprene) (review to be completed in 2024)
- Synthetic organic chemicals manufacturing industry (review to be completed in 2024)
- Polyether polyols production (review to be completed in 2024)
- Chemical manufacturing area sources (review to be completed in 2024)

Commercial sterilization facilities

In the U.S., the operation of EtO sterilization is overseen by the EPA through the National Emissions Standards for Hazardous Air Pollutants (NESHAP) under the Clean Air Act. The EPA is in the process of updating this regulation to reflect their new understanding of the cancer risk from EtO.

The EPA is broadening Toxics Release Inventory (TRI) reporting for EtO to include certain contract sterilization facilities that are not currently required to report this information. In December 2021, the EPA issued a decision extending TRI reporting requirements for EtO to 29 sterilization facilities. These facilities were required to start tracking their chemical activities and releases in January 2022 and submit TRI data beginning in 2024.

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