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# Ethylene Oxide

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Ethylene oxide (also abbreviated as EO and EtO) is a versatile compound used in the production of other chemicals for a variety of industrial applications and everyday consumer products, including household cleaners, personal care items and fabrics.

## Ethylene Oxide Sterilization

A small but important use of ethylene oxide is the sterilization of medical equipment, including the sterilization of personal protective equipment used by doctors and hospitals across the country. It is estimated that ethylene oxide sterilizes 20 billion medical devices each year, helping to prevent disease and infection.<sup>1</sup> The sterilization process is tightly controlled, and the ethylene oxide gas is removed from the products before they are used. According to the U.S. Food and Drug Administration (FDA), “These standards help ensure levels of ethylene oxide on medical devices are within safe limits.”<sup>2</sup>

[Read about more ethylene oxide uses.](#)

## Uses & Benefits

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Ethylene oxide is most commonly used in the production of other chemicals, including the production of solvents, antifreeze, detergents, adhesives, polyurethane foam, and pharmaceuticals. Ethylene oxide is also used in the following applications:

## Product and Industrial Applications

Most ethylene oxide is used as an intermediate in the **production of other chemicals** used to manufacture products, such as fabrics for clothes, upholstery, carpet and pillows. It is used to produce ethylene glycols for **engine antifreeze** that keeps our automobiles performing.

Other ethylene oxide derivatives are used in **household cleaners** and personal care items such as **cosmetics and shampoos**.

Ethylene glycol, which is derived from ethylene oxide, is used to manufacture fiberglass used in products ranging from jet skis to bathtubs to bowling balls, as well as polyethylene terephthalate (PET) plastic resin to make beverage containers and packaging film.

Ethylene oxide derivatives are used as ingredients in industrial cleaners, heat transfer liquids, polyurethanes and plasticizers.

## Medical Applications

Ethylene oxide sterilization processes can **sanitize medical and pharmaceutical products** that cannot support conventional, high-temperature steam sterilization procedures. Delicate, heat-sensitive medical devices that incorporate plastics and electronics could be warped or otherwise damaged by steam sterilization. A low-temperature sterilizer, ethylene oxide gas will not damage these types of medical devices.<sup>3</sup>

Ethylene oxide also is used to sterilize other healthcare products, such as bandages and ointments, reducing potential damage to the product that may occur from other means of sterilization.

Approximately 50 percent of medical supplies are sterilized with ethylene oxide, making it critical to the U.S. healthcare industry.<sup>4</sup>

# Safety Information

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## Ethylene Oxide Exposure

Any potential association between ethylene oxide and cancer is linked only to chronic exposure. There **is minimal hazard risk** for the general population because most people are not exposed to significant quantities of ethylene oxide.

The Occupational Safety and Health Administration's (OSHA) ethylene oxide standard requires employers where ethylene oxide is present in the workplace to monitor employee exposure.<sup>5</sup> Under the OSHA standard, employers must provide appropriate protective clothing and equipment to employees who may be exposed to ethylene oxide. The National Institute of Occupational Safety and Health<sup>6</sup> and the American Conference of Governmental Industrial Hygienists<sup>7</sup> also provide guidance for industrial exposure to ethylene oxide.

## Regulations

Industrial sources of ethylene oxide emissions to the atmosphere are regulated under EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) rules.<sup>8</sup> These standards require, among other things, installation of control devices to reduce emissions, emissions monitoring, performance testing, site-specific operating parameters, and continued reporting and recordkeeping. The 2014 EPA National Emissions Inventory (NEI) reported a downward trend in national ethylene oxide emissions for the industrial sector (from 716.49 tons per year in 2002 to 153.16 tons per year in 2014).

Additionally, companies that make and work with ethylene oxide invest in research and product stewardship technologies so that they can continue to help protect communities, with advanced technologies to track and manage emissions. Manufacturers also share best practices for responsibly producing, shipping, and handling ethylene oxide.

# Answering Questions

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## What is Ethylene Oxide?

Ethylene oxide (also abbreviated as EO and EtO) is a versatile compound used in the production of other chemicals for a variety of industrial applications and everyday consumer products, including household cleaners, personal care items and fabrics textiles.

## What is Ethylene Oxide used for?

Ethylene oxide is most commonly used in the production of other chemicals including the production of solvents, antifreeze, detergents, adhesives, polyurethane foam and pharmaceuticals. A small but important use of ethylene oxide is the sterilization of surgical and medical equipment, including the sterilization of personal protective equipment. It is estimated that ethylene oxide sterilizes 20 billion medical devices each year, helping to prevent disease and infection. Read about more ethylene oxide uses.

## How is ethylene oxide used in sterilization?

Ethylene oxide sterilization processes can sanitize medical and pharmaceutical products that cannot support conventional, high-temperature steam sterilization procedures. A low-temperature sterilizer, ethylene oxide gas will not damage these types of medical devices. Approximately 50 percent of medical supplies are sterilized with ethylene oxide, making it critical to the U.S. healthcare industry. Read more about ethylene oxide sterilization uses.

## Is the general population exposed to ethylene oxide?

Ethylene oxide is present in the environment and is created by various sources, including plants and the heating of cooking oils. The human body also converts ethylene to ethylene oxide. Exposure to ethylene oxide varies across urban, suburban and rural environments.

Ethylene oxide emissions from industrial manufacturing and other applications are strictly regulated under federal and in some cases state and local laws.

## How is ethylene oxide regulated for worker safety?

OSHA has set exposure limits for employees working in facilities where ethylene oxide gas is present. In addition, employers must provide appropriate protective clothing and equipment to employees who may be exposed to ethylene oxide. The National Institute of Occupational Safety and Health<sup>6</sup> and the American Conference of Governmental Industrial Hygienists<sup>7</sup> also provide guidance for industrial exposure to ethylene oxide.

## Is ethylene oxide a carcinogen that can cause cancer?

Any potential association between ethylene oxide and cancer is linked only to chronic exposure. There is minimal cancer risk for the general population because most people are not exposed to significant quantities of ethylene oxide.

In fact, one comprehensive lifetime exposure study of workers in ethylene oxide production facilities found no statistically significant excess cancer risk due to ethylene oxide exposure.<sup>9</sup> A similar result was found in Michigan when the state analyzed the population near a facility that used ethylene oxide in Grand Rapids.<sup>10</sup>

# Has EPA warned of an elevated risk of cancer due to ethylene oxide exposure levels?

In 2016, the EPA Integrated Risk Information System (IRIS) program released an updated cancer value based on modeling. Several independent reviews have raised substantive concerns about EPA's IRIS program generally and its findings with respect to ethylene oxide specifically.

For instance, the Texas Commission on Environmental Quality (TCEQ) has said that EPA's IRIS value for ethylene oxide is "without sound scientific basis."

The ethylene oxide assessment also includes errors in modeling historical exposures to ethylene oxide. These errors combined result in a value that is based on selective science and results in an overly conservative cancer value. In fact, the ethylene oxide cancer value derived from EPA's modeling is 19,000 times lower than the normal, naturally-created levels of ethylene oxide in the human body.

After independent, peer reviewed analysis of the IRIS value by TCEQ, EPA is currently reconsidering the use of the IRIS value in their rulemaking governing emissions from EO facilities producing EO.

## Sources

<sup>1</sup>AdvaMed: <https://www.advamed.org/industry-updates/hot-topics/sterilization-ethylene-oxide/>

<sup>2</sup>FDA – <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices>

<sup>3</sup>CDC – Disinfection and Sterilization: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>

<sup>4</sup>FDA – <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>

<sup>5</sup>OSHA – Occupational Safety and Health Administration's (OSHA) ethylene oxide standard

<sup>6</sup>NIOSH – <https://www.cdc.gov/niosh/npg/npgd0275.html>

<sup>7</sup>American Conference of Governmental Industrial Hygienist – <https://www.acgih.org/>

<sup>8</sup>EPA – EPA’s National Emission Standards for Hazardous Air Pollutants (NESHAP)

<sup>9</sup>Research Gate –

[https://www.researchgate.net/publication/24415937\\_Mortality\\_Study\\_Update\\_of\\_Ethylene\\_Oxide\\_Workers\\_in\\_Chemical\\_Manufacturing\\_A\\_15\\_Year\\_Update](https://www.researchgate.net/publication/24415937_Mortality_Study_Update_of_Ethylene_Oxide_Workers_in_Chemical_Manufacturing_A_15_Year_Update)

<sup>10</sup>Fox News West Michigan – <https://www.fox17online.com/2019/07/24/state-no-unusual-cancer-stats-near-grand-rapids-medical-manufacturer/>