# **ETHYLENE OXIDE**

## A Critical Building Block for

## U.S. Healthcare

Ethylene oxide (EO) is a versatile building block of chemistry.

It helps make many of the products we use every day, such as household cleaners, plastics, safety glass, adhesives, textiles, and detergents.

One area where ethylene oxide is used is in the U.S. healthcare industry.

## (?)

### How is it used?

One important use of ethylene oxide is for the sterilization of medical equipment such as personal protective equipment used by health care professionals and hospitals across the country. It is estimated that ethylene oxide sterilizes 20 billion medical devices each year, helping prevent disease and infection.

- Medical devices that require ethylene oxide sterilization include heart valves, pacemakers, surgical kits, gowns, drapes, ventilators, syringes, and catheters.<sup>1</sup> Ethylene oxide has been used for sterilizing ophthalmologic instruments, ampoules for spinal anesthesia and equipment for intravenous infusions.<sup>2</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.<sup>3</sup> This is particularly important for medical equipment and articles that cannot be exposed to high heat or steam.
- Further, many ethylene oxide derivatives are utilized for medicinal tableting, medical coatings, medical films, solvents or aids in the production of pharmaceuticals and vaccines. Some EO based ingredients are used in eye drops<sup>4</sup> to temporarily relieve redness, burning and irritation of the eyes. Others are used in the treatment of Hepatitis B and C<sup>5</sup> or to treat occasional constipation.<sup>6</sup> Another one is to clean wounds and has been shown to seal membrane pores in skeletal muscle cells and fibroblasts after heat shock.<sup>7</sup>
- Ethylene oxide derivatives may also be used in manufacturing polyester and polyester to make personal protective equipment such as polyethylene terephthalate (PET) multiple-use surgical gowns and masks.
- The demands of our nation's healthcare system continue to grow. Overly conservative restrictions on the production of ethylene oxide could put the needs of the healthcare sector at risk. According to the Centers for Medicare & Medicaid Services, U.S. health care spending accounts for 18.3 percent of our nation's gross domestic product.<sup>8</sup> Our member companies are dedicated to the responsible manufacture and use of ethylene oxide, and we support strong, science-based regulation of this important chemistry.

#### <sup>1</sup> AdvaMed

- <sup>2</sup> The New England Journal of Medicine
- <sup>3</sup> Chemical Safety Facts
- <sup>4</sup> <u>The University of Iowa Department of</u> <u>Ophthalmology and Visual Sciences</u>
- <sup>5</sup> <u>ClinicalInfo.hiv.gov</u>
- <sup>6</sup> <u>MedlinePlus.gov</u>
- 7 International Wound Journal
- <sup>8</sup> Centers for Medicare & Medicaid Services

American<sup>°</sup> Chemistry Council

## Polyethylene glycol (PEG)

Polyethylene glycol (PEG) is a synthesized polymer of ethylene oxide and water that has several chemical properties that make it useful for biological, chemical, and pharmaceutical applications.

PEG is often a polymer of choice in drug delivery systems. It is well-suited for many biomedical applications due to its high solubility in aqueous media, biocompatibility, and good tolerance.<sup>1</sup>

- PEGylated drugs have been approved by the U.S. Food and Drug Administration (FDA) for safe human use for treatment of anemia, severe combined immunodeficiency disease, leukemia, rheumatoid arthritis, age-related macular degeneration, pancreatic cancer, ovarian cancer hepatitis C, multiple sclerosis, hemophilia, gout, and gastrointestinal disorders.<sup>2</sup>
- PEG is also used as a coating for stents and catheters.<sup>3</sup>
- PEG is used in two COVID-19 vaccines.<sup>1</sup> The presence of PEG improves colloidal stability, enhances solubility, extends in vivo circulation time, and decreases the immunogenicity of the vaccines for better safety and efficacy.<sup>4</sup>

PEG is widely used in bioconjugation and nanomedicine

- to prolong blood circulation time and improve drug efficacy.<sup>5</sup>
- PEG is used as the basis for laxative products and is also used for chronic constipation and used for bowel preparation before surgery or colonoscopy.<sup>6</sup>
- In blood banking, PEG is used as an additive to enhance reactivity and to reduce incubation time when testing for unexpected antibodies.<sup>7</sup>
- <sup>1</sup> D'souza, Anisha A., and Ranjita Shegokar. "Polyethylene Glycol (PEG): A versatile polymer for pharmaceutical applications." Expert Opinion on Drug Delivery, vol. 13, no. 9, 17 May 2016, pp. 1257–1275, <u>https://doi.org/10.1080/17425247.2016.1182485</u>.
- <sup>2</sup> Gao, Yongsheng, et al. "PEGylated therapeutics in the clinic." Bioengineering & Translational Medicine, vol. 9, no. 1, 22 Sept. 2023, https://doi.org/10.1002/btm2.10600.
- <sup>3</sup> Center for Devices and Radiological Health. "Medical Device Material Safety Summaries." U.S. Food and Drug Administration, FDA, <u>www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-material-safety-summaries</u>.
- <sup>4</sup> Wang, Mingzhang Maple, et al. "Elucidation of lipid nanoparticle surface structure in mrna vaccines." Scientific Reports, vol. 13, no. 1, 5 Oct. 2023, https://doi.org/10.1038/s41598-023-43898-x.
- <sup>5</sup> Hoang Thi, Thai Thanh, et al. "The importance of poly(ethylene glycol) alternatives for overcoming peg immunogenicity in drug delivery and Bioconjugation." Polymers, vol. 12, no. 2, 2 Feb. 2020, p. 298, <u>https://doi.org/10.3390/polym12020298</u>.
- <sup>6</sup> Wang, Bin Y, et al. "Polyethylene Glycol for chronic constipation in adults." Cochrane Database of Systematic Reviews, 18 Apr. 2007, <u>https://doi.org/10.1002/14651858.cd006502</u>.
- <sup>7</sup> Weldy, L. "Polyethylene glycol antiglobulin test (PEG-AGT)." *Immunohematology*, vol. 30, no. 4, 1 Jan. 2014, pp. 158–160, https://doi.org/10.21307/immunohematology-2019-113.

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