

What Is Ethylene Oxide?

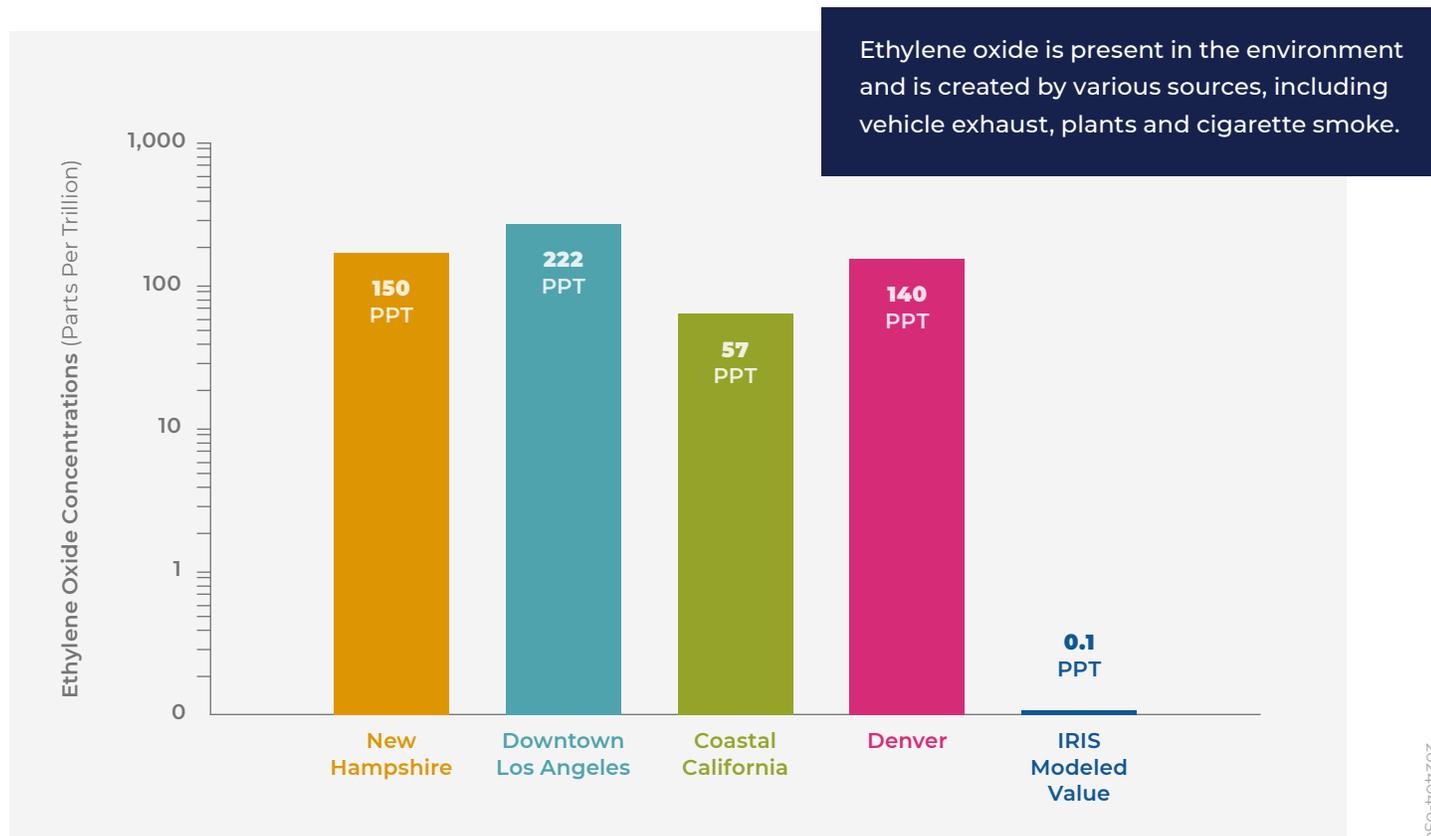
A versatile and valuable building block of chemistry, ethylene oxide (EO) and its derivatives help make many of the products we use every day, such as certain plastics, household cleaners, safety glass, adhesives, textiles, and detergents. A small but important use of ethylene oxide is the sterilization of medical equipment, including the sterilization of personal protective equipment used by doctors and hospitals across the country.

EPA's Integrated Risk Information System (IRIS) Program

The EPA's Integrated Risk Information System (IRIS) program is one source of hazard information that must be combined with other information to assess risks to health and the environment. IRIS reports are not an assessment of risks and IRIS modeled values are not intended to be regulatory standards.

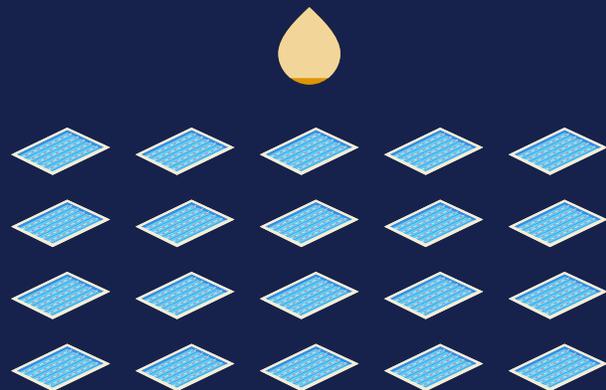
A significantly flawed assessment that was generated by EPA's IRIS program is causing unnecessary alarm and grossly misstates EO's potential impact on public health. The IRIS program has dramatically overestimated the hazard of EO, deeming it unsafe at levels far below levels found in our environment. In fact, EPA's flawed IRIS value is 23,000 times lower than the normal, naturally-created levels of EO in the human body and orders of magnitude lower than levels of EO from other sources measured in ambient air.

Ethylene Oxide in the Air

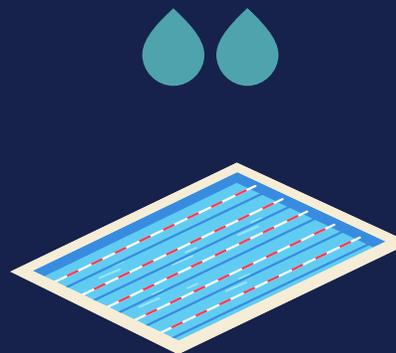


Ethylene Oxide in the Human Body

The concentration of EO modeled by the IRIS Program is **0.1 parts per trillion**, about the same as **0.1 drop of water** in the total volume of **20 olympic sized swimming pools**



A typical concentration of naturally occurring EO in the body of a non-smoker is **2.3 parts per billion**, about the same as **2.3 drops of water** in the total volume of **one Olympic sized swimming pool**



The mean air concentration equivalent to the endogenous concentration in non-smoking humans with no known EO exposures is 2.3 ppb., which is 23,000 times greater than the EO IRIS modeled value of 0.1 ppt. (CR Kirman, AA Li, PJ Sheehan, JS Bus, RC Lewis & SM Hays (2021) Ethylene oxide review: characterization of total exposure via endogenous and exogenous pathways and their implications to risk assessment and risk management, Journal of Toxicology and Environmental Health, Part B, 24:1, 1-29, DOI: 10.1080/10937404.2020.1852988).

What Do Independent Reviews Say About IRIS?

A number of independent reviews also question the IRIS program and its findings. For instance, the Texas Commission on Environmental Quality (TCEQ) has said that, 'the USEPA unit risk factor (URF) for ethylene oxide is not scientifically justified.' In fact, the TCEQ has set the record straight on the flawed IRIS value by publishing its own independent, peer reviewed analysis that found the risk of ethylene oxide is 4,000 times lower than the IRIS program concluded.

Additionally, in 2011, the National Academy of Sciences (NAS) criticized IRIS assessments generally for their poor scientific quality (a result of the IRIS program's unnecessary reliance on overly conservative and default assumptions and outdated scientific information) and made specific recommendations that were not incorporated into the EO assessment. Two EPA Science Advisory Boards also outlined additional key issues with the EO IRIS assessment.

The American Chemistry Council has outlined numerous problems with the methodology and substance of the EO IRIS value and presented scientific evidence in support of an alternative conservative value.

Findings by Other Researchers

Other peer reviewed research confirms the flaws with the IRIS value – in fact, the IRIS value is 15,000 times lower than the value determined by risk assessment modeling conducted at Texas A&M (Valdez-Flores et al., 2010), which incorporates all the available data from the two strongest human epidemiology studies. This approach has been adopted by the European Commission's Scientific Committee on Occupational Exposure Limits.

ACC's Ethylene Oxide Panel's Commitment to Safety & Public Health

ACC Ethylene Oxide Panel Member companies implement advanced safety technology and practices at every step of the production process – from plant design, to personnel safety precautions, equipment maintenance and preparation, transportation, and loading and unloading operations.

The Ethylene Oxide Panel supports policies based on the best available science and research on health, safety & environmental issues arising from the production, use, storage, transportation and disposal of ethylene oxide.