



FACTS ABOUT ETHYLENE OXIDE, MEDICAL STERILIZATION AND MEDLINE

Why Is Ethylene Oxide (EO) Important?

- Ethylene oxide (EO) is the globally accepted and, in many cases, the **only** clinically and scientifically-valid sterilization method of medical supplies.
- EO is used to sterilize the overwhelming majority of medical supplies required for surgery.
- More than 50% – or 20 billion – healthcare products are sterilized with EO every year in the U.S.

Science Supports EO Safety

- EO sterilization of medical supplies has been rigorously examined and proven safe.
- Thirteen studies of sterilant workers and chemical workers conducted over 40 years in five countries show no pattern of increase for any type of cancer.
- Our bodies produce EO as part of the normal metabolic process, and normal human breath carries EO at a level hundreds of times over the levels suggested as “risky”.
- EO is naturally emitted by plant decay, animal waste on farms, heated cooking oil, human respiration and compost.

What the IRIS Assessment Does and Doesn't Mean

- The IRIS risk assessment has come under very heavy criticism from the scientific community.
 - The report included estimated worker exposure levels that were implausibly lower in early years of the sterilant industry.
 - Relied on only one epidemiological study (The NIOSH study)
 - AND came to a different conclusion on the study than NIOSH itself did
 - Used an inappropriate statistical model the EPA recommends against because it overestimates risk.
- EPA has been asked to officially revise the study (IQA Request)
 - World renowned scientists reviewed the IRIS report and put together the IQA request

Banning EO Would Leave Health Systems with No Sterilization Options

- EO is the only option for sterilizing more than 50 percent of medical products.
- Many medical and surgical materials simply cannot be sterilized by alternate methods:
 - Gamma and e-beam radiation can make plastics brittle, or cause certain non-woven materials to literally disintegrate
 - Steam is high temperature and will melt plastics or damage heat sensitive products
 - Hydrogen peroxide and gas plasma are intended for small scale, surface sterilization only and cannot penetrate into devices that have interior chambers or two surfaces that are in contact with each other (as in the piston and barrel of a syringe).

Restricting or Banning EO Would Lead to an Immediate Public Health Crisis.

- Any disruption of EO sterilization facilities would cause a near-immediate public health crisis.
- Illinois hospitals would lose access to sterilized medical packs needed for life-saving surgeries.
- The enormous disruption in the supply chain would put extreme pressure on Illinois' hospital system.
- Hospitals would be forced to cancel surgical procedures and even shut down operating rooms.
- Critical care facilities with high volumes of emergent surgeries would be impacted immediately.
- Conducting non-sterile surgeries is not an option for obvious patient risk and hospital liability.
- Banning EO sterilization would have a significant impact on public health. Necessary medical supplies would quickly become unavailable and would impact the ability to provide quality medical care to patients.

SEE REVERSE FOR MORE INFORMATION ABOUT EO



BACKGROUND AND USES

- First discovered in 1859. First used as a sterilizing agent in the 1930's and patented in 1938.
 - Proven highly effective – EO is unique since it can penetrate packaging and plastic to reach inside tubing, products that have two surfaces that are touching, and connectors.
- Myriad applications: manufacturing skin care products, cosmetics, plastics (e.g., water bottles) and to fumigate spices. It is used in detergents, thickeners, solvents, and to make various organic chemicals such as ethylene glycol (antifreeze).
- Widely used in hospitals and the medical equipment industry to sterilize heat-sensitive tools and equipment, such as disposable plastic syringes, flexible endoscopes, and other reusable instruments that can be damaged by steam or where other methods cannot sufficiently penetrate the product to render it sterile.

Sterilization process – how it works

- Product boxed and on shipping pallet is pre-conditioned to a specific temperature and humidity level.
- Pallet then moved into the chamber, where air is evacuated using nitrogen or inert gases and then humidity is added.
- Next, EO is added and allowed to dwell so it can fully diffuse into the products.
- EO is removed via several vacuum and nitrogen washes.
 - De-gas/aeration room is heated to a high temp to help remove EO
 - De-gas room has negative pressure to prevent gas from going out of the area
 - Room has fresh air makeups to keep air moving
 - High air flow

Abatement technology – emissions reduction

- The gas/nitrogen mix from the sterilization chambers is routed through a “wet scrubber” system – tanks with water and sulfuric acid that react with the EO to produce ethylene glycol.
- The ethylene glycol mix is captured and recycled for industrial use (antifreeze, making polyester fibers).
- Similarly, the air in the heated de-gas room is routed through both a scrubber system and an abator.
- These systems operate at over a minimum of 99% efficiency -- the EPA requirement for reducing EO in emissions.
- Abatement systems have rigorous preventative maintenance to assure they are operating correctly.

Worker safety – how companies protect employees

- EO Sterilization facilities have monitoring systems that continuously monitor the levels of EO in the plant.
- Employees undergo physical exams each year, and monitors worn by employees each quarter are sent to a 3rd party for testing to verify they are within the OSHA exposure safety limits.

Medline

- World Headquarters in Northfield, IL for over 50 years.
- Manufactures, packages and distributes essential medical supplies, including sterile surgical packs that contain all of the disposable items necessary during in-patient and out-patient procedures – from tonsillectomies, C-sections and knee replacements to liver transplants and open-heart surgeries.
- Packs can contain as many as 200 separate items. Examples: Draping, gowns, gauze, plastic tubing, sponges, scalpel blades, and chemotherapy ports.
- Our Waukegan site employs nearly 600 Illinoisans & produces more than 16,000 of sterile packs every day.

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