

What does Medline do?

Medline is a global manufacturer and distributor of essential medical supplies, including sterile surgical packs that contain all of the disposable items necessary for in-patient and out-patient procedures – from tonsillectomies, C-sections and knee replacements to liver transplants and open-heart surgeries. We produce more than 16,000 sterile surgical packs per day and over half a million per year. 135 of the 180 hospitals in Illinois use Medline’s surgical packs.

What is ethylene oxide? What is it used for in the Waukegan plant?

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

Items in each surgical pack we produce and distribute are bundled together in a sealed plastic wrapper with a gas-permeable seal. Packs are sterilized using an FDA-recognized process that uses controlled amounts of heat, humidity and EO gas. This industry-standard process allows packages that contain different types of medical products to be sterilized together in procedure-specific bundles.

Here’s how the sterilization process works:

- The product is boxed and placed on a shipping pallet. Product is pre-conditioned to a specific temperature and humidity level.
- The pallet is 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.

[Click here](#) to watch a video that describes the EO sterilization process in more detail.

Does Medline use EO safely?

Our plant in Waukegan has been safely using EO for decades to sterilize medical equipment. Our emissions have always been at or below the standards set by regulating bodies.

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 that is hundreds of times over the levels suggested as “risky” by the EPA staff’s IRIS risk assessment.

What emissions controls does Medline have in place?

Medline has emissions control systems that operate at over 99% efficiency -- the EPA requirement for reducing EO in emissions.

- 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.
- Abatement systems have rigorous preventative maintenance to assure they are operating correctly.

Can Medline install additional equipment to help reduce emissions further?

Medline currently plans to install additional abatement technology to reduce ethylene oxide emissions from the back vents at our facility, beyond our current permit requirements. Installation will be in Q1 2019 based on the equipment manufacturer's estimates.

We welcome any new factual information that can inform our safe operations. We are dedicated to studying the latest scientific research and investing in new technology to protect our employees and the community.

How does Medline monitor EO emissions—both inside and outside the plant?

Our monitoring systems capture EO levels inside our facility every 20 minutes to identify elevations in EO that would require additional worker safety protocols. As required by the Occupational Health and Safety Agency, all Medline workers are badged to monitor contact with EO and participate in annual medical and respiratory testing.

To measure EO emissions outside the plant, we monitor on a daily basis the quantities of EO used in our sterilization process, which is then repurposed for alternate commercial use. This daily monitoring, which is regularly reported to the EPA, confirms that approximately 1 percent of the EO used may remain in the chamber after products are sterilized and a similarly minute amount left over is scrubbed and emitted through the stack.

Throughout our 24-year history of using EO sterilization at our Waukegan facility, we have consistently operated well below mandated safety and permitted emission levels.

Didn't the EPA air quality testing around the Sterigenics plant in December 2018 show that EO is being emitted into the air?

When looking at this first sample, whatever EO might be in the air from the Sterigenics plant and from car exhaust in the immediate area doesn't seem to be traveling to residential areas in Willowbrook. This initial round of EPA testing confirms what we would expect from the established science regarding EO. Because EO breaks down in the air after it is emitted from a natural or man-made source, we would expect the tests to detect EO immediately next to that source, but not further away.

The EPA has done one round of testing and they expect to do many more over several months, stating they will have a full report in the spring. Our Waukegan plant is in an even less population dense area, and we use about half of the EO volume in our plant as compared to Sterigenics.

What specifically are your concerns about the EPA report on EO?

The 2016 EPA staff-level IRIS report is a working document with no legal binding effect. In it, EPA has discounted decades of epidemiologic studies that showed no increased risk associated with EO.

The IRIS report has come under very heavy criticism from the scientific community. The EPA itself has said it must conduct more studies before any conclusions can be drawn.

The IRIS report has been formally challenged under the Information Quality Act (IQA), which requires federal government agencies to employ sound science in making regulations and disseminating information and provides a mechanism to challenge government information believed to be inaccurate. Medline is seeking a National Academy of Sciences (NAS) review of the IRIS report.

Are the current EPA limits safe? Would more stringent ones better protect the community?

Ethylene oxide (EO) sterilization of medical supplies is a process that has been rigorously examined and proven safe in many scientific studies for decades. EO is used safely and effectively worldwide.

We carefully monitor our use of EO and have consistently operated well below mandated safety and permitted levels throughout our 24-year history of using this process at our Waukegan facility. Though not necessary, we are willing to add additional abatement technology, not required by our permit, if it will take even more of the minute amount emitted from our plant out of the air.

Is there evidence of higher incidents of cancer in Lake County?

The EPA does not track incidents of cancer based in the IRIS report, the NATA map or any of its reports. The NATA map that came out of the EPA IRIS report does NOT reflect incidents of

cancer. Rather, it uses the questionable EPA IRIS data and flawed computer models to incorrectly estimate areas of elevated cancer risk.

Medline has said there are other sources of EO in the area, like auto emissions. What is the science behind that?

In addition to auto exhaust, there are other sources of EO (compost piles, plant decay, heated cooking oil, farms [animal waste], sewage plants and cigarette smoke, among others). Our bodies also produce EO as part of the normal metabolic process, and normal human breath carries EO at a level hundreds of times over the new EPA proposed limit.

Auto exhaust is a significant contributor to EO levels in the atmosphere. Therefore, it's not surprising that if air samples were taken around a building like ours that is in a high traffic area – literally bordered by two highways – they would show an EO presence.

Are there other options to sterilize surgical packs besides EO?

EO was first patented for use as a medical sterilization agent in the late 1930s. Since then, there have been many attempts to find alternatives, but none have been successful to date. EO is currently the only way to safely sterilize many critical medical products. Heat, steam and radiation damage or destroy pieces of a surgical pack (e.g. plastic, cotton, gauze, draping) and are not compatible with many other medical products. Other sterilants, such as hydrogen peroxide, are effective for surface sterilization only.

EO is used safely worldwide as the primary way to sterilize the surgical procedure packs that are critical to our health care system in providing safe and timely patient care and operating room efficiency.

What would happen if Medline was not able to use EO sterilization anymore?

EO is used safely and effectively worldwide. Any disruption of EO sterilization facilities would cause a near-immediate public health crisis. Operating rooms across the country would be severely impacted, limiting access to supplies necessary for lifesaving procedures.

It is no exaggeration to state that surgeries of all kinds would not be able to go forward without sterile equipment. Conducting non-sterile surgeries is not an option for obvious patient risk and hospital liability.

Why did you call upon Congress to request that the National Academy of Sciences (NAS) conduct a formal review of the EPA's IRIS report?

The NAS is a private, non-profit society of distinguished scholars that is charged with providing independent, objective advice to the nation on matters related to science and technology. We have listened to recent concerns about EO sterilization, which stem solely from the 2016 EPA

staff-level IRIS report, which the scientific community has strongly criticized as inconsistent with overwhelming evidence and widely accepted research.

Medline will continue our ongoing work with regulators and experts to improve the safety of our products and operations. We are dedicated to studying the latest scientific research and continuing to evaluate any new technology that can further protect our employees and the community.

How do Medline's EO emissions compare to Sterigenics?

We don't have data on Sterigenics' EO emissions, but we know that Medline uses about half of the EO volume in our plant as compared to Sterigenics. Medline's current emission levels are well below our permit levels and far below the EPA regulatory limits.