

# Ethylene Oxide

## What is ethylene oxide?

Ethylene oxide (EtO) is a colourless gas or liquid that has a sweetish, ether-like odour. It is usually a gas at room temperature. In high concentrations, EtO can be very explosive and it is a powerful solvent for fats, oils and greases. It is used in making anti-freeze, films, bottles, solvents, soaps and detergents and fumigants. Of major concern to CUPE members, however, is the use of ethylene oxide as a sterilant in health care facilities.

## How is EtO used?

EtO is used as a chemical sterilant for items that can't be effectively or safely sterilized by heat or steam, such as rubber goods, oxygen tents, catheters and telescopic instruments. The contaminated goods are exposed to ethylene oxide gas in closed chambers of various types, are removed to air out and are then packaged for reuse in the facility. The gas is supplied in two ways: either in ampoules or small cartridges for one time use in tray-type sterilizers, or as an EtO /inert gas mixture in tanks which are connected to the sterilizer.

A recent survey of EtO use in Ontario hospitals found that there are three common types of sterilizers used.

1. The **tray method** uses undiluted ethylene oxide in a small tabletop cabinet. A unit-dose glass ampoule is opened manually inside a plastic bag containing the materials to be sterilized. The bag is placed in the cabinet and the door is closed.

2. **Unit-dose canisters or cartridges** are used in another type of tabletop sterilizer. In this method, the plastic tip on the cartridge is punctured **after** the cartridge is placed in the sterilizer.

3. **Sterilizers using ethylene oxide in cylinders** are the final type generally found in use. Ethylene oxide diluted with inert gases such as fluorocarbons is supplied to the sterilizer through piping, often from a mechanical room near the sterilizer.

After the sterilizing cycle is complete in this type of system, the used EtO gas is pulled out by a vacuum pump, mixed with water and disposed of through a sewer drain.

While it is the practice in some institutions to let sterilized materials air out in room air, it is becoming more common to provide an aeration cabinet. These cabinets are provided with mechanical ventilation and are able to heat and circulate the air so that the EtO which has been absorbed by the materials can be removed more quickly and vented to the outside.

Throughout the sterilizing process, there are many possible sources of worker exposure to EtO. These include:

- leaks from the gas delivery system (e.g., hoses or piping, tanks);
- releases during sterilizer operation;
- leaking door gaskets;
- unvented chambers;
- releases during exhaust phase of cycle;
- discharge of drains;
- leaks to/in vent lines;
- releases after treatment cycle is complete;
- unloading of chamber and transfer to aerator or storage areas;
- off gassing from stored materials or release from aeration cabinets;
- cylinder changeover operation;
- failure of door locking mechanism;
- major leak or spill.

## Is ethylene oxide harmful?

Health problems linked to ethylene oxide exposure have been seen in both test animals and humans. Effects in humans include:

- irritation of eyes, skin, nose, airways and lungs;
- sensitization of skin (an allergic reaction);
- upset stomach, vomiting and diarrhea;
- loss of feeling in the arms, hands, legs as well as other effects on the central nervous system.

In addition, EtO has been linked to cataract development and blistering or burning of the skin. Long–term or chronic exposure may cause high white–blood cell counts and anemia. Of even more concern to CUPE members, however, is the evidence that EtO is a carcinogen (cancer–causer), causes mutations (changes) in cells and that it affects our ability to have healthy children.

Several studies in a variety of animal species have shown that EtO can cause cancer, and NIOSH (U.S. National Institute for Occupational Safety and Health) has recommended that ethylene oxide be treated as a human carcinogen.

There is very recent evidence from human studies that support the classification of EtO as a human carcinogen. The researchers in a Swedish study found an "unexpected number of cases of leukemia as well as a dramatic excess of stomach cancer in a small production plant with mixed exposure including ethylene oxide.

Ethylene oxide is also considered a reproductive hazard. Mutations (changes) in cells are reported in a number of animal species and there are increasing reports of damage to human chromosomes in exposed workers. The chromosomes carry our genetic code, and damage to the code may cause health effects due to cell damage in the exposed worker. The mutation may also

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be passed on to future generations if germ cells (sperm and ova) are affected.

Evidence of reproductive effects in animals includes reductions of the number of pups per litter and increases in the number of deformed fetuses. In humans, EtO is linked to higher rates of spontaneous abortion (miscarriages).

Clearly, ethylene oxide is a serious threat to health care workers and must be controlled!

## Is there a safe level of exposure?

Available scientific information on ethylene oxide shows a wide variety of toxic and carcinogenic hazards. It is CUPE's policy that there is no known "safe" exposure level for carcinogens. A level of 1 part per million (time weighted average) has been proposed in both the U.S. and Canada, but we have suggested 0.1 ppm as an **interim exposure level** until substitutes can be found or exposures totally eliminated through engineering controls. This is a level that can be attained through engineering and work practice control measures. In fact, a survey of Ontario hospitals in 1984 found no detectable EtO (that is, less than 0.1 ppm) in 17 of 28 personal samples.

## How much EtO are you exposed to?

Basically, the only way to know how much EtO you're exposed to is to measure the levels in the workplace air. There are several methods available for such monitoring, but they vary in their accuracy, cost and ease in analysis. The methods are:

1. Use of "passive flow" badges, or dosimeters, which are worn by a worker for an entire work shift. They are useful if you want to know the average exposure for the workday. These dosimeters are capable of measuring a 1 part per million 8–hour average exposure with a + 25% accuracy. For short-term "peak" exposures, however, the dosimeters are not useful.
   Since it is important to measure the peaks at specific times in the sterilizing cycle (for example, opening sterilizer doors, draining the EtO/water mixture) when levels are potentially high, as well as monitor for leaks, the lack of peak reading ability is a major drawback of the dosimeters.

2. Full cycle monitoring can be done using a number of instruments or sampling set–ups:
   - A portable infrared spectrometer or a portable gas analyzer. These are direct reading instruments which have meters that directly display the ethylene oxide level. These are very accurate, but also quite expensive.
   - Charcoal tubes attached to a low–flow pump. The pump can be worn by the worker to provide an accurate indication of personal exposure.

3. Checking for peaks and leaks using colorimetric tubes and a hand–operated pump, such as the Bendix or Gastec. An effective monitoring program should include:
   - Initial full–cycle measurements using one of the more sophisticated

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instruments or set-ups, such as gas analyzer or charcoal tubes.
- Monitoring for leak detection when equipment is first installed and then on a regular basis.
- Continuous monitoring with monitor providing a visible readout (e.g., on a meter) and with monitor attached to an audible alarm.
- Periodic monitoring of personal breathing zones with pump and charcoal tubes to assess individual worker exposures, to ensure continuous monitor is accurate or in the absence of continuous monitoring.
- Wearing of dosimeters to assess personal exposures.
- Keeping of accurate records which include exposure levels locations, time, etc. Records accessible to workers and reviewed by health and safety committee.

## How can ethylene oxide exposures be controlled?

There are a variety of ways to eliminate or reduce worker exposure to EtO:

1. **SUBSTITUTION.** Alternate substances with less of a health risk can possibly be substituted for EtO, but more research is needed on such substitutes. As well, tray-type table top sterilizers using EtO cartridges or ampoules could be replaced by sterilizers using the EtO/inert gas source.

2. **REDUCE ACTUAL EXPOSURE LEVELS**. Some of the most effective control methods are redesign of equipment and work area and improvement in ventilation or improving maintenance. Some examples are:
   - Ventilation on the sterilizer and aeration cabinet that exhausts directly to the outside.
   - Exhaust hoods or grilles at the sterilizer door, over the sewage drain and gas cylinders in the mechanical room.
   - Increase in aerator capacity so that all materials from the sterilizer can be handled in one load.
   - Modify sterilizers with purge systems that remove additional EtO through vacuum pulsing.
   - Development of a planned maintenance program that includes testing of the tanks, piping and sterilizer for leaks.
   - Positioning the aerator close to the sterilizer.

3. **ISOLATION.** Establish regulated areas (that is, separate rooms) restricting access to those workers whose presence is necessary to the EtO operation. These areas should be under negative pressure so that when the door is opened, air flows into the restricted area and not out into the general supply operations.

4. **CHANGE WORK PRACTICES.** A number of work practice controls will greatly reduce exposures to ethylene oxide.
   - Leave sterilizer area immediately after door is opened and stay out of area for a minimum of 15 minutes or time recommended by the sterilizer manufacturer; put articles in aerator immediately after the open door period.
   - Don't air out sterilized materials in

the general workplace; use a well–ventilated aerator (of course this means that the employer must provide one).

- Organize articles so that those requiring less aeration time can easily be removed or sterilize similar materials together so that time in the aerator is the same.
- Don't add new articles to the aeration cabinet until it's been completely emptied of the earlier load. Follow recommended times for aeration of particular materials.

5. **PERSONAL PROTECTIVE EQUIPMENT.** Use of personal protective equipment, including respirators, is the least effective method of controlling exposures to ethylene oxide.

However, workers exposed to EtO should be provided with special work clothes (e.g., coveralls, gloves and goggles), which must be left in a special hamper or adjacent area before the work area is left.

The requirements of a respirator program for EtO exposed workers go beyond general respirator programs. If workers must wear respirators in case of emergencies, such as leaks and spills, they must be declared medically able to wear a respirator, be fitted quantitatively (that is, actual exposure is measured while they are wearing a respirator), trained in respirator use and limitations and retrained on an annual basis.

Finally, it is crucial that all workers potentially exposed to ethylene oxide are made aware of the hazards and necessary controls and that workplace health and safety committees ensure that workers are effectively protected against EtO exposure.

For more information on ethylene oxide and other hazards to health care workers, contact:

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