California Department of Health Services

Ethylene Oxide (EtO) Fact Sheet

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HEALTH HAZARD SUMMARY: *Ethylene oxide causes cancer in experimental animals, and may increase the risk of cancer in workers who are exposed to it. Women exposed to EtO during pregnancy may have a higher rate of spontaneous abortion (miscarriage). EtO damages the sperm and testicles of test animals, reducing their fertility. Short-term over exposure to EtO can irritate your nose, throat, and eyes, and cause nausea, vomiting, and headache. Longer-term overexposure can damage the nerves in your feet and legs. Liquid EtO or EtO mixed with water is extremely irritating, and lengthy contact can burn your skin or cause an allergic skin reaction.*

HOW TO FIND OUT IF YOU ARE WORKING WITH ETHYLENE OXIDE

EtO is used to sterilize materials that are sensitive to heat or moisture, and most worker exposure happens during such use. Although most EtO is used in the production of other chemicals, these chemical manufacturing processes have very little potential for worker exposure, because the processes are usually tightly sealed and automated. Therefore, this Fact Sheet deals mainly with the hazards of using EtO as a sterilizing agent or fumigant. Ethylene oxide has many other names: EtO, ETO, EO, epoxyethane, oxirane, dihydrooxirene, dimethylene oxide, and others. Trade names include Anprolene,[R] Carboxide,[R] Cry-Oxide,[R] Oxyfume,[R] T-Gas,[R] Steroxide,[R] Pennoxide,[R] and others.

Odor and Appearance: Ethylene oxide is a colorless gas at room temperature. At temperatures below 52^{o}F., it is a clear liquid. Pure EtO is quite flammable and explosive; to reduce this hazard, EtO is usually sold as a mixture with non-flammable inert gases. Although EtO has a faint, sweet, ether-like odor, most people cannot smell it until the amount in the air is far above a safe concentration; therefore, you can be overexposed without knowing it. Do not rely on your sense of smell to warn you that you are being overexposed.

Your Right to Know: Under California's Hazard Communication Standard (Cal/OSHA regulation GISO 5194), your employer must tell you if you are working with any hazardous substances, including ethylene oxide, and must train you to use them safely.

If you think you may be exposed to hazardous chemicals at work, ask to see the Material Safety Data Sheets (MSDSs) for the products in your work area. An MSDS lists the hazardous chemical contents of a product, describes its health and safety hazards, and gives methods for its safe use, storage, and disposal. The MSDS should also include information on fire and explosion hazards, reactivity, first aid, and procedures for handling leaks and spills. Your employer must have an MSDS for any workplace product that contains a hazardous substance, and must make it available to employees on request.

This Fact Sheet is an aid for worker training programs. It does not take the place of a Material Safety Data Sheet.

HOW ETHYLENE OXIDE ENTERS AND AFFECTS YOUR BODY

Ethylene oxide enters your body when it is released into the air you breathe or when the liquid contacts your skin. The most common effect of short-term overexposure is irritation of the skin, eyes, or nose, as described below. Chronic exposure may cause nerve damage, cancer, or effects on the reproductive system.

Cancer: EtO causes cancer in laboratory animals, and studies of exposed workers suggest that it may cause cancer in humans. **Most of your exposure is likely to occur when you open a sterilizer door and transfer materials to an aerator.** It is important to minimize your exposure at these times.

Reproductive System: One study indicated that pregnant women who work with EtO as a sterilant may have an increased risk of spontaneous abortion (miscarriage). EtO causes a similar effect in pregnant animals. It also damages the sperm and testicles of male animals, reducing their fertility. We don't know whether it can affect men the same way. Workers briefly exposed at high levels (such as when opening sterilizer doors) develop chromosome damage. We don't know whether this damage affects their health or their offspring. EtO causes genetic mutations in male animals' sperm which can cause infertility of the male offspring or loss of the developing fetus.

Skin, Eyes, Nose, Throat, and Lungs: EtO can irritate your eyes, nose, and throat when levels in the air reach about 200 ppm (see "Legal Exposure Limits" below). Levels above 1000 ppm (or longer exposures at lower levels) can cause coughing, lung irritation, breathing difficulties, or chest pain. Severe overexposure can cause pulmonary edema (fluid in the lungs), which may not occur until hours after exposure. Pulmonary edema can be fatal; if you have difficulty breathing after a severe overexposure to EtO, you should go to a hospital. Liquid EtO or EtO in a water solution can burn your skin or cause an allergic rash if you allow lengthy direct contact. Effects on your skin may not appear until 1-5 hours after you are exposed. When your clothing (especially cloth or leather) becomes soaked with EtO, the clothing holds the EtO against your skin and can actually make the damage worse.

Nervous System: Short-term high-level exposure to EtO has a mild depressant effect on the brain, somewhat like alcohol. It can cause headaches, nausea, vomiting, drowsiness, weakness, and lack of coordination. Long-term exposure can damage the nerves in your feet and legs, causing numbness, tingling, and weakness. These long-term effects usually disappear within a few months after exposure to EtO is stopped. There is also some evidence that EtO may cause chronic effects on the brain, resulting in short-term memory loss and difficulty concentrating.

TESTS FOR EXPOSURE AND MEDICAL EFFECTS

Under Cal/OSHA regulations (GISO 5220), workers who are regularly exposed to EtO must be offered a complete physical examination at the beginning of their employment, and at least once a year thereafter if their exposure exceeds half of Cal/OSHA's Permissible Exposure Limit. The exam must include a work history, a medical history, and a complete blood count, and must give special attention to the blood, lungs, nervous system, reproductive system, eyes, and skin. Ethylene oxide does not stay in your body. There is no test that can be done after you are exposed that can tell you how much you have been exposed to. You have the right to see and copy your own medical records and records of your exposure to toxic substances. These records are important in determining whether your health has been affected by your work. Employers who have such records must keep them and make them available to you for at least 30 years after the end of your employment.

LEGAL EXPOSURE LIMITS

California's Division of Occupational Safety and Health (Cal/OSHA) sets and enforces workplace chemical exposure limits. Cal/OSHA has adopted a Permissible Exposure Limit (PEL) for the amount of ethylene oxide in your workplace air. The PEL for ethylene oxide is set at one part of ethylene oxide per million parts of air (1 "part per million," or 1 "ppm"). This is about equal to 1.8 milligrams of ethylene oxide per cubic meter of air (1.8 "mg/m3").

Legally, your exposure may be above the PEL at times, but only if it is below the PEL at other times, so that your *average* exposure for any 8-hour workshift is 1 ppm or less. There is also a Short-Term Exposure Limit; your exposure

must not exceed 5 ppm, averaged over any 15-minute period.

Under Cal/OSHA regulations (GISO 5220), if EtO is used where you work, your employer must measure the amount of EtO present in the air in your work area at least once, and must measure it again whenever there is a change in the work situation that could change the expo sure levels. If your exposure is more than half of the PEL, the monitoring must be repeated every six months; if it is above the PEL, monitoring must be repeated at least every three months, until your exposure has been below the PEL for two consecutive measurements. Your employer must notify you in writing of the results of all monitoring performed under the EtO regulations.

If you work with ethylene oxide and have any of the symptoms described above, you may be exposed at more than the legal limit. Talk to your supervisor and/or your union.

REDUCING YOUR EXPOSURE

Your employer is required to protect you from being exposed to chemicals at levels above the legal limits. When possible, employers must use engineering and admini strative controls rather than personal protective equipment to prevent overexposure. For information about how Cal/ OSHA and Cal/OSHA Consultation Service can help you and your employer, see the "Resources" section on page 4.

Substitution: Other methods of sterilization should be used when possible. EtO should only be used for materials which are sensitive to heat or moisture and, therefore, cannot be steam-sterilized.

During Sterilization: The sterilizer door should be kept sealed until the sterilization is completed and the EtO has been removed from the chamber. Gas detection instruments should be used to make periodic checks for leaks around door seals and gas lines.

Transferring Materials to the Aerator: You can be exposed through improper transfer of materials, direct handling of sterilized materials, incomplete aeration, or inadequate ventilation of the aerator. *The highest exposure occurs when the*

sterilizer door is first opened. Levels of EtO in the air may exceed 1000 ppm for a short time. You should leave the immediate area as soon as the door is opened, until enough time has passed for the EtO levels to go down (about 10-15 minutes; this should be determined by previous measurements). Special exhaust ventilation systems can be installed to reduce your exposure. About 5% of the EtO in the sterilizer stays in the sterilized material and the packaging materials, so the materials must be placed in a sealed aerator. Keep sterilized materials as far away from your breathing zone as possible. Avoid handling materials before they are aerated, by keeping materials in one container throughout the procedures. If you must handle individual items, use disposable impermeable gloves.

Changing the Tank: A double-tank system with a T-valve should be used to prevent the release of any EtO during the switch-over to a new tank. An exhaust ventilation system (a hood) should be installed to protect you against accidental releases. Personal protective equipment such as splash-proof goggles or face shield, gloves, and self-contained breathing apparatus may be necessary during some procedures. EtO is usually diluted with an inert gas to reduce its flammability. If pure EtO is used, special precautions must be taken to prevent fire and explosions.

At the Waste Discharge Point: Most sterilizers discharge EtO and water into an open sewer line through a floor drain. If the discharge is not controlled, it can be the largest source of EtO emissions. The high levels of EtO at the point of discharge can be controlled by special techniques, such as a liquid/gas separator and local exhaust ventilation. If the discharge is not controlled, you should not enter the area where the discharge is drained.

Location and Design of Facilities: If EtO levels exceed the PEL, sterilizers and aerators must be located so that personnel other than those required by the operations are not exposed, and the area must be posted to prevent entry by unauthorized personnel. Air flow direction should be toward the sterilizer and aerator locations. All sterilization processes should be centralized in one isolated area. Food, beverages, and smoking materials should not be brought into work areas.

Personal Protective Equipment: If engineering controls cannot sufficiently

reduce exposures, a respirator must be worn and a respiratory protection program must be developed, as outlined in Cal/OSHA regulations (GISO 5144). An industrial hygienist or other knowledgeable person should be consulted to ensure that the equipment is appropriate and is used correctly. Ethylene oxide has poor warning properties, so the cartridge on an air-purifying respirator could wear out and need replacement without your knowing that it was no longer effective. Therefore, only a supplied-air respirator is approved for use with EtO.

If skin contact with ethylene oxide is unavoidable or if splashing may occur, other protective equipment such as gloves, goggles, or faceshields should be worn. Protective clothing should be made of a material resistant to ethylene oxide (such as polychlorinated ethylene). Even the most resistant materials will be penetrated quickly and will become a hazard if they are not replaced often; therefore, we recommend using disposable gloves.

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