

Ethylene oxide (EtO)

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This publication provides practical workplace safety and health information to assist you in making your place of work safer. It is not legal advice. SAIF has made every effort to bring significant Oregon Occupational Safety and Health Administration (Oregon OSHA) regulations to your attention. Nonetheless, compliance with Oregon OSHA remains your responsibility. You should read and understand all relevant Oregon OSHA regulations that apply to your job site(s). You may want to consult with your own attorney regarding aspects of Oregon OSHA that may affect you.

Note: The information in this publication is time sensitive. Do not rely upon this document if its publication date is more than three years old. Please check the “Safety and health” section of our web site at saif.com/safetyandhealth for a more recent, printable copy. You’ll also find a variety of other valuable safety information designed to help your business prevent injuries and control costs.

Ethylene oxide

Ethylene oxide (EtO) is used as an intermediate chemical in the manufacturing of ethylene glycol, a chemical used to manufacture antifreeze and polyester. Ethylene oxide is also used in health care facilities to sterilize medical equipment. Other uses may include as an insect control for nuts, spices, and imported foods. Synonyms and trade names for ethylene oxide include dimethylene oxide, 1,2-epoxy ethane, and oxirane.

Scope and application

The ethylene oxide (EtO) standard applies to all occupational exposures, except where data shows that airborne concentrations do not exceed the action level or short-term exposure limit. If products containing EtO do not exceed these amounts, then the employer must maintain records of objective data supporting the exemption and the basis for reliance on the data.

Occupational exposure limits (OELs)

Oregon Occupational Safety and Health Division (Oregon OSHA)

1. Action level — is 0.5 ppm as an eight-hour time-weighted average (TWA)
2. Permissible exposure limit (PEL) — exposure limit is one part per million (ppm) as an eight-hour, time-weighted average (TWA)
3. Short-term exposure limit (STEL) — is five ppm as a 15-minute exposure

American Conference of Governmental Industrial Hygienists (ACGIH)

1. Threshold limit value – time-weighted average (TLV-TWA) is one ppm based on an eight-hour workday

National Institute for Occupational Safety and Health (NIOSH)

1. Recommended exposure limit (REL) is < 0.1 ppm based on a 10-hour workday.
2. Ceiling limit is five ppm based on a 10-minute excursion sample.

Sampling methods

1. Passive badge personal monitors are a simple way to measure occupational exposure to EtO. The badge is uncapped and snapped into a holder which is attached to the collar or lapel. When the sampling is complete, it is removed, capped, and returned to the laboratory for analysis. OSHA Method 49 approves the use of 3M Ethylene Oxide Monitor #3559 when sampling.
2. Silica gel sorbent tubes designed for sampling EtO in line with an air sampling pump can be worn by employees to measure EtO levels. This can be done over the course of an eight-hour workday to obtain an eight-hour time-weighted average (TWA) exposure. After sampling, the sorbent tube is analyzed by a laboratory and the levels are reported. Careful calibration of air sampling pumps is necessary when utilizing this method.

3. Direct reading instruments (portable or fixed) with EtO sensors on a person or in an area. These instruments record EtO levels over longer time periods and can estimate the eight-hour TWA exposures and short-term or peak exposure levels.

Monitoring requirements

Employers covered by the standard are required to conduct **initial monitoring** for ethylene oxide. The monitoring must include samples for eight-hour TWA and STEL. The monitoring needs to be:

- Representative of the employee's full shift or short-term exposure. The short-term sampling needs to be representative of the employee's highest exposure.
- Representative samples for each job classification taken in each work area and for each shift. This is not necessary if the employer has objective data to show the equivalency among the different work area and shifts.
- Employers may rely on previous monitoring if it has been conducted after June 15, 1983, and if the monitoring meets the sampling requirements and accuracy.

Periodic monitoring needs to be done if initial monitoring shows:

- The exposure(s) is at, or above, the action level, but at, or below, the TWA. If so, then the monitoring shall be repeated for each such employee at least every six months.
- The exposure(s) is above the TWA. If so, then the monitoring needs to be repeated at least every three months.
- The exposure(s) is above the short-term exposure limit. If so, then the monitoring needs to be repeated for each such employee at least every three months, and more often as necessary to evaluate exposure to access short-term exposures.

Termination of monitoring may be done if the sampling results in the following:

- If **periodic** monitoring reveals that employee exposures (of at least two consecutive measurements taken at least seven days apart) are below the action level, the employer may discontinue TWA monitoring for those employees whose exposures meet these requirements.
- If **initial** monitoring reveals that employee exposures are at, or below, the short-term exposure limit, the employer may discontinue short-term exposure monitoring for those employees whose exposures meet these requirements.
- If periodic monitoring reveals that employee exposures (of at least two consecutive measurements taken at least seven days apart) are at, or below, the short-term exposure limit, the employer may discontinue short-term exposure monitoring for those employees whose exposures meet these requirements.

Additional monitoring needs to be done if:

1. Employee exposures vary due to changes in the:
 - a. Production
 - b. Processes
 - c. Control equipment
 - d. Personnel or work practices

2. Whenever spills, leaks, ruptures, or other breakdowns occur that may lead to employee exposure, monitoring either area or personal sampling after cleanup is needed to ensure that exposures have returned to the previous levels.

Accuracy of the monitoring must be at the 95 percent confidence level, and within plus or minus 25 percent for airborne concentrations of EtO at the one ppm TWA, and to within plus or minus 35 percent for airborne concentrations at the action level of 0.5 ppm.

Employee notification of the monitoring shall be within 15 working days after the receipt of the results of any monitoring done under the standard. Notification is to be in writing. The written results can either be distributed to the employees or posted. If the levels are above the TWA, the notice must contain corrective actions being taken to reduce exposures.

Regulated areas

The employer needs to establish regulated areas if the ethylene oxide level exceeds either the TWA or the STEL. The area is to be:

1. Posted at all entrances with a sign that states:

DANGER
ETHYLENE OXIDE
AUTHORIZED PERSONNEL ONLY
CANCER HAZARD AND REPRODUCTIVE HAZARD
RESPIRATOR AND PROTECTIVE CLOTHING
MAY BE REQUIRED TO BE WORN IN THIS AREA.

2. Access to regulated areas shall be limited to authorized persons.
3. Authorized employees need to be trained to recognize the hazards associated with ethylene oxide.
4. Regulated areas need to be designed to minimize the number of employees exposed to ethylene oxide.
5. An employer at a multiemployer worksite who establishes a regulated area shall communicate the restrictions and locations of the regulated areas to the other employers at the worksite.

Engineering controls and work practices need to be instituted to reduce or maintain exposures at, or below, the TWA and the short-term exposure limit when feasible. If controls cannot reduce the exposure to below the TWA, then proper respiratory protection needs to be worn by the employees.

A written plan is necessary if the monitoring results show exposures over the TWA or STEL. This plan must detail how compliance will be reached and should include a schedule for periodic leak detection surveys as well as a plan for emergency situations. Written notice of the plan should be given to the employees. The plan should be reviewed at least every 12 months.

Note: The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA or STEL.

Respiratory protection

Wherever feasible engineering controls and work practices are not sufficient to reduce employee exposure to, or below, the TWA and to, or below, the excursion limit, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them using respiratory protection.

When handling ethylene oxide under the following circumstances, respirators shall be utilized:

- During the interval necessary to install or implement feasible engineering and work practice controls
- In work operations, such as maintenance and repair activities, vessel cleaning, or other activities for which engineering, and work practice controls are not feasible
- In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the TWA or excursion limit
- In emergencies

Where respiratory protection is required, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

Table 1: Minimum requirements for respiratory protection (EtO)

Condition of use or concentration of airborne EtO	Minimum required respirator
Equal to, or less than, 50 ppm	Full face-piece respirator with EtO approved canister, front-, or back-mounted
Equal to, or less than, 2,000 ppm	Positive-pressure-supplied air respirator, equipped with full face-piece, hood, or helmet, or Continuous-flow-supplied air respirator (positive pressure) equipped with hood, helmet, or suit
Above 2000 ppm or unknown (emergency)	Positive-pressure, self-contained breathing apparatus (SCBA), equipped with full face piece, or Positive-pressure full face-piece-supplied air respirator equipped with an auxiliary positive-pressure, self-contained breathing apparatus.
Firefighting	Positive-pressure self-contained breathing apparatus equipped with full face piece
Escape	Any respirator described above

Protective equipment and clothing

Required protective equipment and clothing needs to be provided at no cost to the employee.

Selection of protective equipment needs to be based on the condition of use and the type of hazard being prevented. The type of equipment may include, but is not limited to, eye-, face-, and skin-protective devices.

Emergencies

If the possibility of an emergency involving ethylene oxide exists, then appropriate written procedures need to be adopted and implemented.

Medical surveillance

- A. A medical surveillance program needs to be instituted for all employees exposed to ethylene oxide at, or above, the action level, without regard to the use of respirators, for at least 30 days a year.
- B. The medical surveillance shall be done under the supervision of a licensed physician, and the laboratory tests need to be conducted by an accredited lab.
- C. **Medical examinations** shall be provided at no cost to the employee, including no loss of pay and at a reasonable time and place. These examinations should include detailed information about an individual's work and medical history, and more specifically symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems, and the eyes and skin. Also, a complete blood count should be made. It should include a white cell count (including differential cell count,) red cell count, hematocrit, and hemoglobin. Examinations should be done on the following schedule:
 - 1. Prior to assignment of the employee to an area where exposure may be at, or above, the action level for at least 30 days a year
 - 2. At least annually for each employee exposed at, or above, the action level for at least 30 days in the past year
 - 3. At termination of employment, or reassignment to an area where exposure to EtO is not at, or above, the action level for at least 30 days a year
 - 4. As medically appropriate for any employee exposed during an emergency
 - 5. As soon as possible upon notification that an employee has developed signs or symptoms indicating possible overexposure to EtO, or if the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee's ability to produce a healthy child
 - 6. If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer needs to provide such examinations to effected employees per the physician's recommendations.
- D. The **employer needs to provide the examining physician** the following information:
 - 1. A full copy of the ethylene oxide standard
 - 2. A description of the employee's job duties as they relate to exposure to EtO
 - 3. The employee's actual or anticipated exposure level
 - 4. A description of any personal protective equipment used or to be used

5. Information from previous medical examinations that the current examining physician would not have
- E. The physician needs to provide the employer a **written opinion** for each examination that contains the following information:
1. The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk to his or her health
 2. Any recommended limitations on the employee's exposure or use of personal protective equipment
 3. The physician needs to state that the employee has been informed of any medical conditions which would be aggravated by exposure, and whether these conditions may have resulted from past exposures. The employee needs to be informed if further examination or treatment is needed.
 4. The physician shall not reveal in the written opinion to the employer specific findings or diagnoses unrelated to occupational exposure to EtO.
 5. The employer must provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

Hazard communication

- A. The employer needs to ensure that precautionary labels are affixed to all containers of EtO whose contents can cause exposure at, or above, the action level or whose contents may reasonably be foreseen to cause employee exposure above the short-term exposure limit. The labels must remain affixed when the containers leave the workplace. Labels should comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication Standard, and needs to include the following legend:

DANGER

CONTAINS ETHYLENE OXIDE

CANCER HAZARD AND REPRODUCTIVE HAZARD

- B. Labels should include a warning statement against breathing airborne concentrations of EtO.
- C. Chemical manufacturers and importers must provide appropriate labels and MSDSs to all downstream product users and must comply with the requirements as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication Standard.
- D. **Information and training** shall be provided to employees who are potentially exposed to EtO at, or above, the action level or above the short-term exposure limit at the time of initial assignment, and at least annually thereafter.

Information and training should include:

1. The requirements of the standard with an explanation of its contents, including Appendices A and B
2. Any operations in their work area where EtO is present

3. The location and availability of the written EtO final rule and the medical surveillance program
4. The methods and observations that may be used to detect the presence or release of EtO in the work area
5. The physical and health hazards of EtO
6. The measures employees can take to protect themselves from hazards associated with EtO exposure, including specific procedures the employer has implemented to protect employees from exposure to EtO
7. The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information

Recordkeeping

- A. Employers are required to keep specific records relating to their ethylene oxide compliance program. The records include, but are not limited to:
 1. Accurate record of objective data reasonably relied upon for exemption from the standard. This record needs to include the product qualifying for exemption, source of the objective data, testing protocol and analysis used, description of the operation qualifying for exemption, and other relevant information.
 2. Exposure measurements of the employees shall be maintained in an accurate record and should include the following: data of the measurement, operation being monitored, sampling, and analytical methodology, as well as evidence of their accuracy, number, duration, and results of samples, type of protective devices worn, if any, and the name, Social Security number, and exposure of the employees whose exposures are represented. **These records should be maintained for at least 30 years.**
 3. Medical surveillance records should be maintained for each employee and should include the following information: name and Social Security number of the employee, physician's written opinions, employee medical complaints related to EtO exposure, and copy of information provided to the physician as required by the standard. **These records should be maintained for the duration of employment plus 30 years.**

Resources

Oregon OSHA: Administrative rules and enforcement of the Oregon Safe Employment Act
<https://osha.oregon.gov/rules/pages/default.aspx>

Ethylene Oxide Sterilization Association (EOSA)
<http://eosa.org/>

Ethylene oxide: General occupational safety and health rules (Oregon OSHA)
<https://osha.oregon.gov/OSHARules/div2/div2Z-1047-ethyl-ox.pdf>

Ethylene oxide safety and health topics (Federal OSHA)
<https://www.osha.gov/ethylene-oxide>

Ethylene oxide fact sheet (Federal OSHA)
https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf

Ethylene Oxide: *Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents*, 7th Edition, American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio, 2001.