

NIOSH/OSHA STANDARDS COMPLETION PROGRAM

DRAFT TECHNICAL STANDARD AND
SUPPORTING DOCUMENTATION FOR

*** ETHYLENE OXIDE ***

NIOSH/OSHA Draft Technical Standard
and Supporting Documentation for ETHYLENE OXIDE

The basic text of this document contains the draft technical standard approved by the Joint Review Committee of the NIOSH/OSHA Standards Completion Program and the supporting documentation for the substance ETHYLENE OXIDE.

The SCP draft technical standards are recommendations to the Department of Labor for its consideration in rulemaking and have no legal status until final rules have been promulgated by that agency. This draft standard is provided for your information only.

The References and Sources, Respirator Table Documentation and Use/Exposure and Control Documentation are the working documents used by the various SCP working groups during the development of the draft technical standard and serve as the technical foundation for the standard. The classification for each substance and the regulatory statements were derived following a decision logic established for the various sections of the standard.

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(a) Definitions. (1) "Permissible exposure" means exposure of employees to airborne concentrations of ethylene oxide not in excess of 50 parts per million (ppm) (90 milligrams per cubic meter (mg/M3)) averaged over an eight-hour work shift (time weighted average), as stated in § 1910.1000, Table Z-1.

(2) "Action level" means one-half of the permissible exposure for ethylene oxide averaged over an eight-hour work shift.

(b) Initial determination and exposure measurement. (1) Each employer who has a place of employment in which ethylene oxide is released into the workplace air shall determine if there is any possibility that any employee may be exposed to airborne concentrations of ethylene oxide above the permissible level. The initial determination shall be made each time there is a change in production, process, or control measures which may result in an increase in airborne concentrations of ethylene oxide.

(2) A written record of the initial determination shall be made and shall contain at least the following information:

(i) Any information, observations, or calculations which may indicate employee exposure to ethylene oxide;

(ii) Any measurements of ethylene oxide taken;

(iii) Any employee complaints of symptoms which may be attributable to exposure to ethylene oxide; and

(iv) Date of initial determination, work being performed at the time, location within work site, and employees considered.

(3) If the employer determines that any employee may be exposed to ethylene oxide above the permissible exposure, the exposure of the employee in each work operation who is believed to have the greatest exposure shall be measured. The exposure measurement shall be representative of the maximum eight-hour time weighted average exposure of the employee.

(4) If the exposure measurement taken pursuant to paragraph (b) (3) of this section reveals employee exposure to ethylene oxide above the action level, the employer shall:

(i) Identify all employees who may be exposed above the permissible level; and

(ii) Measure the exposure of the employees so identified.

(5) If an employee exposure measurement reveals that an employee is exposed to ethylene oxide above the action level, but not above the permissible exposure, the exposure of that employee shall be measured at least every three months.

(6) If an employee exposure measurement reveals that an employee is exposed to ethylene oxide above the permissible exposure, the employer shall:

(i) Measure the exposure monthly of the employee so exposed; and

(ii) Institute control measures as required by paragraph (d) of this section; and

(iii) Individually notify, in writing, within five days, every employee who is found to be exposed to ethylene oxide above the permissible exposure. The employee shall also be notified of the results of the exposure measurements and of the corrective action being taken to reduce the exposure to below the permissible exposure.

(7) If two consecutive employee exposure measurements taken at least one week apart reveal that the employee is exposed to ethylene oxide below the action level, the employer may terminate measurement for the employee.

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(8) For purposes of this paragraph, employee exposure is that which would occur if the employee were not using a respirator.

(c) Methods of measurement. (1) An employee's exposure shall be obtained by any combination of long term or short term samples which represents the employee's actual exposure averaged over an eight-hour work shift (See Appendix B (IV) of this section).

(2) The method of measurement shall have an accuracy, to a confidence level of 95 percent, of not less than that given in Table 1.

Table 1

Concentration

Required Accuracy

Above permissible exposure

$\pm$ 25%

At or below permissible exposure

and above the action level

$\pm$ 35%

At or below the action level

$\pm$ 50%

(d) Compliance. (1) No employee shall be exposed to ethylene oxide above the permissible exposure as defined in paragraph (a)(1) of this section.

(2) Employee exposures to airborne concentrations of ethylene oxide shall be controlled to at or below the permissible exposure by engineering and work practice controls.

(i) Engineering and work practice controls shall be instituted to reduce exposures to at or below the permissible exposure, except to the extent that such controls are not feasible.

(ii) Wherever engineering and work practice controls are not sufficient to reduce exposures to at or below the permissible exposure, they shall nonetheless be used to reduce exposure to the lowest level feasible and shall be supplemented by respirators in accordance with paragraph (d)(4) of this section.

(3) Engineering controls. (i) When local exhaust is used to control exposure, measurements which demonstrate system effectiveness, for example, air velocity or static pressure, shall be made at least every three months. Measurements of system effectiveness shall also be made within five days of any change in production, process, or control which might result in an increase in airborne concentrations of ethylene oxide.

(ii) In the design of open surface tank ventilation for the purposes of § 1910.94(d), operations involving ethylene oxide shall be classified as B-1 at 21 degrees C (70 degrees F).

(4) Compliance with the permissible exposure shall not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement engineering or work practice controls; or

(ii) In work situations in which engineering and work practice controls are not feasible; or

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(iii) To supplement engineering and work practice controls when such controls fail to reduce airborne concentrations of ethylene oxide to at or below the permissible exposure; or

(iv) For operations which require entry into tanks or closed vessels; or
(v) In emergencies.

(5) Where respirators are needed and permitted under this paragraph to reduce employee exposure, the employer shall select and provide the appropriate respirator from Table 2 and shall ensure that the employee uses the respirator provided. When an employee informs his employer that he is experiencing eye irritation from ethylene oxide while wearing a respirator allowed in Table 2, the employer shall provide and ensure that the employee use an equivalent respirator with a full facepiece, helmet or hood.

TABLE 2 RESPIRATORY PROTECTION FOR ETHYLENE OXIDE

CONDITION	PERMISSIBLE RESPIRATORY PROTECTION*
Vapor Concentration	
500 ppm or less	Any supplied-air respirator. ----- Any self-contained breathing apparatus.
800 ppm or less	Any supplied-air respirator with a full facepiece helmet or hood. ----- Any self-contained breathing apparatus with full facepiece.
Greater than 800 ppm or entry and escape from unknown concentrations	Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode. ----- A combination respirator which includes a Type C supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure or continuous-flow mode and an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive pressure mode.
Fire Fighting	Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.
Escape	Any gas mask providing protection against organic vapors. ----- Any escape self-contained breathing apparatus.

* Use of supplied-air suits may be necessary to prevent skin contact and respiratory exposure from airborne concentrations of ethylene oxide. Supplied-air suits should be selected, used, and maintained under the immediate supervision of persons knowledgeable in the limitation and potential life endangering characteristics of supplied-air suits. Where

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supplied-air suits are used above a concentration which may be immediately dangerous to life and health (800 ppm), an auxiliary positive-pressure self-contained breathing apparatus must also be worn.

(6) Respirators shall be approved by the Mining Enforcement and Safety Administration (formerly Bureau of Mines) or by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(7) The employer shall institute a respiratory protection program in accordance with § 1910.134(b), (d), (e), and (f).

(e) Fire and safety. (1) The employer shall familiarize himself with the information contained in the Substance Technical Guidelines (Appendix B of this section) for ethylene oxide.

(2) For the purpose of compliance with § 1910.309, locations classified as hazardous locations due to the presence of ethylene oxide shall be Class I, Group B, in accordance with Section 501-5(a), except that Group C equipment may be used if such equipment is isolated by sealing all conduit 0.5 inch size or larger.

(3) For the purpose of compliance with § 1910.157, ethylene oxide is classified as a Class B fire hazard.

(4) For the purpose of compliance with § 1910.178, locations classified as hazardous locations due to the presence of ethylene oxide shall be Class I, Group B.

(5) For the purpose of compliance with § 1910.106, liquid ethylene oxide is classified as a Class IA flammable liquid.

(6) Where a fan is located in ductwork and where ethylene oxide is present in the ductwork in concentrations greater than 7500 ppm (approximately 25% of the lower flammable limit), the fan rotating element shall be of nonsparking material or the casing shall consist of, or be lined with, nonsparking material. There shall be sufficient clearance between the fan rotating element and the fan casing so as to prevent contact.

(7) Sources of ignition such as smoking or open flames are prohibited wherever ethylene oxide is handled, used or stored.

(8) Ethylene oxide shall be stored away from heat and so as not to come in contact with strong oxidizers, strong acids, alkalis, anhydrous chlorides of iron, anhydrous chlorides of aluminum, anhydrous chlorides of tin, iron oxide, and aluminum oxide.

(f) Personal protective equipment. (1) Employers shall provide and ensure that employees use appropriate protective clothing and equipment necessary to prevent any possibility of skin contact with liquid ethylene oxide. Face shields shall comply with § 1910.133 (a)(2), (a)(4), (a)(5), and (a)(6).

(2) Employers shall ensure that clothing wet with liquid ethylene oxide is placed in closed containers for storage until it can be discarded or until the employer provides for the removal of ethylene oxide from the clothing. If the clothing is to be laundered or otherwise cleaned to remove the ethylene oxide, the employer shall inform the person performing the operation of the hazardous properties of ethylene oxide.

(3) Employers shall ensure that any clothing which becomes wet with and non-impervious clothing which becomes contaminated with liquid ethylene oxide be removed immediately and not reworn until the ethylene oxide is removed from the clothing.

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(4) Employers shall provide and ensure that employees use splash-proof safety goggles which comply with § 1910.133(a)(2)-(a)(6) where liquid ethylene oxide may contact the eyes.

(5) Where there is any possibility that an employee's eyes may be exposed to liquid ethylene oxide, employers shall provide an eye-wash fountain within the immediate work area for emergency use.

(g) Spills and disposal. (1) In the event that ethylene oxide is spilled the employer shall immediately eliminate potential sources of ignition, provide available ventilation and then clean up the spill.

(2) Liquid ethylene oxide shall not be allowed to enter a confined space, such as a sewer, because of the possibility of an explosion. Sewers designed to preclude the formation of explosive vapors are permitted.

(h) Sanitation. Employers shall ensure that employees whose skin becomes contaminated with ethylene oxide immediately wash or shower to remove any ethylene oxide from the skin.

(i) Training and information. (1) Each employer who has a workplace in which ethylene oxide is present shall keep a copy of this regulation with Appendixes A, B and C at the workplace. This material shall be made readily available to affected employees.

(2) Each employer who has employees exposed to ethylene oxide above the action level without regard to the use of respirators, or employees who may have any possibility of skin contact or who may have eye contact with liquid ethylene oxide, or employees who work where ethylene oxide presents a fire or explosion hazard, shall annually:

(i) Inform affected employees of the information contained in the Substance Safety Data Sheet for ethylene oxide (Appendix A of this section);

(ii) Advise affected employees as to the signs and symptoms of exposure to ethylene oxide.

(iii) Instruct affected employees to advise the employer of the development of signs and symptoms of overexposure to ethylene oxide which are listed in Appendix A of the section; and

(iv) Provide training to ensure that employees understand the precautions of safe use, emergency procedures, and the correct use of protective equipment relative to ethylene oxide.

(j) Medical surveillance. (1) The employer shall provide medical procedures as required by this paragraph. All medical procedures shall be performed by or under the supervision of a physician at no cost to the employee.

(2) Preplacement medical examination. The employer shall make available to each employee who is exposed, or will be exposed, to airborne concentrations of ethylene oxide above the action level, without regard to the use of respirators, or employees who may have any possibility of skin contact or who may have eye contact with liquid ethylene oxide, a preplacement medical examination which must include the following:

(i) A medical history and physical examination with emphasis on the eyes, blood, lungs, liver, kidneys, nervous system and skin;

(ii) Forced vital capacity (FVC) and forced expiratory volume-one second (FEV (1 second)) tests;

(iii) 14" x 17" chest roentgenogram;

(iv) A complete blood count to include at least red and white cell count, a differential smear, hemoglobin and hematocrit.

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(3) Periodic medical examination. The employer shall make available to each employee exposed to airborne concentrations of ethylene oxide above the action level, without regard to the use of respirators, or employees who may have any possibility of skin contact or who may have eye contact with liquid ethylene oxide, twelve months from the date of the employee's first exposure, and every twelve months thereafter, a periodic medical examination which must include the following:

(i) A medical history and physical examination with emphasis on the eyes, blood, lungs, liver, kidneys, nervous system and skin;

(ii) Forced vital capacity (FVC) and forced expiratory volume-one second (FEV (1 second)) tests;

(iii) A 14" x 17" chest roentgenogram;

(iv) A complete blood count to include at least red and white cell count, a differential smear, hemoglobin and hematocrit.

(4) Alternative medical procedures. If the examining physician chooses to use alternative medical procedures to those specified in paragraphs (j)(2) and (j)(3) of this section, the employer may accept such alternative medical procedures as meeting the requirements of this section provided that the employer:

(i) Obtains a statement from the examining physician setting forth the alternative medical procedures, the rationale for substitution, and evidence that they will be equally effective;

(ii) Informs each exposed worker of the fact that alternative medical procedures to those required in paragraphs (j)(2) and (j)(3) of this section are to be made available.

(5) Interim medical examination. The employer shall provide an interim medical examination for the employee if the employee informs the employer of any of the signs or symptoms of exposure to ethylene oxide which are listed in Appendix A which the employee suspects are caused by exposure to ethylene oxide.

(6) Informing the physician. The employer shall provide to the physician performing any medical examination required by this section the following information:

(i) A copy of this regulation with Appendixes A, B, and C for ethylene oxide;

(ii) A description of the affected employee's duties as they relate to his exposure to ethylene oxide;

(iii) A description of any personal protective equipment and respirators required to be used;

(iv) The results of any measurements which may indicate the affected employee's exposure;

(v) The affected employee's anticipated exposure level; and

(vi) Upon request of the physician, any available information from previous medical examinations of the affected employee.

(7) Where a medical examination is required by paragraphs (j)(2), (j)(3), or (j)(5) of this section, following such examination the employer shall obtain from the examining physician a written opinion which conforms with paragraph (j)(8) of this section.

(8) Physician's written opinion. (i) The physician's written opinion by the examining physician shall specifically state:

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(A) Whether the employee has any detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to ethylene oxide;

(B) Any recommended limitations upon the employee's exposure to ethylene oxide, including limitations upon the use of personal protective equipment and respirators;

(C) That the employee has been informed by the physician of any detected medical conditions which require further medical examination or treatment.

(ii) The physician's written opinion shall not reveal specific medical findings or diagnoses unrelated to the employee's employment.

(iii) The employer shall provide the employee with a copy of the physician's written opinion.

(9) Results of tests. Where a preplacement or periodic medical examination is required by paragraphs (j)(2) or (j)(3) of this section, following such examination the employer shall obtain from the examining physician for inclusion in the employee's medical record:

(i) A recording of the results of the pulmonary function tests and the blood tests;

(ii) The 14" x 17" chest roentgenogram when required, or a medically acceptable copy;

(iii) Where alternative medical procedures have been performed in accordance with paragraph (j)(4) of this section, a recording of such alternative procedures.

(10) No employee shall be exposed to ethylene oxide in such a way as would put the employee at increased risk of material impairment of his health from such exposure. The employer shall base this decision on any information available including the physician's written opinion.

(11) No medical procedure which would be performed pursuant to paragraphs (j)(2) or (j)(3) of this section need be performed if records of a previous such procedure performed within the past six months are acceptable to the examining physician.

(12) If an employee refuses any required medical examination, the employer shall inform the employee of the possible health consequences of such refusal and obtain a signed statement from the employee indicating that the employee understands the risk involved by refusal to be examined.

(13) The employer shall provide emergency medical treatment for any employee injured through exposure to ethylene oxide.

(k) Recordkeeping. (1) Exposure determination. (i) The employer shall keep an accurate record of all determinations required to be made pursuant to paragraph (b)(1) of this section.

(ii) This record shall include the written determination required in paragraph (b)(2) of this section.

(iii) This record shall be maintained until replaced by a more recent record.

(2) Exposure measurements. (i) The employer shall keep an accurate record of all measurements taken to determine employee exposure to ethylene oxide.

(ii) This record shall include:

(A) The date of measurement;

(B) Operations involving exposure to ethylene oxide which are being monitored;

(C) Sampling and analytical method used and evidence of their accuracy;

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- (D) Number, duration, and results of samples taken; and
- (E) Name, social security number and exposure of the employee monitored.
- (iii) This record shall be maintained until replaced by a more recent record but in no event for less than one year.
- (3) Mechanical ventilation. (i) When mechanical ventilation is used as an engineering control, the employer shall maintain an accurate record of the measurements demonstrating the effectiveness of such ventilation required by paragraph (d)(3) of this section.
 - (ii) This record shall include:
 - (A) Date of measurement;
 - (B) Type of measurement taken;
 - (C) Result of measurement.
 - (iii) These records shall be maintained for at least one year.
- (4) Employee training and information. (i) The employer shall keep an accurate record of all employee training and information required by paragraph (i) of this section.
 - (ii) This record shall include:
 - (A) Date of training;
 - (B) Name and social security number of employee trained;
 - (C) Content or scope of training provided.
 - (iii) This record shall be maintained until replaced by a more recent record.
- (5) Medical surveillance. (i) The employer shall keep an accurate record of employee medical surveillance required by paragraph (j) of this section.
 - (ii) This record shall include:
 - (A) The name and social security number of the employee;
 - (B) Results of tests required by paragraph (j)(2) and (j)(3) of this section and results of any tests conducted pursuant to paragraphs (j)(4) of this section;
 - (C) Any employee medical complaints relative to exposure to ethylene oxide;
 - (D) A copy of information provided to the physician pursuant to paragraph (j)(6)(ii), (iii), (iv), (v), and (vi) of this section.
 - (E) Physician's written opinion; and
 - (F) A signed statement of any refusal to be examined.
 - (iii) This record shall be maintained for the duration of and for thirty years after termination of the employment of the affected employee.
- (6) Access to records. (i) All records required to be maintained by this section shall be made available upon request to authorized representatives of the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health.
 - (ii) Each employee or former employee shall have access to the exposure determination and exposure measurement records required to be maintained by this section which indicate his own exposure to ethylene oxide.
 - (iii) Employee medical records required to be maintained by this section shall be made available upon written request to a physician designated by the employee or former employee.
- (1) Employee observation of measurement. (1) The employer shall give each employee or his representative an opportunity to observe any measurement of his exposure to ethylene oxide which is conducted pursuant to this section.

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(2) When observation of measurement of employee exposure to ethylene oxide requires entry into an area where the use of personal protective devices, including respirators, is required, the observer shall be provided with and required to use such equipment and comply with all other applicable safety procedures.

(3) Without interfering with the measurement, observers shall be entitled to:

- (i) Receive an explanation of the measurement procedure.
- (ii) Visually observe all steps related to the measurement of the airborne concentration of ethylene oxide that are being performed at the place of exposure; and
- (iii) Record the results obtained.

NOTE: The information contained in the following appendix for ethylene oxide is neither intended, by itself, to create any additional obligations not otherwise imposed, nor detract from any existing obligations. To the extent that the information supplements this regulation for ethylene oxide, it is advisory in nature.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET
FOR ETHYLENE OXIDE

I. SUBSTANCE IDENTIFICATION

- A. Substance: Ethylene oxide
- B. Permissible Exposure: 50 parts of ethylene oxide per million parts of air (ppm) (90 milligrams of ethylene oxide per cubic meter of air (mg/M3)) averaged over an eight-hour work shift.
- C. Appearance and Odor: Colorless liquid or gas with an odor like ether that is irritating in high concentrations.

II. HEALTH HAZARD DATA

- A. Ways in which the chemical affects your body: Ethylene oxide can affect your body if you inhale it or if it comes in contact with your eyes or skin. It may also affect your body if you swallow it.
- B. Effects of Overexposure:
 - 1. Short-term Exposure: Breathing high concentrations of ethylene oxide may cause nausea, vomiting, irritation of the eyes, nose, throat and lungs with severe breathing difficulties which may be delayed in onset. When excessive amounts of ethylene oxide are inhaled, drowsiness and unconsciousness may occur. Continued skin contact with the liquid or solutions of ethylene oxide may cause burns. When ethylene oxide is spilled on the clothes or shoes and the clothes or shoes are not

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removed, immediate burns may occur. (Contaminated shoes should be discarded.) The liquid or solutions of ethylene oxide may cause severe eye irritation and eye damage. The vapor may irritate or burn moist skin. Large amounts of ethylene oxide evaporating from the skin may cause frostbite.

2. Long-term Exposure: Repeated exposure to ethylene oxide may cause skin sensitization. Ethylene oxide has been found to cause cancer in female mice exposed to ethylene oxide for prolonged periods.
3. Reporting Signs and Symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to ethylene oxide.

III. EMERGENCY FIRST AID PROCEDURES

- A. Eye Exposure: If liquid ethylene oxide or strong concentrations of ethylene oxide vapor get into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.
- B. Skin Exposure: If liquid ethylene oxide or strong concentrations of ethylene oxide vapor get on your skin, immediately flush the contaminated skin with water. If liquid ethylene oxide or strong concentrations of ethylene oxide vapor penetrate your clothing, remove the clothing immediately and flush the skin with water. If irritation or burns are present after washing, get medical attention promptly.
- C. Breathing: If you or any other person breathes in large amounts of ethylene oxide move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.
- D. Swallowing: When solutions containing ethylene oxide have been swallowed and the person is conscious, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.
- E. Rescue: Move affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency rescue procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the locations of the emergency rescue equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

- A. Respirators: Respirators are not the best way to control exposure to ethylene oxide. You can only be required to wear them for routine use if your employer is in the process of installing controls or control measures prove inadequate. You may be required to wear respirators for non-routine

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activities or in emergencies. If respirators are worn, they must have a Mining Enforcement and Safety Administration (MESA) or National Institute for Occupational Safety and Health (NIOSH) approval label. (Older respirators may have a Bureau of Mines approval label.) For effective protection, respirators must fit your face and head snugly. Respirators should not be loosened or removed in work situations where their use is required. If you can smell ethylene oxide while wearing a respirator, the respirator is not working correctly; go immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

- B. Protective Suits: In some work situations the wearing of supplied-air suits or other impervious clothings such as acid suits may be necessary. Your employer should instruct you in their proper use and operation.
- C. Protective Clothing: You must wear appropriate protective clothing and equipment to prevent any possibility of skin contact with liquid ethylene oxide. Replace or repair impervious clothing which has developed leaks.
- D. Eye Protection: You must wear splash-proof safety goggles where liquid ethylene oxide may contact your eyes.

V. PRECAUTIONS FOR SAFE USE, HANDLING AND STORAGE

- A. Ethylene oxide is a flammable liquid. Its vapors can easily form explosive mixtures with air over a wide range of concentrations.
- B. Ethylene oxide must be stored in tightly closed containers in a cool, well ventilated area away from heat, strong oxidizers, strong acids, alkalies, anhydrous chlorides of iron, anhydrous chlorides of aluminum and anhydrous chlorides of tin, and oxides of iron and aluminum.
- C. Sources of ignition such as smoking and open flames are prohibited wherever ethylene oxide is handled, used or stored.
- D. Metal containers in operations involving the transfer of five gallons or more ethylene oxide should be grounded and bonded.
- E. You must immediately remove any non-impervious clothing that becomes contaminated with liquid ethylene oxide and this clothing must not be reworn until the ethylene oxide is removed from the clothing.
- F. Clothing wet with liquid ethylene oxide can be easily ignited. You must immediately remove this clothing and it must not be reworn until the ethylene oxide is removed from the clothing.
- G. If your skin becomes contaminated with ethylene oxide, you must immediately wash or shower to remove any ethylene oxide from your skin.
- H. Fire extinguishers and eye flushing facilities, where provided, must be readily available and you should know where they are and how to operate them.

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- I. Ask your supervisor where ethylene oxide is used in your work area and for any additional safety and health rules.
- VI. ACCESS TO INFORMATION
 - A. Each year your employer is required to inform you of the information contained in this Substance Safety Data Sheet for ethylene oxide. In addition, your employer must instruct you in the safe use of ethylene oxide, emergency procedures, and the correct use of protective equipment.
 - B. Your employer is required to determine whether you are being exposed to ethylene oxide. You or your representative have the right to observe employee exposure measurements and to record the results obtained. If your employer determines that you are being overexposed, he is required to inform you of the exposure and the actions which are being taken to reduce your exposure.
 - C. Your employer is required to keep records of your exposure and medical examinations. Your employer is required to keep exposure data for at least one year and to keep medical data during your employment, and for a period of thirty years following your termination of employment. Your employer is required to make the exposure data available to you upon your request. Your employer is also required to release your medical records to your physician upon your written request.
 - D. Your employer must give you a copy of the physicians written opinion for any physical examination required by this standard.

NOTE: The information contained in the following appendix for ethylene oxide is neither intended, by itself, to create any additional obligations not otherwise imposed, nor detract from any existing obligations. To the extent that the information supplements this regulation for ethylene oxide, it is advisory in nature.

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES
FOR ETHYLENE OXIDE

- I. PHYSICAL AND CHEMICAL DATA
 - A. Substance Identification
 - 1. Synonyms: Dimethylene oxide; 1,2-epoxyethane; oxirane
 - 2. Formula: C_2H_4O
 - 3. Molecular weight: 44.1
 - B.
 - 1. Boiling point (760 mm Hg): 10.4 C (50.7 F)
 - 2. Specific gravity (water = 1): 0.88
 - 3. Vapor density (air = 1 at boiling point of ethylene

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- oxide): 1.5
4. Melting point: -113 C (-171 F)
 5. Vapor pressure at 20 C (68 F): 1095 mm Hg
 6. Solubility in water, % by weight at 20 C (68 F): Miscible in all proportions
 7. Evaporation rate (butyl acetate = 1): Not applicable
 8. Appearance and odor: Colorless liquid or gas with an odor like ether that is irritating in high concentrations.

II. FIRE, EXPLOSION AND REACTIVITY HAZARD DATA

A. Fire

1. Flash point: less than -17.8 C (0 F) (closed cup)
2. Autoignition temperature: 429 C (804 F) (gas in air); 570 C (1058 F) (pure liquid)
3. Flammable limits in air, % by volume: Lower: 3.0; Upper: 100
4. Extinguishing media: Dry chemical
5. Special fire-fighting procedures: Do not use a solid stream of water since a stream will scatter and spread the fire. Use water spray to cool containers exposed to a fire. Fires involving large quantities of liquid ethylene oxide are difficult to extinguish. Such fires will continue to burn until the ethylene oxide is diluted with at least 22 parts of water to one part of ethylene oxide, by volume.
6. Unusual fire and explosion hazards: Ethylene oxide is a flammable liquid. Its vapors can easily form explosive mixtures with air over a wide range of concentrations. All ignition sources must be controlled where ethylene oxide is used, handled or stored. Ethylene oxide vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which ethylene oxide is handled.
7. For purposes of conforming with the requirements of 29 CFR 1910.106, ethylene oxide is classified as a Class IA flammable liquid. For example, 7500 ppm, approximately one-fourth of the lower flammable limit, is one situation in which ethylene oxide is considered to be a potential fire and explosion hazard.
8. For purposes of complying with 29 CFR 1910.309, the classification of hazardous locations as described in Article 500 of the National Electrical Code for ethylene oxide shall be Class I, Group B, except that Group C equipment may be used if such equipment is isolated in accordance with Section 501-5(a) by sealing all conduit 0.5 inch size or larger.

B. Reactivity

1. Conditions contributing to instability: Ethylene oxide polymerizes and explodes when heated above 427 C (800 F).
2. Incompatibilities: Contact with even small amounts of strong acids, alkalis, oxidizers, active catalytic surfaces such as anhydrous chloride of iron, anhydrous

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chloride of aluminum and anhydrous chloride of tin, or with oxides of iron or aluminum can cause violent polymerization and explosion, especially when ethylene oxide is above 29 C (85 F).

3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide) may be released in a fire involving ethylene oxide.
4. Special precautions: Liquid ethylene oxide will attack some forms of plastics, rubber and coatings.

III. SPILL, LEAK AND DISPOSAL PROCEDURES

- A. If ethylene oxide is spilled or leaked, the following steps should be taken:
 1. Remove all ignition sources.
 2. Ventilate area of spill or leaks.
 3. If in the gaseous form, stop flow of gas. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place in the open air, and repair leak or allow cylinder to empty.
 4. If in liquid form, for small quantities, absorb on paper towells. Evaporate in a safe place (such as a fume hood). Allow sufficient time for vapor to completely clear the duct work, then burn the paper. Large quantities can be reclaimed or collected and atomized in a suitable combustion chamber. Ethylene oxide may not be allowed to enter a confined space, such as a sewer, because of the possibility of explosion. Sewers designed to preclude the formation of explosive concentrations of ethylene oxide vapors are permitted.
- B. Persons not wearing protective equipment should be restricted from areas of spills or leaks until cleanup has been completed.
- C. Waste disposal methods: Liquid ethylene oxide may be disposed of by atomizing in a suitable combustion chamber.

IV. MONITORING AND MEASUREMENT PROCEDURES

- A. EXPOSURE ABOVE THE ACTION LEVEL: Measurements taken for the purpose of determining employee exposure under this section are best taken such that the eight-hour exposure may be determined from a single eight-hour sample or two four-hour samples. Several short-time interval samples (up to 30-minutes) may also be used to determine the average exposure level. Air samples should be taken in the employee's breathing (air that would most nearly represent that inhaled by the employee). Sampling and analyses may be performed by instruments such as detector tubes certified by NIOSH under 42 CFR part 84, portable direct-reading instruments, dosimeters, or gas and vapor adsorption tubes with subsequent chemical analysis. The method of measurement must determine the concentration of ethylene oxide to plus or minus 35%.
- B. EXPOSURE ABOVE THE PERMISSIBLE EXPOSURE: The monitoring and measurements under this section should be essentially the same as described above. More than three (3) measurements

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should be taken during the work shift so that increased confidence may be placed in the judgement that the employee has or has not, in fact, been exposed in excess of the permissible limit. Samples should be collected as described in paragraph IV. A. Laboratories performing chemical analyses should be accredited in Industrial Hygiene Chemistry by the American Industrial Hygiene Association. The method of measurement must determine the concentration of ethylene oxide to plus or minus 25%.

C. METHODS: Methods meeting these accuracy requirements are available from the National Technical Information Service, U. S. Department of Commerce, Springfield, Virginia 22161 under the title "NIOSH Analytical Methods for Set T" (Order number XXXXXXXXXX).

D. QUALIFIED PERSONS: Since many of the duties relating to employee protection are dependent on the results of monitoring and measuring procedures, employers should assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. MISCELLANEOUS PRECAUTIONS

A. Store in a cool, well ventilated area.

B. Use of supplied-air suits or other impervious coverings (such as acid suits) may be necessary to prevent skin irritation from ethylene oxide. Supplied-air suits should be selected, used, and maintained under the immediate supervision of persons knowledgeable in the limitations and potential life endangering characteristics of supplied-air suits.

C. Metal containers in operations involving the transfer of five gallons or more of ethylene oxide should be grounded and bonded.

D. Do not use flame to detect leaks.

E. High exposures can occur when transferring ethylene oxide in open containers.

F. Employers should advise employees of all plant areas and operations where their exposure to ethylene oxide could occur.

VI. COMMON OPERATIONS

Common operations in which exposure to ethylene oxide is likely to occur are: During its production and its use as a fumigant and sterilizing agent; and as an intermediate in the manufacture of glycols, glycol ethers, alkanolamines, ethanolamines, and derived products such as plastics, surface active agents.

NOTE: The information contained in the following appendix for ethylene oxide is neither intended, by itself, to create any additional obligations—not otherwise imposed, nor detract from any existing obligations. To the extent the information supplements this regulation for ethylene oxide, it is advisory in nature.

APPENDIX C - MEDICAL SURVEILLANCE GUIDELINES

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I. ROUTE OF ENTRY

Inhalation.

II. TOXICOLOGY

Ethylene oxide is an irritant of the eyes, respiratory tract, and skin; at high concentrations it causes narcosis; it is carcinogenic in female mice. Exposure of several species of animals to concentrations calculated to be greater than 1000 ppm for 2 hours caused lacrimation and nasal discharge followed by gasping and labored breathing; corneal opacity was observed in guinea pigs. Delayed effects occurred after several days and included vomiting, diarrhea, dyspnea, pulmonary edema, paralysis of hind quarters, convulsions, and death; autopsy findings were degenerative changes of the lungs, liver, and kidneys. Mice were accidentally placed for 150 days on ground corn cob bedding treated with ethylene oxide; all of the males died with massive hemorrhage in the thoracic and abdominal cavities, multiple hemorrhages in other sites, failure of the blood to clot, and jaundice; few females were similarly affected but 86 percent of them, 300 to 900 days old, developed tumors of various kinds and sites including ovarian, pulmonary, and malignant lymphomas with leukemia; the incidence of tumors in control females was low. In humans the early symptoms are irritation of the eyes, nose, and throat and a peculiar taste; effects which may be delayed are headache, nausea, vomiting, dyspnea, cyanosis, pulmonary edema, drowsiness, weakness, incoordination, and electrocardiographic abnormalities. Contact of solutions of ethylene oxide with the skin of human volunteers caused characteristic burns; after a latent period of 1 to 5 hours there were edema and erythema and progression to vesiculation with a tendency to coalesce into blebs, and desquamation; complete healing without treatment usually occurred within 21 days with, in some cases, residual brown pigmentation. Application of the pure liquid to the skin caused frostbite; 3 of the 8 volunteers became sensitized to ethylene oxide solutions. The pure liquid or solutions may cause severe eye irritation or damage.

III. SIGNS AND SYMPTOMS

Irritation of the eyes, nose, throat; peculiar taste; headache; nausea, vomiting, diarrhea; dyspnea, cyanosis, pulmonary edema; drowsiness, weakness, incoordination; electrocardiographic abnormalities; eye and skin burns; frostbite; by analogy to effects caused in animals, it may cause convulsions, injury to the liver and kidneys.

IV. SPECIAL TESTS

None in common usage.

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V. TREATMENT

Remove from exposure. Immediately flush eyes and skin with water. If a solution is swallowed, and the person is conscious, induce vomiting. Give artificial resuscitation and administer oxygen if indicated. Consideration should be given to hospitalization and observation for the possible delayed onset of pulmonary edema, and to treatment with corticosteroids if pulmonary edema occurs. Observe for convulsions and initiate appropriate treatment.

VI. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. GENERAL

Most reported effects of ethylene oxide are caused by its irritant properties. Skin sensitization has been reported. It is carcinogenic in female mice causing tumors in multiple sites. It is important that the physician become familiar with plant operating conditions in which exposure to ethylene oxide occurs. Those with skin disease may not tolerate the wearing of protective clothing and those with chronic respiratory disease may not tolerate the wearing of negative pressure respirators.

B. PREPLACEMENT

The following medical procedures must be made available to each employee who is exposed to ethylene oxide:

1. A complete history and physical examination -- The purpose is to detect preexisting conditions that might place the exposed employee at increased risk, and to establish a baseline for future health monitoring. Persons with a history of asthma, allergies, or known sensitization to ethylene oxide would be expected to be at increased risk from exposure. Examination of the eyes, blood, respiratory tract, liver, nervous system and kidneys should be stressed. The skin should be examined for evidence of chronic disorders.
2. A complete blood count -- Ethylene oxide has been shown to cause leukemia in female mice. A complete blood count must be performed including a red cell count, a white cell count, a differential count of a stained smear, as well as hemoglobin and hematocrit.
3. 14" x 17" chest roentgenogram -- Ethylene oxide causes human lung damage. Surveillance of the lungs is indicated.
4. FVC and FEV (1 sec) -- Ethylene oxide is a respiratory irritant. Persons with impaired pulmonary function may be at increased risk from exposure. Periodic surveillance is indicated.

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C. PERIODIC EXAMINATIONS

The above medical examinations are to be repeated on an annual basis.

VII. REFERENCES

1. American Conference of Governmental Industrial Hygienists: "Ethylene Oxide," Documentation of the Threshold Limit Values for Substances in Workroom Air (3d ed., 2d printing), Cincinnati, 1974, p. 112.

2. Hygienic Guide Series: "Ethylene Oxide," American Industrial Hygiene Association Journal, 19:528-529, 1958.

3. Patty, Frank A.: Industrial Hygiene and Toxicology, Vol. II - Toxicology (2d ed. revised), Interscience Publishing Company, New York, 1963, pp. 1626-1634.

4. Manufacturing Chemists Association, Inc.: Chemical Safety Data Sheet, SD-38, Ethylene Oxide, Washington, D.C., 1971, pp. 5, 24-26.

5. Hollingsworth, R.L., et al: "Toxicity of Ethylene Oxide Determined on Experimental Animals," A.M.A. Archives of Industrial Health, 13:217-227, 1956.

6. Sexton, R.J. and E.V. Henson: "Experimental Ethylene Oxide Human Skin Injuries," A.M.A. Archives of Industrial Hygiene and Occupational Medicine, 2:549-564, 1950.

7. Reyniers, J.A., et al: "Multiple Tumors in Female Germfree Inbred Albino Mice Exposed to Bedding Treated with Ethylene Oxide," Journal of the National Cancer Institute, 32:1045-1055, 1964.

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REFERENCES AND SOURCES
ETHYLENE OXIDE
1910.1000

- (e) Fire and Safety
(1) Electrical - Classification based on "Fire Hazard Classification of Chemical Vapors Relative to Explosion-proof Electrical Equipment," H. Carhart et al., National Academy of Sciences, 1973, report to U.S. Coast Guard, report no. CG-D-92-74, p. 14.
- (f) Personal Protective Equipment, and, (h) Sanitation
Eye: Manufacturing Chemists' Association, Chemical Safety Data Sheet; Patty, "Industrial Hygiene and Toxicology;" Union Carbide Corporation, "Toxicology Studies;" International Labour Office, "Encyclopedia of Occupational Health and Safety," Grant, "Toxicology of the Eye"
- Skin: Manufacturing Chemists' Association, Chemical Safety Data Sheets; American Industrial Hygiene Association, "Hygienic Guide Series;" Patty, "Industrial Hygiene and Toxicology;" International Labour Office, "Encyclopedia of Occupational Health and Safety;" American Conference of Governmental Industrial Hygiene, "Documentation of the Threshold Limit Values for Substances in Workroom Air;" Union Carbide Corp., "Toxicology Studies"
- Ingestion: Dow Chemical Co., Material Safety Data Sheet; Deichmann and Gerarde, "Toxicology of Drugs and Chemicals;" Patty, "Industrial Hygiene and Toxicology"

COMMENTS

Eye - Classification: 2

Output statement numbers: 10, 13

Exceptions: 13 added

The MCA reports that "ethylene oxide pure liquid, or in solution, can produce burns of the eyes. . . upon contact." It further notes "the liquid or solutions" may also cause "severe eye irritation or damage."

Patty notes that dilute solutions as low as one per cent may cause "irritation and necrosis of the eyes." Studies by "Hess and Tilton, Walker and Greeson, and McLaughlin have reported that liquid ethylene oxide produces severe irritation and corneal injury." Patty also reports that ". . . experience with human beings has been confined to injury to the eyes . . . without systemic effects."

According to Union Carbide, "the liquid was not tested but may be assumed to cause serious eye burns," and is considered to constitute a "serious hazard." The ILO also reports "severe damage would undoubtedly occur if a concentrated solution or a jet or the liquid were to enter the eye."

According to Grant, "Thiess has reported an instance of a squirt of pure ethylene oxide into one eye of a patient, treated immediately with copious irrigation with water; this resulted only in irritation of the conjunctiva lasting for one day. Thiess quoted Hollingsworth and associates as having

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observed in rabbit eyes after application of a drop of ethylene oxide only intense conjunctivitis which cleared in four days. A corneal burn from ethylene oxide in a workman has been listed by McLaughlin, as also having prompt recovery, but no details of the type of exposure were recorded. Though in aqueous solution . . . ethylene oxide is well known to be vesicant . . . probably the volatility of ethylene oxide and the fact that there are rarely circumstances in which considerable concentrations are kept in protracted contact with the eye account for the mildness of ocular injuries which have been observed clinically so far."

Since the degree of injury to the eye appears to be considerably influenced by the contact time with this substance, and since there are no clear indications that contact has ever resulted in permanent eye damage, it is concluded that a classification of 2 is most appropriate if statement 13 is additionally specified.

Skin - Classification: 1

Output statement numbers: 1, 7b, 14g, 14i, 20a, 21

Exceptions: None

The MCA notes that "liquid ethylene oxide . . . when spilled onto exposed skin is not immediately irritating if it can evaporate freely. Large amounts may cause frostbite. Continued contact may cause burns. Dilute solutions of the liquid are more likely to cause skin burns. Skin sensitization from contact with ethylene oxide has been reported. When spilled in shoes or on clothing, delayed irritation or burns may occur . . ." The Hygienic Guide states, "contaminated rubber and aqueous solutions contacting the skin can cause primary skin injury. Sensitization may occur."

The ACGIH states that "the main toxic problems encountered in industry from ethylene oxide result from cutaneous contact with aqueous solutions of the compound. These solutions cause primary irritation and sensitization of the skin."

According to Union Carbide, "the undiluted chemical caused burns and blister formation on the tender skin of the rabbit belly. Human experience indicates that extensive blister formation will occur following even brief contact with ethylene oxide - water mixtures of 40% - 80%. Lesser or greater concentrations will produce blisters only after more prolonged contact. Ethylene oxide is retained in rubber and leather for long periods of time and cannot be removed by washing. Wearing contaminated footwear may result in serious foot burns. There is considerable evidence which suggests that repeated skin contact with ethylene oxide results in the development of skin sensitivity of long duration."

Patty states that the liquid "is without adverse effect on rabbit and human skin on single mild exposures if the material evaporates rapidly. If large amounts of material are involved, evaporation may cause sufficient cooling to cause 'frostbite.' When confined to rabbit skin, even dilute aqueous solutions produce irritation, edema and

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occasional burns on single short exposures. Sexton and Henson have reported that concentrated ethylene oxide and dilute (1 per cent) aqueous solutions produce blisters and cause blebs on prolonged contact with human skin. Such contact ordinarily results from wearing contaminated clothing (for example: shoes or gloves) or may arise from ethylene oxide becoming entrapped under a ring or watchband. The reaction may not appear for several hours after the exposure. They also demonstrated that ethylene oxide can cause sensitization of the skin."

The boiling point of ethylene oxide is 50.7 degrees F. Since it is miscible in all proportions with water, it is often used in solution. The flash point of the compound is less than zero degrees F.

Since even very dilute solutions can cause skin reactions under some circumstances, it is concluded that a classification of 1 is appropriate.

Ingestion - Classification: 2

Output statement numbers: 20a

Exceptions: None

The Dow Chemical MSDS gives the acute single oral dose LD50 for rats as 330 mg/kg, for guinea pigs as 270 mg/kg, and the lethal dose for a 100 lb man as possibly being between "3 to 4 teaspoonsful."

Deichmann and Gerarde report ethylene oxide as "moderately toxic to rats. At a single dose of 0.1 gm/kg all animals survived. Doses of 0.2 gm/kg killed all the animals."

According to Patty, "when single doses of ethylene oxide were given intragastrically as a 10 per cent solution in olive oil to groups of 5 rats, all animals survived 0.1 g/kg, while 0.2 g/kg killed all animals. A 1 per cent aqueous solution had an intragastric LD50 of 0.33 g/kg for rats and 0.27 g/kg for guinea pigs. The delayed effects of acute exposure include nausea, vomiting, diarrhea, edema of the lungs, paralysis (particularly of the hind quarters), convulsions and death. Prompt deaths are usually due to lung edema; delayed deaths frequently result from secondary infection of the lungs, but general systemic intoxication may also be a factor."

Patty further adds that "serious systemic poisoning from ethylene oxide has been rare . . . Von Oettingen refers to 3 cases reported by Enke, in which headache, vomiting, dyspnea, diarrhea, and lymphocytosis were observed. Hess and Tilton refer to one case reported by Saxon and considered 'severe' in which essentially the same symptomatology, including the lymphocytosis noted above, was observed."

Given the volatility of the substance and the fact that only dilute solutions have an appreciable potential to be ingested, it is concluded that a classification of 2 is most appropriate.

SUBSTANCE TECHNICAL GUIDELINES

The references cited for this document include:

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National Fire Protection Association, "Fire Protection Guide on Hazardous Materials," 5th edition, 1975 (NFPA)

Manufacturing Chemists' Association, Chemical Safety Data Sheet SD-38 (MCA)

BASF Wyandotte Corp., "Ethylene Oxide Handling Manual," Report No. 21, and Technical Bulletin (BASF)

Union Carbide Corp., Material Safety Data Sheet (UCC)

Sources of data items used:

- I. A. 1. Synonyms: NFPA-325M
2. Formula: NFPA-325M
3. Molecular weight: BASF
- B. 1. Boiling point: NFPA-325M, MCA
2. Specific gravity: BASF
3. Vapor density: NFPA-325M, MCA
4. Melting point: MCA
5. Vapor pressure: UCC, BASF
6. Solubility in water: MCA, BASF
7. Evaporation rate: UCC
8. Appearance and odor: NFPA-49, MCA
- II. A. 1. Flash point: NFPA-325M, MCA, UCC
2. Autoignition temperature: NFPA-325M, NFPA-49, MCA
3. Flammable limits: BASF, UCC
4. Extinguishing media: UCC, NFPA-325M, MCA
5. Special fire fighting procedures: NFPA-49, UCC
6. Unusual fire and explosion hazards: NFPA-325M, NFPA-99, UCC
- B. 1. Conditions contributing to instability: MCA, UCC
2. Incompatibilities: NFPA-49, NFPA-491M, UCC, MCA
3. Hazardous decomposition products: None
4. Special precautions: ADL
- III. A. Steps if released or spilled: NFPA-49, MCA
C. Waste disposal method: MCA, UCC
- V. Miscellaneous precautions: NFPA-49, BASF

USE/EXPOSURE AND CONTROL DOCUMENT

References used in the preparation of this document include:

- Browning, E., "Toxicity and Metabolism of Industrial Solvents," Elsevier Publishing Co., 1965 (Browning)
- "Ethylene Oxide," American Conference of Government Industrial Hygienists, Hygienic Guide Series (Hygienic Guides)
- "Ethylene Oxide," Chemical Engineering, 4/29/74, p. 144 (Chem Eng)
- "Ethylene Oxide," Manual Sheet SD-38, Manufacturing Chemists' Association, 1971 (MCA)
- "Ethylene Oxide," Material Safety Data Sheet, Union Carbide (Union Carbide)
- International Labour Organization, "Encyclopedia of Occupational Health and Safety," Geneva, 1972 (ILO)
- Joyner, R. E., "Chronic Toxicity of Ethylene Oxide," Archives of Environmental Health, 8:700 - 710, 1964 (Joyner)
- Kirk, R. and Othmer, D., "Encyclopedia of Chemical Technology," Interscience Publishers, Division of John Wiley, 2nd edition, 1972 (K-O)
- "Merck Index of Chemicals and Drugs," Merck and Co., Inc., Rahway, N.J., 8th edition, 1968 (Merck)
- Stanford Research Institute, "Chemical Economics Handbook," Menlo Park, California (SRI)

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U.S. Environmental Protection Agency, "EPA Compendium of Registered Pesticides," Vol. II - "Fungicides and Nematicides;" Vol. III - "Insecticides, Acaricides, Molluscicides and Antifouling Compounds," Office of Pesticide Programs (EPA Compendium)

References for Specific Use/Exposure

1. Joyner, ILO
2. SRI, Browning
3. SRI, Hygienic Guides
4. SRI
5. SRI, Hygienic Guides
6. Chem Eng, SRI
7. SRI, Chem Eng
8. Merck, EPA Compendium, K-O
9. Merck, K-O

References for Specific Control Methods

1. ILO, MCA, Hygienic Guides

MCA, Hygienic Guides and Union Carbide were the references used in numbers 2 - 6.

7. ILO, Hygienic Guides
8. ILO, Hygienic Guides

RESPIRATOR TABLE DOCUMENTATION

SUBSTANCE: Ethylene oxide

D. O. L. STANDARD: 50 ppm

WARNING PROPERTIES:

Odor Threshold: According to Staub, the odor threshold of ethylene oxide is 700 ppm. The Manufacturing Chemists' Association (MCA) states that if exposure to ethylene oxide is continuous, "a numbing of the sense of smell (will occur); thus harmful concentrations may be reached without any warning by odor."

Eye Irritation Level: Grant states that "exposure of animals to high concentration of the gas has caused lacrimation in cats, and inflammation of the conjunctiva and clouding of the cornea in dogs, cats, rabbits, and especially guinea pigs. . . The eyes of workers excessively exposed to ethylene oxide vapor occasionally showed slight irritation of the conjunctivae (12 cases), but there were no injuries of the cornea and no special treatment was needed. Thiess observed no lacrimatory effect that could be considered a warning symptom."

For the purposes of this standard, half-facepiece respirators are allowed unless eye irritation occurs. If eye irritation occurs, a full facepiece respirator must be worn.

Evaluation of Warning Properties: The odor threshold of ethylene oxide is well above the permissible exposure limit, and there is no quantitative information available concerning the threshold of irritation.

Patty states that "although ethylene oxide is considered to be an irritant gas, neither irritation nor odor can be relied upon to warn of the presence of vapor concentrations harmful upon prolonged or repeated exposure."

Ethylene oxide, therefore, has been treated as a material with poor warning properties. Gas sorbent respiratory equipment is not permitted.

IDLH: 800 ppm

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Basis for IDLH Value: The chosen IDLH is based upon the report in the AIHA Hygienic Guides that "the estimated LC50 for four hours' exposure is approximately 800 to 1500 ppm depending upon the species." In addition, Patty states that for humans 500 ppm is "probably safe for single (no more than 1/wk.) exposures of 1 hour's duration."

Other Toxicological Information: The AIHA Hygienic Guides state that the severity of the health hazards associated with ethylene oxide is "moderate, for both acute and chronic exposure. Volatility is high and pulmonary absorption is rapid. Animal studies have shown irritation of the eyes and respiratory tract. High concentrations cause vomiting, convulsions, and death with the lungs, liver, kidneys, and adrenals showing evidence of injury . . . The estimated LD50 for four hours' exposure is approximately 800 to 1500 ppm, depending upon the species."

Concerning the toxicity of ethylene oxide for rats by single inhalation, Union Carbide Corporation states that "breathing a concentration of 4,000 parts per million was not fatal to any of six animals (rats) after a four-hour exposure. Eight thousand parts per million was fatal to all of six animals in the same period of time."

"Human experience indicates that ethylene oxide causes nausea and vomiting if inhaled in adequate concentrations. The resulting nausea and vomiting may persist for several hours if untreated. There is also evidence that high vapor concentrations can be sufficiently irritating to cause pulmonary edema in man."

According to Spector, a dangerous dose of ethylene oxide for animals is 3000 ppm for a 30- to 60-minute exposure. Exposure to a concentration of 500 ppm for one hour is lethal to guinea pigs. Spector states that ethylene oxide is "not highly toxic to man," and that "3000 ppm (is) tolerated by man for a maximum of 60 minutes."

The following information can be found in a table in Patty:

SUMMARY OF ACUTE RESPONSE OF ANIMALS TO EXPOSURE TO ETHYLENE OXIDE

P.p.m. by vol. in air	Time, hr.	Animal	Results
710	4	Dog	0/3 in 14 days
1100	5	Rat, guinea pig, rabbit	Moderate injury, no deaths
1300 - 1400	4	Dogs	3/3 first day
2200	1 1/2	Cat	Injurious, no deaths
	3	Cat	Death within 24 hours
	4	Guinea pig	Injurious, few deaths
	4	Rabbit	Injurious, no deaths
3000	1	Guinea pig	No deaths
	3	Guinea pig	Death of majority with 1 to 8 days

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Concerning the effects of ethylene oxide on humans, Patty states that 500 ppm is "probably safe for single (no more than 1/wk.) exposures of up to 1 hour's duration."

The NIOSH Toxic Substances List gives the following 4-hour, inhalation LC50 values: 836 ppm for the mouse; 973 ppm for the dog; 1462 ppm for the rat; and 4000 ppm for humans.

The Documentation of TLV's states that the threshold of limit value has been based on chronic toxicity studies, and is believed to be sufficiently low to prevent "ostensible systemic effects."

Since the ILO states that "severe dermatitis may result if the vapour has access to areas of the body kept moist with water or perspiration," supplied-air suits may be necessary.

LFL: 30,000 ppm

VAPOR PRESSURE AT 20 C: Ethylene oxide is a gas at 20 C

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USE/EXPOSURE AND CONTROL DOCUMENT
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Use/Exposure	Principal Route of Entry	Currently Used Control Methods
1. Inhalation of vapor* and skin contact with liquid during synthesis and handling of substance	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
2. Inhalation of vapor and skin contact with liquid during synthesis of ethylene glycol	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
3. Inhalation of vapor and skin contact with liquid during synthesis of nonionic surface active agents (including ethoxylated nonylphenol and ethoxylated mixed alcohols)	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
4. Inhalation of vapor and skin contact with liquid during synthesis diethylene glycol (in manufacture of polyester and polyurethane resins)	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
5. Inhalation of vapor and skin contact with liquid during synthesis of glycol ethers	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
6. Inhalation of vapor and skin contact with liquid during synthesis of ethanolamines	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)

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7.	Inhalation of vapor and skin contact with liquid during synthesis of triethylene and polyethylene glycol	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
8.	Inhalation of vapor and skin contact with liquid during use as an insecticidal or fungicidal fumigant (for bulk stored commodities, foodstuffs, and textile goods; transportation equipment)	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)
9.	Inhalation of vapor and skin contact with liquid during use as a sterilizing agent (including for surgical supplies and users)	A,B	Process enclosure; local exhaust ventilation; general mechanical ventilation; personal protective equipment (gloves, goggles, respiratory protective devices, protective clothing)

- A -- Inhalation
- B -- Skin and eye contact resulting in localized irritation
- C -- Ingestion
- D -- Skin contact resulting in absorption and subsequent systemic poisoning

* There is some question whether these exposures are to the vapor or gaseous phase.