GUIDANCE NOTE
FOR THE SAFE USE OF ETHYLENE OXIDE IN STERILISATION/FUMIGATION PROCESSES [NOHSC:3016(1992)]

1. INTRODUCTION

1.1 Ethylene oxide is a gas with a characteristic ether-like smell at extreme concentration levels. It reacts chemically with various proteins and DNA of micro-organisms resulting in damage to, or destruction of, cell structures. Ethylene oxide gas diffuses readily through paper, fabric, rubber and most plastics. For these reasons, equipment and supplies that cannot withstand moist or dry heat sterilisation may be sterilised by ethylene oxide. Main users of ethylene oxide include:

(a) hospitals — for sterilisation of heat-sensitive instruments or equipment;

(b) industry — manufacturers of hospital and medical supplies;

(c) museums, libraries and archives — for fumigation of paper, fabrics, and wooden and leather products;

(d) some food processors;

(e) sterilisation training institutions; and

(f) herbaria.

1.2 A detailed description of the physical and chemical properties of ethylene oxide is given at Appendix 3 of the *National Code of Practice for the Safe Use of Ethylene Oxide in Sterilisation/Fumigation Processes* [NOHSC:2008(1992)]. Pure ethylene oxide (liquid or gas) is extremely flammable and an air-ethylene oxide mixture can explode if exposed to fire, sparks or if detonated. The severe fire and explosion hazards of ethylene oxide are reduced in most cases by mixing it with a high proportion of either chlorofluorocarbons (CFCs) or carbon dioxide. The mixture is usually supplied in cylinders and the sterilisation gas mixture can be mixed with any proportion of air with minimal risk of the formation of an explosive mixture. However, high percentage ethylene oxide mixtures, for example, 90 per cent ethylene oxide/balance carbon dioxide, are flammable. They require the same non-sparking, flame proofing requirements as pure ethylene oxide, and must be handled accordingly.

1.3 The odour threshold for ethylene oxide is very high (between 500 and 700 ppm). The absence of odour will not ensure the absence of a health hazard. The odour of ethylene oxide cannot be detected until exposure greatly exceeds concentrations considered hazardous. A suitable additive can be used to reduce the odour threshold, for example, a sulphur compound.

STERILISATION

1.4 Ethylene oxide sterilisation is carried out in sterilisers. Detailed specifications required for most sterilisers for hospital use are available in Australian Standard AS 1714 *Sterilizers õ 12/88 Ethylene Oxide õ Hospital Use*[1]. Sterilisers employing 100 per cent ethylene oxide in single use canisters are not specifically covered in this publication, but should comply with the environmental and operator guidance supplied.

1.5 The sterilisation cycle consists of the following phases for automatic, general purpose sterilisers:

(a) an initial chamber evacuation humidification, and ethylene oxide charging phase;

(b) a dwell period during which sterilisation takes place; and

(c) a final chamber evacuation phase that may include aeration.

Most items are sterilised at 54.4°C (130°F) for about 2.5 hours; heat-sensitive items are sterilised at 37.8°C (100°F) for about 5 hours.

AERATION

1.6 It should be noted that repeated evacuation of a sterilisation chamber at the end of the sterilisation cycle is not an effective method for removing all ethylene oxide. Therefore, following sterilisation, it is necessary to remove the gas which is trapped or absorbed in the materials during sterilisation. In hospitals, this is carried out in a combined sterilisation/aeration chamber or in an aeration cabinet. If the residual gas is not removed, it may cause harm to the employees who handle these materials or, occasionally, to the nursing/medical staff or patients. PVC and some rubber products absorb the greatest amounts of ethylene oxide. Metal and glass do not absorb ethylene oxide, but may retain pockets of gas in semi-closed cavities. The primary conditions that affect aeration efficiency in reducing residual ethylene oxide are temperature, dwell time, air convection and load configuration.

1.7 Ethylene oxide is readily removed from most materials within 12 hours by a continuous flow of warm air at 50-60°C in a hospital-type aeration cabinet. Detailed specifications required for aeration cabinets are available in Australian Standard AS 1862 *Aeration Cabinets (for Use with Ethylene Oxide Sterilizers)*[2].

1.8 In industry, aeration is commonly carried out on open shelving in aeration rooms. The shelving area should be isolated and supplied with exhaust ventilation. In industry, aeration can sometimes take weeks or months depending on the materials to be sterilised.

1.9 The Australian Government is a signatory to the Montreal Protocol on Substances that Deplete the Ozone Layer. The Australian and New Zealand Environment and Conservation Council has given a commitment for a 100 per cent phase out of importation and production of CFCs by the end of 1997. In addition, a commitment has been given for a 95 per cent phase out by the end of 1995.

1.10 Several State environment departments are drafting or considering codes for the manufacture and use of ethylene oxide/CFC 12 mixtures for sterilisation processes. These codes provide a strategy for reduction of emissions of CFCs as a first step to achieving the broader objective of elimination. The measures for reduction of emissions of CFCs are very similar to the controls detailed in this guidance note for minimising worker exposure to ethylene oxide.

1.11 The commitment to the phase out of CFCs has considerable implications for the ongoing use of ethylene oxide/CFC mixtures, and for the forms of ethylene oxide sterilisation into the future.

2. HEALTH EFFECTS

MECHANISM OF TOXICITY

2.1 Ethylene oxide is a very reactive chemical and its reactions with other molecules often lead to toxic change. One of the values of the use of ethylene oxide as a sterilant lies in the fact that the ethylene oxide molecule is a potent alkylating agent and reacts chemically with various proteins and the DNA of micro-organisms. These chemical reactions result in damage to cell structures and subsequent destruction of the micro-organisms. As with other alkylating agents, this property indicates a high probability of toxicity to humans.

ROUTES OF EXPOSURE

2.2 Routes of exposure to ethylene oxide include:

(a) inhalation of ethylene oxide gas in air;

(b) skin, eye or mucous membrane contact with the liquid or with ethylene oxide absorbed in solid materials;

(c) oral — residual ethylene oxide in ingested material; and

(d) intravenous — leaching of ethylene oxide from inadequately aerated medical devices inserted intravenously.

ABSORPTION AND EXCRETION

2.3 Ethylene oxide is very soluble in biological tissues such as blood. Absorption is very fast, especially across the lungs, with uptake into the body of a large proportion of the amount inhaled. Skin absorption is less common, though systemic effects (nausea and vomiting) have been shown following accidental skin exposure to a solution of 1 per cent ethylene oxide in water.

2.4 Ethylene oxide is rapidly distributed throughout the body, and rapidly broken down in the body by hydrolysis or by conjugation with glutathione. Residual ethylene oxide and its breakdown products are mainly excreted through the urine, usually within a few hours after exposure.

SHORT TERM (ACUTE) EFFECTS

Acute Effects in Animals

2.5 Animal evidence indicates that ethylene oxide in high concentrations is very toxic in a number of animal species[3].

Animal	Route of Exposure	Toxic Dose
male rats	oral (in water)	LD_{50} 330 mg/kg
male mice	oral (in water)	LD_{50} 365 mg/kg
female mice	oral (in water)	LD_{50} 280 mg/kg
dog	inhalational (gas)	4 hour LC_{L0} 1280 mg/m^3 717 ppm
guinea pig	inhalational (gas)	8 hour LC_{L0} 450 mg/m^3 252 ppm
mouse	inhalational (gas)	4 hour LC_{50} 1500 mg/m^3 840 ppm
rat	inhalational (gas)	4 hour LC_{50} 2630 mg/m^3 1473 ppm
dog	inhalational (gas)	4 hour LC_{50} 1730 mg/m^3 969 ppm

The symptoms reported following these exposures indicate that ethylene oxide is a nasal and respiratory irritant, and that the main targets of toxicity are the respiratory system (congestion and oedema) and the nervous system (ataxia and convulsions).

Acute Effects in Humans

Inhalation

2.6 Acute effects in humans from inhalation are:

(a) High vapour concentrations of ethylene oxide (of the order of 1000 ppm) can cause irritation and damage to the eyes and upper respiratory system, hoarseness, cough, headache, nausea and recurrent vomiting, fatigue and pulmonary oedema.

(b) Less frequently reported effects include muscular weakness, abdominal discomfort and diarrhoea, and nervous system disorders.

Skin Contact

2.7 The accute effects in humans from skin contact are:

(a) Ethylene oxide liquid has the capacity to cause burns on contact with the skin and mucous membranes. These burns resemble frostbite, owing to rapid evaporation and consequent cooling. Symptoms of exposure can be delayed, often appearing one to six hours afterwards.

(b) Delayed skin burns (blisters) can occur if ethylene oxide contaminated shoes and clothing are not removed promptly.

(c) Repeated contact with high vapour concentrations can cause a burning sensation, inflammation of the skin, parched lips and mouth, itching, irritation and allergic dermatitis.

(d) Contact with unaerated articles may cause erythema (skin redness), inflammation and tissue damage.

Eye Contact

2.8 The after effects in humans from eye contact are:

(a) Contact of liquid ethylene oxide with the eyes can cause severe burns.

(b) Conjunctivitis and cataracts have been reported following eye exposure to ethylene oxide.

LONG TERM (CHRONIC) EFFECTS

2.9 Of the exposure routes, the greatest human risk appears to be that associated with frequent and long term exposure to inhaled ethylene oxide vapour in the work environment. Major long term effects of ethylene oxide are outlined below:

(a) Reported chronic effects include a blunted sense of smell, dermatitis, nervous system damage and cataracts. Animal tests show liver and kidney damage. Ethylene oxide can alkylate haemoglobin in humans, causing hemolysis (red cell breakdown).

(b) Mutagenic effects have been observed in laboratory studies and there is evidence of chromosomal damage in humans.

(c) Teratogenic effects (foetal malformations) have been observed in mice. There have been reported increases in spontaneous abortions in exposed hospital sterilising staff, but the evidence of this is equivocal.

(d) Ethylene oxide is an established carcinogen in laboratory animals (causing lung cancer in rats and mice following inhalational exposures at 50 and 100 ppm) and a suspect human carcinogen (causing leukaemia). It is important to note that the inhalational route of exposure which resulted in carcinogenic effects in animals is the same route of exposure as in humans.

The term genotoxic is used for substances capable of initiating genetic damage which may eventually lead to the development of cancer. Ethylene oxide has been shown to be capable of causing damage to DNA, proteins, cellular membranes and cellular organisation. On the basis of these properties, ethylene oxide is considered to be a genotoxic carcinogen.

The International Agency for Research on Cancer (IARC) has noted that there is ***limited*** evidence for the carcinogenicity of ethylene oxide in humans, and

sufficient evidence for carcinogenicity in animals[4,5]. Accordingly, IARC has given ethylene oxide a Category 2A carcinogen status (probably carcinogenic to humans).

2.10 The evidence in Section 2.9 indicates that ethylene oxide is toxic in various body systems. It is also a mutagen, an established animal carcinogen and a probable human carcinogen, and may have adverse reproductive effects on humans.

ETHYLENE OXIDE RESIDUES

2.11 Possible residues (or by-products) are produced mainly by two reactions of ethylene oxide:

(a) From the slow chemical combination with water (or moisture) to form ethylene glycol. Ethylene glycol in liquid form is an irritant to the skin and eyes. Since even dry materials contain some moisture, ethylene glycol formation is unavoidable. Moreover, without moisture, ethylene oxide sterilisation would not be effective.

(b) From its combination with free chloride ions in the product, for example, PVC, in the presence of moisture to form ethylene chlorohydrin (2-chloroethanol). Ethylene chlorohydrin is a potent mutagen, and is readily absorbed through the skin. Studies indicate, however, that ethylene oxide sterilised PVC tubing does not produce toxic levels of ethylene chlorohydrin.

3. EXPOSURE STANDARD

3.1 The national exposure standard for ethylene oxide recommended by the National Commission in its *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [(NOHSC:1003(1991)][6] is as follows:
Time-weighted average (TWA) 1 ppm

TWA: time-weighted average airborne concentration when calculated over a normal eight-hour working day, for a five-day working week.
ppm: parts of gas per million parts of contaminated air by volume.

3.2 Documentation supporting this exposure standard is available[7]. Following detailed review of the presently available information, ethylene oxide has been classified as a Category 2 carcinogen by the National Commission[6]. A Category 2 carcinogen is a probable human carcinogen for which there is sufficient evidence to provide a strong presumption that human exposure may result in the development of cancer.

3.3 Ethylene oxide should be treated as carcinogenic to humans. It should be used and handled with great caution. Exposures to ethylene oxide should be minimised to the lowest practicable levels and under no circumstances should they exceed the national exposure standard.

3.4 Even where the TWA exposure standard is not exceeded, there should be some control of concentration excursions. A process is not considered to be under reasonable control if short term exposures exceed three times the TWA exposure standard for more than a total of 30 minutes per eight-hour working day, or if a single short term value exceeds five times the TWA exposure standard. Further advice can be obtained in the National Commission's *Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [NOHSC:3008(1991)][8].

4. OCCUPATIONAL EXPOSURE

4.1 There are two major routes of exposure for ethylene oxide that a person may encounter in a work situation:

(a) inhalation of vapour; and

(b) direct skin contact with liquid.

4.2 These two types of exposure usually occur at specific times and places and under certain conditions during sterilisation operations. These are summarised below.

4.3 Sterilisation chamber, aeration cabinet or aeration room:

(a) Poorly installed or maintained steriliser/aerator.

(b) During removal of the load from the steriliser on completion of the sterilisation cycle.

(c) In hospitals, from inadequate aeration due to poor ventilation, inadequate heating or insufficient aeration time allowed.

(d) In industrial aeration rooms, during the aeration process; no entry allowed without use of personal protective equipment.

(e) From leaks in the liquid/gas supply lines of the chamber.

(f) During the emptying of vent line condensate traps by maintenance personnel.

4.4 Materials transfer:

(a) While transferring freshly sterilised articles from the sterilisation chamber to the aeration cabinet.

(b) When opening multiple-layered packs after sterilisation.

4.5 Exhaust lines:

(a) Inadequate disposal of exhaust gases.

(b) Leaking fittings.

4.6 Ethylene oxide cylinders:

(a) The procedure for changing cylinders, resulting in the release of liquid and/or vapour ethylene oxide.

(b) From accidental spillage during handling and storage of cylinders.

(c) From poor fittings or connections.

(d) For unit dose 100 per cent ethylene oxide canisters, insufficient aeration of canisters before disposal.

4.7 Safety valves (this section does not apply to systems employing unit dose 100 per cent ethylene oxide canisters):

(a) Excessive pressure build-up in the chamber causing the opening of the safety release valve, resulting in the release of large amounts of ethylene oxide.

(b) Malfunctioning safety valves.

GLOSSARY OF TERMS

Acetylide (ethynide)
A violently explosive compound formed by bubbling acetylene through a solution of a metallic salt.

Acute effect
An effect that occurs immediately or shortly after a single exposure.

ADG (ACTDG) Code
See Australian Code for the Transport of Dangerous Goods by Road and Rail and Dangerous Goods Class.

Aliphatic hydrocarbon
A linear or branched chain organic compound composed only of carbon and hydrogen atoms.

Alkylating
Introduction of an alkyl group into an organic molecule.

Allergic dermatitis
Inflammation of the skin caused by contact with a sensitizing agent.

Ampoule

A glass container used to hold solutions or liquid chemicals which have to be hermetically sealed or kept sterile, but easily accessed when required.

Ataxia

Incoordination of voluntary muscular action, particularly of the muscle groups used in activities such as walking or reaching for objects; due to any interference with the peripheral or central nervous system pathways involved in balancing muscle movements.

Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code)
Means the code prepared by the standing national Advisory Committee on the Transport of Dangerous Goods and endorsed by the Australian Transport Advisory Council. The ADG

Code is based on recommendations prepared by the United Nations Committee of Experts on the Transport of Dangerous Goods. The ADG Code covers the classification, packaging, marking and transport of dangerous goods.

Autoignition temperature
The minimum temperature required to start or cause self-sustained combustion in any substance in the absence of a high temperature ignition source, such as a spark or flame.

Cancer
A malignant tumour which can spread to other organs of the body, as distinct from a benign tumour which cannot. Although leukaemia and some other malignant diseases are not solid tumours, they meet other criteria for cancer and can be, and often are, included under this definition.

Carcinogen
An agent which is responsible for causing cancer.

CAS Number
Chemical Abstracts Registry Number. A number assigned to a single chemical by the United States-based Chemical Abstracts Services. This is the only `one chemical-one number' system covering all publicly known chemicals.

Chronic effects
Harmful effects of a chemical which occur after repeated or prolonged exposures. Chronic effects may also occur some time after exposure has ceased.

Dangerous Goods Class
The class allocated to a substance under the ADG Code.

DNA
Deoxyribonucleic acid. The hereditary material of living organisms.

Encephalopathy
Any of the various diseases that affects the functioning of the brain.

Epoxide
A three membered cyclic ether.

Erythema
Reddening (inflammation) of the skin.

Exothermic
Accompanied by the evolution of heat.

Flammability (explosive) limits
The range of concentrations of a flammable gas or vapour in air at which a flame can be propagated, or an explosion will occur, if a source of ignition is present. Normally expressed as upper and lower limits of this range as percentages in air.

Flash point
The temperature at which a liquid first evolves vapour in sufficient quantity to be ignited by the test flame specified in the approved test method.

Genotoxic
Relating to damage to genetic material.

Hazchem Code
An emergency action code of numbers and letters which gives information to emergency services on the correct action to take in case of spillage or fire involving dangerous goods. Its use is required by the ADG Code.

Impermeable
Not allowing the passage of liquids or gases.

Impervious

Materials which have the property of not allowing the passage of liquids.

Irritant
A chemical which produces local irritation or inflammation on contact with tissues and membranes such as the skin and eyes, or with nasal or lung tissues after inhalation.

LC_{L0}
The lowest concentration (usually in air) of a substance that has been reported to cause death in animals.

LC_{50}
The concentration (usually in air) of a substance that is estimated to produce death in 50 per cent of a population of experimental animals on inhalation for a short period of time.

LD_{50}
The dose of a substance that produces death in 50 per cent of a population of experimental animals. Normally administered orally, dermally or by injection. It is usually expressed as milligrams per kilogram of body weight.

Local effects
Harmful effects at the point of contact or entry into the body (as opposed to systemic effects).

Material Safety Data Sheet (MSDS)
A document that describes the properties and uses of a substance, that is, identity, chemical and physical properties, health hazard information, precautions for use and safe handling information.

Miscibility
The property enabling two or more liquids to mix in any proportion to form a solution.

Mutagen
An agent capable of producing a mutation.

Oedema (edema)

Excessive accumulation of fluid in the tissue spaces of the body due to increased transudation of the fluid from the capillaries.

Olfactory
Pertaining to the capacity to detect by smell.

Poisons Schedule
A classification of substances requiring special labelling and precautions in use. *See* Standard for the Uniform Scheduling of Drugs and Poisons.

Polymer
The product of joining together small, simple chemical units of identical or similar type.

Polymerisation
The process which produces a polymer.

Pulmonary
Fluid accumulation in the lungs, oedema.

PVC
Polyvinyl chloride.

Radical
A reactive group of atoms normally incapable of a separate, prolonged, stable existence.

Specific gravity
The ratio of the density of a substance compared with water.

Standard for the Uniform Scheduling of Drugs and Poisons
The National Health and Medical Research Council's Standard for the Uniform Scheduling of Drugs and Poisons outlines the schedule and labelling requirements for drugs and poisons.

Subsidiary risk

A risk in addition to the class to which dangerous goods are assigned, and which is determined by a requirement to have a subsidiary risk label under the ADG Code.

SUSDP
See Standard for the Uniform Scheduling of Drugs and Poisons.

Systemic effects
Relating to effects of a chemical on the organs and fluids of the body remote from the point of contact or entry (as opposed to local effects).

Teratogen
An agent capable of causing abnormalities in a developing foetus, that is, causing birth defects.

UN Number
A system of four digit numbers assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods. UN Numbers are assigned to one substance or to a group of substances with similar characteristics.

Vapour pressure
The pressure at any given temperature of a vapour in equilibrium with its liquid or solid form.

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The provisions of this guidance note may not necessarily reflect the views of individual members of the Ethylene Oxide State-based Working Group or the Ethylene Oxide Expert Review Group.