STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER

KEEP OUT OF THE REACH OF CHILDREN

DANGER - Breathing of vapors harmful. Exposure to eyes and skin may cause severe irritation. Avoid contact with eyes, skin or clothing.
IN OF CONTACT - Remove all clothing and shoes - flush skin or eyes with plenty of water for at least 15 minutes - GET MEDICAL ATTENTION IMMEDIATELY.

PHYSICAL OR CHEMICAL HAZARDS

Contents Under Pressure: Do not use or store near heat or flame.

Environmental Hazards

LIQUIFIED GAS DANGEROUSLY REACTIVE

STORAGE & DISPOSAL

Store in cool, well ventilated area. Avoid exposure to heat or direct sunlight. When empty return to manufacturer only.

[redacted] OXIDE

Active Ingredient
ETHYLENE OXIDE **100%**

This product contains 7.25 lbs. of Ethylene Oxide per gallon (at 20° C).

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

IF INHALED - Remove to fresh air, if breathing has stopped administer oxygen.

IF ON SKIN - Remove contaminated clothing, shower affected areas with water for 15 minutes.

IF IN EYES - Irrigate with copious amounts of water for 15 minutes.

DANGER

Contains Ethylene Oxide Cancer Hazard and Reproductive Hazard Avoid Breathing this Gas

Distributed by:
ARC CHEMICAL Div.of Balchem Corporation
P.O. Box 160, Slate Hill, N.Y. 10973

EPA Registration No. 36736-2
EPA Est. 36736-NY-01

Net Contents: 400 lbs.

FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
The product is limited to use by medical professionals or appropriately trained technical personnel in medical and industrial use areas.

FOR THE FOLLOWING INTENDED USES

1. As a sterilizing gas for industrial and/or medical uses in 100% Ethylene Oxide Commercial Gas Sterilizers Only. Follow the sterilization procedures specified in the gas sterilizers manufacturers manual, the valve tag attached to this drum, and our booklets entitled, "Principles & Practices of Ethylene Oxide Sterilization" and "Drummed Ethylene Oxide."

2. Repacking of sterilizing gas. Refer to our technical brochure "Drummed Ethylene Oxide" for chemical and physical properties.

3. Formulation of sterilizing gas mixtures. Refer to our technical brochure "Drummed Ethylene Oxide" for chemical and physical properties.
Use within 60 days of fill date.

ACCEPTED
DEC 15 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under 36736-2
EPA Reg. No.

DO NOT DETACH THIS TAG

ETHYLENE OXIDE

ACTIVE INGREDIENT 100%

DANGER: EXTREMELY FLAMMABLE
BREATHING OF VAPOR HARMFUL
CONTACT WITH EYES OR SKIN HARMFUL

USE ONLY IN ACCORDANCE WITH DIRECTIONS ON THIS TAG.

1. **KEEP THIS CONTAINER AND ITS CONTENTS AWAY FROM HEAT, LIGHTS, FLAMES, FIRES AND SPARK-PRODUCING DEVICES.** Ethylene Oxide is extremely flammable and its vapors will explode if ignited.

   Ethylene Oxide vapor decomposes explosively when heated above 550°C. Store and use in adequately ventilated area.
2. THIS CONTAINER IS DESIGNED TO DISCHARGE ONLY LIQUID ETHYLENE OXIDE. IF ETHYLENE OXIDE GAS IS REQUIRED, USE VAPORIZING EQUIPMENT.
3. USE ONLY SPARKPROOF TOOLS. USE ONLY STEEL PIPING AND CONNECTIONS WHEN USING ETHYLENE OXIDE WITH AN INERT GAS. IT MAY CONTAIN ACETYLENE. DO NOT USE COPPER, MAGNESIUM OR SILVER MATERIALS SINCE THEY MAY REACT WITH ACETYLENE AND AN EXPLOSION MAY RESULT. NEVER USE RUBBER. GROUND ALL EQUIPMENT INCLUDING THIS CONTAINER to avoid static sparks. Only explosion-proof electrical equipment should be used where Ethylene Oxide may be present.
4. Keep drum upright for discharge (see 2 above). Connect "Y" valve marked "VENT" (number 7200) through pressure regulator and check-valve to source of inert gas, such as nitrogen.
   The working pressure of this drum is 50 psi gauge.
   DO NOT USE COMPRESSED AIR. DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.
5. Always install check-valve in line from this drum to processing equipment to prevent backflow into drum. Then open valve marked "LIQUID" (number 7201) which is connected to an eductor tube for liquid discharge. **THIS VALVE HAS LEFT-HAND THREADS.**

   Keep valve nos. 7200 and 7201 closed when not in use.

(OVER)

6. Observe all local laws, regulations, ordinances, and insurance regulations covering the storage and use of flammable material.
7. To delay deterioration store out of sun and away from heat. Use within 120 days.
8. **STERILIZATION:** Use Ethylene Oxide only in sterilizers designed for use with Ethylene Oxide. Use Ethylene Oxide in accordance with directions supplied by the sterilizer manufacturer. Sterilizer temperature and pressure influence both exposure time and Ethylene Oxide concentration. The variation of type and quantity of material to be sterilized, how packed, size of sterilizer, types of bacteria to be killed, and chamber relative humidity also affect the exposure time required for sterilization. Gas sterilizer cycle parameters should be those prescribed by the sterilizer manufacturer, if applicable. If other cycle parameters are used, the efficacy of the alternate cycle must be validated and is the responsibility of the user. Aerate sterilized materials before use.
9. **FUMIGATION:** Fumigation with Ethylene Oxide must be performed with only vacuum or gas-tight chambers designed for use with Ethylene Oxide. Aerate fumigated materials before use.
10. **FOOD TREATMENT:21 CFR 193.200**
    "Ethylene Oxide, may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices or other processed natural seasoning materials, except mixtures to which salt has been added..."

    "Ethylene Oxide, either alone or admixed with carbon dioxide or dichlorodifluoromethane, shall be used in amounts not to exceed that required to accomplish the intended technical effects."
11. **THIS TAG MUST REMAIN FIXED TO DRUM AT ALL TIMES. WHEN EMPTY, THIS DRUM SHOULD BE RETURNED TO ORIGINAL SHIPPING POINT WITH A NITROGEN PRESSURE OF 50 PSIG AT 70°F OR EQUIVALENT AT AMBIENT TEMPERATURE. IT IS THE PROPERTY OF:**

ARC CHEMICAL DIVISION
BALCHEM CORP.

(This Tag for Insulated Drums Only)

EPA Registration No 36736-2
EPA Est 36736 NY-01

(10/89)

ACCEPTED
DEC 15 1989
Under the Fed... ...ide,
Fungicide, and R... ...Act,
as amended, for the ...
registered under
EPA Reg. No. 36736-2

PIM 31

36736-2

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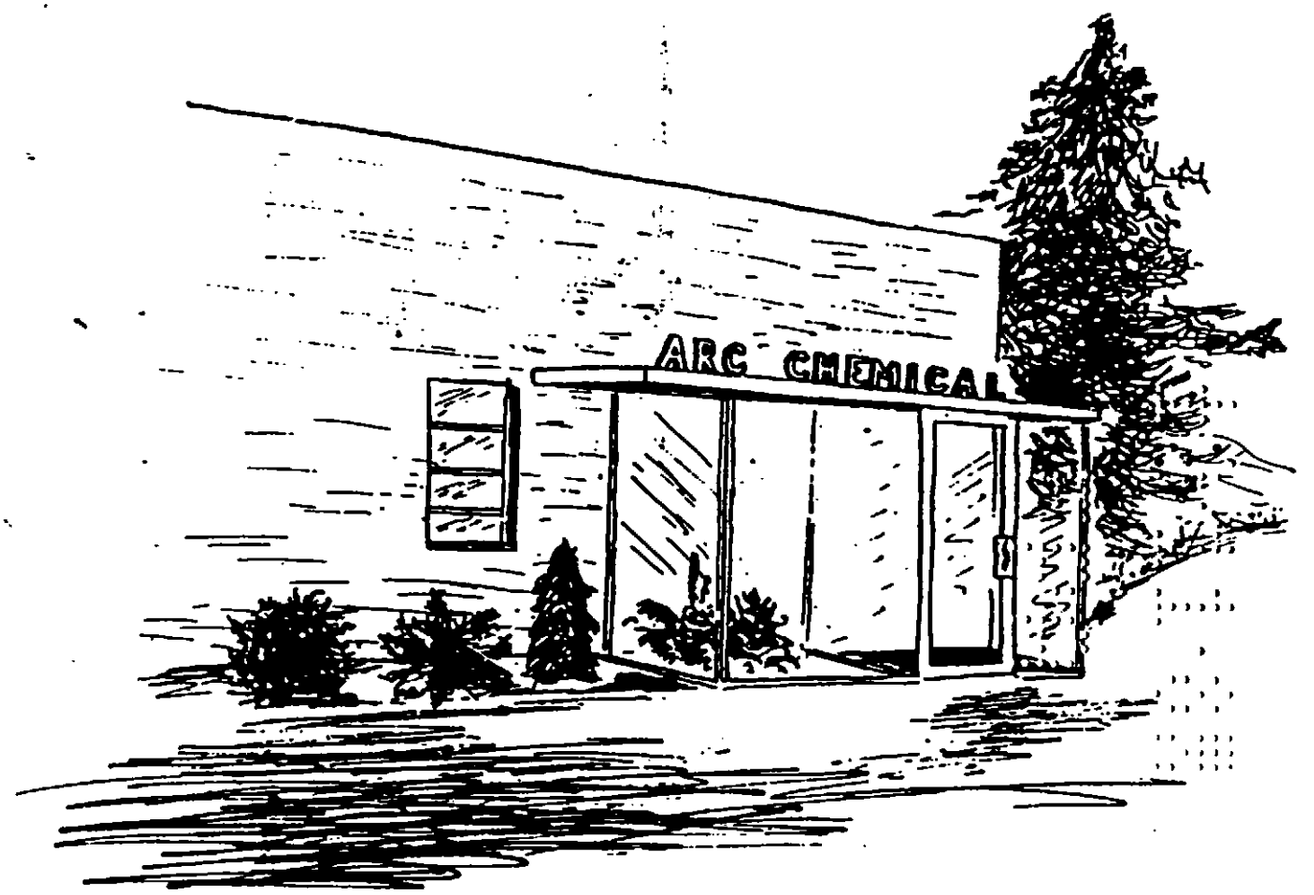
DRUMMED
ETHYLENE OXIDE



ACCEPTED
DEC 15 1988
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 36736-2

ARC

CHEMICAL DIVISION
BALCHEM CORP.

EPA REGISTRATION NO. 36736-2

EPA EST. 36736-NY-01

P.O. Box 180 • Slate Hill, N.Y. 10973 • 914-355-2891 • TWIX 510-280-1725

ARC Chemical Division Balchem Corporation began operation in 1970 to service drummed ethylene oxide users at a time when the sterilization of plastic medical devices was accelerating geometrically. Offering a personalized alternative to an industry dominated by very large corporations, ARC was able to expand and thereby provide service to fumigation and specialized synthesis manufacturers.

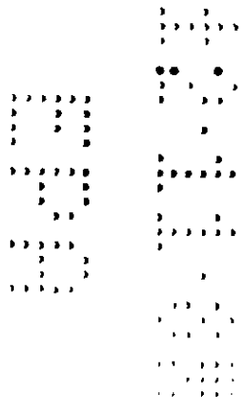
ARC originally produced a line of monomers and ethoxylates, utilizing novel esterification, transterification and ethosylation techniques. Market needs have enabled us to expand our business to include drummed ethylene oxide.

The professional staff at ARC has been associated with the handling of ethylene oxide for 25 years. To service our customers with quality products at reasonable prices we have assembled a team of research, engineering, production and marketing personnel equipped with modern laboratory and plant facilities, careful and precise quality control know-how and modern process technology.

Although a relatively young company, we were 20 years old in January 1987, ARC is well capitalized and is staffed with experienced professionals. The acquisition of a large number of drums has enabled ARC to expand rapidly in a capital and technologically intensive business. ARC purchases about 100 new drums per year and has an active drum refurbishment program. ARC's plant is using the latest drum washing techniques and ultrafiltration apparatus; its facility conforms to the OSHA 1PPM 8HR TWA.

The laboratory is fully equipped including sophisticated instrumentation for in process and finished quality control.

Interstate highways and major trucking firms are close by ARC's plant and there is a railroad siding on the property; both insure prompt and efficient delivery schedules, utilizing its own trucks to key delivery locations, or contract carriers to more remote locations.



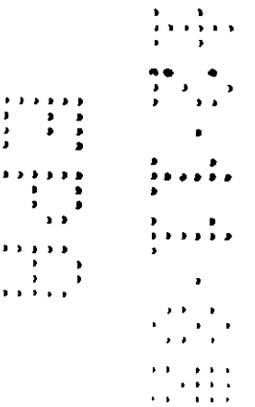
PHYSICAL PROPERTIES OF ETHYLENE OXIDE

LIQUID	
Molecular Weight	44.05
Apparent Specific Gravity at 20/20°C (68/68°F	0.8711
ΔSp.Gr./Δt. at 20 to 30°C (68 to 86°F)	0.00140
Coefficient of Expansion at 20°C (68°F)	0.00161
Water Solubility	Complete
Heat of Vaporization at 1 atm	6.1k kcal/g.mole
Surface Tension	28.0 dynes per cm.
Viscosity at 10°C (50°F)	0.28 cps.
Vapor Pressure at 20°C (68°F)	1095 mm.Hg
Boiling Point at 760mm	10.4°C (50.7°F)
at 300mm	-11.0°C (-12.2°F)
at 10mm	-66°C (-86.8°F)
ΔB.p./Δp. at 740 to 760mm.Hg	0.033°C per mm.
Freezing Point	-112.6°C. (-170.7°F)
Refractive Index, n_D at 7°C (44.6°F)	1.3597
Heat of Fusion	1,236 kcal/g. mole
Specific Heat at 20°C (68°F)	0.44 cal. per g.per°C
Explosive Limits in Air at 760mm.Hg ... Upper	100% by Volume
Lower	3% by volume
Flash Point, Tag open cup (ASTM Method D 1310)	<-18°C (<0°F)
VAPOR	
Critical Temperature	196.0°C (384.8°F)
Critical Pressure	1043 psia
Auto-ignition Temperature in Air at 1 atm	429°C (804°F)
Decomposition Temperature of Pure Vapor at 1 atm	560°C (1040°F)
Heat of Combustion of Gas, gross	312.15 kcal/g.mole
Heat of Formation	12.2 kcal/g.mole
Thermal Conductivity at 25°C (77°F)	0.00002961 cal-cm per sec. per $cm.^2$ per °C.

PHYSICAL PROPERTIES OF ETHYLENE OXIDE continued

SHIPPING DATA

Weight per Gallon at 20°C (68°F)	7.25lb.
at15.56°(60°F)	7.30lb.
Coefficient of Expansion at 50°C (122°F)	0.00177
Flash Point, Tag open cup (ASTM method D 1310)	<18°C (<0°F)
Freight Description	Ethylene Oxide
Dangerous Article Description on Containers	Ethylene Oxide
DOT Label Required	Flammable Liquid



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ARC CHEMICAL DIVISION
BALCHEM CORPORATION P. O. BOX 180 - SLATE HILL - NEW YORK 10973 - TEL. 914 / 355-2891
TWX 510 / 260-1725
FAX 914 / 355-6314

SPECIFICATIONS

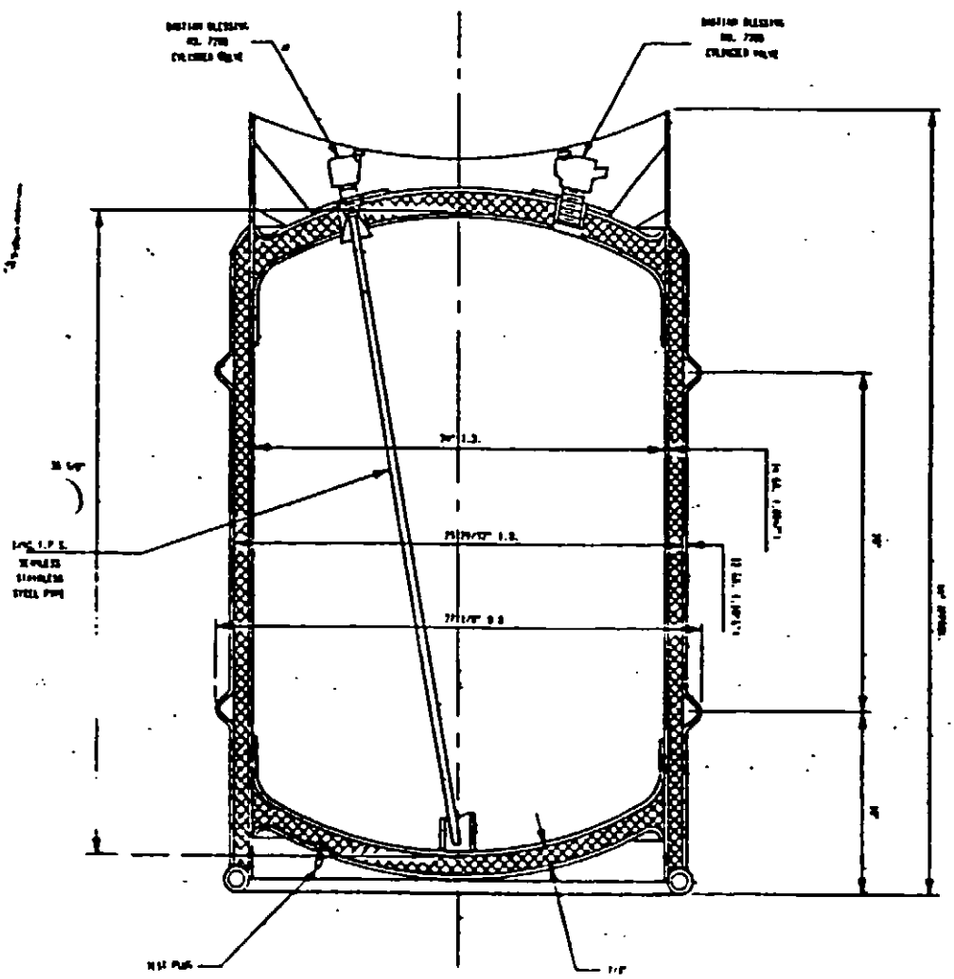
ETHYLENE OXIDE

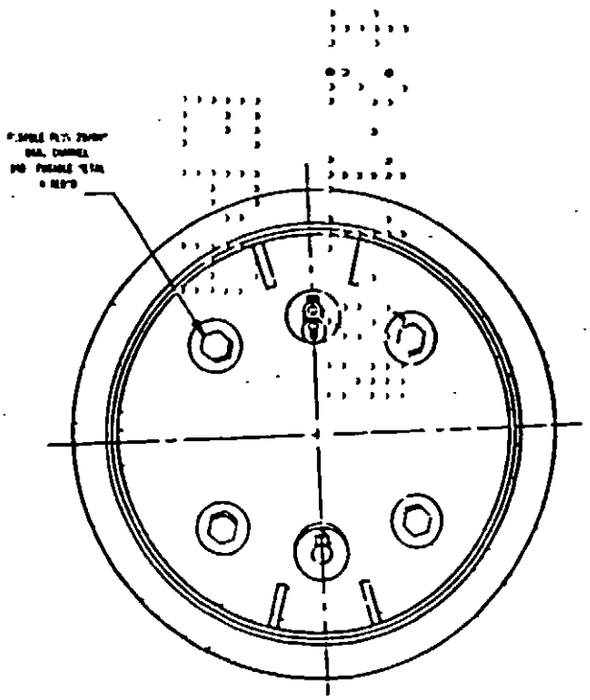
		Specification Limits
1.	Acidity	0.002 per cent by weight, maximum, calculated as acetic acid. This is equivalent to 0.019 mg KOH per gm sample.
2.	Aldehydes	0.0050 per cent by weight, maximum, calculated as acetaldehyde.
3.	Acetylene	Nil
4.	Water	0.03 per cent by weight, maximum
5.	Residue	0.005 gm per 100 ml, maximum
6.	Color	10 platinum-colbalt, maximum
7.	Suspended Matter	Substantially free

Revised
March 27, 1989

CONTAINER INFORMATION

Ethylene oxide is transported in a D.O.T. specified 5P drum. It is a double walled insulated shell drum with a tare weight of approximately 260 pounds. The working pressure of the drum is 50 psig and it is equipped with both a pressure valve set at 75 psig and four fusible metal plugs that melt at 157-170°F. A straight dip tube is also provided. A drawing of the drum showing the details and dimensions is illustrated in the figures.





APPLICATION AND USES

Ethylene oxide is an important chemical in industry today with many uses as an intermediate in the manufacture of a variety of compounds also as a fumigant and sterilant. It is highly reactive due to its strained 3-membered oxirane ring structure making the C-O bonds easy to cleave. In most reactions it is this opening of the ring that takes place. Ethylene oxide is reacted either by introducing the hydroxyethyl group into compounds containing one or more labile hydrogen atoms or by combining with itself via condensation polymerization to form varying chain lengths of water soluble polymers. Both reactions may be combined to form polyethoxylated derivatives of variable surface activity.

STERILIZATION AND FUMIGATION

In systems where heat cannot be used to kill bacteria, fungi and insects, ethylene oxide is highly effective as a sterilizing agent. It is used alone or in mixtures with inert diluents such as carbon idoxide and fluorocarbons serving as a fumigant, fungicide and sterilizing agent.

Use ethylene oxide only in sterilizers designed for use with ethylene oxide.

Use ethylene oxide in accordance with directions supplied by the sterilizer manufacturer.

Sterilizer temperature and pressure influence both exposure time and ethylene oxide concentration. The variation of type and quantity of material to be sterilized, how packed, size of sterilizer, types of bacteria to be killed, and chamber relative humidity also affect the exposure time required for sterilization. Gas sterilizer cycle parameters should be those prescribed by the sterilizer manufacturer, if applicable. If other cycle

parameters are used , the efficacy of the alternate cycle must be validated and is the responsibility of the user.

Aerate sterilized materials before use.

FUMIGATION

Fumigation with ethylene oxide must be performed with only vacuum or gas-tight chambers designed for use with ethylene oxide.

Aerate fumigated materials before use.

FOOD TREATMENT: 21 CFR 193.200

"Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices or other processed natural seasoning materials, except mixtures to which salt has been added..."

"Ethylene oxide, either alone or admixed with carbon dioxide or dichlorodifluoromethane, shall be used in amounts not to exceed that required to accomplish the intended technical effects."

SURFACE ACTIVE AGENTS

Hydrophobic material such as fatty acids, fatty alcohols, fatty amines, fatty amides, alkyl phenols etc. are reacted with ethylene oxide to form surface active adducts which are employed as wetting agents, emulsifiers, detergents, penetrants, solubilizers, foamers and degreasers. These properties are useful to the coating, paper, detergent, agricultural, chemical, textile and other industries.

CARBOHYDRATE AND PROTEIN MODIFICATION

Ethylene oxide is used to prepare modified starches and cellulose by hydroxyethylation. Depending on the degree of substitution these cellulose ethers formed may be soluble in water, alkali or organics. As water soluble compounds they are used in various products as thickeners, binders and protective colloids. Modified proteins are useful as adhesion promoters in latex paint and adhesive formulations.

HIGH MOLECULAR WEIGHT PROTEINS

Polymers and copolymers having properties useful as viscosity control agents are made with ethylene oxide. In addition, it is also an intermediate in the formation of resins with controlled solubility characteristics.

Toxicological Considerations

PERSONNEL SAFETY

Ethylene oxide is a relatively toxic liquid and gas. As a gas it can cause eye irritation and as the liquid, could cause severe eye injury. Contact with either one may produce delayed skin burns as evidenced by large blisters. It is, therefore, recommended that personnel working with EO wear air-supplied positive-pressure full-facepiece respirators or other NIOSH/MSHA-approved self-contained breathing apparatus, close fitting chemical goggles or full-face shield, PVC gloves impermeable to EO, rubber safety shoes, rubber aprons, and use spark-proof tools. Personal protective clothing and equipment must be in accordance with 29 CFR 1910.133.

An effective educational, training and industrial hygiene program should be instituted for the benefit of all persons working with or in the vicinity of ethylene oxide.

The program should include the following: (1) the nature and hazards of the gas; (2) proper handling and usage procedures; (3) first aid measures to be followed in the event of an exposure; (4) emergency procedures. It is preferable that such a program be documented.

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ARC CHEMICAL DIVISION
BALCHEM CORPORATION

Box 180 - State Hill - New York 10973 - TEL 914/355-2891
TWX 510/260-1725
FAX 914-355-6314

Material Safety Data Sheet Approved by U.S. Dept of Labor as Essentially similar to Form OSHA 20

Date: August, 1988

Chemical Name: CAS No. 75-21-8 1,2-Epoxyethane	Trade Name and Synonyms: Ethylene Oxide, ETO, EO, Oxirane, Dimethylene Oxide
Chemical Family: Epoxide	Formula: C_2H_4O
DOT Shipping Name: Ethylene Oxide	DOT Hazard Class: Flammable Liquid

SECTION 1 • PHYSICAL DATA

Boiling Point @ 760 mmHg: 50 °F (10.4°C)	Vapor Density(Air=1): 1.49 @ 40°C	Specific Gravity (H_2O = 1): 0.871	pH of Solution Neutral
Freezing/Melting Point: -111.7°C	Solubility (Weight % in Water) 100%	Density: 20/20°C 7.25 lbs./gal.	Volume % Volatile 100
Vapor Pressure: 1095 mmHg @ 20° C	Evaporation Rate: Rapid	Appearance and Odor: Colorless Gas or Liquid; ether-like odor.	

SECTION 2 • HAZARDOUS INGREDIENTS

	%	Hazard Data
Ethylene Oxide	100	Extremely flammable
		Toxic-Inhalation

SECTION 3 • FIRE AND EXPLOSION HAZARD DATA

Flash Point <0° F (tag closed cup)	Flammable Limits in Air (% by Volume) LEL: 3 UEL: 100	Extinguishing Media: Carbon dioxide, dry chemicals or alcohol base foam

Special Fire Fighting Procedures: Wear NIOSH/MSHA-approved self-contained breathing appartus. Exposed equipment should be cooled with water to prevent overheating. After fire burns out, flush area with water; re-ignition may occur.

Unusual Fire and Explosion Hazards: Vapors are heavier than air and may travel to source of ignition and flash back. May be explosive.

SECTION 4 • HEALTH HAZARD DATA

Permissible Exposure Limits: 1 ppm - TWA(8): 29 CFR 1910.1047; IARC - AND NTP - Noted as probable carcinogen. OSHA - Noted as carcinogen; ACGIH TLV - 1 ppm; OSHA-FL-5ppm

SWALLOWING	A highly unlikely route of exposure. Will cause severe irritation and ulceration of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma.

EMERGENCY TELEPHONE NUMBER: CHEMTREC 800-424 9300

SKIN ABSORPTION	Sustained contact with the skin is unlikely, but can cause headache, dizziness, nausea and vomiting. A dilute solution may penetrate skin, producing a chemical burn.
INHALATION	Causes irritation of the respiratory tract. Depending on the degree of exposure, there may be stinging of the nose and throat, coughing, chest tightness, headache, nausea, vomiting, diarrhea, weakness, drowsiness, cyanosis, loss of coordination, convulsions and coma. Delayed onset pulmonary edema may occur.
SKIN CONTACT	With liquid or solution in water, there may occur a local erythema, edema, and formation of vesicles. There may be a latent period of several hours prior to the onset of these signs. Large volumes of ethylene oxide spilled onto the skin may produce a frostbite-like effect.
EYE CONTACT	Severe irritation with corneal injury from liquid. Moderate irritation from high concentrations of vapor.

SECTION 5 • EFFECTS OF OVEREXPOSURE

This section covers effects of overexposure for inhalation, eye/skin contact, ingestion and other types of overexposure information in the order of the most hazardous and the most likely route to overexposure.

ACUTE Animal studies has shown that exposure has also been associated with the occurence of cancer, reproductive effects, mutagenic changes, neurotoxicity and sensitization. No conclusive human studies.

INHALATION: Ethylene oxide is primarily a central nervous system depressant. Animal studies and human experience have revealed that acute inhalation exposure can progressively cause mucous membrane irritation, CNS depression, lachrymation, nasal discharge, and salivation to gasping, labored breathing, with delayed effects including nausea, diarrhea, edema of the lungs, paralysis convulsions, and death. 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 contributing factor.

EYE CONTACT: Ethylene oxide liquid and diluted aqueous solutions splashed in the eyes can cause severe irritation and may result in permanent eye damage. Ethylene oxide vapors can also cause eye irritation.

SKIN CONTACT: Liquid ethylene oxide in contact with the skin will evaporate and may cause sufficient cooling to result in frostbite. Prolonged contact of liquid or aqueous solutions of ethylene oxide with the skin can cause severe irritation, blistering and edema. Such contact may occur from wearing contaminated clothing or may arise from ethylene oxide becoming entrapped under a ring or watchband. The reaction may not appear for several hours after exposure.

CHRONIC:

Respiratory irritation and chromosomal aberrations. Skin sensitization has been reported in some volunteer subjects.

EMERGENCY AND FIRST AID PROCEDURES:

INHALATION: Remove to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. If breathing is difficult, give oxygen. Call a physician.

EYE OR SKIN CONTACT: Immediately flush eyes and skin with plenty of water (soap and water for skin) for at least 15 minutes. If irritation occurs, consult a physician. Wash contaminated clothing before reuse. Shoes should be discarded.

INGESTION: Give at least two glasses of water. Do not induce vomiting. Call a physician.

NOTES TO PHYSICIAN (including Antidotes):
Through unpublished reports it has been found that, for persistent nausea and vomiting from inhalation of ethylene oxide, an intramuscular injection of phenobarbital (2 grains) is very helpful in controlling such symptoms.

SECTION 6 • REACTIVITY DATA

Stability: Stable	Conditions to Avoid: Contamination with polymerization initiators
Hazardous Polymerization: May Occur	Conditions to Avoid: High temperatures (400° C – Autoignition temperature)

Incompatibility (Materials to Avoid):
Copper, silver, magnesium, mercury and their salts and oxidizers of all types

Hazardous Decomposition Products: Ethylene oxide may decompose or polymerize when in contact with active catalytic surfaces such as anhydrous chlorides of aluminum, iron + tin, oxides of aluminum and iron, metallic potassium, alkali metal hydroxides, acids, organic bases and ammonia The rapid decomposition or polymerization generates heat and may be violent. Reactions are accelerated at higher temperatures and may react explosively, above 85° F.

SECTION 7 • SPILL OR LEAK PROCEDURES

Steps to be Taken if Material is Spilled or Released:
Evacuate area. Remove ignition sources. Provide maximum ventilation. Do not reenter area without proper protective equipment. Shut off source of gas, if possible. Dilute liquid with large quantities of water. Place diluted ethylene oxide in vented stainless steel container for disposal.

Waste Disposal Method: Suggested method is by incineration in approved liquid burning hazardous waste incinerator. Small quantities in diluted water solution might be handled in approved hazardous waste landfill. Contact with local pollution control agency is suggested. Care must be taken when using or disposing of chemical materials and/or their containers to prevent environmental contamination. It is your duty to dispose of the chemical materials and/or their containers in accordance with the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act and all state or local laws/regulations regarding disposal.

SECTION 8 • SPECIAL PROTECTION INFORMATION

Respiratory Protection: Wear air-supplied, positive-pressure full-facepiece respirators or other NIOSH/MSHA - approved respirators for ethylene oxide in environments exceeding the PEL.

Ventilation(type): Local exhaust where handling ethylene oxide indoors cannot be avoided, extra attention should be given to avoiding leaks and providing adequate ventilation.

Eye Protection: Close-fitting chemical safety goggles or full face shield.	Gloves: Gloves impermeable to Ethylene oxide. OSHA recommends PVC.

Other Protective Equipment: Rubber safety shoes, rubber aprons, long-sleeve shirt; eye wash fountain and safety shower in immediate area; spark-proof tools. Personal protective clothing and equipment must be in accordance with 29 CFR 1910.133.

BEST AVAILABLE COPY

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SECTION 9 • SPECIAL PRECAUTIONS

Precautions to be Taken During Handling and Storing:

- •Extremely Flammable.
- •Before unloading, purge air from unloading system.
- •Container and system must be electrically grounded before unloading.
- •Vapors can form explosive mixtures with air over a wide range of concentrations
- •Adequate ventilation must be maintained in storage areas to reduce fire hazard in the event of a leak.
- •Do not store in open, unlabeled, or mislabeled containers.
- •Store in tightly closed container.
- •Do not reuse container for any purpose.
- •Wear protective safety equipment as outlined in Section VIII when handling ethylene oxide.

Other Precautions:

- •Keep away from heat, sparks and flame.
- •Do not inhale vapors.
- •Use only with ventilation sufficient to limit employee exposure to ethylene oxide in work area below established limits.
- •Do not get in eyes, on skin, on clothing.
  Liquid absorbed into clothing, particularly shoes, causes delayed burns. Water solutions of liquid or gas cause immediate burns.
- •Do not take internally.
- •Wash thoroughly after using.

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ACCEPTED
DEC 15 1989
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 36736-2

Robert G. Reynolds
Robert G. Reynolds
Process Engineer
Arc Chemical
Division of Balchem Corporation

36736-2

18-131

Principles and Practice of Ethylene Oxide Sterilization

ARC

CHEMICAL DIVISION
BALCHEM CORP.

ACCEPTED
DEC 15 1980
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 36736-2

EPA REGISTRATION NO. 36736-2

EPA EST. 36736-NY-01

P.O. Box 180 • Slate Hill, N.Y. 10973 • 914-355-2891 • TWIX 510-280-1725

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Table of Contents Page

The purpose of this pamphlet is to provide a brief, easily understandable, non-technical discussion of the principles and practice of Ethylene Oxide Sterilization and the use of Ethylene Oxide Sterilization controls.

It would be impossible to completely cover the subject in this limited space, but we will gladly supply additional information or confer personally on specific problems upon request.

Samples of the various ATI Ethylene Oxide sterilization indicator products mentioned in the booklet, and additional copies of the booklet itself, are available without cost by writing:

ATI Deseret Medical, Inc.
Parke, Davis & Company
11471 Vanowen Street (P.O. Box 9338)
North Hollywood, CA 91605-6269

Introduction

The use of heat for effective sterilization has a long history. Although steam is still the most widely employed and practiced method of sterilization, the required high temperature and moisture can damage certain materials. Many items made of plastic, rubber and metal can not tolerate exposure to the high temperatures of 250°F. (121°C.) and 270°F. (132°C.). This problem led to the development of a sterilizing agent: gaseous ethylene oxide. It proved to have a high penetrating ability and could be used at ambient temperatures. The wide-spread use of ethylene oxide today is based on its ability to destroy microorganisms, such as bacteria and viruses, without damaging sensitive materials. **Ethylene oxide is not a substitute for steam sterilization, but is an alternative method for temperature-sensitive items.**

IMPORTANCE OF STERILIZATION

Definition

The terms sterile, sterilize and sterilization are only accurate when there is the absence and/or destruction of all microorganisms. This includes bacteria, their spores, fungi and viruses. The process of sterilization must destroy all microorganisms, including those which cause disease or infection (pathogens). There can be no compromise in the use of these terms. **An object is either sterile or not sterile. There is no such thing as "almost" or "partially sterile."**

Role of Infection Control

The increasing problem of hospital related infections (nosocomial infections) has focused attention on the vital importance of correct sterilization procedures. Modern hospitals have Infection Control Committees, which both monitor and assure item sterilization procedures. Joint Commission on Accreditation of Hospitals (JCAH) guidelines state that ". . .There shall be an effective infection control program within the hospital." These guidelines affect numerous hospital departments (Central Service, Operating Room, Emergency Room, Obstetric Service, Inhalation Therapy, etc.).

The Central Service Department has an important role in the decontamination, processing, packaging and storage of items which require sterilization. The success of any infection control program ultimately lies with well-trained CS and other technicians who have the daily responsibility of assuring sterilization quality control.

The JCAH has recommended sterilization assurance procedures in part, as follows:

There shall be written policies and procedures for the decontamination and sterilization activities performed in central services and elsewhere in hospital, and for related requirements. These policies and procedures should relate, but are not limited to, the following:

- The receiving, decontamination, cleaning, preparing, disinfecting, and sterilizing of reusable items.
- The assembly, wrapping, storage, distribution, and quality control of sterile equipment and medical supplies.

- The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical, color and bacteriological spore tests for all sterilizers.
- Designation of the shelf life for each hospital-wrapped-and-sterilized medical item and, to the maximum degree possible, for each commercially-prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. Where possible, load control numbers should be used to designate the hospital sterilization equipment used item, including the sterilization date and cycle.
- The recall and disposal or reprocessing of out-dated sterile supplies.
- Specific aeration requirements for each category of gas-sterilized items to eliminate the hazard of toxic residues. Chemical indicators should be used with each package sterilized as required. The use of other sterilization monitors should be defined. In loads undergoing gas sterilization, a live spore control should be used at least weekly and is recommended for incorporation into each sterilizing cycle. When implantable or intra-vascular material undergoes gas sterilization, live spore controls should be used with each load. Where feasible, the results of the spore test should be ascertained prior to use of gas-sterilized items.

Sterilization Methods

Scientific sterilization is less than 200 years old. In its earliest stages, dry heat was the primary method, and is still used for certain materials (e.g., powders). Later, in the 19th century, steam sterilization techniques evolved. Even today, steam sterilization is unquestionably the most effective and economical method of microorganisms destruction. However, heat-sensitive materials are not well-suited for this method.

The introduction of ethylene oxide's sterilizing ability overcame the problems of material damage by heat. The Division of Hospital and Medical Facilities of the U.S. Public Health Service recommends that steam under pressure, dry heat and ethylene oxide be the main sterilization methods used by hospital facilities. Other commercial methods now in use include the high-energy electron beam and gamma radiation.

The Army Chemical Corps was responsible for the development of the ethylene oxide gas sterilization process as used in hospitals. They sought and found a bactericidal and sporicidal gas that was effective at lower temperatures, penetrated porous substances, and did not corrode or damage metal, paper, plastic, rubber, leather, wood or wool. It was also required that the gas be easily removed by aeration, act rapidly, store easily, have low human toxicity, be non-flammable, easily-handled and readily available. The problem of pure ethylene oxide's extreme flammability and explosivity was overcome by mixing it with an inert gas such as carbon dioxide or Freon.

PRINCIPLES OF ETHYLENE OXIDE STERILIZATION

Bacteria, Spores and Viruses

Bacteria, their spores and viruses are a major cause of infection and disease. Bacteria and viruses are capable of reproducing by the millions at very rapid rates. Bacteria exist in what is termed an active or vegetative state, reproducing at regular intervals. They are also capable of survival under extremely adverse conditions by going into a protected dormant state, known as a spore. These spores can survive for extended periods, even under conditions of heat, cold or desiccation which would kill vegetative bacteria. Spores become active when again placed in a favorable environment. It is for this reason that sterilization must be an absolute process, with complete pathogen destruction.

Certain surgically-critical bacteria (notably anthrax and clostridium) can severely complicate the health of a hospitalized patient if not destroyed. For example, any surgical instrument that has only a few surviving bacteria or spores could become greatly contaminated, due to the rapid reproduction of the bacteria. An operative wound exposed to these pathogens could result in delayed patient recovery, infection, and even death. The lethal effects of ethylene oxide on bacteria, spores, viruses and fungi have been experimentally established. The precise mechanism of action is still uncertain. However, it is thought that the gas penetrates the microorganisms and chemically reacts with its proteins. This process disrupts the life functions (metabolism, reproduction) so that the cell can no longer survive.

Critical Variables

Ethylene oxide sterilization is a complex process. In order for it to be an effective sterilizing agent, there must be the proper relationship between the gas concentration, moisture, time and temperature. Alteration of any one of these four variables can affect the others and change the sterilization process. Though these conditions usually vary, based on the specifications of different sterilizer manufacturers, the basic principles can be outlined as follows:

Gas Concentration: In its pressurized container, ethylene oxide is a liquid and must be vaporized to effectively permeate and sterilize the load. Pure ethylene oxide gas is extremely explosive, flammable and toxic. It is, therefore, often mixed with an inert gas to be rendered non-flammable. Gas concentration is measured in milligrams per liter (mg/L) of chamber space. This can be mathematically calculated (if needed) by using readings from the sterilizer pressure gauge. The range of effective concentrations is usually 450mg/L to 1500 mg/L. The higher concentrations usually result in a shorter sterilization time. This however, is based on chamber temperature, and other factors. **The sterilizer manufacturer's instruction should be carefully followed.**

Moisture and Humidity: Moisture is measured in terms of relative humidity. This is the ratio of the amount of water actually present in the air to the greatest amount the air can hold at the same temperature. Ethylene oxide gas is generally considered a dry sterilization process. However, water vapor must be present, but not at the saturated (100% relative humidity) level of steam sterilization. The relative humidity should be at least 30%. Too much moisture however, can cause the formation of ethylene glycol. This is a toxic compound which can remain as a residue in sterilized items and slow the lethal action of ethylene oxide. Dry cells and spores are much more resistant to ethylene oxide sterilization. With some sterilizers the recommended procedure is to "pre-condition" the load by allowing the chamber to be filled with a high-humidity atmosphere for at least 30 minutes. This softens the surface of the spores and thus allows easier and faster penetration of ethylene oxide. With other sterilizers, moisture is added during the cycle. It is theorized that the water "carries" the ethylene oxide into the microorganism, where it can chemically react. Close attention must be paid to proper humidification. It is probably the most common cause of non-sterility in gas-sterilized items.

Time: Exposure times can vary greatly. This is because each load is affected by the relative contamination, density, contents and permeability to ethylene oxide gas. As a result, the sterilization time must be adjusted accordingly. **The sterilizer manufacturer's instructions should be carefully followed.**

Temperature: Ethylene oxide vaporizes (from liquid to gas) at 51°F. (10.5°C.). It can, therefore, be an effective sterilizing agent at temperatures as low as 70°F. (21°C.). Higher temperatures, however, allow shorter cycles by enhancing the gas diffusion rate. The usual operating temperature for ethylene oxide sterilizers varies from 70°F. (21°C.) to 140°F. (60°C.). Temperature also affects the pressure of the gas. If the temperature drops after filling, it would cause a reduction in the gas diffusion rate. A preheated chamber will allow the gas to stay in a gaseous state. Careful attention must be paid to the chamber temperature and gas pressure.

Of the four critical variable essential to EO gas sterilization, only **exposure time** can be accurately measured by the technician. Gas concentration is dependent on how it is supplied and injected into the sterilizer. Temperature is usually read at only one point, and is not indicative of temperature in various parts of the load. In most sterilizers, moisture is not measured. A change in any one of these variables changes the other three. Therefore, **always follow the exposure conditions set by the sterilizer manufacturer.**

Limitations

Ethylene oxide has provided the health care industry with an important sterilization method for those materials which are adversely affected by steam or dry heat sterilization. Nevertheless, this method has some limitations. Ethylene oxide sterilization is a slow process (much slower than steam). It also requires relatively expensive equipment and a skilled operator. Some other common problems include:

1) the necessity to continually monitor temperature, gas concentration and humidity on a manual sterilizer
2) the weakening of and/or surface damage to certain acrylic and polystyrene items, the crazing of some instrument lenses and dissolving of lens cement.
3) the formation of toxic compound by-products.
4) the retarding of gas penetration by protein matter and soil.
5) the inability to sterilize solutions.

Most importantly, recent research indicates that exposure to ethylene oxide is injurious to humans. These health-related problems will be discussed in detail (See page 10: Precautionary Measures Using Ethylene Oxide).

PRACTICE OF ETHYLENE OXIDE STERILIZATION

Sterilizing Equipment

Various kinds of ethylene oxide sterilizers are in use today. These include fully automatic, semi-automatic and manual control systems. They range in size from small table-top room temperature models to large fully-automatic built-in units. The following discussions will compare the small table-top model to the fully-automatic unit:

Table-Top Room Temperature Model

These models were originally designed for sterilizing small objects. They operate for a standardized time cycle, at the ambient room temperature and humidity. In order to compensate for the lower room temperature and humidity, they required a higher gas concentration and the addition of moisture. Because of the hazardous nature of ethylene oxide, a sterilizer should **never** vent directly into a room as some old-style table-top models do.

Automatic Models

A variety of models and operational procedures exist for these sterilizers. Some models incorporate the injection of steam into the sterilizing chamber. This allows more rapid sterilization, because the materials are heated and moistened by the steam.

After sterilization, the ethylene oxide gas is evacuated from the chamber and replaced with filtered air. The load is then removed for aeration. In general, a cycle consists of: conditioning (pre-humidification), gas charging, sterilization period, vacuum phase and filtered air replacement.

Sterilizing Procedures

Always follow the sterilizer manufacturer's operating procedures. The most commonly used steps of operation incorporate the following procedures:

1) **Preparation:** Materials should be surgically clean, free from soil or protein matter (e.g., blood tissue, or fluids), must be towel-dry, and free from water droplets to minimize the formation of ethylene glycol. All caps, plugs, valves should be removed to allow gas penetration. Needles and tubing should be open at both ends. Syringes should be disassembled.
2) **Loading:** Load similar to steam sterilizer. Gas should be allowed to circulate freely. Avoid overloading and dense packs.
3) **Temperature:** Pre-heat to operating temperature. This speeds up the lethal effect of gas.
4) **First Vacuum:** Draw a vacuum. Drawing time varies with chamber size. Rapid reduction of pressure within the chamber can cause bursting of sealed bags. Wrapping materials should "breathe" and adjust to change.
5) **Moisture:** A minimum relative humidity of 30% is needed for standard gas sterilization cycles. Some sterilizer models require the addition of water or wet sponges to supply minimum moisture required. Automatic models inject moisture into the chamber to maintain the proper relative humidity. A conditioning period of 30-60 minutes should follow moisture injection. This time allows for humidification of dry bacterial spores and thus permits rapid lethal action of gas. Some chemical indicators have been developed to reflect insufficient moisture.

6) **Gas Injection:** Recommendations concerning ethylene oxide pressure and concentration vary with sterilizer; follow manufacturer's instructions. Some sterilizers do not allow expansion and preheating prior to chamber entry. Preheating the gas eliminates expansion cooling effects and condensation of gas into liquid (which can cause material damage). Ethylene oxide/carbon dioxide mixtures tend to stratify in large storage cylinders due to their different atomic weights. Therefore, under certain conditions, the final 20% of the remaining cylinder contents may not contain sufficient ethylene oxide to be a sterilizing agent. Ethylene oxide/Freon mixtures avoid this problem.
7) **Exposure Time:** It is imperative to operate sterilizer for the time recommended in the manufacturer's instructions.
8) **Second Vacuum:** At end of exposure time, ethylene oxide is removed from chamber by drawing a second vacuum.
9) **Atmospheric Restoration:** At end of cycle, filtered air is admitted to chamber to restore atmospheric pressure. Sterilizer door should be opened and inhalation of any escaping gas must be avoided. Items should not be removed for at least 5 minutes.
10) **Aeration:** Items must be properly areated to remove residual gas. (For detailed discussion, see below: Aeration).

ADVANTAGES AND DISADVANTAGES

As previously discussed, the main advantage of ethylene oxide sterilization is its ability to sterilize those items which are adversely affected by steam or dry heat. Although ethylene oxide has potential to sterilize most hospital items, a number of disadvantages limit its use. These include toxicity to personnel, higher costs, longer exposure and aeration time. It is not recommended that ethylene oxide replace steam or dry heat sterilization when the latter methods are applicable. But availability of all three methods offer a complete sterilization system for every hospital.

Ethylene oxide can be used to sterilize plastics, rubber, metal, leather, wood, wool, rayons, nylon, glass and virtually every other material. Table 1 shows the more commonly used articles which are compatible with ethylene oxide sterilization. Pure ethylene oxide does not cause damage to most materials. However, it can have adverse effects on some items when it is diluted with Freon (see Precautionary Measures).

Instruments and Equipment

Cautery Sets • Dental Instruments • Eye Knives • Lamps • Needles • Neurosurgical Instruments • Scalpel Blades • Speculae • Lensed Instruments • Microsurgery Instruments

Plastic Goods

Catheters • Heart Pacemakers • Infant Incubators • Nebulizers • Test Tubes • Vials • Prosthesis • Implants

Rubber Goods

Catheters • Drain and Feed Sets • Sheeting • Tubing • Respiratory Tubes

Telescopic Instruments

Bronchoscopes • Cystoscopes • Arthroscopes • Endoscopes • Esophagoscopes • Opthalmoscopes • Otoscopes • Pharyngoscopes • Proctoscopes • Resectoscopes • Sigmoidoscopes • Thoracoscopes • Urethroscopes

Miscellaneous

Blankets • Books • Dilators • Electric Cords • Hair Clippers • Medicine Droppers • Miller-Abbott Tubes • Motors • Pottery • Pumps • Sealed Ampules • Toys

AERATION

Although ethylene oxide gas provides an effective method of sterilization for heat and moisture-sensitive products, excessive residual amounts of EO or its by-products (ethylene glycol and ethylene chlorohydrin) may be harmful to patients and hospital personnel. Exposure to items such as prosthetic devices, surgical instruments, catheters, etc., which have not been properly aerated subsequent to sterilization could result in serious chemical burns as well as skin and mucous membrane irritation. Therefore, adequate aeration time must be allowed following sterilization in order to ensure that any ethylene oxide and its by-products remaining in or on the sterilized devices have been reduced to a safe level.

Medical devices, commercially gas-sterilized before marketing, are usually free of any harmful levels of residual EO or its by-products by the time they reach the hospital.

Suggested aeration times are as follows:

Product	**Recommended Aeration Time**
All materials aerated at room temperature	7 days
All materials aerated in an aerator	8 - 12 hrs. at 122°F. (50°C.) to 140°F. (60°C). **(Request specific instructions from the aerator manufacturer).**

All sterilized items should be stored in a well ventilated area which protects them from extremes of temperature and humidity.

ROLE OF WRAPPING MATERIALS

Introduction

The use of ethylene oxide as a sterilant has enabled the marketing of many new pre-sterilized plastic hospital articles. These items were previously not availabe due to the manufacturer's inability to sterilze many types of plastics. This development has created a need for special packaging materials in which such a product can be sterilized and safely stored until used. Similar types of packaging materials are also available to hospitals.

Muslin wrappers, non-woven paper wrappers, and paper bags are acceptable as ethylene oxide wrapping materials. They are limited, however, by their lack of visility and high porosity. Transparent pouches and tubing are preferable because they allow the user easy identification of the contents.

Not all packaging materials are acceptable for ethylene oxide sterilization. A great deal of testing is often necessary to determine which materials, or combination of materials, is satisfactory. Wrapping materials **not** to be used because of inadequate permeability include:

1) Nylon film
2) Foil
3) Saran
4) Polyvinylchloride (PVC) film

Avoid combinations of materials which make a non-permeable package since gas penetration to the product is essential.

An acceptable ethylene oxide wrapping material must meet the following requirements:

- Readily available in a variety of sizes.
- Permeable to ethylene oxide gas **and** water vapor.
- Must allow air inside the package to escape so that the package will not burst during the vacuum cycle.
- Must protect sterile items from recontamination during storage.

If you are uncertain as to the suitability of a particular packaging material, you should contact the manufacturer of the material for information and guidance concerning the appropriate EO sterilization and aeration procedures to be used.

Before using a new packaging material, it should be tested in the sterilizer in which it will run. Biological indicators should be placed inside the material and sterilized according to instructions. The biological indicators should then be cultured. If the results are negative (no growth), the packaging material is safe to use.

Procedures For Use

Whereas steam tends to descend vertically in a steam sterilizer, ethylene oxide gas diffuses in all directions. Therefore, the position of packs and packages is not as critical when using ethylene oxide gas. Nevertheless, care should be taken not to overload the sterilizer. Compression of plastic-wrapped packs against one another will hinder the evacuation of air. This may increase the chance of having the packages burst open when the chamber pressure decreases as the vacuum is drawn. Compression of the packages may also prevent sufficient penetration of ethylene oxide gas. To reduce the possibility of bursting, remove most of the air from the package before sealing. If bursting still occurs, contact the manufacturer of the packaging material for special instructions to eliminate this problem. Materials which protect items from recontamination during storage inherently have a low air permeability and therefore, have more of a tendency to burst during vacuum cycles. Not all available materials are acceptable for every type of sterilizer; what may be adequate in one will sometimes be unsatisfactory in another.

A recommended procedure is to place a chemical sterilization indicator (such as an ATI STERILOMETER-PLUS/EO or an ATI ETHYLENE OXIDE STERILIZATION INDICATOR) inside each sealed package. These provide immediate visual evidence that sufficient sterilization conditions are met inside the packages. It is also recommended that a biological sterilization indicator (such as an ATI SPORE-O-CHEX) be used with each load.

ATI Pouches and Tubing

ATI Pouches and Tubing were developed to permit the penetration of ethylene oxide gas and moisture. They are available in a variety of sizes, and have an ethylene oxide indicator printed on them.

They can be used in all ethylene sterilizers. Each has an indicator which changes color from yellow to rust/red during ethylene oxide gas sterilization.

Storage Life

The storage life of any sterilized item depends on a number of factors:

a) type and uniformity of wrap packaging material
b) storage conditions (open or closed shelves, frequency of handling, cleanliness of the storage area, use of dust covers)
c) atmospheric conditions (temperature, humidity)

Numerous studies have been conducted on the shelf life of in-hospital sterilized items (packs and packages), but the test results apply only to the materials and storage conditions under which the tests were conducted.

Sterile shelf life must be considered an event-related condition (such as factors, a, b and c described above) rather than only a time-related condition.

However, since the number of the event-related conditions prohibits setting reasonable event-related guideline, the following time-related shelf life limits suggest some guidelines which may be used as a starting point for further investigation:

muslin, nonwoven fabric and paper wraps (all double wrapped)	21 to 30 days
paper bags	21 to 30 days
paper/plastic pouches	21 to 30 days
plastic pouches (heat sealed)	3 months
any of the above immediately placed inside of a heat-sealed dust cover	6 months

It is recommended that all hospital-sterilized materials be used within a 48 hour period. If this is not possible, then over-wrapping with a dust cover should be considered.

STERILIZATION INDICATORS

The preceding topics have shown that a number of important variables must interact in order to assure ethylene oxide sterilization. The materials must be exposed to a specific gas concentration which is critically dependent on the integrated effect of humidity, temperature and time. On most sterilizers, recorders and gauges indicate temperature and pressure conditions in the chamber. However, they do not monitor the conditions within the packs.

The use of certain types of ethylene oxide sterilization indicators placed inside the pack will show whether or not sterilizing conditions have been met. These indicators will monitor all four of the essential elements for gas sterilization. There are several types of indicators available for hospital use.

Biological Sterilization Indicators

The JCAH urges the use of a live bacterial spore test at least weekly and recommends their use in each gas sterilizing cycle. Their effectiveness is based on the theory that if sterilizer conditions are sufficient to kill the specified spores, then nothing else will survive. The resistant spores of **Bacillus subtilis (niger)** are the most commonly used organisms for monitoring ethylene oxide sterilization. Although these biological tests are an integral part of quality control, they do have practical limitation:

Delayed Results: Test results are usually not available for at least 24 hours (and up to 7 days). This makes it impractical to quarantine all goods for that length of time.

Statistical Sampling Problems: The number and frequency of tests required to assure detection of sterilizer failure is not economically feasible. Many more tests would be required to obtain a safe statistical level of confidence.

False Positives: Culturing technique is important so as to avoid contamination of the test which would cause growth from a foreign organism. As a result, a certain number of tests give false positives.

- **Lack of Standardization:** Many commercially-available spore preparations appear to show variations in resistance. This may occur in different lots from the same manufacturer.

However, biological sterilization indicators represent an important method of monitoring sterilization for infection control.

ATI Disposable EO Gas Biological Test Pack

The recommended method for testing an ethylene oxide cycle with biologicals is to place the biological indicator inside a syringe whose tip is open but with the rest of the barrel closed. This syringe is wrapped in a towel and placed in a paper/film pouch. The pouch is placed in the sterilizer with the rest of the load.

ATI has developed a package that simulates this recommended test pack. It includes a self-contained biological indicator inside a package that gives the same resistance characteristics as the standard package. Use of this disposable package eliminates the labor needed to assemble the pack every day, and results in consistent, reliable results from day to day.

•ATI Spore-O-Chex ®

For those hospitals wishing to make up their own test packages, spore strips are available. ATI Spore-O-Chex contain both **B. stearothermophilus** for testing steam cycles and **B. subtilis (niger)** for testing ethylene oxide and dry heat cycles. The live spores of **B. subtilis (niger)** which survive at 15 minutes in 600 mg/L of ethylene oxide at 130°F. (54°C.) and at least 30% relative humidity are killed after 120 minutes of direct exposure to these conditions. As previously stated, JCAH recommends the use of a live bacterial spore test.

Each Spore-O-Chex Biological Sterilization Indicator test set consists of an envelope with 2 test strips on one side and a control strip on the other. Simple and specific instructions to the Supervisor and the Bacteriologist are printed on the envelope. There is also space to record the test data and results. Spore-O-Chex strips are also available in bulk.

There are other methods available, chemical indicators for example, that offer the practical advantage of immediate results and the economy of use in each pack.

Chemical Indicators

The JCAH recommends that chemical indicators be used with each package sterilized. A chemical indicator is a chemical system which, by a visible change, indicates that certain chemical and/or physical conditions have occurred. These indicators are available in various forms. Some react only when exposed to ethylene oxide gas. These are considered "processing indicators". Others react when exposed to sufficient gas concentration, moisture, time and temperature required for ethylene oxide sterilizing conditions. This latter type are "sterilization indicators". However, both forms offer a simple and economical method of checking each load and every pack or package.

•Ethylene Oxide Indicator Tape

Ethylene oxide sterilization does not change the appearance of packs or packaging. It is therefore desirable to differentiate between processed and unprocessed objects by means of identification tape used to seal the packs. The indicator on the ethylene oxide tape changes color when exposed to ethylene oxide gas. This provides visual evidence that a pack has been processed. It does not, however, verify sterilization of the contents.

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•ATI Steam and Gas Labels

These are pressure-sensitive labels with chemical indicators. They can be affixed to any package or article being sterilized. The EO gas chemical indicator changes color from yellow to rust/red when exposed to ethylene oxide gas. A complete failure to react indicates no exposure to ethylene oxide gas. This label provices an immediate visual indication an article has been processed through a sterilizer.

ATI Sterilometer-Plus ® /EO Sterilization Indicators

A lack of proper humidification is probably the single most common malfunction occuring in hospital EO sterilizers. Without adequate humicity, the ethylene oxide has difficulty penetrating the cell wall of the spores and its effectiveness is greatly reduced.

The ATI Sterilometer-Plus/EO is an indicator designed to relay as much information as possible about the conditions during a sterilize cycle, including the presence of adequate moisture. The Sterilometer-Plus/EO is a paper strip indicator with two indicator spots. Both spots are initially orange; when exposed in a properly functioning sterilizer and run through a normal cycle, the left spot turns brown to show exposure to EO gas, and the other spot turns green to indicate that the atmosphere was properly humidified and the correct time and temperature conditions are met. If any of the four essential parameters necessary for EO sterilization are not present, the Sterilometer-Plus/EO shows it immediately. In addition, Sterilometer-Plus/EO is covered with a clear plastic overlay, preventing the indicator ink from coming in contact with items being sterilized.

ATI Ethylene Oxide Sterilization Indicators

These are paper strips with a chemical indicator bar which changes color from yellow to blue when **all four** conditions for EO gas sterilization (sterilization time, EO gas concentration, moisture and temperature) have been obtained. They should be used **inside** a pack or package.

The ATI Ethylene Oxide Indicator changes color from yellow to blue in 30 to 45 minutes when exposed to at least 30% relative humidity in 140°F. at 600 mg/L. At less than 30% relative humidity, the indicator will require additional time to change color. A partial color change to yellowish green or to a green color indicates that the required sterilization conditions may not have been met.

Important Note

When the ATI Ethylene Oxide Indicators fail to react, it is often due to the fact that some sterilizers depend upon the humidity in the air for moisture. This may be insufficient for sterilization. To overcome this lack of moisture, some sterilizer manufacturers recommend that a small sponge or gauze pad saturated with water be placed on the bottom of the sterilizer at the rear. The use of a "conditioning cycle" (as outlined on page 4) is also a recommended procedure for overcoming this lack of moisture.

ATI Product Performance

All ATI Sterilization Indicators meet rigid quality control specifications before being released for sale. These specifications are available from ATI upon request. Random samples of every ATI Sterilization Indicator production lot are tested by an independent clinical laboratory against a standard biological control. All ATI Sterilization Indicators meet (or exceed) the performance specifications of the biological indicators, and copies of the laboratory report are available for any lot on request. Each indicator strip carries a lot number, by which the history of the product can be traced. Figure 1 shows the performance characteristics of the ATI Ethylene Oxide Sterilization Indicator.

ATI Ethylene Oxide Indicator Performance Chart.

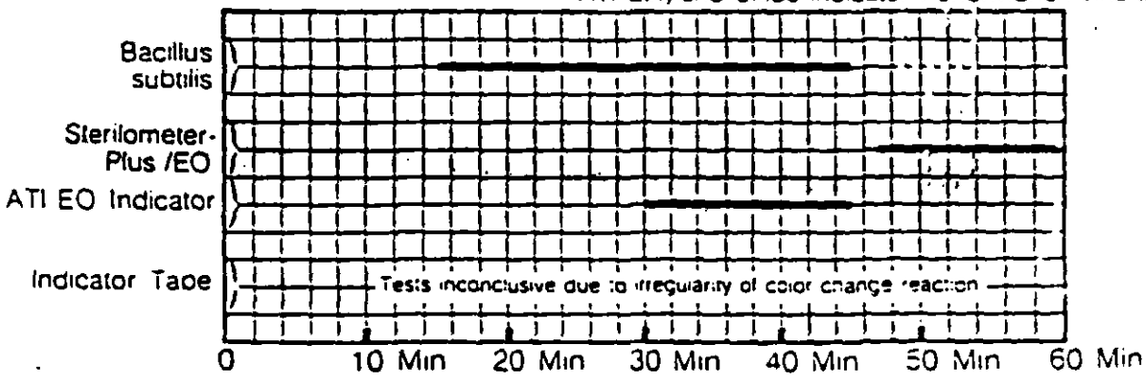

Fig. 1 Time (minutes) required to kill spores or react chemical indicator at 130°F. in 600 mg/L of ethylene oxide at 30% or more relative humidity (Chart in 2 minute increments)

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PRECAUTIONARY MEASURES IN USING ETHYLENE OXIDE

The Effect of Ethylene Oxide Exposure on Personnel

It is well known that ethylene oxide is a strong, effective sterilant. Common sense tells us that if it can destroy microorganisms, it could be harmful to other living things as well. Users of ethylene oxide have long been cautioned to be careful when in areas that could be potential exposure areas, but only within the last few years have the effects of ethylene oxide on humans been studied, and these studies show that exposure to EO should be severely limited.

The primary group responsible for establishing guidelines to ensure a safe environment for workers is the Occupational Safety and Health Administration (OSHA). In late 1984, OSHA published a set of regulations stating exactly the limits of worker exposure to EO, and how these exposures were to be monitored. Essentialy, the Permissible Exposure Limit (PEL) is 1.0 part per million based on an 8-hour Time Weighted Average (TWA).

In order to determine the current worker exposure levels, hospitals were required to perform initial monitoring on all potentially exposed personnel by February 21, 1985. If this initial monitoring shows that exposures exceeded the PEL, the hospitals are required to reduce EO in the air. Also, monitoring must be repeated frequently to be sure EO levels are not increasing. Furthermore, a program of medical surveillance must be established to see if the personnel are showing any ill effects from their exposure, and personnel must be educated about the potential hazards of EO exposure.

If the monitoring shows EO concentrations below the PEL of 1.0 ppm but above 0.5 ppm, equipment modifications are not necessary but medical surveillance and education programs must still be continued, as well as periodic remonitoring to be sure EO levels have not increased.

If the exposure levels are below 0.5 ppm, fewer steps must be taken. Medical surveillance and remonitoring need not be done unless there is a change of equipment or procedures that might cause EO levels to increase significantly.

These regulations are designed to accomplish three things: to determine the extent of exposure of workers to ethylene oxide, to limit that exposure to a safe level, and for the employers and workers to be informed as to effects of EO exposure.

ATI EO Monitor

The ATI EO Monitor is an analytical sampling device which can accurately measure ethylene oxide down to less than 0.1 ppm in air. The device's chromatographic absorption sampling method combined with the thermal desorption and gas chromatographic method of analysis have an accuracy level of ±20.8%. The device can be used as a passive sampling monitor or can be attached to a personal sampling pump for use in the active mode.

The top (yellow) end cap is removed and discarded, allowing diffusion to begin. The other end cap (red) should not be removed. When sampling is finished, the top end cap is replaced to prevent further diffusion taking place. A replacement end cap (red in color) is provided to show that the monitor has been used. The exposure time must be carefully noted. The concept of passive sampling is to measure EO levels over an extended period of time, usually eight hours, but not less than 30 minutes. For shorter term sampling, the monitor can be used in active mode as described next.

During active sampling, a known volume of air is drawn through the tube using a calibrated sampling pump. Sample flowrates of 5-20 ml/min are recommended. Active sampling is ideal for short-term exposure measurements (10-30 minutes). Tube saturation occurs when an excess of 50 mg of EO is trapped.

The ATI EO Monitor fulfills all of the requirements for ethylene oxide monitors set forth in Title 29 part 1019 of the OSHA Code.

SAFETY REQUIREMENTS

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Sterilization and aeration equipment should be:

- **Installed correctly** (in consultation with the manufacturer).
- **Placed properly** (in well ventilated areas).
- **Located remotely** (not adjacent to work areas where employees are normally required to be stationed).
- **Maintained adequately** (by a preventative maintenance program).

- Studied for modification (to provide a local exhaust feature near the door of the sterilizer if appropriate).
- Considered for replacement (as newer designed and more efficient equipment becomes available).

Employees' work environment should be:
- Well ventilated.
- Away from sterilizers.
- Monitored periodically (to determine employees' exposure to ethylene oxide).

Employees should be:
- Carefully trained (in the proper methods for unloading sterilizers and loading aeration cabinets).
- Constantly aware (that improper procedures can expose both the operator and other employees to ethylene oxide unnecessarily).

Only Sterilize With Ethylene Oxide When An Alternate Method (Steam, Dry Heat) Does Not Exist

SAFETY
- For sterilizing in its pure form, pure ethylene oxide gas is extremely flammable. Exercise caution.
- Locate sterilizers in a restricted area to limit unauthorized access.
- Locate sterilizers in a room that has between 6 and 10 air changes per hour.
- Always vent sterilizer exhaust to the **outside**.
- After a complete cycle, open door with caution and do not remove articles for 5 minutes; leave a clear 10 foot radius around sterilizer.
- Vent aerator exhaust to the **outside.**
- Keep records of sterilizer malfunction and repairs.
- Store tanks in special areas to meet building codes and temperature specifications: tanks should be chained to an adequate support.

HEALTH
- Avoid breathing ethylene oxide vapors.
- Avoid direct skin contact.
- Use protective gloves to take items out of sterilizer.
- Minimize handling of sterilized items.
- Report any accidents or prolonged exposure to Supervisor.
- Pull, don't push, loaded carts to the aerator.

MATERIAL DAMAGE
- Freon - diluted ethylene oxide can cause damage to certain plastic materials including: Tenite, Styron, Lucite, and Plexiglas.
- Can cause crazing of some plastic lenses and dissolve some lens glues.

SUMMARY CHECK LIST

Sterilization Principles
- Three main methods: steam, ethylene oxide, dry heat.
- Must kill all microorganisms (bacteria, spores, viruses, fungi).
- Critical ethylene oxide variables:
  1. Gas concentration: 450-1500 mg/L
  2. Temperature: 70°F. (21°C.) to 140°F. (60°C.)
  3. Relative humidity: 30% minimum.
  4. Total cycle time: 2 to 12 hours depending upon the other three variables.

Practice of Ethylene Oxide Sterilization

- General Processing Procedures:
  ALWAYS FOLLOW MANUFACTUERER'S INSTRUCTIONS
- **Models:** Table top - **operate with caution** - do not vent toxic gas into room Automatic. Semi-Automatic.
- **Wrapping materials:** Several types are commercially available. Select with care as each material has advantages and limitations.
- **Aeration:** An important post-sterilization procedure to reduce residual ethylene oxide and its by-products to a safe level. Mechanical aerators are available to accelerate the aeration process.

Ethylene Oxide Indicators

- An important method of monitoring sterilization conditions.
- Biological sterilization indicators: spore culture test recommended with each load.
- Chemical sterilization indicators: provide a color change for immediate check of all four ethylene oxide sterilizing parameters in each package.
- Chemical process indicators: provide a color change when exposed to ethylene oxide gas.

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GLOSSARY

Aseptic: Free from living microorganisms.
Ethylene chlorohydrin: Toxic by-product formed during ethylene oxide sterilization.
Ethylene glycol: Toxic by-product often formed during ethylene oxide sterilization under wet conditions.
Chemical indicator: A chemical system, which, by a visible change, indicates that certain chemical and/or physical conditions have occurred.
Microorganisms: Microscopic organisms such as bacteria or viruses.
Relative Humidity: The ratio of the amount of water vapor actually present in the air to the maximum amount of water the air can contain at the same temperature.
Spore: The dormant state of certain bacteria enabling them to survive adverse conditions.
Sterile: Free from all living organisms.
Thermal Death Time: The shortest period of time required to kill a known microorganism population at a specific temperature.

NOTE: A pamphlet, "Principles and Practice of Steam Sterilization", is available on request.

ACCEPTED
DEC 15 1989
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No 36136-2