Reg # 4816-620 PM-17 191

CODE 722.55

DRIONE® II Insecticide

1-30-90

A DESICANT DUST

LONG LASTING CONTROL FOR UP TO SIX MONTHS

FOR USE IN RESIDENTS, INSTITUTIONS, FOOD PLANTS, MOTELS, THEATERS, SCHOOLS, TRUCK TRAILERS, BOXCARS, HOSPITALS, OFFICE BUILDINGS AND HOTELS

CONTROLS ANTS, COCKROACHES, AND SILVERFISH.

ACTIVE INGREDIENTS	
Pyrethrins	0.10%
*Piperonyl Butoxide, Technical	1.00%
Silica Gel	40.00%
**INERT INGREDIENTS	58.90%
	100.00%

*Equivalent to 0.8% (butylcarbityl)(6-propyl-piperonyl) ether and 0.2% related compounds.

**Contains Petroleum Distillate

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional precautionary statements.

EPA Reg. No. 4816-620 EPA Est. No. 279-NY-1

DRIONE - Registered Trademark of Fairfield American Corporation

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

NON FOOD AREAS:

Homes, institutions, hospitals, office buildings, warehouses, hotels, motels, theaters, schools, truck trailers, and railroad cars: To control crawling insects including ants, cockroaches, silverfish, pillbugs, and millipedes, apply a continuous visible film underneath and behind stoves, refrigerators, and appliances. Treat on, around and behind moldings, shelves, baseboards, pipe openings, cracks, crevices and other areas where insects may hide. Do not use on surfaces that come into direct contact with food. For severe infestations, apply this product behind cabinets and walls, in crawl spaces and in attics at the rate of 16 ounces per 1000 square feet of surface area. In animal quarters, distribute this product at the rate of 3 ounces per 100 square feet of surface area. Repeat treatment as necessary.

APPLICATIONS WITHIN FOOD AREAS OF FOOD HANDLING ESTABLISHMENTS:

Food processing plants and warehouses, bakeries, beverage plants, restaurants, supermarkets, meat and poultry processing plants, hotels, motels, hospitals, and schools: Limited to crack and crevice treatment only. Using a bulbous or similar duster, apply a small amount of material directly into cracks, crevices such as expansion joints between different elements of construction or between equipment bases and the floor, wall, voids, motor housing, junction boxes or switch boxes, conduits or hollow equipment legs where roaches, ants, silverfish, spiders and crickets hide. Care should be taken to avoid depositing the product onto exposed surfaces or introducing the material into the air. Avoid contamination of food or food processing surfaces. Repeat treatment as necessary.

APPLICATIONS OF THIS PRODUCT IN THE FOOD AREAS OF FOOD HANDLING ESTABLISHMENTS, OTHER THAN AS A CRACK AND CREVICE TREATMENT ARE NOT PERMITTED

DISPOSAL

Do not reuse empty container. Wrap container and put in trash collection.

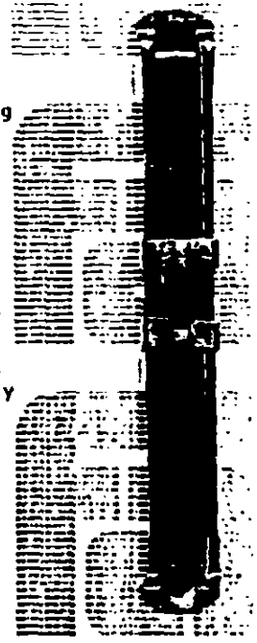
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Avoid inhalation. Containers larger than one pound may not be used or stored in food handling establishments.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to water. Do not apply where runoff is likely to occur. Do not apply when weather conditons favor drift from areas treated. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.



Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

ACCEPTED

APR 8 1982

Under the Federal Insecticide, Fungicide, Rodenticide Act for the registration under EPA Reg. No. 4816-620

BATCH

FAIRFIELD AMERICAN CORPORATION
3932 SALT ROAD

Arc Chemical Division
Balchem Corporation
P.O. Box 180
Stony Hill, NY 10973

Attention: Mary Towle
Regulatory Compliance Coordinator

Gentlemen:

Subject: Sterilizing Gas 6
EPA Registration No. 36736-6
Your Submission Dated August 23, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Note to the file: The label referenced above and dated September 18, 1990 will be the label of record and will supersede the label stamped October 11, 1984. The label of October 11, 1984 should be disregarded. We regret any inconvenience the label of October 11, 1984 may have caused.

Note: We have also adjusted our records regarding the new product name for this product.

If you have any questions concerning this letter, contact Valdis Goncarovs at (703) 557-3663.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

61552:I:V.G.:L31-4:KENCO:09/11/90:10/11/90:CL:JH:DD
R:61553:V.G.:L31-4:KENCO:09/13/90:10/13/90:CL

CONCURRENCES

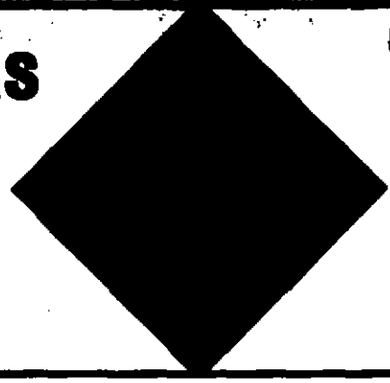
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

STERILIZING GAS 6

COMPRESSED GAS n.o.s.

UN 1956



EPA EST. NO.

- ☐ 35084-NJ-1
- ☐ 35084-MD-1
- ☐ 35084-TN-1
- ☐ 35084-TX-1
- ☐ 35084-CA-1
- ☐ 35084-PA-2
- ☐ 35084-GA-1
- ☐ 36736-NY-01

EPA REG. NO. 36736-6

Active Ingredient	
Ethylene Oxide	12%
Inert Ingredients	88%
Total	100%

TOTAL CONTENTS _____ LBS. NET

Precautionary Statements
Hazards to Humans and Domestic Animals
DANGER

Extremely hazardous liquid and gas under pressure. Inhalation of gas may be fatal. Do not get in eyes, on skin, or on clothing. Ethylene Oxide is odorless. Exposure to toxic levels may occur without warning or detection by the user.

Physical or Chemical Hazards

DANGER: Liquid and gas under pressure. Use equipment rated for cylinder pressure. Store and use with adequate ventilation. Close valve after each use and when empty. Always replace cylinder cap when not in use. Cylinder temperature should not exceed 130°F (54°C). Use in accordance with the sterilizer manufacturers operating instructions.

HEALTH HAZARDS: Inhalation may result in delayed nausea, narcotic and possible neurotoxic effects which could lead to emphysema, bronchitis and pulmonary edema. Exposure to large concentrations causes rapid circulatory insufficiency leading to coma and death. Contact with rapidly evaporating liquids may cause frostbite or cryogenic burns.

FIRST AID: If inhaled, remove to fresh air. If not breathing, give artificial respiration, preferable mouth-to-mouth. If breathing is difficult, give Oxygen. CALL A PHYSICIAN IMMEDIATELY and advise him of the exposure to this gas mixture. In case of eye or skin contact, or frostbite, remove contaminated clothing and flush affected area with lukewarm water. DO NOT USE HOT WATER.

KEEP OUT OF REACH OF CHILDREN

DANGER

Statement of Practical Treatment

In all cases of overexposure, get medical attention immediately. Take person to a doctor or emergency treatment facility.

If inhaled: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If breathing has stopped, give artificial respiration, preferably mouth-to-mouth. Do not give anything by mouth to an unconscious person.

If on skin: Immediately remove contaminated clothing, shoes, and other items covering skin. Wash contaminated skin area thoroughly with soap and water.

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes.

DANGER

CONTAINS ETHYLENE OXIDE
AVOID BREATHING THIS GAS

Directions for Use

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

STORAGE AND DISPOSAL

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

Manufactured by:

ARC CHEMICAL Div. of Balchem Corp
P.O. Box 180
Slate Hill, NY 10973

The purpose of this booklet 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 to:

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 indicator 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 450 mg/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 50°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 variables 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 aerated 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 the 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 to the skin and mucous membrane irritation. Therefore, adequate aeration time must be allowed following sterilization in order to ensure that any ethylene oxide and/or 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 available due to the manufacturer's inability to sterilize 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 the 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 combinations 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:

1) type and uniformity of wrap packaging material.
2) storage conditions (open or closed shelves, frequency of handling, cleanliness of the storage area, use of dust covers).
3) 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, 1, 2, and 3 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, non-woven 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)	6 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 practice limitations:

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.

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 provides 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 occurring in hospital EO sterilizers. Without adequate humidity, the ethylene oxide has difficulty penetrating the cell wall of the spores and its effectiveness is greatly reduced.

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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.

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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. Essentially, 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

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 MANUFACTURER'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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5) Central Service Technical Manual, William H. L. Dornette, M.D., J.D. Editor, (2nd ed.)

GLOSSARY

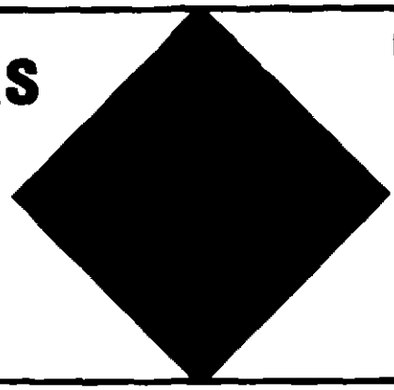
Aseptic: Free from living microorganisms.

PM 31 36736-6

STERILIZING GAS 6

COMPRESSED GAS n.o.s.

UN 1956



EPA EST. NO.

- ☐ 35084-NJ-1
- ☐ 35084-MD-1
- ☐ 35084-TN-1
- ☐ 35084-TX-1
- ☐ 35084-CA-1
- ☐ 35084-PA-2
- ☐ 35084-GA-1
- ☐ 36736-NY-01

EPA REG. NO. 36736-6

Active Ingredient	
Ethylene Oxide	12%
Inert Ingredients	88%
Total	100%

TOTAL CONTENTS _____ LBS. NET

Precautionary Statements
Hazards to Humans and Domestic Animals
DANGER

Extremely hazardous liquid and gas under pressure. Inhalation of gas may be fatal. Do not get in eyes, on skin, or on clothing. Ethylene Oxide is odorless. Exposure to toxic levels may occur without warning or detection by the user.

Physical or Chemical Hazards

DANGER: *Liquid and gas under pressure. Use equipment rated for cylinder pressure. Store and use with adequate ventilation. Close valve after each use and when empty. Always replace cylinder cap when not in use. Cylinder temperature should not exceed 130°F (54°C). Use in accordance with the sterilizer manufacturers operating instructions.*

HEALTH HAZARDS: Inhalation may result in delayed nausea, narcotic and possible neurotoxic effects which could lead to emphysema, bronchitis and pulmonary edema. Exposure to large concentrations causes rapid circulatory insufficiency leading to coma and death. Contact with rapidly evaporating liquids may cause frostbite or cryogenic burns.

FIRST AID: If inhaled, remove to fresh air. If not breathing, give artificial respiration, preferable mouth-to-mouth. If breathing is difficult, give Oxygen. CALL A PHYSICIAN IMMEDIATELY and advise him of the exposure to this gas mixture. In case of eye or skin contact, or frostbite, remove contaminated clothing and flush affected area with lukewarm water. DO NOT USE HOT WATER.

KEEP OUT OF REACH OF CHILDREN

DANGER

Statement of Practical Treatment

In all cases of overexposure, get medical attention *immediately. Take person to a doctor or emergency* treatment facility.

If Inhaled: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If breathing has stopped, give artificial respiration, preferably mouth-to-mouth. Do not give anything by mouth to an unconscious person.

If on skin: Immediately remove contaminated clothing, shoes, and other items covering skin. Wash contaminated skin area thoroughly with soap and water.

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes.

DANGER

CONTAINS ETHYLENE OXIDE
AVOID BREATHING THIS GAS

Directions for Use

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

STORAGE AND DISPOSAL

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

Manufactured by:

ARC CHEMICAL Div. of Balchem Corp
P.O. Box 180
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