BENVICIDE - 12

GASEOUS STERILIZING AGENT

for use in commercial gas sterilizers and in the Ben Venue SERIES II sterilizer.

Ingredients (by weight)	
Active Ingredient Ethylene Oxide	12%
Inert Ingredients	88%

WARNING

KEEP OUT OF REACH OF CHILDREN

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator.

See additional precautions on the right panel.

EPA Reg. No. 5573-3
EPA Est., 5573-OH-1

BEN VENUE LABORATORIES, INC.

270 Northfield Road
Bedford, Ohio 44146

Net Weight:

Benvicide-12 is a gaseous mixture for sterilization of heat or moisture sensitive surgical, medical, pharmaceutical and laboratory supplies. *Typical exposure conditions: Initial vacuum* to be drawn on sterilizer chamber, 25 - 26 inches; Chamber temperature, 130° F.; Relative humidity in chamber, 40 - 50%; *Concentration*, 5 oz. of Benvicide-12 per cu. ft. of chamber volume; Exposure time, 4 6 hours (minimum). The material to be sterilized *requires preconditioning* with water. Sterilized material should be tested for sterility and residual toxicity before use. Please refer to manufacturer of individual sterilizer for detailed directions for use. Use Benvicide-12 only in commercial gas sterilizers that conform to the directions for use recommended in the Technical Bulletin on Benvicide-12

Use Benvicide-12 in 4 oz. SERIES II GAS cans only in the Benvenue Series II gas sterilizer, according to full instructions provided with each sterilizer

CAUTION

1. Vapor harmful. May cause eye damage or irritation of skin, nose, throat and lungs. Avoid contact with skin, eyes and clothing.
2. Do not breathe vapors.
3. Avoid contact with eyes and skin. In case of contact flush skin or eyes with plenty of water: for eyes get medical attention.
4. Remove all clothing and shoes contaminated with liquid and flush skin with plenty of water.
5. Use only in gas-tight sterilizing chamber.
6. Vent sterilizing chamber before opening door.
7. Store at temperature below 75°F.

ANTIDOTE

If swallowed drink large quantities of water immediately in order to reduce the concentration of the chemical in the stomach. If vomiting occurs, give more water to further dilute the chemical. Keep patient comfortable and warm. Call physician immediately

ACCEPTED with COMMENTS
In EPA Letter Dated:
AUG 12 1983

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registration number given above.

RECEIVED
AUG 12 1983
Registration Division (TS-767)

NOT

DESCRIPTION AND INSTRUCTIONS FOR USE OF THE Ben Venue Series II Sterilizer ETHYLENE OXIDE STERILIZER

Bevicide-12 Gas Mixture

NOTE

This sterilizer is designed for use in health care facilities by trained health care personnel, to sterilize heat-sensitive medical and surgical equipment by controlled exposure to ethylene oxide vapor. The improper use of ethylene oxide may be hazardous to your health. We have designed this sterilizer with your safety in mind and therefore urge each user to read these instructions and follow the directions enclosed. It is a violation of Federal Law, and a safety hazard, to use it in ways inconsistent with its labelling.

BEN VENUE SERIES II GAS ~~MIXTURE~~ Sterilizer

INTRODUCTION

The ethylene oxide (EO) gas mixture used in the Series II gas sterilizer is a non-flammable, non-explosive solution of EO (12% by weight) in dichlorodifluoromethane, called "Series II Gas" (Benvicide-12, EPA Reg. No. 5573-3). Four ounces (114 grams) of gas mixture are sealed in an aluminum can closed by a steel cap. To the top of the can is fastened a plastic cup containing a small amount of water. A single one of these combination packages, called "Water/Gas Containers", is used for each sterilization cycle, releasing premeasured amounts of water vapor and EO vapor to condition and sterilize goods.

PRECAUTIONS

EO has always been recognized as a toxic chemical and its application as a sterilizing agent must be performed with care by trained personnel. The design of the Series II Gas Sterilizer minimizes operator exposure, but precautions must nevertheless be taken. It is recommended that this sterilizer, like all EO units, be installed in a location away from work areas and from traffic, and where the ventilation rate is at least ten air changes per hour.

Since Series II Gas containers have considerable internal pressure, they should not be stored at temperatures over 75° F, or near any sources of heat. They must never be punctured in any way other than by being used in the Ben Venue Series II Ethylene Oxide Gas Sterilizer in accordance with directions in this brochure.

Should a container be punctured accidentally, avoid breathing the vapors and do not allow the contents to contact personnel. Remove the container to a strongly ventilated area - if none is available nearby, immerse the leaking can in a pan or a sink full of water. In case of liquid or vapor contact, flush eyes or skin with water for at least 15 minutes, after removing contaminated clothing and shoes.

All used Water/Gas Containers should routinely be disposed of in containers marked <u>non-incinerated</u> trash. The purpose of this requirement is to eliminate the possibility that a full container, mistakenly disposed of in the trash, will be put into the incinerator; such an action might produce flying pieces of metal, and endanger personnel.

The chamber is an aluminum casting with a volume of 32 liters. The lid, mounted on two counterbalancing hinges at the rear of the unit, has a single bar handle, which latches tightly to the chassis when depressed. Two high-security spring-loaded latches are automatically locked by solenoid activated bars; locking is verified electronically. The latches are locked while the sterilizer is operating, and cannot be released until the chamber atmosphere has been purged for 10 minutes. A power failure will not release these safety locks.

The chamber is heated by means of a surface electric heater bonded to the bottom and sides. The temperature of the chamber atmosphere is maintained at 57°C ± 1°C by two sensors, one in the chamber wall, and one in the chamber atmosphere, whose outputs are integrated by a heat controller and monitored by a microprocessor.

The sterilizing gas mixture is "Series II Gas™" (EPA Reg. No. 5573-3), contained in a 4-ounce aluminum can with a crimped-on plated steel cap. Each can contains 4 oz. (114 grams) of this mixture of which 12% (by weight) is ethylene oxide, the active ingredient; thus 13.7 grams of ethylene oxide are introduced into the 32 liter chamber for each sterilization cycle. Series II Gas is non-flammable and non-explosive.

Water required to humidify the chamber atmosphere is contained in a sealed package which is connected to the top of the Series II Gas can. After the goods, in the load containment basket, have been placed in the chamber, the two-container Water/Gas combination is inverted into the piercing assembly cylinder on the floor of the chamber.

The piercing mechanism consists of this vertical cylinder containing a piercing pin and an ejection spring, and of a diaphragm located above this cylinder, in the lid. When the lid is closed, touching the START switch begins the cycle. A vacuum pump evacuates air from the chamber until, when a preset low pressure is reached, the water is released and evaporated. The piercing diaphragm is then activated and it pushes the gas portion of the Water/Gas Container down upon the pin. This releases the sterilizing mixture into the piercing cylinder from which it evaporates into the chamber.

The pressure rise caused by the gas release starts the timing of the sterilizing step, which is set for one hour and 15 minutes. After this, the vacuum pump once again reduces the pressure to a preset low value.

Room air is then drawn through a HEPA sterilizing filter and pumped out via the venting line, while the clock returns to 0:00 and starts timing the purging and aerating steps. Ten minutes after the air-washing starts, the locks on the latches which have prevented the lid from being opened until this time, release, and the lid may now be opened to remove any goods which are not absorptive of ethylene oxide. By this time, the gas concentration in the chamber has been reduced to less than one part per million of airborne ethylene oxide.

If the goods absorb ethylene oxide the aeration must be allowed to continue for the time recommended in the aeration instruction card in the sterilizer drawer. We have found that the maximum time required, for the most absorptive materials, is 8 hours; therefore, the aeration process as well as the timer and the recorder will continue automatically for 8 hours, when the sterilizer signals "COMPLETE" and turns itself off. At any time after the first 10 minutes, the aeration may be stopped by opening the lid; the recorder registers when this has been done by showing a drop in chamber temperature and a shift in the trace made by the pressure-recording pen. When the lid is closed again to provide further aeration of some additional items, the chamber temperature rises and the pressure trace returns to its aeration location.

Each step of the cycle is thus timed and recorded. In addition, the status is indicated by a series of small red lights on the control panel, each of which bears a legend:

- POWER signifies that the sterilizer has been activated.
- WARMING indicates that the heaters are operating, but the chamber is not yet up to operating temperature.
- READY means the walls are warm enough. The goods (in the basket) and the Water/Gas™ Container should be placed in the chamber.
- PRE-WARM shows that the operator has selected the optional step which is needed to warm goods which have been wrapped in insulating materials, up to operating temperature before gas exposure.
- EVACUATE is the first step in the actual sterilization, and includes humidification of the goods.
- GAS RELEASE follows the evacuation and indicates gas is entering the chamber.
- STERILIZE indicates that the gas is contacting the goods; the timer shows how long this exposure has been going on.

- PURGE shows that 1-1/4 hours of gas contact are over, and that the chamber atmosphere is being replaced with sterile air.
- AERATE indicates that the chamber has been PURGED for 10 minutes, the lid latches are unlocked, and the goods are being aerated. The timer shows how long the combined PURGE and AERATE steps have been going on.
- COMPLETE means either that 8 full hours of aeration have followed the sterilization step, or that the operator has touched the COMPLETE switch at some time before 8 hours. The elapsed aeration time may be read from the timer, or from the recorder chart. (The chart moves two inches in an hour.) When the COMPLETE light goes on, the pump, recorder, heater, and other electric components shut off.

INSTALLATION

1. Room Ventilation

While only traces of ethylene oxide a· detectable near the Ben Venue Series II Sterilizer during any part of its cycle, we nevertheless recommend that it only be installed in an a has a ventilation rate of greater than 10 air changes per hour. In conformity with AAMI Document VRSU 3/81, "Good Hospital Practice: Ea iene Oxide Gas - Ventilation Recommendations and Safe Use" - published by the Association for the Advancement of Medical Instrumentation, 27 March 1981.

2. Electrical Connection

The Series II Sterilizer is equipped with a hospital-type grounding plug designed to be inserted into a socket carrying AC current at 110 volts, 60 HZ.

3. Venting the Sterilizer

The gas mixture used in the Ben Venue Sterilizer, unlike that in some other gas sterilizers, is not flammable or explosive, but the effluent must nevertheless be vented outdoors. We have provided a short length of flexible tubing into which an adapter for connecting to the vent tubing will fit. The purchaser must provide and install vent tubing preferably not to exceed 25 feet in length, leading from the sterilizer location to the building exterior. The vent tubing should be no smaller than 1/4 inch inside diameter, and should preferably be rigid, i.e. copper, stainless steel or rigid plastic. Bends in the tubing should be kept to a minimum and rises of more than a few feet should be avoided. There should be only an inch or so of tubing projecting beyond the building wall, and this should be bent downwards to prevent rain and snow from entering. The exhaust end of the tube should be at least 25 feet away from any entry door or openable window, or any air intake to the building. If only flexible tubing is available, care should be taken to install it in such a way that no heavy object can be pushed against it or placed on it. If the vent tube becomes clogged or crimped, the sterilizer will malfunction and cannot be used until the obstruction is cleared.

The vent tube should preferably be one single length without joints or unions; the connections to the sterilizer must be carefully and tightly made to eliminate the possibility of exhaust leaking into the room.

SAFETY FEATURES

Safety of both the patient and the operating personnel is the chief criterion in the conception, design, and engineering of this new sterilizer. A great amount of technical information and scores of recommendations and regulations on the hazards of ethylene oxide have reached the public in the past few years; in developing the Ben Venue Series II we have attempted to produce a completely acceptable sterilizer, not only in its effectiveness, but in its safety aspects as well.

Awareness of the possible harmful effects of ethylene oxide caused us to adopt a conservative approach, and to use as little of this active ingredient as possible, consistent with achieving sterilization.

We have chosen to use just that concentration of ethylene oxide which will sterilize highly contaminated objects in a reasonably short period of time.

The Ben Venue Sterilizer Series II also incorporates a number of other safety features, a few of which are:

1) For the Safety of Operating Personnel

a. The chamber lid, gasket, lock and latch permit no detectable leak (less than 1 ppm) of sterilizing gases into the room at operating pressures and temperatures. The ethylene oxide gas container (Series II Gas) cannot be punctured until the sterilizer lid is closed and latched, and until a vacuum has been created in the chamber.

b. The lid is automatically locked at the start of the cycle, and it cannot be opened until the chamber has been vented to the outdoors and the chamber atmosphere has been diluted with sterile air during 10 minutes of continuous exchange. Air samples taken over the center of the open chamber for 15 minutes after the lid was opened show a peak concentration of ethylene oxide of less than 1 ppm.

c. At the end of the gas-purging step, the sterilizer automatically becomes an aerator. There is thus no need for operating personnel to handle absorptive goods containing possibly large amounts of residual ethylene oxide, as occurs when transferring materials from existing sterilizers to separate aerators. After aerating for 8 hours, the sterilizer automatically turns off. It is possible to manually terminate the cycle earlier, if desired. We shall provide a list of recommended minimum aeration times for various materials, including the effects of various types of packaging.

d. The ethylene oxide mixture (Series II Gas) presents no fire, flash, or explosion hazard.

2) For the Safety of Patients

The Ben Venue Sterilizer Series II serves the safety of the patients by delivering sterile goods, virtually free of dangerous ethylene oxide residues. The operator is assisted in accomplishing this because much of the process is automated. There are also provided "Good Sterilizing Practices" reminders and instructions, and a permanent record of each load sterilized.

a. "Good Sterilizing Practices" are permanently and prominently displayed on the face of the control console, over the recording chart area. The legend reads as follows:

BEFORE OPERATING THIS STERILIZER

1. Press front of drawer to open.
2. Read and follow all instructions.
3. Clean and package items properly.
4. Use Ben Venue Water/Gas containers.
5. Label each strip-chart and package.
6. Select proper aeration time.
7. Include Chem/Biol indicators.

b. The preparation and packaging of goods to be sterilized are critically important. Provided these have been done properly, this sterilizer produces sterile goods, as validated not only by tests on actual instruments, but also by exposing heavily spore-contaminated test objects as specified by the Official Methods of the Association of Official Analytical Chemists (1980). The gas concentration, temperature, humidity, and exposure times are automatic, and not under operator control, so the possibility of operator error is minimized.

c. The automatic aeration feature of the Ben Venue Series II sterilizer has been mentioned above as contributing to the safety of the operator. The chief purpose of aeration, however, is to prevent the patient from being exposed to instruments or implants which retain significant quantities of ethylene oxide. Poly (vinyl chloride) and rubber are two elastomers often used in medical devices which are particularly absorptive of this gas; the best way to desorb the ethylene oxide is to pass fresh, sterile, warm air over such materials, and in this sterilizer, this is done automatically at the end of each cycle. The extent of aeration required depends upon the nature of the material, its size and weight, and also upon the nature of

contact with the patient, whether it be skin, mucous membrane, circulating blood, implant, etc. These times will be experimentally determined, and will appear on instruction cards contained in the sterilizer drawer.

d. A built-in recorder makes a continuous chart of chamber temperatures and pressures during each sterilizing and aerating sequence. Chart labels are provided on which the operator can list what goods were in each sterilizer load, together with load number, date, etc. The chart thus becomes an official record of the time the goods were exposed to gas, and how long they were aerated. It also can indicate when a part of th) load was removed from the chamber, and for how long the remaining materials continued to be aerated.

e. Another safety feature is the fact that the sterilizer Operating Instructions, a list of possible malfunctions and how to correct them, and a list of aeration times required for various materials of construction are permanently fastened in a drawer in the sterilizer chassis, so they are readily available when needed and cannot be mislaid.

3. Malfunctions

A good number of safety features have been introduced for the protection of both operating personnel and patients. The sterilizer is fitted with flow and pressure sensors, thermistors, and microswitches all combined with timing circuits. The microprocessor directs readings to be taken sequentially of the sensor outputs and compared continuously with the normal values programmed into the device. The sterilizing cycle is interrupted if the chamber pressure is too high or too low, chamber temperature too high or too low, gas concentration too low or if the pump or fan, or the power should fail or the vent become clogged. A flashing "MALFUNCTION" signal appears and an audible alarm is sounded to call attention to the malfunction, the nature of which is illuminated on a special panel. The Status Light indicating the stage of the sterilization cycle in which the malfunction occurred remains lit. Permanently fastened in the drawer are instructions for how to recover from malfunctions, which depend both upon what it was and where in the cycle it occurred. In some cases the sequence can be continued, in other cases a simple examination can determine the cause and cure, and in a few cases, a service call is necessary. Altogether, the malfunction system protects the user and the patient from danger, from loads that may not have received the proper sterilizing dosage, and from unexplained excessive doses of ethylene oxide.

PREPARING AND PACKAGING MATERIALS TO BE STERILIZED

The Ben Venue Series II Sterilizer has been designed to operate as automatically as possible, to eliminate the need for continuous operator attendance and to minimize the possibility of errors which might compromise the sterilizing process.

However, there is one critical phase of sterilization which cannot be done by the sterilizing apparatus or its manufacturer, upon which success or failure ultimately depends. This is the manner of preparing and packaging the materials to be sterilized. It is the operator performing this function who determines whether the products will or will not be sterile when they emerge.

Preparing the Materials

Before placing any objects, whether wrapped or not, in the gas sterilizer, the operator must be sure that they meet two criteria: 1) Clean and 2) not dehydrated.

1) Clean: Wash, scrub, brush, or otherwise clean all objects to remove foreign substances such as tissue, blood, pus, etc. Pay special attention to all narrow channels, hinged joints, bristles, and other areas where deposits are likely to cling. Use clean water as a final rinse and jets of air to remove clinging water droplets.

2) Not dehydrated: In order to inactivate micro-organisms by exposing them to ethylene oxide vapor, there must be a small amount of water present. Therefore, do not oven-dry or otherwise heat the wet instruments to remove the last traces of water and do not use a desiccator. Objects may be patted dry with a towel, or allowed to dry at room temperature and humidity before being wrapped and placed in the sterilizer chamber.

Packaging the Materials

Since the sterilizing gas must reach every possibly contaminated surface of the objects being treated, it's important that there be no barriers to the gas. Precautions must therefore be taken with the items themselves, to see that no impermeable caps have been left in place, and for example, that syringe plungers are removed from the barrels, and that needles have no obstruction in their lumens.

In addition to this, the materials used to wrap the goods so their sterility can be maintained after removal from the sterilizer must not be barriers to ethylene oxide, water vapor, or heat.

Nylon and mylar films are gas barriers, as is polyethylene thicker than 0.004 inches (0.01 cm), and these should not be used as wrapping materials.

Muslin cloth (tw[illegible]ble-ply layers) has been used for years for wrapping goods for St[illegible]erilization, and such wraps are permeable to the sterilizer gases. Mus[illegible]owever, delays the transmission of heat from the chamber to the wrapped goods much more than do non-woven or paper instrument wraps; where feasible, we recommend the latter types for packing goods for the Ben Venue Sterilizer.

We have found that folded huck towels, which are routinely included in packs of instruments being steam-sterilized, exert a significant heat-insulating effect, and we recommend they not be used. If for some reason towels must be included such packages must be prewarmed in the chamber before admitting the gas, as is described in the Operating Instructions. (Fifteen minutes prewarming for 2 folded towels, 60 minutes for four towels.)

Paper bags or plastic-Tyvec™ combinations, or polyethylene films thinner than 0.004 inches give good penetration of all necessary heat and gases. If thin polyethylene bags are used, it is necessary to close them with tape, rather than heat-sealing them, because sealed bags tend to burst.

STERILIZATION MONITORS

Two kinds of monitors are recommended for use in ethylene oxide gas sterilizers - chemical and biological.

Chemical indicators are usually tapes or printed legends or devices which turn color when exposed to ethylene oxide. Some are not designed to give a quantitative indication that a sterilizing dose of the chemical has reached them, but they distinguish quickly those packages that have been exposed from those that have not. The association of Operating Room Nurses recommends using a chemical indicator on and in every package sterilized.

Biological indicators (BI) contain specific numbers of bacterial spores (B.subtilis is used for ethylene oxide) of standardized resistance to the sterilizing agent. These organisms are present in greater numbers, and are far more resistant than the normal bacterial burden of cleaned instruments and objects. Thus inactivating a BI gives a considerable margin of safety. Most BI's require care and skill in the process of introducing them into the proper nutrient medium, and all require at least two days to give evidence of growth.

The Joint Commission on Accreditation of Hospitals, in its Accreditation Manual states: "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 intravascular 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."

STERILIZER OPERATING INSTRUCTIONS

STEP	OPERATOR ACTION	STATUS LIGHT	OCCURRENCE
1.	Touch "ON"	POWER	Sterilizer is powered ("TEST").
2.	Touch "WARMUP"	WARMING	Chamber is heating.
3.	Attach filled-out label to end of recorder chart	READY	Chamber is at temperature.
4.	Place basket of goods in chamber, include chem/biol. indicators		
5.	Place Water/Gas (TM) container in piercing assembly		
6.	Close lid		
7.	FOR SPECIAL LOADS Touch "WARMUP" again	PREWARM	Chamber lid locks, recorder, fan and timer start. Goods are warmed until the "START" switch is touched; after 2:00 hours, cycle automatically goes to "EVACUATE"
8.	FOR REGULAR LOADS Touch "START"	EVACUATE	Chamber lid locks, recorder, fan and timer start, chamber evacuation begins.
		GAS RELEASE	Water is released and evaporates for 2 minutes. Then gas is released from pierced container.
		STERILIZE	Timer resets to 0:00. Goods are exposed for 75 minutes. (Timer reads 1:15)
		PURGE	Chamber evacuates, gas vented to outdoors Timer resets to 0:00, pressure trace on recorder offsets. Chamber air-washed for 10 minutes.
		AERATE	
9.	Open lid, remove non-absorptive goods		When lid is opened, pump, fan, timer and heater stop; they turn on again when lid is closed. Aeration continues for 8 hours, or until operator touches "COMPLETE".
10.	Close lid, or, with absorptive goods, leave it closed.		
11.	Touch "COMPLETE"	COMPLETE	Pump, fan, recorder, and heater turn off. Goods may be removed, used Water/Gas container may be discarded in non-incinerated trash. Timer indicates elapsed aeration time.
12.	Fill in, inspect, and file recorder chart		

TO START ANOTHER CYCLE RETURN TO STEP 2

Note: "TEST": At the start of each day it may be desirable to touch this switch, which activates all function indicators and malfunction lights, to be sure that all bulbs are operative. This test can only be activated when only the POWER light is on.

AERATION INSTRUCTIONS

An excess of ethylene oxide contained in absorptive instruments or implants may be harmful to patients. The exact amount of such retained EO which is without effect on tissues or body fluids has not yet been firmly established, and this is the object of much continuing research. In the absence of any official regulatory requirements at this time, we quote from a document entitled "Standard for Ethylene Oxide Sterilization (Proposed)", issued in 1977 by the Association for the Advancement of Medical Instrumentation, AAMI EOS-P 11/77, as follows:

"Par. 3.1 Ethylene Oxide Residue. The maximum level of residual ethylene oxide shall be 250 parts per million in implantable plastic devices. If the level is higher than this in an implantable device, then the manufacturer should demonstrate through appropriate tests that the product is safe."

In the Ben Venue Series II Sterilizer, Series II Gas is applied at a controlled temperature, concentration, and exposure time. The only process variable left up to the operator is the aeration time; we shall provide detailed instructions dealing with this method of removing residual gas from sterilized objects.

Objects made of metal, glass, or impermeable plastics will be free of ethylene oxide after the 10 minutes of chamber purging, and need no further aeration. After this 10 minute period the chamber lid may be opened; if it is not, the sterilizer continues to draw sterilized air from the room into the chamber, and to exhaust it, after contacting the instruments inside, for up to eight hours.

In Section VIII of this report we present data on the rate of desorption of EO from two typical materials used in the manufacture of medical devices, namely, the polymeric coating which constitutes the exterior of flexible fiberoptic endoscopes (such as bronchoscopes and colonoscopes) and medical grade poly (vinyl chloride) "Tygon" tubing.

Based upon the experimental results reported in Section VIII, our Aeration Instructions will state:

"Bronchoscopes, colonoscopes, other flexible endoscopes; aerate at least 75 minutes before removing from chamber.

"Tygon or other PVC tubing: Aerate 8 hours before removing from chamber.