Benvicide is a gaseous non flammable 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 per Cu. Ft. of chamber volume. Exposure time 4-6 hours (minimum). Material to be sterilized may require preconditioning with water or very high relative humidities to hydrate bacterial spores. Sterilized material should be tested for sterility and residual toxicity before use. Please refer to manufacturer of individual sterilizer for recommendation other than condition indicated above.

USDA Reg. No. 55732

Return empty cylinders promptly

BENVICIDE

GASEOUS STERILIZING AGENT

For Use in Commercial Gas Sterilizers

NON-FLAMMABLE

Ingredients
(by weight)

Active Ingredient Ethylene Oxide	11
Inert Ingredients	89

Poison

DANGER

See additional precautions on the right panel.

BEN VENUE LABORATORIES, INC.
270 Northfield Road
Bedford, Ohio 44146

Net Weight

DANGER

1. Do not breathe vapors.
2. Avoid contact with eyes and skin. In case of contact flush skin or eyes with plenty of water; for eyes get medical attention.
3. In case of contact with clothing, immediately remove all contaminated clothing and flush skin with plenty of water.
4. Use only in gas tight sterilizing chamber.
5. Vent sterilizing chamber before opening door.
6. Store at temperatures below 75 F.

ANTIDOTE

If swallowed induce vomiting immediately (give a teaspoonful of salt in a glass of warm water). When possible vomiting should be induced at least three times. Call a physician immediately.

Covered by U.S. Patent
No. 2,891,838

Patented in Canada
1961 No. 612,361

ACCEPTED
Aug 16 1971
55732

BENVICIDE [R]

Benvicide is a noninflammable mixture of 11% ethylene oxide and combinations of halogenated hydrocarbons.

It is presently marketed as Benvicide in the following formula:

Ethylene Oxide		11%
Genetron 12		10.7
Genetron 11		78.3
Cylinder Pressure	70°F	16.0 P.S.I.G.
	90°F	22. P.S.I.G.
Apparent Specific Gravity at 70°F		1.40

The above mixture is the only ethylene oxide - halogenated hydrocarbon mixture which is noninflammable by both the Tag open cup and the flame propagation methods.

Conditions of Sterilization

Sterilization with Ethylene Oxide is function of time of exposure, concentration of Ethylene Oxide in the sterilizer, temperature and moisture content of the organism to be killed. The recommendations of the sterilizer manufacturer should be followed where possible.

Time of Exposure

In general exposure is a function of the Ethylene Oxide concentration in the sterilizer space.

Concentration

For sterilizing, Ethylene Oxide concentrations of 450-1000 mg/liter of chamber space are recommended (1 mg/liter = 1 oz./1000 cu. ft.). All other factors being equal, the higher the concentration of Ethylene Oxide the shorter the exposure time required. Doubling the Ethylene Oxide concentration reduces the sterilization time in half.

The chamber pressures at 130°F using Benvicide at various concentrations are as follows: (This data is based on complete evacuation of the sterilizer before the addition of the gas.)

450 mg. ETO/liter	14.67 P.S.I.A.	(-.03	P.S.I. gauge)
550 mg. ETO/liter	18.0 P.S.I.A.	(3.3	P.S.I. gauge)
600 mg. ETO/liter	19.6 P.S.I.A.	(4.9	P.S.I. gauge)
700 mg. ETO/liter	22.9 P.S.I.A.	(8.2	P.S.I. gauge)
800 mg. ETO/liter	26.1 P.S.I.A.	(11.4	P.S.I. gauge)
900 mg. ETO/liter	29.4 P.S.I.A.	(14.7	P.S.I. gauge)
1000 mg. ETO/liter	32.6 P.S.I.A.	(17.9	P.S.I. gauge)

See Graph also based on the above calculations.

Temperature

Temperature of 120-130°F is usually preferred for Ethylene Oxide sterilization. Sterilization can be carried out at 70°F but a longer exposure period is required. As the temperature is increased the rate of sterilization is increased. Studies have shown that the activity of ethylene oxide increases 2.14 times for each 10°C rise in temperature range of 5° to 37°. In actual

practice it has been suggested that for each 10°C rise in temperature the exposure period could be reduced by one-half.

Humidity

Relative humidity range of 40-50% is recommended in the sterilizer space. Moisture content of the article to be sterilized is a very important factor. If the material to be sterilized has been stored at a relative humidity of 40-50% before sterilization it can be normally sterilized as is, providing the normal "dwell period" recommended by the manufacturer is followed. Material stored at 20% to 40% relative humidity at 70° F should be placed either in a humidification chamber at 60% relative humidity at 100°F for 24 hours before sterilization, or held in the sterilizer for a "dwell period" of 12 hours minimum at 60% relative humidity at 130°F before sterilization. However, if the material has been stored in an extremely dry atmosphere or has been desiccated it should be humidified by wetting with water before sterilization.

Minimum Recommended Sterilization Time & Temperature

Based on 26" Hg pre-vacuum and 40-50% relative humidity.

Chamber Temp.	Chamber Pressure PSIG	ETO mg/L	Usual Exposure Time
130°F	5.3	550	4 hours
130°F	6.8	600	3-1/2 hours
130°F	19.8	1000	2 hours

Even though the above guide lines have been set forth, each load sterilized with ethylene oxide should be checked for sterility by an approved method, either by the use of biological indicators designed for ethylene oxide sterilization, or on the required number of parts actually sterilized, or a combination of both of the above. For sample size, methods, etc., see the latest edition of the U. S. Pharmacopea.

Residuals

Residual ethylene oxide and its by-products, ethylene glycol and ethylene chlorohydrin are highly irritating to tissue and the sterilized parts must be aerated before use.

The time required to eliminate residual ethylene oxide from sterilized products depends on many factors.

As a normal precaution plastic or rubber parts sterilized with ethylene oxide must not be used for a minimum of seven days following sterilization, if stored at room temperature.

This time may be reduced to as low as 12 hours by aeration at 50°C in a properly designed aerator. Commercial products, by necessity, because of sterility testing, will be aerated at least 7 days before use because of the time required for sterility testing. However, because the nature of the packaging, as well as the material used, will affect the aeration time, the product sterilized should be checked for residuals before release for distribution.

Cylinder Storage

Cylinders should be stored in a cool place. They should not be stored near radiators or other sources of heat. When empty they should be promptly returned.