BENVICIDE®-12

GASEOUS STERILIZING AGENT

For Use in Commercial
Gas Sterilizers

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.

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

BENVICIDE^{R}-12 STERILIZING GAS

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BENVICIDE^{R}-12 STERILIZING GAS

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The sterilization of many heat liable materials has required the use of new sterilizing agents. The most widely accepted of these agents has been ethylene oxide because of its effectiveness. However, in the pure state it is highly flammable and for this reason Benvicide^{R}-12 was developed. This mixture reduces the flammability of ethylene oxide without affecting its sporicidal properties.

CHEMICAL AND PHYSICAL PROPERTIES

Ethylene Oxide	12%
Inert Ingredient	88%
Cylinder Pressure	68°F - 50.9

Apparent Specific Gravity of liquid at 68°F - 75.3 pounds/cubic foot

CONDITION OF STERILIZATION

Sterilization with ethylene oxide is a function of time of exposure, concentration of ethylene oxide in the sterilizer, temperature, and moisture content of the materials to be sterilized.

The recommendations of the sterilizer manufacturer should always be followed.

CONCENTRATION

For sterilization, a minimum ethylene oxide concentration of 450 mg/liter of chamber space is recommended (1 gram/liter = 1 oz. per cubic foot).

The chamber pressures at 130°F using BENVICIDE^{R}-12 at various concentrations are as follows. (These data are based on complete evacuation of the sterilizer before addition of BENVICIDE^{R}-12.)

Ethylene Oxide mg/liter	Absolute Pressure Pounds/square Inch	Gauge Pressure Pounds/square Inch
450	14.8	0.1
500	16.45	1.75
600	19.74	5.04
700	23.03	8.33
800	26.32	11.62
900	29.61	14.91
1000	32.90	18.2

Figure 1 is also based on these calculations.

TIME OF EXPOSURE

In general, exposure is a function of the ethylene oxide concentration of the sterilizer space. 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. Time of exposure is also dependent upon the temperature at which the sterilization may be conducted.

TEMPERATURE

Temperature of 130-140°F is usually preferred for ethylene oxide sterilization. Sterilization can be carried out at a temperature as low as 70°F but a longer exposure period is required. Studies have shown that the activity of ethylene oxide increases 2.74 times for each 8°F rise in temperature range of 50-98. In actual practice it has been suggested that for each 18°F 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 presoaking in water for a minimum of one (1) hour immediately before sterilization. Instruments must be precleaned to remove adhering tissue and serous exudates prior to the presoak treatment.

MINIMUM RECOMMENDED STERILIZATION TIME AND TEMPERATURE

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

Chamber Temp.	Chamber Pressure PSIG	EtO mg/liter	Usual Exposure Time
130°F	3.8	500	4-1/2 hours
130°F	7.0	600	3-1/2 hours
130°F	20.2	1000	2 hours

Even though the above guide lines have been [illegible]
with ethylene oxide should be [illegible]
either by [illegible]
sterilization, or [illegible]
combination of both of the above. [illegible]
latest edition of the U.S. Pharmacopeia.

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 materials used, will affect the aeration time, the product sterilized should be checked for residuals before release for distribution.

[illegible] the ANSI Z79 Sub-committee on ethylene oxide sterilization [illegible] developing proposed standards for aeration time and acceptable residual levels. Up to date information can be obtained from this committee.

CYLINDER STORAGE

Cylinders should be stored in a cool place. They should not be stored near radiators, in direct sun, or other source of heat. This cylinder should be returned or disposed of promptly according to the label.

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