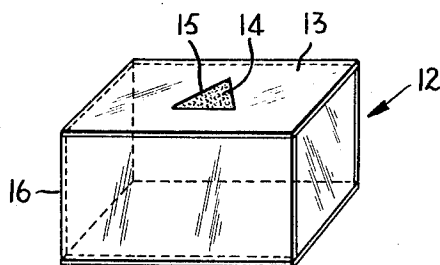
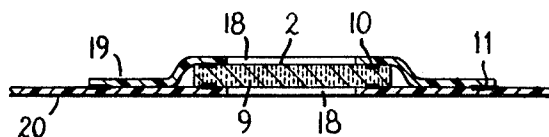
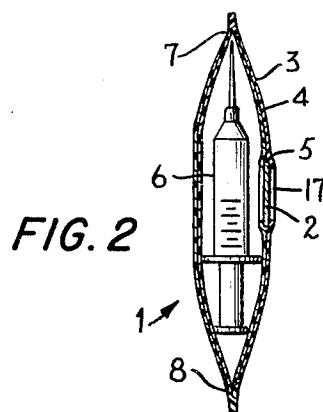
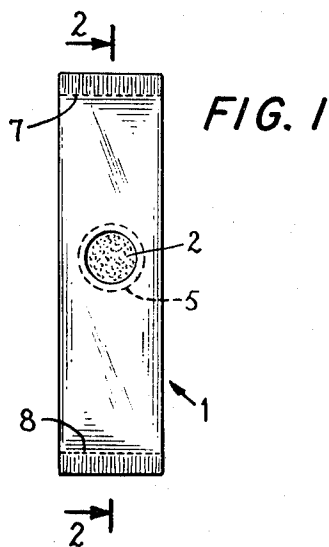


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BREATHER CONTAINER

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13 Claims

ABSTRACT OF THE DISCLOSURE

A breather container is provided that is at constant equilibrium pressure with the surrounding atmosphere, whether gas or liquid, and is yet closed in a manner to prevent contamination of either the container contents or the atmosphere by interchange of bacteria and other microorganisms. Because the container of this invention permits gas flow between the inside and the outside thereof, it has the additional advantage of permitting gas-sterilization of the contents after the container has been closed.

This invention provides a breather container which is always at an equilibrium pressure with the surrounding atmosphere. More particularly, the invention provides a container having a wall breather which permits inward or outward flow of gases, to achieve such equilibrium pressure, but excludes contaminants such as bacteria and other microorganisms.

Modern surgical and medical techniques require completely sterile apparatus and equipment; similarly, the exploration of space also requires great care to avoid contamination of the space environment by earth organisms.

Generally, sterile or safe packaging requires sealing a product in a fluid-impervious package. An irregularly shaped object can be wrapped and sealed in a tight thermoplastic flexible wrapping such as polyethylene or polyester sheets. Modern techniques for forming such packages around irregularly shaped objects are highly economical and automated.

When flexible wrapping materials are used, however, the pressure within the package becomes a problem, whenever the ambient or external pressure is substantially different. A flexible package sealed at sea level at airplane elevations can encounter an outside air pressure substantially less than the pressure within the package. The result is that the gas within the flexible wrapper expands, causing a ballooning of the flexible wrapper, and rupture of the package, if the pressure differential is sufficiently great, and the wrapper sufficiently weak.

The danger can be lessened by using thicker, heavier wrappers, or a rigid container, but this is not always feasible, especially if such sheet material is unsuitable for the automated packaging equipment. Nor is it always feasible to package under vacuum, another alternative.

A problem often encountered in the packaging of surgical devices is difficulty in sterilization. To ensure the complete asepsis of the device, the device is best exposed to a sterilizing gas atmosphere at elevated temperatures. If the material is to be packaged in a gas tight sealed container, the sterilization must take place before sealing. This of course provides opportunities for contamination of the interior of the package from the time the package is removed from the sterilizing atmosphere until it is sealed. To install the sealing equipment within the gas sterilizing atmosphere is not easy, and would increase the expense of the operation. Where a device is first sealed in a porous container and then exposed to a sterilizing atmosphere, sterilization of the device can be obtained. Difficulty arises, however, inasmuch as the porous containers heretofore used for this purpose, were

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not liquid-repellent and within a short time allowed bacteria to re-enter, thereby, contaminating the device sealed within. This occurs since although the pores of containers heretofore used were small enough to prevent the passage of bacteria-entrained in air, they were not normally small enough to prevent the passage of bacteria carried by a liquid such as water. Thus, after a time when moisture, condensed on the exterior of the container, bacteria was carried through the pores of the container. Furthermore, flexing of the porous container, such as can occur due to changes in the ambient pressure, can distort the pores of the container walls and thus change the pore size, and possibly pass through the distorted pores larger particles than intended.

For these reasons, although porous containers for storing sterile parts had been heretofore known, such containers were unable to store products in a sterile condition for long periods of time, especially if flexing of the container might take place during storage.

In accordance with the present invention, a breather container is provided that is at constant equilibrium pressure with the surrounding atmosphere, whether gas or liquid, and is yet closed in a manner to prevent contamination of either the container contents or the atmosphere by interchange of bacteria and other microorganisms. Because the container of this invention permits gas flow between the inside and the outside thereof, it has the additional advantage of permitting gas-sterilization of the contents after the container has been closed. In the present invention the sterilized instrument can be stored for long periods of time without danger of bacteria contamination, in as much as the porous material is preferably liquid repellent or hydrophobic and thereby prevents the passage of bacteria laden moisture. Also, the surface area of the breather material is kept small relative to the size of the container. Therefore, the porous material need not flex to any significant extent thereby minimizing the possibility that the enlargement of the material will occur.

The breather container of this invention comprises, in combination, walls defining the container, and a relatively small breather in at least one wall of the container, having pores large enough to permit the flow of fluids but too small to permit the passage of microorganisms between the interior and the exterior of the container. The remainder of the container walls are impermeable to fluids. Preferably, the breather is hydrophobic and has a pore size which excludes the through flow of particles less than 0.5 micron in diameter, and optimally less than 0.2 micron diameter. This is sufficient to prevent the passage of substantially all harmful air-borne bacteria, and other microorganisms, such as molds, fungi, and spores. Since it is known that a given pore size will prevent the passage of smaller particles if they are carried by a gas rather than a liquid, it is advantageous to utilize a breather with hydrophobic or liquid repellent qualities. This will ensure the passage of only gasses, and prevent the possibility of the contents becoming contaminated through the seepage of condensed moisture. Due to the fact that a given actual pore size will remove different size particles depending upon whether it is used in a liquid or gas, the pore size of the breather will be referred to hereinafter as the effective pore size, i.e., the size of the maximum diameter of particles that can pass through the breather whether in a liquid or gas.

This invention is of particular application to bag-like containers having flexible walls, but it is applicable to flexible walled containers of any shape as well as to semi-rigid and rigid containers of any desired shape.

The container can be adapted for use in any fluid environment, such as in the atmosphere, or underseas, since the breather can be open to flow of both liquids and

gases. It can be used, for example, when the porous portion is not hydrophobic to bring up water-borne specimens from the ocean depths, without fear of contamination by materials from the intermediate depths, or from the surface; the water pressure within the container is equalized continuously, as the package is drawn to the surface. For example, a sample of silt can be removed from the ocean floor, using remote control linkages from a bathyscaphe, and placed into an open breather container. The container can then be closed by remote control, and carried to the surface outside of the bathyscaphe. As the vessel moves upwardly towards the surface, the pressure within the container is kept at equilibrium, via the breather, preventing bursting of the container, which otherwise might occur at or near the surface of the sea, were the container to have been non-porous. The breather does not, however, permit contamination of the material within the container by particles such as microorganisms encountered en route to the surface due to the small pore size.

Similarly, cultures of microorganisms can be packaged within these breather containers. The containers can be put in any atmosphere without danger of exchange of microorganisms with that atmosphere, maintaining the bacteria at ambient pressure.

The breather of the container of the present invention is a microporous material, preferably having an effective pore size in the environment in which it is to operate of less than about 0.5 micron and preferably less than about 0.2 micron.

The breather must have a fluid flow capacity sufficient to pass atmospheric or contained fluid at a rate that will prevent bursting of the container in the event of a sudden change of ambient pressure. The flow capacity of the breather is dependent, inter alia, on its size. Thus, a large breather might be thought desirable to obtain a high flow capacity. On the other hand, it is extremely important that the breather be kept as small as possible so that the flexing of the container does not cause the breather to flex to such a degree that its pores are distorted and the pore size enlarged. In addition, the porous breather is normally more subject to puncture than the container material. Thus, to provide as puncture proof a container as possible the breather should be kept as small as possible. Furthermore, if the flexibility of a large breather is less than that of the container, it could interfere with the proper flexing of the container.

It has been found in accordance with this invention that a relatively small breather can be employed to ensure maximum strength, durability and reliability and yet still provide a sufficient flow capacity to prevent bursting of the container or even prolonged inflation or deflation of the container upon a rapid change in ambient conditions.

The flow capacity of the breather is dependent upon the size and fluid flow characteristics of the breather material, which depend upon the nature of the fluid environment, i.e. whether in a gas or liquid, as well as the type of liquid or gas, and the nature of the microporous material. It has been found however, that a great number of microporous materials provide a sufficient flow capacity such that only a small size breather is required.

One or more breathers can be provided in the walls of the container, but only one is usually necessary. The required surface area of the breather portion depends on the size of the container, the atmospheric pressure differential in which the container will be used, and the rate of atmospheric pressure change. However, the total surface area of the breather is usually quite small relative to the expanded internal volume of the container and yet is sufficiently large to provide the necessary flow capacity for equilibrium pressure in the event of a sudden change in ambient pressure outside the container. In fact, a breather of four square inches or less has been found to be sufficient in nearly all instances. As a general rule

for most conditions the ratio of breather surface area to expanded internal container volume should be in the range of from about 15×10^{-2} in.²/in.³ to as small as about 0.2×10^{-2} in.²/in.³. For example, to illustrate the relative size of the breather material, consider a flexible container for an object 2 in. x 2 in. x 6 in. in size. If this container is subjected to gradual changes in ambient pressure, and is stored in a clean atmosphere the breather portion can be as small as 0.25 in. diameter.

The shape or thickness of the breather is not critical. The breather can be in the form of one or more circular, elliptical, triangular or polygonal sections, or the sections can be in the form of a strip or band running lengthwise of or encircling the container. Where the breather area is required in a very small space, the breather material can be corrugated.

Some microporous materials have layers in which the pores provide an extremely tortuous fluid flow path. Such materials are extremely effective in preventing the passage of bacteria, especially gas-borne bacteria, and can capture particles which have an effective diameter smaller than the diameter of the pores. It is believed that such particles are caught by impingement upon the walls of the tortuous pores. However, a liquid flowing through such a pore is more likely to carry a small particle through than a gas. Therefore, a breather that is to remove such small particles as can enter the pores, as well as those that cannot enter the pores, should be liquid-repellent, and particularly water-repellent, to prevent the passage of any liquid such as water which may condense on the surface of the breather and which would tend to carry these smaller particles through the pores. Microporous materials such as ceramic and certain membranes do not have tortuous pores, and therefore their largest pore must have a diameter small enough to prevent any organism to be removed from entering the pore.

Microporous materials that can be used can be made of any fibrous material such as cotton, jute, sisal, hemp, flax, linen, wood fiber, metal wire, such as stainless steel, copper and aluminum, plastic filaments (monofilaments and yarn) such as polytetrafluoroethylene, fluorinated ethylpropylene resins, nylon, polyvinyl chloride, polyacrylonitrile, esters of terephthalic acid and ethylene glycol, cuprammonium rayon, acetate rayon, viscose rayon and polyvinylidene chloride; these can be formed in non-woven mats, bats or layers having pores the largest of which is less than 1 micron and preferably less than 0.5 micron; and papers of various types, made up of cellulose fibers, cellulose cloth, plastic fibers, such as polyvinyl chloride, cellulose acetate, polyvinylidene chloride, nylon, and any of the other plastic filaments mentioned above, coated or impregnated with any of these fibrous materials as a microporous layer.

Impregnated and/or coated microporous sheet materials in particular can be made with less than 0.5 micron pores and include the microporous materials of U.S. Patents Nos. 3,053,762 to Adiletta, dated September 1962, 3,158,532 to Pall et al., dated Nov. 24, 1964, 3,238,056 to Pall et al., dated Mar. 1, 1966, 3,246,767 to Pall et al., dated Apr. 19, 1966, and 3,353,682 to Pall et al., dated Nov. 21, 1967. These materials are preferred.

Also useful for this purpose are microporous ceramic discs and plates and the microporous cellulose derivatives and synthetic resin membranes described in U.S. Patents Nos. 1,421,341 to Zsigmondy, 1,693,890 and 1,720,670 to Duclaux, 2,783,894 to Dovell, 2,864,777 to Robinson, and 2,944,017 to Cotton.

Liquid repellency is obtained by treatment with a material that repels the liquid, when it is disposed on the surfaces of the pore walls of the microporous material. The repellent material can be applied from a solution or dispersion thereof, in a solvent or dispersant which desirably includes a binder, to retain the repellent on the pore wall surfaces, unless the repellent is reactive therewith, and can bond itself thereto.

The application can be by printing, spraying, coating, impregnating, dipping, or by exposure to a vapor, such as that of a low boiling silicone compound. It is necessary to use a technique that results in thorough treatment of the entire length of the pores, from surface to surface of the material. This requires impregnation of the wall surfaces of the pores from end to end, and is best achieved by allowing the solution or dispersion of the repellent to flow into and through the pores in the treated zone, by capillarity or by pressure application.

It will be appreciated that in nonwoven substrates, such as paper, nonwoven bats, and microporous layers formed by laydown from a fluid dispersion, the through pores that extend from one surface to another are composed of interconnected pores which are the interstices between the particulate material of which the material is made.

The amount of repellent that is required depends upon the effectiveness of the material as a repellent, and the volume of pores being treated. Usually less than 25% by weight of the volume being treated and preferably from 0.025% to 15% by weight of the volume is sufficient.

For a hydrophobic or water-repellent surface, there can be used silicone resins and silicone oils of the general type $R_n-Si-O-Si-R_n$, where n is 1 or 2, n is 1 in the case of the fluids, and n is 2 in the case of the solids, which contain cross-links between chains. Mixtures containing species in which n is from 1 to 3 can also be used. R is a hydrocarbon group having from one to eighteen carbon atoms.

Also useful are the quaternary ammonium salt derivatives of silicone compounds described in U.S. Patent No. 2,738,290, dated Mar. 13, 1956. These are substantive to cellulosic materials, as noted in the patent. Also, hydrophobic oils and waxes can be used, in appropriate circumstances, where they can be made permanent.

If the material is liquid-repellent, and it is desired to make it liquid-wetting for example when operating in a liquid environment, it is advantageous to apply a liquid-wetted material thereto. The same treatment principles and proportions apply to liquid-wetted materials as to liquid-repellent materials. Typical wetting agents that are suitable are polyvinyl alcohol, alkyl aryl polyether alcohols, melamine formaldehyde resins, and the like. These wetting agents can be applied from a dispersion or emulsion.

A breather formed of liquid repellent material is preferred, because it can be used even when the container may be subjected to immersion in a liquid or to an extremely damp or humid atmosphere, such as may be found in a tropical rain forest. With this type of breather, even if the container were to be stored under such humid conditions, and water were to condense on the surface of the container, water and entrained bacteria could not wick through the breather to contaminate the contents within the container.

The walls of the container of this invention can be of any suitable wrapper material, and are closed and sealed if desired against fluid flow at all points except the breather. Preferably, the wrapper material is a flexible, transparent, plastic. Optimally, for ease of fabrication the plastic is a thermoplastic synthetic resin. Examples of transparent thermoplastic flexible sheet materials include polyethylene, polypropylene, polyvinyl chloride, vinyl chloride-vinylidene chloride copolymer, polyesters, thermoplastic moisture-resistant coated regenerated cellulose or cellophane; flexible translucent materials include certain polyvinyl chloride sheet, polypropylene and polyethylene. If a rigid container is desired, the above materials can be in rigid form, e.g. polyvinyl chloride and vinyl chloride-vinylidene chloride copolymers, as well as poly(methyl methacrylate), poly(methyl acrylate), ureaformaldehyde resins, melamine-formaldehyde resins, polystyrene, polyamides, polytetrafluoroethylene, polyfluorotrichloroethylene, polycarbonates and

phenol-formaldehyde resins. The fluoroethylene-based materials are especially useful, if an inert high-melting material must be used.

The rigid containers can be made of molded or cast polymers, in any desired shapes and sizes.

Metal-walled containers can also be used. Such containers can be formed from flexible metal foil, metal sheet, or rigid plates. Examples of metals which are useful include aluminum, stainless steel and other stainless alloys, nickel, chromium, vanadium, molybdenum and manganese alloys.

The breather must be securely sealed to the container wall, in a fluid-tight seal. The bonding suitable for joining the breather to the container wall depends on the physical and chemical nature of the walls and breather. Generally, the bonding can include heat-sealing, solvent-sealing, adhesive-bonding, welding, brazing, sintering, soldering, and pressure-bonding, as well as mechanical means of joining as by clamps, screws or bolts.

In the preferred embodiment of this invention, the container material is formed of a thermoplastic synthetic resin such as polypropylene, polyethylene and polyvinyl chloride, which permits the use of heat-bonding or solvent-bonding. If desired, however, such materials can of course be joined to the breather by adhesive bonding. When using either heat-sealing or solvent-sealing, the container material and/or any thermoplastic resin present on the porous material is softened, the two materials are pressed together, and permitted to harden. A leakproof seal is formed at the joint between the two materials.

Where the breather and container walls are formed of the same or compatible thermoplastic resins, both resins can be heat-softened, or solvent softened, and with or without pressure caused to flow together, so that when hardened, a strong bond is formed. Where the breather or container either is not thermoplastic or is much higher melting than the other, a strong bond can be formed between the two by softening only the lower melting thermoplastic resin. When the resin forming the container wall is softened, and pressure is applied, the softened resin flows into the pores of the breather porous material, and when the resin is permitted to harden, a leakproof bond is formed, firmly securing the container wall to the breather.

In a preferred embodiment of this method, two of the thermoplastic resin sheets forming the container walls are used, one on either side of the breather, so as to bond to the breather from both sides, thus forming a stronger joint.

The invention further provides a process for sterilizing materials packaged within a closed container of this invention having a liquid repellent breather. Preferably, the material is gas-sterilized, by autoclaving in a sterilizing gas atmosphere. A liquid-repellent breather permits the passage of the sterilizing gas to the interior of the container, but prevents the passage of bacteria laden gas or moisture.

In this process the material is first sealed in the container, having a liquid-repellent breather, and then sterilized in a gas atmosphere, usually ethylene oxide or beta-propiolactone vapor, or autoclaved in a steam atmosphere.

The steam autoclave is heated to elevated temperatures of at least about 250° F., and preferably of at least about 300° F., preferably for from about 15 to about 30 minutes. The time for sterilization depends upon the temperature and the sterilizing atmosphere. The maximum sterilization temperature is limited by the sterilization gas used and the heat stability of the breather container and its contents. To determine the completeness of sterilization, the packaged product is subjected to sterilization in an autoclave having a sterilizing gas atmosphere together with a separately packaged bacteria culture serving as a control. When the sterilizing process has been completed, the package containing the bacteria culture is removed, and the bacteria culture placed in a culture medium. If the microorganisms of the culture

fail to propagate, the sterilization of the packaged article has been confirmed.

The packaged bacteria culture can contain a mixture of microorganism cultures of various types, to ensure that all of the bacteria which might be contaminating the material to be sterilized are destroyed.

The attached drawings show preferred embodiments of the invention.

FIGURE 1 is a side of a sealed flexible breather container.

FIGURE 2 is a cross-sectional view of the flexible breather container of FIGURE 1 taken along the line 2—2, when viewed in the direction of the arrows, in which is packaged a hypodermic needle.

FIGURE 3 is an enlarged cross-sectional view of the breather portion of the flexible container, wherein is shown one method of attaching the breather portion to the container.

FIGURE 4 shows an hermetically sealed rigid breather container.

The flexible breather container of FIGURES 1 and 2 comprises a bag 1 made of two thermoplastic resin sheets 3 and 4 containing a window 17 cut through both sheets. A liquid repellent breather portion 2 in the form of a disc slightly larger than the window 17 is integrally bonded or heat sealed between the two sheets at the window 17 along circumference 5. A hypodermic syringe 6 to be sterilized is snugly packaged within the bag 1, such that under normal handling conditions the needle will not punch through the walls and allow contamination to enter. Both ends of the bag are hermetically sealed along the lines 7 and 8. Since an average hypodermic syringe is usually less than 1.0 in diameter by 6 in. long, the size of the breather portion required for the flexible container housing the syringe can be as small as .25 in. diameter, if the container is stored in a relatively clean constant atmosphere usually found in medical institutions. However, for ease of manufacture and for usage under diverse conditions, such as in a tropical humid climate, a larger diameter breather portion, approximately .5 in. to 1.0 in. diameter is employed in the embodiment of FIGURES 1 and 2.

The flexible breather container of FIGURES 1 and 2 can also be formed with a leak-proof fold and groove type closure seal at one end, such that the container may be opened and resealed without its being destroyed.

Alternatively, the entire bag can be made of a single thermoplastic resin sheet, such as polyethylene, and a smaller outer sheet in the area of the window only. This is illustrated by FIGURE 3. A window 18 is cut through the sheet 20 comprising the wall of the bag and through the outer sheet 19. The breather disc 2, slightly larger than the window 18, is inset between the two sheets 19 and 20. The outer sheet 19 is then heat-sealed to the bag wall 20 along its circumference 11, and the breather disc 2 is bonded or heat-sealed around its entire circumference at 10.

As a further alternate breather portion can be secured over a window in a single sheet bag without the use of an outer sheet.

For any of the alternates discussed above the breather portion can be heat-sealed or bonded to the thermoplastic resin sheets as follows. When the resin sheets are softened, and pressure is applied, resin flows into the pores 9, shown in FIGURE 3, and at least in some instances flows all the way through the pores forming a continuous matrix of resin engulfing the outer perimeter of the breather. The amount of resin in the pores depends upon the pressure applied, the temperature, the pore size and configuration and any interaction between the breather and the thermoplastic resin.

The breather material is prepared in sheet form following the procedure of Example 1 of U.S. Patent No. 3,353,682. The average pore size of this material is 0.1 micron and the maximum pore size less than 0.35 micron

as determined by 100% removal of the bacteria, *Serratia marcescens*.

This material is then treated with General Electric's RTV-112 silicone resin, to render it water-repellent. The treatment is carried out by impregnation using a 5% solution of RTV-112 silicone resin solution in perchloroethylene, followed by evaporation of the solvent, and curing the resin at 40% relative humidity and at 25° C. for 18 hours. The deposition rate is approximately 0.1 cc. of solution per square centimeter of breather material, extending to the opposite side of the material.

The breather container of FIGURE 4 comprises a rigid container 12, wherein the cover 13 includes a triangular breather 14. The rigid container 12 is molded of transparent poly(methyl methacrylate) resin, and the cover 13 is sealed to the lower portion of the container 16 by solvent-bonding after the instruments to be sterilized have been placed therein. The breather 14 is formed of the same material described above for the flexible container of FIGURES 1, 2 and 3, and is joined to the cover 13 by solvent-bonding the material at the edges of a triangular hole 15, slightly smaller in size than the breather 14. The material forming the edges of the triangular hole are softened using acetone and the breather 14 is pressed against the edges of the triangular opening. The acetone is permitted to evaporate, and the poly(methyl methacrylate) thereby hardens, forming a seal between the breather 14 and the container cover 13. Where a rapid change in ambient pressure is likely, a structural support can be provided for the breather portion to prevent its deformation. This will assure that the pore size is not altered due to severe flexing.

As in the case of the flexible breather containers described above, the breather portion of the rigid container can be made in any convenient shape. Furthermore, a plurality of breather portions can be used and located in any convenient position on any side.

The rigid container can also be constructed with a hinged top, where it is desired to have it reusable. Likewise, other materials such as stainless steel or aluminum can be used for constructing the box.

All of the containers described herein can be used in the process of this invention for sterilizing material in a closed container. Polypropylene and poly(methyl methacrylate) resins each have a sufficiently high melting point and are sufficiently inert to withstand gas sterilization at 400° F. Preferred embodiments of carrying out the process for sterilizing packaged articles are as follows:

EXAMPLE 1

A hypodermic needle is packaged within the flexible liquid-repellent breather container described in FIGURE 1 above. The package is placed in an autoclave together with a similar package containing a culture of *E. coli* bacteria, which is placed in the autoclave immediately adjacent to the package containing the hypodermic needle. The two packages are subjected to sterilizing conditions at 25° C. in an atmosphere of ethylene oxide. After 24 hours both packages are removed, the package containing the bacteria culture is opened and the culture placed in a broth culture medium. After 48 hours, no visible signs of bacteria colony growth were noted, indicating complete sterilization of the *E. coli* culture.

EXAMPLE 2

The sterilization process of Example 1 is repeated but using moist heat autoclave with no vacuum at 121° C. (250° F.), maintaining the packages in the sterilizing atmosphere for 15 minutes. Complete sterilization of the bacteria culture is also obtained by this process.

Having regard to the foregoing disclosure the following is claimed as the inventive and patentable embodiments thereof:

1. A breather container comprising, in combination, walls defining the container; and a relatively small breather in at least one wall of the container which com-

prises a liquid repellent microporous filter material having an effective pore size of less than about 0.5 micron in diameter to permit the flow of gases but prevent the passage of microorganisms between the interior and the exterior of the container whether said microorganisms are entrained in a liquid or in a gas.

2. A breather container according to claim 1, wherein the ratio of breather surface area to the expanded internal volume of the container is in the range of about 0.2×10^{-2} in.²/in.³ to 15×10^{-2} in.²/in.³.

3. A breather container according to claim 1, wherein the surface area of the breather is less than 4 square inches.

4. A breather container according to claim 1, wherein the container has flexible walls.

5. A breather container according to claim 4, wherein the breather is dimensioned according to overall size of the container so as to be relatively sufficiently small to resist flexing.

6. A breather container according to claim 1, wherein the container has semi-rigid walls.

7. A breather container according to claim 1, wherein the container has rigid walls.

8. A breather container according to claim 1, wherein the container walls are formed of a thermoplastic synthetic resin sheet.

9. A breather container according to claim 8, wherein

the breather also comprises thermoplastic synthetic resin material, and is fused-bonded to the thermoplastic synthetic resin container wall.

10. A breather container according to claim 8, wherein the breather is sandwiched between two plies of the thermoplastic synthetic resin sheet.

11. A breather container according to claim 1, wherein the breather is formed of a microporous resin-impregnated fibrous material.

12. A breather container according to claim 1, in the form of a flexible bag.

13. A sterile package comprising a closed container according to claim 1, and an article therewithin.

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