Jan. 18, 1966 G. A. CROWE, JR., ETAL 3,229,813

STERILE PACKAGE

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Fig. 1.

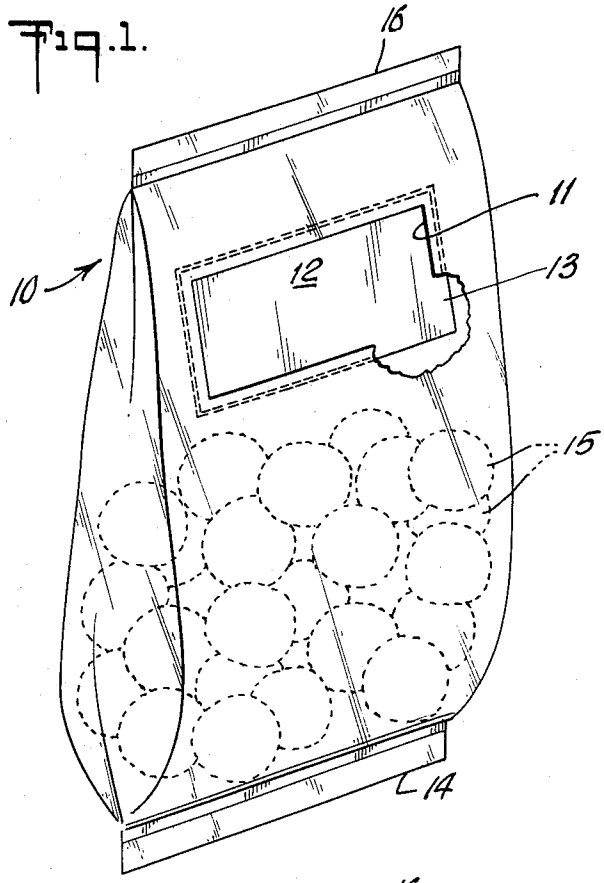
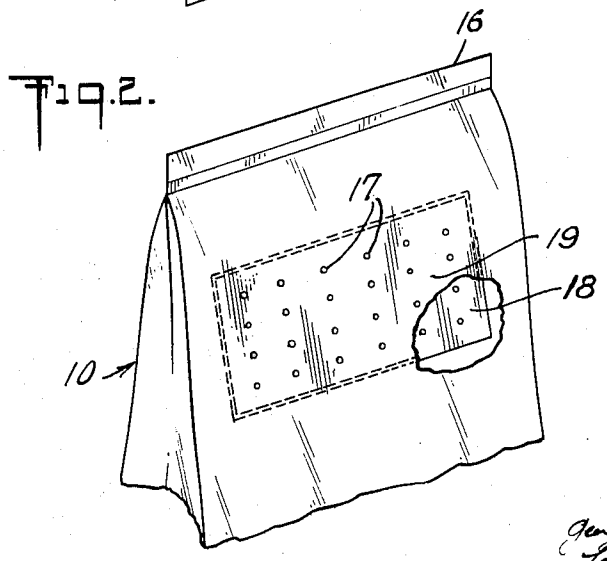


Fig. 2.



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STERILE PACKAGE

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The present invention is drawn to bags and similar packages formed of plastic sheet material and more particularly to sealed plastic packages the contents of which have been sterilized after being packaged.

Because of the advantages in merchandising derived from displaying the contents of a package, it has become common practice to place many articles in transparent plastic bags or containers. Besides readily displaying the merchandise, the transparent plastic bag or other container has the further advantage that the plastic sheet material from which the container is made is relatively inexpensive, is tough, giving a strong flexible package, and is readily sealed, particularly where formed of a thermoplastic sheet material. Plastic bags formed of thermoplastic films or sheets are easily prepared and articles packaged and sealed therein since thermoplastic sheet material can be purchased in the form of tubes, which may then be cut into the desired length, heat sealed at one end to form a bag, filled with the article to be packaged and the remaining open end then heat sealed to complete the sealed package. Such a package would seem to be ideally suited for the sterile packaging of surgical sponges, cotton balls, bandages and similar items which must be maintained in a sterile condition up to the time of their removal from the package and use. However, despite the many advantages offered by the use of thermoplastic and other resin sheets or films for packaging, considerable difficulty is encountered, because of the relatively impermeable nature of such materials, when attempts are made to sterilize bags and similar packages made therefrom after the contents have been sealed therein.

When sterilizing a packaged item, it is customary to first draw a vacuum on the package to an absolute pressure of between about 1/10 and 1/40 of an atmosphere. The package is then subjected to steam, if steam sterilization is being employed, at a pressure of about 2 atmospheres and a temperature of about 240° F. to 250° F. After being subjected to the steam for about 20 to 30 minutes, the package is brought back to atmospheric pressure. Where chemical sterilization is employed, after the initial evacuation, the package is subjected to steam at about 160° F. at a pressure of about 1/3 atmosphere, after which a sterilizing gas is added and the pressure increased to about 2 atmospheres. The pressure on the package is then reduced to somewhat less than atmospheric pressure to draw off the sterilizing gas and the package then permitted to come to atmospheric pressure. Since thermoplastic and other resin films or sheets offer substantial resistance to the passage of air, when bags are made of these materials not only does the sterilizing steam or sterilizing gas not adequately penetrate the package to sterilize its contents, but the radical changes in pressure, particularly at elevated temperatures, make it extremely difficult to keep the package from rupturing at some point. This exposes the contents to contamination after the sterilizing cycle is completed.

It is an object of the present invention to make plastic bags and similar packages the sealed contents of which are readily sterilized by conventional sterilizing processes without exerting undue strain on the package. Other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings, wherein are set forth

by way of illustration and example certain embodiments of this invention.

It has now been discovered that bags and similar packages made from thermoplastic and other resin sheet or film materials can be readily sterilized and the contents thereof maintained sterile if openings are formed in the side of the bag and these openings sealed with a sheet of porous paper in the manner hereinafter described. The openings may be either in the form of a single window, which is covered by the porous paper, or may be in the form of a plurality of relatively small openings covered by the paper sheet.

The practice of the present invention is further described by reference to the drawings, in which:

FIG. 1 illustrates one modification of the invention in which a single window is used; and

FIG. 2 illustrates the preferred form of the invention in which a plurality of openings are provided backed by a sheet of porous paper.

Referring to the drawings, FIG. 1 illustrates a transparent bag **10** formed of polyethylene or other suitable transparent thremoplastic sheet material. The bag may be formed from a tube of polyethylene, a portion of which has been removed to form a window **11** which is covered by a sheet of paper **12** sufficiently wide that its marginal edges **13** extend over the edge of the polyethylene sheet surrounding the window **11**. The paper cover is bonded to the polyethylene sheet along this marginal edge **13** by the application of heat and pressure. The polyethylene tube is formed into bag **10** by bringing its bottom edges together and heat sealing as at **14**. The tag so formed is filled with cotton balls **15** or other article to be packaged and sealed closed by clamping the top edge **16** together at a sufficiently high temperature to obtain a good heat seal.

The window **11** may vary in size, although it is generally undesirable to make the window too large since this has a tendency to weaken the package, the paper of the window generally being more readily torn than the polyethylene or other thermoplastic sheet material from which the bag is formed. The window should be large enough, however, to permit sufficient breathing to prevent rupture of the package during the sterilization cycle and allow the entry of sterilizing gases where chemical sterilization is employed. It has been found that the paper, covering the open area provided in the bag, should not be substantially less than about 6 square inches for each 1½ liters of cubic contents of the package.

In order to prevent the possible tearing of the paper window, it may be desirable to use the modification illustrated in FIG. 2, in which a substantially stronger package is illustrated. In the package of FIG. 2, the openings **17** in the thermoplastic sheet material are made in the form of a plurality of small holes grouped together and then covered with a sheet of paper **18**. By this structure, the thermoplastic sheet material **19** between the openings **17** protects the paper **18**, giving a stronger package. Where small openings are used in this manner rather than a single large opening, as illustrated in FIG. 1, the unsealed paper area should not be substantially less than about 6 square inches for every 1½ liters of volume inside the bag. The open area in the film, however, can be substantially smaller, satisfactory results being obtained with a single ⅛-inch diameter hole in the film over the paper with a package volume of about 1200 cc.

The porous paper used should be sufficiently strong to resist tearing both during sterilization and during shipping and handling. Otherwise, the same may be torn with the result that the contents of the package will become contaminated. Papers having a wet strength of not appreciably less than about 1.4 lbs. per inch width and a dry strength of not less than about 8.5 lbs. per inch are found to be sufficiently strong for use in the present invention.

The paper used should be impervious to airborne bacteria, and for this reason papers more porous than those having a porosity rating of 45 seconds are generally unsatisfactory. The preferred papers preferably have a porosity, as shown by the Gurley-Hill S-P-S Tester, of about 65 seconds to 180 seconds. This method of porosity testing is the T.A.P.P.I. standard T. 460–m49 and is the time for passage of 100 ml. of air through 1 square inch of paper. The porosity rating of any paper in the above units can be obtained from most paper manufacturers for the papers they sell.

With appreciably lower porosities, i.e., with time factors greater than 180 seconds, it is found difficult to completely sterilize the package contents with conventional steam or chemical sterilization methods, the paper offering too much resistance to flow of the sterilizing gas. Also, there is some tendency for the package to rupture during the sterilizing cycle. Where the paper has an appreciably greater porosity, as shown by a test time reading of appreciably less than 45 seconds, there is too much danger of air-borne bacteria passing through the paper window and contaminating the contents of the package.

Although papers having a pore size suffiicently large to give a reading of 45 seconds have been found to satisfactorily filter out air-borne bacteria, there is always the possibility that the paper is not of good stock and uniform quality. Accordingly, it is the safest practice to check any new stock. Also, papers used should be of a high grade and uniform quality so as to avoid the possible inclusion of inferior sheets of unsatisfactory pore size. The ability of a paper to act as a bacterial filter is tested in the following manner. The sample paper is fabricated into rectangular envelopes, and a gauze pad is placed into each envelope. The edges of each envelope are securely sealed with adhesive or cellophane tape and the packages are then steam sterilized according to U.S.P. procedures, Sterilization Process C. Upon removal, the packages are exposed to air-borne bacterial penetration normally encountered in various storage conditions. After exposure for several weeks, the contents of each envelope are tested for sterility as outlined in U.S.P., Sterility Tests for Liquids and Solids, Sterility Test for Purified Cotton, Gauze, and Surgical Dressings. Papers allowing no contamination are acceptable bacterial filters.

Where the plastic sheet material used in preparing packages of the present invention is thermoplastic, it should have a softening temperature in excess of 80° C. The preferred materials are both transparent and thermoplastic. Polyethylene films have been found to be highly suitable where the polyethylene has a softening temperature in excess of 80° C. Among other suitable film or sheet materials are films or thin sheets of polyethylene terephthalate, cellulose, cellulose acetate, polystyrene, polyvinyl chloride and polyvinylidene chloride.

The invention has been illustrated in connection with one embodiment thereof, although many modifications are within its spirit. It is to be limited, therefore, only by the scope of the appended claims.

Having thus described our invention, we claim:

1. A bacteria impervious air permeable sealed package comprising a flexible container formed of a substantially air impervious material, a sterile article in said container, a plurality of small holes through said impervious material in the side of said container, a paper sheet on the inside of said container over said holes having an area substantially greater than said holes, said paper sheet being sealed to said impervious material by a seal extending around said holes and around an unsealed area of said paper sheet of not less than about 6 square inches for each 1½ liters of maximum volume of said container, said paper cover having a porosity of 45 seconds to 180 seconds, a wet strength of not less than about 1.4 lbs. per inch width and a dry strength of not less than about 8.5 lbs. per inch width.

2. A bacteria impervious air permeable sterile package comprising a container formed of flexible, transparent, thermoplastic sheet material, a sterile article in said container, an open area in the side of said container through said thermoplastic sheet material of not less than that of a circular opening of about ⅛-inch diameter, said open area being made up of a plurality of small openings, a paper cover inside said container over said open area and of a size substantially larger than said open area so as to extend beyond the edges thereof, said paper cover being sealed to said thermoplastic sheet around said open area, the seal extending around an area of paper not less than 6 square inches for each 1½ liters maximum volume of said container, said paper cover having a porosity of 45 seconds to 180 seconds, a wet strength of not less than about 1.4 lbs. per inch width and a dry strength of not less than about 8.5 lbs. per inch width.

3. A bacteria impervious air permeable sterile package comprising a flexible container formed of a tube of flexible, transparent, thermoplastic sheet material, said tube being sealed shut at both ends, a sterile article in said container, an open area through said thermoplastic sheet material in the side of said container of not less than that of a circle having a diameter of about ⅛-inch, said open area being made up of a plurality of small openings, a paper cover inside said container over said open area and of a size substantially larger than said open area so as to extend beyond the edges thereof, said paper cover being sealed to said thermoplastic sheet material around said open area, the seal extending around an area of paper not less than 6 square inches for each 1½ liters maximum volume of said container, said paper cover having a porosity of 45 seconds to 180 seconds, a wet strength of not less than about 1.4 lbs. per inch width and a dry strength of not less than about 8.5 lbs. per inch width.

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