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Moore et al.

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[54] **METHOD OF STERILE PACKAGING**

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[*] Notice: The portion of the term of this patent subsequent to Apr. 3, 1970, has been disclaimed.

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 112,762, Feb. 4, 1971, Pat. No. 3,725,003, which is a continuation-in-part of Ser. No. 873,786, Nov. 4, 1969, Pat. No. 3,618,283.

[52] **U.S. Cl.** ..... **21/58,** 53/21 FC, 53/25

[51] **Int. Cl.**.... **A61l 13/00,** B65b 55/18, B65b 55/14

[58] **Field of Search** ..... 53/21 FC, 25; 21/2, 58, 21/99

[56] **References Cited**

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Reddish, "Antiseptics, Disinfectants, Fungicides, and Chemical and Physical Sterilization," (1957), 2nd Ed., pp. 247, 248, 282, 320, 327, 328.

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[57] **ABSTRACT**

A method of sterile packaging which involves the steps of partially filling a container with any of a number of anti-bacterial agents in liquid or semi-liquid form which contain iodine as the active ingredient, then sealing the container so that the air space is formed above the liquid within the container, and finally heating the container and its contents (which may include a solid object to be sterilized immersed or partially immersed in the liquid) to a temperature substantially below the boiling point of the liquid, and at a pressure of about one atmosphere, until the interior surfaces of the container above and below the liquid level, and the entire contents of such containers, are sterilized.

7 Claims, No Drawings

METHOD OF STERILE PACKAGING

RELATED APPLICATIONS

This application is a continuation-in-part of our co-pending application Ser. No. 112,762, filed Feb. 4, 1971 now U.S. Pat. No. 3,725,003, which is in turn a continuation-in-part of our application Ser. No. 873,786, filed Nov. 4, 1969, now U.S. Pat. No. 3,618,283.

BACKGROUND

The aforementioned U.S. Pat. No. 3,618,283 discloses a method for the sterile packaging of surgical sponges and other articles in sealed flexible wrappers. During the packaging operation, and immediately following the sealing of the wrappers, each package is squeezed or compressed so that all of the surfaces within the package will be flushed or wetted by the germicidal soap solution contained within the package. Subsequent heating of the package at a low enough temperature to avoid rupturing the flexible walls of the wrapper results in sterilization of all of the surfaces contacted by the liquid or, in other words, all of the surfaces within the package.

SUMMARY

A main aspect of this invention lies in the discovery that all surfaces within such a package will be sterilized by a procedure similar to the one described even where some of the surfaces are not flushed or contacted by the anti-bacterial solution. Obtaining complete sterilization under such conditions is believed most unexpected. The word "sterilization" as used herein means a method wherein no organisms are found living after treatment and in which even the most resistant organisms (spores) give no evidence of viability following such treatment.

The method involves the steps of first partially filling a bottle, bag, or other suitable container with a solution, usually but not necessarily an aqueous solution, containing, or capable of releasing, free iodine. After partially filling the container with such a solution, and after placing in the container those items (if any) to be sterilized, the container is sealed so that an air (or gas) space is disposed above the liquid. Thereafter, the container and its contents are heated to a temperature well below the boiling point of the liquid and at a pressure of about one atmosphere. In general, the temperature to which the container and its contents are heated will fall within the range of about 130° to 210° F., but usually below 180° F., the particular temperature depending upon the solution used and the duration of the heating step. The heating operation is continued until all organisms, including spores, are killed, the interval normally falling within the range of 2 to 24 hours.

The iodine preparations used in connection with the present method are conventional. Iodine preparations or complexes which liberate free iodine in aqueous solution are highly effective for use in connection with the method of this invention. An aqueous iodofor solution having an available iodine concentration within the range of 0.0012 to 3.0 percent is suitable. The heating step should be carried out at a temperature within the range indicated, and preferably within the range of approximately 130° to 150° F., for a period in excess of 2 hours.

Sterilization is complete even though surface portions within the container are never directly contacted by the liquid. Normally the space above the liquid in the container will be filled with air; however, other gases might be substituted if desired. As previously mentioned, it is particularly significant that the gas and all surfaces on which the gas impinges become sterile at temperatures far below what is normally considered a sterilizing temperature (autoclaving temperature is about 220° F.) and below the boiling temperatures of the liquids at normal atmospheric pressure.

The effectiveness of the sterilization procedure, and the details of specific applications of the operative procedure, will be evident from the following illustrative examples:

EXAMPLE I

An iodofor soap solution marketed under the designation "GSI" by Huntington Laboratories, Huntington, Indiana, was mixed with water in the proportions of 3 parts water to 1 part iodofor solution. Such solution is believed to be a mixture of phosphate ester of polyethoxylated nonylphenol with iodine bound to the phosphate, sodium N-(2-cocoamidoethyl)-N-(2-hydroxyethyl) alycinate, alkyl phenoxypoly (ethyleneoxy) ethylester of phosphoric acid, phosphoric acid, and cetyl alcohol, making available (prior to dilution) 0.75 to 1.25 percent free iodine. The available iodine of the diluted solution was approximately 0.312 percent and had a vapor pressure of about 2.5 millimeters at 150° F. (65° C.).

Ninety milliliters (ml) of the diluted solution was placed in a 200 cubic centimeter (cc) large mouth bottle. A Bacillus Subtilis (globigii) spore strip was secured by wire to the inside of the bottle cap so that when the cap was fitted tightly upon the bottle the spore strip was disposed half the length of the bottle above the liquid. Ten such bottles were partially filled and provided with spore strips as thus described. Five of them were inverted, thus wetting the spore strips with the solution. After being left in inverted position for 30 minutes, each was returned to an upright position. The five were then placed in upright position in a rack in an oven.

The other five bottles were not inverted and care was taken to avoid wetting of the spore strips. Such bottles were placed in the oven at the same time and under the same conditions as the preceding five bottles. A single control bottle was prepared in the same manner described above and its spore strip was left dry.

All bottles but the control were heated in an oven for 3 hours at a temperature of 140° to 150° F. None of the spore strips in any of the 10 test bottles revealed any evidence of spore growth or an indication of viable microorganisms. Spore growth was clearly apparent on the spore strip in the control bottle.

EXAMPLE II

An iodofor solution marketed under the designation "Prepodyne 2019" by West Chemical Products, Long Island City, New York, containing approximately 1.0 percent available iodine, was diluted with 3 parts water, resulting in a diluted solution having about 0.23 percent free iodine.

Ten ml of the above solution were placed into a flexible plastic bag open at one end. Three swabs, each composed of a four inch length of hollow plastic tubing

with a ball of absorbent rayon at one end thereof, were placed into the bag with their absorbent ends facing downwardly. The absorbent rayon at the ends of the swabs absorbed approximately 8 ml of the solution. Bacillus Subtilis (globigii) spore strips were then inserted into the exposed open ends of the swab handles. Care was teken to prevent the remaining liquid from wetting the spore strips or the inside (or outside) surfaces at the upper ends of the handles. The open upper end of the bag was then closed by heat sealing.

Five packages prepared as described above were heated to 135° F. for 3 hours. One additional package was maintained at room temperature as a control. Thereafter, the packages were opened and the swabs were dissected and placed into incubation tubes along with the spore strips which had been supported in the swab handles. None of the swabs and spore strips from the heated packages revealed any evidence of spore growth or any indication of viable microorganisms. There was bacterial growth on the control swab as well as spore growth on the strip from the control package.

EXAMPLE III

An iodofor scrub solution marketed under the designation "Surgidine" by Carter Wallace, Inc., of Cranbury, New Jersey, containing approximately 1.25 percent available iodine, was diluted with 3 parts water, resulting in a diluted solution having about 0.26 percent free iodine.

Twenty One ml of the diluted solution were placed into a flexible plastic pouch which was open at its upper end and which was approximately 3 inches by 6 inches in size. A sponge of polyurethane foam having dimensions of 2½ inches by 3½ inches by 1¼ inches was inserted into the pouch and absorbed most of the solution; however, the solution did not completely saturate or wet the entire sponge. A *Bacillus Subtilis* (globigii) spore strip was inserted into a slit in the side upper end of the sponge. Care was taken not to agitate the package or to squeeze the sponge during this procedure and when the open upper end of the pouch was thereafter closed by heat sealing.

Five packages were prepared as described above and were stored at room temperature for 2 days. The packages were then opened and the spore strips were removed. After incubation, spore growth was clearly evident on all of the strips.

Five other packages prepared as above were heated to 150° F. for a period of 2½ hours. The packages were opened and the spore strips were removed and incubated. None of the spore strips revealed any evidence of spore growth or any indication of viable microorganisms.

All of the tests carried out in the examples given above were performed in accordance with the specifications of the Association of Official Analytical Chemists (AOAC) for the use of spore strips in the determination of sterility. It will be observed that sterilization was achieved in all of such tests at relatively low iodine concentrations, well below the preferred maximum of 1.0 percent available iodine and, in fact, at concentrations of available iodine no greater than about 0.312 percent (Example I).

While in the foregoing we have disclosed the method of the invention in considerable detail for purposes of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the spirit and scope of the invention.

We claim:

1. A method of sterile packaging comprising the steps of partially filling a container with a solution of a standard anti-bacterial agent having an available iodine concentration within the range of 0.0012 to 3.0 percent; then sealing said container to provide a gas space above said solution within the sealed container; and thereafter heating said container and its contents to a temperature substantially below the boiling point of said solution and at a pressure of about one atmosphere until the interior surfaces of said container above and below the liquid level, and the entire contents of said container, are sterilized.

2. The method of claim **1** in which said container and its contents are heated to a temperature within the range of about 130° to 150° F.

3. The method of claim **1** in which said gas space contains air.

4. The method of claim **1** wherein the contents of said container includes a solid object to be sterilized, said method comprising the step of placing said object within said container prior to said sealing step.

5. The method of claim **4** wherein at least a portion of said object is disposed in said space above the level of said liquid.

6. The method of claim **5** wherein the portion of said object is disposed above the level of said liquid throughout said filling, sealing, and heating steps.

7. The method of claim **2** in which said container and its contents are heated to a temperature within the range of 140° to 150° F. for a period in excess of two hours.

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