

[54] **STERILE PACKAGING METHOD**

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

[56]

References Cited

UNITED STATES PATENTS

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[57]

ABSTRACT

A sterile packaging method which involves the steps of sealing a suitable fluid or solid product within a container capable of withstanding prolonged exposure to temperatures up to 212° F., and thereafter heating the container and its contents for an extended period, but at a temperature substantially below the boiling point of water, until the container's interior surfaces and contents are sterilized.

5 Claims, No Drawings

STERILE PACKAGING METHOD

RELATED APPLICATIONS

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

BACKGROUND

The aforementioned co-pending application Ser. No. 873,786 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, the packages are squeezed or compressed so that all of the surfaces within the packages will be flushed or wetted by the germicidal soap solution contained within the packages. Subsequent heating at a low enough temperature to avoid rupturing the flexible walls of the wrappers results in sterilization of all of the surfaces contacted by the liquid or, in other words, all of the surfaces within the packages.

Co-pending application Ser. No. 112,762 is concerned with the further discovery that sterilization may be achieved even where some of the surfaces of the packages are not flushed or contacted by the anti-bacterial solution. A container is simply filled partially with an anti-bacterial agent solution and, after placing in the containers those additional 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 1 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 degrees F., the particular temperature selected depending upon the anti-bacterial agent 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.

SUMMARY

The present invention is concerned with the further related discovery that sterilization, as determined by accepted testing methods now available, may be achieved even in the absence of an anti-bacterial agent if the subboiling heating step is continued long enough and if at least some moisture is present in the container. Periods of heat treatment of 24 hours or more are involved. Since such treatment occurs at a temperature substantially below the boiling point of water, the danger or rupturing or breaking the container by reason of liquid volatilization, or the build up of excessive internal pressure, is avoided or greatly reduced. While the method may be used in conjunction with rigid containers formed of material capable of withstanding temperatures of 210° F. or even higher, it is particularly effective where sterilization of the contents of bags and other flexible-walled containers is desired. The contents of such containers may be solid, as in the case of surgical drapes, bandages, and instruments, or may be liquid such as, for example, parenteral fluids, or may even be gaseous. Since water in either liquid or vapor state must be present in at least limited quantities, the

contents of the packages will in many instances consist of products or substances of different phases.

DESCRIPTION

It is generally agreed that bacterial spores are more resistant to thermal inactivation than other microorganisms. The term "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 sporicidal test recommended by the Association of Official Analytical Chemists and by other organizations suggest that *Bacillus subtilis* (Globigii) or *Bacillus stearothermophilus* be used, and the tests carried out in determining the results of the present invention are in accordance with those recommendations.

The method involves the step of first sealing a product in a container formed of a material capable of withstanding temperatures up to 212° F. The container may be formed of glass, metal, or any of a variety of suitable plastic materials which are liquid impermeable. Polyethylene, polyvinyl chloride, and polypropylene, and gas-impermeable laminates of such plastics with metal foil, have been found effective. In the case of a flexible container formed of thermoplastic material, the sealing may be achieved by a direct application of heat (heat sealing), although cementing and other suitable sealing techniques may be used. Rigid containers may be provided with sealing caps or may be sealed by any other means as well known in the art.

The product sealed within the container may take any of a wide variety of forms. Quite commonly, such product will be a solid item such as a surgical sponge, garment, bed sheet, instrument, or some other article capable of withstanding temperatures up to 212° F. Alternatively, the product might be a liquid or a gas. In any case, whether the contents are solid, liquid, or gaseous, some water in either liquid or vapor form is believed essential. Where the contents of the package consist primarily of an aqueous solution an abundance of water will obviously be present. Where such contents consist primarily of a solid article then the remaining air or gas space within the package must contain some moisture.

After the sealing step, the container and its contents are heated to a temperature substantially below 212° F. and above a minimum temperature of about 170° F. for a period in excess of 24 hours. The duration of the heating step depends largely on the nature of the contents and the extent of contamination prior to packaging. Heating periods of 7 days or more may be required to achieve sterilization where the only moisture present is in the form of water vapor. The duration of the heating step may also be reduced by heating the contents at a temperature within the upper portion of the temperature range; however, care must be exercised to maintain a temperature well below the boiling point of water. A preferred range, subject to some variation depending upon the characteristics of the specific contents, is believed to be 190 to 205° F.

The heating step is performed at a pressure of approximately one atmosphere. Since increased external pressures are not required in order to prevent explosive rupture or breakage of the container, it is believed apparent that the present method is particularly advantageous where such containers take the form of flexible

bags or wrappers. The heating operation is continued at approximately atmospheric pressure until all organisms, including spores, are killed, the interval falling within the range of 24 hours to 200 or more hours.

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

Five 6 ounce bottles were each filled with tap water from the same source and were sealed. Prior to sealing *Bacillus stearothermophilus* spore strips from the same lot were placed in the bottles, each spore strip being in direct contact with the water contained therein. Thereafter, four of the bottles and their contents were heated at 175° F. ($\pm 3^\circ$) for 7, 8, 10 and 13 days, respectively. The remaining bottle, used as a control, was maintained at room temperature. Following such treatment, each of the bottles was opened and its spore strip examined for growth. None of the four spore strips in the bottles which had been heated showed any evidence of growth and none revealed any viable micro-organisms. Evidence of spore growth was clearly apparent on the spore strip of the control.

EXAMPLE II

The procedure of Example I was repeated except that the bottles (2) were heated for 4 and 6 days, respectively, at a temperature of 175° F. ($\pm 5^\circ$). The *Bacillus stearothermophilus* spore strips in both of the heated bottles and in the control revealed evidence of spore viability. The combined results of Examples I and II therefore revealed that sterilization, as evidenced by the destruction of *Bacillus stearothermophilus*, occurs in a period of over 6 days when ordinary tap water is heated at a temperature of approximately 175° F.

EXAMPLE III

Isotonic saline was sealed in four foil wrappers each containing approximately 30 cc of such liquid. Prior to sealing, a *Bacillus stearothermophilus* spore strip was inserted into each package. Three of the packages were heated to 200° F. ($\pm 3^\circ$) and at atmospheric pressure; the remaining package was left unheated and used as a control. Two of the packages, heated for 3 and 4 days, respectively, contained spore strips with viable micro-organisms. Such viability was also evidenced by the spore strip of the control. However, the spore strip for the remaining package, heated continuously for 6 days, revealed no viable spores.

EXAMPLE IV

The procedure of Example III was carried out at the same temperature but with different time intervals and a different micro-organism. *Bacillus subtilis* (Globigii) spore strips were placed in each of 5 foil packs containing isotonic saline and the packages were then sealed. One pack was used as a control and the remaining four were heated for 1, 2, 3 and 4 days, respectively. The spore strips of all of the heated packs revealed no evidence of spore viability, in contrast to the control where such viability was apparent.

EXAMPLE V

Reportedly polluted water, taken from the White River in Indianapolis, Indiana, was placed in four 200

cc bottles and the bottles were then sealed. One was used as a control; the remaining 3 bottles were heated at 175° F. ($\pm 3^\circ$) for 3, 4, and 5½ days, respectively. Thereafter, the contents of the bottles were filtered through Millipore filter pads and were incubated to culture the micro-organisms retained thereby. Examination of the pads revealed no viable micro-organisms on those pads through which liquid had been filtered from bottles heated for 4 and 5½ days, respectively. Viable spores were present on those pads moistened by the contents of the control bottle and by the contents of the bottle heated for 3 days.

EXAMPLE VI

Seven amber glass bottles, each of approximately 6 ounce capacity, were half filled with distilled water. *Bacillus stearothermophilus* spore strips from the same batch were secured to the covers for each of the bottles and the bottles were then sealed so that the spore strips were suspended in the upper portions of the bottles out of direct contact with the liquid. One bottle was used as a control; the remaining 6 were heated at 200° F. ($\pm 3^\circ$) for 1, 2, 3, 4, 5 and 6 days, respectively. The spore strips of the control (which had been maintained at room temperature) and the bottle which had been heated for only one day revealed viable micro-organisms. The spore strips of the bottles heated for 2 days or more revealed no viable spores.

The test was repeated using *Bacillus subtilis* (Globigii) spore strips. Again, the spore strips in the control bottle and in the bottle heated for one day carried viable spores; all of the remaining bottles (i.e., those heated for 2 days or more) contained spore strips which revealed no viable spores following such treatment.

EXAMPLE VII

Two groups of identical laparotomy sponges were used in the following test. Each sponge consisted of 20 layers of creped absorbent paper encased in a liquid-permeable spun-bonded nylon-polyethylene laminate marketed under the designation "Cerex" by Monsanto Company, St. Louis, Mo. Into the center of each sponge was placed a spore strip, one group of 11 sponges containing *B. stearothermophilus* spore strips and the other group of 11 sponges containing *B. subtilis* (Globigii) spore strips. Thereafter, each of the sponges was moistened slightly with distilled water (to approximately 50 percent of its total weight) and sealed in an aluminum foil wrapper. The packages were then heated at a temperature of over 190° F. and under 200° F. for the intervals set forth in the following tables, and with the results as indicated. Negative results mean that no viable spores were present on the strips following treatment.

B. *Stearothermophilus*

	Heating Time (days)	Results
60	1	positive
	2	positive
	3	negative
	4	negative
	5	negative
	6	negative
	7	negative
65	8	negative
	9	negative
	10	negative
	11	0 (control)
		positive

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B. Globigii

Item	Heating Time (days)	Results
1	1	negative
2	2	"
3	3	"
4	4	"
5	5	"
6	6	"
7	7	"
8	8	"
9	9	"
10	10	"
11	0 (control)	positive

While in the foregoing we have disclosed an embodiment 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 sealing a product comprising a liquid which is at least predominately water within a container capable of withstanding exposure to temperatures up to 212° F. at atmospheric pressure, and heating said container and its contents for at least 24 hours at a temperature above

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170° F. and below 212° F., and below the boiling temperature of said liquid, until the container's interior surfaces and its contents are sterilized.

2. The method of claim 1 in which said contents also includes a solid article capable of withstanding temperatures up to 212° F.

3. A method of sterile packaging comprising the steps of sealing a product comprising a liquid which is at least predominately water within a container capable of withstanding exposure to temperatures up to the boiling point of water at atmospheric pressure, and heating said container and its contents at approximately atmospheric pressure and for at least 24 hours at a temperature above 170° F. and below 212° F., and below the boiling temperature of said liquid, until the container's interior surfaces and contents are sterilized.

4. The method of claim 3 in which said heating falls within the range of 190° to 205° F.

5. The method of claim 3 in which said product comprises a solid article to be sterilized, said contents of said container also including a gas containing water vapor.

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