GAS STERILIZABLE PACKAGE

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3 Claims

ABSTRACT OF THE DISCLOSURE

This application discloses a sterile package formed from a base sheet and a cover sheet hermetically sealed to one another in a generally continuous annular heat seal area surrounding a central product receiving area, thereby defining an enclosed compartment for a sterile product. The cover sheet is made up of a barrier layer having a heat sealing surface facing the base sheet and a gas permeable but bacteria impermeable protective layer laminated to the opposite surface of the barrier layer. The barrier layer defines a multiplicity of relatively small perforations arranged in a general uniform pattern throughout its area and the perforations extend through the barrier layer so as to communicate with the inside surface of the protective layer and the enclosed compartment. Thus, a sterilizing gas may be passed through the protective layer and then through the perforations and into the enclosed compartment to sterilize its contents, although the protective layer will prevent the passage of bacteria therethrough. A particular relationship between the width of the heat seal area, the closest distance between the adjacent perforations in the barrier layer and the average maximum transverse dimension or diameter of the perforations also is disclosed. This relationship allows the package to be formed without the necessity for registering the perforations with the heat seal area.

The present invention relates to hermetically sealed packages for sterile products and, more particularly, to such packages which are intended to be internally sterilized by using a sterilizing gas which penetrates the package after it has been sealed.

Packages of this general type have been proposed wherein the sheets from which the packages are formed are in themselves gas permeable even though they are impermeable to bacteria. Thus, continuous sheets of polyethylene, or the like, have been suggested for this purpose. The main problem with this approach is that, if the continuous sheet is sufficiently thick to provide the necessary strength and protection against contamination, the sterilization time is extended to the point where it is economically undesirable due to the slow permeation of the sterilizing gas through the sheet. On the other hand, if a porous paper sheet is used, the package is subject to contamination by moisture and other liquids and, in strippable packages, the paper may delaminate to encapsulate the contents of the package during opening.

To overcome this, various types of special gas permeable portions in the form of windows, valves, ports and the like, have been suggested for incorporation in different parts of the sterilizer. The inclusion of special portions of this type generally increases the cost of fabrication and introduces a point of weakness from the standpoint of the desired sterile protection.

The present invention contemplates a new all-purpose sterile package which may be gas sterilized quickly, yet provides a sterile shield until the end of the life of the package. This package involves no extra cost in its fabrication and may be stripped open easily without danger of delamination when the package is designed to be opened by stripping.

The package of this invention generally comprises a base sheet and a cover sheet hermetically sealed to one another in a generally continuous annular heat seal area surrounding a central product receiving area, and thereby defining an enclosed compartment for a sterile product.

In a preferred form, corresponding portions of the base sheet and the cover sheet are unsealed outwardly of the annular heat seal area to provide opposed stripping flaps which may be pulled away from one another to open the package and provide access to the sterile product without danger of contaminating the product.

When the term "annular" or "generally annular" is used in this application to describe the shape of the heat seal it means that the sealing area is generally ring shaped and has appreciable width. However, the inner and/or outer peripheries of the sealing area may be circular, rectangular, or of any other geometric configuration which is best for packaging a particular product. For example, in the sealing area may be generally rectangular with a triangular peak facing the stripping flaps when the package is designed to be strippable.

The essential novelty of this invention lies in the composition and structure of the cover sheet and the relationship between the structure of the cover sheet and the dimensions of the annular heat seal area. The cover sheet comprises a perforated barrier layer having a heat sealing surface facing the base sheet, and a continuous protective layer laminated to the opposite surface of the barrier layer. The protective layer is impermeable to bacteria and gas permeable to the extent that, under the conditions of sterilization, the sterilizing gas can pass through the protective layer quickly to enter the perforations in the barrier layer. The cover sheet is so composed and constructed that it may be laminated to the base sheet during fabrication of the package and formation of the annular seal thereof without regard to the relative lateral position of the base sheet and the cover sheet, or the perforations therein.

According to this invention, this is accomplished by providing a barrier layer which defines a multiplicity of relatively small perforations distributed in a generally uniform pattern throughout the area of the cover sheet. These perforations extend through the entire thickness of the barrier layer in such a way as to be in communication with the compartment containing the sterile product, on the one hand, and the inside surface of the protective layer, on the other hand. It has been determined that, when the size and spacing of the perforations in the barrier layer bear a certain definite relationship to the dimensions of the annular heat seal area, the cover sheet and the base sheet may be superimposed with respect to one another in the fabrication of the package without regard to the position of any particular perforation and yet provide a package which possesses all of the desired properties of the product of the invention. This relationship may be expressed most generally by stating that the width of the heat seal area, the closest distance between adjacent perforations in the barrier layer each must be several times the average maximum transverse dimension of the individual perforations. Of course, for circular or cylindrical perforations, their average maximum transverse dimension is their diameter. Preferably, the closest distance between adjacent perforations is at least about four (4) times the average maximum transverse dimension of the individual perforations.

In packages of this general type, it has been determined that there is provided a minimum sealed width portion which must be maintained in the heat seal area to assure that the package cannot be contaminated by lateral permeation through the heat seal. This minimum sealed width is approximately 0.1 inch. For
this reason, it is preferred that the closest distance between adjacent perforations in the barrier layer of the cover sheet be at least about 0.1 inch. Generally, however, the closest distance between adjacent perforations is within the range of about 0.35 inch to about 0.75 inch. This, not only provides a greater margin of safety from the standpoint of sterility, but also may provide some what greater flexibility in package design.

In the package of this invention, the barrier layer of the cover sheet performs the two-fold function of providing strength to the cover sheet and acting as a barrier to the stresses which occur in the opening of the package thereby preventing delamination of the cover sheet. This latter function is particularly important when the package is designed to be opened by stripping the cover sheet away from the base sheet to open the package at the seal.

In the preferred form of strippable package according to this invention, the barrier layer comprises a relatively strong and impermeable barrier sheet and a heat seal layer facing the base sheet, and the perforations pass through the barrier sheet and the heat seal layer. It has been determined that for ease in opening the package without sacrificing strength and sterility in this type of package the various package components should bear a particular relation to one another. The strength of the seal between the base sheet and the heat seal layer, on the one hand, and the seal between the barrier sheet and the heat seal layer, on the other hand, and the tensile strength of the barrier sheet, each should be greater than the tensile strength of the heat seal layer. In addition, the strength of the seal between the base sheet and the heat seal layer and the tensile strength of the barrier sheet each should be greater than the strength of the seal between the barrier sheet and the heat seal layer. When this relationship exists, the heat seal layer of the cover sheet tears on each side of the heat seal area and the heat seal layer remains bonded to the base sheet and separates from the barrier sheet in the heat seal area, so that the package strips open cleanly without danger of delamination or encapsulation when the stripping flaps are pulled away from one another to open the package.

The protective layer, on the other hand, cooperates with the perforated barrier layer by acting as a screen which prevents bacteria from entering the perforations in the barrier layer. In addition, in the preferred form of package of this invention, the protective layer is impermeable to moisture and thereby prevents contamination of the package by moisture or any other liquid which might otherwise enter the perforations in the barrier layer. The protective layer may be in the form of a relatively thin continuous film of a plastic which may be laminated directly to a metal foil barrier layer, or it may be in the form of a laminate of bacteria impermeable paper, and a very thin inner layer of polyethylene, or the like, which is substantially continuous so as to render the protective layer substantially impermeable to moisture. If the package need not be moisture impermeable, the inner laminating layer need only be sufficient to adhere the paper to the barrier layer. In one form of this invention the protective layer may depend for its permeability characteristics entirely upon an inner continuous layer of a material such as polyethylene, but may include an outer layer of paper, or the like, which protects the continuous layer from the relatively high temperature heat sealing dies used in forming the package.

Other and further advantages of this invention will occur to one skilled in the art from the following description and claims, taken together with the drawings wherein:

FIG. 1 is a schematic plan view of one embodiment of a package according to this invention, partially broken away to show the arrangement of the various sheets and layers making up the cover sheet thereof.

FIG. 2 is a schematic view partly in section and partly in elevation taken along the line 2—2 of FIG. 1.

FIG. 3 is a greatly enlarged schematic sectional view of a portion of the heat seal area of FIG. 2 facing the drawings with the sterile product removed therefrom for the sake of clarity.

FIG. 4 is a similarly enlarged schematic fragmentary plan view of a portion of the heat seal area of the package of the foregoing figures.

Referring to the drawings, there is shown a sterile package 11 according to a preferred embodiment of this invention, which comprises a base sheet 12 and a cover sheet 13 hermetically sealed to one another in a generally continuous annular heat seal area 14 surrounding a central product receiving area 15. Thus, the sealed sheets 12 and 13 together define an enclosed compartment 16 for a sterile product 17 located therein.

The cover sheet 13 comprises a barrier layer 18 having a heat sealing surface 19 facing the base sheet 12 and a continuous gas permeable protective layer 21 on its surface opposite to the base sheet. The barrier layer 18, in turn, comprises a strong and relatively impermeable barrier sheet 22, such as an aluminum foil, and an inner heat seal layer 23 of a material such as a vinyl chloride polymer which will seal both to the foil and the base sheet. The heat seal layer 23 presents the sealing surface 19. The protective layer 21 comprises an outer strength sheet 24 of a gas permeable but bacteria impermeable porous paper, and an inner laminating layer 25 which attaches the paper 24 to the barrier layer 18. The laminating layer 25, is capable of forming a strength seal between the paper and the foil of the barrier layer, and is permeable to sterilizing gases under the conditions of sterilization. Preferably, the laminating layer 25 is in the form of a substantially continuous coating of a moisture impermeable thermoplastic material, such as polyethylene, so that the laminating layer also is impermeable to moisture.

The barrier layer 18 defines a multiplicity of relatively small perforations 26 distributed in a generally uniform pattern throughout the area of the cover sheet 13. The perforations 26 extend through the entire thickness of the barrier layer, including the heat seal layer 23 and are in communication with the compartment 16 and the inside surface of the protective layer 21 in the product receiving area 15. The protective layer 21, which is substantially impermeable to bacteria and moisture (although permeable to sterilizing gases), is disposed so as to cover all of the perforations 26 in the barrier layer 18. As a result, the inside of the compartment 16 and the product 17 contained therein may be sterilized by passing a sterilizing gas, such as ethylene oxide through the strength sheet 24 and the laminating layer 25, and then through the perforations 26 in the product receiving area 15, as indicated by the arrows in FIG. 3. Thereafter, the interior of the package and contents are protected against contamination by bacteria and moisture and maintained sterile by the protective layer 21 which covers the perforations 26 in the cover sheet 13.

The strength of the seal between the base sheet 12 and the heat seal layer 23 of the cover sheet and the strength of the seal between the barrier sheet 22 and the heat seal layer 23, and the tensile strength of the barrier sheet 22, each is greater than the tensile strength of the heat seal layer 23. In addition, the strength of the seal between the base sheet 12 and the heat seal layer 23 and the tensile strength of the barrier sheet 22 each is greater than the seal layer between the barrier sheet 22 and the heat seal layer 23. This assures that the package will open cleanly and easily without danger of delamination or encapsulation of its contents when the stripping flaps are pulled away from one another to open the package.

The base sheet 12 is thermo-formed in the product receiving area 15 to define a blister, or dished out portion, 27 which cooperates with the cover sheet 13 to provide a
relatively deep compartment 16 for the sterile product 17. The product receiving area 15, shown, is circular and surrounded by a circular, annular, heat seal area 14 wherein the cover sheet is scaled to the base sheet. The radial width of this heat seal area is designated W. The base sheet 12 and the cover sheet 13 present corresponding portions which extend beyond the annular heat seal area 14 at one side of the compartment to provide opposed stripping flaps 28 and 29 for opening the package.

The perforations 26 are circular in transverse dimension and are arranged in the barrier layer in a square pattern, as best shown in FIG. 1. Since these perforations are substantially uniform in size, their average maximum transverse dimension is their diameter, designated d in the drawings. The closest distance between adjacent perforations is designated S, as shown in FIGS. 1 and 3. It will be seen from the drawings that the closest distance between adjacent perforations S is considerably more than four (4) times the average maximum transverse dimension d of the individual perforations. Also, it is quite important as stated hereinafter that the distance S be at least about 0.1 inch in order to assure that the minimum sealed width of the annular heat seal area, W minus d in FIG. 4, is no less than 0.1 inch.

In one form of this embodiment of the invention, the perforations 26 may be about .02 inch—.025 inch in diameter and the closest distance S between adjacent perforations typically may be about .5 inch when the width W of the heat seal area is approximately .125 inch—.15 inch. The barrier sheet 22 may be an aluminum foil layer of approximately 1/16th mil thick, having a heat seal layer of vinyl chloride coated thereon at a dry weight of approximately seven (7) pounds per square feet and being about 0.5 mil thick when the base sheet is formed from a vinyl-chloride film about 15 mils in thickness. The protective layer may comprise a porous paper about 5 mils thick adhered to the foil sheet by a laminating layer of polyethylene of about 0.5 mil or less in thickness.

As indicated hereinafter, the protective layer 21 of the cover sheet 13 preferably incorporates a continuous film or sheet which is impermeable to both bacteria and moisture. If this sheet is formed from a material such as polycarbonate, which is capable of resisting relatively high temperatures, the protective layer need include no other protective element, since the continuous polycarbonate sheet will not be damaged by the sealing dies. However, when the continuous sheet is formed from a relatively low melting material, such as polyethylene, an outer layer of paper or some other material which will not be damaged by the temperature of the sealing dies should be included in the protective layer. Similarly, although the base sheet 12 has been shown as a single layer film, it may be formed by laminating different sheets or films in such a way that the resulting laminate may be sealed to the cover sheet 13 and still provide the desired sterile protection. In the preferred form of this invention the base sheet also is thermo-formable to provide a central compartment or blister for receiving the sterile product and the base sheet preferably is capable of forming a strippable seal with the cover sheet.

Having described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope.

What is claimed is:

1. A sterile package which comprises a base sheet and a cover sheet hermetically sealed to one another in a generally continuous annular heat seal area surrounding the product to be received wherein the base sheet comprises an enclosed compartment for a sterile product, and a sterile product in said compartment, said cover sheet comprising a barrier layer having a heat sealing surface facing said base sheet, and a continuous gas permeable and bacteria impermeable protective layer laminated to the opposite surface of the barrier layer, said protective layer also being substantially impermeable to moisture, said barrier layer defining a multiplicity of relatively small perforations distributed in a generally uniform pattern throughout the area of the cover sheet and extending through the entire thickness of the barrier layer so as to be in communication with said compartment and the inside surface of the protective layer covering all of the perforations in the barrier layer, the width of the heat seal area and the closest distance between adjacent perforations in the barrier layer each being several times the average maximum transverse dimension of the individual perforations.

2. A sterile package according to claim 1, wherein the said closest distance between adjacent perforations is at least about four (4) times the average maximum transverse dimension of the individual perforations.

3. A sterile package according to claim 1, wherein the said closest distance between adjacent perforations is at least about 0.1 inch.

4. A sterile package according to claim 3, wherein the said closest distance between adjacent perforations is about 0.35 to about 0.75 inch.

5. A sterile package according to claim 1, wherein the protective layer comprises an outer strength layer and an inner substantially moisture impermeating laminating layer.

6. A sterile package according to claim 5 wherein the outer strength layer is a gas permeable paper.

7. A sterile package according to claim 1, wherein corresponding portions of the base sheet and the cover sheet are unsealed to one another outwardly of the heat seal area to provide opposed stripping flaps for opening the package by pulling the stripping flaps away from one another.

8. A sterile package according to claim 7, wherein the barrier layer comprises a relatively strong and impermeable barrier sheet and a heat seal layer facing the base sheet and said heat seal layer is sealed to the barrier sheet and the base sheet, the strength of the seal between the base sheet and the heat seal layer and the strength of the seal between the barrier sheet and the heat seal layer and the tensile strength of the barrier sheet each being greater than the tensile strength of the heat seal layer, and the strength of the seal between the base sheet and the heat seal layer and the tensile strength of the barrier sheet each being greater than the strength of the seal between the barrier sheet and the heat seal layer, whereby the package may be stripped open easily by pulling the stripping flaps away from one another to tear the heat seal layer on each side of the heat seal area and separate the heat seal layer from the barrier sheet in the heat seal area.

9. A sterile package which comprises a base sheet and a cover sheet hermetically sealed to one another in a generally continuous annular heat seal area surrounding a central product receiving area and thereby defining an enclosed compartment for a sterile product, and a sterile product in said compartment, said cover sheet comprising a barrier layer having a heat sealing surface facing said base sheet, and a continuous gas permeable and bacteria impermeable protective layer laminated to the opposite surface of the barrier layer, said barrier layer defining a multiplicity of relatively small perforations distributed in a generally uniform pattern throughout the area of the cover sheet and extending through the entire thickness of the barrier layer so as to be in communication with said compartment and the inside surface of the protective layer in the product receiving area, said barrier layer comprising a relatively strong and impermeable barrier sheet and a heat seal layer facing the base sheet, said perforations passing through the barrier sheet and the heat seal layer, and said pro-
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tective layer covering all of the perforations in the barrier layer, the width of the heat seal area and the closest distance between adjacent perforations in the barrier layer each being several times the average maximum transverse dimension of the individual perforations.

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