Sept. 27, 1960 H. F. MASO ET AL 2,954,116

RUPTURABLE SEAL PACKAGE WITH STERILIZED MOIST CONTENTS

Filed May 6, 1957 2 Sheets-Sheet 1

Fig. 1.

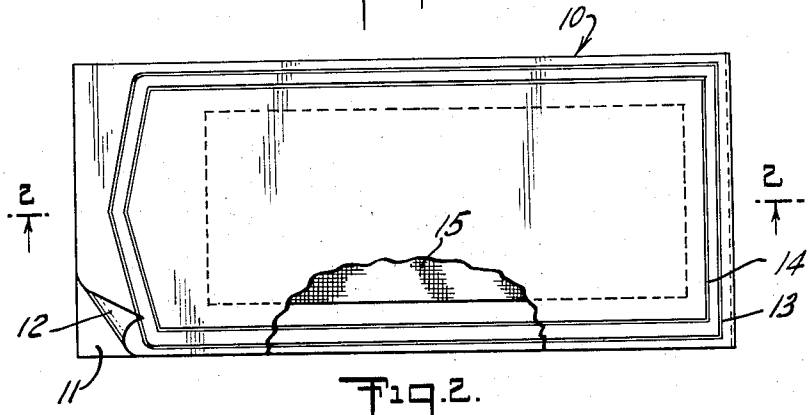


Fig. 2.

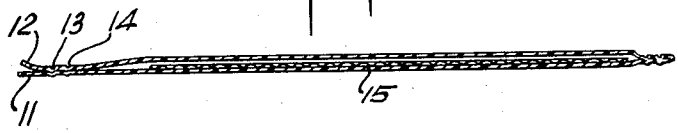


Fig. 3.

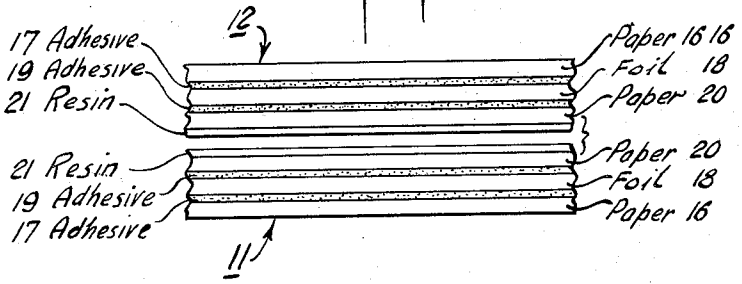
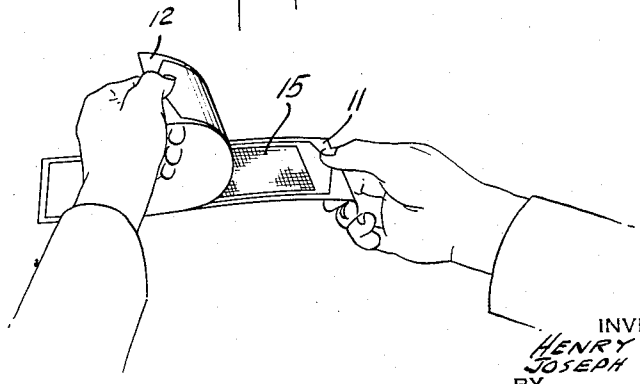


Fig. 4.



INVENTORS:
HENRY F. MASO
JOSEPH N. MASCI
BY
Domenic F. Bargiorni
ATTORNEY

Sept. 27, 1960 H. F. MASO ET AL 2,954,116

RUPTURABLE SEAL PACKAGE WITH STERILIZED MOIST CONTENTS

Filed May 6, 1957 2 Sheets-Sheet 2

Fig. 5.

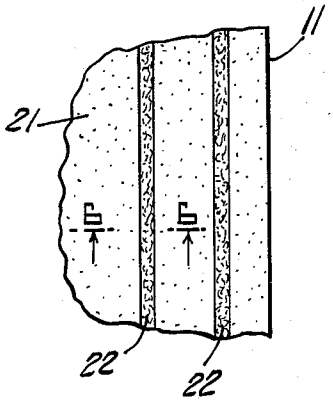


Fig. 6.

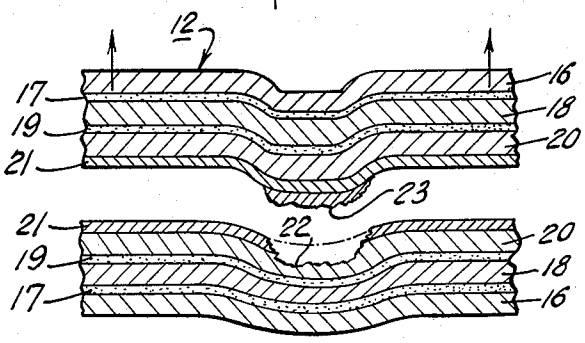


Fig. 7.

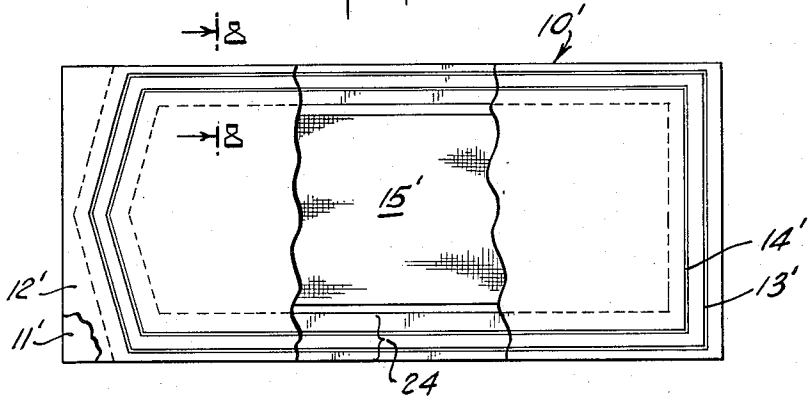
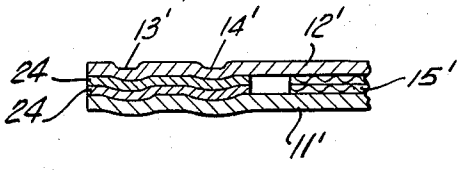


Fig. 8.



INVENTORS:
HENRY F. MASO
JOSEPH N. MASCI
BY
ATTORNEY

United States Patent Office 2,954,116 Patented Sept. 27, 1960

2,954,116

RUPTURABLE SEAL PACKAGE WITH STERILIZED MOIST CONTENTS

Henry F. Maso, New Brunswick, and Joseph N. Masci, Metuchen, N.J., assignors to Johnson & Johnson, a corporation of New Jersey

Filed May 6, 1957, Ser. No. 657,206

11 Claims. (Cl. 206—56)

This invention relates to a packaged sterilized material, such as a moist surgical dressing, the package of which may be opened conveniently by merely pulling apart two sections thereof with rupture of the seal, whereby the sterilized contents are exposed for ready access.

Various materials have been packaged in sterilized form, some of these being in envelope type packages. In order to open the envelope, the package is broken, for instance, by tearing the walls thereof. Such packages suffer from the drawback that this method of opening may tend to contaminate the contents by contact thereof with the torn edge of the outer surface of the package. Other packaging means which have been used include rather heavy resin coated metal foils; however, these are highly unattractive from the economic viewpoint, especially for relatively low cost sterilized surgical dressings. Still other materials have been packaged in coated paper or the like materials having relatively low melting resin or wax type coatings and these cannot be heat sterilized satisfactorily without "blocking". Some of these have pressure-sensitive type adhesives, which may be resealed after opening, and thus raise a possible question as to the sterility of the contents. The art is confronted by the particularly difficult problem of providing a sterilized package containing sterilized moist surgical dressings which are applied to open wounds, which package may be opened conveniently without contamination of the moist dressing.

The discoveries associated with the invention relating to solution of the above problem, and the objects achieved in accordance with the invention as set forth herein include: the provision of a sterilized package provided with opening tabs and having contents sterilized in situ therein, which contents include water, which package includes an inner pair of highly compacted rupturable layers closed together around the contents by at least one adhesive resin seal line, this resin being one which does not become tacky at 230° F., which resin penetrates part way through or into the rupturable layers at the seal lines but at most leaving at least 10% of the cross section thereof unpenetrated so that the package may be opened by manually pulling these layers apart so as directly to expose the contents, rupture of resin and layer from layer at the seal line is obtained; the provision of such a package wherein the highly compacted layers are of glassine, and they are laminated to a flexible metal foil, such as, aluminum foil; the provision of such a package wherein the weight of the adhesive resin is in the range of 1.0 to 6# per ream, the maximum width of the seal line is ⅛ inch and the minimum width thereof is 1/64 inch, the outer side of the foil is laminated to paper, the foil thickness is in the range of 0.2 to 2.0 mils, and each of the paper layers is of a weight in the range of about 15 to 65# per ream; the provision of such a package wherein the outer side of the foil is laminated to kraft paper, the package has two seal lines, each about 1/32 inch in width and spaced 3/16 inch apart, the outer line being about 3/32 inch from the edge of the package and

the inner line at least ¼ inch from the edge of the enclosed material; the provision of such a package wherein the multiple laminate comprises per ream 3.5# of a resin composition made up of 5% di-octylphthalate and 95% by weight of a vinyl chloride and vinyl acetate copolymer containing about 91% of the chloride; the provision of such a package wherein the multiple laminate comprises per ream 1.5# of a resin composition made up of 5% di-octylphthalate and 95% by weight of a vinyl chloride and vinyl acetate copolymer containing about 91% of the chloride; the provision of such a package wherein the multiple laminate comprises per ream 3.5# of a resin composition made up of 15% di-octylphthalate and 85% by weight of a vinyl chloride and vinyl acetate copolymer containing about 91% of the chloride; and other objects which will be apparent as details and embodiments are set forth hereinafter.

In connection with the description of the invention, reference will be made to the accompanying drawings wherein Figure 1 illustrates a top view of a sealed package of the invention, with a broken away portion showing the contents. Figure 2 illustrates a cross section view taken along lines 2, 2 of Figure 1. Figure 3 illustrates schematically cross sectional views of the two sides of the package before sealing. Figure 4 illustrates the package in partially opened form. Figure 5 illustrates the inner surface of one side of a package after opening. Figure 6 illustrates an enlarged cross sectional view taken along lines 6, 6 of Figure 5. Figure 7 illustrates a top view of another embodiment of the invention, with a partially broken away portion showing the contents. Figure 8 illustrates an enlarged cross sectional view taken along lines 8, 8 of Figure 7.

In order to facilitate a clear understanding of the invention, the following preferred specific embodiments are described in detail.

Example 1

This example relates to a packaged sterilized surgical dressing. This dressing is impregnated with an aqueous petroleum emulsion, and these materials are retained in the package upon sterilization.

The multiple laminate is prepared in conventional manner containing the following materials, respectively (per 3000 sq. ft. ream):

25# kraft white paper (free from added humectant)
8# polyethylene (0.5 mil melt index 4.0, softening point 200° F.)
0.35 mil aluminum foil
8# polyethylene (0.5 mil melt index 4.0, softening point 200° F.)
25# glassine (blue-green super calendered paper)
3.5# resin (high melting)

A preferred resin composition is made up of 5% di-octylphthalate and 95% by weight of a vinyl resin having the following properties:

Polyvinylchloride	Ca. 91%.
Hydroxyl	Ca. 2.3%.
Polyvinyl acetate	Ca. 3.0%.
Intrinsic viscosity	Ca. 0.55 in cyclohexanone at 20° C.
Appearance	Powdered white solid, at least 98% passing through 200 mesh.
Solubility	Forms a pale straw-colored clear solution at 18% solids in methyl isobutyl ketone with a viscosity at 20° C. of 150–300 centipoises.

As to softening point, print type softening point tests made on one mil films of this resin over steel under 1# per sq. in. load for 15 minutes showed this resin required 210° F. for a print. Ball and ring type softening point tests made on cast films of this resin showed 302° F.

Although the package may be prepared in any con-

venient size, a preferred commercial form is illustrated in Figure 1 of the accompanying drawing wherein the package **10** is composed of bottom layer **11** and top layer **12**. The two heat seal lines **13** and **14** are spaced from and surround the dressing **15**. Figure 2 illustrates a cross sectional view of this package, with similar indicia.

The composition of the laminates is set out in Figure 3, in the following sequence: paper **16**, adhesive **17**, foil **18**, adhesive **19**, paper **20**, and resin **21**.

A sheet of this material about 21 by 4.5 inches is prepared, and a piece of the surgical dressing is appropriately set upon one-half (lengthwise) section thereof (vinyl resin side), and the other half of the sheet is folded thereover. Then the package is sealed by heating by means of a die block along two narrow lines 1/32 inch in width, and spaced 3/16 inch apart, the outer line of which is spaced 3/32 inch from the edge of the package. The inner line is at least 1/4 inch from the enclosed dressing. The lines join in the form of an apex at the end of the package which is to be opened. The sealing is at a die block temperature of 400 to 410° F. and at a die pressure of 40 lbs. per sq. in. gauge, and the die dwell time is 1.25 seconds.

Then the package is sterilized at a temperature of 250° F., the moisture within the package providing moist sterilization conditions. During this sterilization, external pressure is applied to the package so that the pressure differential between the outside and inside of the package is not higher than 5# per sq. in. gauge.

In opening the package as illustrated in Figure 4, the two tabs or extensions beyond the apex of the heat seal lines are grasped in the hands and pulled apart, similar indicia to Figure 1 being used. When so pulled apart, the paper layer is ruptured along the heat seal line as illustrated in Figure 5, and shown in Figure 6 in enlarged cross sectional view taken along the lines **6, 6** of Figure 5, the ruptured paper residual portion **22** and the removed ruptured paper portion **23**.

The rupturability of the seal is tested by means of a spring balance having a scale of 1 to 16 ounces (such as the Chatillon Spring Balance) mounted horizontally in a rigid support stand. The hook of the balance is fitted with a small flat blade approximately 3/8 inch in length and mounted at right angles to the direction of the pull. A tested strip is prepared by cutting the envelope around its periphery parallel to and inside the heat seal lines to provide a strip approximately 1/2 inch wide. The test strip is placed on the blade and is drawn steadily in a horizontal plane so that both faces of the strip are drawn around the blade, one face on one side and the other on the other side. The tension exerted on the blade in forcing the bonded surfaces apart is read directly on the balance scale.

Envelopes tested before sterilization having a tension in the range of 2 to 8 ounces, preferably 3 to 5 ounces, and after sterilization in the range of 2 to 20 ounces or above, preferably 5 to 8 ounces, are satisfactory.

Dressings in the foregoing envelopes are sterile when tested in accordance with conventional procedures (U.S. Pharmacopoeia).

This example represents a particularly difficult packaging problem, satisfactorily solved in accordance with the invention. This is indeed surprising when one considers the many materials which were tested and found unsatisfactory, such as the following. Metal foils or paper or laminations thereof coated with microcrystalline wax or blends of such waxes failed upon sterilization; there was delamination of the waxy layer from the foil or paper when the package tabs were pulled apart. Plastic films or paper coated with various conventional relatively low melting resinous material of the polyvinylchloride, polyvinylidene or polyethylene types failed upon sterilization; i.e., the latter coatings fused together or "blocked" with resulting delamination when the package tabs were pulled apart.

Example 2

Example 1 is repeated except that the inner or resin sealing material is applied as strips **24** as illustrated in Figure 7. These strips are slightly wider than the heat seal lines, and the remainder of the glassine is not coated or covered thereby. Figure 8 illustrates a cross section view of this modification taken along the lines **8, 8** of Figure 7, showing the bottom side **11'**, the top side **12'**, the dressing **15'**, the two heat seal lines **13'** and **14'**, and the resin strips **24**. If desired, a single strip could be used. This package is comparable to that of Example 1 as far as sterility and rupturability properties. However, it is more economical inasmuch as there is a lower requirement of resin.

Example 3

Example 1 is repeated except that the laminate contains 1.5# of the resin (high melting), and satisfactory packages are obtained as to rupturability and sterility; but, of course, this modification is more economical.

Example 4

Example 1 is repeated except that the resin composition (high melting) contains 15% of the plasticizer, and satisfactory results are obtained.

Example 5

Example 1 is repeated except that the resin composition (high melting) is a vinylidene chloride acrylonitrile copolymer having a specific gravity of 1.60, and a blocking temperature of up to about 320° F.; and satisfactory results are obtained.

Example 6

Example 1 is repeated except that the resin composition (high melting) is an ethylene derived polymer having a density of about 0.94, a softening point above 250° F., a melt index of 0.1–4.0, and a tensile strength of 2500–5500 pounds per square inch at yield point; and satisfactory results are obtained.

Comparable results to the foregoing are achieved with various modifications thereof, including the following: the heat seal resin or resin composition must be of the high melting type, i.e., does not become tacky at a temperature of 230° F., preferably of 250° F. If this resin melts or becomes tacky at sterilization temperature, the seal becomes inoperative; e.g., by breaking because of sterilization or alternatively, by causing the seal to widen or "block" thus destroying the desired rupturability property. In other words, instead of the package opening upon pulling the tabs, there is delamination between layers of the laminate, or tearing through the laminate. The weight of the resin coating is desirably in the range of 1.5# to 4# per ream, although satisfactory results are obtained at weights as high as 6.0# per ream or as low as 1.0# per ream. Less than 1.0# per ream tends to give discontinuous coatings or heat seal lines, thus ruining the desired sterility property.

An essential requirement is that the resin adhere sufficiently to the layer or paper to give a proper seal, but that it should not penetrate the layer or paper so as to give a through bond to the next resin layer. The latter may be an outer coating on the layer or paper. If there is a through bond, the rupturability property is lost and upon attempted opening of the package, the sheets tear or delaminate. The penetration should be not over 90%, preferably not over 50% through the layer or paper. The maximum width of the seal line (which may be straight or irregular, but preferably free from sawtooth edges) is such as to permit ready rupturability of the seal at moderate force, e.g., about 1/8 inch maximum, and the minimum width is sufficient to provide an hermetic seal that maintains sterility, e.g., about 1/64 inch minimum. If desired, a plurality of seal lines may be used.

The heat seal resin composition may be any of the high

melting types, melting below the paper scorching temperature under the sealing conditions, which provide the desired adherence to the paper. These may be typified by the various vinyl resin polymers and copolymers, vinylidene resin polymers and copolymers, and the higher melting polyethylenes, which do not become tacky at 230° F.

The paper layers may be in the range of about 15 to 65# per ream, and the metal foil may be in the range of 0.2 to 2.0 mils thickness. The interlaminate adhesives between the paper and the foil may be any of the conventional bonding resins, including the above-mentioned types, and for economic reasons, the amount thereof is preferably just adequate to achieve the desired adhesion between the layers; however, higher amounts are operative. Generally, the upper practical amount would not be more than twice the desired practical minimum. They may or may not soften somewhat under sterilization temperature conditions, without harm in view of the continuous bond between the respective layers.

In view of the foregoing disclosures, variations or modifications thereof will be apparent, and it is intended to include within the invention all such variations and modifications except as do not come within the scope of the appended claims.

We claim:

1. A hermetically sealed package having contents sterilized in situ therein which comprises a pair of laminated sheets with the contents between them, the edges of said sheets overlapping and extending beyond the edges of said contents to provide edge portions of said sheets around the edges of said contents, each of said sheets in said edge portions comprising an outer barrier layer and an inner adhesive resin layer of a material which does not become tacky at 230° F., at least one of said sheets comprising an intermediate highly compacted rupturable layer between said outer and inner layers, said outer barrier layer and said rupturable layer being bonded together and the bond between said barrier layer and said rupturable layer being capable of resisting moist sterilizing conditions, said sheets being arranged with the inner resin layers of said edge portions facing one another and said sheets being closed together around said contents by at least one resin heat seal line joining the edge portions of said sheets, the resin of the superimposed sheets being fused together along said seal line and the sheets presenting opposed unsealed opening tab portions beyond the seal line at one end of the package, the resin layers and the seals between said resin layers and between each of said resin layers and the contiguous layer in each sheet along said seal line being sufficient to provide a hermetic seal and being stronger than said highly compacted layer so that the highly compacted layer will rupture at said seal line when said opening tabs are pulled in opposite directions, whereby the package may be opened with facility to expose its contents directly merely by pulling the tabs away from one another to rupture said highly compacted layer.

2. A method for producing a package of claim 1 which comprises heat sealing the appropriately arranged two adhesive resin layers around the contents by a sealing means maintained at a temperature of 400 to 410° F. under a pressure of about 40# per square inch gauge for a time of about 1.25 seconds.

3. A package of claim 1 wherein the highly compacted layer is of glassine, and the barrier layers are of a flexible metal foil.

4. A package of claim 3 wherein the weight of the adhesive resin in said edge portions is in the range of 1.0 to 6# per ream, the maximum width of the seal line is ⅛ inch and the minimum width thereof is 1/64 inch, the outer side of the foil being laminated to paper, the foil thickness being in the range of 0.2 to 2.0 mils and each of the paper layers is of a weight in the range of about 15 to 65# per ream.

5. A package of claim 4 wherein the outer side of the foil is laminated to kraft paper, the package having two seal lines, each about 1/32 inch in width and spaced 3/16 inch apart, the outer line being about 3/32 inch from the edge of the package, and the inner line at least ¼ inch from the edge of the enclosed material.

6. A package of claim 5 wherein the multiple laminate comprises per ream 3.5# of a resin composition made up of 5% di-octylphthalate and 95% by weight of a vinyl chloride and acetate copolymer containing about 91% of the chloride.

7. A package of claim 5 wherein the multiple laminate comprises per ream 1.5# of a resin composition made up of 5% di-octylphthalate and 95% by weight of a vinyl chloride and acetate copolymer containing about 91% of the chloride.

8. A package of claim 5 wherein the multiple laminate comprises per ream 3.5# of a resin composition made up of 15% di-octylphthalate and 85% by weight of a vinyl chloride and acetate copolymer containing about 91% of the chloride.

9. A package of claim 1 which comprises a pair of closely spaced parallel adhesive resin seal lines joining the edge portions of the sheets.

10. A package of claim 9 wherein each of the pair of seal lines is about 1/32 inch in width and the lines are spaced about 3/16 inch apart and about 3/32 inch from the edge of the package, the inner line of said pair being at least about ¼ inch from the edge of the enclosed material.

11. A hermetically sealed package having contents sterilized in situ therein which comprises a pair of laminated sheets with the contents between them, the edges of said sheets overlapping and extending beyond the edges of said contents to provide edge portions of said sheets around the edges of said contents, each of said sheets in said edge portions comprising an outer barrier layer, an inner adhesive resin layer of a material which does not become tacky at 230° F. and an intermediate highly compacted rupturable layer, said outer barrier layer and said rupturable layer being bonded together and the bond between said barrier layer and said rupturable layer being capable of resisting moist sterilizing conditions, said sheets being arranged with the inner resin layers of said edge portions facing one another and said sheets being closed together around said contents by at least one resin heat seal line joining the edge portions of said sheets, the resin of the superimposed sheets being fused together along said seal line and the sheets presenting opposed unsealed opening tab portions beyond the seal line at one end of the package, the resin layers and the seals between said resin layers and between each of said resin layers and its respective highly compacted rupturable layer along said seal line being sufficient to provide a hermetic seal and being stronger than said highly compacted layers so that at least one of the highly compacted layers will rupture at said seal line when said opening tabs are pulled in opposite directions, whereby the package may be opened with facility to expose its contents directly merely by pulling the tabs away from one another to rupture one of said highly compacted layers.

References Cited in the file of this patent

UNITED STATES PATENTS

1,983,520	Charch et al.	Dec. 11, 1934
2,328,579	Pelosi	Sept. 7, 1943
2,468,517	Salfisberg	Apr. 26, 1949
2,476,832	Donia	July 19, 1949
2,500,549	Ketay et al.	Mar. 14, 1950
2,668,769	Schlienz	Feb. 9, 1954
2,717,174	Casanovas	Sept. 6, 1955
2,814,428	Magill	Nov. 26, 1957

FOREIGN PATENTS

747,162	Great Britain	Mar. 28, 1956