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Jones

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[54] **HEAT SEALED PACKAGE**

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[58] **Field of Search** ..... 117/157, 76, 64 C; 229/3.1, 68 R; 156/245; 21/58; 206/63 R, 363, 438, 439, 440, 441, 46 PV, 46 ST, 48 T

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[57] **ABSTRACT**

The invention relates to a package for a sterilised disposable article, the package having opposing base materials bonded together along marginal portions by a heat sealed adhesive and peelable apart to open the package. One of the base materials is paper which has been neutrally sized to prevent absorption of the adhesive. The outer surface of the paper is preferably machine glazed for porosity and pore size control. The adhesive may be applied all over the unglazed surface of the paper but in a discontinuous form to permit passage of a sterilising gas into the sealed package.

6 Claims, No Drawings

HEAT SEALED PACKAGE

This invention relates to a heat sealed package having opposing base materials which are heat sealed together along marginal portions but can be peeled apart to open the package, at least one of the base materials being paper. The invention also relates to a paper base material.

The invention is particularly but not exclusively applicable to heat sealed packages containing disposable surgical instruments, syringes or other articles used in surgery or medicine. Such packages are required to meet a number of conditions, e.g. they must allow their contents to be sterilised after heat sealing, they must retain their contents in a sterilised condition until opened, and they must be openable in such a manner as to permit their contents to be removed without contamination. The last condition may be met by providing a peelable heat seal which permits a smooth and clean peeling apart of the opposing base materials of the package. The present invention provides a package which satisfies the above conditions.

In this specification the term "neutrally sized" is used to means sized under neutral conditions with a pH value in the range 7.2 to 8.3 inclusive and using an alkyl ketene dimer as the sizing agent.

According to one aspect of the invention there is provided a package comprising opposing base materials bonded together along marginal portions by means of a heat sealed adhesive and peelable apart to open the package, wherein one of the base materials is neutrally sized paper.

According to another aspect of the invention, in a preferred embodiment a base material for the package is paper which has been neutrally sized, machine glazed on one surface, and has all over its unglazed surface a heat sealable adhesive applied in a discontinuous form.

Machine glazed paper is paper which has one surface made smooth, for example by drying the paper on a heated polished metal cylinder forming part of a paper-making machine. The other or unglazed surface of the paper remains relatively rough.

Machine glazed paper has good strength characteristics and can be made to a specified porosity and maximum pore size. Where a package is to be sterilised internally by means of ethylene oxide or a mixture of ethylene oxide and inert gas, the paper base material preferably has a Bendtsen porosity between the limits of 60–120 cc/min. To minimise the risk of bacteria entry into the sealed package, the paper should have a basic weight not less than 50g/m2, and preferably not less than 55g/m2, whilst the maximum pore size should be not greater than 10 mym. Maximum pore size may be measured by the method described in "Interpretation of Paper Properties in Terms of Structure" by Dr. H. Corte and Dr. O. J. Kallmes, in the Transactions of the Oxford Symposium 1961, "The Formation and Structure of Paper", published by the Technical Section of the British Paper & Board Makers Association (Incorporated), London, E.C.4.

For a gas-sterilised package it is not necessary for the other base material to be porous. This other base material may be either a film of a thermoplastics material, or a laminate comprising two or more layers of similar or dissimilar plastics materials, or a plastics coating upon a porous substrate such as for example a polyethylene coated paper, whether made by laminating polyethylene film to paper or by an extrustion coating process. For gas sterilisation purposes it is necessary to have the coating on the porous base material either in a discontinuous form or of such a gas permeability that the required Bendsten porosity is achieved.

Alternatively, the other base material may be porous, in which case it may be a paper with a smooth finish on one surface. Such a finish may be produced by machine glazing, by supercalendering, or by glassine calendering. This porous material should have a porosity and maximum pore size which are not greater that those of the neutrally sized paper forming the opposite base material in the gas-sterilisable package.

As a further alternative in a gas-sterilisable package, the porous base material may be a non-woven fabric or paperlike material but with the same relative limitations on porosity and maximum pore size as just quoted.

NEUTRAL SIZING AGENTS

These agents are alkyl ketene dimers. An example of such an agent is AQUAPEL ketene dimer which is marketed by the Hercules Powder Co. Ltd., of London, England.

ADHESIVES

These may be heat seal compositions such as solvent-based thermoplastic coating compositions based on ethylene/vinyl acetate copolymers. Alternatively, the adhesives may be water-based dispersions of ethylene/-vinyl acetate interpolymers and may contain wax or other modifiers, or the adhesive may be a hot-melt adhesive which may contain polyisobutylene and paraffin wax. The weight of adhesive coating is between 1 and 20 gms per square metre and preferably is between 2 and 10 gms per square metre in the coated area, depending on the second base material.

EXAMPLE 1

Bleached kraft paper forming a first base material was neutrally sized and then machine glazed on one surface. The Bendtden porosity was between the limits of 60–120 cc/min and the maximum pore size was not greater that 10 mym. The paper was coated all over its unglazed surface with a heat sealable lacquer adhesive, sold under the trade name ADCOTE by Morton-Williams Limited., of Hounslow, Middlesex, England which is a solvent-based thermoplastic material. The adhesive was applied in a grid form by means of a gravure cylinder and then dried. The advantage of coating the paper all over its unglazed surface in a discontinuous form is that the paper may be used for packages of different sizes or sealing areas.

With the paper held horizontal, coated side upwards, an article to be packaged was placed on the paper and then a second base material, in the form of a non-porous laminate. of 12.5 mym polyester film/38 mym polyethylene film, was placed over the article with its polyethylene film facing downwards and heat sealed along its marginal portions in a Sentinel heat sealer to the opposing paper base material to form a sealed pouch-type packaging containing the article. The interior of the sealed package was gas sterilised, using ethylene oxide or a known gaseous mixture of ethylene oxide and inert gas.

The neutral sizing agent prevented absorption of the adhesive by the paper base material both during appli-

cation and subsequent heat sealing. However the relative roughness of the unglazed surface of the paper assisted the bonding of the adhesive to the paper and in the sealed package the bond strength of the heat seal was found to be commercially acceptable. The discontinuous form of the applied adhesive made it possible to penetrate the whole area of the package with the sterilising gas. The package was then peeled open in a smooth manner and with a clean peel, i.e. without visible transfer of fibre from the rough paper surface to the polyethylene film, thereby minimising possible contamination of the sterilised article in the package.

The external glazed surface of the package was suitable for good quality printing.

EXAMPLE II

A paper base material produced as described in Example I was heat sealed to an opposing base material consisting of untreated unplasticised polyvinyl chloride film on a Sentinel heat sealer. After gas sterilisation of the interior of the interior of the sealed package, the bond strength of the heat seal was tested and found commercially acceptable. When the opposing base materials were peeled apart, they separated in a smooth and clean manner with no visible transfer of fibres from the rough surface of the paper to the polyvinyl chloride film.

EXAMPLE III

A package was made as described in Example I except that the non-porous laminate was replaced by a bleached kraft paper having the same characteristics and treatment as described in the first paragraph of Example I but without the adhesive, the first paper base material being heat sealed to the unglazed surface of the second paper base material.

EXAMPLE IV

A package was made as described in Example III except that the heat sealable lacquer adhesive was coated on to the machine glazed surface of the first paper base material.

EXAMPLE V

Packages were made as described in Example I, Example III and Example IV respectively, except that the adhesive used was a water-based ethylene vinyl acetate/wax dispersion thermoplastic coating sold under the trade name ELVAX-D by the Du Pont Company of London, England.

EXAMPLE VI

Packages were made as described in Example I and Example III respectively, except that the heat sealable lacquer adhesive applied to the first base material was a hot melt adhesive sold under the trade name LUNAMELT PS by Industrial Waxes Limited of London, England.

EXAMPLE VII

A package was made as described in Example I except that gas sterilisation was replaced by Gamma irradiation at 5 megarads.

In Examples III–VII the bond strength of the heat seal was commercially acceptable. Furthermore, when the opposing base materials were peeled apart they separated in a smooth manner and with a clean peel.

The invention is not limited to pouch-type packages. For example the neutrally sized paper base material may be peelably heat sealed to an open top rigid container so as to close it, the container body being of thermo-formed untreated unplasticized polyvinyl chloride, or cellulose acetate, or a laminate of polyethylene and untreated unplasticized polyvinyl chloride or cellulose acetate.

Instead of applying the adhesive all over one surface of the first base material, it may be applied to the sealing areas only, in which case it need not be applied in discontinuous form.

I claim:

1. A package comprising opposing base materials bonded together at marginal portions by means of a heat sealed adhesive which allows the base materials to be peeled apart cleanly to open the package, one of the base materials comprising paper which has been sized under neutral conditions with a pH value in the ranges 7.2 to 8.3 inclusive using an alkyl ketene dimer, and which has a machine glazed surface.

2. a package according to claim **1**, wherein the machine glazed surface of the paper base material is an outer surface of the package.

3. A package according to claim **1**, wherein the adhesive was applied to the unglazed surface of the neutrally sized paper in a discontinuous form to allow a sterilising gas to pass through it.

4. A package according to claim **3**, wherein the adhesive was applied in grid form or dotted form.

5. A package according to claim **1**, wherein the neutrally sized paper, excluding the sizing, has a weight not less than 55g/m^2, a maximum pore size not greater than 10 mym, and a Bendtsen porosity of 60–120 cc/min.

6. A base material for a package as claimed in claim **3**, wherein the base material is a neutrally sized paper which has been sized under neutral conditions with a pH value in the range 7.2 to 8.3 inclusive using an alkyl ketene dimer, which has been machine glazed on one surface, and which has, on its unglazed surface, a heat sealable adhesive applied in a discontinuous form.

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