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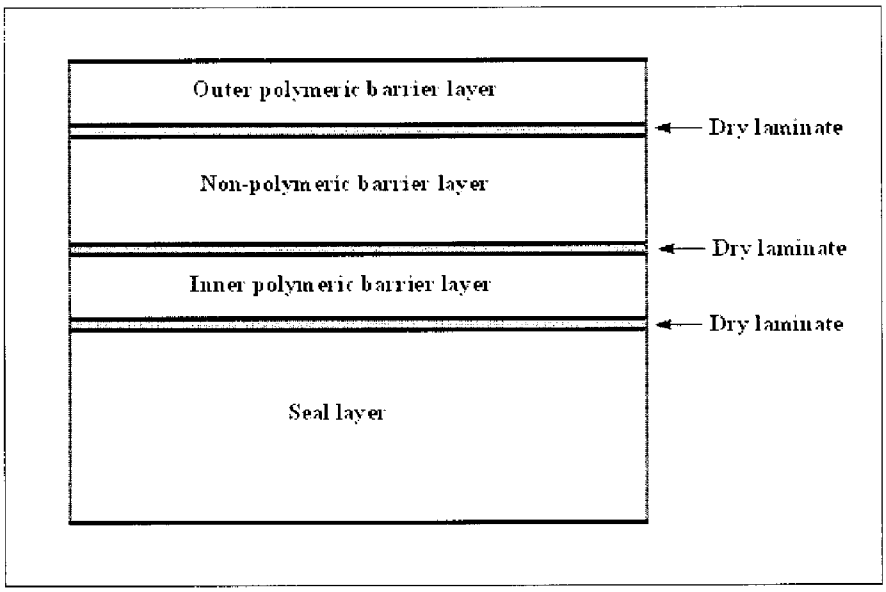
(54) **Title:** HEAT SEALABLE, RETORTABLE LAMINATED FOIL

[Fig. 1]



(57) **Abstract:** A heat sealable, retortable laminated foil capable of being heat sealed to itself or to a polypropylene substrate. The foil includes: an outer polymeric barrier layer; an intermediate barrier layer; an inner polymeric barrier layer; and a heat sealable layer. Packages produced utilizing the laminate are suitable for the autoclave sterilisation and subsequent storage of a contact lens and its attendant saline for a period of time in excess of 2 years.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Description

HEAT SEALABLE, RETORTABLE LAMINATED FOIL

Technical Field

[0001] The present invention relates to contact lens packaging and, more particularly, to a laminated film that allows an improved economic form of package for a contact lens which satisfies lens packaging criteria, including sterility and environmentally sensitive disposability.

Background Art

[0002] Soft disposable contact lenses are commonly contained in disposable packages. As packaging adds to the overall cost of the lens, it should be made as economically as possible but without compromise to the requisite packaging criteria. The traditional blister pack packaging for disposable lenses (both bi-weekly and daily) consists of a polypropylene receptacle for the lens (herein after referred to as a "boat"), topped by a multi-layer film consisting of polyethylene, aluminum, a bonding agent and polypropylene. The boat is usually an injection molded plastic which has high stiffness but is capable of limited elastic deflection and includes a preformed recess. The boat is filled with a suitable storage solution, preferably saline, and receives a single lens in situ. The blister pack is then autoclaved using steam and pressure to terminal sterility. These blister packs are presented to the patient in boxes of individual packs or as multiple blister strips.

[0003] The marketing objective is to present the contact lens to a patient in an aesthetically pleasing package that both satisfies the statutory requirements for sterility and stability, and allows the patient to remove the lens safely and easily. The packaging is used only once and is discarded after the lens is removed. This impacts the costs of the lens/ package combination. In order to reduce the overall price of the lens to the patient, the cost of the packaging should be kept to an absolute minimum. In addition, disposability of lens packages necessitates conformity with ecological standards.

[0004] The lens must be kept hydrated while in the package. The package must be well sealed and should minimize water vapor transmission through the boat and laminated layer to maximize the shelf life and prevent drying out of the lens contained therein. In use, the user removes the laminated material from a flange formed on the boat by peeling back the cover to expose the lens immersed in a hydrating solution.

[0005] A variety of contact lens packages, particularly disposable contact lens packages including preformed blister packs, are taught in the prior art. As exemplified in the prior art, conventional wisdom in the contact lens industry has been to provide preformed stiff packaging which protects the lens from damage from applied load.

Examples of typical prior art blister packs are shown in: U.S. Patent No. 5,704,468; U.S. Patent No. 4,392,569; U.S. Patent No. 5,620,088; U.S. Patent No. 5,620,088; U.S. Patent No. 4,691,820; U.S. Patent No. 5,823,327; U.S. Patent No. 5,853,085; EP Patent Publication No. 1 092 645 A1; EP Patent Publication No. 1 092 645. One problem with many blister packs is that the force required to peal off the film layer from the blister has a high peak, followed by a rapid decrease in the amount of force required to open the main part of the seal. This can result in a jerky movement and spilling the contents when the blister is opened. U.S. Patent Application 2004/0172098 has attempted to address this issue by the use of a foil comprising a layer of aluminum laminated with a film comprising a mixture of butane-1 polymer, polypropylene, an inorganic filler and optionally high density polyethylene. In this foil, the inorganic filler switches the foil-blister bond from an adhesive failure to a cohesive failure so as to reduce the force required to open the package, but at the same time being capable of resisting bursting during retorting or autoclaving.

[0006] Flexible retort packages are also known, however, not for use with contact lenses. U.S. Patent No. 4,769,261 discloses a seal layer for use in large institutional sized retort pouches comprising an ABA film structure, wherein the A layers are each composed of a blend of a minor amount of an elastomer and a major amount of a polyolefin and the B layer is composed of a blend of a major amount of an elastomer and a minor amount of polyolefin. Retort pouches made with the ABA film structure as the seal layer exhibit improved impact strength. There is no teaching in the '261 patent to use a retort package for housing a contact lens.

[0007] EP Patent Publication No. 0 129 388 describes a sachet formed by sealing together an optically transparent film so as to enclose a contact lens plus hydration solution. This teaching is however directed at maintaining the contact lens in its natural equilibrium shape so as to allow optical measurement to be conducted without opening the pack. In an additional aspect of this teaching, the sachet is provided with a holder or support within the sachet in which the lens is retained to assist in securing the lens to allow such optical measurements as back surface radius of curvature to be made. It is clear therefore that EP '388 is directed at maintaining a contact lens in its equilibrium shape.

[0008] Japanese Patent Publication No. 6-258603 similarly describes a resin film pack for the storage of contact lenses. The package is formed from a suitable resin material by sealing three of the four sided together, leaving the fourth side open to insert the contact lens plus storage solution. Once the lens and solution have been placed within the package, the fourth side is then heat sealed. There is no provision within this teaching for the opening of the package. Since the contact lens is placed into the pre-formed package through its open end, there is no provision for favorably orientating

the lens for user convenience.

[0009] In common with most retortable sachet-style packages, the contact lens packaging described in EP Patent Publication No. 0 129 388 and Japanese Patent Publication No. 6-258603 are designed to be opened by tearing off one end of the sachet, and retrieving the contents through the opened end. The provision of a peelable seal is generally held to be incompatible with a retortable package, since the pressure differentials encountered between the inside of the pack and the outside may lead to failure of the seal. Peelable seals are generally only found in non-retortable sachet packages.

[0010] US Patent No. 4,279,344 however does describe a foil suitable for use in a peelable, retortable sachet packages. The foil is a multilayer laminate comprising a polyethylene terephthalate outer layer adhesion bonded to an aluminum barrier layer, which in turn is bonded to a heat sealable layer comprising polypropylene, or a polyethylene-polypropylene copolymer to which has been blended an ionomer. There is no teaching in the '344 patent to use the retortable, peelable laminate for contact lens applications.

[0011] Whilst the teachings within the '344 patent pertain to maintaining sterility of medical devices, there is no direction within the teaching for the maintenance of an aqueous solution for a prolonged periods of storage, such as would be required for the storage of a contact lens over its shelf-life, which is typically 5 years. A defect within the foil structure, such as a pinhole in the aluminum will have the effect of significantly increasing the water vapour permeability of the whole foil. Since a contact lens must be packed with a small quantity of saline, any loss of water vapour from the package will lead to an increase in the salinity of the saline, which will subsequently impact the basic parameters (diameter, base curve, water content etc) of the lens, thus reducing its shelf life. The requirement to maintain a water vapour barrier becomes more acute with contact lens packages of the type described in PCT Patent Application Serial No. PCT/IB2005/000388, published as WO05708539, since the volume of saline contained within these packages is typically 0.15ml.

[0012] One method of reducing the probability of pinhole defects within the aluminum foil of the '344 patent would be to use a relatively thick aluminum foil. Typical foils used in prior art contact lens blister applications will have an aluminum thickness of around 70 micron, and such foils are generally selected for use in contact lens applications as they offer a degree of certainty that the aluminum barrier layer will be free of pinhole defects.

[0013] Furthermore, any pinholes within the bonding layer will allow the saline solution to contact the aluminum, thus potentially allowing corrosion of the aluminum film to occur. This will be of particular importance for films with a thin (ie <30 micron) thickness of aluminum. Such bonding layer pinholes are commonly found in co-extruded laminates.

Disclosure of Invention

[0014] The use of a relatively thick (ie >50 micron) aluminum layer within a contact lens packaging laminate will typically have an impact on the overall esthetic look and feel of the laminate.

[0015] Most typical prior art foils used in contact lens packaging applications typically will have a metallic feel. For instance, if a prior art contact lens packaging foil is distorted by folding, the foil will show little tendency to recover its undeformed shape, since the overall mechanical properties of the laminate will be dominated by the metallic nature of the aluminum layer (ie the foil will exhibit a plastic deformation).

[0016] This may often lead to wrinkling of the foil when the blister package is sterilised by autoclaving. This wrinkling is believed to be caused by both pressure differentials experienced by the pack during the heat-up and cool-down phases of the autoclave cycle, and also by differential expansion of the foil and the blister boat to which it is sealed. The effects of differential expansion will be much more pronounced in sachet style packages containing spring members as described in US Patent No. 7,086,526 particularly on the bottom foil of the package, that is the foil to which the spring disk is affixed.

[0017] By reducing the thickness of the aluminum layer, it is possible to confer a more paper-like feel to the foil laminate, in which all but the most severe distortions will recover elastically, since the mechanical properties of the laminate will be dominated by the polymer films used in its construction. The ability of the foil to recover elastically from all but the most severe distortions will significantly reduce its tendency to wrinkle during autoclave sterilisation.

[0018] However, any significant reduction in the thickness of the aluminum foil within the laminate will increase the risk of pinhole defects within the foil which will compromise the water vapour barrier properties of the laminate. Figure 2 shows how the porosity of aluminum foil will vary with its thickness.

[0019] The present inventive foil seeks to overcome these disadvantages with current prior art contact lens packaging laminates by utilizing multiple barrier layers within the laminate so as to allow the use of a thin (>30 micron) layer of aluminum, with said laminate having a more esthetic look and feel. The present inventive foils may be formed into peelable sachets which may be sterilised by autoclave. The inventive foils may also be used with a conventional contact lens blister.

Brief Description of the Drawings

[0020] [fig.1]FIG.1 is an enlarged fragmentary view of the disclosed laminate.
[fig.2]FIG.2 is a chart showing how the porosity of an aluminum foil will vary with foil thickness.

Best Mode for Carrying Out the Invention

[0021] Figure (1) shows the typical configuration of the inventive foil. The foil comprises a laminate consisting of an outer polymeric barrier layer, an intermediate barrier layer, an inner polymeric barrier layer and a seal layer. In a most preferred embodiment, the foil is constructed by adhesion lamination, so that these layers are separated by dry laminate layers. In a less preferred embodiment, the foil is produced by extrusion lamination.

[0022] The present invention will now be described according to the preferred, but non-limiting, embodiments and with reference to the accompanying illustrations. In the following passages, different aspects of the invention are defined in more detail. Each aspect so defined may be combined with any other aspect or aspects unless clearly indicated to the contrary. In particular, any feature indicated as being preferred or advantageous may be combined with any other feature or features indicated as being preferred or advantageous.

[0023] The inventive foil comprises an outer polymeric barrier layer, an intermediate barrier layer, an inner polymeric barrier layer and a seal layer. The foil may be constructed by adhesive lamination, (in which each of the instant layers will be separated by an adhesion layer), or by co-extrusion. The nature and function of each layer of the foil will be described.

[0024] Outer Polymeric Barrier Layer

In the preferred embodiment, the outer polymeric barrier layer comprises a polymeric film with a maximum water vapour permeability of 100 g/m^2.24 hr. The polymeric film should also have a minimum tensile strength of 150MPa and a maximum elongation to break of 140%. A highly preferred material is a biaxially drawn polyester film with a thickness of 12 micron. Suitable materials include those produced by Unitika Ltd of Japan and marketed under the trademark designation of "Emblet Polyester Film". Suitable grades are Emblet PHT 12 or Emblet PET-12. Since it is the outer barrier layer that forms the exterior of the pack, the outer barrier layer may also be optionally printed. In a highly preferred embodiment, the outer barrier layer may be printed on its inner surface, for instance using a 4 colour photo-gravure process, although any suitable printing process known in the art may be employed. If no printing is employed, the visual appearance of the finished laminate will substantially be that of the internal layers of the foil.

[0025] The use of a barrier material will also allow for a wider selection of inks for the printing, since the barrier nature of the biaxially drawn polyester film will protect the ink from the deleterious effects of steam during sterilisation. Furthermore, by suitably selecting the grade of polyester film, it is also possible to modify the visual appearance

of the final printed foil. For example, if a gloss finish is desired, then Emblet PET-12 may be selected. If a matt finish is required, then Emblet PHT 12 may be selected.

[0026] Intermediate Barrier layer

In a preferred embodiment, the foil will also comprise a non-polymeric intermediate barrier layer. Said non-polymeric intermediate barrier layer may consist of paper, or preferably aluminum and will have a thickness of between 1 micron and 50 micron. In a highly preferred embodiment, the non-polymeric intermediate barrier layer will comprise an aluminum foil with a thickness of 20 micron. Preferably, the aluminum will be produced by slow rolling, and a suitable 20 micron foil is supplied by Showa Denko Packaging Co.,Ltd, Japan.

[0027] In a second embodiment, the intermediate barrier layer comprises a fluoropolymer film. Suitable examples are polychloro-trifluoroethylene (Aclar) or ethylene-tetrafluoroethylene-copolymer (Halar) film, both of which are supplied by Honeywell Specialty Materials, Morristown, N.J. In these embodiments, the overall laminate will be transparent to visible light.

[0028] In another less preferred embodiment, the intermediate barrier layer will comprise a metal such as aluminum or a ceramic (for instance silicon dioxide, or barium oxide) vacuum deposited onto the outward facing surface of the inner polymeric barrier layer. In this embodiment, the intermediate barrier layer will have a thickness of between 5 and 500 A. When a ceramic barrier layer is used, the resultant laminate may be transparent to visible light.

[0029] Inner polymeric barrier layer

The inner polymeric barrier layer comprises a polymeric film with a maximum water vapour permeability of 100 g/m^2.24 hr. The polymeric film should also have a minimum tensile strength of 150MPa and a maximum elongation to break of 140%. In a preferred embodiment, the inner polymeric barrier layer comprises a biaxially drawn polyester film with a thickness of 12 micron. Suitable materials include those produced by Unitika Ltd of Japan and marketed under the trademark designation of "Emblet Polyester Film". A suitable material is Emblet PET-12.

[0030] Seal layer

The seal layer comprises of a polymeric material capable of being heat sealed to itself, or to a standard polypropylene contact lens blister package to form a peelable seal. Once sealed, the bond formed between the two sheets of laminate, or between the laminate and standard blister pack will be sufficiently strong to maintain seal integrity during sterilisation by autoclave, yet will be capable of being opened by peeling back the laminate. Typically, the force required to peel back the laminate (using a 90^o pull) should be below 15N. Ideally, the bond will fail during opening via a cohesive failure of the seal layer, rather than by an adhesive failure of the bond itself.

[0031] In a preferred embodiment, the seal layer will comprise a 35 micron thick melt cast polyolefin copolymer film with a minimum melting point of 130 °C. Suitable materials are TP6 cast polyolefin copolymer, produced by Okamoto, Japan or Sholex Allomer SA-001, produced by Showa Denko, Japan. Other suitable seal layers are those described in the '344 patent, and those described in U.S. Patent No. 5,106,917.

[0032] In a second embodiment, the seal layer may also contain non toxic antimicrobial agents blended into the polymer. The antimicrobial agents should have a low solubility in water, but be capable of migration within the seal layer, particularly at elevated temperatures. When such a foil is used for a sachet-style contact lens package such as disclosed in WO2005/082721, the front surface of the contact lens will be held in intimate contact with the seal layer of the top laminated foil, and therefore sufficient antimicrobial agent will transfer to the front surface of the lens to mitigate the transfer of microbial species from finger to lens to eye. Examples of some suitable antimicrobial agents are triclosan, furanones, Protectol DA (2,4-dichlorobenzyl alcohol), Amical PC (diiodomethyl-p-sulfone), paraben, etc. Other similar biocides known in the art may also be used. Other functional additives may similarly be blended into seal layer polymer to provide for additional specific functions. Examples may include, but are not limited to, antioxidants, and oxygen scavengers. The seal layer polymer may also contain an inorganic filler such as talc to enhance the peelability of the laminate.

[0033] Dry laminate layer(s)

In a most preferred embodiment, the inventive laminate will be produced by adhesion lamination, using a dry laminate process. In this process, an adhesive is evenly spread over one surface of a film, and the coated film is allowed to dry to a tack. The coated film is then adhered to a second film by passing both through a roller. The process is then repeated for subsequent layers. The thickness of the dry laminate layers will preferably be between 1 and 5 microns, and most preferably be between 1 and 3 micron. The lamination adhesives selected may be solvent based or solvent-free.

[0034] In the preferred embodiment, the lamination adhesive may comprise a polyester or polyurethane resin (or combination thereof) in a non-toxic organic solvent such as ethyl acetate. Suitable lamination adhesives are TM-250, a polyester-type adhesive produced by Toyo Morton Co., Ltd., Japan, and CAT-RT86 l, a urethane type adhesive also produced by Toyo Morton Co. Ltd. In a most preferred embodiment, a mixture of both TM-250 and CAT 86 L is used as the adhesion laminate. The adhesives used should produce a minimum laminate strength of 1.96 N/15mm, as determined by the method of Japanese standard JIS Z 1707.

[0035] In a less preferred embodiment, some or all of the layers of the laminate may be formed by co-extrusion. In this event, the dry laminate layers between said co-extruded layers will be absent.

[0036] Completed laminate

The complete laminate will have a total thickness of between 40 150 micron, preferably between 50 and 100 micon. In the most preferred embodiment, the total thickness will be between 75 and 95 micron, and will have a maximum heat seal strength of 20.0N/15mm, as determined by the method of JIS Z 1707. The water vapour transmission rate, as determined by JIS Z 0208 (at 40 °C and 90% RH) will preferably be below 10 g/m^2.24 hr, or preferably below 1 g/m2.24 hr. In a most preferred embodim ent, the water vapour transmission rate will be below 0.05 g/m2.24 hr.

Claims

[1] A heat sealable, retortable laminated foil for maintaining an aqueous solution, comprising:
an outer polymeric barrier layer formed of a biaxially drawn polyester film having a water vapour permeability less than 100 g/m^2.24 hr;
an intermediate non-polymeric barrier layer having a thickness less 50 microns;
an inner polymeric layer having an inward facing surface and an outward facing surface; and
a seal layer formed of a meltcast polyolefin copolymer film having a melting point between 130 °C and 200 °C.

[2] The heat sealable, retortable laminated foil according to claim 1, wherein the intermediate non-polymeric barrier layer comprises an aluminum foil with a thickness of less than 20 microns.

[3] The heat sealable, retortable laminated foil of claim 2, wherein the aluminum foil comprises a slow rolled aluminum foil.

[4] The heat sealable, retortable laminated foil according to claim 1, wherein the intermediate non-polymeric barrier layer comprises a fluoropolymer film.

[5] The heat sealable, retortable laminated foil according to claim 1, wherein the intermediate non-polymeric barrier layer comprises one of a metal or a ceramic vacuum deposited onto the outward facing surface of the inner polymeric barrier layer, having a thickness of between 5 and 500 A.

[6] The heat sealable, retortable laminated foil according to claim 5, wherein the polymeric film has a tensile strength of at least 150Mpa and an elongation to break of less than 140%.

[7] The heat sealable, retortable laminated foil according to any one of claims 1-6, wherein the inner polymeric barrier layer comprises a biaxially drawn polyester film with a water vapour permeability of less than 100 g/m^2.24 hr.

[8] The heat sealable, retortable laminated foil according to claim 7, wherein the polymeric film has a tensile strength of at least 150Mpa and an elongation to break of less than 140%.

[9] The heat sealable, retortable laminated foil according to any one of claims 1-8, wherein the laminated foil is heat sealed to itself to form a contact lens packaging in a form of a peelable sachet.

[10] The heat sealable, retortable laminated foil according to any of claims 1-9, wherein:
the seal layer is configured to be separated from a sealed surface by cohesive failure of the seal layer in the presence of a 90 degree pull separation force less

than 15 Newtons (N); and

said seal layer is approximately 35 microns thick.

[11] The heat sealable, retortable laminated foil according to any of claims 1-10, wherein a seal created by sealing said seal layer to itself creates a heat seal having a heat seal strength of less than 20.0N/15mm.

[12] An autoclaveable foil laminate capable of being peelably sealed to itself so as to form a pouch configured to store a hydrated contact lens and attendant hydration solution for prolonged periods, wherein said laminate comprises:

an outer polymeric barrier layer formed of a biaxially drawn polyester film having a water vapour permeability less than 100 g/m^2.24 hr, a tensile strength of at least 150Mpa and an elongation to break of less than 140%;

an intermediate non-polymeric barrier layer having a thickness less 50 microns, said intermediate non-polymeric barrier layer including a slow rolled aluminum foil;

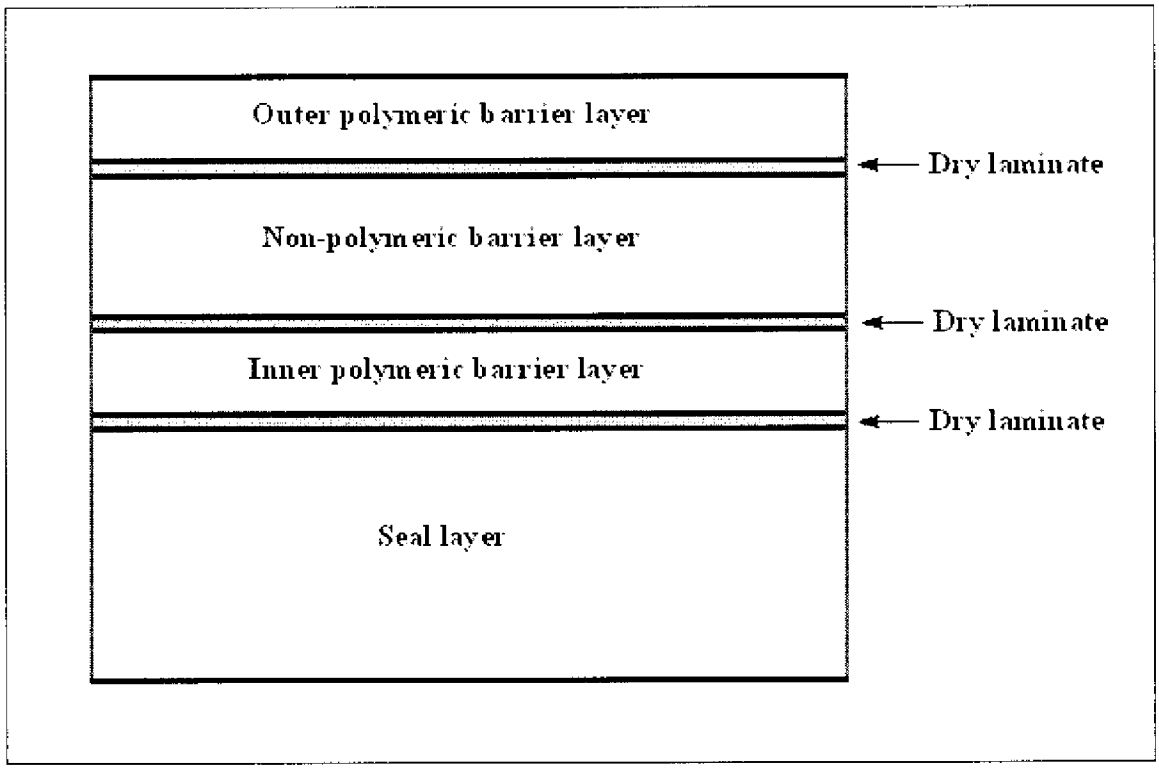
an inner polymeric layer having an inward facing surface and an outward facing surface, the inner polymeric layer being a biaxially drawn polyester film having a water vapour permeability less than 100 g/m^2.24 hr, a tensile strength of at least 150Mpa and an elongation to break of less than 140%; and

a seal layer formed of a meltcast polyolefin copolymer film with a thickness of approximately 35 microns, said seal layer having a melting point between 130 °C and 200 °C.

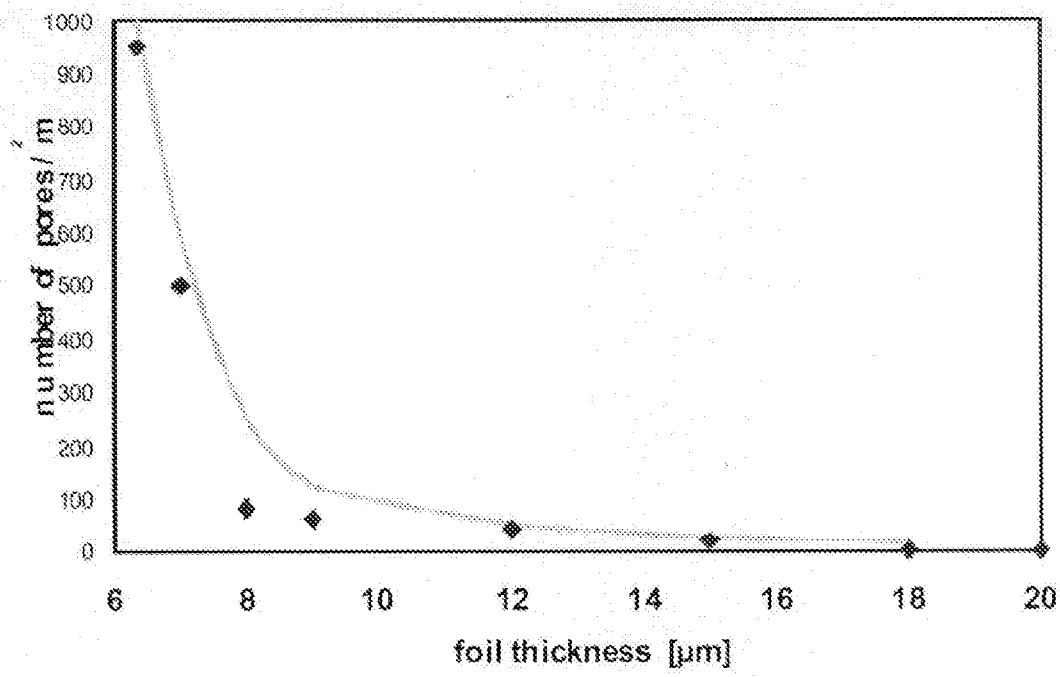
[13] The autoclaveable foil laminate according to claim 12, wherein the laminated foil is heat sealed to itself to form a contact lens packaging in a form of a peelable sachet, said peelable sachet having a seal created by sealing said seal layer to itself creates a heat seal having a heat seal strength of less than 20.0N/15mm.

[14] The autoclaveable foil laminate according to any of claims 12 or 13, wherein a junction between each of the outer polymeric barrier layer, the intermediate barrier layer, and the inner polymeric barrier layer is formed by a dry laminate process.

[Fig. 1]


Outer polymeric barrier layer
Dry laminate
Non-polymeric barrier layer
Dry laminate
Inner polymeric barrier layer
Dry laminate
Seal layer

[Fig. 2]


number of pores / m²
1000
900
800
700
600
500
400
300
200
100
0
6
8
10
12
14
16
18
20
foil thickness [μm]

INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2008/002951

A. CLASSIFICATION OF SUBJECT MATTER
INV. B32B15/08 B32B27/10 B32B27/32 B32B27/36 B65D75/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B32B B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/038895 A1 (MOTEKI YOSHIJI [JP] ET AL) 8 November 2001 (2001-11-08) claim 1 paragraphs [0067], [0090]	1,2
A	EP 1 787 800 A (ALCAN TECH & MAN LTD [CH]) 23 May 2007 (2007-05-23) claims	1-14
A	US 4 279 344 A (HOLLOWAY JR FRED W) 21 July 1981 (1981-07-21) abstract examples column 2, lines 58-61	1-14

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
2 February 2009	11/02/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Somerville, Fiona

INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2008/002951

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 209 094 A (DAINIPPON PRINTING CO LTD [JP]) 29 May 2002 (2002-05-29) figure 1(a) examples paragraphs [0042], [0061]	1-14
A	US 2004/238380 A1 (NEWMAN STEPHEN D [SG]) 2 December 2004 (2004-12-02) paragraph [0263]	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/JP2008/002951

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