

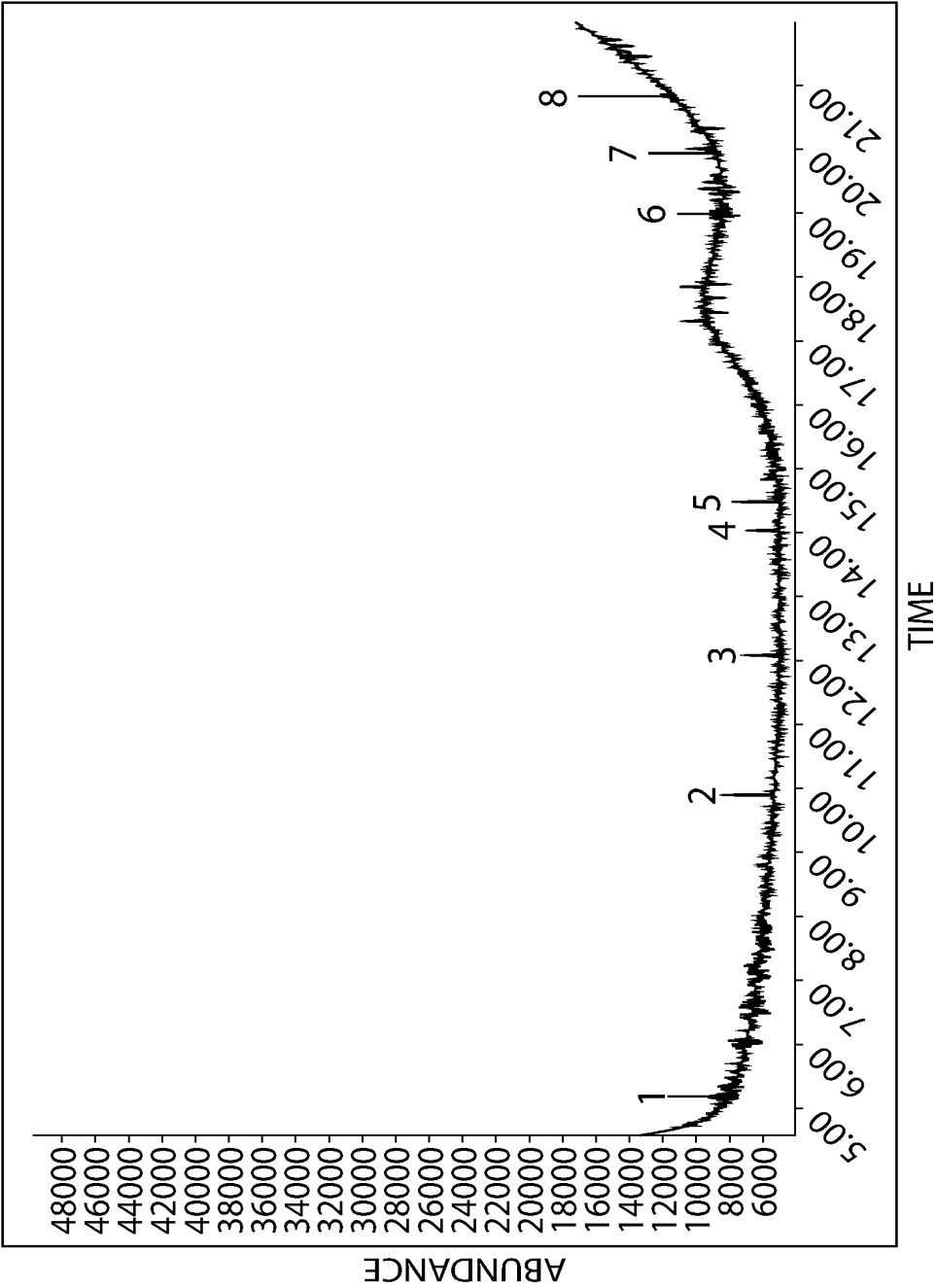


FIG. 17

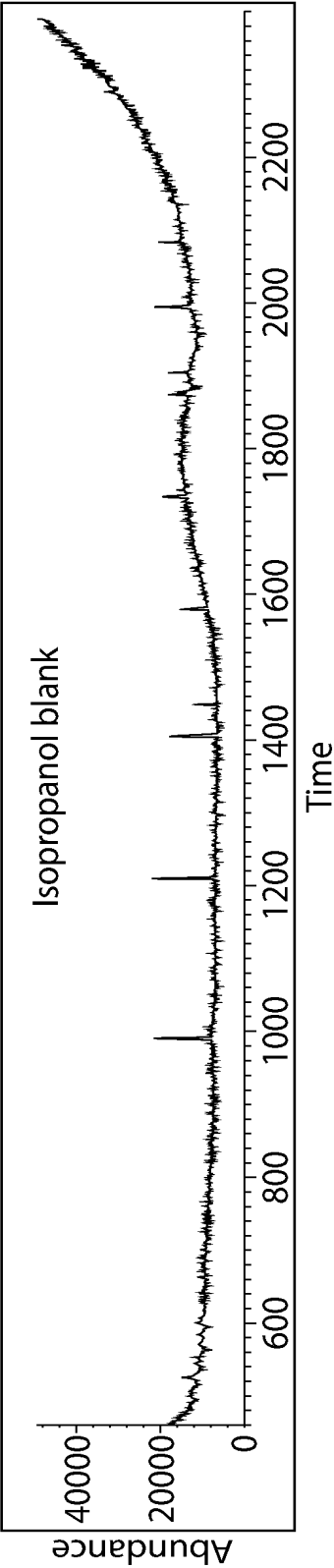


FIG. 18

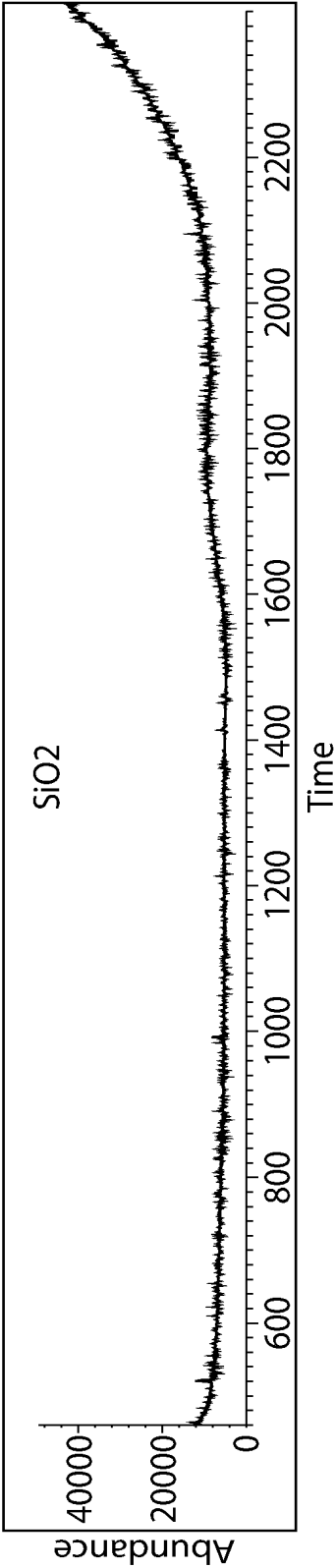


FIG. 19

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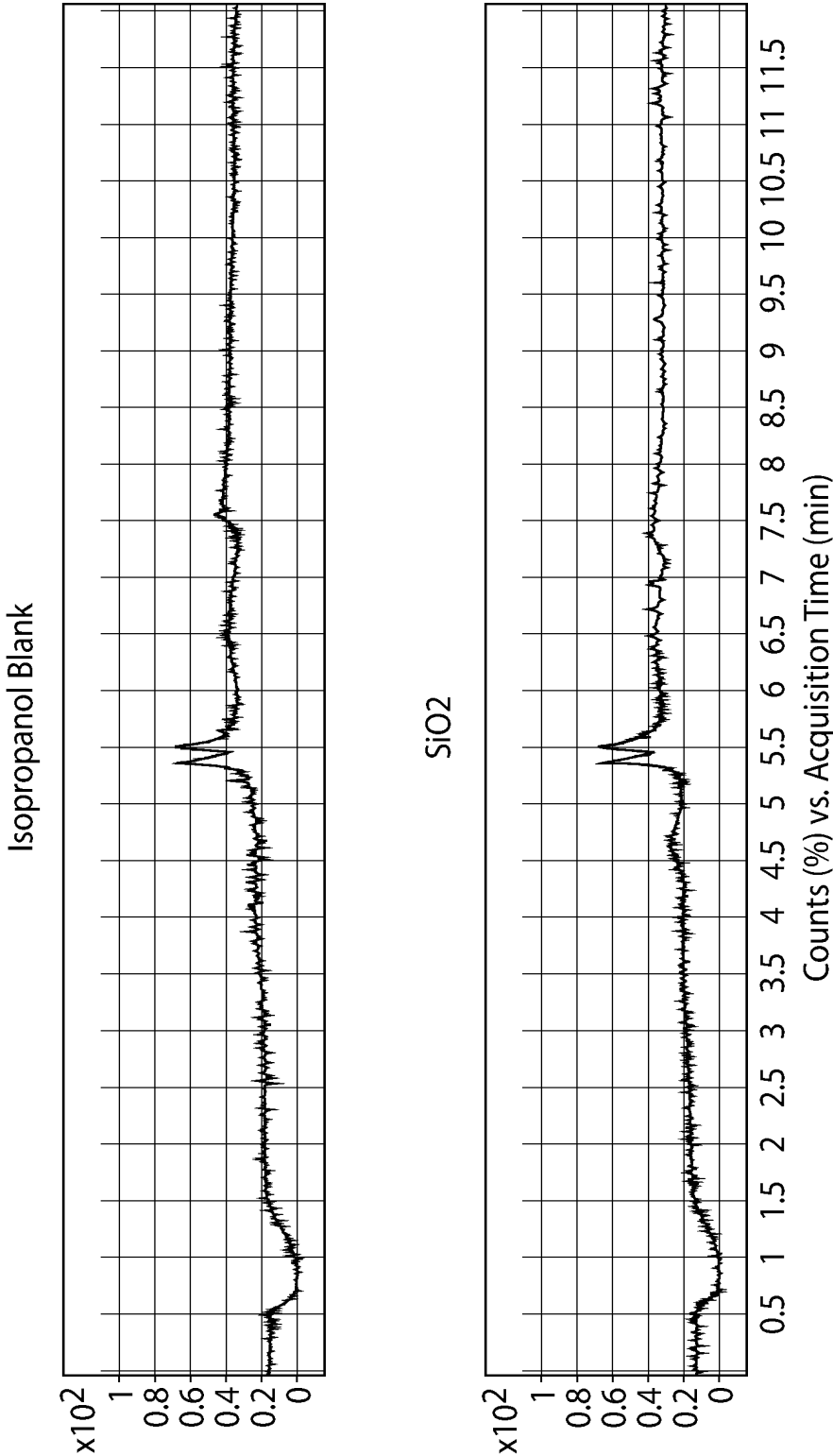


FIG. 20

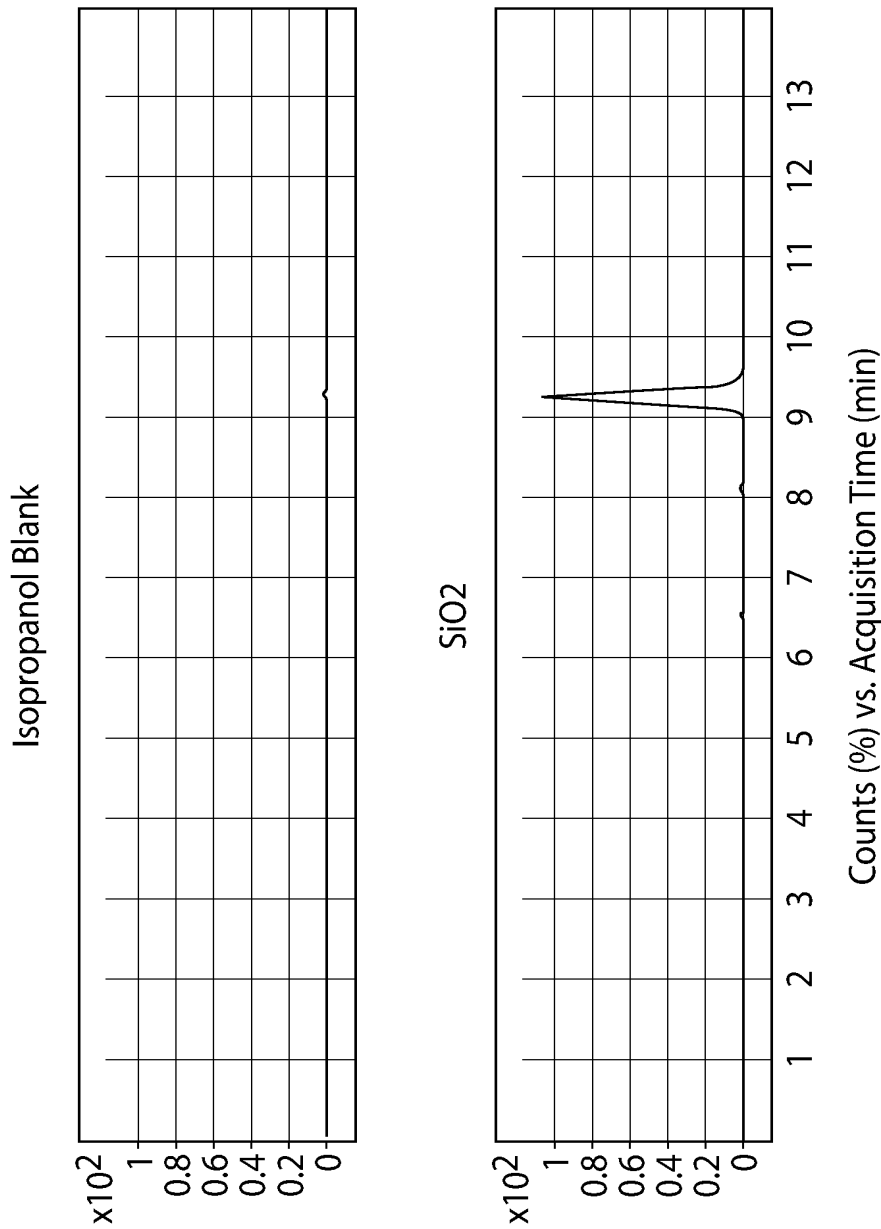


FIG. 21

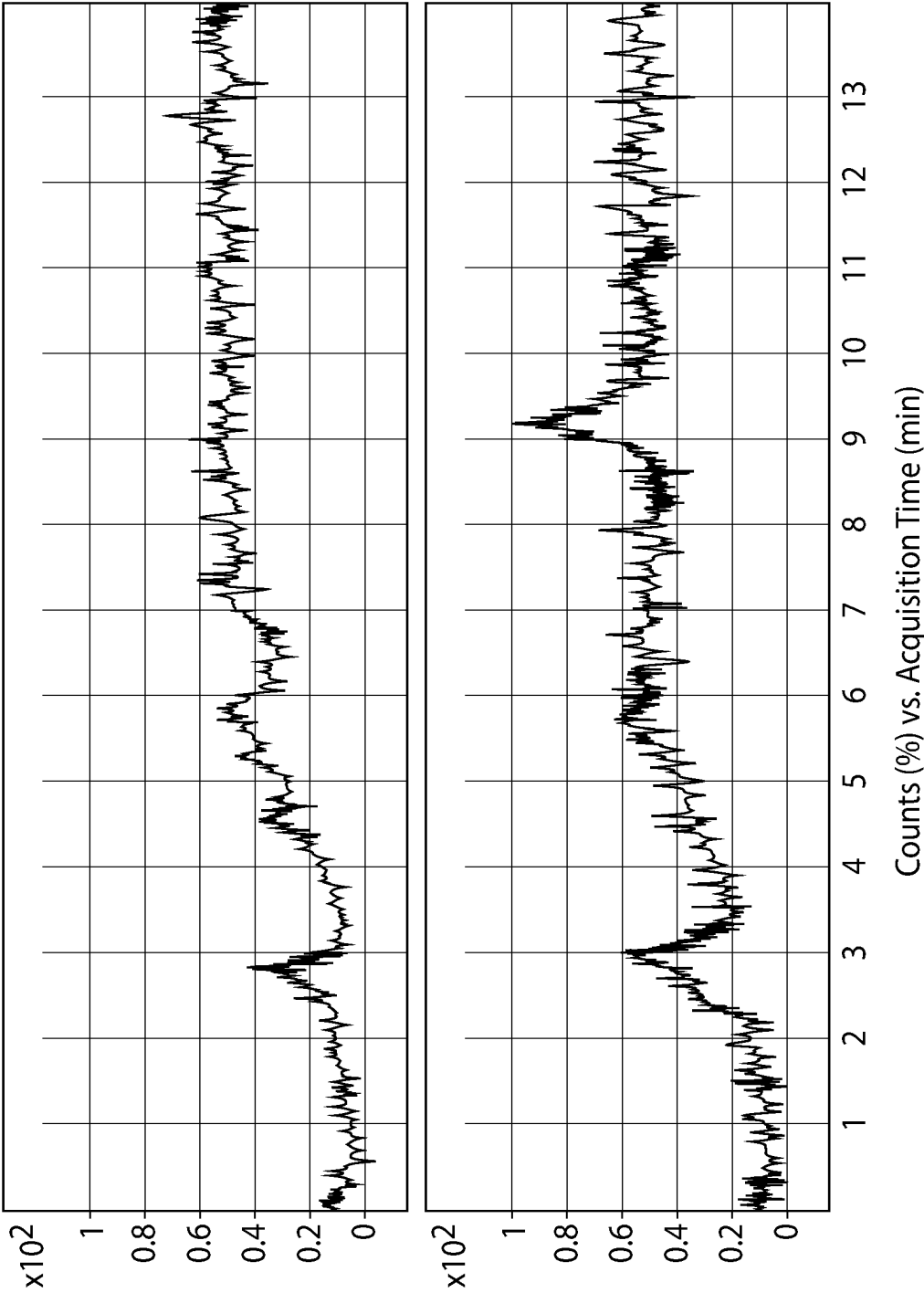


FIG. 22

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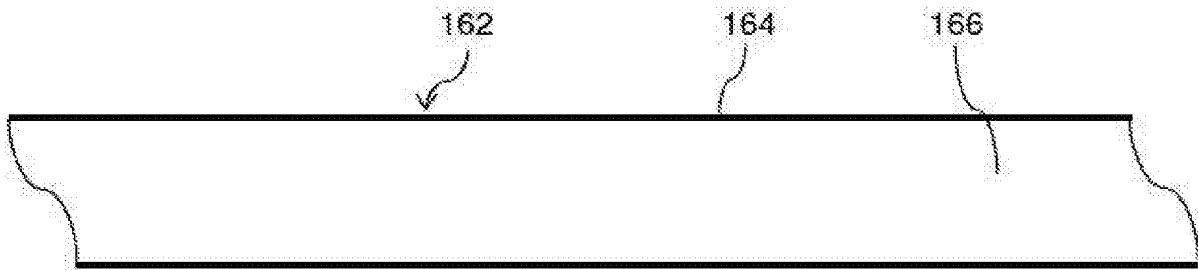


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/037674

A. CLASSIFICATION OF SUBJECT MATTER

INV. C08J7/12 B01L3/00
ADD. C08J7/18

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)

C08J B01L

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 practicable, 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	<p>SPIERINGS ET AL: "Water absorption and the effects of moisture on the dynamic properties of synthetic mountaineering ropes", INTERNATIONAL JOURNAL OF IMPACT ENGINEERING, PERGAMON, GB, vol. 34, no. 2, 17 November 2006 (2006-11-17), pages 205-215, XP005771420, ISSN: 0734-743X, DOI: 10.1016/J.IJIMPENG.2005.08.008 the whole document</p> <p>----- -/-</p>	<p>1,5, 8-12, 16-18, 21-24</p>



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search

8 September 2016

Date of mailing of the international search report

30/09/2016

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/037674

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	J.V. DA MAIA ET AL: "Influence of gas and treatment time on the surface modification of EPDM rubber treated at afterglow microwave plasmas", APPLIED SURFACE SCIENCE, vol. 285, 1 November 2013 (2013-11-01), pages 918-926, XP055300824, AMSTERDAM, NL ISSN: 0169-4332, DOI: 10.1016/j.apsusc.2013.09.013	1-12, 16-27
Y	the whole document	1-27
X	----- EP 2 251 452 A2 (CV HOLDINGS LLC [US]) 17 November 2010 (2010-11-17)	1-18, 21-27
Y	paragraphs [0864] - [0875]; example 15; table 17	1-27
Y	----- EP 1 859 866 A1 (GENETIX LTD [GB]) 28 November 2007 (2007-11-28) paragraphs [0002] - [0004], [0007], [0011], [0017], [0018], [0025], [0068] - [0076]; table 1	1-27
Y	----- US 2004/062882 A1 (LIEBMANN-VINSON ANDREA [US] ET AL) 1 April 2004 (2004-04-01) paragraphs [0001], [0004], [0012] - [0016]; examples 7,8	1-27
Y	----- DE 100 66 431 B4 (EPPENDORF AG [DE]) 24 October 2013 (2013-10-24) paragraphs [0002], [0005], [0012] - [0018], [0030], [0031] -----	1-27

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/037674

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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			WO 2004031266 A2 15-04-2004
			ZA 200503222 B 28-06-2006
DE 10066431	B4	24-10-2013	NONE



(51) International Patent Classification:

A61K 47/02 (2006.01) *B65D 65/40* (2006.01)
A61K 47/30 (2006.01) *B65D 85/00* (2006.01)

(21) International Application Number:

PCT/US2016/065127

(22) International Filing Date:

6 December 2016 (06.12.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/264,105 7 December 2015 (07.12.2015) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: OXYGEN SCAVENGING FILMS, PACKAGES, AND RELATED METHODS

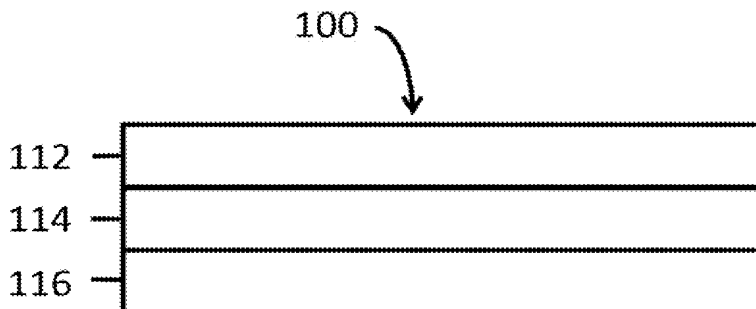


FIG. 1

(57) Abstract: Disclosed herein films and packages formed therefrom for packaging oxygen-sensitive products. The films include a product contact layer comprising COC and catalyst. Introduction of a gas flush including hydrogen gas to a package made from said films helps provide for the catalytic combination of molecular hydrogen and molecular oxygen to remove oxygen from a headspace of the package.

OXYGEN SCAVENGING FILMS, PACKAGES, AND RELATED METHODS

BACKGROUND

[0001] The present disclosure relates generally to the field of films for use in packaging applications. More specifically, the present disclosure relates to films and packages formed therefrom for packaging oxygen-sensitive products such as oxygen-sensitive pharmaceutical products.

SUMMARY

[0002] One embodiment relates to a package for an oxygen-sensitive pharmaceutical product providing for oxygen scavenging without the presence of a hydrogen generator. The package comprises at least one pharmaceutical product storage space and a first multilayer film. The first multilayer film comprises a product contact layer comprising COC and a hydrogenation-accelerating catalyst and a gas barrier layer exterior to the product contact layer.

[0003] Another embodiment relates to an oxygen scavenging film for packaging an oxygen-sensitive product, the product comprising a pharmaceutical active agent. The film comprises a gas barrier layer and a product contact layer. The product contact layer comprises COC and a palladium catalyst.

[0004] Another embodiment relates to a method of making an oxygen scavenging film. The method comprises providing a COC, providing a palladium catalyst, compounding the COC and the palladium catalyst; and creating a product contact layer comprising the COC and palladium catalyst.

[0005] Another embodiment relates to a method for achieving a sufficiently oxygen-free product storage space in a package. The method comprises utilizing a multilayer packaging film

and introducing a gas flush into the product storage space, the gas flush including hydrogen gas and an inert gas. The multilayer film comprises a product contact layer comprising COC and a catalyst as well as a gas barrier layer disposed exterior the product contact layer. The multilayer packaging film at least in part defines a product storage space.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a schematic cross-sectional view of a multilayer film according to an exemplary embodiment.

[0007] FIG. 2 is a schematic cross-sectional view of a multilayer film according to another exemplary embodiment.

[0008] FIG. 3 is a schematic cross-sectional view of a multilayer film according to another exemplary embodiment.

[0009] FIG. 4 is a schematic cross-sectional view of a multilayer film according to another exemplary embodiment.

[0010] FIG. 5 is a top plan view of a flat format package for a thin format pharmaceutical product according to an exemplary embodiment.

[0011] FIG. 5A is a cross-sectional view of the package of FIG. 5 taken along line A-A according to an exemplary embodiment.

[0012] FIG. 6 is a top perspective view of a package that is a blister package according to an exemplary embodiment.

[0013] FIG. 6A is a cross-sectional view of the package of FIG. 6 taken along line A-A according to an exemplary embodiment.

[0014] FIG. 7A is a perspective view of a partially formed flat format package for a thin format pharmaceutical product according to an exemplary embodiment.

[0015] FIG. 7B is a perspective view of the flat format package for a thin format pharmaceutical product of FIG. 7A shown closed according to an exemplary embodiment.

[0016] FIG. 8 is a plan view of a pouch according to an exemplary embodiment.

[0017] FIG. 9 is a plan view of a pouch according to an exemplary embodiment.

[0018] FIG. 10 is a perspective view of a bag according to an exemplary embodiment.

DETAILED DESCRIPTION

[0019] The pharmaceutical industry has a particularly high demand for packaging solutions which demonstrate moisture, dust, UV and/or gas barriers, because these properties are often desired for maintaining the integrity of the product therein.

[0020] In many current packaging configurations, significant amounts of oxygen are retained within the package (i.e., in the headspace or volume adjacent the product contained within the package) after sealing (or otherwise enclosing) the product in the product storage space. For oxygen-sensitive products, including, in particular, pharmaceutical products, the presence of oxygen in the package can result in oxidation that detrimentally impacts the product, for example, the efficacy of the product and/or shelf life of the product. Accordingly, it is generally desirable to package oxygen-sensitive products in a way that minimizes exposure to oxygen.

[0021] It has been found that minimizing exposure of a pharmaceutical product to oxygen is particularly desirable in many transdermal patch and oral strip applications (hereafter referred to at times as thin format pharmaceutical products). These pharmaceutical applications often contain pharmaceutical active agents that are sensitive to oxygen exposure (e.g., alkaloids, ethinyl estradiol, estradiol, etc.). For example, the Applicant has found that the integrity of transdermal patches involving nicotine (an alkaloid) can be compromised by presence of oxygen in a package as well as by the packaging itself because of the migration of chemicals.

[0022] Relatedly, minimizing exposure of a pharmaceutical product to oxygen is also particularly desirable for other types of pharmaceutical products including oxygen-sensitive pharmaceutical active agents. For example, the Applicant has found that the rapidly-evolving electronic cigarette (“e-cigarette”) market would particularly benefit from the disclosed innovations, not only because e-cigarettes utilize a pharmaceutical active agent (nicotine), but also because sales environments for e-cigarettes generally require (or at least benefit from) relatively long shelf lives (e.g., drug stores, convenience stores). Moreover, some nicotine-containing products may yellow with exposure to oxygen, making them less desirable to consumers.

[0023] Other examples of oxygen-sensitive pharmaceutical active agents include, but are not limited to, fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. It should be understood that, for the purposes of this application, the word pharmaceutical product as used herein will include any product including a compound for use as a medicinal drug or non-medicinal drug (e.g., tobacco products and other products including nicotine, etc.).

[0024] One way to minimize oxygen exposure within a package is to use an oxygen scavenger.

[0025] Early references disclose use of oxygen scavengers “sandwiched” or otherwise disposed between layers of a film. For example, US Patent 3,255,020 discloses catalysts (Nobel metal of the group consisting of palladium and platinum) sandwiched between two different layers of a film (e.g., PE and foil), with one of those layers being a gas permeable membrane. Oxygen is removed by a catalytic combination with hydrogen. These references generally teach against the use of a catalyst having a small particle size (e.g., due to difficulty positioning the particles between the walls of a multi-wall bag).

[0026] Some food-packaging-focused references teach the use of oxidizable polymers that participate in the oxygen level reductions. Free radical oxidation is the principle mechanism employed, which is complex and highly chemically reactive. The packaging films of these

references most often integrate an oxidizable polymer that uses UV or other radiation to initiate the oxidation reaction, after the package is closed. While included in the film, the oxidizable polymers are generally separated/distanced from products (e.g., not included in a product contact layer) because the reaction involving the oxidizable polymer creates undesirable byproducts (e.g., odor, chemical species, etc.) and these byproducts may negatively affect sealing of the package as well as the quality of the product within the package. Some references overcome these negative effects by including byproduct absorbers, which are themselves undesirable for other reasons. Moreover, oxidizable polymers are themselves consumed during the absorption reaction; this is in contrast to catalysts, which consume oxygen without themselves being consumed.

[0027] Still other references utilize Nobel metal catalysts in combination with water-activated hydrogen generators. While water-activated hydrogen generators may be suitable for the beverage containers for which they are commonly utilized, these generators are not desirable for packaging moisture-sensitive products. For example, US Patent 8,906,299 titled "Scavenging oxygen" highlights the central role of the water-activated hydrogen generators in this art. This reference describes a container that includes a shell made from a polymer (e.g., PET) and incorporating a catalyst (e.g., a palladium catalyst). A closure for the bottle incorporates a plug. The plug includes a hydrogen source (e.g., a hydride). In use, the headspace of the closed beverage container contains a significant amount of water vapor. When this water vapor contacts the hydride of the plug, the hydride produces molecular hydrogen that migrates into the polymer matrix of shell and then combines with oxygen (e.g., already enclosed in the bottle or which may have entered the container through its permeable walls). A reaction between the hydrogen and oxygen takes place, catalyzed by the catalyst, and water is produced. Thus, oxygen is scavenged and the contents of the container are protected from oxidation. For such systems, inclusion of the hydrogen generator in the oxygen scavenging system is beneficial because, over time, hydrogen is continuously produced allowing the consumption of the continuously ingressing oxygen. Moreover, a low water vapor level within the package is not required (or even necessarily desirable) for such applications as it is for many pharmaceutical applications.

[0028] Provided herein are oxygen scavenging films for packaging an oxygen-sensitive pharmaceutical product containing a pharmaceutical active agent. Also provided herein are packages formed from said film, methods of making said packages and said film, and methods for achieving an oxygen-free or sufficiently oxygen-free headspace of the packages formed from said film.

[0029] Referring generally to the FIGURES, the oxygen scavenging films 100, 200, 300, 400 include an catalyst that is a hydrogenation-accelerating catalyst, desirably a palladium or platinum catalyst that promotes the reaction of molecular oxygen and molecular hydrogen, even more desirably a nanoparticle catalyst. When considering cost, a palladium catalyst is generally preferred to platinum catalyst. As will be discussed in more detail below, oxygen scavenging takes place without the use of a hydrogen generator, is not activated by UV or other radiation, and is incorporated directly into a polymer layer.

[0030] Generally, the catalyst is included in a product contact layer (i.e., a material layer that is intended to be in contact with a contained product and/or that is adjacent to or in facing relationship with such a product without any intervening material layers, as when there is a gap or space between the contained product and the product contact layer). According to exemplary embodiments disclosed herein, the product contact layer comprises a cyclic olefin copolymer (COC), such as an ethylene norbornene copolymer. In general, COCs exhibit a high glass transition temperature (greater than 50° C), optical clarity, low heat shrinkage, low moisture absorption and low birefringence. These materials have been produced by a number of polymerization techniques which include chain polymerization of cyclic monomers such as 8, 9, 10-trinorborn-2-ene (norbornene) of 1, 2, 3, 4, 4a, 5, 8, 8a-octa-hydro-1, 4:5, 8-dimethanonaphthalene (tetracyclododecene) with ethane; or ring-opening metathesis of various cyclic monomers followed by hydrogenation.

[0031] In some exemplary embodiments, the product contact layer comprises at least 90 wt.% COC.

[0032] In some exemplary embodiments, the product contact layer comprises at least 95 wt. % COC.

[0033] In some exemplary embodiments, the product contact layer comprises at least 100 wt. % COC.

[0034] In some exemplary embodiments, the product contact layer comprises at least 50 wt. % COC.

[0035] In some exemplary embodiments, the product contact layer comprises at least 75 wt. % COC.

[0036] The COC in the product contact layer may be blended with compatible polymers such as polyolefins (e.g. polyethylene, LLDPE, EAO copolymers, LDPE), colorants, processing aids and the like.

[0037] The Applicant was initially concerned that introduction of a catalyst might disrupt the COC matrix and even create gaps in the polymeric structure, thereby negatively impacting the anti-scalping properties (i.e., resistance migration of chemicals, such as pharmacological active agents or excipients, from the product to the film/layer) of the oxygen scavenging films of this disclosure. Anti-scalping performance is an important consideration for a number of the pharmaceutical products (e.g., nicotine patches or fentanyl patches, lidocaine patches, e-cigarette cartridges, intermediate and bulk transport of the same, iodine, alcohol wipes, etc.) that benefit from the films disclosed herein. In earlier work, Applicant found that use of polymers and components in a blend with the COC may undesirably affect the anti-scalping performance of COC, particularly in a product contact layer, (i.e., resistance to migration of chemicals, such as pharmacological active agents or excipients, between the product and the film/layer).

[0038] Applicant was happily surprised when testing indicated that a catalyst did not negatively impact the anti-scalping properties of the oxygen scavenging films of this disclosure. In fact, Applicant unexpectedly observed the opposite of its expected result in nicotine uptake

tests, which indicated an improvement in anti-scalping performance (rather than the expected compromised performance) with the addition of a palladium catalyst.

[0039] In one test, a control film (100% Topas® COC 8007-600) and an oxygen-scavenging film (Topas® COC 8007-600 with 100ppm palladium catalyst, Hycat 280-10119-1 from ColorMatrix) were cut into 1 inch x quarter inch strips and hung from wires in a glass jar containing undiluted liquid nicotine, but not in direct contact with the liquid nicotine. Both sides of the strips were exposed to nicotine vapor. The nicotine uptake of one set of strips was measured at 2 weeks, the other set of strips at 4 weeks, by immediately (upon removal from its respective jar) dissolving each strip in 1.5ml Isopropanol overnight to help ensure extraction. Gas chromatography was used to analyze the resultant solutions. Table 1 shows the results of the strips analyzed at 2 weeks reporting the area beneath the characteristic peak of nicotine, an indication of the quantity of nicotine present. Table 2 shows the results of the strips analyzed at 4 weeks.

Table 1 – Nicotine Uptake at 2 weeks

	CONTROL FILM (100% Topas COC 8007-600)	OXYGEN-SCAVENGING FILM (Topas COC 8007-600 with 100ppm palladium catalyst, Hycat 280-10119-1 from ColorMatrix)
SAMPLE 1	48.1	44.3
SAMPLE 2	53.0	43.5
SAMPLE 3	49.4	43.4
AVERAGE	50.2	43.7

Table 2 – Nicotine Uptake at 4 weeks

	CONTROL FILM (100% Topas COC 8007-600)	OXYGEN-SCAVENGING FILM (Topas COC 8007-600 with 100ppm palladium catalyst, Hycat 280-10119-1 from ColorMatrix)
SAMPLE 1	51.7	48.3
SAMPLE 2	61.8	44.1
SAMPLE 3	54.8	54.0
AVERAGE	56.1	48.8

[0040] Notably, achieving the benefits of embodiments of the oxygen scavenging films and packages disclosed herein involves utilizing a gas flush of the product storage space that includes hydrogen gas rather than utilizing a hydrogen generator. Use of hydrogen generators can be particularly disadvantageous for pharmaceutical applications because hydrogen generators require moisture-activation. As noted above, moisture can detrimentally affect the integrity of many pharmaceutical products; thus, it is desirable to minimize moisture in a package, particularly avoiding a need to include it for the system to function.

[0041] The oxygen scavenging films of the present disclosure further include a gas barrier layer. The gas barrier layer is configured to prevent the ingress of oxygen to a sealed package and the egress of hydrogen from a sealed package. As will be discussed in more detail below, prevention of the egress of hydrogen is particularly desirable because hydrogen retention can facilitate the continuation of the catalyzed reactions between molecular hydrogen and oxygen well after the package has been closed (by heat seal, cold seal, or other suitable method known to those of skill in the art). To effectively reduce the oxygen level inside the package to zero or other sufficiently low percent by weight, the hydrogen level needs to remain high enough so as not to become the limiting factor in the catalyzed reaction.

[0042] In this way, a product storage space or headspace that is sufficiently oxygen-free (sufficiently oxygen-free being dependent on the application) for many oxygen-sensitive products can be achieved. What's more, an oxygen-free headspace can be achieved, where an oxygen-free headspace for the purposes of the discussion of oxygen-sensitive pharmaceutical products in this application is a headspace that achieves 0.0% oxygen gas by volume. Applicants have achieved a headspace measuring less than 0.0 % oxygen as measured by an Agilent 7890A Gas Chromatograph with a 5975C MSD detector in selective ion mode. In one such case, the oxygen in the headspace was measured to be 75ppm, or 0.0075% oxygen by volume. Before oxygen measurements were taken, the machine was calibrated using a two point (2.1 and 21%) oxygen calibration curve. A gas tight syringe was used to remove 1 ml of headspace from a test pouch. This headspace was injected into the GC, and the resulting area of the oxygen peak was recorded. The oxygen content of the headspace was then determined to be 75 ppm utilizing this peak and the oxygen calibration curve.

[0043] More generally, sufficiently oxygen-free may be considered in terms of percent of oxygen gas by volume or by other relevant metrics. For example, sufficiently oxygen-free may be examined by the percent change in the oxygen percent by volume between two relevant periods of time, such as a point (1) promptly following closing the package and a point (2) X number of days later (e.g., X=1,2, 5, 10, 365, etc.). The desirable metric may depend on the application. For instance, the same type of package may be run through two different gas flush processes, one resulting in a starting oxygen gas percent by volume of 2% and the other 1%; in such a case, the same percent volume reduction in the oxygen gas content between the same start and end points may be sufficient for one and insufficient for the other (e.g., an 90% reduction in oxygen between closing and day 10 might leave 0.2% oxygen gas by volume in one headspace and 0.1% in the other; if a sufficiently oxygen-free headspace for the application is 0.15% oxygen gas by volume, then one package is sufficiently oxygen-free where the other is not).

OXYGEN SCAVENGING FILM

[0044] Referring to FIG. 1, an oxygen scavenging film 100 is shown including a product contact layer 112, gas barrier layer 114, and an exterior layer 116 according to an exemplary embodiment.

[0045] According to an exemplary embodiment, layers 112, 114 and 116 are be combined by coextrusion methods (e.g., blown film coextrusion).

[0046] According to other exemplary embodiments, adhesive layers may be disposed between layers 112 and 114 and layers 114 and 116, but are not shown for simplicity and clarity. Any adhesive layer suitable for promoting adhesion between the respective layers may be used, as would be understood by one of skill in the art.

[0047] According to still other exemplary embodiments, a combination of adhesive lamination and coextrusion may be used to combine the layers of the oxygen scavenging film 100.

[0048] It is further contemplated that other layers may be disposed between layers 112 and 114 and layers 114 and 116 (e.g., to serve functional purposes, such as a primer layer).

[0049] Referring further to FIG. 1, the product contact layer 112 comprises COC and one or more hydrogenation-accelerating catalysts that catalyze the scavenging of oxygen (e.g., a palladium catalyst, a platinum catalyst, a combination of such catalysts, etc.). As will be discussed in more detail below, COC provides particularly good anti-scalping benefits that are particularly beneficial for packaging of pharmaceutical products that have pharmaceutical active agents.

[0050] It is contemplated that the product contact layer 112 may comprise a blend of COC and another thermoplastic material such as, but not limited to homopolymers and copolymers of polyethylene. It is also contemplated that COC may be the only thermoplastic material in the product contact layer 112.

[0051] According to an exemplary embodiment, the product contact layer 112 comprises at least 90 wt. % of a COC. According to some of the exemplary embodiments wherein the product contact layer 112 comprises at least 90 wt. % of an ethylene norbornene copolymer, the ethylene norbornene copolymer has a glass transition temperature in a range from 50°C to 138°C; as discussed in more detail in International Application No. PCT/2015/015246 entitled “Anti-Scalping Pharmaceutical Packaging Film”, which is incorporated herein by reference, these exemplary embodiments provide particularly beneficial resistance to migration of chemicals, such as pharmacological active agents or excipients, between the product and the film.

[0052] According to another exemplary embodiment, the product contact layer comprises at least 75 wt. % of an ethylene norbornene copolymer. The remaining 25 wt. % may include another thermoplastic material such as, but not limited to homopolymers and copolymers of polyethylene.

[0053] According to still other exemplary embodiments, the product contact layer may comprise less than 75 wt. % COC. Depending on the anti-scalping needs for the application, the remaining wt. % may beneficially include, among other things, other thermoplastic materials with relatively good anti-scalping properties.

[0054] According to an exemplary embodiment, forming the product contact layer includes providing a COC, providing a palladium catalyst, and compounding the catalyst (e.g., in the form of a palladium nanoparticle solution) with the COC. One example of a commercially available COC resin for use in the present invention is Topas 8007-600 from Topas Advanced Polymers, although other types of COC resins may be used according to other exemplary embodiments. Exemplary of a commercially available palladium nanoparticle solution is Hycat 280-10119-1 from ColorMatrix Group. Standard compounding processes can be used to introduce the palladium nanoparticle solution into a polymer melt, as would be understood by those of skill in the art. Alternatively, known, albeit less common, methods of incorporating the catalyst into the polymer may include performing this operation during polymerization. It should be noted that

the catalyst need not be a nanoparticle catalyst. Rather, suitable catalyst sizes include the range wherein the catalyst does not detrimentally disrupt anti-scalping performance (given the application) or other key product layer performance characteristics.

[0055] The catalyst is desirably present in the product contact layer 112 at a level high enough to achieve desirable oxygen scavenging, but not so high as to undesirably affect other performance considerations (e.g., anti-scalping performance, tackiness, color, etc.) for the product contact layer.

[0056] According to an exemplary embodiment, in a product contact layer utilizing Topas 8007-600 and Hycat 280-10119-1, the palladium catalyst is desirably present in the product contact layer within the range of 25ppm to 200ppm. Generally, the lower limit of the range reflects the amount of the catalyst included to achieve the desired oxygen reduction. The upper limit generally reflects the amount at which the addition of additional palladium catalyst particles undesirably impacts the performance of the compound to be formed into the product contact layer. Above 200ppm, it was found that the Topas 8007-600 and Hycat 280-10119-1 compound used to form the product contact layer became undesirably tacky.

[0057] According to other exemplary embodiments, a palladium catalyst is desirably present in a product contact layer within the range of 20ppm to 400ppm.

[0058] According to an exemplary embodiment, the product contact layer comprises a palladium catalyst at 100PPM.

[0059] According to an exemplary embodiment, the product contact layer comprises a palladium catalyst at 75PPM.

[0060] According to an exemplary embodiment, the product contact layer comprises a palladium catalyst at 125PPM.

[0061] According to still other exemplary embodiments, the desirable range of the palladium catalyst (in ppm) may vary depending on the COC type/blend, catalyst format and/or catalyst type.

[0062] According to still other exemplary embodiments, it is contemplated that additives may be included in the product contact layer (e.g., processing additives).

[0063] Referring further to FIG. 1, the gas barrier layer 114 is disposed exterior to the product contact layer 112 (i.e., relative to the product storage space). As noted earlier, the gas barrier layer helps prevent ingress of oxygen and egress of hydrogen (and other gasses) to a closed package (e.g., sealed, heat sealed, cold sealed, etc.). Practically, this means that, in combination with product contact layer 112, gas barrier layer 114 helps retain hydrogen and facilitates achieving an oxygen-free headspace of a package made from the film 100 (or at least a sufficiently oxygen-free headspace, depending on the application). According to the exemplary embodiment shown, the gas barrier layer 114 includes a metallic foil. According to other exemplary embodiments, the gas barrier layer may comprise any metallic foil such as, but not limited to, aluminum, tin, copper, blends thereof and the like; these materials are well known in the art. According to still other exemplary embodiment, the gas barrier layer comprises a metallized polymer layer. Any conventional metallization technique known to those skilled in the art can be used to form a metallized polymer layer. One exemplary metallization technique is vacuum deposition wherein the metal is vacuum evaporated and then deposited onto the polymer layer. (See, William Goldie in *Metallic Coating of Plastics*, Vol. 1, Electrochemical Publications Limited, Chap. 12 (1968).) A metal may be deposited onto a polymer layer by vapor deposition techniques, typically by applying the molten metal under vacuum by such techniques as electron beam evaporation, sputtering, induction heating, or thermal evaporation. A particularly specific technique for metallization is by electron beam vacuum evaporation deposition methods. According to some embodiments of a metallized polymer layer, the average thickness of the metal is within the range of about 1.0 to 100 nanometers. According to other exemplary embodiments of a metallized polymer layer, the average thickness of the metal is

within the range of about 3 to 25 nanometers. (1 micron equals 10^{-7} meters, and 1 nanometer equals 10^{-8} meters.) Regardless, it is generally desirable that the metal coating has a thickness less than the polymer substrate on which it is deposited, preferably substantially less than said substrate.

[0064] Referring further to FIG. 1, the exterior layer 116 is the exterior or outermost layer of the film 100 according to an exemplary embodiment. The exterior layer 116 is configured to prevent damage to a product in a package formed from a film 100 due to handling and other external influences. In addition, the exterior layer 116 is configured to prevent damage to the product contact layer 112 and the gas barrier layer 114. According to the exemplary embodiment shown in FIG. 1 the exterior layer 116 is a biaxially oriented polyester terephthalate (OPET).

[0065] According to other exemplary embodiments, the exterior layer may include, but is not limited to, aromatic polyesters such as, but not limited to, polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG), aliphatic polyesters such as, but not limited to, polylactic acid (PLA); polyhydroxyalkonates including but not limited to polyhydroxypropionate, poly(3-hydroxybutyrate) (PH3B), poly(3-hydroxyvalerate) (PH3V), poly(4-hydroxybutyrate) (PH4B), poly(4-hydroxyvalerate) (PH4V), poly(5-hydroxyvalerate) (PH5V), poly(6-hydroxydodecanoate) (PH6D); or polyamides such as, but not limited to, oriented and unoriented nylon 6, nylon 66, nylon 6/66 and blends thereof, polystyrenes such as, but not limited to, high impact polystyrene (HIPS), general purpose polystyrene (GPPS), and styrene block copolymer (SBC). HIPS is sometimes called rubber-modified polystyrene and is normally produced by copolymerization of styrene and a synthetic rubber. (See Wagner, et al., "Polystyrene," The Wiley Encyclopedia of Packaging Technology, Second Edition, 1997, pp. 768-771 (John Wiley & Sons, Inc., New York, New York).) Examples of HIPS include but are not limited to Impact Polystyrene 825E and Impact Polystyrene 945E, both of which are available from Total Petrochemicals USA, Inc.; EB6025 Rubber Modified High Impact

Polystyrene, which is available from Chevron Phillips Company (The Woodlands, Texas); and 6210 High Impact Polystyrene, which was at one time available from Ineos Nova LLC (Channahon, Illinois). Alternatively, the thermoplastic film may comprise a polyolefin such as polyethylene including, but not limited to, high density polyethylene (HDPE), medium density polyethylene (MDPE), low density polyethylene (LDPE), linear low density polyethylene (LLDPE), very low density polyethylene (VLDPE), ultra-low density polyethylene (ULDPE) and blends thereof, or polypropylene and blends thereof. A non-limiting example of high density polyethylene includes Alathon® M6020 from Equistar Chemicals LP (Houston, Tex.). Other specific non-limiting examples of HDPE include Alathon® M6020 available from Equistar Chemicals LP (Houston, Tex.); Alathon® L5885 available from Equistar Chemicals LP (Houston, Tex.); ExxonMobil™ HDPE HD 7925.30 available from ExxonMobil Chemical Company (Houston, Tex.); and ExxonMobil™ HDPE HD 7845.30 available from ExxonMobil Chemical Company (Houston, Tex.). In one particular embodiment, the thermoplastic film is uniaxially oriented. In another particular embodiment, the thermoplastic film is biaxially oriented.

[0066] According to still other exemplary embodiments, the exterior layer includes paper or a paper-like material.

[0067] FIG. 2 shows another exemplary embodiment of an oxygen scavenging film 200 including a product contact layer 212 and a gas barrier layer 214 according to an exemplary embodiment. The film 200 is substantially similar to film 100 except that film 200 does not include an exterior layer. Film 200 may be itself used to form an oxygen scavenging package or may be coupled to one or more additional films to achieve desired film characteristics (e.g., laminated to a semi-rigid thermoformable packaging material) before being formed into a package.

[0068] FIG. 3 shows another exemplary embodiment of an oxygen scavenging film 300 including a product contact layer 312, a gas barrier layer 314, and an exterior layer 316 according to an exemplary embodiment. According to this exemplary embodiment, the film 300

is palindromic (e.g., the structure is A/B/A, A/B/C/B/A, etc.), both the product contact layer and the exterior layer comprising COC and a catalyst. In some exemplary embodiments the catalyst is a palladium catalyst that is present in the range of 50-200ppm. In other exemplary embodiments, a film may be substantially palindromic wherein the product contact layer includes COC and a catalyst, while the exterior layer comprises COC but no catalyst.

[0069] The gas barrier layer 314 comprises EVOH according to an exemplary embodiment. EVOH is otherwise known as saponified or hydrolyzed ethylene vinyl acetate copolymer, and refers to a vinyl alcohol copolymer having an ethylene comonomer. EVOH is generally prepared by the hydrolysis (or saponification) of an ethylene-vinyl acetate copolymer. The degree of hydrolysis is preferably from about 50 to 100 mole percent, more preferably, from about 85 to 100 mole percent, and most preferably at least 97%. It is well known that to be a highly effective oxygen barrier, the hydrolysis-saponification must be nearly complete, i.e. to the extent of at least 97%. EVOH is commercially available in resin form with various percentages of ethylene and there is a direct relationship between ethylene content and melting point. For example, EVOH having a melting point of about 175° C or lower is characteristic of EVOH materials having an ethylene content of about 38 mole% or higher. EVOH having an ethylene content of 38 mole% has a melting point of about 175° C. With increasing ethylene content the melting point is lowered. Also, EVOH polymers having increasing mole percentages of ethylene have greater gas permeabilities. A melting point of about 158° C corresponds to an ethylene content of 48 mole %. EVOH copolymers having lower or higher ethylene contents may also be employed. It is expected that processability and orientation would be facilitated at higher contents; however, gas permeabilities, particularly with respect to oxygen, may become undesirably high for certain packaging applications which are sensitive to microbial growth in the presence of oxygen. Conversely, lower contents may have lower gas permeabilities, but processability and orientation may be more difficult.

[0070] FIG. 4 highlights another exemplary oxygen scavenging film. Like oxygen scavenging film 300 of FIG. 3, the oxygen scavenging film 400 shown in FIG. 4 includes a product contact

layer 412 comprising COC and a catalyst, a gas barrier layer 414 that comprises EVOH, and an exterior layer 416 that comprises COC. Oxygen scavenging film 400 further includes layers 420 and 422, layer 420 being interior to gas barrier layer 414 and layer 422 being exterior to gas barrier layer 414. According to one exemplary embodiment, layers 420 and 422 include HDPE. Layers 420 and 422 are configured to protect the EVOH gas barrier layer from moisture. According to other exemplary embodiments, layers 420, 422 may provide this and/or other benefits (e.g., structural, processing, etc.).

[0071] It will be appreciated by those reviewing this disclosure that the exemplary films disclosed herein may further include layers in addition to the product contact layer and gas barrier layer. This includes an exterior layer as well as other layers that may be disposed between the product contact layer and the gas barrier layer and/or disposed between the gas barrier layer and an exterior layer.

PACKAGE

[0072] The oxygen scavenging films of the present disclosure may be used to make pharmaceutical packaging in any number of formats. The films are particularly beneficial for transdermal patch applications, oral strip applications, e-cigarette cartridge applications, and other pharmaceutical applications involving oxygen-sensitive pharmaceutical active agents; for these applications the integrity of these pharmaceutical active agents may be detrimentally impacted by a number of externalities, one of them being oxygen.

[0073] Moreover, as discussed earlier in this disclosure, another significant consideration for pharmaceutical packaging for many pharmaceutical products involving pharmaceutical active agents is the ability of the film to resist migration of the pharmacological active agents (or excipients) between the product and the film; stated otherwise, it is desirable for packaging for these applications to be anti-scalping. The Applicant was recently surprised to find that COC provides particularly good anti-scalping performance, as disclosed in PCT/US2015/015246 filed on February 10, 2015 and titled "Anti-Scalping Pharmaceutical Packaging Film". It is disclosed therein that both the glass transition temperature of the layer comprising ethylene

norbornene copolymer and the Hansen Solubility Parameter (HSP) of the active pharmacological agent to be stored in contact (direct or indirect) with the product contacting layer comprising ethylene norbornene copolymer can be factors in determining whether the product contacting layer can serve as an effective anti-scalping layer. Thus, it is understood that some embodiments of the films disclosed herein are particularly beneficial where the Hansen Solubility Parameter RED values of one or more of the excipients for the COC are 0.5 or greater. More desirably, the RED values are 0.6, 0.7, 0.8, 0.9, or 1 or greater.

[0074] Referring to FIGS. 5 and 5A, an oxygen scavenging pharmaceutical package 500 that is a flat format pouch for a transdermal patch, oral strip or similar application is shown made from a suitable oxygen scavenging film of this disclosure, such as film 100, according to an exemplary embodiment. The package 500 includes a product storage space 510 that is shown containing an exemplary product 502 such as a transdermal patch or oral thin strip and otherwise defining a headspace 512.

[0075] Referring in particular to FIG. 5A, the package 500 includes a first side wall 514 generally opposite a second side wall 516 with the product storage space 510 being located generally therebetween according to an exemplary embodiment. The first side wall 514 is shown coupled to the second side wall 516 by a heat seal 518. According to exemplary embodiments, the package is made exclusively (e.g., both of the first side wall and the second side wall) of an oxygen scavenging film of the present disclosure (e.g., film 100, film 200, film 300, film 400)). In some of these exemplary embodiments one oxygen scavenging film structure is used to make the package (e.g., using a form fill seal process including sealing the product contact layer of the film to itself), while in other exemplary embodiments more than one oxygen scavenging film structure may be used in combination to make a package. According to still other exemplary embodiments, films other than those of this disclosure may be used in combination with the oxygen scavenging films of this disclosure (e.g., the first side wall is an oxygen scavenging film of this disclosure and the second side wall is not).

[0076] The head space 512 is shown as being sufficiently oxygen-free, and, in fact, oxygen-free (having less than 0.0% oxygen by volume). As will be discussed in more detail below, to achieve the oxygen-free headspace 512, a gas flush was introduced to the product storage space 510 through a gas flush opening (see, e.g., FIG 7A) before package 500 was closed (here, by heat sealing). The gas flush comprised hydrogen. The hydrogen reacted with oxygen to reduce the level of oxygen within the head space, catalyzed by the palladium catalyst.

[0077] According to the exemplary embodiment, the first side wall 514 and the second side wall 516 of the package 500 both comprise a multilayer film that is film 100.

[0078] According to an another exemplary embodiment, one of the first side wall and the second side wall comprises a film according to the present disclosure (e.g., film 100) and the other of the first side wall and the second side wall is any film that includes a gas barrier layer.

[0079] For example, the other wall comprises a product contact layer including COC, a gas barrier layer that is foil, and an exterior layer that includes a polyester, such as polyester terephthalate (PET). As another example, the other wall includes an ethylene copolymer and a gas barrier layer.

[0080] According to other exemplary embodiments, the first side wall 514 and the second side wall 516 of the package 500 both comprise a multilayer film that is film 300.

[0081] Referring to FIGS. 6 and 6A, an oxygen scavenging pharmaceutical package 600 for a pharmaceutical product that includes a pharmaceutical active agent is shown according to an exemplary embodiment. The package 600 is shown as a blister package including a product storage space 610 that is shown containing an exemplary pharmaceutical product 602 (e.g., an e-cigarette cartridges, a tablet, a capsule, a lozenge, etc.) and otherwise defining a headspace 612. It should be noted that, for ease of discussion, product storage space 610 will be used to refer collectively to the plurality of product storage spaces as shown in the blister package, headspace 612 will similarly be used to collectively refer to the headspaces as shown, and pharmaceutical product 602 will be used to collectively refer to the products as shown. That being said, it will be

understood more generally that a package may include one or more product storage spaces, each product storage space being singular or collective of more than one subspace (e.g., similar to pockets 620). Relatedly, a given product storage space (or subspace) may include one or more products for some applications (e.g., each pocket 620 may include one or more than one pharmaceutical products).

[0082] Referring in particular to FIG. 6A, the package 600 comprising an oxygen scavenging film of the present disclosure includes a lid 614, shown as blister lidding or a top blister component, generally opposite a container 616, shown as a blister base or bottom component, with the product storage space 610 being generally defined by pockets 620 according to an exemplary embodiment. The lid 614 is shown coupled to the container 616 by a heat seal 618.

[0083] The headspace 612 is shown sufficiently free of oxygen. As will be discussed in more detail below, to achieve the sufficiently oxygen-free headspace 612, a gas flush was introduced to the product storage space 610 before the lid 614 was sealed to the container 616 to close package 600. The gas flush comprises hydrogen. The hydrogen reacts with oxygen to reduce the level of oxygen within the head space, catalyzed by the palladium catalyst.

[0084] According to an exemplary embodiment, the lid 614 comprises the oxygen scavenging film 100.

[0085] According to another exemplary embodiment, lid 614 comprises an alternative of the oxygen scavenging film 100 wherein the exterior layer is paper rather than OPET. According to other exemplary embodiments, the lid 614 comprises any oxygen scavenging film according to the present disclosure suitable for use as a blister lidding component. According to still other exemplary embodiments, the lid 614 is not an oxygen scavenging film, but is any lidding film suitable for use with a blister base component that comprises a suitable oxygen scavenging film according to the present disclosure.

[0086] According to an exemplary embodiment, the container 616 comprises oxygen scavenging film 400.

[0087] According to another exemplary embodiment, the container 616 comprises oxygen scavenging film 300, where oxygen scavenging film 300 a forming web that is thermoformable or thermoforming. According to other exemplary embodiments, the container 616 comprises any oxygen scavenging film according to the present disclosure suitable for use as a blister base component. According to still other exemplary embodiments, the container is not an oxygen scavenging film, but is any blister base component suitable for use with a blister lidding component comprising a suitable oxygen scavenging film according to the present disclosure. According to still other exemplary embodiments, the container comprises a film that is a cold forming film.

[0088] According to one exemplary embodiment, the pharmaceutical product 602 includes e-cigarette cartridges. E-cigarette cartridges include nicotine, which is oxygen-sensitive and susceptible to scalping in many traditional pharmaceutical industry packaging formats. For such an application, it is desirable (though not necessary) to have both the lid and the container comprise oxygen scavenging films according to the present disclosure. For example, including film 100 and film 400, respectively. According to other exemplary embodiments, the product contact layers of both films comprise at least 90 wt.% of COC, at least one of the films being an oxygen scavenging film according to the present disclosure.

[0089] It is worth noting that, when the blister lidding component and blister container component are not both films according to the present disclosure, it may be desirable for the film(s) that are not films according to the present disclosure to have suitable anti-scalping characteristics for use with the given pharmaceutical active agent.

[0090] Even where the films are both films according to this disclosure, the wt.% COC in the product contact layer may be the same or may be different. According to some embodiments, the product contact layers of both films comprise at least 90 wt.% of COC. According to other exemplary embodiments, the product contact layer of one film comprises at least 90 wt.% of COC, while the product contact layer of the other film comprises less than 90 wt.% of COC.

According to still other exemplary embodiments, the product contact layers of both films comprise less than 90 wt.% of COC.

[0091] Referring to FIGS. 8, an oxygen scavenging package 800 that is a pouch or bag comprises an oxygen scavenging film of the present disclosure according to an exemplary embodiment. The package 800 includes a product storage space 810 that is shown containing an exemplary product 802, such as an e-cigarette cartridge, and otherwise defining a headspace 812. A body 820 of the package 800 may be made entirely or in part from one or more of the oxygen scavenging films of the present disclosure. For example, film 100 may be used to make the body 820.

[0092] FIG. 9 shows another exemplary embodiment of an oxygen scavenging package 900 that is a pouch or bag comprises an oxygen scavenging film of the present disclosure.

Referring to FIG. 10, an oxygen scavenging package 1000 that is a bag, specifically an intermediate transport or bulk bag, is shown comprising an oxygen scavenging film of the present disclosure according to an exemplary embodiment. In a product storage space 1010 a pharmaceutical product 1002 is shown as a reel of transdermal patches or oral thin strips.

[0093] Pouch or bag formats such as packages 800, 900, and 1000 are particularly desirable for transporting pharmaceutical products that are in a pre-end-consumer state (e.g., because the products are being transferred in bulk or still require further processing). For example, transdermal patches connected in a reel format may be transported in a bag that is an intermediate form of packaging (e.g., prior to the end-consumer packaging format of a flat-format pouch) for further processing (e.g., separation) at a later time. Of course, the pouches and bags need not be an intermediate packaging format, but may be the end-consumer packaging format (e.g., e-cigarettes cartridges).

[0094] According to an exemplary embodiment, the films of the present disclosure may be used for still other package formats, including, but not limited to, formats where the container is

a tray with lidding and still other formats where the container (e.g., a tray) is in a bag or similar enclosure.

[0095] According to exemplary embodiments, the headspace of the packages disclosed herein may include 1% or less oxygen gas by volume. In some exemplary embodiments, the headspace may include 0.5% or less oxygen gas by volume. In some exemplary embodiments, the headspace may include 0.2% or less oxygen gas by volume. In some exemplary embodiments, the headspace may include 0.1% or less oxygen gas by volume. In other exemplary embodiments, the headspace may be an oxygen-free headspace (0.0 % oxygen gas by volume). In still other exemplary embodiment, a sufficiently oxygen-free headspace can be achieved, where a headspace has reached an oxygen gas level by volume that is suitable or otherwise desirable for a given application. Generally, the oxygen gas measurement assumes a suitable or predetermined passage of time to allow for oxygen scavenging.

[0096] Packages 500, 600, 800, 900, 1000, and others contemplated by this disclosure may be made by any suitable methods known in the art, as would be appreciated by a person of skill in the art.

EXAMPLE 1

[0097] Example 1 is an example film structure and method of manufacture for a film intended for use in packaging pharmaceutical products such as transdermal patches and oral strips. The structure of this exemplary film when finished is OPET/PEI/LDPE/EAA/Aluminum Foil/EAA/LDPE/(COC +palladium).

[0098] The base film was comprised of five layers having an ordered structure of:

[0099] /Layer 1 / Layer 2/ Layer 3/Layer 4/Layer 5/ corresponding to:

[0100] /exterior layer 1 / primer layer 2/bulk layer 3/adhesive layer 4/ barrier layer 5/; or more particularly,

[0101] /OPET/PEI/LDPE/EVA/Aluminum Foil/.

[0102] Layer 1 was a commercially available 0.92 mil, biaxially oriented polyethylene terephthalate (OPET) film corona treated on one side. The treated OPET film received a second corona treatment on the previously treated side prior to receiving an anchor coating of a water-based polyethyleneimine (PEI) primer (Layer 2) that was contact coated onto the corona treated side of the OPET film and dried just prior to lamination of the OPET film to 0.35 mil aluminum foil (Layer 5) using a coextrusion of LDPE (Layer 3) and EAA (Layer 4). Layers 3 and 4 were produced by the two-layer coextrusion of LDPE and EAA. The anchor coated side of the OPET film was laminated to 0.35 mil aluminum foil with a coextrusion of LDPE and EAA. The LDPE was a blend of 87.5 wt.% LDPE laminate resin and 12.5 wt.% of a white colorant in a carrier resin. The oxygen and moisture barrier was provided by a commercially available packaging grade aluminum foil.

[0103] A three-layer coextrusion of EAA, LDPE and a blend of ethylene-norbornene copolymer (COC) and palladium nanoparticles is extrusion coated onto the corona treated aluminum foil.

[0104] The film is well suited to package articles for collecting or administering a pharmaceutical product including a pharmaceutical active agent, such as transdermal drug delivery patches or oral thin strips. The film has advantageous moisture barrier, oxygen barrier, anti-scalping properties, as well as oxygen scavenging when the package is flushed with a gas flush including hydrogen as discussed later in this disclosure.

EXAMPLE 2

[0105] Example 2 is an example film structure and method of manufacture for a film intended for use as a lidding for a blister package. The structure of this exemplary film when finished is aluminum foil/EAA/LDPE/(COC + palladium)

[0106] A three-layer coextrusion of EAA, LDPE and a blend of ethylene-norbornene copolymer (COC) and palladium nanoparticles is extrusion coated onto the corona treated aluminum foil.

EXAMPLE 3

[0107] Example 3 is an example film structure and method of manufacture for a film intended for use as a container that is a blister base component for a blister package. The film is a cold forming film. The structure of this exemplary film when finished is aluminum OPA/adhesive/aluminum/EAA/LDPE/(COC + palladium)

[0108] The film may be manufactured by adhesive laminating the OPA to aluminum foil. EAA, LDPE, and the COC + palladium are coextruded. The lamination and coextrusion are then extrusion laminated together (the EAA adjacent to the aluminum foil).

METHOD OF ACHIEVING A SUFFICIENTLY OXYGEN-FREE HEADSPACE AND/OR OXYGEN-FREE HEADSPACE

[0109] Exemplary embodiments of a method for achieving a sufficiently oxygen-free headspace in a pharmaceutical package include utilizing an oxygen scavenging film according to the present disclosure. As discussed in more detail above, these oxygen scavenging films comprise a gas barrier layer and a product contact layer comprising COC and hydrogenation-accelerating palladium (or platinum) catalyst. A gas flush is introduced into a pharmaceutical storage space of the package. The gas flush includes hydrogen that combines with oxygen in the presence of a catalyst to remove the oxygen gas from the headspace.

[0110] Referring to FIGS. 7A and 7B, the pharmaceutical package is a flat format pouch 700 particularly well suited for transdermal patch and oral strip applications according to an exemplary embodiment. FIG. 7A shows the package 700 wherein the product storage space 710

is shown having an opening 704 providing access thereto. The pharmaceutical product 702 (e.g., a transdermal patch or oral strip) is shown already positioned in the product storage space 710. A gas flush 706 is introduced through opening 704, which functions as the gas flush opening. The upper limit of a range of the ratio of inert gas to hydrogen gas in the gas flush should reflect the flammability limit of the hydrogen gas in the flush (i.e., being lower than that limit). The lower end of the ratio range desirably reflects a quantity that is sufficient to react with the required amount of oxygen, as defined by the application. An exemplary gas flush includes nitrogen gas and hydrogen gas in a ratio in the range of 99.5:0.5–94.6:5.4. According to a particular embodiment, the gas flush includes nitrogen gas and hydrogen gas in an approximate ratio of 95:5. As would be appreciated by one of skill in the art, any suitable method of introducing the gas flush for such an application may be utilized. Generally, the flush may include inert gases other than nitrogen gas (e.g., carbon dioxide, etc.).

[0111] Referring in particular to FIG. 7B, a heat seal 718 is subsequently completed so that it completely encloses the product storage space 710 and formally defines a headspace 712 of the product storage space 710. Immediately after the gas flush, a reduced amount of oxygen gas remains (e.g., 0.5-2% of the headspace by volume is oxygen gas). The palladium catalyst catalyzes the reaction between the molecular hydrogen and the molecular oxygen. Because of the gas barrier layer, the hydrogen substantially remains in the product storage space 710 and additional oxygen gas is substantially prevented from entering the product storage space 710. The molecular hydrogen and the molecular oxygen continue to react, catalyzed by the palladium catalyst, until the headspace 712 is sufficiently free of oxygen gas. No additional energy sources, generators or other inserts are required. The pharmaceutical product 702 is substantially uncompromised by oxygen or moisture. No additional inputs or steps are required after the package 700 is sealed closed to remove the oxygen.

[0112] Utilizing the above-described gas flush process, a film sample of COC with 100ppm Pd was compared to a high oxygen barrier lamination containing foil and Barex® resin by INEOS as the sealant. Table 3 shows the results in % volume of oxygen gas.

Table 3 – oxygen gas percentages by volume

	Day 0	Day 4	Day 6	Day 12
COC w/100ppm Pd	0.8%	0.3%	0.2%	0.1%
Barex	0.8%	0.8%	0.8%	0.8%

[0113] As indicated in Table 3, the sample of COC with 100ppm palladium catalyst significantly reduced the oxygen in the headspace of the 6 inch by 6 inch foil based pouches, whereas the oxygen level in the foil based pouch with the Barex® sample enclosed therein remained constant.

[0114] It is worth noting that the oxygen percentage by volume may be reduced to a sufficient or even oxygen-free level more quickly than indicated by this test. For example, a package with a smaller headspace and larger surface area will scavenge faster. For example, Applicant was able to provide an oxygen-free environment within a test package in less than one day. As would be understood by a person of skill in the art, other factors may impact the rate of reduction of oxygen by percent volume (e.g., temperature, catalyst distribution within the polymer (e.g., including considering layer thickness), catalyst loading level, etc.).

EXAMPLE 4

[0115] Applicant created a film including a product contact layer comprising COC (Topas® 8007F-600) and palladium catalyst (ColorMatrix Hycat 280-10119-1) at about 100ppm. This film was formed using a collapsed bubble method of manufacture; accordingly, both the product contact layer and the exterior layer comprise COC (Topas® 8007F-600) and palladium catalyst (ColorMatrix Hycat 280-10119-1) at 100ppm. A 3 inch by 3 inch sample of the film (i.e., total scavenger surface area of 18in²) was placed in a 5 inch by 5 inch pouch (~150cc internal volume) made from a clear barrier film along with 1mL of liquid nicotine in the product storage space of the pouch. The headspace of the pouch was flushed with a 95:5 nitrogen-to-hydrogen gas mixture and hermetically sealed. An initial headspace oxygen level was measured using a calibrated Mocon® Checkpoint II Portable Headspace Analyzer (i.e. Day 0 oxygen levels given in Table 4). Headspace oxygen levels could be tested by other common methods including

internal package indicators such as the Mocon® Optech O2 model P. The pouch was stored at 39°C, 16% RH, and the oxygen gas level was measured at various time intervals, as seen in Table 4. The pouches were resealed after each headspace test. The tests were run in duplicate, using the same oxygen scavenging film. As can be seen from the results in Table 4 below, both films according to the present disclosure achieved an oxygen-free headspace.

Table 4 – oxygen gas percentages by volume

	Day 0	Day 1	Day 6	Day 9
Oxygen scavenging film 1	1.4	1.1	0.2	0.1
Oxygen scavenging film 2	0.9	0.7	0.0	0.0

[0116] It is contemplated that films may not include a gas barrier layer, the oxygen scavenging capabilities of the product contact layer (the product contact layer being as described above) being sufficient for the application (i.e., type of product, level of oxygen sensitivity, storage needs, etc.).

[0117] It is further contemplated that the layer comprising COC and a palladium (or platinum) catalyst may be disposed exterior to a product contact layer. For example, a layer of COC may be disposed immediately adjacent to the product storage space and the layer comprising COC and palladium catalyst is exterior thereto. In still other exemplary embodiments, a relatively thin layer of a polymer (e.g., PE or other polyolefin, APET) may be disposed immediately adjacent to the product storage space and another layer comprising COC and palladium catalyst is exterior thereto. In addition, a product contact layer comprising COC and palladium may be discontinuously exposed (e.g. under a pattern applied cold seal layer). Alternatively, the discontinuous layer may comprise COC and palladium catalyst (e.g., pattern applied).

[0118] It is further contemplated that the films and other aspects of this disclosure may be utilized beneficially for applications other than pharmaceutical applications for which it is desirable to scavenge oxygen (e.g., food, beverages, etc.).

[0119] It is further still contemplated that the films, packages, and other aspects of this disclosure may be utilized in combination with desiccant technologies or other moisture absorbing technologies (e.g., for applications where the product has an especially high water sensitivity.)

[0120] As used herein, unless otherwise indicated, "product contact layer," generally refers to the interior surface film layer of a package, whether or not the product contained in the package is in contact with that surface film layer. In a packaged product, the product contact layer can be in contact with the pharmaceutical active agent. As used herein, "in contact with the pharmaceutical active agent," in the context of a layer of a film, means that under typical storage conditions some portion of the active agent will contact the layer. The active agent may be in direct contact with the product contacting layer or may be in indirect contact with the layer. Indirect contact between the active agent and the product contacting layer can occur, for example, due to volatilization of the active agent or an active agent carrier within the package to cause the active agent, which is not stored in direct contact with the product contacting layer, to contact the layer. However, even if the active agent is not in contact with the sealing layer, it may be desirable for the product contact layer to be anti-scalping to provide assurance that if an active agent accidentally became exposed to the sealing layer, the sealing layer would not substantially scalp the active agent.

[0121] The term "adhesive layer," or "tie layer," refers to a layer or material placed on one or more layers to promote the adhesion of that layer to another surface. Preferably, adhesive layers are positioned between two layers of a multilayer film to maintain the two layers in position relative to each other and prevent undesirable delamination. In some exemplary embodiments a peelable tie layer may be used which is designed to have either cohesive failure or delamination from one or both adjacent layers upon application of a suitable manual force to provide an opening feature for a package made from the film. Unless otherwise indicated, an adhesive layer can have any suitable composition that provides a desired level of adhesion with the one or more surfaces in contact with the adhesive layer material. Optionally, an adhesive layer placed

between a first layer and a second layer in a multilayer film may comprise components of both the first layer and the second layer to promote simultaneous adhesion of the adhesive layer to both the first layer and the second layer to opposite sides of the adhesive layer.

[0122] As used herein, singular forms “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a “structured bottom surface” includes examples having two or more such “structured bottom surfaces” unless the context clearly indicates otherwise.

[0123] As used herein, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements. The use of “and/or” in certain instances herein does not imply that the use of “or” in other instances does not mean “and/or”.

[0124] As used herein, “have”, “has”, “having”, “include”, “includes”, “including”, “comprise”, “comprises”, “comprising” or the like are used in their open ended inclusive sense, and generally mean “include, but not limited to”, “includes, but not limited to”, or “including, but not limited to”.

[0125] “Optional” or “optionally” means that the subsequently described event, circumstance, or component, can or cannot occur, and that the description includes instances where the event, circumstance, or component, occurs and instances where it does not.

[0126] For purposes of the present disclosure, recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.). Where a range of values is “greater than”, “less than”, etc. a particular value, that value is included within the range.

[0127] Any direction referred to herein, such as “top,” “bottom,” “left,” “right,” “upper,” “lower,” “above,” “below,” and other directions and orientations are described herein for clarity in

reference to the figures and are not to be limiting of an actual device or system or use of the device or system. Many of the devices, articles or systems described herein may be used in a number of directions and orientations.

[0128] Unless otherwise expressly stated, it is in no way intended that any method set forth herein be construed as requiring that its steps be performed in a specific order. Accordingly, where a method claim does not actually recite an order to be followed by its steps or it is not otherwise specifically stated in the claims or descriptions that the steps are to be limited to a specific order, it is no way intended that any particular order be inferred. Any recited single or multiple feature or aspect in any one claim can be combined or permuted with any other recited feature or aspect in any other claim or claims.

[0129] It is also noted that recitations herein refer to a component being “configured” or “adapted to” function in a particular way. In this respect, such a component is “configured” or “adapted to” embody a particular property, or function in a particular manner, where such recitations are structural recitations as opposed to recitations of intended use. More specifically, the references herein to the manner in which a component is “configured” or “adapted to” denotes an existing physical condition of the component and, as such, is to be taken as a definite recitation of the structural characteristics of the component.

[0130] While various features, elements or steps of particular embodiments may be disclosed using the transitional phrase “comprising,” it is to be understood that alternative embodiments, including those that may be described using the transitional phrases “consisting” or “consisting essentially of,” are implied.

[0131] Thus, methods, systems, devices, compounds and compositions for oxygen scavenging films and packages made therefrom are described. Various modifications and variations of the invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific embodiments, it should be understood that the invention as claimed should not be unduly limited

to such specific embodiments. Indeed, various modifications of the described modes for carrying out the invention which are apparent to those skilled in film manufacturing or related fields are intended to be within the scope of the following claims.

[0132] It will be apparent to those skilled in the art that various modifications and variations can be made to the present inventive technology without departing from the spirit and scope of the disclosure. Since modifications, combinations, sub-combinations and variations of the disclosed embodiments incorporating the spirit and substance of the inventive technology may occur to persons skilled in the art, the inventive technology should be construed to include everything within the scope of the appended claims and their equivalents.

RECITATION OF NON-LIMITING AND NON-EXCLUSIVE EXEMPLARY EMBODIMENTS

1. An oxygen scavenging film for packaging a product, the film comprising a product contact layer comprising COC and a palladium catalyst.
2. The film of claim 1, wherein the product is an oxygen-sensitive product.
3. The film of any of claims 1 or 1, wherein the product is a pharmaceutical product.
4. An oxygen scavenging film for packaging an oxygen-sensitive pharmaceutical product, the pharmaceutical product comprising a pharmaceutical active agent, the film comprising:
 - a gas barrier layer; and
 - a product contact layer comprising COC and a palladium catalyst.
5. The film of any of claims 1-4, wherein the palladium catalyst is disposed within the COC at a level of 25ppm-400ppm.
6. The film of any of claims 1-5, wherein the palladium catalyst is disposed within the COC at a level of 50ppm-200ppm.

7. The film of any of claims 1-6, wherein the palladium catalyst comprises a nanoparticle palladium catalyst.
8. The film of any of claims 1-7, further comprising an exterior layer, wherein the gas barrier layer is disposed between the exterior layer and the product contact layer.
9. The film of any of claims 1-8, wherein the gas barrier layer comprises a metallic foil layer.
10. The film of any of claims 1-8, wherein the gas barrier layer comprises an EVOH layer.
11. The film of any of claims 1-10, wherein the film is a flexible film.
12. The film of any of claims 1-9, wherein the film is a thermoforming film.
13. The film of any of claims 1-9, wherein the film is a cold forming film.
14. The film of any of claims 1-13, wherein the pharmaceutical active agent is an alkaloid.
15. The film of any of claims 1-14, wherein the pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine.
16. The film of any of claims 1-15, wherein the pharmaceutical product is an e-cigarette cartridge.
17. A package for a pharmaceutical product comprising the film of any of claims 2-13.
18. A flat format package for a pharmaceutical product comprising the film of any of claims 2-9.

19. A blister package for a pharmaceutical product that comprising the film of any of claims 2-16.
20. A blister package component comprising the film of any of claims 2-16.
21. The blister package component of claim 20, wherein the blister package component is a blister lidding component.
22. The blister package component of claim 20, wherein the blister package component is blister base component.
23. A flat format pouch for an oxygen-sensitive thin format pharmaceutical product providing for oxygen scavenging without the presence of a hydrogen generator, the package comprising:
- a thin format pharmaceutical product storage space; and
 - at least one gas-flush opening providing for ingress and egress of gas to the thin format pharmaceutical product storage space; and
 - a first multilayer film comprising:
 - a product contact layer comprising COC and hydrogen-gas-activated palladium catalyst.
24. The flat format package of claim 23, wherein the first multilayer film further comprises a gas barrier layer exterior to the product contact layer.
25. The flat format package of any of claims 23-24, wherein the hydrogen-gas-activated palladium catalyst comprises a nanoparticle hydrogen-gas-activated palladium catalyst.
26. The flat format package of any of claims 23-25, wherein the hydrogen-gas-activated palladium catalyst is disposed in the COC.
27. The flat format package of any of claims 23-26, wherein the palladium catalyst is disposed within the COC of the first multilayer film at a level of 25ppm-400ppm.

28. The flat format package of any of claims 21-27, wherein the palladium catalyst is disposed within the COC of the first multilayer film at a level of 50ppm-200ppm.

29. The flat format package of any of claims 21-28, further comprising a first side wall generally opposite a second side wall, the first side wall and second side wall substantially defining the thin format pharmaceutical product storage space.

30. The flat format package of any of claims 21-29, wherein the first wall comprises the first multilayer film and the second wall comprises a second multilayer film different from the first multilayer film.

31. The flat format package of any of claims 21-29, wherein the first wall and the second wall comprise the first multilayer film.

32. The flat format package of any of claims 21-32, wherein the gas barrier layer of the first multilayer film comprises a metallic foil.

33. The flat format package of any of claims 21-33, wherein the gas barrier layer of the first multilayer film comprises an aluminum foil.

34. The flat format package of any of claims 21-34, wherein the first multilayer film further comprises an exterior layer.

35. The flat format package of any of claims 21-35, wherein the exterior layer of the first multilayer film is PET.

36. The flat format package of any of claims 21-36, wherein the exterior layer of the first multilayer film is OPET.

37. The flat format package of any of claims 21-35, wherein the exterior layer of the first multilayer film comprises paper.

38. The flat format package of claim 30, wherein the second multilayer film comprises a gas barrier layer.

39. The flat format package of claim 38, wherein the gas barrier layer of the second multilayer film comprises a metallic foil.

40. The flat format package of any of claims 38-39, wherein the gas barrier layer of the second multilayer film comprises an aluminum foil.

41. A package for an oxygen-sensitive pharmaceutical product providing for oxygen scavenging without the presence of a hydrogen generator, the package comprising:

at least one pharmaceutical product storage space; and

a first multilayer film comprising:

a product contact layer comprising COC and a hydrogen-gas-activated palladium catalyst; and

a gas barrier layer exterior to the product contact layer; and

a second multilayer film sealable to the first multilayer film.

42. The package of claim 41, wherein the first multilayer film is a lidding film.

43. The package of claim 42, wherein the gas barrier layer of the lidding film comprises a metallic foil layer.

44. The package of any of claims 41-43, wherein the second multilayer film includes a gas barrier layer.

45. The package of any of claims 41-44, wherein the gas barrier layer of the second multilayer film is EVOH.

46. The package of any of claims 41-44, wherein the gas barrier layer of the second multilayer film is a metallic foil layer.

47. The package of any of claims 41-46, wherein the second multilayer film includes a product contact layer, the product contact layer of the second multilayer film comprises COC.

48. The package of any of claims 41-47, wherein the package is a blister package.

49. The package of any of claims 41-46, wherein the package includes a tray.

50. The package of claim 41, wherein the second multilayer film is a lidding film.

51. The package of claim 50, wherein the second multilayer film comprises a gas barrier layer.

52. The package of any of claims 50-51, wherein the gas barrier layer of the second multilayer film comprises a metallic foil.

53. The package of any of claims 50-52, wherein the first multilayer film is a forming web.

54. The package of any one of claims 50-53, wherein the gas barrier layer of the first multilayer film is EVOH.

55. The package of any of claims 50-54, wherein the second multilayer film includes a product contact layer.

56. The package of any of claims 50-55, wherein the product contact layer comprises COC.

57. The package of any of claims 41-56, wherein the first multilayer film is sealed to the second multilayer film and there is 1% or less oxygen gas by volume in a headspace of the pharmaceutical product storage space.

58. The package of any of claims 41-56 wherein the first multilayer film is sealed to the second multilayer film and a headspace of the pharmaceutical product storage space is oxygen-free.

59. The package of any of claims 41-56, wherein the first multilayer film is sealed to the second multilayer film and there is 0.0% oxygen gas by volume in a headspace of the pharmaceutical product storage space.

60. The package of any of claims 41-56, wherein a headspace of the pharmaceutical product storage space includes hydrogen gas and nitrogen gas introduced during a gas flush.

61. The package of any of claims 41-60, wherein the palladium catalyst is a nanoparticles palladium catalyst.

62. The package of any of claims 41-61, wherein the palladium catalyst is dispersed within the COC of the first multilayer film at a level of 25ppm-400ppm.

63. The package of any of claims 41-62, wherein the palladium catalyst is dispersed within the COC of the first multilayer film at a level of 50ppm-200ppm.

64. A method for achieving a sufficiently oxygen-free product storage space in a package, the method including:

utilizing a multilayer packaging film, comprising:

a product contact layer comprising COC and a hydrogen-gas-activated palladium catalyst; and

a gas barrier layer disposed exterior the product contact layer;

wherein the multilayer packaging film at least in part defines the product storage space; and

introducing a gas flush into the product storage space, the gas flush including hydrogen gas.

65. The method of claim 64, wherein the package is a pharmaceutical package.
66. The method of any of claims 64-65, further comprising closing an opening to the product storage space.
67. The method of any of claims 64-66, further comprising providing for the hydrogen-gas-activated palladium catalyst to catalyze an oxidation reaction between molecular hydrogen and molecular oxygen.
68. The method of any of claims 64-67, wherein the gas flush further includes an inert gas.
69. The method of any of claims 64-68, wherein the ratio of the inert gas to hydrogen gas is between about 99.5:0.5 and 94.6:5.4.
70. The method of any of claims 64-69, wherein the ratio is about 95:5.
71. The method of any of claims 64-70, wherein the inert gas is nitrogen.
72. The method of any of claims 64-71, further comprising disposing an oxygen-sensitive product into the product storage space.
73. The method of any of claims 72, wherein the oxygen-sensitive product includes a pharmaceutical active agent.
74. The method of any of claims 72-73, wherein the pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine.
75. The method of any of claims 72-74, wherein the oxygen-sensitive product comprises an alkaloid.

76. The method of any of claims 64-75, wherein the gas barrier layer includes metallic foil.

77. The method of any of claims 64-76, further comprising reducing the oxygen gas content in a headspace of the product storage space to 1% or less by volume oxygen gas.

78. The method of any of claims 64-77, further comprising reducing the oxygen gas content in a headspace of the product storage space to 0.2% or less by volume oxygen gas.

79. The method of any of claims 64-78, further comprising reducing the oxygen gas content in a headspace of the product storage space to 0.1% or less by volume oxygen gas.

80. The method of any of claims 64-79, further comprising reducing the oxygen gas content in a headspace of the product storage space until it is oxygen-free.

81. The method of any of claims 64-80, wherein the palladium catalyst is a nanoparticle palladium catalyst.

82. The method of any of claims 64-81, wherein the palladium catalyst is dispersed within the COC of the first multilayer film at a level of 25ppm-400ppm.

83. The method of any of claims 64-82, wherein the palladium catalyst is dispersed within the COC of the first multilayer film at a level of 50ppm-200ppm.

84. The method of any of claims 64-83, wherein the pharmaceutical package is a blister package.

85. The method of any of claims 64-84, wherein the pharmaceutical package includes a cold formed container.

86. The method of any of claims 64-84, wherein the pharmaceutical package includes a tray.

87. The method of any of claims 64-83, wherein the pharmaceutical package is a flat format pouch.

88. A method of making an oxygen scavenging film for packaging an oxygen-sensitive product, the method comprising:
providing COC;
providing a plurality of palladium catalyst;
compounding the COC and the palladium catalyst; and
creating a product contact layer comprising the COC and palladium catalyst.

89. The method of claim 88, wherein the product is a pharmaceutical product.

90. The method of any of claims 88-89, wherein the product includes a pharmaceutical active agent.

91. The method of any of claims 88-90, further comprising coupling the product contact layer to a gas barrier layer.

92. A method of making an oxygen scavenging package, comprising:
utilizing a multilayer packaging film, the multilayer packaging film comprising:
a product contact layer comprising COC and a hydrogen-gas-activated palladium catalyst; and
a gas barrier layer; and
forming a package including the multilayer film.

93. The method of claim 92, wherein the product is a pharmaceutical product comprising a pharmaceutical active agent.

94. The method of any of claims 92-93, wherein the package is a flat format package.

95. The method of any of claims 92-93, wherein the package is a blister package.

96. The method of any of claims 92, 93 or 95, wherein the package includes a cold formed container.

97. The method of any of claims 92, 93 or 95, wherein the package includes a tray.

WHAT IS CLAIMED IS:

1. A package for an oxygen-sensitive pharmaceutical product providing for oxygen scavenging without the presence of a hydrogen generator, the package comprising:
at least one pharmaceutical product storage space; and
a first multilayer film comprising:
a product contact layer comprising COC and a hydrogenation-accelerating catalyst; and
a gas barrier layer exterior to the product contact layer.
2. The package of claim 1, wherein the hydrogenation-accelerating catalyst is selected from the group consisting of a palladium catalyst and a platinum catalyst.
3. The package of any of claims 1-2, wherein the gas barrier layer comprises a metallic foil layer.
4. The package of any of claims 1-2, wherein the gas barrier layer comprises EVOH.
5. The package of any of claims 1-4, further comprising a second multilayer film including a product contact layer, the product contact layer of the second multilayer film being coupled to the product contact layer of the first multilayer film.
6. The package of claim 5, wherein the product contact layer of the second multilayer film comprises COC.
7. The package of any of claims 1-6, wherein the package is an e-cigarette cartridge package.
8. The package of any of claims 1-7, wherein the package includes a tray.

9. The package of any of claims 1-4, wherein the product contact layer of the first multilayer film is sealed to itself.
10. The package of any of claims 1-9, wherein there is 1% or less oxygen gas by volume in a headspace of the pharmaceutical product storage space.
11. The package of any of claims 1-10, wherein the pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine.
12. An oxygen scavenging film for packaging an oxygen-sensitive product, the product comprising a pharmaceutical active agent, the film comprising:
 - a gas barrier layer; and
 - a product contact layer comprising COC and a palladium catalyst.
13. The film of claim 12, wherein the palladium catalyst is a nanoparticle palladium catalyst disposed within the COC at a level of 25ppm-400ppm.
14. The film of any of claims 12-13, wherein the oxygen scavenging film is a flexible film.
15. The film of any of claims 12-13, wherein the oxygen scavenging film is a cold forming film.
16. The film of any of claims 12-13, wherein the oxygen scavenging film is a thermoforming film.
17. The film of any of claims 12-16, wherein the pharmaceutical active agent is an alkaloid.
18. A flat format package for a pharmaceutical product comprising the oxygen scavenging film of any of claims 12-17.
19. A blister package component comprising the film of any of claims 12-17.

20. A method of making the oxygen scavenging film for any of claims 12-19, the method comprising:
- providing the COC;
 - providing the palladium catalyst;
 - compounding the COC and the palladium catalyst; and
 - creating a product contact layer comprising the COC and palladium catalyst.
21. A method for achieving a sufficiently oxygen-free product storage space in a package, the method including:
- utilizing a multilayer packaging film, comprising:
 - a product contact layer comprising COC and a catalyst; and
 - a gas barrier layer disposed exterior the product contact layer;
 - wherein the multilayer packaging film at least in part defines a product storage space; and
 - introducing a gas flush into the product storage space, the gas flush including hydrogen gas and an inert gas.
22. The method of claim 21, further comprising disposing an oxygen-sensitive product into the product storage space.
23. The method of any of claims 21-22, wherein the oxygen-sensitive product includes a pharmaceutical active agent selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine.
24. The method of any of claims 21-23, further comprising reducing the oxygen gas content in a headspace of the product storage space to 1% or less by volume.
25. The method of any of claims 21-24, further comprising reducing the oxygen gas content in a headspace of the product storage space to 0.2% or less by volume.

26. The method of any of claims 21-25, further comprising reducing the oxygen gas content in a headspace of the product storage space to 0.1% or less by volume.

27. The method of any of claims 21-26, further comprising reducing the oxygen gas content in a headspace of the product storage space until it is oxygen-free.

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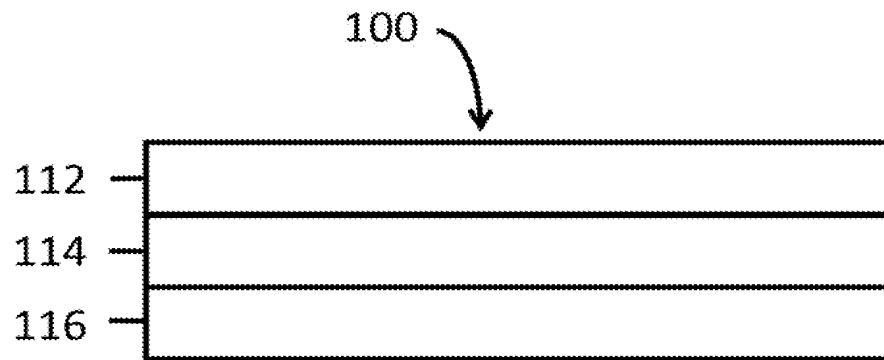


FIG. 1

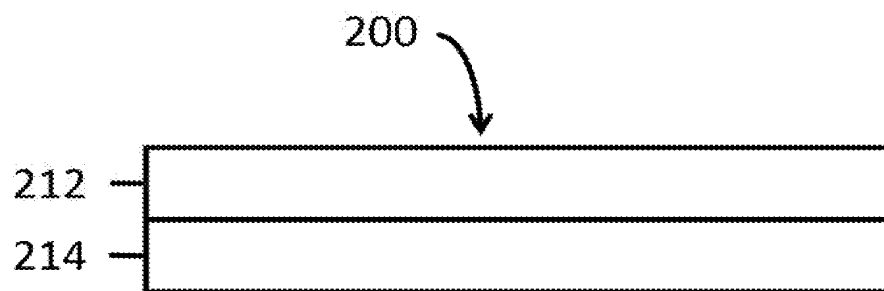


FIG. 2

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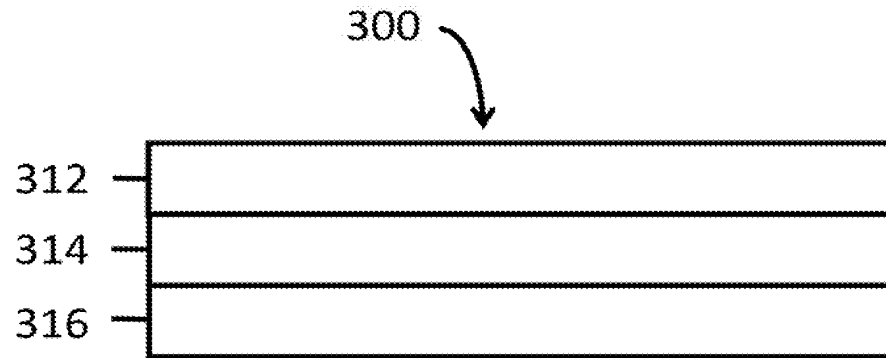


FIG. 3

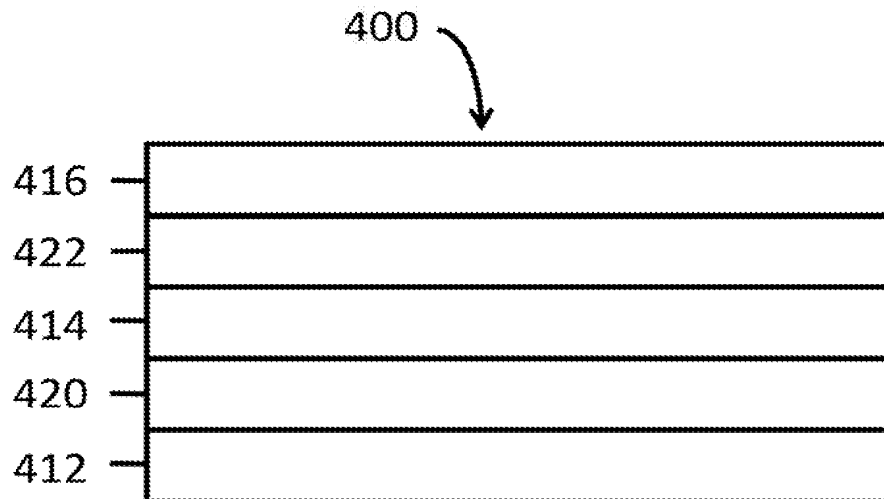


FIG. 4

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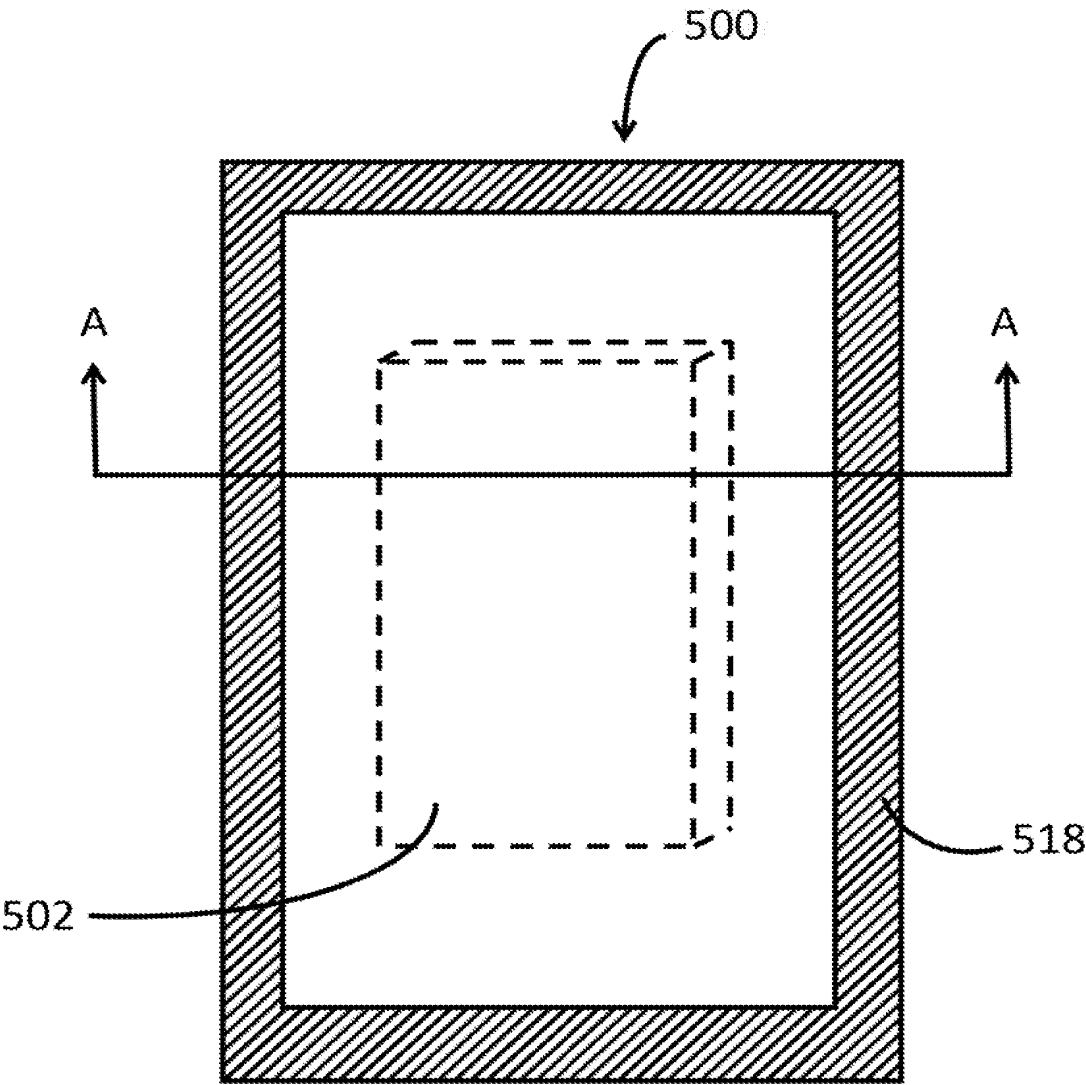


FIG. 5

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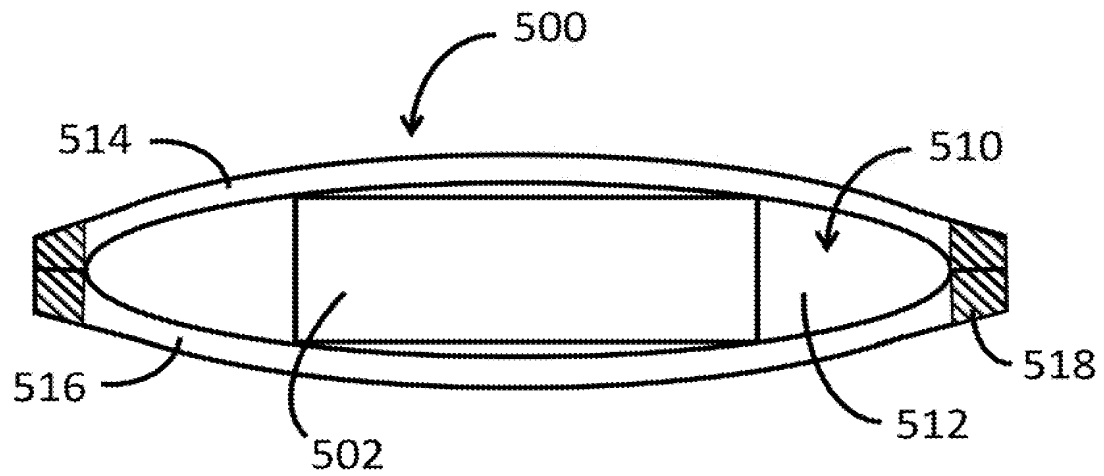


FIG. 5A

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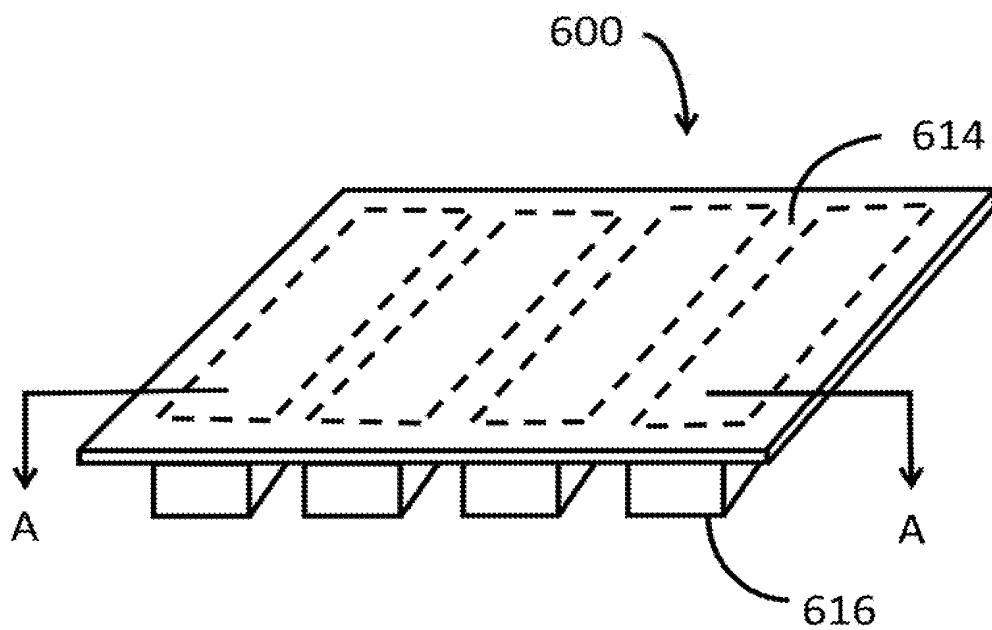


FIG. 6

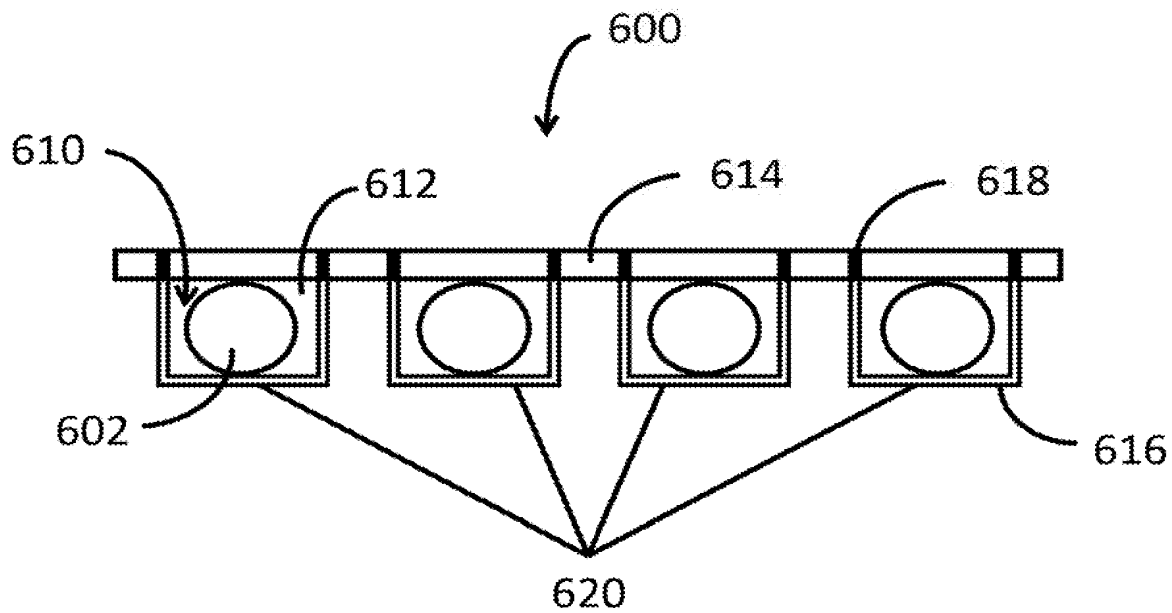


FIG. 6A

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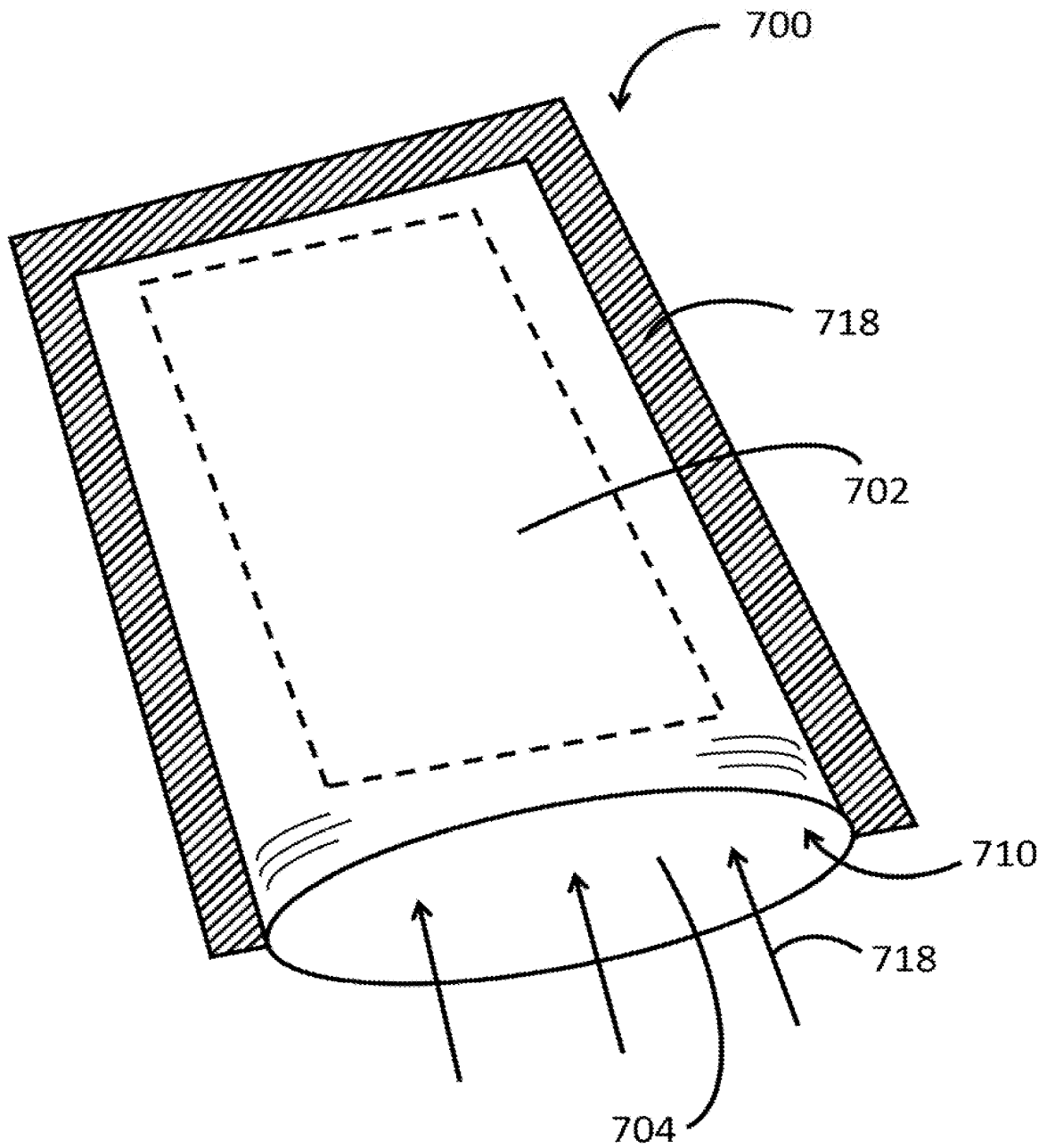


FIG. 7A

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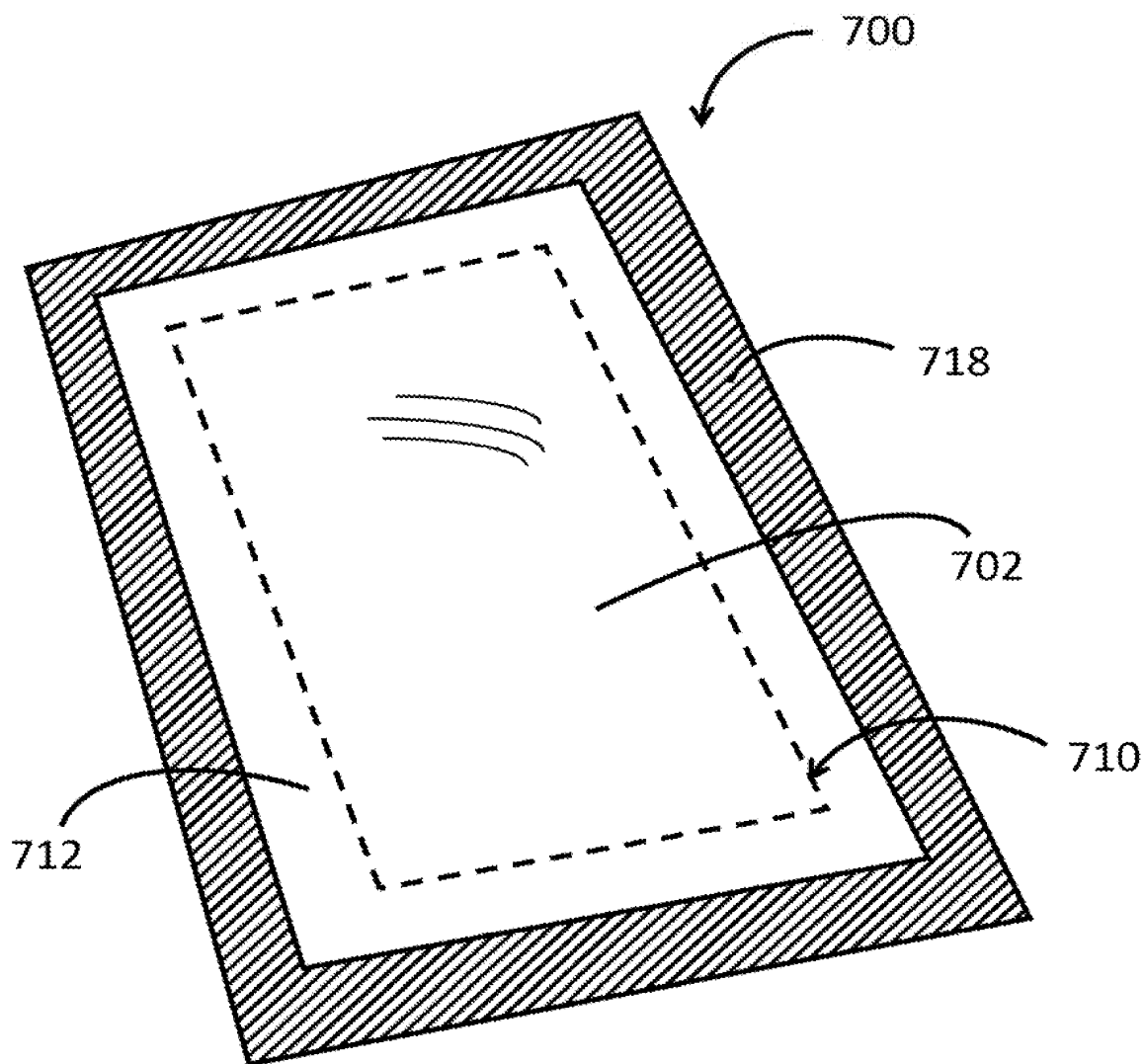
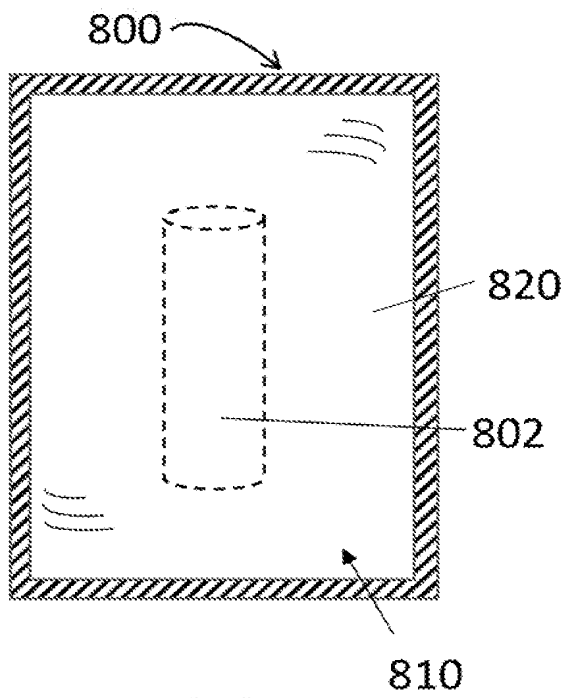
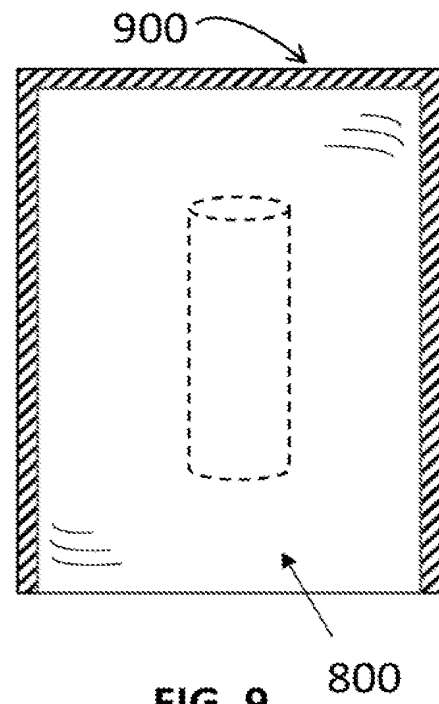
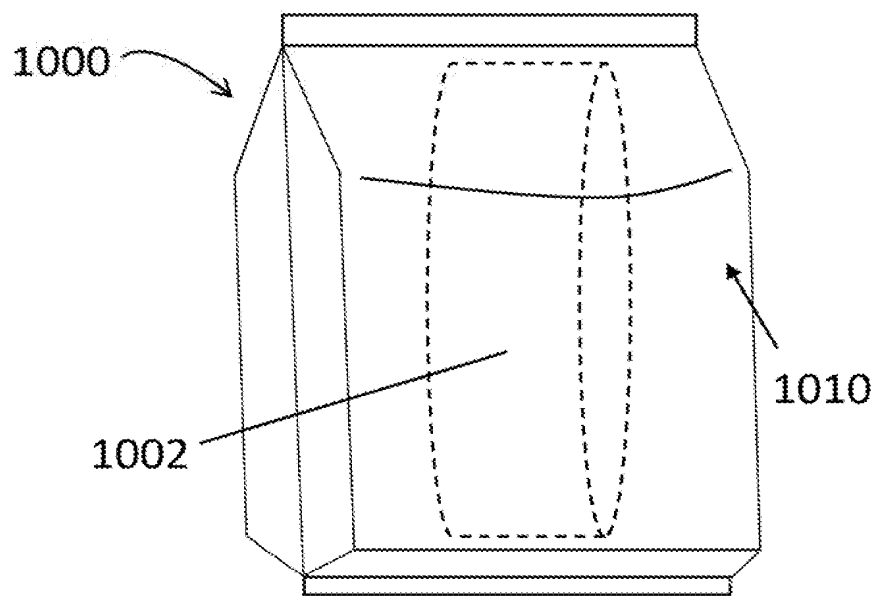


FIG. 7B



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/065127

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 47/02; A61K 47/30; B65D 65/40; B65D 85/00 (2017.01)

CPC - A61K 47/02; A61K 47/30; B65D 65/40; B65D 85/00; B65D 85/70 (2017.01)

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)

See Search History document

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

USPC - 206/223; 206/524.1; 206/524.2; 206/524.3; 206/524.4; 252/188.24; 424/400; 424/412 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2015/0225151 A1 (OSBORN et al) 13 August 2015 (13.08.2015) entire document	1-4, 12-16, 21-23
Y	US 3,255,020 A (FERRELL) 07 June 1966 (07.06.1966) entire document	1-4, 12-16, 21-23
Y	US 2011/0097548 A1 (BHANDARI et al) 28 April 2011 (28.04.2011) entire document	15, 16
A	US 2014/0370278 A1 (E I DU PONT DE NEMOURS AND COMPANY) 18 December 2014 (18.12.2014) entire document	1-4, 12-16, 21-23
A	US 6,756,130 B1 (ROBERT) 29 June 2004 (29.06.2004) entire document	1-4, 12-16, 21-23
A	US 6,793,994 B2 (TSAI et al) 21 September 2004 (21.09.2004) entire document	1-4, 12-16, 21-23

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

23 January 2017

Date of mailing of the international search report

16 FEB 2017

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Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/065127

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 5-11, 17-20, 24-27
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.



(51) International Patent Classification:
B65D 75/36 (2006.01)

(21) International Application Number:
PCT/US2016/065439

(22) International Filing Date:
7 December 2016 (07.12.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14/961,486 7 December 2015 (07.12.2015) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: PRODUCT PACKAGING WITH COC-COC SEALING INTERFACE

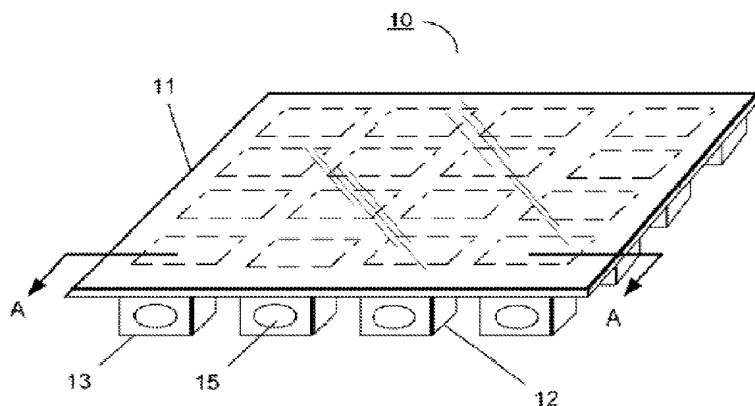


Fig. 1

(57) Abstract: A package includes a base component having a product contacting layer including at least 50% by weight of a cyclic olefin copolymer, and a lidding component having a product contacting layer including at least 50% by weight of a cyclic olefin copolymer. The product contacting layer of the base component is sealed to the product contacting layer of the lidding component such that a cavity is formed.

PRODUCT PACKAGING WITH COC-COC SEALING INTERFACE

BACKGROUND

[0001] The present application relates generally to packaging materials and configurations for commercial packaging operations. According to one particular embodiment, the packaging may be provided in the form of tray and lid packaging, container and lid packaging, blister packaging, or “push-through” packaging.

[0002] Blister packaging is employed widely for commercial packaging of food products, personal care products, and human health products such as pharmaceuticals, and medical devices or precision instruments. The use of this type of packaging has become widespread mainly due to the ability to incorporate suitable moisture, dust, ultraviolet (UV), and/or gas barriers into the packages when such properties are desired for maintaining the integrity or efficacy of the product contained therein. For example, blister packaging is extensively used in the pharmaceutical industry for packaging of medicaments or the like in capsule, lozenge, or pill form because the integrity of the medicament can be maintained through the proper selection of materials used to form the packages.

[0003] For preparing blister packages or push-through packages, generally a thermoplastic film is first processed by vacuum forming or pneumatic forming so as to form blisters or cavities thereon, namely portions having a predetermined contour that generally corresponds to the size and shape of each specific product to be received or contained therein. After the so-blistered film has been solidified, each blister is charged with the product to be packaged and a second or lidding film is then covered over each blister and sealed to the first film. The second lidding film is often a laminate material which can be ruptured by a simple finger-rupture or peeled off from the first film to allow access to a packaged item. Conventional materials used for forming the blistered film have included transparent plastics such as polyvinylchloride (PVC), polyvinylidene chloride (PVdC), and polychlorotrifluoroethylene (PCTFE), commonly referred to as ACLAR® (Honeywell/Allied Signal).

[0004] Packaging for pharmaceuticals or other moisture-sensitive articles desirably exhibits not only low moisture permeability, but also other properties such as chemical inertness, clarity, rigidity, and/or uniform thickness. Conventional materials for such blister packaging generally suffer from certain shortcomings, however. For example, the use of polyvinylchloride (PVC) and polyvinylidene chloride (PVdC) have been shown to have poor and/or insufficient moisture-proofing properties required by the pharmaceutical industry. While ACLAR® exhibits relatively low moisture vapor transmission, its use in blister packaging is relatively costly as compared to alternative materials. Additionally, in some cases, undesirable migration of chemicals or other components of the product, such as pharmacological active agents or excipients, between the product and the packaging materials (e.g., film, film layer, etc.) may occur (i.e., scalping or leaching).

[0005] There is therefore a need in the art for improved packaging materials and configurations that may provide sufficient moisture vapor barrier, anti-scalping, and chemical inertness properties and that is aesthetically pleasing enough to present the products contained therein while being cost effective to manufacture.

SUMMARY

[0006] One embodiment relates to a package including: a base component comprising product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer, and a lidding component comprising product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer. The product contacting layer of the base component is sealed to the product contacting layer of the lidding component such that a cavity is formed.

[0007] The base component may be a multilayer thermoplastic film. The multilayer thermoplastic film may include: the product contacting layer comprising at least 50% by weight of the cyclic olefin copolymer, a first interior layer, a core layer, a second interior layer, and an exterior layer. The exterior layer may include at least one of cyclic olefin copolymer (COC), polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene

terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG), biaxially oriented nylon (BON), or polylactic acid (PLA). The first interior layer and the second interior layer may each comprise a high density polyethylene nucleation additive, and may each further include a hydrocarbon resin. The first interior layer and the second interior layer each may include a bimodal high density polyethylene having a distribution of a low molecular weight region and a high molecular weight region. The first interior layer and the second interior layer each may be in direct contact with an exterior layer. The core layer may include an ethylene vinyl acetate copolymer, and may be in direct contact with the first interior layer and the second interior layer. The exterior layer of the base component may include at least 50% by weight of a cyclic olefin copolymer.

[0008] The lidding component of the package may include: an optional exterior layer; a barrier layer; and the product contacting layer comprising at least 90% by weight of a cyclic olefin copolymer. The barrier layer may be a foil layer. The exterior layer may be at least one of paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate. The lidding component may further include an interior layer disposed between the exterior layer and the barrier layer. The interior layer may include at least one of polyethylene and an adhesive.

[0009] The cyclic olefin copolymer of at least one of the base component or the lidding component may include norbornene and ethylene monomers. The seal between the product contacting layer of the base component and the product contacting layer of the lidding component may have a seal strength of at least 800 grams force per inch.

[0010] A second embodiment relates to a lidding component for a package, the lidding component including: an optional exterior layer, a barrier layer, and a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer. The product contacting layer being configured to seal to a product contacting layer of a base component. The barrier layer may be a foil layer. The exterior layer may be at least one of paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate. The lidding component

may further include an interior layer disposed between the exterior layer and the barrier layer. The interior layer may include at least one of polyethylene and an adhesive.

[0011] A third embodiment relates to a method of forming a package. The method includes: sealing a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer of a base component to a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer of a lidding component to form a cavity. The method may further include forming the base component by a blown coextrusion process. The base component may be any of the base components described above. The method may also further include forming the lidding component by lamination process. The lidding component may be any of the lidding components described above. The sealing may be a heat sealing process.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] References are made to the accompanying drawings that form a part of this disclosure, and which illustrate the embodiments in which the systems and methods described in this specification can be practiced.

[0013] FIG. 1 is a schematic view of a package according to a non-exclusive and non-limiting exemplary embodiment, shown in the form of a blister package.

[0014] FIG. 2 is a cross-sectional view of the package of FIG. 1 taken along line A-A.

[0015] FIG. 3 is a cross-sectional view of a portion of a package according to another exemplary embodiment.

[0016] FIG. 4 is a cross-sectional view of a portion of a package according to another exemplary embodiment.

[0017] FIG. 5 is a cross-sectional view of a portion of a package according to another exemplary embodiment.

[0018] FIG. 6 is a cross-sectional view of a portion of a package according to another exemplary embodiment.

[0019] FIG. 7 reports blister package nicotine uptake as a function of time for a blister package according to one embodiment and a control blister package.

DETAILED DESCRIPTION

[0020] Embodiments described and depicted herein relate generally to packages formed from a base component (e.g., a blister portion, tray portion, or container portion in which one or more products to be packaged are contained or housed) and a lidding component (e.g., a cover, film, or lid coupled to the base component for sealing or closing the product(s) within the base component). The base component and the lidding component may be separate components before they are sealed together. It should be understood, however, that the concepts described herein may also apply to other types of packaging, which have a plurality of components to be joined or sealed together in manners similar to those described herein, and such other packaging types are intended to fall within the scope of the present disclosure.

[0021] According to an exemplary embodiment, the base component and the lidding component are independently formed from multilayer polymeric materials, and the layers of the base component and lidding component in facing contact with each other (i.e., the sealing surfaces of each) include a cyclic olefin copolymer (COC) material. Such facing layers may also be referred to herein as a product contact layer or a product contacting layer, since the contained product(s) may contact, directly or indirectly, all or a portion of such layer when the product(s) are contained within the package.

[0022] A representative blister package 10 as described herein is shown in FIGS. 1 and 2 according to one non-exclusive and non-limiting exemplary embodiment. Blister package 10 includes a thermoformed base component 12 and a lidding component 11. The base component 12 and the lidding component 11 are sealed together to form sealed flange regions surrounding cavities 13 (e.g., compartments, storage areas, openings, chambers, channels, etc.). The cavities

13 define individual areas or regions for receiving and containing one or more products 15, such as a tablet, patch, or cartridge. As will be appreciated by those reviewing the present disclosure, any of a wide variety of product types may be contained within the blister package 10.

According to one particular embodiment, the product may be a replacement cartridge for an electronic cigarette system. Alternative packages that may be formed using the base component and the lidding component described herein include tray and lid packages and container and lid packages.

Base Component

[0023] As used throughout this disclosure, the term “base component” refers to multilayer thermoplastic film or a roll of multilayer thermoplastic film both of which may be thermoformed, partially thermoformed, or not thermoformed at all. The multilayer thermoplastic film may include layers that do not include a thermoplastic materials, such as metal foils or paper. In one exemplary embodiment, the sequence of layers in the multilayer thermoplastic film of the base component is palindromic. As used throughout this application, the term “palindromic” refers to a multilayer film, the layers of which are substantially symmetrical. Non-limiting examples of palindromic films are films or sheets having the layer sequence of configurations: A/B/A or A/B/B/A or A/B/C/B/A or A/B/C/D/C/B/A or A/B/C/B/D/B/C/B/A or A/B/E/D/E/B/C/B/E/D/E/B/A, etc. A palindromic thermoplastic film may be coextruded as a symmetrical cast or a blown film using coextrusion methods generally well known in the art. An alternative method of producing palindromic films is by the use of blown coextrusion of non-symmetrical film or sheet structures followed by collapsing the blown bubble around a central core layer. An exemplary method of producing a base component may include producing a single-bubble blown film by forcing a non-palindromic film composition through a multi-manifold circular die head to form a cylindrical bubble. The cylindrical bubble may be immediately quenched, such as by a cooled water bath, solid surface, and/or air, and collapsed onto itself and formed into a palindromic film.

[0024] According to another exemplary embodiment, the sequence of layers in the multilayer thermoplastic film of the base component is non-palindromic. An example of a layer sequence configuration of a non-palindromic film would be A/B/C or A/B/C/A.

[0025] In one embodiment, the thermoformed base component may be characterized as a palindromic film formed from a non-symmetrical film having a generic layer sequence configuration of A/B/C which is coextruded by blown film coextrusion techniques and collapsed upon itself to produce a layer sequence configuration of A/B/C/B/A. In this embodiment, the thermoformed base component includes a film where layer A is an exterior layer comprising a cyclic olefin copolymer (COC). Layer B may be an interior layer comprising at least one of a high density polyethylene (HDPE), a blend of high density polyethylene, a high density polyethylene nucleation additive and optionally, a hydrocarbon resin, a bimodal high density polyethylene having a distribution of a low molecular weight region and a high molecular weight region, or a high density polyethylene (HDPE) and may have a thickness of between about 38.1 μm and about 190.5 μm (about 1.5 mil to about 7.5 mil). Layer C is a central core layer. The central core layer C may be any suitable polymeric material which can be blown coextruded and collapsed upon itself. One non-limiting example of such polymeric materials is ethylene vinyl acetate copolymer (EVA).

[0026] In another embodiment, the thermoformed base component may be characterized as a non-palindromic film having a layer sequence configuration of A/B/C/B/D which is coextruded by blown film coextrusion techniques and is not collapsed upon itself. In this embodiment, the thermoformed base component includes a film where layer A is an exterior layer comprising a material selected from the group consisting of cyclic olefin copolymer (COC). Layer B may be an interior layer comprising a high density polyethylene (HDPE), a blend of high density polyethylene, high density polyethylene nucleation additive and optionally, a hydrocarbon resin (HDPE-Blend), a bimodal high density polyethylene having a distribution of a low molecular weight region and a high molecular weight region (HDPE-Bimodal), or a high density polyethylene and has a thickness of between about 38.1 μm to about 190.5 μm (about 1.5 mil to about 7.5 mil). Layer C is a central core layer, and layer D is an exterior layer comprising a

different material than layer A. Layer D may include at least one of polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG) biaxially oriented nylon (BON), and polylactic acid (PLA). Core layer C may be any thermoplastic material. In one particular embodiment, core layer C comprises ethylene vinyl acetate copolymer (EVA).

[0027] The thermoformed base component may also include additional film layers. For example, the base component may include additional interior layers, such as an oxygen barrier and a moisture barrier, disposed between the external layers and the core layer. Additionally, the base component may include tie layers disposed between the interior layers of the multilayer film.

[0028] The multilayer thermoplastic film of the thermoformed base component may include any number of film layers and film layer compositions depending upon both functional and aesthetic requirements of the base component. It is desirable that the multilayer thermoplastic film includes one or more film layers which are barrier materials and substantially chemically inert when in contact with a product. The term “barrier” refers to a material that controls permeability of one or more elements through a film structure including moisture, chemicals, heat, odor, and oxygen or other gases. A barrier material may be provided by a single film layer or multiple film layers acting individually or in concert with each other, respectively. The phrase “substantially chemically inert” as used herein refers to materials that generally are not reactive with the product with which it comes into contact with and does not leech chemical ingredients into the product with which it comes into contact. According to an exemplary embodiment, the base component comprises a multilayer thermoplastic film which provides an average water vapor transmission rate of less than about $0.500 \text{ g/m}^2/\text{day}$ or less than about $0.250 \text{ g/m}^2/\text{day}$ or less than about $150 \text{ g/m}^2/\text{day}$ or less than about $0.131 \text{ g/m}^2/\text{day}$ or less than about $0.110 \text{ g/m}^2/\text{day}$ at 100° F (37.8° C) and 90% relative humidity and has a thickness of about 10 mil (about 254

micron) before being thermoformed. The aforementioned features may be achieved by a multilayer thermoplastic film comprising at least 3, 4, 5, 7, 8, 9, 10, 11, 12, 13, or more layers.

[0029] In one embodiment as depicted in FIG. 3, thermoformed base component 12 comprises a multilayer thermoplastic film 100 comprising a five-layer structure of a first exterior layer 101, a first interior layer 102, a central core layer 103, a second interior layer 104, and a second exterior layer 105. In one embodiment, first and second exterior layers 101 and 105 comprise the same materials. In another embodiment, first and second exterior layers 101 and 105 comprise different materials. The first exterior layer 101 is a product contacting layer that includes a cyclic olefin copolymer (COC).

[0030] For example, in one embodiment, first and second exterior layers 101 and 105 each comprise a cyclic olefin copolymer (COC). The COC contained in the first exterior layer 101 may be the same as the COC contained in the second exterior layer 105. Alternatively, the COC contained in the first exterior layer 101 may be different than the COC contained in the second exterior layer 105. First and second interior layers 102 and 104 each comprise at least one of a high density polyethylene (HDPE), a blend of a high density polyethylene and a high density polyethylene nucleation additive with an optional hydrocarbon resin (HDPE-Blend), or a bimodal high density polyethylene having a distribution of a low molecular weight region and a high molecular weight region (HDPE-Bimodal), and have a thickness of between about 38.1 μm to about 190.5 μm (about 1.5 mil to about 7.5 mil). Core layer 103 comprises ethylene vinyl acetate copolymer (EVA). Alternatively, the first exterior layer 101 comprises cyclic olefin copolymer (COC) and the second exterior layer 105 comprises a different material than first exterior layer 101 which includes at least one of polypropylene (PP); aromatic polyesters such as, but not limited to, polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG); aliphatic polyesters such as, but not limited to, polylactic acid (PLA); polyhydroxyalkonates including but not limited to polyhydroxypropionate, poly(3-hydroxybutyrate) (PH3B), poly(3-hydroxyvalerate) (PH3V), poly(4-hydroxybutyrate) (PH4B), poly(4-hydroxyvalerate) (PH4V), poly(5-hydroxyvalerate) (PH5V), poly(6-hydroxydodecanoate)

(PH6D); biaxially oriented nylon (BON); or polystyrenes such as, but not limited to, high impact polystyrene (HIPS), general purpose polystyrene (GPPS), and styrene block copolymer (SBC).

[0031] As used herein, the term “cyclic olefin copolymer” refers to copolymers having at least one norbornene structural moiety within the repeating backbone of the polymer. Suitable COCs for use in the present invention may have a heat deflection temperature under load (0.45 MPa) of at least about 75° C, 130° C, 150° C, 170° C, or more. The COCs utilized herein may have a glass transition temperature in a range from about 50° C to about 178° C such as from about 65° C to about 138° C. Examples of commercially-available cyclic olefin copolymers include, but are not limited to, the TOPAS® family of resins which is supplied by Celanese Corporation (Irving, TX, USA). The COC containing product contact layers are anti-scalping layers, in that they resist migration of chemicals, such as active agents, from the product to the packaging materials (either through direct contact with the product or through volatiles components from the product impinging on or migrating to the packaging material). Such migration of chemicals from the product to packaging materials is commonly referred to as “scalping.” The COC containing product contact layers are advantageously characterized as being anti-scalping with regard to at least nicotine and fentanyl.

[0032] As utilized herein, a product contacting layer of a film is considered to serve as an effective “anti-scalping layer” for pharmacological active agents if (i) a lower amount of an active agent migrates into the product contacting layer of the film (the test film) than migrates into a substantially similar film having a polyethylene (PE), such as a linear low density polyethylene homopolymer, product contacting layer (the reference film) when a product containing the active agent is in direct contact with the product contacting layers of the test and reference films; or (ii) an amount of the active agent that migrates into the product contacting layer of the film (the test film) is not more than 15% greater than migrates into a substantially similar film having a Barex® product contacting layer (the reference film) when a product containing the active agent is in direct contact with the product contacting layers of the test and reference films. Preferably, the product is sealed in a cavity formed, at least in part, by the test film and the product is sealed in a cavity formed, at least in part, by the reference film. The

sealed product can be stored under identical conditions prior to testing to determine whether less active agent has migrated into the product contacting layer of the test film than the reference film. A film may still have anti-scalping properties even if it is not an effective anti-scalping layer as defined above. For example, a film that is not an effective anti-scalping layer for pharmacological active agents may exhibit sufficient anti-scalping properties for other applications.

[0033] The COCs utilized herein may be are commercially available amorphous, transparent copolymers of ethylene with norbornene made by polymerization with a metallocene catalyst. These commercially available COCs reportedly have high transparency and gloss, excellent moisture barrier and aroma barrier properties, high stiffness, high strength, excellent biocompatibility and inertness and are easy to extrude and thermoform. The COC materials may have an ethylene-norbornene comonomer content of about 20 to about 40 mole% ethylene and about 30 to about 60 mole% norbornene. In some embodiments, the COC materials described herein may include polymeric units derived from essentially only ethylene and norbornene comonomers.

[0034] A “product contacting layer” refers to a layer that under typical storage conditions some portion of the product or an active agent contained within the product will contact the layer. The active agent may be in direct contact with the product contacting layer or may be in indirect contact with the product contacting layer. Indirect contact between the active agent and the product contacting layer can occur, for example, due to volatilization of the active agent or an active agent carrier within the package to cause the active agent, which is not stored in direct contact with the product contacting layer, to contact the layer. The product contacting layer includes at least 50% by weight of COC, such as at least 75% by weight of COC, at least 90% by weight of COC, at least 95% by weight COC, or 100% by weight COC. In the case that the product contacting layer contains less than 50% by weight COC, the anti-scalping properties of the product contacting layer may be undesirably reduced.

[0035] The product contacting layer also functions as a “heat sealing layer” or “heat sealable layer” which are used interchangeably herein to refer to a layer which is heat sealable i.e., capable of fusion bonding by conventional indirect heating means which generate sufficient heat on at least one film contact surface for conduction to the contiguous film contact surface and formation of a bond interface therebetween without loss of the film integrity. The bond interface between contiguous inner layers of the produced seal preferably has sufficient physical strength to withstand the packaging process and subsequent handling. Advantageously, the bond interface is preferably sufficiently thermally stable to prevent gas or liquid leakage therethrough when exposed to above or below ambient temperatures e.g. during one or more of the following: packaging operations, storage, handling, and transport.

[0036] As used throughout this application, the term “polypropylene” refers to a homopolymer or copolymer having a propyl or C-3 linkage between monomer units. A non-limiting example of a suitable propylene copolymer is Propylene 4170 available from Total Petrochemicals USA, Inc. (Houston, Tex.). Other non-limiting examples of polypropylenes include Polypropylene 3287WZ, which is available from Total Petrochemicals USA, Inc. (Houston, Tex.); and H02C-00 Polypropylene Homopolymer, which is available from Ineos Olefins & Polymers USA (League City, Tex.).

[0037] As used throughout this application, the term “polyester” refers to a homopolymer or copolymer having an ester linkage between monomer units which may be formed, for example, by condensation polymerization reactions between a dicarboxylic acid and a diol. The ester linkage can be represented by the general formula: $[O-R-OC(O)-R'-C(O)]_n$ where R and R' are the same or different alkyl (or aryl) group and may be generally formed from the polymerization of dicarboxylic acid and diol monomers containing both carboxylic acid and hydroxyl moieties. The dicarboxylic acid (including the carboxylic acid moieties) may be linear or aliphatic (e.g., lactic acid, oxalic acid, maleic acid, succinic acid, glutaric acid, adipic acid, pimelic acid, suberic acid, azelaic acid, sebacic acid, and the like) or may be aromatic or alkyl substituted aromatic (e.g., various isomers of phthalic acid, such as paraphthalic acid (or terephthalic acid), isophthalic acid and naphthalic acid). Specific examples of a useful diol include but are not

limited to ethylene glycol, propylene glycol, trimethylene glycol, 1,4-butane diol, neopentyl glycol, cyclohexane diol and the like. Polyesters may include a homopolymer or copolymer of alkyl-aromatic esters including but not limited to polyethylene terephthalate (PET), amorphous polyethylene terephthalate (APET), crystalline polyethylene terephthalate (CPET), glycol-modified polyethylene terephthalate (PETG) and polybutylene terephthalate; a copolymer of terephthalate and isophthalate including but not limited to polyethylene terephthalate/isophthalate copolymer. Aliphatic esters include but not limited to polylactic acid (PLA); polyhydroxyalkonates including but not limited to polyhydroxypropionate, poly(3-hydroxybutyrate) (PH3B), poly(3-hydroxyvalerate) (PH3V), poly(4-hydroxybutyrate) (PH4B), poly(4-hydroxyvalerate) (PH4V), poly(5-hydroxyvalerate) (PH5V), poly(6-hydroxydodecanoate) (PH6D); and blends of any of these materials. A non-limiting example of PETG is Eastar™ Copolyester 6763, which is also available from Eastman Chemical Company (Kingsport, Tenn.).

[0038] As used herein, the term “polylactic acid” is used synonymously throughout this disclosure to describe homopolymers or copolymers having an ester linkage between monomer units and can be represented by the general formula: $[-OCH(R)C(O)-]_n$ where $R=CH_3$. Polylactic acid may be fabricated by polymerizing lactic acid, which is mostly produced from by carbohydrate fermentation of corn. Polylactic acid may be also produced by polymerization of lactide which obtained by condensation of two lactic acid molecules. Polylactic acid has a glass transition temperature ranging from 50° C to 80° C, while the melting temperature ranges from 130° C to 180° C. Polylactic acid is known by those skilled in the art and fully disclosed in U.S. Pat. Nos. 5,698,322; 5,142,023; 5,760,144; 5,593,778; 5,807,973; and 5,010,145, the entire disclosure of each of which is hereby incorporated by reference. Examples of commercially available polylactic acid are sold under the trademark NatureWorks™ PLA Polymer in grades 4031-D, 4032-D, and 4041-D from Cargill Dow LLC, Minneapolis, Minn., U.S.A.

[0039] As used throughout this application, the term “polystyrene” or “PS” refers to a homopolymer or copolymer having at least one styrene repeating linkage (such as benzene (i.e., C_6H_5) having an ethylene substituent) within the repeating backbone of the polymer. The styrene linkage can be represented by the general formula: $[CH_2-CH_2(C_6H_5)]_n$. Polystyrene may be

formed by any method known to those skilled in the art. Examples of styrenic polymers include but are not limited to high impact polystyrene (HIPS), general purpose polystyrene (GPPS) and styrene block copolymer (SBC). HIPS is sometimes called rubber-modified polystyrene and is normally produced by copolymerization of styrene and a synthetic rubber. (See Wagner, et al., "Polystyrene," The Wiley Encyclopedia of Packaging Technology, Second Edition, 1997, pp. 768-771 (John Wiley & Sons, Inc., New York, New York), which is incorporated in its entirety in this application by this reference.) Examples of HIPS include but are not limited to Impact Polystyrene 825E and Impact Polystyrene 945E, both of which are available from Total Petrochemicals USA, Inc; EB6025 Rubber Modified High Impact Polystyrene, which is available from Chevron Phillips Company (The Woodlands, Texas); and 6210 High Impact Polystyrene, which is available from Ineos Nova LLC (Channahon, Illinois). GPPS is often called crystal polystyrene, as a reference to the clarity of the resin. Examples of GPPS include but are not limited to Crystal Polystyrene 524B and Crystal Polystyrene 525B, both of which are available from Total Petrochemicals USA, Inc. Styrene block copolymers (SBC) include styrene butadiene copolymers (SB). The styrene-butadiene copolymers that are suitable for packaging applications are those resinous block copolymers that typically contain a greater proportion of styrene than butadiene and that are predominantly polymodal with respect to molecular weight distribution. (See Hartsock, "Styrene-Butadiene Copolymers," The Wiley Encyclopedia of Packaging Technology, Second Edition, 1997, pp. 863-864 (John Wiley & Sons, Inc., New York, New York), which is incorporated in its entirety in this application by this reference.) A non-limiting example of SB is DK13 K-Resin® Styrene-Butadiene Copolymer, which is available from Chevron Phillips Chemical Company (The Woodlands, Texas).

[0040] As used herein, the phrase "high density polyethylene" or "HDPE" refers to homopolymers of ethylene that have densities of about 0.960 g/cm^3 to about 0.970 g/cm^3 as well as copolymers of ethylene and an alpha-olefin (such as 1-butene or 1-hexene) that have densities of about 0.940 g/cm^3 to about 0.958 g/cm^3 . In contrast, a low density polyethylene (LDPE) generally has a density of about 0.915 g/cm^3 to about 0.930 g/cm^3 . HDPE is inclusive of polymers made with Ziegler or Phillips type catalysts and polymers made with single-site

metallocene catalysts. A non-limiting example of high density polyethylene includes Alathon® M6020 from Equistar Chemicals LP (Houston, Tex.). Other specific non-limiting examples of HDPE include Alathon® M6020 available from Equistar Chemicals LP (Houston, Tex.); Alathon® L5885 available from Equistar Chemicals LP (Houston, Tex.); ExxonMobil™ HDPE HD 7925.30 available from ExxonMobil Chemical Company (Houston, Tex.); and ExxonMobil™ HDPE HD 7845.30 available from ExxonMobil Chemical Company (Houston, Tex.).

[0041] In one particular embodiment, first and second exterior layers 101 and 105 each independently include at least 50%, 75%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or more cyclic olefin copolymer (COC) by weight relative to the total weight of the layer, and first and second interior layers 102 and 104 each comprise high density polyethylene (HDPE).

[0042] In another preferred embodiment, the first exterior layer 101 includes at least 50%, 75%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or more cyclic olefin copolymer (COC) by weight relative to the total weight of the layer, the second exterior layer 105 comprises at least 50%, 60%, 70%, 80%, 90%, 95% or more of another material by weight relative to the total weight of the layer. The another material of the second exterior layer 105 may be at least one of polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG), or polylactic acid (PLA). The first and second interior layers 102 and 104 may each include high density polyethylene (HDPE) and have a thickness of at least 20%, 25%, 30%, 35% or more of the total thickness of the multilayer thermoplastic film 100. The first and second interior layers 102 and 104 may each have a thickness of between about 38.1 μm and about 190.5 μm (about 1.5 mil to about 7.5 mil).

[0043] In another particular embodiment, the first and second interior layers 102 and 104 each include a blend of a high density polyethylene and a high density polyethylene nucleation

additive (HDPE-Blend). As used herein, the phrase "nucleation additive" means a material that increases high density polyethylene crystallinity as a result of its incorporation into HDPE. Such nucleation additives typically provide better control over crystallization rates. Examples of nucleation additives include minerals such as chalk, talc, clay, kaolin, silicates and the like, and organic agents such as salts of aliphatic or aromatic carboxylic acids, aromatic salts, metallic salts of aromatic phosphorous compounds, quinaridones, and aromatic amides. Further examples include zinc glycerolate, calcium glycerolate, calcium hexahydrophthalate, zinc hexahydrophthalate, salts and the like, and mixtures thereof. In one embodiment, the nucleation additive comprises calcium hexahydrophthalate. The nucleation additive may be present in each interior layer of HDPE in an amount from about 0.2% to about 3.5% by weight relative to the total weight of the layer.

[0044] In another embodiment, the first and second interior layers 102 and 104 each include a blend of a high density polyethylene, a high density polyethylene nucleation additive and/or a hydrocarbon resin (HDPE-Blend). The hydrocarbon resin may be present in the first and second interior layers 102 and 104 in an amount from about 3% to about 16% by weight relative to the total weight of the layer. As used herein, the phrase "hydrocarbon resin" refers to a product produced by polymerization from coal tar, petroleum, and turpentine feed stocks, as defined by ISO Standard 472, "Plastics – Vocabulary" incorporated by reference herein to the extent that it discloses hydrocarbon resins. A hydrocarbon resin may comprise any of those hydrocarbon resins disclosed in U.S. Pat. No. 6,432,496, issued Aug. 13, 2002, or in U.S. Patent Application 2008/0286547, published Nov. 20, 2008, both of which are incorporated in their entireties in this application by this reference. More specifically, as a non-limiting example, the hydrocarbon resin may include petroleum resins, terpene resins, styrene resins, cyclopentadiene resins, saturated alicyclic resins, or mixtures thereof. Additionally, as a non-limiting example, the hydrocarbon resin may include a hydrocarbon resin derived from the polymerization of olefin feeds rich in dicyclopentadiene (DCPD), from the polymerization of olefin feeds produced in the petroleum cracking process (such as crude C9 feed streams), from the polymerization of pure monomers (such as styrene, α -methylstyrene, 4-methylstyrene, vinyltoluene, similar pure

monomer feedstocks, or any combination thereof), from the polymerization of terpene olefins (such as α -pinene, β -pinene, or d-limonene) or from a combination thereof. The hydrocarbon resin may be fully or partially hydrogenated. Specific examples of hydrocarbon resins include but are not limited to Plastolyn® R1140 Hydrocarbon Resin available from Eastman Chemical Company (Kingsport, Tenn.), Regalite® T1140 available from Eastman Chemical Company (Kingsport, Tenn.), Arkon® P-140 available from Arakawa Chemical Industries, Limited (Osaka, Japan) and Piccolyte® S135 Polyterpene Resins available from Hercules Incorporated (Wilmington, Del.).

[0045] In another embodiment, the first and second interior layers 102 and 104 each include high density polyethylene having a bi-modal molecular weight distribution having a low molecular weight region and a high molecular weight region (HDPE-Bimodal).

[0046] The interior layers may be barrier layers. The interior layers may provide gas barrier functionality and moisture barrier functionality, and this functionality may be provided by a single barrier layer or by separate barrier layers.

[0047] A gas barrier layer may be an oxygen barrier layer. An oxygen barrier is preferably selected to provide a sufficiently limited oxygen permeability such that the packaged product is protected from undesirable deterioration or oxidative processes. For example, a film may comprise an oxygen barrier having an oxygen permeability that is low enough to prevent oxidation of oxygen sensitive products and substances to be packaged in the film - e.g., oxygen sensitive articles such as transdermal patches (such as nicotine or fentanyl patches). Preferably an oxygen barrier provides an oxygen permeability of less than or equal to $10 \text{ cm}^3/100 \text{ inches}^2/24 \text{ hours at } 1 \text{ atmosphere and } 23^\circ \text{ C}$, such as less than $0.016 \text{ cm}^3/\text{m}^2 \text{ per } 24 \text{ hours at } 1 \text{ atmosphere}$. To protect oxygen sensitive articles from deterioration from oxygen contact over time the oxygen barriers of the base components according to the present invention may provide an oxygen transmission rate (O_2TR) of less than 1, preferably less than 0.1, more preferably less than 0.01, and most preferably less than $0.001 \text{ g}/100 \text{ inches}^2 \text{ at } 24 \text{ hours at Room}$

Temperature (RT) ($\sim 23^{\circ}\text{C}$) and 1 atmosphere, such as $<0.001 \text{ g/m}^2$ at 24 hours at RT and 1 atmosphere.

[0048] A moisture barrier may provide a sufficiently limited moisture permeability such that the packaged product is protected from undesirable deterioration. For example, a moisture barrier may have a moisture permeability that is low enough to prevent deleterious effects upon packaged products, such as transdermal drug patches or other moisture sensitive products. A preferred film according to various embodiments will have a water or moisture transmission rate (WVTR) of less than $0.01 \text{ g/100 inches}^2$ per 24 hours at Room Temperature (RT) (23°C) and 1 atmosphere. In some embodiments, a film has a WVTR of less than $0.01 \text{ g/100 inches}^2$ per 24 hours at RT and 1 atmosphere, such as less than $0.001 \text{ g/100 inches}^2$ per 24 hours at RT and 1 atmosphere.

[0049] A barrier layer as described herein may include any suitable material. An oxygen barrier layer may include EVOH, polyvinylidene chloride, polyamide, polyester, polyalkylene carbonate, polyacrylonitrile, nanocomposite, a metallized film such as aluminum vapor deposited on a polyolefin, etc., as known to those of skill in the art. Suitable moisture barrier layers include aluminum foil, PVDC, or polyolefins such as LDPE or LLDPE. It is desirable that the thickness of the barrier layer be selected to provide the desired combination of the performance properties sought e.g. with respect to oxygen permeability, and delamination resistance, and water barrier properties. Suitable thicknesses of the barrier layer are less than 15%, e.g. from 3 to 13% of the total film thickness and preferably less than about 10% of the total thickness of the multilayer film. Greater thicknesses may be employed. For example, the thickness of an oxygen barrier layer may advantageously be less than about 0.45 mil (about 10.16 microns) and greater than about 0.05 mil (about 1.27 microns), including thicknesses of 0.10 mil, 0.20 mil, 0.25 mil, 0.30 mil, 0.40 mil, or 0.45 mil.

[0050] In one exemplary embodiment, the central core layer 103 comprises an ethylene vinyl acetate copolymer (EVA) and more preferably, an ethylene vinyl acetate copolymer (EVA) having a 12% by weight vinyl acetate content. Non-limiting examples of EVA include

Escorene™ Ultra LD 705.MJ available from ExxonMobil Chemical Company (Houston, Tex.), Escorene™ Ultra LD 768.MJ available from ExxonMobil Chemical Company (Houston, Tex.) and Ateva® 2861AU available from Celanese Corporation (Edmonton, Alberta, Canada).

[0051] Exemplary five-layer embodiments of the base component described above may include, but are not limited to the following layer sequences and general layer compositions: COC/HDPE/EVA/HDPE/COC; COC/HDPE-Blend/EVA/HDPE-Blend/COC; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/COC; COC/HDPE/EVA/HDPE/PP; COC/HDPE-Blend/EVA/HDPE-Blend/PP; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/PP; COC/HDPE/EVA/HDPE/PETG; COC/HDPE-Blend/EVA/HDPE-Blend/PETG; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/PETG; COC/HDPE/EVA/HDPE/APET; COC/HDPE-Blend/EVA/HDPE-Blend/APET; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/APET; COC/HDPE/EVA/HDPE/PET; COC/HDPE-Blend/EVA/HDPE-Blend/PET; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/PET; COC/HDPE/EVA/HDPE/OPET; COC/HDPE-Blend/EVA/HDPE-Blend/OPET; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/OPET; COC/HDPE/EVA/HDPE/PLA; COC/HDPE-Blend/EVA/HDPE-Blend/PLA; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/PLA; COC/HDPE/EVA/HDPE/HIPS; COC/HDPE-Blend/EVA/HDPE-Blend/HIPS; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/HIPS; COC/HDPE/EVA/HDPE/GPPS; COC/HDPE-Blend/EVA/HDPE-Blend/GPPS; COC/HDPE-Bimodal/EVA/HDPE-Bimodal/GPPS; COC/HDPE/EVA/HDPE/SBC; COC/HDPE-Blend/EVA/HDPE-Blend/SBC; and COC/HDPE-Bimodal/EVA/HDPE-Bimodal/SBC.

[0052] The above examples may further include a tie layer comprising a tie layer material, such as between a high density polyethylene layer and the second exterior layer. The term "tie layer," or "adhesive layer," refers to a layer or material placed on one or more layers to promote the adhesion of that layer to another surface. Preferably, adhesive layers are positioned between two layers of a multilayer film to maintain the two layers in position relative to each other and prevent undesirable delamination. In some embodiments a peelable tie layer may be used which

is designed to have either cohesive failure or delamination from one or both adjacent layers upon application of a suitable manual force to provide an opening feature for a package made from the film. Unless otherwise indicated, an adhesive layer can have any suitable composition that provides a desired level of adhesion with the one or more surfaces in contact with the adhesive layer material. Optionally, an adhesive layer placed between a first layer and a second layer in a multilayer film may comprise components of both the first layer and the second layer to promote simultaneous adhesion of the adhesive layer to both the first layer and the second layer to opposite sides of the adhesive layer. Tie layer materials may include, but are not limited to, unmodified polyolefins such as polyethylenes and ethylene vinyl acetate copolymers, unmodified ester copolymers such as ethylene acrylate copolymers and ethylene methacrylate copolymers, unmodified ethylene acid copolymers such as ethylene acrylic acid copolymers, and blends thereof. Tie layer materials may also include modified polyolefins including, but not limited to anhydride modified polyethylenes, anhydride modified ethylene vinyl acetate copolymers, modified ester copolymers such as anhydride modified ethylene acrylate copolymers, modified ethylene acid copolymers such as anhydride modified ethylene acrylic acid copolymers, and blends thereof. Tie layer materials may further include a blend of an unmodified polyolefin, unmodified ester copolymer, or unmodified ethylene acid copolymer and a modified polyolefin, modified ester copolymer, or modified ethylene acid copolymer. In a preferred embodiment, a tie layer may be present between a layer comprising high density polyethylene and the second exterior layer comprising polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG) or polylactic acid (PLA).

[0053] In another exemplary embodiment as depicted in FIG. 4, thermoformed base component 12 comprises a multilayer palindromic thermoplastic film 200 which comprises a thirteen-layer symmetrical structure of a first exterior layer 201, a first interior layer 202, a second interior layer 203, a third interior layer 204, a fourth interior layer 205, a fifth interior

layer 206, a sixth interior layer 207, a central core layer 208, a seventh interior layer 209, an eighth interior layer 210, a ninth interior layer 211, a tenth interior layer 212, an eleventh interior layer 213, and a second exterior layer 214. In this embodiment, film 200 comprises two exterior layers each comprising cyclic olefin copolymer (COC), two discrete interior layers each comprising ethylene vinyl alcohol copolymer (EVOH), and four discrete interior layers each comprising high density polyethylene (HDPE). This thirteen-layer embodiment has the following layer sequence and general layer composition:

COC/HDPE/tie/EVOH/tie/HDPE/EVA/HDPE/tie/EVOH/tie/HDPE/COC. The HDPE containing layers may include a HDPE nucleation additive and a hydrocarbon resin, and provide moisture barrier functionality. The EVOH containing layers provide oxygen barrier functionality.

[0054] The total thickness of multilayer thermoplastic films of the thermoformed base component 12 of the present invention is generally from about 12.7 μm (0.5 mil) to about 508 μm (20 mil), such as from about 50.8 μm (2 mil) to about 254 μm (10 mil), or from about 76.2 μm (3 mil) to about 203.2 μm (8 mil).

Lidding Component

[0055] The packages of the present invention also include a lidding component which includes a cyclic olefin copolymer product contacting layer that is heat-sealable to the product contacting layer of the base component.

[0056] One exemplary embodiment of a lidding component 11 is depicted in FIG. 5. In this embodiment, lidding component 11 comprises a laminate 300 having a first exterior layer 301, an interior layer 302 and a second exterior layer 303. The second exterior layer 303 is a product contacting layer that includes at least 50% by weight of a cyclic olefin copolymer relative to the total weight of the layer, the first exterior layer 301 comprises paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate, and interior layer 302 comprises a metal foil such as aluminum. A tie or adhesive layer disposed between and bonding exterior layer 301 and interior layer 302 together may also be provided.

[0057] The second exterior layer 303 may include at least 50%, 75%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99% or more cyclic olefin copolymer (COC) by weight relative to the total weight of the layer. In one embodiment, the second exterior layer may consist of a cyclic olefin copolymer. The COC contained in the second exterior layer 303 may be any of those described above. The COC contained in the lidding component may be the same as the COC contained in the base component. Alternatively, the COC contained in the lidding component may be different than the COC contained in the base component.

[0058] The exterior layer may be any appropriate material. For example, the exterior layer may include paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate. The exterior layer may serve to protect the lidding component from damage and/or to provide additional strength to the lidding component.

[0059] The interior layer may be any appropriate metal foil. For example, the interior layer may be an aluminum foil. The metal foil may have a thickness of on the order of about 25.4 μm (about 1 mil). The foil serves as a barrier layer. The functions of the interior layer and the first exterior layer may be combined in a single layer, such as in a lidding component that includes only a barrier layer and a product contacting layer.

[0060] The lidding component may be produced using an extrusion coating apparatus and methods which are well known to those skilled in the art. The extrusion coating apparatus may include a multi-manifold flat die head through which a two-layer film composition may be forced and extrusion coated onto the shiny surface of a metallic foil. The metallic foil may be pre-treated prior to extrusion coating by printing a primer coat onto the matte surface of the foil. An exterior layer, such as paper or oriented polyethylene terephthalate, may be attached to the foil before or after the extrusion coating process.

[0061] In another exemplary embodiment as depicted in FIG. 6, lidding component 11 includes a multilayer film 500 which has a four-layer structure of a first exterior layer 501, a first interior layer 502, a second interior layer 503, and a second exterior layer 504. In this embodiment, first exterior layer 501 includes paper or oriented polyethylene terephthalate. The first interior layer

502 includes a polyethylene extrudate or adhesive, and the second interior layer 503 includes a metal foil. The second exterior layer 504 is a COC containing product contact layer of the type described above. This four-layer embodiment of the lidding component has the following layer sequence and general layer composition: COC/PE/foil/COC. An additional tie or adhesive layer may optionally be present between the second interior layer 503 and the second exterior layer 504.

Package

[0062] The packages as described herein can be manufactured using methods known in the art. Generally, the cavities are thermoformed from the base components of the present invention in-line just prior to filling the cavities with a product to be packaged. The thermoformed cavities may have any appropriate geometry, and are not limited to the specific configuration illustrated in FIG. 1 (e.g., the package may have a greater or lesser number of compartments, the compartments may have different sizes and/or shapes, etc.). The lidding component is then unwound from a roll and brought into contact with the formed and filled base component such that the cyclic olefin copolymer product contacting layer of the lidding component contacts the cyclic olefin copolymer product contacting layer of the base component. The lidding and base components are heat sealed, typically using a heated platen. Some areas of the package may not be sealed to provide a starting point for peeling off the lidding component prior to removing the product. If the lidding component is not pre-printed, printing is generally done just before heat sealing. After heat-sealing, the individual cavities may be perforated using methods known in the art so that they can be removed at point of use.

[0063] The packages as described herein may alternatively include a base component in the form of a tray or a container. The tray or container base portions may be formed by any appropriate process, and may have any appropriate geometry. For example, a cold forming process may be utilized to form a container from a base component, with the container being subsequently sealed to the lidding component to form a complete container and lid package.

[0064] The seal between the lidding component and the base component has a seal strength of at least 800 grams force per inch, such as at least about 1,000 grams force per inch, at least about 1,200 grams force per inch, or more. The seal produced between the COC-containing product contacting layers of the base component and the lidding component is significantly stronger than that of a COC-containing layer heat sealed to a polyvinylchloride (PVC) layer or polyacrylate layer. For example, layers that contain at least 50% by weight COC may produce seal peel strengths of only about 200 gf when heat sealed with polyvinylchloride (PVC) layers or polyacrylate layers, and such a seal strength may be insufficient for some package applications. The sealing of the lidding component to the base component produces a cavity where all of the surfaces exposed to the product are formed by the cyclic olefin copolymer product contacting layers of the lidding component or the base component. In this manner, the packages disclosed herein provide cavities in which every surface exposed to the product is formed of an anti-scalping material, while also providing the desired seal strength. The strength of the seal may be influenced by the design of the package, such as the geometry, and the product requirements.

[0065] The packages described herein may be utilized as packaging for nicotine containing products. Examples of nicotine containing products include nicotine cartridges for electronic cigarettes, nicotine gum, and nicotine transdermal patches. The cyclic olefin copolymer product contacting layers of the lidding component and the base component resist the uptake of nicotine, enhancing the shelf life and efficiency of the package. The packages may also be utilized as packaging for other products, such as pharmaceuticals or medications. A pharmaceutical product for packaging in a package described herein can include any suitable pharmaceutical active agent. In some embodiments, the pharmaceutical active agent is selected from the group consisting of fentanyl, nicotine, lidocaine, estradiol, clonidine, ethinyl estradiol, oxybutynin, buprenorphine, granisetron, methylphenidate, and scopolamine. In some embodiments, one or more of the listed pharmaceutical active agents are included in a pharmaceutical product, such as a transdermal patch.

Non-Limiting Examples

[0066] Blister packages with COC-containing product contacting layers of the type described herein were tested to determine the degree of nicotine uptake in the packaging. The product contacting layers were formed from a commercially available CXBTM sealant layer structure on a SKYBLUETM blister packaging film, the product contacting layers were 100% by weight COC. A blister package with product contacting layers of polychlorotrifluoroethylene (PCTFE) and polyvinylchloride (PVC) was utilized as a control. The same amount of nicotine was placed in each blister package, and the amount of nicotine uptake in the test blister packaging materials, after washing out the nicotine from the blister package, was measured after 1 week, 2 weeks, and 4 weeks of elapsed time.

[0067] As shown in Table 1 and FIG. 7, the blister packages with COC-containing product contacting layers exhibited significantly less uptake of nicotine than the control blister packages with PVC product contacting layers. Thus, the blister packages with COC-containing product contacting layers of the present invention exhibited greater resistance to nicotine scalping than other common blister packages, such as those with PCTFE and PVC product contacting layers.

Table 1

Blister Package	Nicotine Uptake (mg)		
	Week 1	Week 2	Week 4
PCTFE/PVC	9.11	16.74	17.13
COC (SKYBLUE TM CXB TM film)	0.71	0.62	1.00

[0068] As used herein, singular forms “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a “structured bottom surface” includes examples having two or more such “structured bottom surfaces” unless the context clearly indicates otherwise.

[0069] As used herein, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements. The use of “and/or” in

certain instances herein does not imply that the use of “or” in other instances does not mean “and/or”.

[0070] As used herein, “have”, “has”, “having”, “include”, “includes”, “including”, “comprise”, “comprises”, “comprising” or the like are used in their open ended inclusive sense, and generally mean “include, but not limited to”, “includes, but not limited to”, or “including, but not limited to”.

[0071] “Optional” or “optionally” means that the subsequently described event, circumstance, or component, can or cannot occur, and that the description includes instances where the event, circumstance, or component, occurs and instances where it does not.

[0072] The words “preferred” and “preferably” refer to embodiments of the disclosure that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the inventive technology.

[0073] For purposes of the present disclosure, recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.). Where a range of values is “greater than”, “less than”, etc. a particular value, that value is included within the range.

[0074] Any direction referred to herein, such as “top,” “bottom,” “left,” “right,” “upper,” “lower,” “above,” “below,” and other directions and orientations are described herein for clarity in reference to the figures and are not to be limiting of an actual device or system or use of the device or system. Many of the devices, articles or systems described herein may be used in a number of directions and orientations.

[0075] Unless otherwise expressly stated, it is in no way intended that any method set forth herein be construed as requiring that its steps be performed in a specific order. Accordingly, where a method claim does not actually recite an order to be followed by its steps or it is not

otherwise specifically stated in the claims or descriptions that the steps are to be limited to a specific order, it is no way intended that any particular order be inferred. Any recited single or multiple feature or aspect in any one claim can be combined or permuted with any other recited feature or aspect in any other claim or claims.

[0076] It is also noted that recitations herein refer to a component being “configured” or “adapted to” function in a particular way. In this respect, such a component is “configured” or “adapted to” embody a particular property, or function in a particular manner, where such recitations are structural recitations as opposed to recitations of intended use. More specifically, the references herein to the manner in which a component is “configured” or “adapted to” denotes an existing physical condition of the component and, as such, is to be taken as a definite recitation of the structural characteristics of the component.

[0077] While various features, elements or steps of particular embodiments may be disclosed using the transitional phrase “comprising,” it is to be understood that alternative embodiments, including those that may be described using the transitional phrases “consisting” or “consisting essentially of,” are implied.

[0078] In the foregoing description, it will be readily apparent to one skilled in the art that varying modifications may be made to the present disclosure without departing from the scope and spirit of the disclosure. Since modifications, combinations, sub-combinations and variations of the disclosed embodiments incorporating the spirit and substance of the inventive technology may occur to persons skilled in the art, the inventive technology should be construed to include everything within the scope of the appended claims and their equivalents. The embodiments illustratively described herein suitably may be practiced in the absence of any element or elements, limitation or limitations, which is not specifically disclosed herein. The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention that in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention. Thus, it should be

understood that although the present invention has been illustrated by specific embodiments and optional features, modification and/or variation of the concepts herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention.

WHAT IS CLAIMED IS:

1. A package comprising:
 - a base component comprising a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer; and
 - a lidding component comprising a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer;wherein the product contacting layer of the base component is sealed to the product contacting layer of the lidding component such that a cavity is formed.
2. The package of claim 1, wherein the base component is a multilayer thermoplastic film that comprises:
 - the product contacting layer comprising at least 50% by weight of the cyclic olefin copolymer,
 - a first interior layer,
 - a core layer,
 - a second interior layer, and
 - an exterior layer comprising at least one material selected from the group consisting of cyclic olefin copolymer (COC), polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG), biaxially oriented nylon (BON), and polylactic acid (PLA).
3. The package of claim 2, wherein the first interior layer and the second interior layer each comprise at least one of a high density polyethylene nucleation additive or a hydrocarbon resin.
4. The package of claim 2, wherein the first interior layer and the second interior layer each comprise a bimodal high density polyethylene having a distribution of a low molecular weight region and a high molecular weight region.

5. The package of claim 2, wherein the core layer comprises an ethylene vinyl acetate copolymer.
6. The package of claim 2, wherein the exterior layer of the base component comprises at least 50% by weight of a cyclic olefin copolymer.
7. The package of claim 1, wherein the cyclic olefin copolymer of at least one of the base component or the lidding component comprises norbornene and ethylene monomers.
8. The package of claim 1, wherein the lidding component comprises:
a barrier layer; and
the product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer.
9. The package of claim 8, wherein the lidding component further comprises an exterior layer disposed over the barrier layer that comprises at least one of paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate.
10. The package of claim 14, wherein the lidding component further comprises an interior layer disposed between the exterior layer and the barrier layer that comprises at least one of polyethylene and an adhesive.
11. The package of claim 1, wherein the seal between the product contacting layer of the base component and the product contacting layer of the lidding component has a seal strength of at least 800 grams force per inch.
12. A lidding component for a package comprising:
a barrier layer; and
a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer, wherein the product contacting layer is configured to seal to a product contacting layer of a base component.

13. The lidding component of claim 19, further comprising an exterior layer disposed over the barrier layer that comprises at least one of paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate.

14. The lidding component of claim 13, further comprising an interior layer disposed between the exterior layer and the barrier layer that comprises at least one of polyethylene and an adhesive.

15. A method of forming a package, comprising:
sealing a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer of a base component to a product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer of a lidding component to form a cavity.

16. The method of claim 15, further comprising forming the base component by a blown coextrusion process and forming the lidding component by a lamination process.

17. The method of claim 15, wherein the sealing is a heat sealing process.

18. The method of claim 15, wherein the base component is a multilayer thermoplastic film that comprises:
a product contacting layer comprising at least 50% by weight of the cyclic olefin copolymer,
a first interior layer,
a core layer,
a second interior layer, and
an exterior layer comprising at least one material selected from the group consisting of cyclic olefin copolymer (COC), polypropylene (PP), high impact polystyrene (HIPS), general purpose polystyrene (GPPS), styrene block copolymer (SBC), polyethylene terephthalate (PET), oriented polyethylene terephthalate (OPET), amorphous polyethylene terephthalate (APET), glycol-modified polyethylene terephthalate (PETG), biaxially oriented nylon (BON), and polylactic acid (PLA).

19. The method of claim 18, wherein the exterior layer of the base component comprises at least 50% by weight of a cyclic olefin copolymer.

20. The method of claim 15, wherein the lidding component comprises:
a barrier layer; and
the product contacting layer comprising at least 50% by weight of a cyclic olefin copolymer.

21. The method of claim 20, wherein the lidding component further comprises an exterior layer disposed over the barrier layer that comprises at least one of paper, biaxially oriented nylon, biaxially oriented polypropylene, or oriented polyethylene terephthalate.

22. The method of claim 15, wherein the lidding component further comprises an interior layer disposed between the exterior layer and the barrier layer that comprises at least one of polyethylene and an adhesive.

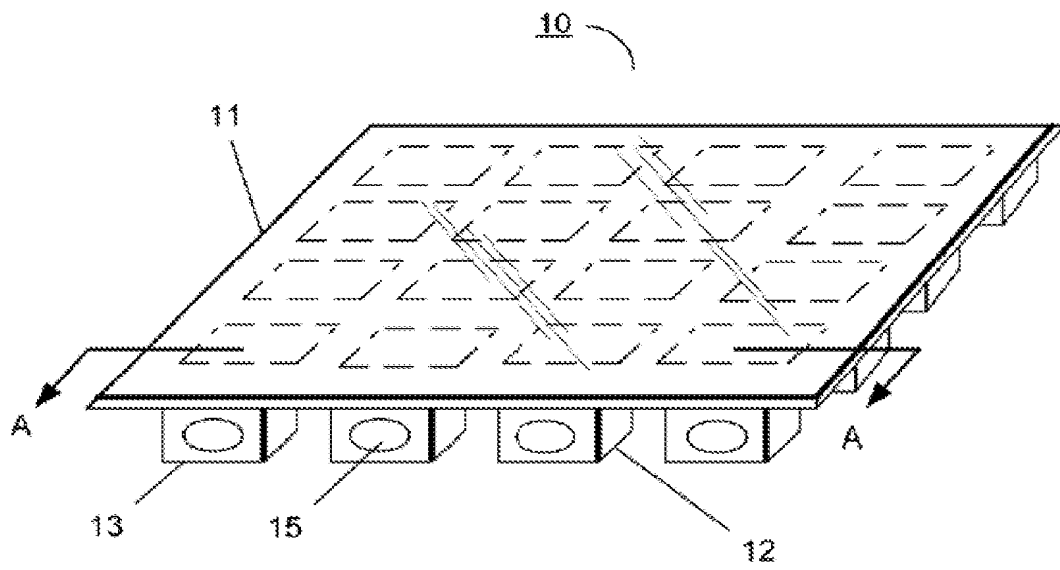


Fig. 1

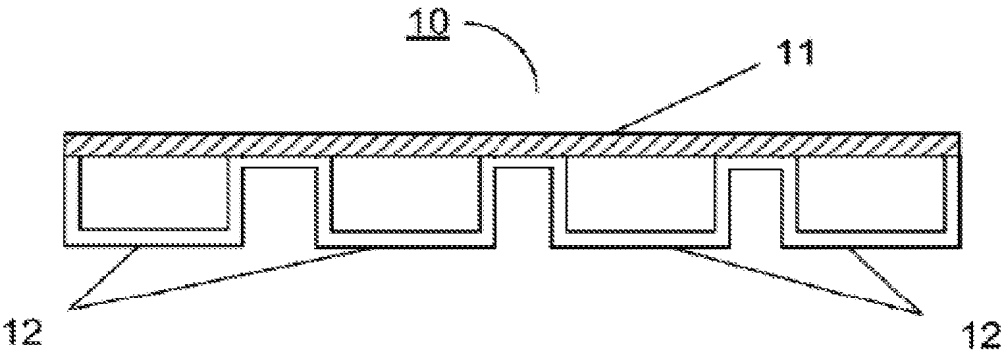


Fig. 2

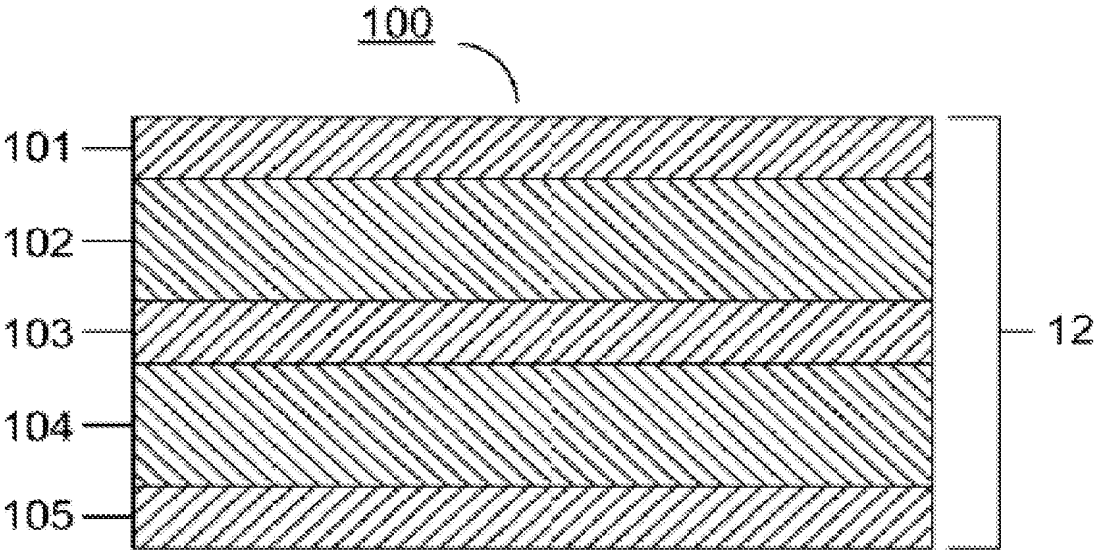


Fig. 3

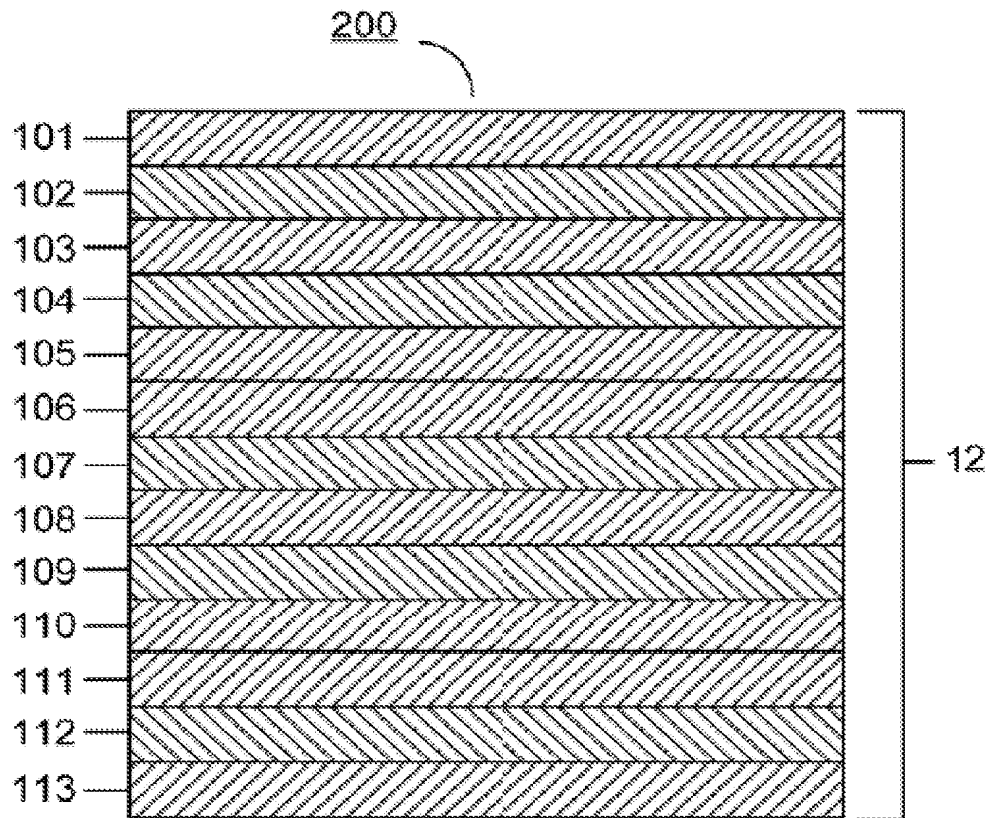


Fig. 4

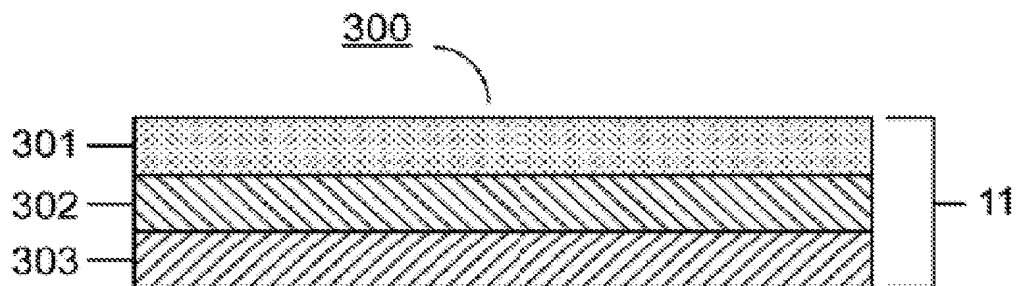


Fig. 5

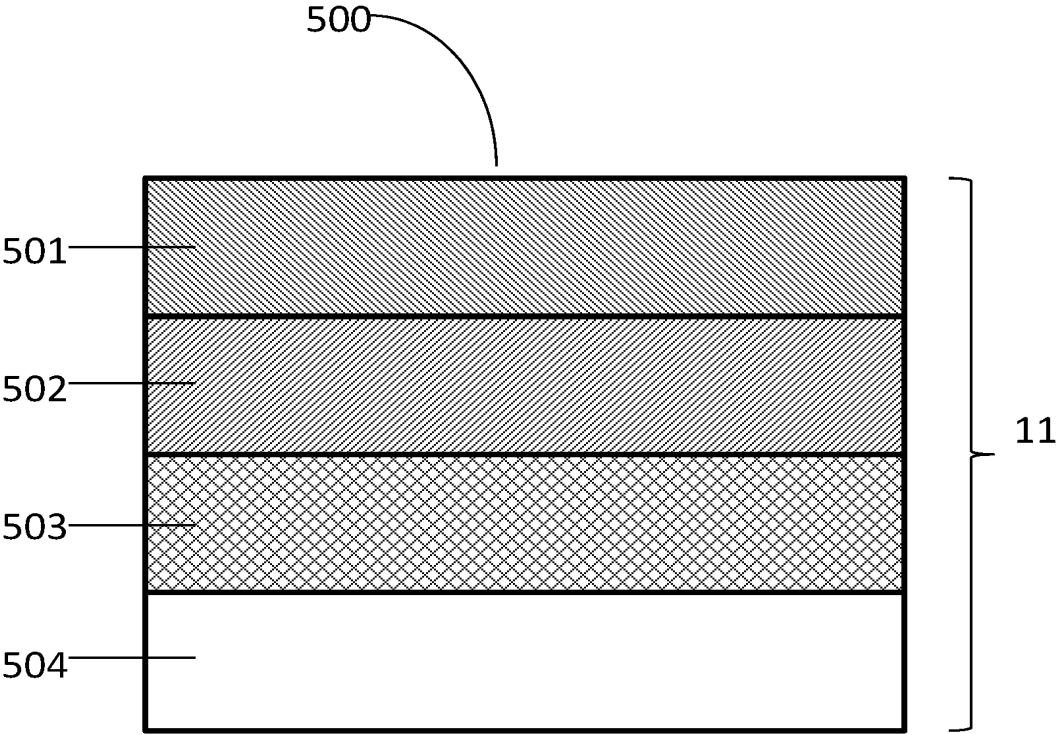


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/65439

A. CLASSIFICATION OF SUBJECT MATTER

IPC - B65D 75/36 (2017.01)

CPC - B65D 75/327, 75/36

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)

See Search History document

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

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/0283029 A1 (RIIS JL et al.) October 8, 2015; figures 4, 6; paragraphs [0056], [0066], [0070], [0090], [0097], [0122]	1, 2, 5, 7-10, 12-18, 20-22
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Y		3, 4, 6, 11, 19
Y	US 2015/0298439 A1 (BEMIS COMPANY INC) October 22, 2015; figure 1; paragraphs [0033], [0048])	3, 6, 19
Y	WO 2007/104513 A1 (BOREALIS TECHNOLOGY OY) 20 September 2007; abstract; page 2, lines 25-31	4
Y	US 2007/0278114 A1 (KANE JP et al.) December 6, 2007; paragraphs [0043], [0048]	11
A	US 2007/0212539 A1 (YAMADA T et al.) September 13, 2007; entire document	1-22
A	US 5,783,273 A (YAMAMOTO Y et al.) July 21, 1998; entire document	1-22
A	US 2009/0042026 A1 (PASBRIG E) February 12, 2009; entire document	1-22

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

05 February 2017 (05.02.2017)

Date of mailing of the international search report

21 FEB 2017

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

Electronic Acknowledgement Receipt

EFS ID:	37759731
Application Number:	15780999
International Application Number:	
Confirmation Number:	7187
Title of Invention:	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/Sherry Soares
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.US (87942.0009)
Receipt Date:	15-NOV-2019
Filing Date:	
Time Stamp:	08:54:53
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no
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File Listing:

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Total Files Size (in bytes):			85355981		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Christensen et al.

Application No.: 15/780,999

Filed: June 1, 2018

For: A METHOD FOR PROVIDING AN
EXTREME CHEMICAL RESISTANT
FILM, A FILM
AND LAMINATE OBTAINABLE
THEREFROM

Docket No.: P006DK.WO.US (87942.0009)

Customer No.: 109682

Confirmation No.: 7187

Examiner:

Art Unit:

**INFORMATION DISCLOSURE
STATEMENT**

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being
filed via EFS-Web with the United States Patent
and Trademark Office on November 15, 2019.

By: /Sherry Soares/
Sherry Soares

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter “the Form”) with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/Paul M. Schramm/

Paul M. Schramm
Reg. No. 62,050

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Salt Lake City, UT 84147
Tel: 303-473-2700
Fax: 303-473-2720

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	15/780,999
Filing Date	01 June 2018
First Named Inventor	Christensen et al.
Title	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	P006DK.WO.US (87942.0009)

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul M. Schramm/	Date (Optional)	
Name	Paul M. Schramm	Registration Number	62,050
Title (if Applicant is a juristic entity)	Attorney		
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number

15/780,999

Filing Date

01 June 2018

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)



I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

OR

26582



I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:



The address associated with the above-mentioned Customer Number

OR



The address associated with Customer Number: 26582

OR

Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Danapak Flexibles A/S



Inventor or Joint Inventor (title not required below)



Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)



Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)



Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is provided below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Date (Optional)

8/6-2018

Name

LARS

Title

CEO

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.33, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9198 and select option 2.

**DECLARATION FOR UTILITY OR DESIGN APPLICATION
USING AN APPLICATION DATA SHEET
and
ASSIGNMENT**

We, Lars Christensen, Peter Johansen and Torben Fogtmann, as the inventors, hereby declare that this declaration is directed to:

Title of Invention: A METHOD FOR PROVIDING AN EXTREME
CHEMICAL RESISTANT FILM, A FILM AND
LAMINATE OBTAINABLE THEREFROM

Filing Date: 01 June 2018

Application No.: 15/780,999

which is a 371 national phase of the below-identified international patent application:

Title of Invention: A METHOD FOR PROVIDING AN EXTREME CHEMICAL
RESISTANT FILM, A FILM AND LAMINATE
OBTAINABLE THEREFROM

Filing Date: 29 December 2016

Application No.: PCT/EP2016/082876

The above-identified applications were made or authorized to be made by us.

We believe that we are the original inventors of a claimed invention in the applications.

We hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WHEREAS, Lars Christensen, a citizen of Denmark, residing at Slagelse, Denmark; Peter Johansen, a citizen of Denmark, residing at Odense C, Denmark; and Torben Fogtmann, a citizen of Denmark, residing at Nyborg, Denmark; hereinafter referred to as "Assignors," are the inventors described and set forth in the above-identified applications;

WHEREAS, Danapak Flexibles A/S, located at Slagelse, Denmark; hereinafter referred to as "Assignee," is desirous of acquiring an ownership interest in the invention and applications listed above and in any U.S. Letters Patent and Registrations which may be granted on any patent application claiming priority from the same;

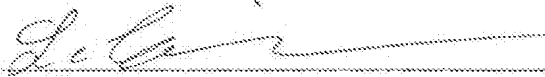
For good and valuable consideration, receipt of which is hereby acknowledged by the Assignors, Assignors have assigned, and by these presents do assign to Assignee all right, title and interest in and to the invention and application and to all foreign counterparts (including patent, utility model and industrial designs), and in and to any Letters Patent and Registrations which may hereafter be granted on any patent application claiming priority from the same in the United States and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention. The right, title and interest is to be held and enjoyed by Assignee and Assignee's successors and assigns and as fully and

exclusively as it would have been held and enjoyed by the Assignors had this Assignment not been made, for the full term of any Letters Patent and Registrations which may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof.

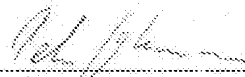
Assignors further agree that Assignors will, without charge to Assignee, but at Assignee's expense, (a) cooperate with Assignee in the prosecution of U.S. Patent applications and foreign counterparts on the invention and any improvements, (b) execute, verify, acknowledge and deliver all such further papers, including applications and instruments of transfer, and (c) perform such other acts as Assignee lawfully may request to obtain or maintain Letters Patent and Registrations for the invention and improvements in any and all countries, and to vest title thereto in Assignee, or Assignee's successors and assigns.

IN TESTIMONY WHEREOF, Assignors have signed their names on the date indicated.

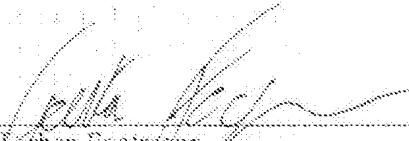
Dated: 08-06-2018


Lars Christensen

Dated: 08.06.2018


Peter Johansen

Dated: 09-06-2018


Torben Fogtjann

Electronic Acknowledgement Receipt

EFS ID:	32928199
Application Number:	15780999
International Application Number:	
Confirmation Number:	7187
Title of Invention:	A METHOD FOR PROVIDING AN EXTREME CHEMICAL RESISTANT FILM, A FILM AND LAMINATE OBTAINABLE THEREFROM
First Named Inventor/Applicant Name:	Lars Christensen
Customer Number:	26582
Filer:	Paul M. Schramm/we Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P006DK.WO.US (87942.0009)
Receipt Date:	20-JUN-2018
Filing Date:	
Time Stamp:	13:58:55
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		15780999PoADecAssign_.pdf	1237162	yes	4
			346e5f931ba61ee92c9cf6f54ceea31ac6e9cd68		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Power of Attorney	1	2	
Oath or Declaration filed	3	4	
Warnings:			
Information:			
Total Files Size (in bytes):		1237162	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>			

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT5015471

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT
CONVEYING PARTY DATA	
Name	Execution Date
LARS CHRISTENSEN	06/08/2018
PETER JOHANSEN	06/08/2018
TORBEN FOGTMANN	06/08/2018
RECEIVING PARTY DATA	
Name:	DANAPAK FLEXIBLES A/S
Street Address:	STRUDBERGSVEJ 3
City:	SLAGELSE
State/Country:	DENMARK
Postal Code:	4200
PROPERTY NUMBERS Total: 1	
Property Type	Number
Application Number:	15780999
CORRESPONDENCE DATA	
Fax Number:	(303)473-2720
<i>Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.</i>	
Phone:	(303) 473-2700
Email:	wcnishida@hollandhart.com
Correspondent Name:	HOLLAND & HART LLP
Address Line 1:	222 SOUTH MAIN STREET
Address Line 2:	SUITE 2200
Address Line 4:	SALT LAKE CITY, UTAH 84147
ATTORNEY DOCKET NUMBER:	P006DK.WO.US (87942.0009)
NAME OF SUBMITTER:	PAUL M. SCHRAMM
SIGNATURE:	/Paul M. Schramm/
DATE SIGNED:	06/20/2018
This document serves as an Oath/Declaration (37 CFR 1.63).	
Total Attachments: 2	
source=15780999Assignment#page1.tif	
source=15780999Assignment#page2.tif	

**DECLARATION FOR UTILITY OR DESIGN APPLICATION
USING AN APPLICATION DATA SHEET
and
ASSIGNMENT**

We, Lars Christensen, Peter Johansen and Torben Foghmann, as the inventors, hereby declare that this declaration is directed to:

Title of Invention: A METHOD FOR PROVIDING AN EXTREME
CHEMICAL RESISTANT FILM, A FILM AND
LAMINATE OBTAINABLE THEREFROM

Filing Date: 01 June 2018

Application No.: 15/780,999

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WHEREAS, Danapak Flexibles A/S, located at Slagelse, Denmark; hereinafter referred to as "Assignee," is desirous of acquiring an ownership interest in the invention and applications listed above and in any U.S. Letters Patent and Registrations which may be granted on any patent application claiming priority from the same;

For good and valuable consideration, receipt of which is hereby acknowledged by the Assignors, Assignors have assigned, and by these presents do assign to Assignee all right, title and interest in and to the invention and application and to all foreign counterparts (including patent, utility model and industrial designs), and in and to any Letters Patent and Registrations which may hereafter be granted on any patent application claiming priority from the same in the United States and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention. The right, title and interest is to be held and enjoyed by Assignee and Assignee's successors and assigns and as fully and

exclusively as it would have been held and enjoyed by the Assignors had this Assignment not been made, for the full term of any Letters Patent and Registrations which may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prologation or extension thereof.

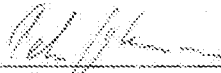
Assignors further agree that Assignors will, without charge to Assignee, but at Assignee's expense, (a) cooperate with Assignee in the prosecution of U.S. Patent applications and foreign counterparts on the invention and any improvements, (b) execute, verify, acknowledge and deliver all such further papers, including applications and instruments of transfer, and (c) perform such other acts as Assignee lawfully may request to obtain or maintain Letters Patent and Registrations for the invention and improvements in any and all countries, and to vest title thereto in Assignee, or Assignee's successors and assigns.

IN TESTIMONY WHEREOF, Assignors have signed their names on the date indicated.

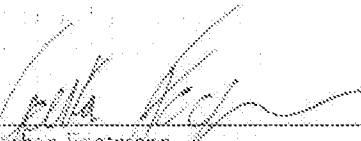
Dated: 08-06-2018


Lars Christensen

Dated: 08.06.2018


Peter Johansen

Dated: 08-06-2018


Torben Fogtmann



(51) International Patent Classification:

B32B 7/12 (2006.01) *B32B* 27/08 (2006.01)
B32B 15/08 (2006.01) *B32B* 27/30 (2006.01)
B32B 15/082 (2006.01) *B32B* 27/32 (2006.01)
B32B 15/085 (2006.01) *B32B* 27/36 (2006.01)
B32B 15/20 (2006.01)

(21) International Application Number:

PCT/EP2016/082876

(22) International Filing Date:

29 December 2016 (29.12.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

15202962.5 29 December 2015 (29.12.2015) EP

(71) Applicant: **DANAPAK FLEXIBLES A/S** [DK/DK];
Strudsbergvej 3, 4200 Slagelse (DK).

(72) Inventors: **CHRISTENSEN, Lars**; Østerbro 54, 4200
Slagelse (DK). **JOHANSEN, Peter**; Munkebjergvej 3, 2.
sal, 5000 Odense C (DK). **FOGTMANN, Torben**;
Hjortevænget 174, 5800 Nyborg (DK).

(74) Agent: **AWAPATENT A/S**; Rigersgade 11, Denmark,
1316 Copenhagen K (DK).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN,
KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA,
MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG,
NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS,
RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY,
TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN,
ZA, ZM, ZW.

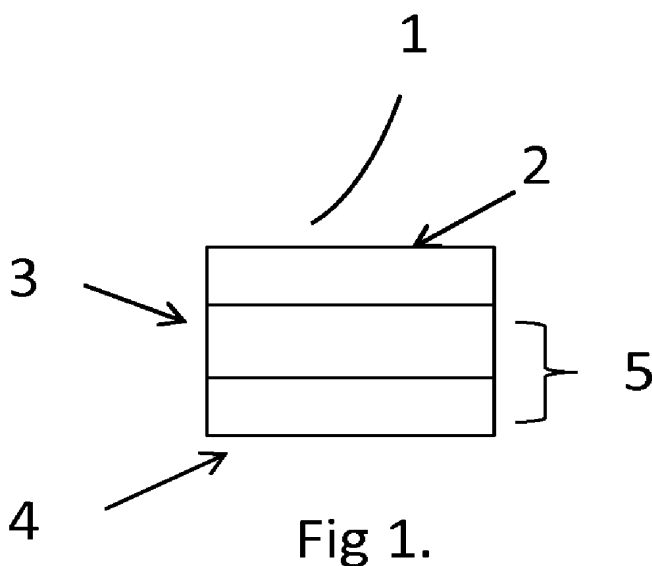
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))

[Continued on next page]

(54) Title: A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM



(57) Abstract: The present invention relates to a method
for providing an extreme chemical resistant film whereby a
tie layer and a contact layer are coextruded with a base lay-
er, such as a metal foil, as well as films and laminates ob-
tained by the method and uses of the films and laminates to
pack aggressive chemical substances such as nicotine, lido-
caine, fentanyl and rivastigmine.

Published:

— *with international search report (Art. 21(3))*

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

AWA DENMARK A/S
Strandgade 56
1401 København K
DANEMARK

Date of mailing (day/month/year) 05 June 2018 (05.06.2018)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 137098	
International application No. PCT/EP2016/082876	International filing date (day/month/year) 29 December 2016 (29.12.2016)

1. The following indications appeared on record concerning:			
☐ the applicant	☐ the inventor	☒ the agent	☐ the common representative
Name and Address AWAPATENT A/S Strandgade 56 1401 København K Denmark		State of Nationality	State of Residence
		Telephone No. 004543995511	
		Facsimile No. 004543999911	
		E-mail address dk@awapatent.com	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:			
☐ the person	☒ the name	☐ the address	☐ the nationality ☐ the residence
Name and Address AWA DENMARK A/S Strandgade 56 1401 København K Denmark		State of Nationality	State of Residence
		Telephone No. 004543995511	
		Facsimile No. 004543999911	
		E-mail address dk@awa.com ☐ Notifications by e-mail authorized	
3. Further observations, if necessary: Please note the change of e-mail address, as indicated in Box 2.			
4. A copy of this notification has been sent to:			
☒ the receiving Office	☐ the International Preliminary Examining Authority		
☐ the International Searching Authority	☒ the designated Offices concerned		
☐ the Authority(ies) specified for supplementary search	☐ the elected Offices concerned		
	☐ other:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Blanc Veronique e-mail pct.team5@wipo.int Telephone No. +41 22 338 74 05
Facsimile No. +41 22 338 82 70	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 137098	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2016/082876	International filing date (<i>day/month/year</i>) 29 December 2016 (29.12.2016)	Priority date (<i>day/month/year</i>) 29 December 2015 (29.12.2015)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DANAPAK FLEXIBLES A/S		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 9 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;">☒</td> <td style="width: 30%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	☒	Box No. I	Basis of the report	☐	Box No. II	Priority	☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐	Box No. IV	Lack of unity of invention	☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	☐	Box No. VI	Certain documents cited	☐	Box No. VII	Certain defects in the international application	☒	Box No. VIII	Certain observations on the international application
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☐	Box No. VI	Certain documents cited																							
☐	Box No. VII	Certain defects in the international application																							
☒	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 03 July 2018 (03.07.2018)</p> <p>Authorized officer Nora Lindner</p> <p>e-mail: pct.team5@wipo.int</p>
--	--

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2016/082876

International filing date (day/month/year)
29.12.2016

Priority date (day/month/year)
29.12.2015

International Patent Classification (IPC) or both national classification and IPC
INV. B32B7/12 B32B15/08 B32B15/082 B32B15/085 B32B15/20 B32B27/08 B32B27/30 B32B27/32 B32B27/36

Applicant
DANAPAK FLEXIBLES A/S

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Mazet, Jean-François

Telephone No. +31 70 340-0



Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>9-12, 15, 18, 20, 26-28, 30, 31</u>
	No: Claims	<u>1-8, 13, 14, 16, 17, 19, 21-25, 29</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-31</u>
Industrial applicability (IA)	Yes: Claims	<u>1-31</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item VIII

Certain observations on the international application

1. The expressions "*aggressive chemical resistant*" (used *inter alia* in claims 1, 13, 16, 21, 29) and "*aggressive chemical substance*" (used *inter alia* in claim 16, 21, 29) are relative and therefore unclear (Article 6 PCT).

There is no unambiguous and well-defined technical meaning for the term "*aggressive chemical*" or "*aggressive chemical substance*", since all kind of compound, inclusive water, may be regarded as "*aggressive*" to a certain extent depending on the substrate which they are in contact with, and the conditions of this contact. On the same manner, and in spite of the passage in the description on page 17, lines 23 to 28, the term "*resistant*" and "*resistance*" used in the claims are also unclear since any material may be considered as "*aggressive chemical resistant*" depending not only on the kind of chemical but also on the conditions of contact (time, temperature, static or dynamic contacts, extent of the surface contacted etc.).

Similarly, the expressions "*resistant against nicotine, rivastigmine, fentanyl and/or lidocaine*" (used *inter alia* in claims 24 and 25) is relative and therefore unclear (Article 6 PCT). Indeed, any material can be regarded as resistant against nicotine, rivastigmine, fentanyl and/or lidocaine to a certain extent, depending of the conditions of contact and the criteria for defining the "*resistance*" taken into account.

Finally, the expression "*chemical resistance*" (used in *inter alia* in claim 22) is also relative and therefore unclear (Article 6 PCT).

It should be noted however than even if these expressions are unclear, they have a certain limiting effect on the scope of the claims.

2 Furthermore, claims 1, 13, 16, 21 and 22 characterise the polymer comprised in the contact layer by a unusual parameter, i.e. the "*RED value based on Hansens Solubility parameter (HSP)*". Let alone that this parameter is a) quite uncommon, b) does not allow comparison with the prior art, and c) that the method for measuring this parameter is not included in the claim, it is clear from the passage on page 4, lines 1-28 that the values obtained for a given polymer will necessarily strongly depend on the substance regarded as an "*aggressive chemical*". It follows that defining a polymer by a RED value based on Hansens Solubility parameter (HSP) towards a chemical without indicating which chemical compound is taken into account does not make sense. It is indeed believed that it will always exist a chemical for which the RED value of a given polymer will be > 0.8 , whatever the polymer chosen.

3. Dependent claims 10, 11 and 12 refer to methods for producing a film, said methods being characterised by the use of the film to wrap a composition (claim 10), the type of composition (a patch, claim 11) and a test performed on the package (claim 12). All these features are related to the use of the produced film and are therefore independent of the process for making the film: they are obviously not features characterising the process for making the film. This is quite confusing and renders the subject-matter of these claims totally unclear (Article 6 PCT). The very same applies to claims 26, 27 and 28.

4. It follows that the subject-matter of claims 1, 10-13, 16, 21, 22, 24, 25-29 is not clearly defined (Article 6 PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- | | |
|----|---|
| D1 | US 6 120 860 A (BOWEN WILLIAM E [US] ET AL) 19 September 2000 (2000-09-19) |
| D2 | US 2005/037162 A1 (ADAMS JOHN PETER [US]) 17 February 2005 (2005-02-17) |
| D3 | US 2004/234790 A1 (SMITH WILLIAM STUART [US] ET AL) 25 November 2004 (2004-11-25) |
| D4 | WO 00/44559 A1 (PHARMACIA & UPJOHN AB [SE]; LEVANDER GUSTAV [SE]; KARLSSON ANDERS H F) 3 August 2000 (2000-08-03)cited in the application |
| D5 | WO 2005/037539 A1 (DU PONT [US]; MORRIS BARRY ALAN [US]; TROUILHET YVES M [CH]) 28 April 2005 (2005-04-28) |
| D6 | EP 2 939 667 A1 (NIPRO PATCH CO LTD [JP]) 4 November 2015 (2015-11-04) |
| D7 | WO 2013/004243 A1 (FERTIN PHARMA AS [DK]; NIELSEN KAJ HOVHAVE [DK]) 10 January 2013 (2013-01-10) |

- D8 US 2005/112337 A1 (JESTER RANDY D [US]) 26 May 2005
(2005-05-26)
- D9 DATABASE WPI
Week 201579
Thomson Scientific, London, GB;
AN 2015-71769A
XP002759263,
& WO 2015/174502 A1 (NICHIBAN KK) 19 November 2015 (2015-11-19)
- D10 WO 91/09731 A1 (ALZA CORP [US]) 11 July 1991 (1991-07-11)

1. Independent claims 1, 13, 16, 21, 22, 24, 25, 29

1.1 Novelty (Article 33(2) PCT)

1.1.1 Document **D1** discloses a heat sealable laminate (column 5, line 65 to column 6, line 26) formed from an "aggressive chemical resistant" film (see column 2, line 49 to column 3, line 7) for packaging "aggressive chemical substances" (for instance polymer adhesive and coating systems containing aggressive solvents such as xylene and toluene, see column 1, lines 54-59) and a method for providing the same, said method comprising the steps of coextruding a layer comprising a tie layer and a sealant layer (see column 4, lines 32 - 63: comprising a nylon layer, a tie layer and a EVA sealant layer = contact layer) and coating / adhering this coextruded layer (column 4, lines 49-51) to a water and/or oxygen resistant a base layer ("*high barrier material*", for instance aluminium foil, nylon coated on both sides with polyvinylidene chloride copolymer, polyvinylidene chloride vinyl chloride copolymers, see column 4 lines 11-15).

No "RED values based on Hansens Solubility parameter" for the polymers towards the aggressive chemicals have not been indicated in D1. However, since the structure and composition of the multilayered film of D1 are identical to the structure and composition of the film of the present application, and taking into account the severe clarity problems of the present claims related the "RED value" parameter (see here above at section Re Item VIII), **the subject-matter of at least independent claims 1, 13, 16, 21 and 22 cannot be regarded as novel in view of the disclosure of D1 (Article 33(2) PCT).**

1.1.2 Document **D2** discloses (see [0012], [0023], [0028][0045], claims; see all the samples discloses in the Table on pages 2 and 3, and especially sample E) a multilayer film obtained by providing a base layer (aluminium foil) coated by coextruding a layer comprising a tie layer (EAA, EMAA, anhydride-modified polyolefin) and a contact layer/sealable layer which can be made of or comprise a cyclic olefin copolymer (COC). The COC is one of the polymers which is presented in the present application as "resistant against nicotine, rivastigmine, fentanyl and/or lidocaine" (see for instance present claim 25, see also passages of the description of the application, on page 13, lines 24 to 27; page 14, lines 5 to 8; page 14, lines 21 to 24; page 15, lines 2 to 5). It follows that the product disclosed by D2 has necessarily "a RED values based on Hansens Solubility parameter towards nicotine, rivastigmine, fentanyl and/or lidocaine of > 0.8 ". Again, even if no "RED values based on Hansens Solubility parameter" have been indicated in D2, the structure and composition of the multilayered film of D2 are identical to the structure and composition of the film of the present application, and taking into account the severe clarity problems of the present claims (see here above at section Re Item VIII), **the subject-matter of at least independent claims 1, 13, 16, 21, 22, 24, 25 and 29 cannot be regarded as novel in view of the disclosure of D2 (Article 33(2) PCT).**

1.1.3 Document **D3** (see figure 1, paragraphs [0004] and [0005]) is also considered as disclosing all the technical features of **at least independent claims 1, 13, 16, 21, 22** which cannot be considered as novel when taking into account the severe numerous clarity problems of the present claims (see here above at section Re Item VIII)

1.2 Inventive step (Article 33(3) PCT)

Taking into account the severe clarity problems of the present claims (see here above at section Re Item VIII), it is considered that the subject-matter of independent claims 1, 13, 16, 21, 22, 24, 25 and 29 differs from the disclosure of D4 (see D4, claims 1, 7, 8, 9 and 13, page 2, lines 14-20, page 6, line 12 to page 7, line 4, example 1) mainly by the presence of a tie layer. However, the use of a tie layer in the field of laminates and multilayered product for packaging is so common, well-known and even implicit to the skilled person that it can not be regarded as involving an inventive step (see for instance documents D1, D2, D3, D5, D7 etc.)

It follows that the subject-matter of independent claims 1, 13, 16, 21, 22, 24, 25 and 29 lacks inventive step in view of the disclosure of D4 (Article 33(3) PCT).

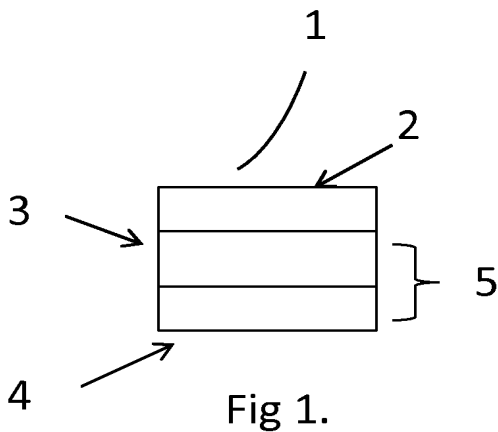
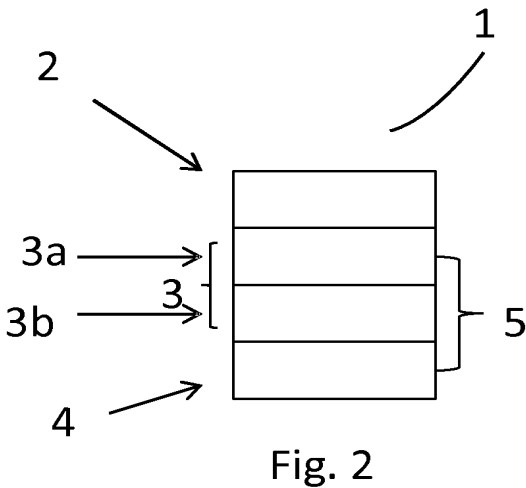
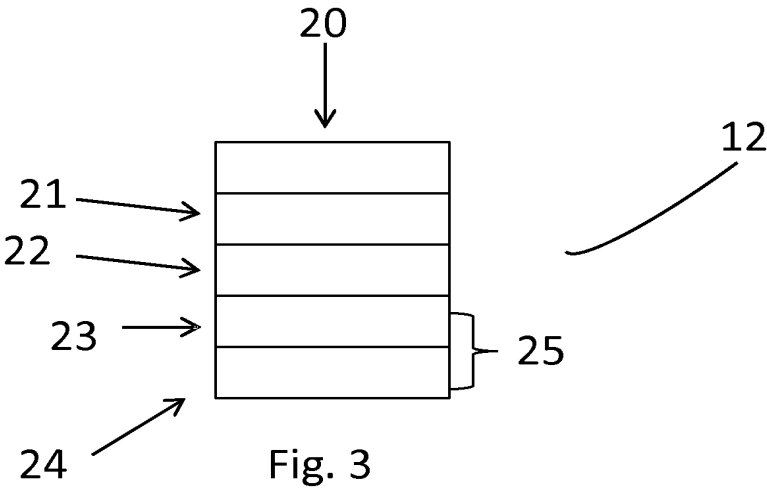
2. Dependent claims 2-12, 14, 15, 17-20, 23, 26-28, 30, 31

Dependent claims 2-12, 14, 15, 17-20, 23, 26-28, 30, 31 do not contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT) because they relate to additional characteristics which *either* are disclosed by D1 (present claims 2-6, 19), D2 (present claims 2-8, 14, 17, 19, 23) and/or D3 (present claims 2, 3, 4, 19), *or* do not seem to solve, in a non obvious way, an objective problem associated with the teaching of the prior art as represented by D1-D10 (present claims 9-12, 15, 18, 20, 26-28, 30, 31), the subject-matter of these claims only defining some embodiments which come within the scope of the customary practice followed by persons skilled in the art without any unexpected technical effect being associated with.

PCT

Print Out (Original in Electronic Form)

VIII-2-1	Declaration: Entitlement to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate: Name (LAST, First)	In relation to this international application Danapak Flexibles A/S is entitled to apply for and be granted a patent by virtue of the following:
VIII-2-1(i v)		an assignment from CHRISTENSEN, Lars to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)
VIII-2-1(i v)		an assignment from JOHANSEN, Peter to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)
VIII-2-1(i v)		an assignment from FOGTMANN, Torben to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)



2/3

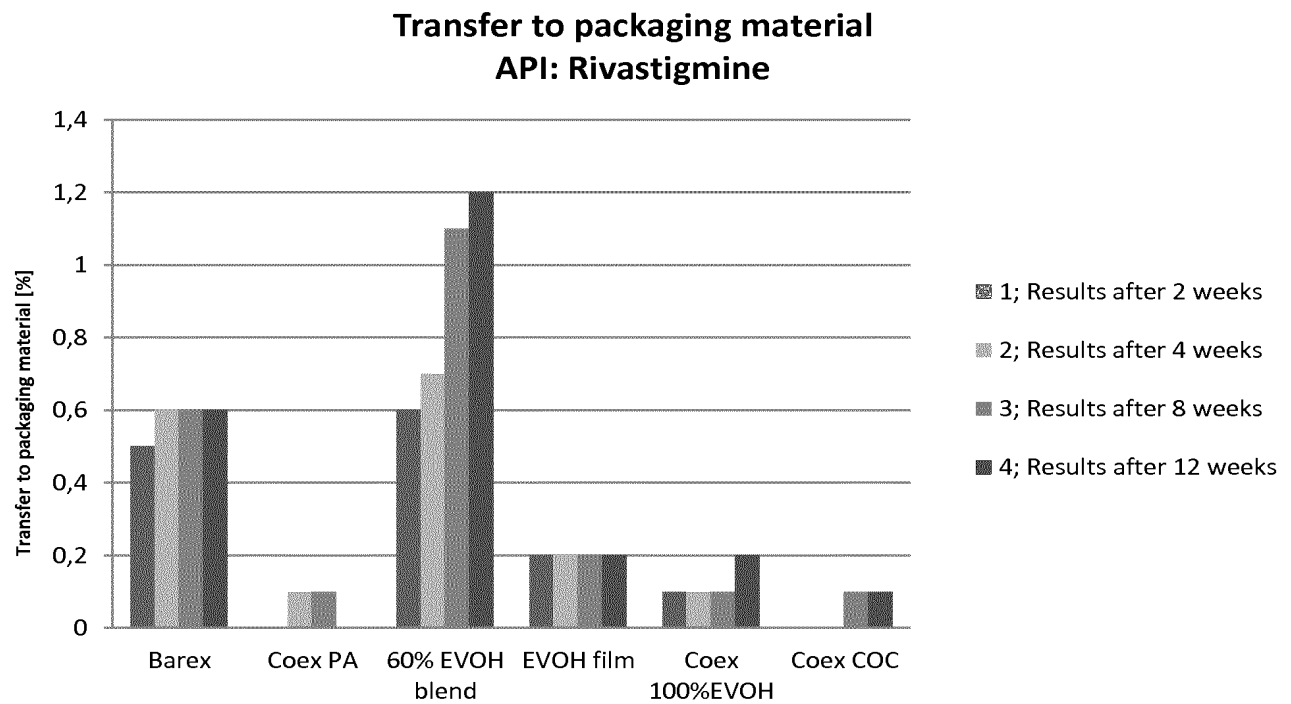


Fig. 4

3/3

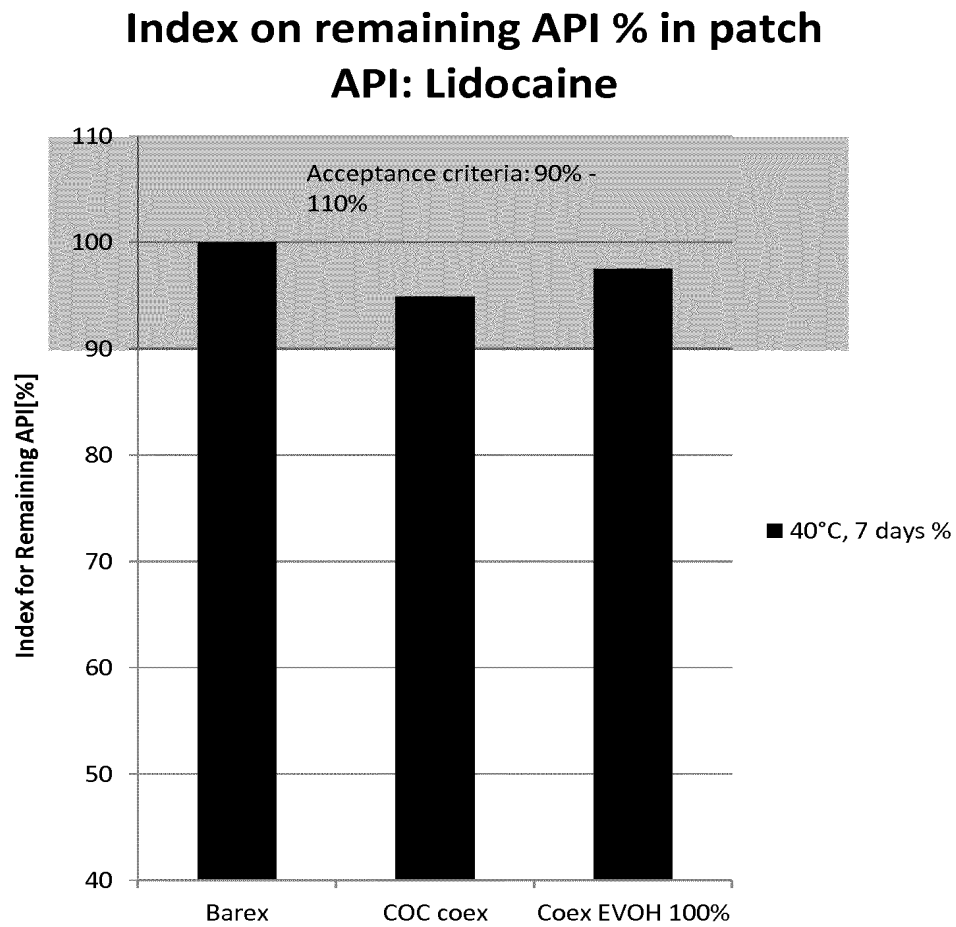


Fig. 5

C L A I M S

1. A method for providing a, e.g. aggressive chemical resistant, film, said method comprising the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- 5 ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and
- 10 the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer; and,

wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even

15 more preferred 0.8 to 5, and most preferred 1 to 2.

2. A method according to claim 1, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated poly-

20 esters, and/or fluoro polymers.

3. A method according to any one of the claims 1 to 2, wherein the tie layer is made of 1, 2, 3, 4 or 5 layers.

4. A method according to claim 3, wherein all the layers of the tie layer are coextruded with the contact layer.

25 5. A method according any one of the preceding claims, wherein the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl meth-

30 acrylate, and more preferably a maleic anhydride.

6. A method according to any one of the claims 1 to 4, wherein the tie layer comprises at least two layers, and wherein the first layer comprises a copolymer according to claim 5 and the at least second or more layer(s) comprises a material selected from EEA, PE, EMA, EAA or a combination.

35 7. A method according to any one of the preceding claims, wherein

the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

8. A method according to anyone of the preceding claims wherein the contact layer is a polymer selected from the group consisting of a cyclic
5 olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

9. A method according to anyone of the preceding claims, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading of the film is not more than 40 g/m².

10 10. A method according to any of the preceding claims, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocaine and rivastigmine

11. A method according to claim 10, wherein the composition is a patch.

15 12. A method according to claim 10 or 11, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

13. An aggressive chemical resistant film comprising at least a base
20 layer, which is water and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, more preferred a RED value in the range of 0.8 to
25 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

14. A film according to claim 13, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, such as polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluoropolymers; and/or
30

the tie layer is constituted of one layer and wherein the layer is made of a copolymer, said copolymer comprising a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a third polymer, which third polymer is preferably made of a material selected
35 from glycidyl methacrylate, and more preferably maleic anhydride; and/or

wherein the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

15 15. A film according to claims 13 or 14, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading of the film is not more than 40 g/m².

16. A laminate for packing an aggressive chemical substance said laminate comprising at least

10 - a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film according to any of claims 13 to 15, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer having a
15 RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2; and, where the base layer side of the film is facing the first outer layer.

20 17. A laminate according to claim 16, wherein the laminate further comprises a second outer layer facing the exterior side of the outer layer, preferably the second outer layer is a paper layer.

18. A laminate according to any of the claims 16 to 17, wherein the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine.

25 19. A laminate according to claim 16, 17, and 18, wherein the laminate is heat sealable.

30 20. A laminate according to claim 16 to 19, wherein a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 2% of the active ingredient is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

21. An aggressive chemical substance packed in a heat sealable laminate, said heat sealable laminate comprising

35 - a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextru-

sion layer comprising a tie layer and a contact layer, wherein the base layer side of the film is facing the outer layer; and, wherein the contact layer comprises a polymer having a RED value of > 0.8 , more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even
5 more preferred 0.8 to 5, and most preferred 1 to 2.

22. Use of a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8 , preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a
10 base layer which is water and/or oxygen resistant, said film is coated to a, optionally coextruded, layer comprising a tie layer and the contact layer.

23. Use according to claim 22, wherein the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

15 24. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or lidocaine, and wherein said method comprises the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- ii) coextruding a layer comprising a tie layer and a contact layer to
20 provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer,
25 wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine, fentanyl and/or lidocaine of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

30 25. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or lidocaine, and wherein said method comprises the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- ii) coextruding a layer comprising a tie layer and a contact layer to
35 provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

26. A method according to claim 25, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocaine, fentanyl and rivastigmine

27. A method according to claim 26, wherein the composition is a patch.

28. A method according to claim 26 and 27, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

29 A laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film according to claim 25, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

30. A laminate according to claim 29, wherein the laminate is wrapped around a composition comprising the aggressive chemical substance and wherein a maximum of 10% w/w, preferably a maximum of 5% w/w, even more preferably a maximum of 1.5% w/w, most preferably a maximum of 0.5% w/w of the aggressive chemical substance based on nominal content is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

31. A laminate according to claim 30, wherein the aggressive chemical substance is selected from the group consisting of rivastigmine, lidocaine, fentanyl and nicotine.

A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM

The present invention relates to a method for providing an extreme
5 chemical resistant film whereby a tie layer and a contact layer are coextruded
with a base layer, such as a metal foil, as well as films and laminates ob-
tained by the method and uses of the films and laminates to wrap aggressive
chemical substances such as nicotine, fentanyl, lidocaine and rivastigmine.

10 **Background of the invention**

In the pharmaceutical industry substances, including highly aggres-
sive substances such as nicotine, fentanyl, rivastigmine and lidocaine, are
packed as tablets in inhalers, patches etc. resulting in special requirements
for the packing, laminate, or film for sealing these substances in order to en-
15 sure that no adverse degradation takes place.

One common example is the problem relating to the packaging of
nicotine, in particular as nicotine patches, because nicotine is highly aggres-
sive towards its environment and highly volatile. These properties are prob-
lematic for the consumer safety and product durability if not addressed, be-
20 cause it is important that the amount of nicotine in, for example a tablet,
gum or a patch is stable and complies with the product specification. Further,
it is important to avoid adverse reactions between the packaging and the
pharmaceutical substance. Additionally, from a business perspective a long
stable shelf time is highly desirable. Thus, the chemical requirements of a
25 packaging, film or laminate are typically:

- Resistance towards highly aggressive substances such as nicotine.
- Inert properties for ensuring that chemical compounds do not migrate
from the exterior environment of for example a laminate, through the
laminate getting into contact with a sealed substance;
- 30 - Possibly ensuring that the packaging is child proof to increase safety of
potentially hazardous compounds.

A known polymer that fulfils the requirements of extreme chemical
resistance and inert properties is a polyacrylonitrile (PAN) based film, which
is sold for example as resins under the trademark Barex®, which is manufac-
35 tured *i.a.* by the company Ineos. Barex® is widely used and approved for

drugs and food applications and is used because it is a good barrier towards oxygen, nitrogen and carbon dioxide compared to other common polymers, and because it has excellent chemical resistance towards different functional groups such as hydrocarbons, ketones, esters, alcohols, bases and acids
5 and/or pharmaceuticals such as nicotine. Furthermore, extruded Barex® resin is heat stable and therefore weldable at a temperature around 160 - 220°C, which makes it possible to use in flexible packagings. However, Barex® is sold at a high prize due to the difficulties in the production and subsequent extrusion to film resulting in a high loss of material. Furthermore,
10 the water and oxygen resistance of Barex® is not satisfactory for all purposes.

Another solution can be found in WO 00/44559 disclosing a material for packaging nicotine containing products (e.g. patches, tablets, lozenges, nasal spray), wherein the material comprises a polymer based on dimethyl-
15 2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers. Further, it is disclosed that a polymeric film is combined with other barrier materials in a laminate to further improve the barrier characteristic of the laminate. The preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.

20 In addition to the barrier properties, in particular for pharmaceuticals, it is important that the concentration of the substances is stable and reliable, which also poses requirements of the packaging and laminates in terms of inertness and permeability.

Hence, given the increased market and demands for packagings,
25 there is an instant need for finding solutions for packaging, of in particular highly aggressive substances and pharmaceuticals, which fulfil all the requirements while still being economical.

Summary of the invention

30 With this background it is an object of the present invention to provide solutions that meet one or more of the needs described above, that is, *i.a.* provide impermeability and inertness to a packaging. Furthermore, it is an object to provide a laminate that is weldable at temperatures suitable for the manufacture of flexible wrappings, such as for use in preparing packag-
35 ings for patches. It is a further object to provide methods and products that

are cost efficient without compromising the quality of the products.

Accordingly, in a first aspect this is solved by a method for providing, e.g. an aggressive chemical resistant, film, said method comprising the steps of:

- 5 i) providing a base layer, which is water and/or oxygen resistant;
- ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere
- 10 to the base layer to provide the, e.g. aggressive chemical resistant, film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of >
- 15 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred between 1 to 2.

It has surprisingly been found that when coextruding the tie layer and the contact layer according to the invention, the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of

20 the final film and laminates and wrappings made with the film. The coextrusion also results in a better adherence of the various layers resulting in a homogenous film in which the layers do not separate.

While it was previously believed that usable polymers should be hydrophobic (in order to repel water from the surroundings), the present inventors have found that by providing the film according to the invention where the coextrusion layer comprises a tie layer and a contact layer, and where the contact layer comprises a polymer having a relative energy difference (RED) value in the range 0.8 to 10 relative to the aggressive substance, it has surprisingly turned out that the desired effect of the laminate being inert

25 to aggressive compounds, such as nicotine, rivastigmine and lidocaine, while still providing a barrier to external factors such as water/moist and oxygen, is obtained.

A polymer candidate for use as a contact layer in the present invention is selected by calculating the RED value, which is generally used to predict the solubility of a polymer in a particular solvent, or the compatibility of

35

two polymers in a blend. In the present invention the RED values for various polymer/solvent systems have been calculated, wherein the polymer is the polymer forming the contact layer, and the solvent is an aggressive chemical substance such as nicotine, rivastigmine, fentanyl and lidocaine etc.

- 5 The RED value for the polymer and the aggressive chemical substance is calculated by using the theory of the Hansen solubility Parameters (HSP), which is described in C.M. Hansen: "Hansen Solubility Parameters, A User's Handbook", CRC Press, Boca Raton, 1999.

10 The HSP system between the polymer and the aggressive chemical substance is described by parameters set up in a 3 dimensional coordinate system:

- δ_D for dispersion cohesion energy
- δ_P for dipolar cohesion energy
- δ_H for hydrogen bonding cohesion energy

15

The HSP distance, R_a , between polymer and the aggressive chemical substance is given by:

$$R_a^2 = 4(\Delta \delta_D)^2 + \Delta \delta_P^2 + \Delta \delta_H^2$$

20 The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

The relation between the HSP distance, R_a and RED is given as:

$$RED = R_a/R_o$$

25 Where R_o is the interaction radius, which determines the radius of the sphere in Hansen space, and the center are the three Hansen parameters. All values are calculated or determined with empiric data and it is known to the person skilled in the art how to calculate the values.

The obtained RED value indicates whether or not the polymer is likely to dissolve in the aggressive chemical substance or not:

RED < 1 the polymer and the aggressive chemical substance will dissolve

30 RED = 1 the polymer and the aggressive chemical substance will partially dissolve

RED > 1 the polymer and the aggressive chemical substance will not dissolve

35 The resulting RED value is used to give an indication of the likelihood of dissolution or not.

All values can be calculated using the Hansen Solubility Parameter in Practice by (HSPiP) Software, commercially available at <http://hansen-solubility.com>.

Contact layer polymers according to the invention surprisingly turned
5 out to have a RED value in the range from 0.8 and higher, preferably, 0.8 to 10 and more preferred 0.8 to 5 and most preferred 1 to 2. It is highly unexpected that polymers which in theory range from being soluble to insoluble with an aggressive substance to be packed fulfill the requirements set for films according to the invention as is supported by the examples provided
10 here with.

The base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluoro polymers.

15 According to the invention water and/or oxygen resistance is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below $1 \text{ cm}^3/\text{m}^2/24\text{hr}/\text{bar}$ according to ASTM standard D3985 at 23°C and 0% RH and/or water (or moisture) vapor transfer rate (WVTR) equal to or below $1 \text{ g}/\text{m}^2/24\text{hr}$ according to ASTM standard F1249 at 38°C and 90%RH,
20 preferably both the WVTR and the OTR are below $0.01 \text{ g}/\text{m}^2/24\text{hr}$ or $0.01 \text{ cm}^3/\text{m}^2/24\text{hr}/\text{bar}$ respectively.

According to the invention, the base layer of the film is selected to provide a number of properties to the film and a laminate and packaging comprising the film. The base layer may give desired barrier and support
25 properties to the final laminate. Furthermore, the base layer may in one embodiment be a gas and water impermeable base layer, more preferably a water and/or oxygen resistant base layer.

In embodiments where the contact layer is hygroscopic the base layer is preferably made of a metal foil, preferably aluminum.

30 Aluminum is price competitive, a superior barrier of all gases and moisture and furthermore similar to other metal-like materials aluminium has good dead-fold properties, i.e. it does not unfold once folded, it reflects radiant heat, and gives a decorative appeal to laminates and packages.

According to the invention the tie layer is selected to provide sufficient
35 adhesion between the base layer and the coextrusion layer. The tie layer

er may give melt strength and support the coextrusion coating of both the tie layer and the contact layer. It is preferred that the melting profile of the tie layer polymers and the contact layer polymers are in the same range to provide optimal films that do not separate. Preferably both layers comprise polymers that melt at the operating temperature of the process of the invention and even more preferred the melting profiles (i.e. melting points) should differ with less than 30°C, preferably with 0-15°C, such as 5-15°C.

In one embodiment the tie layer is made of 1, 2, 3, 4 or 5 layers. In this way, the properties of the film and resulting laminates and packagings may be improved to accommodate the specific chemical and physical properties of the contact layer and/or the base layer.

In a further embodiment all the layers are coextruded with the contact layer for a simplified processing and for ensuring homogeneity of the layers.

In a further embodiment the tie layer is constituted of one layer where the layer is made of a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride. Most preferably the tie layer has a melting profile similar to that of the contact layer.

According to the invention the contact layer must be chemically resistant to the aggressive substance and excipient if present ultimately to be packed. Further it must show an extreme low absorption of the aggressive substances migrating through the film or laminate. The degree of absorption for a given substances is typically dictated by the manufacturer of the substance but often the accepted values lie in the range of 0 to 1 % (w/w). For some products up to 10 % (W/W) is acceptable typically for products with a low initial API content. The absorption is calculated as the weight of API in packaging relative to the initial weight of the API in the commercial product.

Hence, in the context of the present invention aggressive chemical resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12 weeks or less.

In one preferred embodiment the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH).

In a further embodiment the tie layer and contact layer comprise the same polymer, such as a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH) the latter being particularly preferred.

The HSP and RED Values calculated using <http://hansen-solubility.com>, mentioned above resulted in the following values for the preferred polymers according to the invention using lidocaine/rivastigmine as solvent (API):

Table 1: HSP and RED values for preferred polymers according to the invention

Polymer	D	P	H	RED value (chi)
Lidocaine/ Rivastigmine	18.1	8.2	6.1	-
PA 66	16	11	24	1.72
COC	18	3	2	1.32
EVOH	20.5	10.5	12.3	1.12

It has surprisingly been shown that when the contact layer comprises any of the polymers from the group above, having a relatively low RED (i.e. between 1 and 2) value a chemical resistant film and also laminate may be obtained even though the mentioned polymers chemically represent different polymer types. Tests have shown that the resistance of laminates in which the film is coated with the preferred polymers shows results unexpectedly superior to those of laminates coated/laminated with Barex®.

EVOH is normally used in laminates due to the superior oxygen barrier properties of EVOH. However, EVOH is known to be very hydrophilic and hydroscopic (i.e. has a high WVTR), hence it is surprising that a EVOH polymer is usable in the context of the present invention where water resistance is a desired property. Also, PA has typically been used in laminates due to the superior mechanical properties like tear strength or as a barrier. As for EVOH it is unexpected that PA may be used as a contact layer and/or co-extrusion layer (i.e tie and contact layer) for providing a chemical resistant film due to the hydrophilic nature of PA.

Because of the hydrophilic nature of PA and EVOH, in a preferred embodiment, the film obtained according to the invention may be tightly packed in a moisture barrier, in particular if it has to be stored. The film or laminate according to the invention may be packed immediately after manufacture of the chemical resistant film or laminate and should be kept safely
5 packed until further use, for example in a packing line.

COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates. Without the wish to be bound by any theory this is believed to be due to the stress which
10 the polymer is subjected to during an extrusion process. The stress causes irregular heating and melting within the COC, resulting in the final film or laminate to be unacceptable from a visual point of view for use in various packaging industries. Hence, it is very surprising that the inventors of the present invention have succeeded in providing a coextrusion layer comprising
15 COC as a contact layer for sealing aggressive substances. The inventors have found that an improved processing of COC is obtained when COC is coextruded with a tie layer having a glass transition temperature higher than or equal to that of a COC polymer such as a terpolymer of ethylene, acrylic ester and maleic anhydride. In another embodiment of the invention the tie layer has a
20 melting point that differs from COC with 30°C or less, preferably with 0-15°C, such as 5-15°C.

In a further embodiment, the melting point of the tie layer is at least the same as COC, preferably 5 to 30 °C higher, more preferably 15 to 30 °C higher than COC.

25 To obtain a satisfactory coextrusion layer it is important that the polymer constituting a contact layer and a copolymer constituting a tie layer are compatible with respect to the melting characteristic of the polymers and the copolymer. As an effect of having been able to process a chemical resistant laminate with a coextrusion layer laminated to a base layer, thin laminates
30 may be obtained, and generally improved process ability during the manufacture of the laminates or wrappings are achieved.

Consequently, in one embodiment the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m² and/or the contact layer has a loading in the range of 4 to 20 g/m² and the loading
35 of the laminate is not more than 40 g/m².

In terms of the invention loading means the amount of polymer left, in the layer when the film has dried.

In a particular embodiment the contact layer of the coextrusion layer is made from a blend of at least two polymers. Using blends can be a means
5 for reducing the costs and for adapting the physical and chemical properties of the co-extrusion process, such as reducing or increasing the melting temperature to comply with the profile of the tie layer(s) and the polarity of the blend to improve the adhesion properties of the layers and hence the robustness of the final product.

10 In a preferred embodiment the contact layer consists of one polymer type. Experiments showed that using one type of polymer resulted in improved resistance of the film and laminate towards the chemical substance to be packed.

According to an embodiment, in any of the blends or homo layers at
15 least one of or all the polymer(s) forming the contact layer of the coextrusion layer is a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol. Each of the polymers are commercial available for example under the trade-names EVAL® C109B sold by Kuraray, Sellar PA 3426 R sold by Dupont®, 6013M-07 sold by Topas®.

20 In one embodiment the cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol makes up at least 50% w/w of the blend, preferably at least 60% w/w, more preferably at least 80% w/w, most preferably at least 95% w/w.

The adhering of step iv) preferably occurs instantly for example by
25 cooling the co-extrudate in cooling cylinders during the lamination process.

According to the invention a chemical resistant film has various applications. In an embodiment of the invention, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, lidocaine and rivastigmine.

30 In a particular embodiment of the invention, wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/- 10% in comparison to a Barex® patch as index 100.

In a further aspect of the invention an aggressive chemical resistant
35 film is provided, said film comprising at least a base layer, which is water

and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and whereby the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2. Films according to the invention are resistant to aggressive chemical substances.

the term "aggressive chemical resistant film" means a film which when in contact with an aggressive substance does not allow more than 10 %, such as 5% w/w or 1.5% w/w based on the nominal content of the aggressive chemical to migrate to the packaging material.

In one embodiment the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, polyamide, polyvinylidene chloride, silicon oxide coated polyesters, and/or fluoropolymers.

In a further embodiment the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

In a particular embodiment the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

In yet an embodiment the tie layer and the contact layer is the same material.

In a further embodiment the film is heat sealable. A heat sealable film or laminate is a laminate that is capable of sealing to itself during heat sealing without creating any deformation of films or laminates, which is highly undesired, especially, during the final wrapping of the product. The deformation is undesirable in relation to quality assurance, where any deformation must be noted and explained, which is highly labor intensive. Furthermore, the legislation in many countries is very strict. Hence, film and/or laminates with any deformation are not allowable for packing active ingredients.

In yet another aspect the invention relates to a laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;
 - an aggressive chemical resistant film as described above comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer wherein the base layer side
- 5 of the film is facing the first outer layer.

In one embodiment the first outer layer may be made from a material selected from but not limited to paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations. It is preferred that the first outer layer is a combination of materials when polyester based sheets are used.

10

In an embodiment the first outer layer and the film are laminated to provide the packaging in one piece. Laminating the first outer layer to the film provides a strong laminate, which is easy to wrap, and, it is ensured that the individual parts of the laminate do not fall apart.

15 In another embodiment the laminate further comprises a second outer layer facing the exterior side of the first outer layer, preferably the second outer layer is a paper layer. The paper layer is typically printed with the name, color and/or logo of the product and manufacturer of the product. It is also contemplated that the first outer layer is printed.

20 It is also contemplated that an adhesive agent may be applied between the second and first outer layers. The adhesive layer may be the same or different from the tie layer. Additional suitable adhesives are adhesives approved for use in packaging products for human use and are well known to the skilled person. A suitable adhesive may be selected from but is not limited to polyurethane based adhesives, epoxy based adhesives, or acrylic based adhesives.

25

The laminate of the present invention must be inert and impermeable to the aggressive chemical substance which the laminate is wrapped around. Hence, in an embodiment of the invention a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 1.5%, most preferably a maximum 0.5% of the aggressive chemical is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

30

In a further embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine.

35 These compounds are known as aggressive chemicals/compounds and re-

quire specialized packaging.

Hence, the invention also contemplates an aggressive chemical substance packed in a laminate or packaging as explained above and a method for providing the packaging the chemical substance, said method comprising
5 the steps of:

a) providing a base layer

b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

c) coating the coextrusion layer to the base layer;

10 d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an coextrusion layer coated to the base layer;

e) providing a highly aggressive substance to the contact layer side
15 of the film; and

f) sealing the chemical resistant film, preferably by heat sealing, in such a way to provide a hollow interior space for sealing the highly aggressive substance, said hollow space having an interior side and an exterior side, wherein the interior side of the film is the contact layer of the coextrusion
20 layer and the exterior side of the film is the base layer.

In a preferred embodiment the highly aggressive substance is selected from the group consisting of nicotine, lidocaine, rivastigmine, and fentanyl.

It is also contemplated that a first outer layer may be applied to the
25 film; the first outer layer is made of a mechanically wear resistant material and typically serves to protect from children being able to break the sealed film, laminate or wrapping.

A packaging should preferably comply with International standards such as 16 CFR §1700.20 (for USA) and ISO 8317 (2003) corresponding to
30 DIN EN ISO 8317 (2004) (for Europe).

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate

It is also contemplated that a second outer layer may be applied to
35 the film and/or laminate; the second outer layer is typically a paper layer.

The paper layer is typically printed with the logo or colors etc. of the supplier of the product. The second outer layer is preferably applied when there is a first outer layer.

It is contemplated that the first and/or second outer layer is laminated to the film before steps e) and f) for example in one combined coextrusion and laminating step.

In yet another aspect, the invention provides the use of a polymer having a RED value of > 0.8 , preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant coated to a, optionally co-extruded, layer comprising a tie layer and the contact layer.

In a further embodiment the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol. Specific films according to the invention comprise but are not limited to base layer/tie-layer/contact-layer (the latter two coextruded) EAA/PE/COC, EAA/EMA/COC, EAA/terpolymer/COC, terpolymer/PE/COC, EAA/terpolymer/EVOH, EAA/terpolymer/PA, or EAA/PA.

Specific films according to the invention that are resistant to nicotine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, Al/EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

In a further embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to rivastigmine

comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, Al/EAE and maleic anhydride/COC.

5 In an embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

10 In a further embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

 In yet another embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene,
15 acrylic ester and maleic anhydride.

 Specific films according to the invention resistant to lidocaine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%,
20 Al/EVOH/EVOH, Al/terpolymer of EAE and maleic anhydride/COC.

 In an embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

25 In a further embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

 In yet another embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene,
30 acrylic ester and maleic anhydride.

 Specific films according to the invention resistant to fentanyl comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%,
35 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%,

Al/EVOH/EVOH, AL/terpolymer of EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

In a further embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

The invention should not be restricted to the above combinations. Further combinations are within the scope of the invention.

In another aspect of the invention is provided a method for providing an aggressive chemical resistant film said film being resistant to nicotine, rivastigmine and/or and lidocaine, and wherein said method comprises the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine and/or lidocaine of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

It has surprisingly been shown that films provided from polymers having a red value between 0.8 and 10 relative to rivastigmine, lidocaine and/or nicotine and coextruded as stipulated above have superior resistance to said chemical substances.

In a further aspect of the invention is provided a method for provid-

ing an aggressive chemical resistant film against nicotine, rivastigmine and/or and lidocaine, said method comprising the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- ii) coextruding a layer comprising a tie layer and a contact layer to
5 provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer,
10 wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

It has surprisingly been shown that polymers of cyclic olefin copolymer, polyamide and ethylene vinyl alcohol, when coextruded, provide a resistant film, which performs at least as well as films known in the prior art for
15 packaging compounds such as nicotine, lidocaine and rivastigmine.

Conveniently, the polymers used in the present invention have the advantage of being easy accessible thereby providing a more cost efficient production.

20 **Figures**

Figures 1 is a cross section of an embodiment of a chemical resistant film according to the invention

Figure 2 is a cross section of another embodiment of a chemical resistant film according to the invention.

25 Figure 3 is a cross section of a laminate according to the invention.

Figure 4 shows the results of an absorption study of rivastigmine as API wrapped in laminates according to the invention as compared to a commercial available laminate with the commercial available polymer film Barex® after storing for 2, 4, 8 and 12 weeks at 40°C.

30 Figure 5 shows the amount of lidocaine remaining in a patch after 7 days at 40°C for embodiments of the laminate according to the invention and in comparison, with a commercial available Barex® laminate.

Detailed description

35 The invention will now be described in greater details. Each specific

embodiment and variation of features applies equally to each aspect of the invention unless specifically stated otherwise.

The film, laminate and packaging according to the present invention is intended to be used in packaging highly aggressive substances such as nicotine, rivastigmine, fentanyl or lidocaine, however, the invention should not
5 be limited to these specific substances.

The term "film" according to the invention contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact
10 layer.

Where the contact layer is laminated, for example using an EVOH film, the contact layer and tie layer may be either coextruded, or, the contact film layer may be laminated to the base layer optionally with an intermediate tie layer or the tie and contact layers may be the same material.

15 The term "laminate" according to the invention contemplates the film to which a further layer is laminated, such as a first outer layer.

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

20 The term "highly aggressive substance" should be understood as a substance which is both very reactive with metals, acids, bases or functional groups such as ketones, alcohols, hydro carbons and/or esters, and/or, volatile but also easily migrates through barriers. Similarly, the term "aggressive chemical resistant film" means a film which when in contact with an aggressive
25 substance does not allow more than 1.5 % w/w of nominal content to migrate to the packaging material or that 90-110% w/w of the aggressive chemical substance remains in the product when compared to Barex® as index 100.

Therefore, the films, laminates or packagings applicable for packing
30 highly aggressive substances should have both chemical-resistant properties but also limit the migration of the aggressive substance through the film, laminate or packaging. The aggressive substance according to the invention is also or alternatively susceptible to degradation when exposed to ambient conditions, such as oxygen and water, it is volatile and able to migrate or a
35 combination. Specifically, the aggressive substance is selected from but not

limited to nicotine, oils, such as spearmint and peppermint oil, licodaine, fentanyl or rivastigmine.

The term "oxygen and water resistant" as used in the context of the present invention contemplates material for which the oxygen transfer rate (OTR) and/or water vapor transfer rate (WVTR) is no more than 1 preferably
5 no more than 0.1 as also indicated above. The term WVTR may also be referred to as the moisture vapor transfer rate (MVTR). WVTR and MVTR are equivalent.

The term "mechanically wear resistant layer" as used for the first
10 outer layer in the context of the present invention should be a material which is suitable for the manufacture of a flexible packaging. The mechanically wear resistant layer may be chosen from materials such as polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets or combinations.

15 Further, the mechanically wear resistant material can be provided as a film that is biaxially oriented to give the film higher seal strength. The term "biaxial oriented" should be understood such that the provided polymer film has been stretched in both a longitudinal and a transverse direction during manufacturing.

20 The term "exterior side" should be understood in its broadest term. The term exterior environment is used for defining the direction opposite of the side that is facing the highly aggressive substance to be sealed by a laminate or packaging of the present invention. This means that the term exterior environment is independent on whether additional layers are coated, laminated or otherwise attached to the film. Thus, the word is used for specifying
25 which direction a side of a layer is facing.

The various embodiments of the invention will now be illustrated with references to the figures and examples.

With reference to figure 1 a film of the invention will now be described in greater detail. The extreme chemical resistant film, 1, is obtained
30 by providing a base layer, 2. A coextrusion layer, 5, comprising a tie layer, 3, and a contact layer, 4, is coated to one side of the base layer, 2, according to the method of the invention and is allowed to adhere. The base layer, 2, and the coextrusion layer, 5, define the film according to all the aspects of the
35 invention. Consequently, the film is provided with a base layer side, 2, and a

coextrusion layer side 5, wherein the base layer side, 2, is intended for facing the exterior environment and the coextrusion layer side, 5, is intended for facing the highly aggressive substance to be sealed.

5 The coextrusion layer may be coated to the aluminium layer by a coextrusion system generally known in the art to provide the coextrusion layer coated on the first side of the aluminum layer. The coextrusion layer may be applied in an amount of 7-40 g/m³. After coating of the aluminium layer and subsequently cooling, the coextrusion layer is adhered to the side of the tie layer facing away from the aggressive chemical substance.

10 The coextrusion is preferably performed at a temperature of 240-330°C, more preferred 270 - 300°C and the speed of the application/coating is in the range of 150 to 600 m/min. The equipment suitable for extruding and laminating films and laminates according to the invention may be obtained from Bobst.

15 When using coextrusion, it is possible to obtain a multi layer which is thinner than multilayer layers provided by sequential film application techniques without compromising the extreme chemical resistance properties of the first laminate. Hence, the present invention does not only provide an extreme chemical resistance laminate, and packaging comprising the same but
20 at the same time the manufacturing process is more cost effective since less polymer, forming the contact layer, has to be used.

Another embodiment of a film in which the tie layer comprises two layers is illustrated in figure 2. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. The coextrusion layer, 5, comprises a tie
25 layer, 3, comprising a first layer, 3a, and a second layer, 3b, and a contact layer 4. The coextrusion layer is coated onto one side of the base layer, 2, according to the method of the invention and is allowed to dry.

In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene
30 (PE) as the second layer, 3b, where the first layer of EAA faces the base layer and second layer of the PE faces the contact layer, 4.

The extreme chemical resistant film according to the invention is intended for use as a component of a packaging suitable for sealing a highly aggressive substance. The film may constitute the packing itself.

35 To further improve the mechanical wear resistance of the film a first

outer layer may be laminated to the base layer side of the film or simply be wrapped around the film to provide a laminate. Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the invention, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.

The first outer layer, 21, is a mechanically wear resistant layer which adds safety properties to the wrapping ensuring that the wrapping is not inadvertently opened. Hence, the outer layer can also be seen as a child proof layer meaning that the layer is made of a material and is sealable in such a way that it is difficult for children to open. Additionally, the outer layer may be provided with a second outer layer, 20.

The second outer layer, 20, is typically a paper layer, wherein the paper layer is facing the exterior environment; the exterior facing side of the second layer may be printed as desired. The second outer layer, such as the paper layer is added to improve the stiffness of the packaging in addition to providing a printing platform.

Furthermore, it is within the inventive concept of the present invention that an adhesive agent is applied between the first outer layer and the base layer and/or between the first outer layer and the second outer layer. The obtained packaging may then be assembled in such a way that the various layers do not part during handling, printing and/or packaging of the substance to be packed.

After production, the film, laminate or packaging may be stored as rolls ready for use in further lamination or packaging of the aggressive substance to be packed.

In use, the packaging is sealed around the substance to be packed so that the contact layer of the coextrusion layer faces the interior side and the substance, and, the base layer, first outer layer or second outer layer, as applicable, face the exterior side, so as to create a hollow interior for containing the, substance, such as the aggressive substance.

The sealing of the packaging is achieved in such way that the contact layer of the coextrusion layer is facing the aggressive substance so that the remaining part of the package is protected by the contact layer of the coex-

trusion layer. In this way, the aggressive substance is encompassed by the inner side of packaging and will therefore only have direct contact with the contact layer of the coextrusion layer.

In general, the order in which the different layers of the packaging according to the invention are applied to the base layer is flexible. Hence, the first outer layer may be applied before the coextrusion layer and the other way around. The order depends on which production line is suitable in a specific situation.

In more details the packaging according to the present invention may in one embodiment be manufactured by obtaining a film comprising a base layer, such as an aluminum layer and a coextrusion layer comprising a biopolymer of ethylene and acrylic acid as a tie layer and EVOH as the contact layer coated to the aluminium as described above. The base layer side of the film may then be provided with an adhesive agent and subsequently laminated to a biaxial orientated PET-film which is the first outer layer, i.e. the mechanically wear resistant layer. The PET-film is further provided with an adhesive agent on the exterior side of the mechanically wear resistant layer and is subsequently laminated to a paper layer for providing the final packaging.

An aggressive substance, such as but not limited to lidocaine, is placed on the contact layer side of the laminate which is welded around the substance, such as to form a pouch with an inner side and an outer side. Accordingly, the interior of the pouch consists of the coextrusion layer, where the contact layer of EVOH facing the aggressive substance thereby protects the rest of the provided packaging and the exterior side is the paper layer.

In general, the lamination procedure for laminating the mechanically wear resistant or paper layer to each other or to the base layer is routine procedure for the person skilled in the art.

According to all aspects of the invention the base layer may be selected from but not limited to a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicon or aluminium oxide coated polyesters, and/or fluoro polymers, such as commercial Alu foil from e.g. Hydro, or AlOx coated PET films obtainable from e.g. Toray Films Europe, or SiOx coated PET films obtainable from e.g. Celplast under the tradename Ceramis.

According to all aspects of the invention the tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third
5 polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride, such as the commercial product Lotader® 3410 sold by Arkema or Nucrel® 0609HSA sold by Dupont®

According to all aspects of the invention the contact layer may be made of a material selected from cyclic olefin copolymer, a polyamide, or, an
10 ethylene vinyl alcohol or mixtures thereof, such as the commercial products EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont® or COC 6013M-07, COC 8007F-600, or 9506F500 sold by Topas® or EVOH obtainable from Nippon Gohsei under the tradename Soarnel.

According to all aspects of the invention the first outer layer may be
15 made of a material selected from paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations, such as the commercial product F-PAP sold by Flexpet.

The invention will now be illustrated in more details with reference to the following non limiting examples.

20

RED Calculation

Determination of the HSP values and interaction radius for nicotine, rivastigmine, fentanyl and lidocaine requires that the solubility of the drug is evaluated against at least 16 solvents having a range of polar and hydrogen
25 bonding properties. The methodology of determining HSP values, interaction radius and RED values are described in C.M. Hansen: "Hansen Solubility Parameters, A User's Handbook", CRC Press, 2007, Second Edition and exemplified in EP 2 895 531.

Typical solvents used to determine the HSP may be but is not limited
30 to the solvents present in table 2.

Table 2: Typical solvents used to determine the HSP of a polymer or substance of interest.

Typical solvents used in Determining of HSP of rivastigmine, lidocaine, fentanyl and nicotine	
Chemical name	Trade Designation or Alternate Name
Acetonitrile	Acetonitrile
Ethylene glycol n-Butyl Ether	Butyl CELLOSOLVE™ Glycol Ether
Dibutyl Ether	Dibutyl Ether
Dimethyl Formamide	Dimethyl Formamide
Dimethyl Sulfoxide	Dimethyl Sulfoxide
Methanol	Methyl alcohol
2-Butanone	Methyl Ethyl Ketone
4-Methyl-2-pentanone	Methyl Isobutyl Ketone
n-Butyl Acetate	n-Butyl Acetate
n-Heptane	n-Heptane
1-Propanol	n-Propyl Alcohol
o-Dichlorobenzene	1,2-Dichlorobenzene
Tetrahydrofuran	Tetrahydrofuran
Toluene	Methylbenzene
Propylene Carbonate	Propylene Carbonate
Water	Water

- For assessing the solubility of Rivastigmine, Lidocaine, fentanyl and nicotine in the solvents an experimental measurement is performed. The solubility is assessed based on the visual observation of 0.5 g of the chemical substance in a vial with 5 cm³ solvent at room temperature. The vial is capped with a polyethylene-lined lid and labeled with the solvent loaded. The vials are placed in a vial shaker at low speed at room temperature. After 24 hours, the samples are removed from the vial shaker, and allowed to sit for 30 min before they are visually rated. The rating is performed by giving each solvent a score being 0 for insoluble and 1 for soluble. The numerical ratings are then entered into the HSPiP software program to obtain the HSP (Hansen solubility parameters). R (radius) values for the compound of relevance, e.g. nicotine, rivastigmine, fentanyl and/or lidocaine is inserted, and a report is

generated. The report lists the final parameters and R values calculated for nicotine, rivastigmine, fentanyl and/or lidocaine. The report also lists the solvents used in the evaluation, their HSP values (taken from a database), the rating of the visual observations, and their RED values with a specific polymer of interest.

Example 1- performance of a laminate according to the invention compared to a commercially used laminate

A study was conducted to evaluate the performance of four laminates according to the present invention as compared to a commercially available laminate product comprising Barex® as the contact layer.

The wrappings according to the invention were compared to the performance of a Barex® laminate currently used in the field.

The test is a resistance test, wherein the migration of rivastigmine to the laminates is evaluated.

Table 3: The composition of the 6 wrappings was as follows, laminates 1 to 5 are laminates according to the invention

	Adhesive/Polymer layer Coextrusion layer	Base layer	First outer layer	Second Outer layer
Commercially used Barex® laminate (prior art)	Adhesive/ Barex® film	Al	PET	Paper
Laminate 1	Tie layer: Bipolymer of ethylene and acrylic acid (Nucrel 0609 HAS) Contact layer: PA (Selar PA 3426R)	Al	PET	
Laminate 2	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 60% (EVAL C109B) and PE 40%	Al	PET	
Laminate 3	Tie and contact layer: EVOH film (EVAL C109B)	Al	PET	
Laminate 4	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 100% (EVAL C109B)	Al	PE	PET
Laminate 5	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: COC	Al	PE	PET

*Between the paper/PET, PET/Al, and Al/EVOH film layers an adhesive was applied.

Laminates 1 to 5 were obtained according to the method of the invention. For laminates 1, 2, 4 and 5 a coextrusion layer was coated to the base layer and in laminate 3 the combined tie and contact layer was laminated to the base layer. For the co-extrusion layers, the loading of the tie layers was between 4-18 g/m² and the loading of the contact layer was 8-12 g/m².

The resulting laminates were wrapped around a patch containing rivastigmine as API and the migration of the API to the packaging material/wrapping was measured after 2, 4, 8 and 12 weeks at 40 °C. The API in the wrapping was measured by extracting the packaging and analysing the amount of API therein using Mass spectrometry.

The Rivastigmine patches tested were commercially available patches originally containing 9.5 mg API/patch.

The results are shown in figure 4 illustrating the resulting migration of rivastigmine (weight API extracted from the laminate) to the laminate in percentage of the content of the original patches of 9.5 mg.

The columns are denoted 1, 2, 3 and 4 respectively to the order they are shown from left to right in figure 4. Hence column 1 (furthest to the left) for each contact layer polymer used shows the results for the 6 laminates after two weeks. Column 2 shows the results for the 6 laminates after four weeks. Column 3 shows the results for the 6 laminates after 8 weeks, and column 4 shows the results for the 6 laminates after 12 weeks.

The Barex® laminate is a reference known for applicability in the art and comparison were made for evaluating the properties of the laminates according to present invention.

From the figure it is clear that the results for laminates according to the invention obtained by coextrusion of either of EVOH, PA, or COC as well as laminating EVOH provides for an improved chemical resistant laminate compared to the commercially used Barex® laminate, meaning that less migration occurs.

Also, a contact layer, illustrated as laminate 2, of a blend of EVOH and PE was prepared and tested. Though the properties of this blend with rivastigmine as API resulted in a higher migration of the API than Barex®, the rate is still below the limit demanded in the industry and hence, it illustrates that blends as provided in laminate 2 are usable alternatives to

Barex® as well. Surprisingly though the tie/contact layer made of 100% EVOH was markedly superior to the blend.

Also, a contact layer, illustrated as laminate 3, a film of EVOH laminated to aluminum was prepared and tested. Surprisingly, it was shown that the use of EVOH in the form of a film laminated to aluminum provided a chemical resistant laminate.

Example 2 - stability test of a chemical substance wrapped in laminates according to the invention and wrapped in a prior art product using

10 Barex®

Similar to the test described in example 1, laminates according to the invention were prepared as outlined in table 4 below. A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.

15

Table 4: Packagings for lidocaine stability test.

	Barex Commercially used Barex® laminate (prior art)	COC coex same as laminate 5 of example 1	Coex EVOH same as laminate 4 of exam- ple 1
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Stability of the API is important to ensure that the dose indicated on the packaging is correct. A value of 90% - 110% of the original dose after one week when stored at 40°C using Barex® as index 100 is considered acceptable. Figure 5 illustrates the results of the test where the y-axis indicates the weight decrease of the two laminates according to the invention using Barex as index 100.

As can be seen from figure 5, both inventive laminates have a lower value than the index 100 Barex® comparative product, however with a value within the acceptable limits. The lower %value of the laminates according to the invention indicates that more lidocaine has disappeared from the patch.

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

AWAPATENT A/S
Strandgade 56
1401 København K
DANEMARK

Date of mailing (day/month/year) 03 July 2017 (03.07.2017)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 137098	
International application No. PCT/EP2016/082876	International filing date (day/month/year) 29 December 2016 (29.12.2016)

1. The following indications appeared on record concerning:			
☐ the applicant	☐ the inventor	☒ the agent	☐ the common representative
Name and Address AWAPATENT A/S Rigensgade 11 1316 Copenhagen K Denmark		State of Nationality	State of Residence
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		Facsimile No. 004543999911	
		E-mail address dk@awapatent.com	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:			
☐ the person	☐ the name	☒ the address	☐ the nationality ☐ the residence
Name and Address AWAPATENT A/S Strandgade 56 1401 København K Denmark		State of Nationality	State of Residence
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		Facsimile No. 004543999911	
		E-mail address dk@awapatent.com ☐ Notifications by e-mail authorized	
3. Further observations, if necessary:			
4. A copy of this notification has been sent to:			
☒ the receiving Office	☐ the International Preliminary Examining Authority		
☐ the International Searching Authority	☐ the designated Offices concerned		
☐ the Authority(ies) specified for supplementary search	☐ the elected Offices concerned		
	☐ other:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nissen Diana e-mail diana.nissen@wipo.int Telephone No. +4122 338 8054
Facsimile No. +41 22 338 82 70	

PCT REQUEST

Print Out (Original in Electronic Form)

0	For receiving Office use only	
0-1	International Application No.	PCT/EP2016/082876
0-2	International Filing Date	29 DEC 2016 (29.12.2016)
0-3	Name of receiving Office and "PCT International Application"	RO/EP
0-4	Form PCT/RO/101 PCT Request	
0-4-1	Prepared Using	PCT Online Filing Version 3.5.000.251e MT/FOP 20141031/0.20.5.20
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	European Patent Office (EPO) (RO/EP)
0-7	Applicant's or agent's file reference	137098
I	Title of Invention	A method for providing an extreme chemical resistant film
II	Applicant	
II-1	This person is	Applicant only
II-2	Applicant for	All designated States
II-4	Name	Danapak Flexibles A/S
II-5	Address	Strudsbergsvej 3 4200 Slagelse Denmark
II-6	State of nationality	DK
II-7	State of residence	DK
III-1	Applicant and/or inventor	
III-1-1	This person is	Inventor only
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III-1-4	Name (LAST, First)	CHRISTENSEN, Lars
III-1-5	Address	Østerbro 54 4200 Slagelse Denmark
III-2	Applicant and/or inventor	
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III-2-3	Inventor for	All designated States
III-2-4	Name (LAST, First)	JOHANSEN, Peter
III-2-5	Address	Munkebjergvej 3, 2. sal 5000 Odense C Denmark

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III-3	Applicant and/or inventor	
III-3-1	This person is	Inventor only
III-3-3	Inventor for	All designated States
III-3-4	Name (LAST, First)	FOGTMANN, Torben
III-3-5	Address	Hjortevænget 174 5800 Nyborg Denmark
IV-1	Agent or common representative; or address for correspondence	
	The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	Agent
IV-1-1	Name	AWAPATENT A/S
IV-1-2	Address	Rigensgade 11 Denmark 1316 Copenhagen K Denmark
IV-1-3	Telephone No.	004543995511
IV-1-4	Facsimile No.	004543999911
IV-1-5	e-mail	dk@awapatent.com
IV-1-6	Agent's registration No.	694
V	DESIGNATIONS	
V-1	The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.	
VI-1	Priority claim of earlier regional application	
VI-1-1	Filing date	29 December 2015 (29.12.2015)
VI-1-2	Number	15202962.5
VI-1-3	Regional Office	EP
VI-2	Priority document request	
	The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1

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VI-3	Incorporation by reference : where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.		
VII-1	International Searching Authority Chosen	European Patent Office (EPO) (ISA/EP)	
VIII	Declarations	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	—	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	1	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	—	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	—	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	—	

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VIII-2-1	Declaration: Entitlement to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate: Name (LAST, First)	In relation to this international application Danapak Flexibles A/S is entitled to apply for and be granted a patent by virtue of the following:
VIII-2-1(i v)		an assignment from CHRISTENSEN, Lars to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)
VIII-2-1(i v)		an assignment from JOHANSEN, Peter to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)
VIII-2-1(i v)		an assignment from FOGTMANN, Torben to Danapak Flexibles A/S, dated 20 January 2016 (20.01.2016)

PCT REQUEST

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IX	Check list	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	5	✓
IX-2	Description	27	✓
IX-3	Claims	5	✓
IX-4	Abstract	1	✓
IX-5	Drawings	3	✓
IX-7	TOTAL	41	
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	-	✓
IX-19	Other	Pre-conversion archive	✓
IX-20	Figure of the drawings which should accompany the abstract	Fig. 1	
IX-21	Language of filing of the international application	English	
X-1	Signature of applicant, agent or common representative	(PKCS7 Digital Signature)	
X-1-1	Name	AWAPATENT A/S	
X-1-2	Name of signatory	Sidsel Hauge 23178	
X-1-3	Capacity (if such capacity is not obvious from reading the request)	(Unknown)	

FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	29 DEC 2016 (29.12.2016)
10-2	Drawings:	✓
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	
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Bescheinigung

Die angehefteten
Unterlagen stimmen mit der
als ursprünglich eingereicht
geltenden Fassung der auf
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Certificate

The attached documents are
exact copies of the text in
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Attestation

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européen qui est spécifiée à
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Patentanmeldung Nr.

Patent application No.

Demande de brevet n°

15202962.5 / EP15202962

The organization code and number of your priority application, to be used for filing abroad under the Paris Convention, is EP15202962.

Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.



V. Joseph

Anmeldung Nr:
Application no.: 15202962.5
Demande no. :

Anmeldetag:
Date of filing: 29.12.15
Date de dépôt :

Anmelder / Applicant(s) / Demandeur(s):

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Bezeichnung der Erfindung / Title of the invention / Titre de l'invention:
(Falls die Bezeichnung der Erfindung nicht angegeben ist, oder falls die Anmeldung in einer Nicht-Amtssprache des EPA eingereicht wurde, siehe Beschreibung bezüglich ursprünglicher Bezeichnung.
If no title is shown, or if the application has been filed in a non-EPO language, please refer to the description for the original title.
Si aucun titre n'est indiqué, ou si la demande a été déposée dans une langue autre qu'une langue officielle de l'OEB, se référer à la description pour le titre original.)

A method for providing an extreme chemical resistant film

In Anspruch genommene Priorität(en) / Priority(Priorities) claimed / Priorité(s) revendiquée(s)
Staat/Tag/Aktenzeichen / State/Date/File no. / Pays/Date/Numéro de dépôt:

Am Anmeldetag benannte Vertragsstaaten / Contracting States designated at date of filing / Etats contractants désignées lors du dépôt:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL
PT RO RS SE SI SK SM TR

The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to wrap aggressive chemical substances such as lidocaine and rivastigmine.

Background of the invention

In the pharmaceutical industry substances, including highly aggressive substances such as Rivastigmine and Lidocaine, are packed as tablets in inhalers, patches etc. resulting in special requirements for the packing, laminate, or film for sealing these substances in order to ensure that no adverse degradation takes place.

One common example is the problem relating to the packaging of nicotine, in particular as nicotine patches, because nicotine is highly aggressive towards its environment and highly volatile. These properties are problematic for the consumer safety and product durability if not addressed, because it is important that the amount of nicotine in, for example a tablet, gum or a patch is stable and complies with the product specification. Further, it is important to avoid adverse reactions between the packaging and the pharmaceutical substance. Additionally, from a business perspective a long stable shelf time is highly desirable. Thus, the chemical requirements of a packaging, film or laminate are typically:

- Resistance towards highly aggressive substances such as nicotine.
- Inert properties for ensuring that chemical compounds do not migrate from the exterior environment of for example a laminate, through the laminate getting into contact with a sealed substance;
- Possibly ensuring that the packaging is child proof to increase safety of potentially hazardous compounds.

A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyacrylonitrile (PAN) based film, which is sold for example as resins under the trademark Barex®, which is manufactured *i.a.* by the company Ineos. Barex® is widely used and approved for drugs and food applications and is used because it is a good barrier towards oxygen, nitrogen and carbon dioxide compared to other common polymers, and because it has excellent chemical resistance towards different functional

groups such as hydrocarbons, ketones, esters, alcohols, bases and acids and/or pharmaceuticals such as nicotine. Furthermore, extruded Barex® resin is heat stable and therefore weldable at a temperature around 160 - 220°C, which makes it possible to use in flexible packagings. However, Barex® is sold at a high prize due to the difficulties in the production and subsequent extrusion to film resulting in a high loss of material. Furthermore, the water and oxygen resistance of Barex® is not satisfactory for all purposes.

Another solution can be found in WO 00/44559 disclosing a material for packaging nicotine containing products (e.g. patches, tablets, lozenges, nasal spray), wherein the material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers. Further, it is disclosed that a polymeric film is combined with other barrier materials in a laminate to further improve the barrier characteristic of the laminate. The preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.

In addition to the barrier properties, in particular for pharmaceuticals, it is important that the concentration of the substances is stable and reliable, which also poses requirements of the packaging and laminates in terms of inertness and permeability.

Hence, given the increased market and demands for packagings, there is an instant need for finding solutions for packaging, of in particular highly aggressive substances and pharmaceuticals, which fulfil all the requirements while still being economical.

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Summary of the invention

With this background it is an object of the present invention to provide solutions that meet one or more of the needs described above, that is, *i.a.* provide impermeability and inertness to a packaging. Furthermore, it is an object to provide a laminate that is weldable at temperatures suitable for the manufacture of flexible wrappings, such as for use in preparing packagings for patches. It is a further object to provide methods and products that are cost efficient without compromising the quality of the products.

Accordingly, in a first aspect this is solved by a method for providing an aggressive chemical resistant film, said method comprising the steps of:

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i) providing a base layer, which is water and/or oxygen resistant;
ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

5 iv) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens
10 Solubility parameter (HSP) towards an aggressive chemical of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred between 1 to 2.

It has surprisingly been found that when coextruding the tie layer and the contact layer according to the invention, the respective layers can be
15 thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates and wrappings made with the film. The coextrusion also results in a better adherence of the various layers resulting in a homogenous film in which the layers do not separate.

While it was previously believed that usable polymers should be hydrophobic (in order to repel water from the surroundings), the present inventors have found that by providing the film according to the invention where the coextrusion layer comprises a tie layer and a contact layer, and where the contact layer comprises a polymer having a relative energy difference (RED) value in the range 0.8 to 10 relative to the aggressive substance, it
20 has surprisingly turned out that the desired effect of the laminate being impermeable to aggressive compounds, such as nicotine, rivastigmine and lidocaine, while still providing a barrier to external factors such as water/moist and oxygen, is obtained.

A polymer candidate for use as a contact layer in the present invention is selected by calculating the RED value, which is a value used to predict the solubility of one material in another and form a solution. In the present invention the RED values for various polymer/solvent systems have been calculated, wherein the polymer is the polymer forming the contact layer, and the solvent is an aggressive chemical substance such as nicotine, rivastigmine and lidocaine etc.
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The RED value for the polymer and the aggressive chemical substance is calculated by using the theory of the Hansen solubility Parameters (HSP), which is described in C.M. Hansen: "Hansen Solubility Parameters, A User's Handbook", CRC Press, Boca Raton, 1999.

5 The HSP system between the polymer and the aggressive chemical substance is described by parameters set up in a 3 dimensional coordinate system:

- δ_D for dispersion cohesion energy
- δ_P for dipolar cohesion energy
- 10 — δ_H for hydrogen bonding cohesion energy

The HSP distance, R_a , between polymer and the aggressive chemical substance is given by:

$$R_a^2 = 4(\Delta \delta_D)^2 + \Delta \delta_P^2 + \Delta \delta_H^2$$

15 The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

The relation between the HSP distance, R_a and RED is given as:

$$RED = R_a/R_o$$

20 Where R_o is the interaction radius, which determines the radius of the sphere in Hansen space, and the center are the three Hansen parameters. All values are calculated or determined with empiric data and it is known to the person skilled in the art how to calculate the values. The obtained RED value indicates whether or not the polymer is likely to dissolve in the aggressive chemical substance or not:

- 25 RED < 1 the polymer and the aggressive chemical substance will dissolve
- RED = 1 the polymer and the aggressive chemical substance will partially dissolve
- RED > 1 the polymer and the aggressive chemical substance will not dissolve

30 The resulting RED value is used to give an indication of the likelihood of dissolution or not.

All values can be calculated using the Hansen Solubility Parameter in Practice by (HSPiP) Software, commercially available at <http://hansen-solubility.com>.

35 Contact layer polymers according to the invention surprisingly turned

out to have a RED value in the range from 0.8 and higher, preferably, 0.8 to 10 and more preferred 0.8 to 5 and most preferred 1 to 2. It is highly unexpected that polymers which in theory range from being soluble to insoluble with an aggressive substance to be packed fulfill the requirements set for
5 films according to the invention as is supported by the examples provided here with.

The base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicon or
10 aluminium oxide coated polyesters, and/or fluoro polymers. According to the invention water and/or oxygen resistant is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below $1 \text{ cm}^3/\text{m}^2/24\text{hr}/\text{bar}$ according to ASTM standard D3985 at 23°C and 0% RH and/or water (or moisture) vapor transfer rate (WVTR) equal to or below $1 \text{ g}/\text{m}^2/24\text{hr}$ accord-
15 ing to ASTM standard F1249 at 38°C and 90%RH, preferably both the WVTR and the OTR are below 0.01.

According to the invention, the base layer of the film is selected to provide a number of properties to the film and a laminate and packaging comprising the film. The base layer may give desired barrier and support
20 properties to the final laminate. Furthermore, the base layer may in one embodiment be a gas and water impermeable base layer, more preferably a water and/or oxygen resistant base layer.

In embodiments where the contact layer is hygroscopic the base layer is preferably made of a metal foil, preferably aluminum.

25 Aluminum is price competitive, a superior barrier of all gases and moisture and furthermore similar to other metal-like materials aluminium has good dead-fold properties, i.e. it does not unfold once folded, it reflects radiant heat, and gives a decorative appeal to laminates and packages.

According to the invention the tie layer is selected to provide sufficient
30 adhesion between the base layer and the coextrusion layer. The tie layer may give melt strength and support the coextrusion coating of both the tie layer and the contact layer. It is preferred that the melting profile of the tie layer polymers and the contact layer polymers are in the same range to provide optimal films that do not separate. Preferably both layers comprise pol-
35 ymers that melt at the operating temperature of the process of the invention

and even more preferred the melting profiles (i.e. melting points) should differ with less than 30°C, preferably with 0-15°C, such as 5-15°C.

In one embodiment the tie layer is made of 1, 2, 3, 4 or 5 layers. In this way, the properties of the film and resulting laminates and packagings may be improved to accommodate the specific chemical and physical properties of the contact layer and/or the base layer.

In a further embodiment all the layers are coextruded with the contact layer for a simplified processing and for ensuring homogeneity of the layers.

In a further embodiment the tie layer is constituted of one layer where the layer is made of a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride. Most preferably the tie layer has a melting profile similar to that of the contact layer.

According to the invention the contact layer must be chemically resistant to the aggressive substance and excipient if present ultimately to be packed. Further it must show an extreme low absorption of the aggressive substances migrating through the film or laminate. The degree of absorption for a given substances is typically dictated by the manufacturer of the substance but often the accepted values lie in the range of 0 to 1 % (w/w). For some products up to 10 % (W/W) is acceptable typically for products with a low initial API content. The absorption is calculated as the weight of API in packaging relative to the initial weight of the API in the commercial product.

Hence, in the context of the present invention aggressive chemical resistant film means that no more than 1% (or sometimes no more than 10%) is transferred to the packaging material after 24 weeks. Typically, the uptake is complete after 12 weeks or less.

In one preferred embodiment the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH). The HSP and RED Values calculated using <http://hansen-solubility.com>, mentioned above resulted in the following values for the preferred polymers according to the invention using lidocaine/rivastigmine as solvent (API):

Table 1: HSP and RED values for preferred polymers according to the invention

Polymer	D	P	H	RED value (chi)
Lidocaine/ Rivastigmine	18.1	8.2	6.1	-
PA 66	16	11	24	1.72
COC	18	3	2	1.32
EVOH	20.5	10.5	12.3	1.12

It has surprisingly been shown that when the contact layer comprises any of the polymers from the group above, having a relatively low RED (i.e. close to 1) value a chemical resistant film and also laminate may be obtained even though the mentioned polymers represent different polymer types. Tests have shown that the resistance of laminates in which the film is coated with the preferred polymers shows results unexpectedly superior to those of laminates coated/laminated with Barex®.

EVOH is normally used in laminates due to the superior oxygen barrier properties of EVOH. However, EVOH is known to be very hydrophilic and hydroscopic (i.e. has a high WVTR), hence it is surprising that a EVOH polymer is usable in the context of the present invention where water resistance is a desired property. Also, PA has typically been used in laminates due to the superior mechanical properties like tear strength or as a barrier. As for EVOH it is a surprise that PA may be used as a contact layer for providing a chemical resistant film due to the hydrophilic nature of PA.

Because of the hydrophilic nature of PA and EVOH, in a preferred embodiment, the film obtained according to the invention may be tightly packed in a moisture barrier in particular if it has to be stored. The film or laminate according to the invention may packed immediately after manufacture of the chemical resistant film or laminate and should be kept safely packed until further use, for example in a packing line.

COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates. Without the wish to be bound by any theory this is believed to be due to the stress which the polymer is subjected to during an extrusion process. The stress causes irregular heating and melting within the COC, resulting in the final film or

laminate to be unacceptable from a visual point of view for use in various packaging industries. Hence, it is very surprising that the inventors of the present invention have succeeded in providing a coextrusion layer comprising COC as a contact layer for sealing aggressive substances.

5 To obtain a satisfactory coextrusion layer it is important that the polymer for providing a contact layer and a copolymer for providing a tie layer is compatible with respect to the melting characteristic of the polymers and the copolymer. As an effect of having been able to process a chemical resistant laminate with a coextrusion layer laminated to a base layer, thin laminates
10 may be obtained, and generally improved process ability during the manufacture of the laminates or wrappings are achieved.

Consequently, in one embodiment the tie layer or plurality of layers constituting the tie layer, has a thickness in the range of 7 to 20 g/m² and/or the contact layer has a thickness in the range of 4 to 20 g/m² and the thick-
15 ness of the laminate is not more than 40 g/m².

In a particular embodiment the contact layer of the coextrusion layer is made from a blend of at least two polymers. Using blends can be a means for reducing the costs and for adapting the physical and chemical properties of the co-extrusion process, such as reducing or increasing the melting tem-
20 perature to comply with the profile of the tie layer(s) and the polarity of the blend to improve the adhesion properties of the layers and hence the robustness of the final product. In a preferred embodiment the contact layer consists of one polymer type. Experiments showed that using one type of polymer resulted in improved resistance of the film and laminate towards the
25 chemical substance to be packed.

In any of the blends or homo layers at least one of or the polymer(s) forming the contact layer of the coextrusion layer is a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol. Each of the polymers are commercial available for example under the tradenames EVAL® C109B sold by Ku-
30 raray, Selar PA 3426 R sold by Dupont®, 6013M-07 sold by Topas®.

In one embodiment the cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol makes up at least 50% of the blend, preferably at least 60%, more preferably at least 80%, most preferably at least 95.

The adhering of step iv) occurs instantly by cooling the co-extrudate
35 in cooling cylinders during the lamination process.

In a further aspect of the invention an aggressive chemical resistant film comprising at least a base layer, which is water and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and whereby the tie layer comprises at least one layer
5 and wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2. Films according to the invention are resistant to aggressive chemical substances.

In one embodiment the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, polyamide, polyvinylidene chloride, silicium oxide coated
10 polyesters, and/or fluoropolymers.

In a further embodiment the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a
15 terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

In a particular embodiment the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.
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In a further embodiment the film is heat sealable. A heat sealable film or laminate is a laminate that is capable of sealing to itself during heat sealing. Deformation of films or laminates is highly undesired especially during the final wrapping of the product.
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In yet another aspect the invention relates to a laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film as described above comprising
30 a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer wherein the base layer side of the film is facing the first outer layer;

In one embodiment the first outer layer may be made from a material selected from but not limited to paper, polyethylene or polyamide based
35 sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or

combinations. It is preferred that the first outer layer is a combination when polyester based sheets are used.

In an embodiment the first outer layer and the laminate are laminated to provide the packaging in one piece. Laminating the outer layer to the first laminate provides a strong laminated, which is easy to wrap, and, it is ensured that the individual parts of the laminate do not fall apart.

In another embodiment the laminate further comprises a second outer layer facing the exterior side of the first outer layer, preferably the second outer layer is a paper layer. The paper layer is typically printed with the name, color and/or logo of the product and manufacturer of the product. It is also contemplated that the first outer layer is printed.

It is also contemplated that an adhesive agent is applied between the second and first outer layers. The adhesive layer may be the same or different from the tie layer. Additional suitable adhesives are adhesives approved for use in packaging products for human use and are well known to the skilled person. A suitable adhesive may be selected from but is not limited to polyurethane based adhesives, epoxy based adhesives, or acrylic based adhesives.

In one embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine. These compounds are known as aggressive chemicals/compounds and require specialized packaging.

Hence, the invention also contemplates an aggressive chemical substance packed in a laminate or packaging as explained above and a method for providing the packaging the chemical substance, said method comprising the steps of:

- a) providing a base layer
- b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;
- c) coating the coextrusion layer to the base layer;
- d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an coextrusion layer coated to the base layer;
- e) providing a highly aggressive substance to the contact layer side

of the film; and

f) sealing the chemical resistant film, preferably by heat sealing, in such way to provide a hollow interior space for sealing the highly aggressive substance, said hollow space having an interior side and an exterior side, wherein the interior side of the film is the contact layer of the coextrusion layer and the exterior side of the film is the base layer.

In a preferred embodiment the highly aggressive substance is selected from the group consisting of nicotine, lidocaine, and rivastigmine

It is also contemplated that a first outer layer may be applied to the film; the first outer layer is made of a mechanically wear resistant material and typically serves to protect from children being able to break the sealed film, laminate or wrapping.

The packaging should preferably comply with International standards such as 16 CFR §1700.20 (for USA) and ISO 8317 (2003) corresponding to DIN EN ISO 8317 (2004) (for Europe).

It is also contemplated that a second outer layer may be applied to the film; the second outer layer is typically a paper layer. The paper layer is typically printed with the logo or colors etc. of the supplier of the product.

It is contemplated that the first and/or second outer layer is laminated to the film before steps e) and f) for example in one combined coextrusion and laminating step.

In yet another aspect, the invention provides the use of a polymer having a RED value of > 0.8 , preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant coated to a, optionally co-extruded, layer comprising a tie layer and the contact layer.

In a further embodiment the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

Specific films according to the invention comprise but are not limited to base layer/tie-layer/contact-layer (the latter two coextruded) EAA/PE/COC, EAA/EMA/COC, EAA/terpolymer/COC, terpolymer/PE/COC, EAA/terpolymer/EVOH, EAA/terpolymer/PA, or EAA/PA.

Figures

Figures 1 is a cross section of an embodiment of a chemical resistant film according to the invention

Figure 2 is a cross section of an embodiment of the chemical resistant film according to the invention.

Figure 3 is a cross section of a laminate according to the invention.

Figure 4 shows the results of an absorption study of rivastigmine as API wrapped in a laminate according to the invention as compared to and a commercial available laminate with the commercial available polymer film Barex® after storing for 2, 4, 8 and 12 weeks at 40°C.

Figure 5 shows the amount of licodaine remaining in a patch after 7 days at 40°C for embodiments of the laminate according to the invention and a commercial available Barex® laminate.

Detailed description

The invention will now be described in greater details. Each specific embodiment and variation of features applies equally to each aspect of the invention unless specifically stated otherwise.

The film, laminate and packaging according to the present invention is intended to be used in packaging highly aggressive substances such as nicotine, rivastigmine or lidocaine, however, the invention should not be limited to these specific substances.

The term film according to the invention contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact layer. Where the contact layer is laminated, for example using an EVOH film, the contact layer and tie layer may be either coextruded, or, the contact film layer may be laminated to the base layer optionally with an intermediate tie layer.

The term laminate according to the invention contemplates the film to which a further layer is laminated, such as a first outer layer.

A packaging is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

The term highly aggressive substance should be understood as a

substance which is both very reactive with metals, acids, bases or functional groups such as ketones, alcohols, hydro carbons and/or esters, and/or, volatile but also easily migrates through barriers. Therefore, the films, laminates or packagings applicable for packing highly aggressive substances should have both chemical-resistant properties but also limit the migration of the aggressive substance through the film, laminate or packaging. The aggressive substance according to the invention is also or alternatively susceptible to degradation when exposed to ambient conditions, such as oxygen and water, is volatile and able to migrate or a combination. Specifically, the aggressive substance is selected from but not limited to nicotine, oils, such as spearmint and peppermint oil, licodaine or rivastigmine.

The term oxygen and water resistant as used in the context of the present invention contemplates material for which the oxygen transfer rate (OTR) and/or water vapor transfer rate (WVTR) is no more than 1 preferably no more than 0.1 as also indicated above. The term WVTR may also be referred to as the moisture vapor transfer rate (MVTR). WVTR and MVTR are equivalent.

The term mechanically wear resistant layer as used for the first outer layer in the context of the present invention should be suitable for the manufacture of a flexible packaging. The mechanically wear resistant layer may be chosen from materials such as polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets or combinations.

Further, the mechanically wear resistant material can be provided in a film that is biaxially oriented to give the film higher seal strength. The term biaxial oriented should be understood such that the provided polymer film has been stretched in both a longitudinal and a transverse direction during manufacturing.

The term exterior side should be understood in its broadest term. The term exterior environment is used for defining the direction opposite of the side that is facing the highly aggressive substance to be sealed by a laminate or packaging of the present invention. This means that the term exterior environment is independent on whether additional layers are coated, laminated or otherwise attached to the film. Thus, the word is used for specifying which direction a side of a layer is facing.

The various embodiments of the invention will now be illustrated with

references to the figures and examples.

With reference to figure 1 the film of the invention will now be described in greater detail. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. A coextrusion layer, 5, comprising a tie layer, 3, and a contact layer, 4, is coated to one side of the base layer, 2, according to the method of the invention and is allowed to adhere. The base layer, 2, and the coextrusion layer, 5, define the film according to all the aspects of the invention. Consequently, the film is provided with a base layer side, 2, and a coextrusion layer side 5, wherein the base layer side, 2, is intended for facing the exterior environment and the coextrusion layer side, 5, is intended for facing the highly aggressive substance to be sealed.

The coextrusion layer may be coated to the aluminium layer by a coextrusion system generally known in the art to provide the coextrusion layer coated on the first side of the aluminum layer. The coextrusion layer may be applied in an amount of 7-40 g/m³. Subsequently, the aluminum layer coated with the coextrusion layer is adhered. The coextrusion is preferably performed at a temperature of 240-330°C, more preferred 270 - 300°C and the speed of the application/coating is in the range of 150 to 600 m/min. The equipment suitable for extruding and laminating films and laminates according to the invention may be obtained from Bobst.

When using coextrusion, it is possible to obtain a multi layer which is thinner than multilayer layers provided by sequential film applications techniques without compromising the extreme chemical resistance ability of the first laminate. Hence, the present invention does not only provide an extreme chemical resistance laminate, and packaging comprising the same but at the same time the manufacturing process is more cost effective since less polymer, forming the contact layer, has to be used.

Another embodiment of the film in which the tie layer comprises two layers is illustrated in figure 2. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. The coextrusion layer, 5, comprises a tie layer, 3, comprising a first layer, 3a, and a second layer, 3b, and a contact layer 4. The coextrusion layer is coated to one side of the base layer, 2, according to the method of the invention and is allowed to dry.

In the embodiment illustrated the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene

(PE) as the second layer, 3b, where the first layer of EAA faces the base layer and second layer of the PE faces the contact layer, 4.

The extreme chemical resistant film according to the invention is intended for use as a component of a packaging suitable for sealing a highly aggressive substance. The film may constitute the packing itself.

To further improve the mechanical wear resistance a first outer layer may be laminated to the base layer side of the film or simply be wrapped around the film. Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the invention, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.

The first outer layer, 21, is a mechanically wear resistant layer which adds safety properties to the wrapping ensuring that the wrapping is not inadvertently opened. Hence, the outer layer can also be seen as a child proof layer meaning that the layer is made of a material and sealable in such a way that it is difficult for children to open. Additionally, the outer layer may be provided with a second outer layer, 20.

The second outer layer, 20, is typically a paper layer, wherein the paper layer is facing the exterior environment; the exterior facing side of the second layer may be printed as desired. The second outer layer, such as the paper layer is added to improve the stiffness of the packaging in addition to providing a printing platform.

Furthermore, it is within the inventive concept of the present invention that an adhesive agent is applied between the first outer layer and the base layer and/or between the first outer layer and the second outer layer. The obtained packaging may then be assembled in such a way that the various layers do not part during handling, printing and/or packaging of the substance to be packed.

After production the film, laminate or packaging may be stored as rolls ready for use in further lamination or packaging of the aggressive substance to be packed.

In use, the packaging is sealed around the substance to be packed so that the contact layer of the coextrusion layer faces the interior side and the substance, and, the base layer, first outer layer or second outer layer, as

applicable, face the exterior side, so as to create a hollow interior for containing the, substance, such as the aggressive substance.

The sealing of the packaging is achieved in such way that the contact layer of the coextrusion layer is facing the aggressive substance so that the remaining part of the package is protected by the contact layer of the coextrusion layer. In this way, the aggressive substance is encompassed by the inner side of packaging and will therefore only have direct contact with the contact layer of the coextrusion layer.

In general, the order in which the different layers of the packaging according to the invention are applied to the base layer is flexible. Hence, the first outer layer may be applied before the coextrusion layer and the other way around. The order depends on which production line is suitable in a specific situation.

In more details the packaging according to the present invention may in one embodiment be manufactured by obtaining a laminate comprising a base layer, such as an aluminum layer and a coextrusion layer comprising a biopolymer of ethylene and acrylic acid as a tie layer and EVOH as the contact layer coated to the aluminium as described above. The base layer side of the first laminate may then be provided with an adhesive agent and subsequently laminated to a biaxial orientated PET-film which is the first outer layer, i.e. the mechanically wear resistant layer. The PET-film is further provided with an adhesive agent on the exterior side of the mechanically wear resistant layer and is subsequently laminated to a paper layer for providing the final packaging.

An aggressive substance, such as but not limited to lidocaine, is placed on the contact layer side of the laminate which is welded around the substance, such as to form a pouch with an inner side and an outer side. Accordingly, the interior of the pouch consists of the coextrusion layer, where the contact layer of EVOH facing the aggressive substance thereby protects the rest of the provided packaging and the exterior side is the paper layer.

In general, the lamination procedure for laminating the mechanically wear resistant or paper layer to each other or to the base layer is routine procedure for the person skilled in the art.

According to all aspects of the invention the base layer may be selected from but not limited to a metal foil, preferably aluminum foil, a poly-

mer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluoro polymers, such as commercial Alu foil from e.g. Hydro, or AlOx coated PET films obtainable from e.g. Toray Films Europe, or SiOx coated PET films obtainable from e.g. Celplast under the tradename Ceramis.

According to all aspects of the invention the tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride, such as the commercial product Lotader® 3410 sold by Arkema or Nucrel® 0609HSA sold by Dupont®

According to all aspects of the invention the contact layer may be made of a material selected from cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol or mixtures thereof, such as the commercial products EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont® or COC 6013M-07, COC 6007F-600, or 9506-600 sold by Topas® or EVOH obtainable from Nippon Gohsei under the tradename Soarnel.

According to all aspects of the invention the first outer layer may be made of a material selected from paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations, such as the commercial product F-PAP sold by Flexpet.

The invention will now be illustrated in more details with reference to the following non limiting examples.

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Example 1- performance of a laminate according to the invention compared to a commercially used laminate

A study was conducted to evaluate the performance of four laminates according to the present invention as compared to the commercial available product comprising Barex® as the contact layer.

The wrappings according to the invention were compared to the performance of a Barex® laminate currently used in the field.

The test is a resistance test, wherein the transfer of a rivastigmine to the laminate is evaluated.

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Table 2: The composition of the 6 wrappings was as follows, laminates 1 to 5 are laminates according to the invention

	Adhesive/Polymer layer Coextrusion layer	Base layer	First outer layer	Second Outer layer
Commercially used Barex® laminate (prior art)	Adhesive/ Barex® film	Al	PET	Paper
Laminate 1	Tie layer: Bipolymer of ethylene and acrylic acid (Nucrel 0609 HAS) Contact layer: PA (Selar PA 3426R)	Al	PET	
Laminate 2	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 60% (EVAL C109B) and PE 40%	Al	PET	
Laminate 3	EVOH film	Al	PET	
Laminate 4	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 100% (EVAL C109B)	Al	PE	PET
Laminate 5	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: COC	Al	PE	PET

*Between the paper/PET, PET/Al, and Al/EVOH film layers an adhesive was applied.

Laminates 1 to 5 were obtained according to the method of the invention, wherein a for laminates 1,2,4 and 5 a coextrusion layer was coated to the base layer and in laminate 3 where the contact layer was laminated to the base layer. The thickness of the tie layers were between 4-18 g/m² and the thickness of the contact layer was 8-12 g/m².

The resulting laminates were wrapped with rivastigmine as API and the transfer of the API to the packaging material/wrapping) was measure after 2, 4, 8 and 12 weeks at 40 °C. The API in the wrapping was measured by extracting the packaging and analysis the amount of API using Mass spectrometry

The Rivastigmine patches tested were commercially available patches containing 9.5 mg API/patch.

The results are shown in figure 4 illustrating the resulting transfer of rivastigmine (weight API extracted from the packaging) to the laminate in percentage of the content of the original patches of 9.5 mg.

The columns are denoted 1, 2, 3 and 4 respectively to the order they are shown from left to right in figure 4. Hence column 1 (furthest to the left) for each contact layer polymer used shows the results for the 6 laminates after two weeks. Column 2 shows the results for the 6 laminates after four weeks. Column 3 shows the results for the 6 laminates after 8 weeks, and column 4 shows the results for the 6 laminates after 12 weeks.

The Barex® laminate is a reference known for applicability in the art and comparison were made for evaluating the properties of the laminates according to present invention.

From the figure it is clear that the results for laminates according to the invention obtained by coextrusion of either of EVOH, PA, or COC as well as laminating EVOH provides for an improved chemical resistant laminate compared to the commercially used Barex® laminate.

Also, a contact layer, illustrated as laminate 2, of a blend of EVOH and PE was prepared and tested. Though the properties of this blend with rivastigmine as API resulted in a higher transfer than Barex®, the rate is still below the demanded limit and hence, it illustrates that blends are usable alternatives to Barex® as well. Surprisingly though the contact layer made of 100% EVOH was markedly superior to the blend.

Also, a contact layer, illustrated as laminate 3, a film of EVOH laminated to aluminum was prepared and tested. Surprisingly, it was shown that the use of EVOH in the form of a film laminated to aluminum provided a chemical resistant laminate.

5

Example 2 - stability test of a chemical substance wrapped in laminates according to the invention and wrapped in a prior art product using Barex®

Similar to the test described in example 1, laminates according to the invention were prepared as outlines in table 3 below. A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.

Table 3: Packagings for lidocaine stability test.

	Barex Commercially used Barex® laminate (prior art)	COC coex same as laminate 5 of example 1	Coex EVOH same as laminate 4 of exam- ple 1
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Stability of the API is important to ensure that the dose indicated on the packaging is correct. A value of 90% - 110% of the original dose after one week when stored at 40°C using Barex® as index 100 is considered acceptable. Figure 5 illustrates the results of the test where the y-axis indicates the weight decrease of the two laminates according to the invention using Barex as index 100.

20

As can be seen from figure 5, both inventive laminates have a lower value than the index 100 Barex® comparative product, however with a value within the acceptable limits. The lower value of the laminates according to the invention indicates that more lidocaine has disappeared from the patch.

25

C L A I M S

1. A method for providing an aggressive chemical resistant film, said method comprising the steps of:

- i) providing a base layer, which is water and/or oxygen resistant;
- 5 ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;
- iii) coating the coextrusion layer to the base layer;
- iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and
10 the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8 , more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most
15 preferred 1 to 2.

2. A method according to claim 1, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated poly-
20 esters, and/or fluoro polymers.

3. A method according to any one of the claims 1 to 2, wherein the tie layer is made of 1, 2, 3, 4 or 5 layers.

4. A method according to claim 3, wherein all the layers of the tie layer are coextruded with the contact layer.

25 5. A method according any one of the preceding claims, wherein the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl meth-
30 acrylate, and more preferably a maleic anhydride.

6. A method according to any one of the claims 1 to 4, wherein the tie layer comprises at least two layers, and wherein the first layer comprises a copolymer according to claim 5 and the at least second or more layer(s) comprises a material selected from EEA, PE, EMA, EAA or a combination.

35 7. A method according to any one of the preceding claims, wherein

the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

8. A method according to anyone of the preceding claims wherein the contact layer is a polymer selected from the group consisting of a cyclic
5 olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

9. A method according to anyone of the preceding claims, wherein the tie layer or plurality of layers constituting the tie layer, has a thickness in the range of 7 to 20 g/m² and/or the contact layer has a thickness in the range of 4 to 20 g/m² and the thickness of the film is not more than 40 g/m².

10. An aggressive chemical resistant film comprising at least a base
10 layer, which is water and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and whereby the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility
15 parameter (HSP) of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

11. A film according to claim 10, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, such as polyamide, polyvinylidene
20 chloride, silicium or aluminium oxide coated polyesters, and/or fluoropolymers; and/or

the tie layer is constituted of one layer and wherein the layer is made of a copolymer, said copolymer comprising a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a
25 third polymer, which third polymer is preferably made of a material selected from glycidyl methacrylate, and more preferably maleic anhydride; and/or

wherein the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

12. A film according to claims 10 or 11, wherein the tie layer or plu-
30 rality of layers constituting the tie layer, has a thickness in the range of 7 to 20 g/m² and/or the contact layer has a thickness in the range of 4 to 20 g/m² and the thickness of the film is not more than 40 g/m².

13. A laminate for packing an aggressive chemical substance said
35 heat sealable laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film according to claims 10 to 12 comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2 and where the base layer side of the film is facing the first outer layer.

10 14. A laminate according to claim 13, wherein the heat sealable laminate further comprises a second outer layer facing the exterior side of the outer layer, preferably the second outer layer is a paper layer.

15 15. A laminate according to any of the claims 13 to 14, wherein the heat sealable laminate encloses a compound selected from the group consisting of nicotine, rivastigmine and lidocaine.

16. A laminate according to claim 13, 14, and 15, wherein the laminate is heat sealable.

17. An aggressive chemical substance packed in a heat sealable laminate, said heat sealable laminate comprising

20 - a first outer layer made of a mechanically wear resistant material;

 - an aggressive chemical resistant film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer wherein the base layer side of the film is facing the outer layer and wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

25 18. Use of a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant coated to a, optionally co-extruded, layer comprising a tie layer and the contact layer.

35 19. Use according to claim 18, wherein the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene

vinyl alcohol.

Awapatent A/S

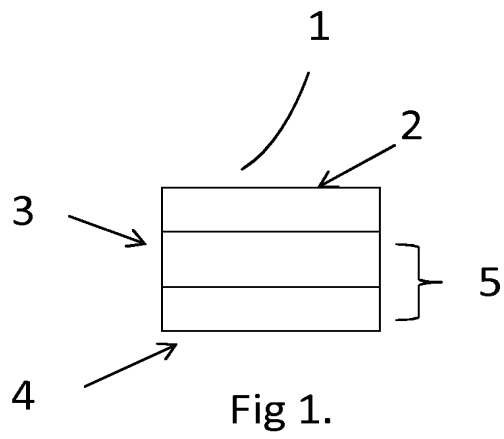
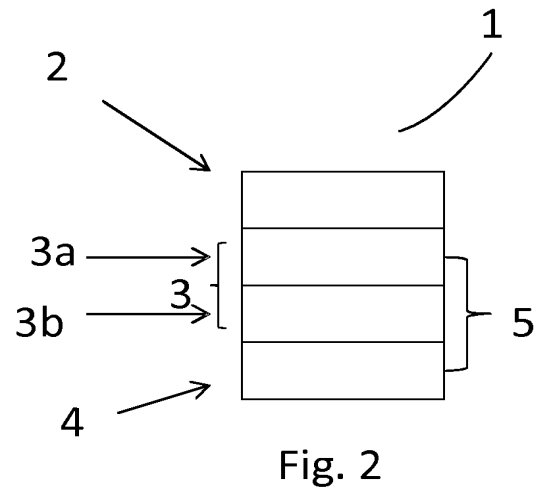
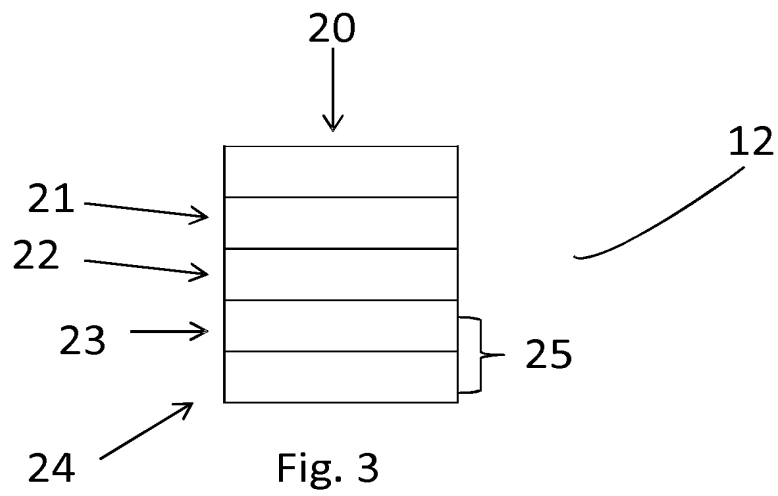
A method for providing an extreme chemical resistant film

A B S T R A C T

5

The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to pack aggressive chemical
10 substances such as lidocaine and rivastigmine.

(Fig. 1)



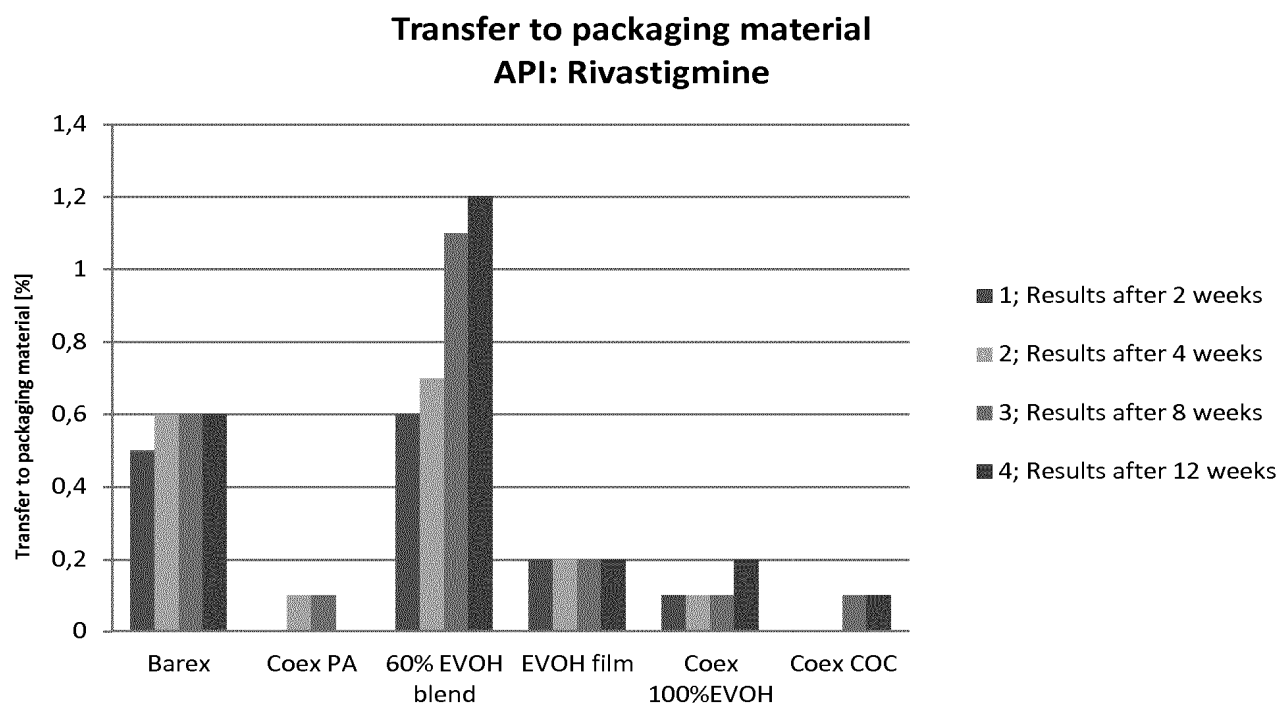


Fig. 4

Index on remaining API % in patch
API: Lidocaine

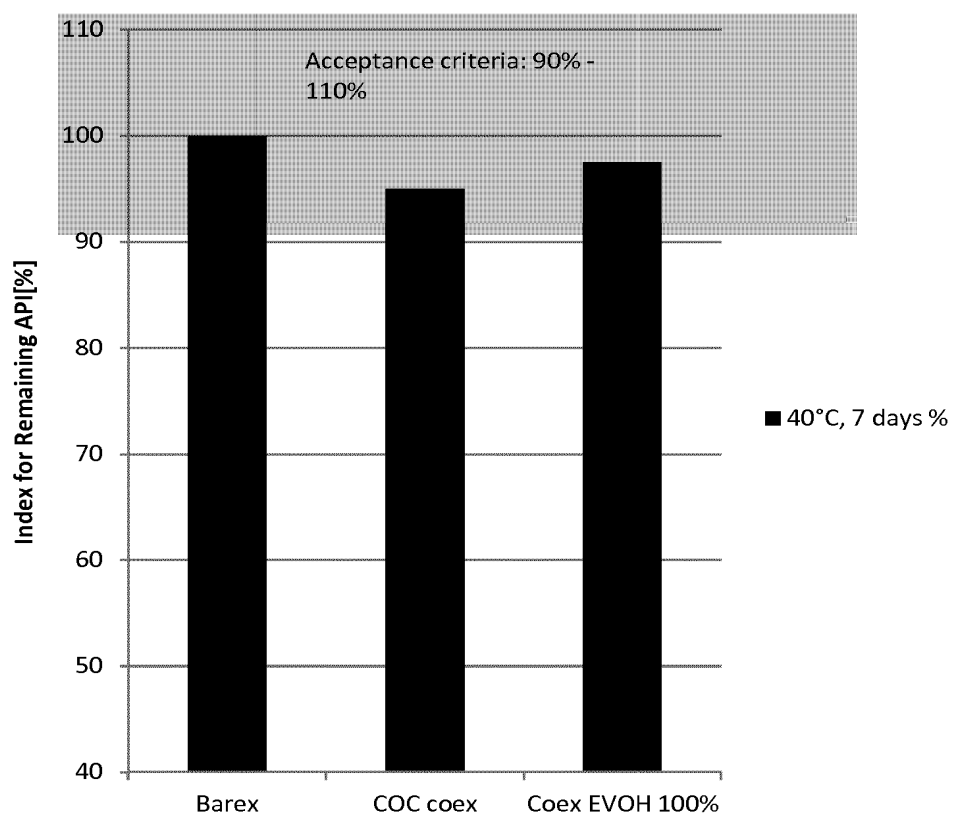


Fig. 5

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Document details:	Country/Office: EP
	Number: 15202962.5
	Filing date: 29 December 2015 (29.12.2015)
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	01	US 6,120,860-A	09-19-2000	Bowen et al.	8 pgs.
	02	US 2005/037162-A1	02-17-2005	John Peter Adams	12 pgs.
	03	US 2004/234790-A1	11-25-2004	Smith et al.	4 pgs.
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	05	WO 00/44559-A1	05-03-2000	Levander et al.	16 pgs.	
	06	WO 2005/037539-A1	04-28-2005	Morris et al.	22 pgs.	
	07	EP 2 939 667-A1	11-04-2005	Nipro Patch Co. Ltd.	24 pgs.	
	08	WO 2013/004243-A1	01-10-2013	Fertin Pharma AS	28 pgs.	
	09	WO 91/08731-A1	07-11-1991	Alza Corp.	23 pgs.	
	10	WO 2015/174502-A1	11-19-2015	Nichiban KK	36 pgs.	

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(51) International Patent Classification ⁷ : B32B 27/06, B65D 75/26, C08G 63/189, 63/60	A1	(11) International Publication Number: WO 00/44559 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/SE00/00017 (22) International Filing Date: 12 January 2000 (12.01.00) (30) Priority Data: 9900215-6 26 January 1999 (26.01.99) SE (71) Applicant (for all designated States except US): PHARMACIA & UPJOHN AB [SE/SE]; S-112 87 Stockholm (SE). (72) Inventors; and (75) Inventors/Applicants (for US only): LEVANDER, Gustav [SE/SE]; Tullingebergsvägen 32, S-146 45 Tullinge (SE). KARLSSON, Anders, H., F. [SE/SE]; Per Wickenbergsgatan 1, S-217 54 Malmö (SE). HILDINGSSON, Ingemar [SE/SE]; Smedjegatan 2 C, S-222 37 Lund (SE). (74) Agent: HEDENSTRÖM, John; Pharmacia & Upjohn AB, Box 941, S-251 09 Helsingborg (SE).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: NEW USE		
(57) Abstract		
<p>A material for packaging a nicotine containing product comprising a polymer based on dimethyl-2,6-naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, such as polyethylene naphthalate (PEN) or polytrimethylene naphthalate (PTN), or a liquid crystal polymer (LCP). The material may be laminated to another polymer or to metal foil.</p>		

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NEW USE

Technical field

The present invention relates to materials for packaging nicotine-containing products.

Background art

For many years tobacco smoking has been one of the major health problems throughout the world. Smoking is now recognized as the main cause for e.g. high blood pressure and lung cancer. However, because of the addictive nature of nicotine it is utterly difficult for heavy smokers to completely stop smoking. An acceptable alternative to smoking has been to provide nicotine in a form or manner other than by smoking, e.g. as a chewing gum containing nicotine as an active ingredient, see e.g. US 3,845,217. Other products used as substitutes for smoking are tablets containing nicotine, see e.g. US 5,543,424, devices for allowing nicotine to be inhaled through an elongated tube, see e.g. US 5,501,236, nicotine containing nasal sprays, see e.g. US 5,656,255, patches for administering nicotine transdermally, see e.g. US 4,915,950, etc.

The primary requirement when packaging drugs and food is the demand that the package must protect the product against penetration of moisture and oxygen from the environment. Very seldom the product itself constitutes any problems. Nicotine, on the other hand, is very aggressive towards its environment and migrates through most known materials. It is also very hygroscopic and therefore sensitive to moisture and when exposed to oxygen or air the nicotine turns brown. Because of the toxicity of nicotine and because the expected shelf-life for nicotine containing products is as long as up to two years, commonly used materials within the package industry, e.g. polypropylene, polyethylene and polyvinyl chloride therefore cannot be used for nicotine containing products.

A known polymer which fulfills the requirements of oxygen, water and nicotine impermeability is commercially available under the trademark Barex[®], being a copolymer made of acrylonitrile and methylmethacrylate and grafted to nitrile rubber on the main chain. Due to the copolymerization with methylmethacrylate the polymer becomes softer and is possible to process. Barex[®] is available with different amounts of nitrile rubber, is amorphous and is a glass polymer at room temperature.

The temperature range within which Barex[®] may be processed is, however, very narrow rendering the polymer difficult to process resulting in a large amount of discarded material. This is partly due to Barex[®] having a temperature dependent elasticity. Today, Barex[®] is also associated with a high price.

5 The use of Barex[®] in a nicotine impermeable container is disclosed in US 5,501,236.

Summary of the invention

It is therefore an object of the present invention to provide an alternative material to Barex[®], which exhibits favorable characteristics of oxygen, water and nicotine impermeability, but which does not suffer from the above-mentioned drawbacks. According to
10 the invention it is therefore suggested an alternative nicotine impermeable packaging material for a nicotine-containing product having the characterizing features of the claims.

The material of the invention comprises polyethylene naphthalate, polytrimethylene
15 naphthalate and/or a liquid crystal polymer, LCP, and has excellent characteristics of oxygen, water and nicotine impermeability. Due to the temperature ranges the polymers of the invention are favorable to process and will have an acceptable price. The material of the invention is known *per se*, but its excellent nicotine barrier properties have not been known. Neither has its use for making packages for nicotine-containing products been
20 contemplated.

Detailed description of the invention

The packaging material of the invention is intended for use in connection with nicotine containing products for therapeutic treatment of patients having an addiction to nicotine. Examples of such products are chewing gums, sublingual tablets, nasal sprays,
25 nicotine patches and nicotine inhaling devices, all marketed through Pharmacia & Upjohn. These products are all classified as drugs and thus, the requirements of product stability are high. The expected shelf life is two years without any noticeable change regarding composition, concentration and dosage. Specific ranges for allowed variations have been established in accordance with requirements from the authorities, e.g. Food
30 and Drug Administration, FDA, in the USA.

In chewing gums the nicotine is usually present in the form of a complex with an insoluble cation-exchanger, which is disbursed in a gum base, in order to be stabilized. In

tablets the nicotine is usually present in the form of an inclusion complex. Only small amounts, if any, of nicotine are in contact with the package for chewing gums and tablets and thus, the demand for a nicotine barrier becomes lower for these products. The pH for a chewing gum is usually slightly above 4.

5 In nasal spray the nicotine is present in a liquid solution having a concentration of approximately 10 mg/ml and a pH of approximately 7. The nasal spray is distributed in glass flasks inert to the aggressiveness of nicotine. However, the nicotine solution also comes into contact with seals and pumping devices made of polymeric material.

10 In a patch and in an inhaling device primarily nicotine vapor comes into contact with the package. Here the concentration depends on the vapor pressure of the nicotine that varies with temperature. In room temperature the concentration in a patch is approximately 250 mg/ml. In a patch and in an inhaling device the pH is approximately 9 - 10.

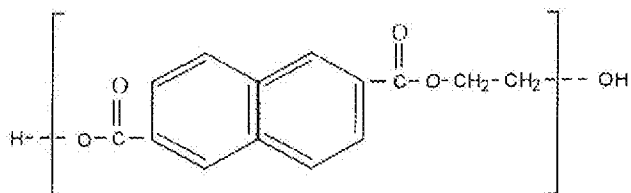
15 A number of factors are important when materials for nicotine-containing packages are chosen. The nicotine must not migrate through the packaging material and disappear from the system or be accumulated uncontrollably in the packaging material. Also, the nicotine must be protected from oxygen due to the fact that it is easily decomposed in contact with air or oxygen. Products containing nicotine also turns brown or yellow when only small amounts of decomposition products are present resulting in cosmetic drawbacks long before any stability limits have been passed. A good oxygen barrier is
20 therefore of utmost importance.

 Besides the above mentioned primary demands on good nicotine resistance and low oxygen permeability, other important factors to take into consideration regarding packaging materials for nicotine-containing products are water and moisture permeation,
25 processability, price and environmental impact.

 The water barrier is important especially in the nasal spray where loss of water has large impact on the concentration of the product. Water barrier characteristics are also important in other forms of distribution since water may have an impact on permeation characteristics of the polymer. Great consideration should also be taken to the process-
30 ability since large-scale industrial production is considered where even small problems may involve large costs.

With the aim to find a packaging material for the packaging of a nicotine-containing product, which fulfills the above mentioned demands two different types of polymers, were found.

The first of these materials is PEN, polyethylene naphthalate:

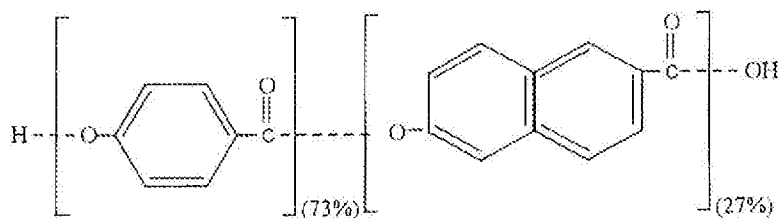


PEN is polyester based on dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers. Dimethyl-2,6-naphthalene dicarboxynate and -2,6-naphthalene dicarboxylic acid monomers are e.g. sold by Amoco under the trade name NDC and NDA-monomer respectively. PEN is semicrystalline and is a glass polymer at room temperature.

There are other polymers, such as PTN (polytrimethylene naphthalate) which are based on the same monomers. PTN differs from PEN only in that the ethylene chain has been exchanged to a propylene chain. It is also envisageable to use polymers comprising both dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.

PEN differs from PET (polyethylene terephthalate), which is another, more commonly used polyester, in that the benzene ring in the PET molecule has been exchanged for naphthalene in PEN. This makes the PEN structure more rigid than the PET structure and the features of PEN more favorable for this invention than the features of PET.

The second nicotine impermeable polymer of the invention is polyester based Liquid Crystal Polymer, LCP. One example thereof is Vectra[®] A 530 having the following structure:



LCPs constitute a group of materials, which have a characteristic molecular structure. LCP polymers consist of rigid rod-like macromolecules that align in the melt to produce a liquid-like structure. This specific structure brings considerable improvement in mechanical properties compared with conventional polymers and a number of other exceptional properties. The monomers are hydroxy benzoic acid and hydroxy naphthenic acid. A typical LCP polymer, such as the above-mentioned Vectra® A 530, is filled with 30 % of mineral filler. The LCP material has a dense structure as a consequence of high crystallinity, is chemically resistant and has extremely low diffusion rates for oxygen and water.

According to the invention it was surprisingly found that in addition to the above mentioned barrier properties against water and oxygen PEN, PTN and LCP also exhibit excellent barrier properties against nicotine. In below Table 1 is shown a comparison of the properties of Barex® 210, PEN 14991 and Vectra® A 530. For comparison is added a polymer, Isoplast 2530 (a polyurethane having better barrier characteristics than other polyurethanes due to its high glass transition temperature), which does not have good nicotine impermeability.

Barex® is marketed by British Petroleum, PEN by Shell and by Eastman, Vectra® by Ticona and Isoplast by Dow.

Table 1

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Opacity	Transparent	Transparent	Opaque	Transparent
Morphology				
Crystallinity	Amorphous	Semi crystalline	High Crystalline	Amorphous
Permeability				
Oxygen cm ³ ·mm/m ² ·day·atm	0,3	1,5	0,02	2,4
Water g·mm/m ² ·day	2.0	0,7	0,05	1,2

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Nicotine Resistance	Excellent	Excellent Equivalent to Barex	Excellent Equivalent to Barex	Not acceptable Inferior to Barex
Processing				
Extrusion	+	+	+	+
Injection Molding	+	+	+	+
Vacuum Forming	+	+	~	
Blow Molding	+	+		+
Applications				
Film	+	+	+	+
Laminate	+	+	+	+
Injection Mould details	+	+	+	+
Blow Mould details	+	+		+
Blisters	+	+	-	

The nicotine resistance of the captioned polymer materials was investigated with sorption tests as follows. Pieces of the respective materials were placed in glass bottles containing nicotine solution and were stored therein at room temperature for 1, 2 and 4 weeks. Subsequently the amounts of nicotine sorbed into the respective polymer materials were extracted from the polymers and analyzed by UV, HPLC and GC. The values for Barex 210 were used as reference levels.

As explained above PTN, marketed through Shell, is chemically very similar to PEN. In polymer chemistry it is a commonly accepted principle that close chemical similarity implies similar physical/chemical properties. Hence the above good results for PEN implies that also PTN has good nicotine barrier properties.

The nicotine impermeable polymers PEN and PTN of the invention can be used alone in film applications or may be combined with other barrier materials in a laminate to further improve the barrier characteristics of the packaging material. Suitable materials for laminating are metal, especially aluminium, foils and other polymers, e.g. polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), and fluoropolymers, all of which are good oxygen and water barriers. Other polymer materials also suitable are

ethylene vinyl alcohol copolymer (EVOH) and polyvinyl alcohol (PVA), which are excellent oxygen barriers, and ionomers (i.e. ionically crosslinked thermoplastic polymers, whereof Surlyn® from DuPont is an example), polyethylene (PE), and polypropylene (PP), which have good water barrier properties.

5 LCP is most suitable for use in injection molded applications. PEN, PTN and LCP may be alloyed with other polymers, such as PET. Such an alloy can then be processed as PET, but due to the incorporation of PEN, PTN or an LCP the alloy is conferred superior barrier properties compared to pure PET.

The invention will now be further described and illustrated by reference to the following example. It should be noted that this example should not be construed as limiting
10 the invention in any way.

Example 1

An endless sheet of aluminium foil, which optionally on one face is laminated with a thin polymer layer, of e.g. polyethylene or polyethylene terephthalate, is rolled off from a storage roll and passes an applicator which on the other side of the aluminium foil or
15 aluminium foil laminate applies a continuous layer of PEN, PTN or an LCP, by means of an extrusion coating device. The thickness of the aluminium foil is within the range of 5 – 50 µm, preferably within the range of 8 – 20 µm. The amount of applied polymer may vary, but the thickness thereof is preferably such that a well integrated and substantially intact layer is formed after drying. A suitable thickness range of PEN, PTN or an LCP is
20 1 – 100 µm, preferably 8 – 50 µm.

Subsequently patch pouches are manufactured by dividing the laminate into two sheets forming an upper and a lower part of the patch pouch. Subsequently and by means of a vacuum device a nicotine-containing patch is placed on one of the sheets whereupon
25 the other sheet is placed on the patch. Finally the sheets are heat sealed together along their edges to form a pouch.

In Example 1 the nicotine impermeable materials are used to make a package which totally encloses a nicotine-containing product. The present materials are also useful for partially enclosing and/or for sealing a package for a nicotine-containing product.
30 PEN, PTN and LCP, may also be used for all other applications where presently Barex® is used. One such application is the sealing of polymer tubes, containing polymer plugs with nicotine, for the nicotine inhaling device presently marketed by Pharmacia & Up-

john and in essence being disclosed in US 5,501,236. Also said polymer tubes may be made of the materials according to the present invention. Such tubes may e.g. be made by injection molding. The materials may also be used in blisters for nicotine chewing gums or tablets and for sealing glass flasks containing nicotine nasal spray.

5 The materials are also suitable for packages wherein dosage forms such as tablets, lozenges or similar are cast directly into the package. Thereby the package is to the extent necessary formed as mould(s) into which is cast the substance to be formed into tablets, lozenges or similar, said material achieving its final shape and form upon solidification in the package. In each such package may e.g. be cast one or more tablets, lozenges etc. After casting the package may be folded or likewise to provide for a nicotine-impermeable package for the cast tablets, lozenges etc. If necessary the package material
10 may be provided with some added material or thin sheet accounting for that the substance which is cast will not stick to the package material.

CLAIMS

1. A material for packaging a nicotine-containing product, characterized in that it comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.
2. A material for packaging a nicotine-containing product, characterized in that the material comprises a liquid crystal polymer, LCP.
3. A material according to claim 1, characterized in that the polymer is polyethylene naphthalate, PEN.
4. A material according to claim 1, characterized in that the polymer is polytrimethylene naphthalate, PTN.
5. A material according to claim 2, characterized in that the LCP comprises hydroxy benzoic acid and hydroxy naphthenic acid.
6. A material according to any one of the preceding claims, characterized in that it further comprises other polymer(s), preferably one or more of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
7. A material according to anyone of the preceding claims, characterized in that it is laminated with one or more metal and/or polymer foil(s).
8. A material according to claim 7, characterized in that it is laminated with aluminum foil.

9. A material according to anyone of the preceding claims, characterized in that it is used for totally enclosing, partially enclosing and/or for sealing a package for a nicotine containing product.

5 10. A material according to anyone of the preceding claims, characterized in that it is used for a package that is provided with moulds or equivalent into which is cast a substance that upon solidification in the package receives its final form and shape.

10 11. A material according to claim 10, characterized in that it is used for a package in which are directly cast tablets or lozenges.

15 12. A material according to anyone of the preceding claims, characterized in that it is used for packaging a patch for transdermally administering nicotine, a nicotine containing chewing gum, a nicotine containing tablet, a spray for nasal administration of nicotine, or a device for inhaling nicotine.

13. Use of a material according to anyone of the preceding claims for the manufacturing of a package for keeping nicotine-containing products.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/00017

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: B32B 27/06, B65D 75/26, C08G 63/189, C08G 63/60
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)

IPC7: B32B, C08G, B65D

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

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9109731 A1 (ALZA CORPORATION), 11 July 1991 (11.07.91) --	1-13
A	US 5225199 A1 (OSAFUMI HIDAKA ET AL), 6 July 1993 (06.07.93) --	1,3-4,6-13
A	EP 0656389 A1 (NKK CORPORATION), 7 June 1995 (07.06.95) --	1,3-4,6-13
A	US 5326848 A (TSUGUNORI KASHIMURA ET AL), 5 July 1994 (05.07.94) -- -----	2,5-13

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 May 2000

Date of mailing of the international search report

18-05-2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE00/00017**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see next page

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

- I. Claim 1, 3-4 and parts of 6-13 relates to a material for packaging a nicotine-containing product, which material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.
- II. Claim 2, 4 and parts of 6-13 relates to a material for packaging a nicotine-containing product, which material comprises a liquid crystal polymer, LCP.

The special technical feature of invention I is a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.

The special technical feature of invention II is a polymer based on a liquid crystal polymer.

The special technical feature of invention II is not the same as or corresponding to the special technical feature of invention I.

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.

PCT/SE 00/00017

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9109731 A1	11/07/91	AT 166029 T	15/05/98
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		AU 7167491 A	24/07/91
		CA 2032446 A	22/06/91
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		DE 69115445 D,T	20/06/96
		DK 484543 T	22/01/96
		EP 0484543 A,B	13/05/92
		SE 0484543 T3	
		ES 2081477 T	01/03/96
		JP 2505674 B	12/06/96
		KR 9505865 B	02/06/95
		WO 9116044 A	31/10/91
EP 0656389 A1	07/06/95	US 5858490 A	12/01/99
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		EP 0466085 A,B	15/01/92
		JP 5001139 A	08/01/93
		JP 5001140 A	08/01/93
		JP 5005028 A	14/01/93

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
28 April 2005 (28.04.2005)

PCT

(10) International Publication Number
WO 2005/037539 A1

(51) International Patent Classification: **B32B 15/08**,
27/32

(21) International Application Number:
PCT/US2004/034347

(22) International Filing Date: 15 October 2004 (15.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/512,545 17 October 2003 (17.10.2003) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, GR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
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TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:

--- with international search report

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

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ADHESION OF FOIL TO THERMOPLASTIC POLYMERS

(57) Abstract: Disclosed is a multilayer structure, which comprises or is produced from a foil laminated to thermoplastic composi-
tions using ethylene/butyl acrylate copolymer compositions as a tie layer. The multilayer structures can be useful as packaging films
and industrial films. Also disclosed is a lamination process for producing the structure. Further disclosed are packages comprising
the structures.

WO 2005/037539 A1

TITLE

ADHESION OF FOIL TO THERMOPLASTIC POLYMERS

FIELD OF THE INVENTION

This invention relates to adhesion of foil to thermoplastic
5 compositions comprising ethylene/butyl acrylate copolymer, to multilayer
structures comprising foil laminated to thermoplastic compositions, and to
packages comprising these multilayer structures.

BACKGROUND OF THE INVENTION

Aluminum foil (Al) is used extensively in the food packaging industry
10 as a moisture and gas barrier. Because of foil's poor flex crack resistance,
inability to form a hermetic seal, and cost, it is typically combined with
other materials such as paper, polyethylene (PE) and oriented
polypropylene (OPP) in multilayer structures. Applications include many
dry food packages such as powdered drink mix pouches as well as non-
15 packaging applications. Some common multi-layer structures include
Paper/LDPE/Al/LDPE and OPP/primer/LDPE/Al/LDPE in which LDPE is
low-density polyethylene and the paper or OPP provide stiffness and a
surface for printing. The primer allows LDPE to bond to the OPP
substrate; the first LDPE layer provides adhesion to the aluminum foil and
20 the second acts as a sealing layer.

These structures are typically made by extrusion coating or
lamination, which involves laying down a molten curtain of the polymer
between the substrates moving at high speeds as they come into contact
with a cold roll. Adhesion of polyethylene to foil can be accomplished by
25 processing at high coating temperatures (300 to 330°C) so that a portion
of the polyethylene oxidizes. Oxidization of the LDPE creates polar
species that provide moderate adhesion to the aluminum foil.

In many applications, rather than using a coated layer of LDPE as
the sealant, a LDPE or LLDPE (linear low-density polyethylene) film is
30 used. For example: Paper/LDPE/Al/LDPE/PE-film. The PE-film may be

LDPE or LLDPE, but is typically LLDPE-based. A PE film has a number of advantages over a LDPE coating: For example, the PE-film can be made thicker than a coating, allowing for caulking of the seal interface. LLDPE-films provide higher seal strength. Blown films have better strength and tear resistance. Blown films provide greater stiffness. Blown films, processed at much lower temperatures than extrusion coating, have less taste and odor problems (associated with the oxidation of the LDPE).

LDPE is the predominant resin currently used for extrusion lamination. However, a substantial problem with using LDPE to extrusion laminate PE-films to aluminum foil is that the adhesion of the LDPE to aluminum foil "ages down" with time. Adhesion of LDPE to aluminum foil is only marginal to begin with, but over a time period of one to several weeks, the bond strength often declines to a level that is no longer functional for the application. One explanation is that the aging may be associated with secondary crystallinity of the LDPE. During the lamination process, the LDPE is quenched very quickly and little primary crystallization can occur. Over time, small "secondary" crystals may form. As PE crystallizes, it shrinks. Shrinkage can put a stress on bonds and reduce peel strength. The LDPE-Al bond is the weakest of the bonds in the structure (bonds of the LDPE to the PE-film are typically inseparable), and so its peel strength is reduced.

In adhering foil to non-polar polymer compositions, use of an additional polymeric composition as an adhesive or "tie" layer can be beneficial. Often, more polar polymeric materials adhere to foil more readily than less polar materials. However, polar polymers that adhere well to foil may not adhere well to non-polar polymers. Therefore, a tie layer preferably provides a balance of properties that allow it to adhere both to foil and to non-polar polymers.

Chemical primers are sometimes used to promote adhesion to non-polar substrates, but this adds costs and causes environmental concerns with solvent-based systems. Thus, it is desirable to adhere foil to non-polar polymer compositions without the use of primers.

SUMMARY OF THE INVENTION

The invention comprises a composition that can comprise or be produced from a multilayer structure. The structure can comprise or be produced from at least one layer of foil; at least one layer of an
5 ethylene/butyl acrylate copolymer composition; at least one layer of a thermoplastic polyolefin composition; and optionally additional layer comprising paper, polyester, polyamide, ethylene vinyl alcohol, polyethylene vinyl acetate, ethylene/acrylic acid copolymer or an ionomer thereof, polyvinylidene chloride, anhydride-modified ethylene homo- and
10 co-polymer, or combinations of two or more thereof.

The invention also comprises a process that can enhance adhesion of foil to thermoplastic compositions. The process can comprise combining, such as extruding, an ethylene/butyl acrylate copolymer composition between a layer of foil and a layer of a thermoplastic
15 polyolefin composition.

The invention also comprises packages comprising the multilayer structure.

DETAILED DESCRIPTION OF THE INVENTION

Thermoplastic compositions are polymeric materials that can flow
20 when heated under pressure. Melt index (MI) is the mass rate of flow of a polymer through a specified capillary under controlled conditions of temperature and pressure. Melt indices reported herein are determined according to ASTM 1238 at 190 °C using a 2160 g weight, with values of MI reported in grams/10 minutes. The thermoplastic compositions
25 described herein are suitable for preparation of films and multilayer structures by extrusion processing.

The term "foil" as used herein refers to a thin, flexible film or sheet of metal, particularly aluminum. It also refers to multilayer structures in which at least one layer of aluminum is adhered to additional layers of
30 other materials, provided at least one face of the multilayer structure is a layer of aluminum.

The term "ethylene/butyl acrylate copolymers" includes copolymers of ethylene and butyl acrylates wherein the alkyl moiety contains four

carbon atoms. "Ethylene/butyl acrylate (abbreviated EBA)" means a copolymer of ethylene (abbreviated E) and butyl acrylate (abbreviated BA). Of note are ethylene/butyl acrylate copolymers prepared from *n*-butyl acrylate comonomers (EnBA). Of note are ethylene/butyl acrylate
5 copolymers prepared from *i*-butyl acrylate comonomers (EiBA). Preferred are EnBA copolymers.

The relative amount of the butyl acrylate comonomer incorporated into ethylene/butyl acrylate copolymer can, in principle, vary broadly from a few weight percent up to as high as 40 weight percent of the total
10 copolymer or even higher. The relative amount of the butyl acrylate group present in the ethylene/butyl acrylate copolymer can be viewed as establishing how and to what degree the resulting ethylene copolymer is to be viewed as a polar polymeric composition.

Preferably, the butyl acrylate comonomer has a concentration range
15 of from 5 to 30 weight %, alternatively from 7 to 27 weight %, of the ethylene/butyl acrylate copolymer, more preferably from 15 to 30 weight %, alternatively from 17 to 27 weight %.

Ethylene/butyl acrylate copolymers can be prepared by processes well known in the polymer art using either autoclave or tubular reactors.
20 The copolymerization can be run as a continuous process in an autoclave: ethylene, butyl acrylate, and optionally a solvent such as methanol (see US Patent 5,028,674) are fed continuously into a stirred autoclave of the type disclosed in US 2,897,183, together with an initiator. The rate of addition can depend on variables such as the polymerization temperature,
25 pressure, and concentration of the butyl acrylate monomer in the reaction mixture needed to achieve the target composition of the copolymer. In some cases, it may be desirable to use a telogen such as propane, to control the molecular weight. The reaction mixture is continuously removed from the autoclave. After the reaction mixture leaves the reaction
30 vessel, the copolymer is separated from the unreacted monomers and solvent (if solvent was used) by conventional means, e.g., vaporizing the nonpolymerized materials and solvent under reduced pressure and at an elevated temperature.

Tubular reactor produced ethylene/butyl acrylate copolymer can be distinguished from the more conventional autoclave produced ethylene/butyl acrylate as generally known in the art. Thus the term or phrase "tubular reactor produced" ethylene/butyl acrylate copolymer, for purposes of this invention, denotes an ethylene copolymer produced at high pressure and elevated temperature in a tubular reactor or the like, wherein the inherent consequences of dissimilar reaction kinetics for the respective ethylene and butyl acrylate comonomers is alleviated or partially compensated by the intentional introduction of the monomers along the reaction flow path within the tubular reactor. As generally recognized in the art, such a tubular reactor copolymerization technique can produce a copolymer having a greater relative degree of heterogeneity along the polymer backbone (a more blocky distribution of comonomers), tend to reduce the presence of long chain branching and will produce a copolymer characterized by a higher melting point than one produced at the same comonomer ratio in a high pressure stirred autoclave reactor. Tubular reactor produced ethylene/butyl acrylate copolymers are generally stiffer and more elastic than autoclave produced ethylene/butyl acrylate copolymers.

Tubular reactor produced ethylene/butyl acrylate copolymers of this nature are commercially available from E. I. du Pont de Nemours and Company (DuPont), Wilmington, Delaware.

The actual manufacturing of the tubular reactor ethylene/butyl acrylate copolymers as previously stated is preferably in a high pressure, tubular reactor at elevated temperature with additional introduction of reactant comonomer along the tube and not merely manufactured in a stirred high-temperature and high-pressure autoclave type reactor. However, similar ethylene/butyl acrylate copolymeric material can be produced in a series of autoclave reactors wherein comonomer replacement is achieved by multiple zone introduction of reactant comonomer as disclosed in US patents 3,350,372; 3,756,996; and 5,532,066, and as such these high melting point materials can be considered equivalent.

For additional general discussion regarding the differences between tubular reactor produced and autoclave produced ethylene/alkyl acrylate copolymers, see Richard T. Chou, Mimi Y. Keating and Lester J. Hughes, "High Flexibility EMA made from High Pressure Tubular Process", Annual
5 Technical Conference - Society of Plastics Engineers (2002), 60th(Vol. 2), 1832-1836. CODEN: ACPED4 ISSN:0272-5223; AN 2002:572809.

Ethylene/butyl acrylate copolymers suitable for use in this invention are available from DuPont. See Table A for specific examples of ethylene/butyl acrylate copolymers available from DuPont.

10

Table A

Copolymer	Butyl acrylate weight %	Melt Index (g/10min)
EBA-1	7	1.1
EBA-2	7	1.1
EBA-3	17	1.5
EBA-4	17	1.8
EBA-5	27	4.3
EBA-6	17	7.4

The ethylene/butyl acrylate copolymers available for use in the invention can vary in molecular weight, as shown by the range of melt index in Table A. The specific selection of the melt index (MI) grade of polymer component(s) can be influenced by balancing the processibility of
15 the EBA in extrusion lamination with the needs for adhesion between the foil and the thermoplastic composition. Preferred are ethylene/butyl acrylate copolymers having MI's from about 4 to about 12 g/10min. Of note are EBA-5 and EBA-6, having MI's of 4.3 and 7.4 g/10min, respectively.

20 The EBA compositions useful in this invention may optionally further comprise additives such as thermal and ultraviolet (UV) stabilizers, UV absorbers, antistatic agents, processing aids, fluorescent whitening agents, pigments, lubricants, etc. These conventional ingredients may be present in the compositions used in this invention in quantities that are
25 generally from 0.01 to 20 weight %, preferably from 0.1 to 15 weight %, so long as they do not detract from the adhesion functionality of the polymer.

The EBA compositions useful in this invention may optionally further comprise from about 1 to about 30 weight %, preferably from 5 to 25 weight %, more preferably 10 to 20 weight % of a polyolefin, such as polyethylene or polypropylene. The polyolefin may be added to the EBA compositions to improve compatibility with the polyolefin substrate.

The optional incorporation of such conventional ingredients into the compositions can be carried out by any known process. This incorporation can be carried out, for example, by dry blending, by extruding a mixture of the various constituents, by conventional masterbatch technique, or the like. The optional polyolefin may also be incorporated as part of a recycle process.

Polyolefins suitable for use in the present invention can be polypropylene or polyethylene polymers and copolymers comprising ethylene or propylene. Polyethylenes (PE) and polypropylene (PP) can be prepared by any means known to one skilled in the art including well-known Ziegler-Natta catalyst polymerization (e.g., US 4,076,698 and US 3,645,992), metallocene catalyst polymerization (e.g., US 5,198,401 and US 5,405,922), and by free radical polymerization. Because the means are well known to one skilled in the art, the description of which is omitted for the interest of brevity. PE polymers can include linear or branched polyethylenes such as high density polyethylene (HDPE), LLDPE, very low or ultra low density polyethylenes (VLDPE or ULDPE), and LDPE. The densities of polyethylenes suitable for use in the invention include all known PE and can range from 0.865 g/cc to 0.970 g/cc. Linear polyethylenes for use herein can incorporate alpha-olefin comonomers such as butene, hexene or octene to decrease their density within the density range so described. The term "polyethylene" when used herein is used generically to refer to any or all of the polymers comprising ethylene described above.

PP polymers can include homopolymers, random copolymers, block copolymers and terpolymers of propylene. Copolymers of propylene include copolymers of propylene with other olefins such as ethylene, 1-butene, 2-butene and the various pentene isomers, etc. and preferably

copolymers of propylene with ethylene. Terpolymers of propylene include copolymers of propylene with ethylene and one other olefin. Random copolymers, also known as statistical copolymers, are polymers in which the propylene and the comonomer(s) are randomly distributed throughout the polymeric chain in ratios corresponding to the feed ratio of the propylene to the comonomer(s). Block copolymers are made up of chain segments consisting of propylene homopolymer and of chain segments consisting of, for example, random copolymer of propylene and ethylene. The term "polypropylene" when used herein is used generically to refer to any or all of the polymers comprising propylene described above.

Additional information relating to block copolymers and to their manufacture may be found particularly in chapters 4.4 and 4.7 of the work "Block Copolymers" edited by D. C. Allport and W. H. Janes, published by Applied Science Publishers Ltd in 1973.

The multilayer structure can be produced by a process including extrusion coating or lamination, involves laying down a molten curtain of the ethylene/butyl acrylate copolymer composition between the foil and polyolefin film substrates moving at high speeds (e.g., from about 100 to 1000 feet per minute and preferably from about 300 to 800 feet per minute) as they come into contact with a cold roll. The melt curtain can be formed by extruding the ethylene/butyl copolymer composition through a flat die. The temperature of the ethylene/butyl copolymer composition as it leaves the die is preferably about 300 to 340°C and most preferably about 310 to 330°C. The air gap between the die exit and cold roll is typically about 3 to 15 inches, preferably from about 5 to about 10 inches. Higher temperatures generally give higher adhesion values, subject to the limitations of the thermal stability of the polymer. Lower line speeds and higher air gaps also favor adhesion. Typically, the time in the air gap (TIAG) defined as the air gap divided by the line speed should be between about 50 and 100 ms for optimal adhesion in extrusion lamination. See V. Antonov and A. Soutar, 1991 TAPPI PLC Conference Proceedings, page 553. The laminate is cooled on a cold roll and hauled off at a line speed of

between about 100 and 1000 feet/minute, preferably between about 300 and 800 feet/minute.

Films useful in lamination processes can be made by virtually any method known to those skilled in this art. The film can be either a single
5 layer or multilayer polymeric film. As such, the film and film structures can be typically cast, extruded, co-extruded, laminated and the like, including orientation (either uniaxially or biaxially) by various methodologies (e.g., blown film, mechanical stretching or the like). Various additives can be present in the respective film layers including the presence of tie layers
10 and the like. The additives can be one or more antioxidants, thermal stabilizers, ultraviolet (UV) light stabilizers, pigments and dyes, fillers, delustrants, anti-slip agents, plasticizers, anti-block agents, other processing aids, and the like.

The film can be produced according to any known methods. For
15 example, a primary film can be produced by extruding the compositions using so-called "blown film" or "flat die" methods, which are well known to one skilled in the art. A blown film can be prepared by extruding the polymeric composition through an annular die and expanding the resulting tubular film with an air current to provide a blown film. Cast flat films can
20 be prepared by extruding the composition through a flat die. The film leaving the die is cooled by at least one roll containing internally circulating fluid (a chill roll) or by a water bath to provide a cast film.

A film can be further oriented beyond the immediate quenching or casting of the film. The process comprises the steps of extruding a
25 laminar flow of molten polymer, quenching the extrudate and orienting the quenched extrudate in at least one direction. "Quenched" describes an extrudate that has been substantially cooled below its melting point to obtain a solid film material.

The film can be unoriented, oriented in a uniaxial direction (e.g.
30 machine direction), or oriented in a biaxial direction (e.g. machine direction and transverse direction). The film is preferably biaxially oriented by drawing in two mutually perpendicular directions in the plane of the film for a satisfactory combination of mechanical and physical properties.

Orientation and stretching apparatus to uniaxially or biaxially stretch film are known in the art and may be adapted by those skilled in the art to produce films of the present invention. Examples of such apparatus and processes include, for example, those disclosed in US patents 3,278,663; 5 3,337,665; 3,456,044; 4,590,106; 4,760,116; 4,769,421; 4,797,235 and 4,886,634.

A blown film may be oriented using a double bubble extrusion process, where simultaneous biaxial orientation may be effected by extruding a primary tube which is subsequently quenched, reheated and 10 then expanded by internal gas pressure to induce transverse orientation, and drawn by differential speed nip or conveying rollers at a rate which will induce longitudinal orientation.

The processing to obtain an oriented blown film is known in the art as a double bubble technique, and can be carried out as disclosed in US 15 3,456,044. A primary tube can be melt extruded from an annular die. This extruded primary tube can be cooled quickly to minimize crystallization. It is then heated to its orientation temperature (for example, by means of a water bath). In the orientation zone of the film fabrication unit a secondary tube is formed by inflation, thereby the film is radially expanded in the 20 transverse direction and pulled or stretched in the machine direction at a temperature such that expansion occurs in both directions, preferably simultaneously; the expansion of the tubing being accompanied by a sharp, sudden reduction of thickness at the draw point. The tubular film is then again flattened through nip rolls. The film can be reinflated and 25 passed through an annealing step (thermofixation), during which step it is heated once more to adjust the shrink properties.

In one embodiment, the film is formed by an extrusion process that causes the polymer chains in the film to be generally aligned in the direction of extrusion. Linear polymers, after being highly oriented 30 uniaxially possess considerable strength in the orientation direction, but less strength in the transverse direction. This alignment can add strength to the film in the direction of extrusion.

The film used in this invention may be treated by means of corona discharge, ozone or other means standard in the industry, although treatment is not required for good adhesion to the EBA adhesive layer. The film is laminated to a substrate such as foil using an EBA composition as an adhesive layer to provide a multilayer structure of this invention. The adhesion of the multilayer structure is typically improved by increasing the thickness of the EBA layer. The thickness of the EBA layer is preferably between about 10 and 40 microns and most preferably between about 15 and 30 microns thick.

- 10 A multilayer structure comprising (a) at least one layer of foil; (b) at least one layer of an ethylene/butyl acrylate copolymer composition; (c) at least one layer of a thermoplastic polyolefin composition; and optionally (d) a material selected from the group consisting of paper, polyesters such as polyethylene terephthalate, polyamides, polyethylene vinyl alcohol, polyethylene vinyl acetate, ethylene/acrylic acid copolymers and ionomers thereof, polyvinylidene chloride and anhydride-modified ethylene homo- and co-polymers.

- 20 The multilayer structures can be prepared as described above in which a foil-containing substrate (prepared for example, by lamination or extrusion coating) is adhered to a film comprising a polyolefin using an EBA copolymer composition as an adhesive layer. The foil-containing substrate, the film comprising the polyolefin (or both) may be a multilayer structure.

- 25 Of note is a multilayer structure comprising a layer comprising oriented polyester (particularly polyethylene terephthalate), a layer comprising ethylene/acrylic acid copolymer, a layer comprising foil, a layer comprising an ethylene/butyl acrylate copolymer composition, and a layer comprising polyethylene. Also of note is a multilayer structure comprising: a layer comprising foil, a layer comprising an ethylene/butyl acrylate copolymer composition, and a layer comprising polypropylene.

The multilayer structures as disclosed herein are useful in packaging applications or as packaging materials. They may also be used

as industrial films (for example, as a structural component in insulation sheeting).

The packaging materials may also be processed further by, for example but not limitation, printing, embossing, and/or coloring to provide
5 a packaging material to provide information to the consumer about the product therein and/or to provide a pleasing appearance of the package.

The packaging materials may be formed into packages, such as pouches, by standard methods well known in the art. Accordingly, this invention provides packages comprising multilayer structures as described
10 above.

The following Examples are merely illustrative, and are not to be construed as limiting the scope of the invention described and/or claimed herein.

EXAMPLES

15 General procedures used to prepare the laminates

The laminates were prepared using an extrusion laminating process. Substrate A was combined with substrate C using an adhesive layer B.

Substrate A

20 In Examples 1 through 8, substrate A was a laminate of oriented polyester (OPET) and aluminum foil: 13-microns OPET /19-microns ethylene/acrylic acid (E/AA) copolymer with 7 weight % AA/9-microns aluminum foil. The OPET was Melinex® 7100 supplied by DuPont Teijin Films. The (E/AA) copolymer was Nucrel® 30707, an ethylene acrylic acid
25 copolymer with 7% AA manufactured by DuPont. Substrate A was prepared by extruding the E/AA copolymer using a 4.5-inch diameter, 126-inch long, single screw extruder (with an exit temperature of 321 °C) through an ER-WE-PA feedblock with a 40-inch wide (internally deckled to 29 inches) Cloeren edge bead reduction die having a 30-mil gap operated
30 at 321 °C and backpressure 500 psig to form a 19-micron-thick layer laid down between the foil and OPET layers. The die plug and blade settings were 2.25 and 1.5 inches, respectively. The air gap between the die exit

and the nip (where the extrudate contacts the foil and OPET film) was 8 inches. The assembly was then passed over a chill roll that was operated at 10°C. The line speed was 500 feet per minute.

Adhesive Layer B

- 5 The resins used for the lamination adhesive layer B in the Examples described below are listed in Table 1, wherein MA stands for methyl acrylate, EA stands for ethyl acrylate, BA stands for butyl acrylate and AA stands for acrylic acid. Resins e and f were EBA resins that were used in lamination processes in accordance with this invention to prepare
- 10 multilayer structures of this invention. Resin a was a polyethylene composition that can be blended with an EBA resin to form an EBA/PE composition used in accordance with this invention (or used as an adhesive composition in Comparative Examples). The other resins listed in Table 1 were used for preparation of Comparative Examples.

15

Table 1

Resin	MI (g/10min)	Co- monomer	Wt. %	Mole %	Autoclave (A) or Tubular (T)	Comment
a	7	None	0	0	A	0.918 g/cc, LDPE
b	9	MA	13	4.6	T	
c	6	MA	9	3.1	T	
d	6	EA	13	4.7	T	
e	7	BA	17	4.3	T	EBA-5
f	4	BA	27	7.4	T	EBA-6
g	6	MA	20	8.3	A	
h	7	AA	7	2.8	A	
i	11	AA	3	1.2	A	

Substrate C

- Substrate C was a 50 μ thick polyethylene blown film made of 80% of a butene LLDPE (Sclair 11E1 manufactured by Nova) and 20% high
- 20 pressure LDPE (Novapol LF-0219A manufactured by Nova). The film was prepared on a Walex blown film line with an 8-inch diameter Victor die. The take-off speed was 38 feet per minute, the frost line height was 26 inches, the blow-up ratio was 2.7 and the layflat was 34 inches. Die gap was 15 thousandths of an inch. Processing temperature was 210 °C.

The laminate A/B/C was prepared by extruding the adhesive polymer using a 4.5-inch diameter, 126-inch long, single-screw extruder. The extrudate from the extruder flowed through an ER-WE-PA feedblock with a 40-inch wide (internally deckled to 29 inches) Cloeren edge bead reduction die having a 30-mil gap, blade set at 1.5 inches and plug set at 2.25 inches. The adhesive layer B was laid down between substrates A and C such that it contacted the foil layer of Substrate A.

Tests Employed in Examples

Peel Strength: One-inch wide strips were cut in the machine direction from near the center of the laminate. The layers were separated at the A – B interface unless otherwise noted and pulled in a tensile tester at room temperature in a “T-peel” configuration at a separation speed of 12 inches/min. The average force required to separate the layers divided by the width was reported as the peel strength. Five separate determinations were averaged together for a given mean value (values in tables were rounded to the nearest 10, with values ending in 5 rounded up). Also reported was the standard deviation (Std). See ASTM F904. Green peel strength was measured within four hours of producing the structure. Peel strength on the same sample was typically measured again after being stored in a 50% relative humidity, 23 °C controlled environment for one, four and six weeks.

The mode of failure reported in Tables 2 through 5 was characterized by the following descriptors:

- P = peels cleanly away from the substrate,
- LS = B/C film layers split,
- E = elongation of the peel arm as it was pulled away from the substrate,
- D = C layer peels from the B layer while B stays with layer A, and
- FT = foil tear.

Examples 1, C1 to C3

The laminate A/B/C was prepared using an extruder exit temperature of 321°C, air gap of 8 inches, line speed of 500 feet/minute, chill roll temperature of 10°C, lead-in of -0.6 inches, and nip pressure of 60 psig. The nip to chill roll contact across the 740 mm width was from about

13 to about 15 mm. The thickness of layer B was from about 0.6 to about 0.8 mils.

Table 2

Ex.	Layer B	Green			Peel Strength to Foil, g/in								
					1 week			4 weeks			6 weeks		
		Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode
1	f	1240	120	E/P	1390	50	E/P	1470	40	E/P	1530	20	E/P
C1	a	310	20	P	220	10	P	240	10	P	240	10	P
C2	h	720	120	P	660	200	P	750	230	P	590	110	P
C3	i	1070	360	LS, P, D	630	220	P, P/D	1060	340	P, EP, PD	910	520	P, E/LS, P, E/P

5

Examples 2 to 4, C4 to C9

The laminate A/B/C was prepared using an extruder exit temperature of 321 °C, air gap of 8 inches, line speed of 500 feet/minute, chill roll temperature of 10 °C, lead-in of -0.5 inches, and nip pressure of 60 psig. The nip to chill roll contact across the 740mm width was from about 13 to about 15 mm. The thickness of layer B was from about 0.6 to about 0.8 mils.

Table 3

Ex	Layer B	Green			Peel Strength to Foil, g/in								
					1 week			4 weeks			6 weeks		
		Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode
2	f	1120	120	P, P/LS	1260	140	E/P	1460	130	E/P	1410	40	P/D, LS
3	e	1140	160	P, P/LS	1250	190	E/P, E/P/D	1300	230	P, E/P, P/D	1350	40	LS, E/P/D
4	80% f, 20% a	1190	160	P	1180	160	P	1330	160	P, E/P	1460	40	LS
C4	a	260	10	P	230	10	P	230	10	P	230	10	P
C5	h*	740	160	P/LS	370	10	P	310	60	+	130	10	+
C6	g	640	30	P	590	30	P	610	10	P	710	160	E/P
C7	b	760	90	P, D, LS	730	120	P/D, LS	830	140	P/D, LS	1160	220	D, E/P
C8	c	530	50	P	510	40	P	510	40	P	690	200	P
C9	d	930	130	E/P, LS	1020	200	P/D, LS	1240	350	P, D, LS	1030	150	P, LS

* 282 °C exit extruder and die.

+ PE from tie

15

Examples 5 to 8: Effect of extrusion temperature.

The laminate A/B/C was prepared using resin f for layer B, air gap of 8-inches, line speed of 500 feet/minute, chill roll temperature of 10°C, lead-in of -0.5 inches, and nip pressure of 60 psig. The nip to chill roll contact across the 740mm width was from about 13 to about 15 mm. The

thickness of layer B was from about 0.6 to about 0.8 mils. The extrusion temperature was varied from about 545 to about 326 °C.

Table 4

Ex.	Extrusion Temperature, °C	Peel Strength to Foil, g/in											
		Green			1 week			4 weeks			8 weeks		
		Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode	Mean	Std	Mode
5	285	800	170	P, LS	710	160	P, LS	510	210	P, LS	510	120	P
6	303	790	20	P	810	50	P	720	40	P	770	70	P
7	314	1120	150	P	1020	100	E/P, P	1180	210	P, E/P	1290	100	P, E/P
8	326	1170	180	P	1210	200	E/P, P	1560	310	.	1600	310	E/P

* E/P, LS, E/P/D

5

Examples 9 and 10: Laminations of aluminum foil and BOPP.

In Examples 9 and 10, substrate A was 30-micron thick aluminum foil, adhesive polymer layer B was resin f and substrate C was a biaxially oriented polypropylene (BOPP, grade 17MB400 manufactured by ExxonMobil). Resin f was extruded in a 3.5-inch diameter extruder with a melt temperature of 330°C. It was fed through an Egan feed-block and T-slot die with external deckles. The die gap was 0.7 mm and the die width 720 mm. Chill roll temperature was 12°C, air gap 150 mm, line speed 100 meters/minute. The specific force applied in the nip was 5.4 N/m. The Corona treatment was set at a power of 4.5 kW.

15

Table 5

Ex.	Substrate A	Layer B Resin	Substrate C	Green PS, g/in To Foil	Green PS, g/in To BOPP
9	Al foil	f	Corona-BOPP	510-760	510-760
10	Al foil	f	BOPP	760	760

Inspection of the peel strength data in Tables 1 through 5 showed that use of ethylene/butyl acrylate copolymers as adhesive layers in lamination of foil to polyolefins provided significantly better adhesion and that this adhesion was maintained over time.

20

Example 11

Substrate A was the same OPET/Nucrel/foil laminate disclosed in examples 1-8. Adhesive layer B was "f" from Table 1. Substrate C was 0.7-mil OPP film from Toray Plastics (grade Y117), Japan. Laminate A/B/C was prepared as disclosed for Examples 1-8. Specific processing

25

conditions were 324°C coating temperature, 400 feet/minute line speed, 6-inch air gap, 10 °C chill roll temperature, 60 psig nip pressure, and -0.5-inch lead-in.

Peel strength measurements were attempted green at 1 week and 4 weeks. The peel to the foil or to the OPP could not be started indicating that the adhesive strength exceeded the tear strength of the OPP.

Examples 12 and 13

Substrate A was 2-mil aluminum foil. Substrate B was "I" from Table 1. Substrate C was a 0.6-mil OPP film from Applied Extrusion Technologies (grade B602) that was corona treated on one side and untreated on the other. Laminate A/B/C was prepared as described for Examples 1-8. Specific processing conditions were 321°C coating temperature, 500 feet/minute line speed, 8-inch air gap, 10 °C chill roll temperature, 60 psig nip pressure, and -0.5-inch lead-in. The results are shown in Table 6 where the secondary substrate in Example 12 was treated OPP and for Example 13 was untreated OPP.

Table 6- Peel Strength to Foil, g/in

Example	Green			1 week			4 weeks		
	Mean	Standard	Mode	Mean	Standard	Mode	Mean	Standard	Mode
12	1210	100	p	1500	120	Peel	1610	120	P/D/T
13	1120	95	L, S, P	1430	90	P, P/T	1530	225	P/D/T

Attempt to measure the peel strength between Layer B and Layer C (tie layer and OPP) failed to get the peel started. It indicates that the adhesive strength exceeded the tear strength of the OPP.

What is claimed is:

1. A multilayer structure comprising or produced from at least one layer of foil, preferably aluminum foil; at least one layer of an ethylene/butyl acrylate copolymer composition, which preferably
5 comprises from 1 to 30 weight % of a polyolefin; at least one layer of a thermoplastic polyolefin, which is preferably polyethylene, polypropylene, or both; and optionally at least one additional layer comprising or produced from paper, polyester, polyamide, ethylene vinyl alcohol, polyethylene vinyl acetate, ethylene/acrylic acid copolymer or an ionomer thereof,
10 polyvinylidene chloride, anhydride-modified ethylene polymer, or combinations of two or more thereof.
2. The multilayer structure of claim 1 further comprising at least one additional layer.
3. The multilayer structure of claim 1 or 2 wherein the ethylene/butyl
15 acrylate copolymer is produced in a tubular reactor.
4. The multilayer structure of 1, 2, or 3 wherein the foil is the aluminum foil.
5. A package comprising or produced from a multilayer structure as recited in claim 1, 2, 3, or 4.
- 20 6. The package of claim 5 that is formed into a pouch.
7. A process comprising combining or extruding an ethylene/butyl acrylate copolymer composition between a layer of foil and a layer of a thermoplastic polyolefin composition whereby a multilayer structure as recited in claim 1, 2, 3, or 4 is produced.

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US2004/034347

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 B32B15/08 B32B27/32

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)

IPC 7 B32B

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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 98/21286 A (H.B. FULLER LICENSING & FINANCING, INC) 22 May 1998 (1998-05-22) page 9, line 16 - line 24; claims 1, 2, 9	1, 2, 5, 6
X	US 3 924 051 A (WIGGINS ET AL) 2 December 1975 (1975-12-02) column 3, line 60 - line 64; claims column 6, line 31 - line 33 examples VI, VII	1, 2, 4, 5

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex

* Special categories of cited documents:

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

11 February 2005

Date of mailing of the international search report

14/03/2005

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/034347

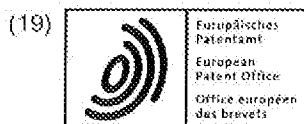
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(11) **EP 2 939 667 A1**

(12) **EUROPEAN PATENT APPLICATION**
published in accordance with Art. 153(4) EPC

(43) Date of publication:
04.11.2015 Bulletin 2015/45

(21) Application number: **13867096.3**

(22) Date of filing: **26.12.2013**

(51) Int Cl.:
A61K 9/70 (2006.01) **A61J 1/00** (2006.01)
A61K 31/27 (2006.01) **A61K 31/465** (2006.01)
A61K 47/32 (2006.01) **A61M 37/00** (2006.01)
A61P 25/28 (2006.01) **A61P 25/34** (2006.01)

(86) International application number:
PCT/JP2013/084950

(87) International publication number:
WO 2014/104220 (03.07.2014 Gazette 2014/27)

(84) Designated Contracting States:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO
PL PT RO RS SE SI SK SM TR**
Designated Extension States:
BA ME

(30) Priority: **28.12.2012 JP 2012288950**
19.08.2013 JP 2013169987

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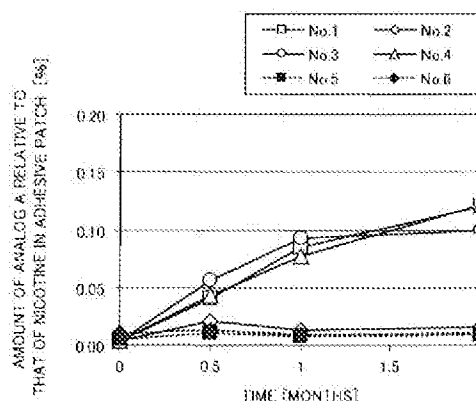
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(54) **PACKAGING**

(57) The objective of the present invention is to provide a method of preventing an oxygen-caused alteration of a drug in an adhesive patch enclosed inside a packaging container. The present invention is a package body comprising a packaging container and a drug-containing adhesive patch enclosed inside the packaging container, wherein the amount of oxygen gas inside the package body is 20 μ L or less, and the concentration of oxygen gas is 17.0 to 25.0 vol%. This packaging does not have to contain an oxygen scavenger as a separate member distinct from the drug-containing adhesive patch. Further, the amount of oxygen gas may be 4 μ L/mg or less per amount of a drug in the drug-containing adhesive patch.

FIG. 1A



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