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(54) Benævnelse: **BIOLOGISK NEDBRYDELIG LUGTBARRIEREFILM**

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WO-A1-2013/106361
JP-A- 2008 221 809
US-A- 5 009 648
US-A- 5 853 639
US-A1- 2009 151 058
US-A1- 2009 179 069
US-A1- 2009 191 780
US-A1- 2009 246 496
US-A1- 2010 032 084
US-A1- 2011 027 590
US-A1- 2011 108 185
US-B1- 6 245 437
US-B1- 8 399 077

DESCRIPTION

BACKGROUND

[0001] The present disclosure relates to odor barrier films, and more particularly to biodegradable odor barrier films for medical uses such as ostomy, continence, and bowel management applications.

[0002] Gas and odor barrier films are known and widely used in the medical field. Many such films have a barrier layer that contains chlorine; other barrier layers are chlorine-free. Chlorine-containing barrier layers use, for example, copolymers of viaylidene chloride vinyl chloride (VDC-VC) copolymers) and vinylidene chloride methyl acrylate copolymer (VDC-MA copolymers). These chlorine-containing films have exceptionally high malodour-causing compound barrier properties and are typically not adversely affected by the presence of moisture. One drawback to the use of chlorine-containing compounds is that these compounds, generally, present environmental issues in disposal, for example, incineration of materials ate use. Another drawback is that specialized equipment is required to process these materials due to the corrosive nature of the chlorine compounds.

[0003] Thus, barrier films including a barrier layer formed of chlorine-free vinyl alcohol based polymers, such as ethylene vinyl alcohol (EVOH) copolymers and polyvinyl alcohol) (PVOH) were developed. However, ostomy products and other applications relating to storing and transporting bodily waste are highly demanding and typically subject materials used in such products to high levels of moisture. Further, it is extremely important that the odor barrier properties of the material are, and remain high throughout their useful life. Unfortunately, these barrier films including barrier layers formed of vinyl alcohol based polymers have been found to have reduced barrier performance in the presence of humidity.

[0004] Farther, mere are multilayer barrier films including a barrier layer comprising a polyamide. For example, Giori, U.S. Patent No. 7,270,860, which is assigned to the Applicant of the present application, discloses a five layer film including an odor barrier layer formed from a blend of amorphous polyamide and anhydride-modified olefin polymer. WO2011/056861, which is also assigned to the Applicant of the present application, also discloses a multilayer film including an odor barrier layer comprising amorphous polymaide. Such multilayer films are chlorine free, and provide improved moisture and odor barrier characteristics, tear strength, comfort and "quietness" when compared to other chlorine free films. However, although they are more environment friendly than the chlorine containing films, these barrier films are not biodegradable.

[0005] Efforts have been made to develop biodegradable ostomy, continence, and bowel management appliances. However, biodegradable films have been insufficient for providing odor barrier properties in these applications. Thus, partially biodegradable appliances, such as

flushable ostomy pouch products including an inner pouch formed from a biodegradable film and an outer pouch formed of a conventional non-biodegradable odor barrier film, have been developed. For example, a "pouch-in-pouch" ostomy appliance includes an inner pouch made from a biodegradable film, which can be flushed in a toilet, and an outer pouch made from a conventional non-biodegradable barrier film, which provides odor barrier properties. However, such partially biodegradable appliances are more complicated to manufacture, thus, more expensive, and typically require additional steps in use, which make them less desirable to users.

[0006] Accordingly, there is a need for an odor barrier film that is biodegradable and has sufficient odor barrier and physical properties for me in ostomy, continence, and bowl management products.

[0007] US2011027590 (A1) discloses a production process of a sequentially biaxially-oriented polyglycolic acid film, which includes Step 1 of stretching an amorphous polyglycolic acid sheet in one direction at a stretching temperature within a range of from 40 to 70 DEG C. and a primary draw ratio of 2.5 to 7.0 times, thereby forming a uniaxially oriented film; Step 2 of causing the uniaxially oriented film to pass through within a temperature environment controlled to a temperature within a range of from 5 to 40 DEG C. and lower by at least 5 DEG C. than the stretching temperature in Step 1; Step 3 of stretching the uniaxially oriented film in a direction perpendicular to the stretching direction in Step 1 at a stretching temperature within a range of from 35 to 60 DEG C. and higher by at least 3 DEG C. than the temperature in Step 2, thereby forming a biaxially oriented film, the area stretch ratio of which is 11 to 30 times; and Step 4 of subjecting the biaxially oriented film to a heat treatment at 70 to 200 DEG C.

[0008] US6245437 (B1) discloses a composite gas barrier film having a layer structure comprises a thermoplastic resin film laminated on at least one side of a film formed from polyglycolic acid containing at least 60 wt. % of a repeating unit represented by the following formula (1):wherein the polyglycolic acid film is a film formed from polyglycolic acid having a melt viscosity, eta* of 500 to 100,000 Pass as measured at a temperature of the melting point of the polymer +20° C. and a shear rate of 100/sec, a melting point Tm of at least 150° C., and a melt enthalpy, DELTAHm of at least 20 J/g. An adhesive layer is provided between the polyglycolic acid film and the thermoplastic resin film. The film has excellent oxygen gas barrier property and/or carbon dioxide gas barrier property.

[0009] JP2008221809 (A) discloses a heat-sealable film having barrier functionality is made of a multilayer laminated resin film having at least three layers which is produced by coextruding a biodegradable resin layer made of a resin composition containing a biodegradable resin as a main component, a barrier resin layer, and a biodegradable resin layer made of a resin composition containing a biodegradable resin as the main component in turn. The biodegradable resin layers are made of resin compositions containing mixed resins prepared by kneading 51-99 pts.wt. of a polylactic acid resin and 1-49 pts.wt. of a softening modifier, respectively. The barrier resin layer is made of a barrier resin composition containing polyglycolic acid as the main component.

[0010] US5009648 (A) discloses biodegradable composite films comprising a starch containing blended polymeric film and a barrier material coated or laminated to the blended film. The use of such composite films in ostomy pouches and other medical products is described. Also described is an ostomy pouch construction in which an adhesive label is affixed to the pouch so as to reduce the escape of odor from the stomal aperture.

[0011] US2009151058 (A1) describes a chemical protective enclosure comprising a waterproof outer surface comprising an impermeable portion and an air diffusive portion, and further comprising a chemically adsorptive material substantially adjacent the air diffusive portion, wherein there is sufficient diffusion of breathable air into the chemical protective enclosure to sustain life.

[0012] US8399077 (B1) discloses a film is, and in particular, a film having at least one gas barrier layer that comprises a noise-dampening polymer resin and of a polyglycolic acid resin. The polyglycolic-based films provide excellent gas barrier properties while maintaining a desirable level of softness and low noise making them ideal for a variety of medical applications.

[0013] US2009246496 (A1) relates to a film of biodegradable material plasticized with a plasticizer of low vapour pressure, the film comprising on one or both surfaces a coating of glass or metal. Hereby a dilemma is solved: Glass and metal can only be vapour-deposited on polymers that do not contain plasticizers, as the plasticizer evaporates during the vacuum process. By selecting plasticizers with a low vapour pressure, the problems due to evaporation are solved.

BRIEF SUMMARY

[0014] The present disclosure provides a biodegradable odor barrier film as defined in claim 1; a bowel management tube as defined in claim 5; and an ostomy pouch as defined in claim 6. Advantageous features are provided in dependent claims.

[0015] Biodegradable odor barrier films and biodegradable odor barrier tubes for ostomy, continence and bowel management applications are provided according to various embodiments. Such films and tubes include a barrier layer formed essentially from poly glycolic acid (PGA) to provide excellent mechanical and odor barrier properties along with biodegradability desired in ostomy, continence, and bowel management applications.

[0016] A biodegradable odor barrier film for ostomy, continence and bowel management applications is provided. The biodegradable odor barrier film includes a barrier layer comprising a biodegradable resin. The barrier layer has a biodegradability that meets the requirements of ASTM D6400, EN 13432 or 1SO14855. Further, the biodegradable odor barrier film has a dimethyl disulfide (DMDS) breakthrough time greater than about 200 minutes

when tested according to the modified Test Operations Procedure (TOP) 8-2-501 as provided in this disclosure.

[0017] The barrier layer comprises polyglycolic acid (PGA) in a concentration greater than about 90 percent by weight (% wt). The barrier layer is formed from a blend comprising about 90% wt. to about 99% wt. of PGA and a polymeric chain extender.

[0018] The barrier layer has a first side and a second side. The biodegradable odor barrier film includes a first outer layer disposed on the first side, and a second outer layer disposed on the second side, such that the barrier layer is sandwiched between the first and second outer layers. The first and second outer layers are also biodegradable, such that the biodegradable odor barrier film has a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855.

[0019] The first and second outer layers may include a biodegradable material selected from the group consisting of starch, starch blends, polyvinyl alcohol, ethylene-vinyl alcohol copolymer, cellulose derivatives, soy protein, polycaprolactone, polylactic acid, copolyester, polyhydroxyalkanoates, and polybutylene succinate. The first and second outer layers comprise at least 70%wt. of a copolyester based on terephthalic acid, adipic acid, and 1,4-butanediol. The first and second outer layers may also include an antiblock agent, a slip agent, and/or a blowing agent.

[0020] In some embodiments, the biodegradable odor barrier film further includes first and second tie layers disposed between the barrier layer, and the first and second outer layers, respectively, in which each tie layer contacts a respective side of the barrier layer. The tie layers may be formed from a maleated polyolefin or an epoxidized polyolefin.

[0021] In another embodiment, a thickness of the barrier layer may make up about 3% to about 20% of a total thickness of the biodegradable odor barrier film. For example, a total thickness of the film may be between about 10µm and about 1.000µm, in which a thickness of the barrier layer may be between about 0.5µm and about 50µm.

[0022] A bowel management tube may be formed using any of the biodegradable odor barrier films discussed above, in which the biodegradable odor barrier film has a total thickness between about 500 µm and 1,000µm, and the barrier layer has a thickness between about 2 µm and about 50 µm.

[0023] In another aspect, an ostomy pouch according to claims 6 or 7 comprising a biodegradable odor barrier film according to claims 1-4 is provided. The ostomy pouch includes a first side wall and a second side wall The first and second side walls are formed from a biodegradable odor barrier film having a biodegradability mat meets the requirements of ASTM D6400, EN13432 or ISO14855, and a dimethyl disulfide (DMDS) breakthrough time greater than about 200 minutes, or greater than 1440 minutes, when tested according to the modified TOP 8-2-50. The ostomy pouch also includes a stoma-receiving opening on the first

side wail.

[0024] The ostomy pouch according to any of the embodiments discussed above may include at least one nonwoven layer attached on one or both of the first and second side walls. The nonwoven layer may also be formed from a biodegradable material.

[0025] Other aspects, objectives and advantages will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The benefits and advantages of the present embodiments will become more readily apparent to those of ordinary skill in the relevant art after reviewing the following detailed description and accompanying drawings, wherein:

FIG. 1 is a cross-sectional illustration of a three-layer biodegradable film in accordance with an embodiment of the present disclosure:

FIG. 2 is a cross-sectional illustration of a five-layer biodegradable film in accordance with another embodiment;

FIG. 3 is a cross-sectional illustration of an exemplary ostomy pouch including a biodegradable film; and

FIG. 4 is an illustration of an exemplary bowel management tube made from a biodegradable material.

DETAILED DESCRIPTION

[0027] While the present disclosure is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment with the understanding that the present disclosure is to be considered an exemplification and is not intended to limit the disclosure to the specific embodiment illustrated.

[0028] Referring now to the figures and in particular to FIG. 1, there is shown a biodegradable multilayer film 10 according to an embodiment The film 10 may be a three-layer film including a barrier layer 12 comprising a biodegradable resin that can be composted to carbon dioxide, water and biomass under aerobic conditions in municipal and industrial aerobic composting facilities, being polyglycolic acid (PGA). The film 10 also includes first and second outer layers 14, 16, in which the barrier layer 12 may be sandwiched between the outer layers 14, 16.

[0029] The barrier layer 12 may be the thinnest layer of the film 10 making up less than about 20% of the total thickness, for example, between about 3% and 15% of the total thickness. The barrier layer 12 has biodegradability that satisfies the test protocols of ASTM D6400, EN 13432, or ISO14855. The barrier layer 12 is also substantially impermeable to malodor causing compounds typically encountered in ostomy pouches. Such malodor causing compounds can include sulfur containing compounds and indoles. Examples of sulfur-containing compounds include dimethyl disulfide, dimethyl trisulfide, diethyl disulfide, hydrogen sulfide and methyl mercaptan. Examples of indoles, and other malodor causing compounds include 3-methyl indole and methanethiol. Other compounds will be recognized by those skilled in the art. Further, the barrier layer imparts tear strength to the film.

[0030] Polyglycolic acid (PGA) resin is particularly suitable for the barrier layer. PGA has superior oxygen, carbon dioxide, and water vapor barrier properties. Further, the inventors of the present application have discovered that PGA also has excellent odor barrier properties, which are only minimally affected by moisture content, which makes the PGA particularly suitable for ostomy, continence and bowl management applications. The PGA resin can have similar biodegradability as cellulose, and can typically degrade into carbon dioxide and water in compost within about one month.

[0031] A first outer layer 14 may be disposed on one side of the barrier layer 12, and a second outer layer 16 may be disposed on the other side of the barrier layer 12. Each of the outer layers 14, 16 may be substantially biodegradable and may comprise one or more biodegradable material that is compatible with the PGA resin in the barrier layer 12. The materials for the outer layers 14, 16 are carefully selected to provide desired film characteristics for a particular application, for example, biodegradability, water solubility, and heat sealability. Suitable biodegradable materials for the outer layers 14, 16, which are compatible with PGA resin include, but are not limited to polycaprolactone (PCL), polylactic acid (PLA), copolyester, potyhydroxyalkanostes (PHAs), and polybutylene succinate (PBS).

[0032] For ostomy pouch applications, at least one of the outer layers may be formed of a biodegradable material having good sealing characteristics, for example, heat sealability, suitable for forming a pouch, while the other outer layer may be formed of a biodegradable material, which can provide comfort against a user's skin.

[0033] The barrier layer 12 is formed from a blend comprising at least 90% wt. PGA resin, for example about 99% wt. PGA resin. Each of the outer layers 14, 16 may be formed from a blend comprising a biodegradable polymeric material compatible with the PGA resin, for example, an aliphatic-aromatic copolyester resin, such as copolyester based on terephthalic acid, adipic acid, 1,4-butanediol and modular units. Such copolyester resins provide good flexibility and toughness, and are reasonably low cost, which make them suitable for ostomy, continence, and bowel management applications.

[0034] The blend for the outer layers 14, 16 may also include an antiblock agent, such as $CaCO_3$ and talc, and/or a slip agent, which can improve extrudability and reduce the risk of the

outer layers 14, 16 sticking to a chill roller. Further, the blend may also include a blowing agent. In one embodiment, the barrier layer 12 and outer layers 14, 16 are coextruded.

[0035] In other embodiments, the biodegradable multilayer film can include more than three layers.

[0036] FIG. 2 shows another embodiment of a biodegradable multilayer film 100. The film 100 may be a five-layer film including a barrier layer 102, tie layers 108, 110, and outer layers 104, 106. Similar to the biodegradable film 10 of FIG. 1, the barrier layer 102 is formed essentially from a biodegradable material PGA resin. The outer layers 104, 106 are also formed essentially from one or more biodegradable materials.

[0037] As shown in FIG. 2, on either side of the barrier layer 102 may be a tie layer 108, 110. Each of the tie layers 108, 110 may be formed from a material that is compatible with the PGA resin in the barrier layer 102. The tie layers 108, 110 facilitate adhesion of the barrier layer 102 to the remainder of the film structure. Outer layers 104, 106 are arranged adjacent to the tie layers 108, 110, respectively.

[0038] Suitable tie layer materials that are compatible with PGA resin include, but are not limited to, resins with maleic anhydride, such as maleated polyolefins (e.g. resins available under trade name Bynel® from DuPont), or resins including epoxy functionality, such as epoxidized polyolefins (e.g. resins available under trade name Lotader® from Arkema).

[0039] In other embodiments, a biodegradable multilayer film can have various layer structures to provide desired film characteristics for ostomy, continence, or bowel management applications. For example, a biodegradable film for ostomy pouch applications may include seven layers with ABCDCBA structure, in which A represents skin/seal layers, B represents inner layers, C represents tie layers, and D represents a barrier layer formed of PGA resin. Other examples include a six-layer film including a barrier layer, two tie layers, an inner layer, and two skin layers (i.e. ABCDCA), and a five-layer film including a barrier layer, two tie layers and two outer layers (i.e. ACDCA, BCDCB or ACDCB). The biodegradable multilayer films according to various embodiments include a barrier layer formed essentially of PGA resin, and other layers which are substantially biodegradable.

[0040] FIG. 3 is a cross-sectional illustration of a one-piece ostomy pouch 20 made using a biodegradable odor barrier film comprising PGA resin. The ostomy pouch 20 generally includes a pouch 22 and a skin barrier 24. The pouch 22 includes first and second opposing walls 26, 28, which are sealed around peripheral edges 30 thereof to define a cavity 32 for collecting body waste. Each of the walls 26, 28 is formed of a biodegradable odor barrier film comprising PGA resin, such as the three-layer film 10 of FIG. 1 or the five-layer film 100 of FIG. 2. The pouch 22 also includes a first nonwoven layer 34 attached to the first wall 26, and a second nonwoven layer 36 attached to the second wall 28. The nonwoven layers 34, 36 are attached to the respective walls 26, 28 via heat sealing or an adhesive. The nonwoven layers 34, 36 may be formed from one or more biodegradable materials, and thus, substantially

biodegradable. In other embodiments, the ostomy pouch 20 may not include a nonwoven layer or include only one nonwoven layer.

[0041] FIG. 4 is a bowel management tube 40 comprising a biodegradable odor barrier layer comprising PGA resin. The bowel management tube 40 can be made using a biodegradable odor barrier film according to various embodiments in the present disclosure. For example, the bowel management tube 40 can be made using the three-layer film 10 of FIG. 1, or the five-layer film 100 of FIG. 2. Further, the bowel management tube 40 may be coextruded as a multilayer tubing including an odor barrier layer comprising PGA resin, and inner and outer layers comprising a biodegradable material similar to the above described biodegradable film embodiments.

Sample Multilayer Biodegradable Films

[0042] Four different three-layer film samples including a barrier layer formed essentially from PGA resin were prepared. Each of the film samples includes a barrier layer and two outer layers as shown in FIG. 1.

[0043] Sample 303-2 had a total thickness of about 43µm. The barrier layer 12 had a thickness of about 4µm and comprised about 99% wt. of PGA (Kuredux® PGA B35 from Kureha) and about 1% wt. of an oligomeric chain extender based on multiple epoxy functional groups (Joncryl® ADR 4368 from BASF). Each of the outer layers 14, 16 had a thickness of about 19.5µm and was formed from a blend comprising biodegradable polymeric materials. The blend included about 78.5% wt. of Ecoflex® F Blend C1200 from BASF (copolyester based on terephthalic acid, adipic acid, and 1, 4-butanediol), about 20% wt. of Ecoflex® Batch AB1 from BASF (antiblock agent masterbatch including about 60% wt. of fine chalk and about 40% wt. of Ecoflex® F Blend C1200), and about 1.5% wt. of Ecoflex® Batch SL1 from BASF (slip agent masterbatch including about 10% wt. of erucamide and about 90% wt. of Ecoflex® F Blend C1200.)

[0044] Sample 303-3 had a total thickness of about 69µm. The barrier layer 12 had a thickness of about 4µm and comprised about 99% wt. of PGA (Kuredux® PGA B35 from Kureha) and about 1% wt. of an oligomeric chain extender based on multiple epoxy functional groups (Joncryl® ADR 4368 from BASF). Each of the outer layers 14, 16 had a thickness of about 32.5µm and was formed of the same blend used for the outer layers of Sample 303-2.

[0045] Sample 303-4 had a total thickness of about 56µm. The barrier layer 12 had a thickness of about 6µm and comprised about 99% wt. of PGA (Kuredux® PGA B35 from Kureha) and about 1% wt. of an oligomeric chain extender based on multiple epoxy functional groups (Joncryl® ADR 4368 from BASF). Each of the outer layers 14, 16 had a thickness of

about 25µm and was formed of the same blend used for the outer layers of Sample 303-2.

[0046] Sample 303-5 had a total thickness of about 58µm. The barrier layer 12 had a thickness of about 3µm and comprised about 99% wt. of PGA (Kuredux® PGA B35 from Kureha) and about 1% wt. of an oligomeric chain extender based on multiple epoxy functional groups (Joncryl® ADR 4368 from BASF). Each of the outer layers 14, 16 had a thickness of about 27.5µm and was formed of the same blend used for the outer layers of Sample 303-2. The sample films are summarized in Table 1

TABLE 1 - Sample Biodegradable Odor Barrier Films

Sample Number	Outer Layer	Barrier Layer	Outer layer
303-2 (43µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (19.5µm)	99% wt. Kuredux® PGA B35 + 1% wt. Joncryl® ADR 4368 (4µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (19.5µm)
303-3 (69µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (32.5 µm)	99% wt. Kuredux® PGA B35 + 1% wt. Joncryl® ADR 4368 (4µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (32.5 µm)
303-4 (56µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (25µm)	99% wt. Kuredux® PGA B35 + 1% wt. Joncryl® ADR 4368 (6µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (25µm)
303-5 (58µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (27.5µm)	99% wt. Kuredux® PGA B35 + 1% wt. Joncryl® ADR 4368 (3µm)	78.5% wt. Ecoflex® F Blend C1200 + 20% wt. Ecoflex® Batch AB1 + 1.5% wt. Ecoflex® Batch SL1 (27.5µm)

[0047] The film samples and a control film sample were tested for tensile properties in both the machine direction (MD) and the transverse direction (TD). The control film sample was prepared using a multilayer odor barrier film, which is commercially used in some ostomy pouches. The control film sample had a total thickness of about 76 µm, and included an odor barrier layer having a thickness of about 5 µm and comprising vinylidene chloride-methyl acrylate copolymer.

[0048] The samples were also tested for odor barrier properties. Following a modified version of Test Operations Procedure (TOP) 8-2-501 for Permeation and Penetration of Air-

Permeable, Semi-permeable, and Impermeable Materials with Chemical Agents or Simulants, a time for dimethyl disulfide (DMDS) to permeate through a film sample was measured. In this test, 15% wt. DMDS in isopropyl myristate solvent was used as a challenging gas with nitrogen carrier gas. The flow rate of the carrier gas across a sample film was 125 cc/min and the temperature in the test chamber was 38±2°C. A breakthrough time, which is a time for the DMDS challenging gas to permeate through a sample film and reach 1 part per million (ppm) concentration, was measured using gas chromatography (GC). The test results of the samples and control film are summarized in Table 2, below.

TABLE 2 - Tensile and Odor Barrier Test Results

	Sample 303-2	Sample 303-3	Sample 303-4	Sample 303-5	Control
Total Film Thickness (µm)	43	69	56	58	76
Barrier Layer Thickness (µm)	4	4	6	3	5
Machine Direction (MD) Tensile Properties					
Tensile Strength (psi)	3753	3726	4156	3655	2543
Elongation at Break (%)	476	481	518	504	568
Modulus (1,000 psi)	93.7	89.5	76.6	87.3	23.3
Transverse Direction (TD) Tensile Properties					
Tensile Strength (psi)	3230	2898	2946	2058	1705
Elongation at Break (%)	457	505	391	267	761
Modulus (1,000 psi)	110.5	102.4	110.0	68.7	24.8
Gas Chromatography (GC) Odor Testing (Modified TOP 8-2-501)					
Dimethyl Disulfide (DMDS) Breakthrough Time (minutes)	>1440	>1440	>1440	>1440	141

[0049] As shown in Table 2, the sample biodegradable films including a barrier layer comprising PGA provided significantly improved odor barrier properties when compared to the control film sample. Further, the sample biodegradable films also had better or comparable tensile properties as the control film sample. Thus, the sample biodegradable films can be used to make durable ostomy appliances having excellent odor barrier properties.

[0050] In the present disclosure, all percentages of constituents are by weight, unless otherwise indicated. In the present disclosure, the words "a" or "an" are to be taken to include both the singular and the plural. Conversely, any reference to plural items shall, where appropriate, include the singular. All of the concentrations noted herein as percentage are percent by weight unless otherwise noted.

REFERENCES CITED IN THE DESCRIPTION

Cited references

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Patent documents cited in the description

- US7270860B [0004]
- WO2011056861A [0004]
- US2011027590A1 [0007]
- US6245437B1 [0008]
- JP2008221809A [0009]
- US5009648A [0010]
- US2009151058A1 [0011]
- US8399077B1 [0012]
- US2009246496A1 [0013]

Patentkrav

1. Biologisk nedbrydelig lugtbarrierefilm (10) til stomi-, kontinens- og tarmstyringsanvendelser, hvilken lugtbarrierefilm omfatter:

et barrierelag (12), der er dannet ud fra en blanding, der omfatter 90 til 99 vægt-% PGA og en polymer kædeforlænger, hvor barrierelaget (12) har en første side og en anden side;

et første yderlag (14), der er anbragt på den første side, og et andet yderlag (16), der er anbragt på den anden side, således at barrierelaget (12) er indesluttet mellem det første og det andet yderlag (14, 16);

hvor det første og det andet yderlag (14, 16) omfatter mindst 70 vægt-% af en copolyester på basis af terephthalsyre, adipinsyre og 1,4-butandiol; og

hvor den biologisk nedbrydelige lugtbarrierefilm (10) har en biologisk nedbrydelighed, der opfylder kravene i ASTM D6400, EN13432 eller ISO14855, og en dimethyldisulfid (DMDS)-gennembrudstid på mere end 200 minutter ved test ifølge den modificerede afprøvningsfremgangsmåde ("Test Operations Procedure", TOP) 8-2-501 som defineret i beskrivelsen.

2. Film (10) ifølge krav 1, hvor det første og det andet yderlag (14, 16) yderligere omfatter et antiblokeringsmiddel, et glidemiddel og/eller et opblæsningsmiddel.

3. Film (10) ifølge et hvilket som helst af kravene 1 eller 2, hvor en tykkelse af barrierelaget (12) udgør 3 % til 20 % af en samlet tykkelse af filmen (10).

4. Film ifølge et hvilket som helst af kravene 1, 2 eller 3, hvor en samlet tykkelse af filmen (10) er mellem 10 µm og 1.000 µm, og en tykkelse af barrierelaget (12) er mellem 0,5 µm og 50 µm.

5. Tarmstyringsslange (40), der er dannet af filmen (10) ifølge et hvilket som helst af kravene 1-4, hvor filmen (10) har en samlet tykkelse på mellem 500 µm og 1.000 µm, og barrierelaget (12) har en tykkelse på mellem 2 µm og 50 µm.

6. Stomipose (20), der omfatter:

en første sidevæg og en anden sidevæg (26, 28), hvor den første og den anden sidevæg (26, 28) er dannet ud fra filmen (10) ifølge et hvilket som helst af kravene 1-4,

og hvor filmen (10) har en dimethyldisulfid (DMDS)-gennembrudstid på mere end 1440 minutter ved test ifølge den modificerede afprøvningsfremgangsmåde ("Test Operations Procedure", TOP) 8-2-501 som defineret i beskrivelsen; og en stomamodtagende åbning på den første sidevæg.

7. Stomipose (20) ifølge krav 6, der yderligere indbefatter mindst ét nonwoven-lag (34, 36), som er fastgjort på den ene eller begge af den første og den anden sidevæg (26, 28), hvor nonwoven-laget (34, 36) er dannet ud fra et biologisk nedbrydeligt materiale.

DRAWINGS

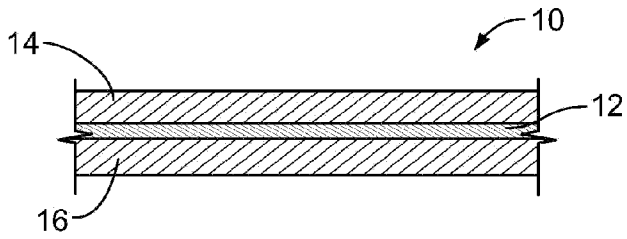

FIG. 1

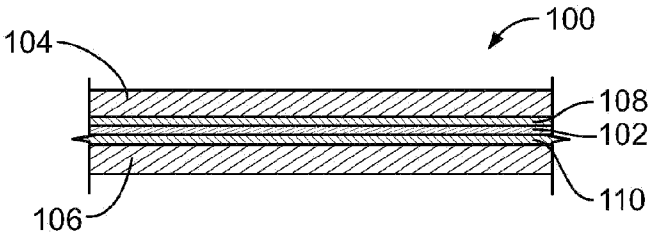

FIG. 2

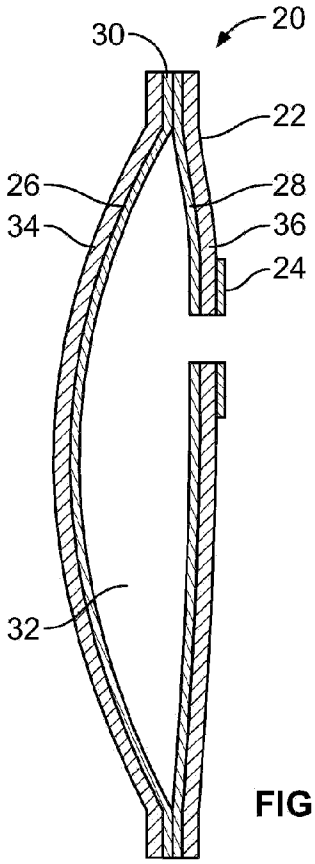

FIG. 3

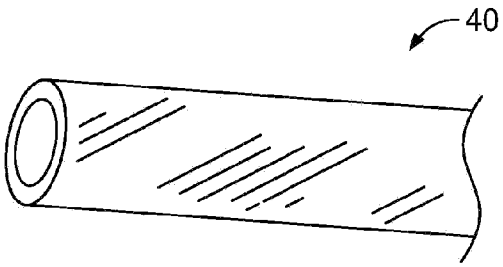

FIG. 4