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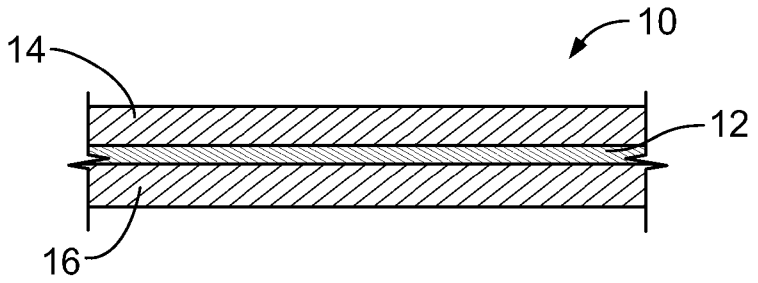

FIG. 1

(57) Abstract: A biodegradable odor barrier film for ostomy, continence and towel management applications includes a barrier layer comprising at least about 90% wt. polyglycoiic acid. The biodegradable odor barrier film provides excellent mechanical and odor barrier properties desired in ostomy, continence and bowel management applications.

BIODEGRADABLE ODOR BARRIER FILM

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 vinylidene chloride vinyl chloride (VDC-VC) copolymers) and vinylidene chloride methyl acrylate copolymer (VDC-MA copolymers). These chlorine-containing films have exceptionally high malodor-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 after 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 poly(vinyl 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] Further, there 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 and incorporated herein by reference, discloses a five layer film including an odor barrier layer formed from a blend of amorphous polyamide and anhydride-modified olefin polymer. WO 2011/056861, which is also assigned to the Applicant of the present application and incorporated herein by reference, also discloses a multilayer film including an odor

barrier layer comprising amorphous polyamide. 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 use in ostomy, continence, and bowl management products.

BRIEF SUMMARY

[0007] 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 polyglycolic acid (PGA) to provide excellent mechanical and odor barrier properties along with biodegradability desired in ostomy, continence, and bowel management applications.

[0008] In one aspect, 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, EN13432 or ISO14855. 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.

[0009] In one embodiment, the barrier layer comprises polyglycolic acid (PGA) in a concentration greater than about 90 percent by weight (% wt.). For example, the barrier layer may be formed from a blend comprising about 90% wt. to about 99% wt. of PGA and a polymeric chain extender. In another example, the barrier layer may be formed of about 100% wt. PGA.

[0010] The barrier layer has a first side and a second side. In some embodiments, the biodegradable odor barrier film may include a first outer layer disposed on the first side, and a second outer layer disposed on the second side, such that the barrier layer may be sandwiched between the first and second outer layers. The first and second outer layers may also be biodegradable, such that the biodegradable odor barrier film has a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855.

[0011] 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. For example, the first and second outer layers may 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.

[0012] 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.

[0013] 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.

[0014] 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 500μm and 1,000μm, and the barrier layer has a thickness between about 2μm and about 50μm.

[0015] In another aspect, an ostomy pouch comprising a biodegradable odor barrier film 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 that meets the requirements of ASTM D6400, EN13432 or ISO14855, and a dimethyl disulfide (DMDS) breakthrough time greater than about 200 minutes when tested according to the modified TOP 8-2-50. The ostomy pouch also includes a stoma-receiving opening on the first side wall.

[0016] In some embodiments, the first and second walls may be formed of a biodegradable odor barrier film, which includes a barrier layer comprising polyglycolic acid (PGA) in a concentration greater than about 90 percent by weight (% wt.) For example, the barrier layer may be formed from a blend comprising about 90% wt. to about 99% wt. of PGA and a polymeric chain extender. In another example, the barrier layer may be formed of about 100% wt. PGA

[0017] In some embodiments, the biodegradable odor barrier film may include a first outer layer and a second outer layer disposed on each side of the barrier layer, such that the barrier layer may be sandwiched between the first and second outer layers. The first and second outer layers may also be biodegradable, such that the biodegradable odor barrier film has a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855. In such embodiments, the first and second outer layers may include 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.

[0018] 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.

[0019] 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

[0020] 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:

[0021] FIG. 1 is a cross-sectional illustration of a three-layer biodegradable film in accordance with an embodiment of the present disclosure;

[0022] FIG. 2 is a cross-sectional illustration of a five-layer biodegradable film in accordance with another embodiment;

[0023] FIG. 3 is a cross-sectional illustration of an exemplary ostomy pouch including a biodegradable film; and

[0024] FIG. 4 is an illustration of an exemplary bowel management tube made from a biodegradable material.

DETAILED DESCRIPTION

[0025] 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.

[0026] 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, for example, polyglycolic acid (PGA). The film 10 also may include first and second outer layers 14, 16, in which the barrier layer 12 may be sandwiched between the outer layers 14, 16.

[0027] 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, EN13432, 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.

[0028] 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.

[0029] 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, polyhydroxyalkanoates (PHAs), and polybutylene succinate (PBS).

[0030] 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.

[0031] In one embodiment, 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.

[0032] 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.

[0033] In other embodiments, the biodegradable multilayer film can include more than three layers or less than three layers. For example, a two-layer film may include a barrier layer formed essentially of PGA resin and an outer layer formed of a biodegradable material compatible with the PGA resin. In some embodiments, a biodegradable film may be a single layer film comprising PGA resin.

[0034] 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 may be formed essentially from a biodegradable material, preferably PGA resin. The outer layers 104, 106 are also formed essentially from one or more biodegradable materials.

[0035] 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.

[0036] 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).

[0037] 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 a biodegradable material, such as PGA resin, and other layers which are substantially biodegradable.

[0038] 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 may be 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.

[0039] 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. In other embodiments, the bowel management tube 40 can be extruded as a single layer tube comprising PGA resin. 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

[0040] 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.

[0041] 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.)

[0042] 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.

[0043] 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.

[0044] 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	Outer Layer	Barrier Layer	Outer layer

Number			
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 (32.5µm)	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 (32.5µm)
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)

[0045] 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.

[0046] 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

[0047] 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.

[0048] 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.

[0049] From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the present invention. It is to be understood that no limitation with respect to the specific embodiments illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

CLAIMS

What is claimed is:

1. A biodegradable odor barrier film for ostomy, continence and bowel management applications, comprising:

a barrier layer comprising a biodegradable resin, the barrier layer having a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855; and

the biodegradable odor barrier film having a dimethyl disulfide (DMDS) breakthrough time greater than about 200 minutes when tested according to the modified Test Operations Procedure (TOP) 8-2-501.

2. The film of claim 1, wherein the barrier layer comprises polyglycolic acid (PGA) in a concentration greater than about 90 percent by weight (% wt.).

3. The film of claim 1, wherein the barrier layer is formed from a blend comprising about 90% wt. to about 99.9% wt. of PGA and a polymeric chain extender.

4. The film of claim 1, wherein the barrier layer is formed of about 100% wt. PGA.

5. The film of any of claims 1-4, wherein the barrier layer has a first side and a second side, wherein a first outer layer is disposed on the first side and a second outer layer is disposed on the second side, such that the barrier layer is sandwiched between the first and second outer layers, wherein the first and second outer layers are biodegradable, and the film has a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855.

6. The film of claim 5, wherein the first and second outer layers 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.

7. The film of claim 5, wherein the first and second outer layers comprise at least 70%wt. of a copolyester based on terephthalic acid, adipic acid, and 1,4-butanediol.

8. The film of any of claims 6-7, wherein the first and second outer layers further comprises an antiblock agent, a slip agent, and/or a blowing agent.

9. The film of any of claims 5-8, further comprising first and second tie layers disposed between the barrier layer and the first and second outer layers, respectively, the tie layers formed from a maleated polyolefin or an epoxidized polyolefin, wherein each tie layer contacting a respective side of the barrier layer.

10. The film of any of claims 5-9, wherein a thickness of the barrier layer makes up about 3% to 20% of a total thickness of the film.

11. The film of any of claims 5-10, wherein a total thickness of the film is between about 10μm and about 1,000μm, and a thickness of the barrier layer is between about 0.5μm and about 50μm.

12. A bowel management tube formed of the film of any of claims 1-11, wherein the film has a total thickness between about 500μm and 1,000μm, and the barrier layer has a thickness between about 2μm and about 50μm.

13. An ostomy pouch comprising:

a first side wall and a second side wall, wherein the first and second side walls are formed from a biodegradable odor barrier film having a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855, and a dimethyl disulfide (DMDS) breakthrough time greater than about 1440 minutes when tested according to the modified Test Operations Procedure (TOP) 8-2-501; and

a stoma-receiving opening on the first side wall.

14. The ostomy pouch of claim 13, wherein the biodegradable odor barrier film includes a barrier layer comprising polyglycolic acid (PGA) in a concentration greater than about 90 percent by weight (% wt.).

15. The ostomy pouch of claim 14, wherein the barrier layer is formed from a blend comprising about 90% wt. to about 99% wt. of PGA and a polymeric chain extender.

16. The ostomy pouch of any of claims 13-15, wherein the barrier layer has a first side and a second side, wherein a first outer layer is disposed on the first side and a second outer layer is disposed on the second side, such that the barrier layer is sandwiched between the first and second outer layers, wherein the first and second outer layers are biodegradable, and the film has a biodegradability that meets the requirements of ASTM D6400, EN13432 or ISO14855.

17. The ostomy pouch of claim 16, wherein the first and second outer layers comprise at least 70%wt. of a copolyester based on terephthalic acid, adipic acid, and 1,4-butanediol.

18. The ostomy pouch of claim 17, wherein the first and second outer layers further comprises an antiblock agent, a slip agent, and/or a blowing agent.

19. The ostomy pouch of any of claims 13-18, further including at least one nonwoven layer attached on one or both of the first and second side walls, wherein the nonwoven layer is formed from a biodegradable material.

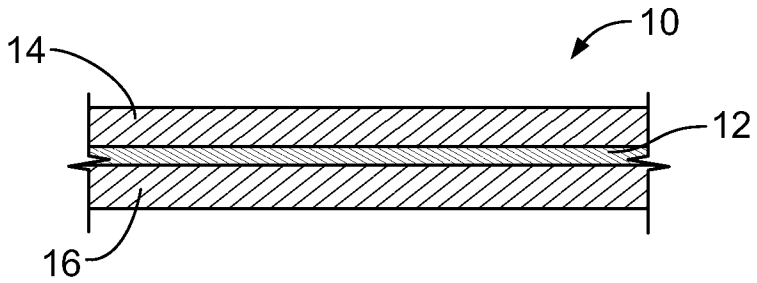

FIG. 1

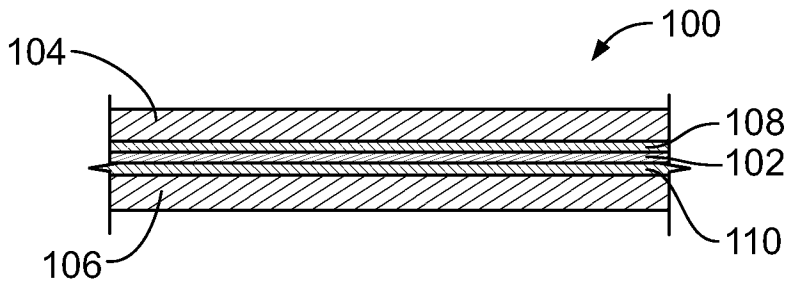

FIG. 2

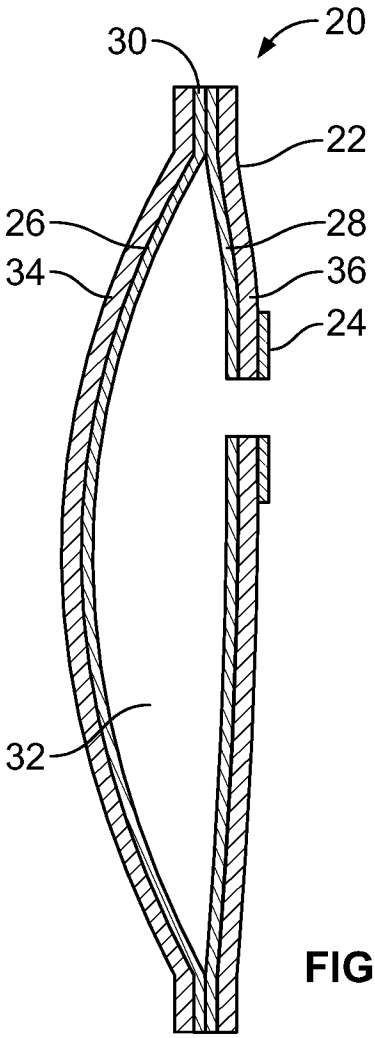

FIG. 3

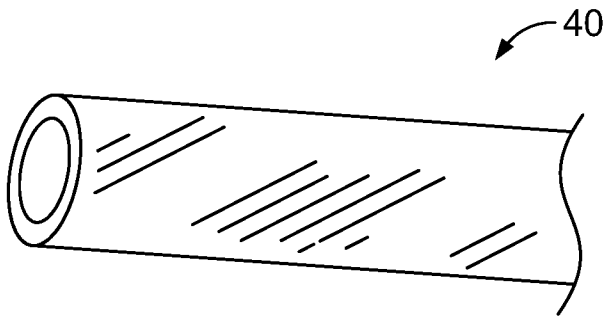

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/33674

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 5/445, 5/448; B32B 27/08 (2014.01)
CPC - A61F 5/445; B32B 7/02, 27/306
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(8): A61F 5/44, 5/441, 5/445, 5/448; A61M 5/00; B29C 47/04; B32B 7/02, 27/06, 27/08, 27/28, 27/36; C08L 101/16 (2014.01)
CPC: A61F 2005/4402, 5/445, 5/448; B32B 7/02, 27/06, 27/08, 27/28, 27/306, 27/36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 383/113; 428/35.2, 35.4, 35.7, 36.6; 604/336

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Google Scholar; ProQuest; IP.com; ASTM D6400, bag, barrier, biodegradable, film, gas, laminate, layer, malodor, multilayer, odor, ostomy, permeable, polyglycolic acid, pouch, sulfur, TOP 8-2-501, transmission, vapor

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 8,399,077 B1 (BEKELE, S) 19 March 2013; figure 1; column 1, line 37 to column 2, line 22; column 3, lines 23-25; column 4, lines 45-46; column 5, lines 18-19; column 12, lines 35-37	1-4, 5/1-4, 6/5/1-4, 7/6/5/1-4, 13-15, 16/13-15, 17/16/13-15, 18/17/16/13-15
Y	US 2011/0027590 A1 (ABE, S) 03 February 2011; paragraphs [0002], [0038]-[0041], [0090], [0098], [0102]-[0103]	1-4, 5/1-4, 6/5/1-4, 7/6/5/1-4, 13-15, 16/13-15, 17/16/13-15, 18/17/16/13-15
Y	US 2009/0151058 A1 (FARNWORTH, B et al.) 18 June 2009; figures 3-4; paragraphs [0053], [0055]; Table 1	1-4, 5/1-4, 6/5/1-4, 7/6/5/1-4, 13-15, 16/13-15, 17/16/13-15, 18/17/16/13-15
A	US 2009/0191780 A1 (SCHIFFER, DK et al.) 30 July 2009; paragraph [0027]	7/6/5/1-4, 17/16/13-15, 18/17/16/13-15
A	US 2011/0108185 A1 (HOKARI, Y et al.) 12 May 2011; entire document	1-7, 13-18
A	US 6,245,437 B1 (SHIIKI, Z et al.) 12 June 2001; entire document	1-7, 13-18
A	US 5,853,639 A (KAWAKAMI, Y et al.) 29 December 1998; entire document	1-7, 13-18

☒ Further documents are listed in the continuation of Box C. ☐

* 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	Date of mailing of the international search report
20 August 2014 (20.08.2014)	11 SEP 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

International application No.

PCT/US14/33674

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/0179069 A1 (SCHMIDT, H et al.) 16 July 2009; entire document	1-7, 13-18
A	US 2010/0032084 A1 (BENADDI, H) 11 February 2010; entire document	1-7, 13-18
E, Y	WO 2013/106361 A1 (HENDERSON, KO) 18 July 2013; entire document	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/33674

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.: 8-12 and 19
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.