(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 November 2014 (06.11.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/179550 A2

(51) International Patent Classification:
A61L 15/58 (2006.01)

(21) International Application Number:
PCT/US2014/036338

(22) International Filing Date:
1 May 2014 (01.05.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
201310158514.5 2 May 2013 (02.05.2013) CN

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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, 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, KZ, LA, LC, LK, LR, LS, LT, 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, 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:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: HYDROCOLLOID DRESSING AND METHOD FOR PREPARING THE SAME

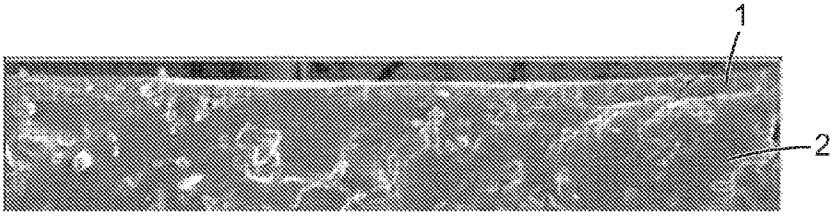

Fig. 4a

(57) Abstract: The present disclosure provides a hydrocolloid dressing, comprising: a hydrocolloid layer; and a polymer film layer, disposed on the hydrocolloid layer; wherein the polymer film layer is formed by coating a polymer solution or a liquid polymer. The present disclosure also provides a method for preparing a hydrocolloid dressing, comprising: forming a hydrocolloid layer; coating a polymer solution or a liquid polymer on the hydrocolloid layer; and drying.

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HYDROCOLLOID DRESSING AND METHOD FOR PREPARING THE SAME

Technical Field

The present disclosure relates to a hydrocolloid dressing, particularly to a hydrocolloid dressing having a polymer film, wherein the polymer film is formed by *in situ* coating. The present disclosure also relates to a method for preparing a hydrocolloid dressing.

Background

Hydrocolloid dressings are a kind of widely used dressing for wounds. Hydrocolloid dressings usually comprise a hydrocolloid layer with a lower allergenicity, and a layer of polymer film coated on the hydrocolloid layer. Currently, in the preparation of hydrocolloid dressings, normally a polymer film is pre-extruded onto a release liner or other substrate material; then laminated onto a hydrocolloid layer at the time of extruding the hydrocolloid layer; and then the release liner or the other substrate material is peeled off. Since the polymer film is laminated with the hydrocolloid layer after formation of the film, the hydrocolloid dressings prepared by this conventional method do not have a sufficient binding force between the two layers, which easily leads to a problem of "bubbles", that is, bubbles due to a separation of the two layers caused by absorption of wound effusion, which appears during use.

Therefore, there is a need for a hydrocolloid dressing with a stronger binding force between the hydrocolloid and polymer films.

Summary of Disclosure

The present disclosure provides a hydrocolloid dressing, comprising a hydrocolloid layer, and a polymer film layer disposed on the hydrocolloid layer, wherein the polymer film layer is formed by coating a polymer solution or a liquid polymer.

According to some embodiments provided by the present disclosure, when the hydrocolloid layer and the polymer film layer are peeled off, the ratio of the area of the peeled off portion to the overall area is less than 100%.

According to some other embodiments provided by the present disclosure, when the hydrocolloid layer and the polymer film layer are peeled off, the ratio of the area of the peeled off portion to the overall area is 100%, and the peel force is higher than 60 oz/0.5 in.

The present disclosure also provides a method for preparing a hydrocolloid dressing comprising:

forming a hydrocolloid layer;

coating a polymer solution on the hydrocolloid layer; and

drying.

The present disclosure obtains a hydrocolloid dressing having a stronger binding force between the hydrocolloid layer and the polymer film layer *via* formation of the polymer film coated on the hydrocolloid layer by using an *in situ* coating process, which saves the substrate material used for prefabrication of the polymer, and therefore can reduce cost of the process.

Brief Description of Drawings

Fig. 1 is an illustration of a method for preparing a hydrocolloid dressing according to one embodiment of the present disclosure.

Fig. 2 is an illustration of the preparation of a sample for the soaking test in the present disclosure.

Fig. 3(a) and Fig. 3(b) are photographs showing results of Examples and a Comparative Example of the present disclosure in the soaking test, with Fig. 3(a) showing the polyurethane film side, Fig. 3(b) showing the hydrocolloid side, and from left to right, showing Comparative Example 1, Example 1, Example 2, and Example 3, respectively.

Fig. 4(a) and Fig. 4(b) are scanning electron microscope (SEM) photographs showing cross sections of the hydrocolloid dressings in an Example and a Comparative Example of the present disclosure, with Fig. 4(a) showing Example 1, and Fig. 4(b) showing Comparative Example 1.

Specific Embodiments

The present disclosure provides a hydrocolloid dressing, comprising a hydrocolloid layer and a polymer film layer disposed on the hydrocolloid layer, wherein the polymer film is formed by *in situ* coating. The present disclosure also provides a method for preparing a hydrocolloid dressing.

The hydrocolloid dressings prepared by the conventional method do not have a sufficient binding force between the two layers, which easily leads to a problem of “bubbles” during use. This could be attributed to two reasons: the hydrocolloid layer swells after absorption, while the polymer film layer does not; and wound effusion spreads into positions where the binding of the two layers is relatively low, causing a separation of the two layers which look like “bubbles”.

The present disclosure utilizes an *in situ* coating process to apply a polymer solution or a liquid polymer on the hydrocolloid layer directly, and then dry the solvent to form a polymer film layer on the hydrocolloid *in situ*. Since the polymer solution or liquid polymer is still in a form of flowable liquid when being coated onto the hydrocolloid, and therefore can spread along undulations on the surface of the hydrocolloid to contact with the hydrocolloid layer sufficiently and also adhere to the hydrocolloid more firmly when forming a film. As a result, the binding force between the hydrocolloid and the polymer film can be substantially enhanced. A hydrocolloid dressing with a stronger binding force between the two layers which reduces generation of "bubbles" during use can be obtained by such a process.

Herein, the term "hydrocolloid" refers to a viscous adhesive comprising a gel forming agent and therefore capable of absorbing water, commonly used for tending wounds.

Herein, the term "*in situ* coating" refers to coating directly rather than coating off line on a certain substrate.

Without any specific definition, percentages, parts, ratios, concentrations and the like used herein are all based on weight.

The present disclosure provides a hydrocolloid dressing, comprising a hydrocolloid layer and a polymer film layer disposed on the hydrocolloid layer, wherein the polymer film layer is formed by coating a polymer solution or a liquid polymer.

In some embodiments of the present disclosure, since the binding force between the hydrocolloid layer and the polymer film layer is very high, the two layers cannot be peeled off as a whole. When the two layers are peeled off, the layer with a lower breaking strength in the two layer ("the peeled off layer") is broken, and a part of the peeled off layer is peeled off from the other layer while the rest is still adhered to the other layer. That is to say, in these embodiments, when the two layers are peeled off, the ratio of the area of the peeled off portion to the overall area is less than 100%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 95%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 90%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 80%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 70%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 60%. In some other embodiments, the ratio of the area of the peeled off portion to the overall area is less than about 50%. In still some other embodiments, the ratio of the area of the peeled off portion to the overall

area is less than about 40%. In some embodiments, the ratio of the area of the peeled off portion to the overall area is more than about 5%. In some other embodiments, the ratio of the area of the peeled off portion to the overall area is more than about 10%. In still some other embodiments, the ratio of the area of the peeled off portion to the overall area is more than about 15%. In still some further embodiments, the ratio of the area of the peeled off portion to the overall area is more than about 20%. Herein, "the area of the peeled off portion" refers to the area of the portion wherein the two layers are no longer adhered to each other after peeling off. The above mentioned "overall area" and "the area of the peeled off portion" are both calculated based on the area where the peel force is applied.

In some embodiments of the present disclosure, the binding force between the hydrocolloid layer and the polymer film layer is relatively high, and it is possible to peel off the two layers as a whole, while the peel force is more than about 60 oz/0.5 in. When the two layers are peeled off as a whole, neither of the two layers can be broken. That is to say, in these embodiments, when the two layers of the hydrocolloid dressing are peeled off, the ratio of the area of the peeled off portion to the overall area is 100%, and peel force is more than about 60 oz/0.5 in. In some embodiments, the peel force to peel off the two layers of the hydrocolloid dressing as a whole is more than about 70 oz/0.5 in. In some embodiments, the peel force to peel off the two layers of the hydrocolloid dressing as a whole is more than about 90 oz/0.5 in. In some embodiments, the peel force to peel off the two layers of the hydrocolloid dressing as a whole is more than about 110 oz/0.5 in. In some embodiments, the peel force to peel off the two layers of the hydrocolloid dressing as a whole is more than about 130 oz/0.5 in. In some embodiments, the peel force to peel off the two layers of the hydrocolloid dressing as a whole is more than about 150 oz/0.5 in.

In some embodiments of the present disclosure, the present disclosure provides a hydrocolloid dressing, comprising a hydrocolloid layer and a polymer film layer disposed on the hydrocolloid layer, wherein the polymer film layer is formed by coating a polymer solution or a liquid polymer. The binding force between the hydrocolloid layer and the polymer film layer of the hydrocolloid dressing, or the peel force to peel off the two layers, is higher than or equals to the breaking strength of the hydrocolloid layer or the polymer film layer. In some embodiments, the binding force between the hydrocolloid layer and the polymer film layer of the hydrocolloid dressing, or the peel force to peel off the two layers, is higher than or equals to the breaking strength of each of the hydrocolloid layer and the polymer film layer.

Based on 100 wt% of the weight of the hydrocolloid layer, the material for forming the hydrocolloid layer comprises 5-55 wt% of a gel forming agent and 10-90 wt% of an adhesive base.

The gel forming agent mainly acts to provide water absorption, and is normally a hydrophilic polymer capable of absorbing liquid, which swells instead of being dissolved after absorption due to a crosslinked structure. Usable hydrophilic polymers include natural, semisynthetic, or synthetic hydrophilic polymeric compounds. The natural hydrophilic polymeric compounds include polysaccharide-type polymers, such as pectin, gum arabic, guar gum, agar, starch, xanthan gum, dextran, and the like; and protein-type or polypeptide-type polymers, such as gelatin, albumin, casein, and the like. The semisynthetic hydrophilic polymeric compounds include carboxymethyl cellulose, sodium carboxymethyl cellulose, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, methyl hydroxypropyl cellulose, sodium alginate, carboxymethyl starch, and the like. The synthetic hydrophilic polymeric compounds include acrylic polymers (such as polyacrylic acid and polyacrylamide), polyvinyl alcohol, polyvinyl pyrrolidone, polyethylene glycol, polyvinyl methyl ether, and the like. The above mentioned hydrophilic polymeric compounds can be used alone or as a mixture of two or more hydrophilic polymeric compounds.

Commercially available products can be used, and examples thereof include, but are not limited to, one or more selected from: HS100000YP2 hydroxyethyl cellulose from Clariant Chemicals (China) Ltd., FH5000 sodium carboxymethyl cellulose or PE32 FGX cellulose gum from Wealthy Chemical Industry (Suzhou) Co. Ltd. (China), crosslinked sodium carboxymethyl cellulose from FMC BioPolymer (USA), hydroxypropyl methyl cellulose and hydroxyethyl cellulose from Shanghai Honest Chem. Co. Ltd. (China), carboxymethyl starch from Fuhua Siccative Factory, Gongyi city, Henan province (China), or Luquasorb 1030 Superabsorbent Polymer from BASF AG (Germany).

Based on 100 wt% of the weight of the hydrocolloid layer, the content of the gel forming agent in the hydrocolloid layer is 5-55 wt%, preferably 10-50 wt%, and more preferably 20-40 wt%.

The adhesive base mainly assists in shaping and providing tackiness, flexibility, etc. The adhesive base can be polymeric elastomers, such as polyolefins, and examples thereof include, but are not limited to, polyisobutylene, polyisoprene, polybutene and polybutadiene, and copolymers comprising at least one olefin polymer block, e.g. poly(styrene/olefin/styrene) block copolymers, such as poly(styrene/isobutylene/styrene), poly(styrene/butene/styrene), poly(styrene/butadiene/styrene), poly(styrene/isoprene/styrene), poly(styrene/ethylene/butene/styrene), etc. The above mentioned polymers can be used alone, or as a mixture of several polymers. In some embodiments, one or more selected from polybutadiene, polyisoprene, and polyisobutylene is/are used. In some embodiments, one or

more selected from cis-1,4-polybutadiene rubber, polyisoprene, and polyisobutylene is/are used.

Commercially available products can be used as the adhesive base, and examples thereof include, but are not limited to, one or more selected from: BR9000 polybutadiene (cis-1,4-polybutadiene rubber) from Qilu Petroleum Chemicals Co., SINOPEC, Natsyn 2210 polyisoprene from Goodyear Company, USA, SDG-8650 polyisobutylene from Hangzhou Sunda Plastics Co. Ltd. (China), LM-MH from ExxonMobil Chemical Company (USA), PIB 6H polyisobutylene from RitChem (USA), and polyisobutylene Oppanol B10- B15, Glissopal 1000, Glissopal 1300, and Glissopal 2300 from BASF AG (Germany).

Tackiness can be adjusted by using polymers of various molecular weights. By using a polymer having lower molecular weight, a higher tackiness can be provided. Polymers used as the adhesive base usually have molecular weights in a range of Mn=1,000-1,000,000, preferably in a range of Mn=5,000-90,000, and more preferably in a range of Mn=10,000-80,000. A mixture of two or more polymers having different molecular weights can be used as the adhesive base to obtain the desired tackiness.

In some embodiments, the polymer used as the adhesive base has a glass transition temperature (Tg) of -200 to 300°C, preferably -190 to 250°C, and more preferably -180 to 200°C.

In some embodiments, the polymer used as the adhesive base has a Mooney viscosity (ML-4', at 100°C) of 10-100, and preferably 30-70.

In some embodiments, the polymer used as the adhesive base has a Staudinger index (intrinsic viscosity) of 20-60 ml/g, and preferably 30-50 ml/g.

Based on 100 wt% of the weight of the hydrocolloid layer, the content of the adhesive base in the hydrocolloid layer is 10-90 wt%, preferably 20-85 wt%, more preferably 30-80 wt%, even more preferably 40-80 wt%, further more preferably 50-80 wt%, and still further more preferably 60-80 wt%.

The material for forming the hydrocolloid layer optionally further comprises a tackifying resin, in order to further adjust the tackiness of the product.

Based on the total weight of the hydrocolloid layer, the content of the tackifying resin in the hydrocolloid layer is 0-50 wt%, preferably 5-40 wt%, and more preferably 5-30 wt%.

The tackifying resin can be one or more selected from: aliphatic, alicyclic, and aromatic copolymer petroleum resins, and the like; terpene resins; terpene-styrene resins; coumarone-terpene resins; rosin resins; and hydrogenates of the above resins, etc. Preferable tackifying resins are selected from aliphatic

and alicyclic petroleum resins; terpene resins and terpene-styrene resins. The most preferable tackifying resins are selected from aliphatic and alicyclic petroleum resins.

Examples of the commercially available products which can be used as the tackifying resin include, but are not limited to, one or more selected from: Eastotac H-100R Resin from Eastman Chemical Company (USA), Wingtack 95 from CRAY VALLEY (France), Escorez 5340 from ExxonMobil Chemical Company (USA), and Sylvalite RE80HP Rosin Ester from Arizona Chemicals (USA).

Polymers which can be used for forming the polymer film layer in the hydrocolloid dressing can be any material commonly used in the art, especially the polymers that can be dissolved in a volatile solvent or water and have film forming property. Specific examples thereof include, but are not limited to, one or more selected from: polyurethanes, polyolefins such as polyethylene or polypropylene, polyesters, polyamides, acrylic acid (ester) polymers, olefin copolymers such as ethylene-vinyl acetate copolymers. Among others, polyurethanes, polyesters, polyethylene or ethylene-vinyl acetate copolymers are preferable, and polyurethanes or ethylene-vinyl acetate copolymers are more preferable. Preferably, polymers with good biocompatibility and water resistance, such as polyurethanes, are used. The term "acrylic acid (ester) polymers" refers to acrylic acid polymers and acrylic ester polymers, including methacrylic acid polymers and methacrylic ester polymers.

There is no specific limitation to the molecular weight, glass transition temperature (Tg), etc. of the polymer. However, in view of being advantageous for the *in situ* coating, the weight average molecular weight of the polymer is 2,000-1,000,000, preferably 2,000-900,000, more preferably 2,000-800,000, and most preferably 2,000-700,000. In order to achieve a better binding force with the hydrocolloid layer, polymers having a lower surface energy, such as silicones and the like, should be avoided. More preferably, polymers having a surface energy close to that of the hydrocolloid layer are used, and examples of such polymers include, but are not limited to, polyurethanes, polyolefins such as polyethylene or polypropylene, polyesters, etc.

In one embodiment, a polyurethane (PU) layer is used as the polymer film layer. Examples of the polyurethane which can be used include, but are not limited to, aliphatic polyether polyurethanes, aliphatic polyester polyurethanes, aromatic polyether polyurethanes, and aromatic polyester polyurethanes, and preferably aromatic polyether polyurethanes. Examples thereof include, but are not limited to, di- (or poly-) cyanate polyether polyurethanes, di- (or poly-) cyanate polyesters polyurethanes,

and the like, wherein "di- (or poly-) cyanate" and "di- or poly-cyanate" can be used interchangeably, both referring to dicyanate or polycyanate, which can be selected from hexamethylene diisocyanate, naphthalene diisocyanate, toluene diisocyanate (TDI), diphenylmethane diisocyanate (MDI), hydrogenated toluene diisocyanate, hydrogenated diphenylmethane diisocyanate, isophorone diisocyanate, and the like. More preferably, polyurethanes having a swellability close to that of the material of the hydrocolloid layer are used.

For the convenience of performing the *in situ* coating and forming a polymer film layer having a suitable thickness, the polymer solution or liquid polymer used in the present disclosure has a viscosity of 100 cps or higher, 500 cps or higher, 1000 cps or higher, 3000 cps or higher, 6000 cps or higher, or 10000 cps or higher, and 150000 cps or lower, 130000 cps or lower, 110000 cps or lower, 90000 cps or lower, 70000 cps or lower, or 50000 cps or lower. In order to be more advantageous for performing the coating and obtain a hydrocolloid dressing having a higher binding force between the two layers, for example, the polymer solution or liquid polymer used may have a viscosity in a range of 100-150000 cps, preferably 500-130000 cps, more preferably 1000-110000 cps, even more preferably 3000-90000 cps, still more preferably 6000-70000 cps, and most preferably 10000-50000 cps. In view of different ranges of viscosity, different coating processes may be utilized. For example, when the viscosity is relatively low, curtain coating, web roll coating and the like can be used; and when the viscosity is high, comma roll coating, doctor blade coating, extrusion coating and the like can be used. They can achieve the same coating effect. The viscosity of the solution can be measured by using a Brookfield VII viscometer. The above mentioned viscosity is Brookfield viscosity at 25°C.

By weight, the concentration of the polymer solution (solid content) can be 5% or more, 10% or more, 15% or more, 20% or more, or 25% or more, and 90% or less, 80% or less, 70% or less, 60% or less, 50% or less, or 40% or less, for example, 5-90%, 10-80%, 15-70%, or 20-50%.

There is no specific limitation to the solvent for forming the polymer solution. The solvent may be one or more selected from water, alcohols, esters, aliphatic hydrocarbons, aromatic hydrocarbons, ketones, and amides. For example, the solvent may be one or more selected from the following solvents: isopropyl alcohol, ethyl acetate, heptane, toluene, xylene, water, dimethyl formamide (DMF), butanone, and the like.

Commercially available polymer solutions can be used to form the polymer film layer. Examples of commercially available polymer solutions include V-Coat AB5454LV, V-Coat AB5858LV, and V-Coat

775 from Jiaxing Puyou Chemicals Co. Ltd., China, which are solutions of diphenylmethane diisocyanate (MDI) polyether polyurethanes in DMF/butanone and DMF/butanone/toluene slightly differing in indexes of viscosity etc., respectively.

The thicknesses of the hydrocolloid layer and the polymer film layer in the hydrocolloid dressing can be selected according to actual need. The thickness of the hydrocolloid layer mainly influences water absorption and comfortableness of the dressing, while the thickness of the polymer film layer influences permeability and comfortableness of the dressing. The thickness of the hydrocolloid layer is 10-5000 microns, preferably 15-4500 microns, more preferably 20-4000 microns, and most preferably 25-3500 microns. The thickness of the polymer film layer is 4-200 microns, preferably 4-180 microns, more preferably 4-160 microns, and most preferably 4-140 microns.

In some embodiments, the hydrocolloid dressing further comprises a protective layer, such as a release liner. The protective layer is in contact with the outer surface of the hydrocolloid layer, i.e., in contact with the surface opposite to the surface where the hydrocolloid layer being in contact with the polymer film layer, to protect the hydrocolloid layer. When being used, the protective layer is removed, and the hydrocolloid layer is adhered to a position in need of using the dressing. The release liner can be any type commonly used in the art. Materials can be used as the release liner include, but are not limited to, cellophane paper, laminated paper, polyester films, polypropylene films, etc., preferably being coated with silicone resins.

The present disclosure also provides a method for preparing a hydrocolloid dressing, comprising:

forming a hydrocolloid layer;

coating a polymer solution or a liquid polymer on the hydrocolloid layer; and

drying.

Fig. 1 is an illustration of a method for preparing a hydrocolloid dressing according to one embodiment of the present disclosure. Specific steps are as described below.

The hydrocolloid layer is formed by extruding, pressing, or coating. For example, various materials for forming the hydrocolloid layer are banburyed in a kneading machine to form a block, and then extruded or pressed by an extruding machine or a sheeting machine combined with a certain die to form a

sheet, or can be mixed and extruded directly by the extruding machine, to obtain the hydrocolloid layer. Subsequently, the polymer solution is coated on the hydrocolloid layer, and dried by using an oven to remove the solvent. Optionally, the product is wound up.

In some embodiments, the hydrocolloid layer is formed by extrusion. Conditions known in the art can be used. For example, in some embodiments, the extrusion temperature is 80-120°C.

There is no specific limitation to the method of coating the polymer solution or the liquid polymer, and the method can be any one of comma roll coating, web roll coating, dip coating, doctor blade coating, extrusion coating, and the like.

The drying step in the method for preparing a hydrocolloid dressing can be performed under conditions of 30-300°C, preferably 35-270°C, and more preferably 40-250°C. In some embodiments, the drying step is performed at 40-200°C. Various temperature gradients can be set as needed to achieve a better drying effect.

In order to further improve the integrity of the hydrocolloid *per se*, crosslinking can also be performed after drying, so as to crosslink and bind the unsaturated chains within the polymers in the formulation of the hydrocolloid. There is not limitation to the crosslinking method. Gamma radiation, UV radiation, electron beam radiation, and the like can be used. A crosslinking agent can also be added into the formulation to perform crosslinking. Examples of the crosslinking agent usable herein include, but are not limited to, dicumyl peroxide (DCP), benzoyl peroxide (BPO), di-tert-butyl peroxide (DTBP), and the like.

In one embodiment, gamma radiation is used to crosslink the sample, with the dosage of the gamma radiation set at 5-100 kGy.

The hydrocolloid dressing of the present disclosure is obtained by *in situ* coating a polymer solution or a liquid polymer on the hydrocolloid layer to form a polymer film layer, wherein the binding force between the hydrocolloid layer and the polymer film layer thus obtained is stronger, as compared with the conventional approach of pre-extruding the polymer film, and then combining with the hydrocolloid layer at the same time of extruding the hydrocolloid layer. According to some examples of the present disclosure, since the binding force between the hydrocolloid layer and the polymer film layer is very high, the two layers cannot be peeled off as a whole. When the two layers are peeled off, the ratio of the area of the peeled off portion to the overall area is less than 100%. According to some examples of the present

disclosure, the binding force between the hydrocolloid layer and the polymer film layer is relatively high, and it is possible to peel off the two layers as a whole, while the peel force to peel off the two layers as a whole is more than 60 oz/0.5 in. When the two layers are peeled off as a whole, the ratio of the area of the peeled off portion to the overall area is 100%.

In some embodiments, the hydrocolloid dressing is subjected to a peel test to measure the ratio of the area of the peeled off portion to the overall area as well as the peel force between the two layers. The measurements can be performed by using a tensile tester. For example, the test can be performed as follows. The polymer layer of the hydrocolloid dressing is fixed on the plate of the tensile tester, e.g. by adhesion via a double-sided adhesive tape or an adhesive. The hydrocolloid layer is then affixed by using a test tape which has a width that is at least the same as that of the hydrocolloid dressing, leaving an excessive portion at least on one end. When performing the test, the excessive portion on the one end of the test tape is folded back at 180°, and fixed on the clamp of the tensile tester. The tensile tester is started to measure the peel force, and the area of the peeled off portion is observed. The binding force between the polymer layer and the double-sided adhesive tape or the adhesive used for fixing the polymer layer should reach to a certain level, being at least higher than the peel force between the hydrocolloid layer and the polymer layer. For example, a double-sided adhesive tape or an adhesive having a binding force above 55 oz/0.5 in, preferably a double-sided adhesive tape or an adhesive having a binding force above 75 oz/0.5 in, more preferably a double-sided adhesive tape or an adhesive having a binding force above 95 oz/0.5 in, still more preferably a double-sided adhesive tape or an adhesive having a binding force above 115 oz/0.5 in, further more preferably a double-sided adhesive tape or an adhesive having a binding force above 135 oz/0.5 in, and even more preferably a double-sided adhesive tape or an adhesive having a binding force above 155 oz/0.5 in is used. The binding force between the test tape used and the hydrocolloid layer should reach to a certain level, being at least higher than the peel force between the hydrocolloid layer and the polymer layer. For example, a test tape having a binding force above 55 oz/0.5 in, preferably a test tape having a binding force above 75 oz/0.5 in, more preferably a test tape having a binding force above 95 oz/0.5 in, still more preferably a test tape having a binding force above 115 oz/0.5 in, further more preferably a test tape having a binding force above 135 oz/0.5 in, and even more preferably a test tape having a binding force above 155 oz/0.5 in is used. In some embodiments, the adhesive tape obtained under a series number of 2525 from 3M Co., US is used as the test tape, and a double-sided adhesive tape obtained under a series number of 4951 from 3M Co., US is used as the

double-sided adhesive tape for fixing the polymer layer.

In some embodiments, the breaking strength of each of the hydrocolloid layer and the polymer film layer is measured, respectively, and compared with the peel force of the two layers. The breaking strength can be measured by methods commonly used in the art, such as by using a tensile tester. In some embodiments, two ends of a strip of sample to be tested are fixed on the clamps of the tensile tester, respectively. The tensile tester is started to stretch the sample until it is broken. The force at break is recorded as the breaking strength.

The present disclosure is described in more details by the following Examples. However, they should not be interpreted as limiting the scope of the present disclosure in any manner.

Examples

Materials used in the Examples are summarized in Table 1. Equipments used in the Examples are summarized in Table 2.

Table 1. Materials used in the Examples

Components	Type	Supplier	Note
cis-1,4-Polybutadiene rubber	BR9000	Qilu Petroleum Chemicals Co., SINOPEC	Mooney viscosity (ML-4', at 100°C): 45
Polyisoprene	Natsyn 2210	Goodyear Tire & Rubber Company, USA	Mooney viscosity (ML-4', at 100°C): 50-65
Polyisobutylene	PIB 6H	Rit-Chem Co., Inc., USA	Staudinger index: 34.5-39.0
Polyisobutylene	SDG-8650	Zhejiang Sunda New Materials Co. Ltd., China	Staudinger index: 33.5-39.0 Viscosity average molecular weight: 65000±5000
Hydroxyethyl cellulose	HS100000YP2	Clariant Chemicals (China) Ltd.	Brookfield viscosity: 16000 to 21000 mpas
Sodium carboxymethyl cellulose	FH5000	Wealthy Chemical Industry (Suzhou) Co. Ltd. (China)	Brookfield viscosity: 5000 to 6000 mpas
Polyurethane solution	V-Coat AB5454LV	Jiaxing Puyou Chemicals Co. Ltd., China	Solid content: 30% Solvent: DMF/butanone Brookfield viscosity (25°C): 12,000-18,000 cps
Polyurethane solution	V-Coat AB5858LV	Jiaxing Puyou Chemicals Co. Ltd., China	Solid content: 30% Solvent: DMF/butanone/toluene Brookfield viscosity (25°C): 25,000-40,000

			cps
Polyurethane solution	V-Coat 775	Jiaxing Puyou Chemicals Co. Ltd.,China	Solid content: 30% Solvent: DMF/butanone/toluene Brookfield viscosity (25°C): 85,000-110,000 cps

Table 2. Equipments used in the Examples

Equipments	Type	Supplier	Operation Conditions
Vacuum kneading machine	NH100-300L	Rugao Fengguang Kneading Machinery Co. Ltd., China	Kneading for 1-2 hours, and then kneading under vacuum (degree of vacuum: 0.02-0.1 MPa) for 1 hour
Rubber extruding machine		Zhoushan Yuze Rubber & Plastics Machinery Co. Ltd., China	Extrusion temperature being 50-150°C.
Solvent-type applicator		Kunshan Guotai Machinery & Electronics Technology, China	Oven being set at a temperature of 30-300°C.
Gamma radiator		Shenzhen Jinpengyuan Radiation Technology Co. Ltd., China	Gamma dosage: 5-100 kGy
Tensile tester	SP-2000	IMASS Inc., USA	Testing under conditions of 23°C and 53% relative humidity
Scanning electron microscope	JSM-6360LV	Shimadzu Corporation, Japan	

Example 1

Based on the total weight of the raw materials used, 35% of BR9000 cis-1,4-polybutadiene rubber from Qilu Petroleum Chemicals, 45% of PIB 6H polyisobutylene from RitChem Co., Inc., and 20% of HS 100000 YP2 hydroxyethyl cellulose from Clariant Chemicals were charged into the vacuum kneading machine and kneaded normally for 1-2 hours, and then kneaded under vacuum (degree of vacuum: 0.07 MPa) for 1 hour.

The above mixture was put into the rubber extruding machine, and extruded to a hydrocolloid sheet having an average thickness of 0.5 mm. The extrusion temperature was 80-120°C.

V-Coat AB5454LV polyurethane solution (solid content: 30%, viscosity: 12,000-18,000 cps/25°C) from Jiaxing Puyou was coated onto the above extruded hydrocolloid sheet by the solvent-type applicator using a comma roll with a gap set at 83 microns. The solvent was removed by using an oven which was set at a temperature gradient of 40-200°C. After drying, a polyurethane film having an average thickness of 25 microns was formed on the hydrocolloid layer.

The sample was crosslinked by gamma ray, and the gamma dosage was set at 20-60 kGy.

Example 2

Based on the total weight of the raw materials used, 50% of Natsyn 2210 polyisoprene from Goodyear Company, USA, 20% of SDG-8650 polyisobutylene from Hangzhou Sunda, and 30% of FH5000 sodium carboxymethyl cellulose from Wealthy Chemical Industry (Suzhou) were charged into the vacuum kneading machine and kneaded normally for 1-2 hours, and then kneaded under vacuum (degree of vacuum: 0.05 MPa) for 1 hour.

The above mixture was put into the rubber extruding machine, and extruded to a hydrocolloid sheet having an average thickness of 1 mm. The extrusion temperature was 80-120°C.

V-Coat AB5858LV polyurethane solution (solid content: 30%, viscosity: 25,000-40,000 cps/25°C) from Jiaxing Puyou was coated onto the above extruded hydrocolloid sheet by the solvent-type applicator. The solvent was removed by using an oven which was set at a temperature gradient of 40-200°C. After drying, a polyurethane film having an average thickness of 30 microns was formed on the hydrocolloid layer. The sample was crosslinked by gamma ray, and the gamma dosage was set at 10-50 kGy.

Example 3

By using the same formulation and process conditions as in Example 2, a hydrocolloid sheet having an average thickness of 1 mm was prepared.

V-Coat 775 polyurethane solution (solid content: 30%, viscosity: 85,000-110,000 cps/25°C) from Jiaxing Puyou was coated onto the above extruded hydrocolloid sheet by the solvent-type applicator. The solvent was removed by using an oven which was set at a temperature gradient of 40-200°C. After drying, a polyurethane film having an average thickness of 30 microns was formed on the hydrocolloid layer. The sample was crosslinked by gamma ray, and the gamma dosage was set at 10-50 kGy.

Comparative Example 1

A hydrocolloid dressing was prepared by laminating hydrocolloid with a prefabricated film.

First, V-Coat AB5454LV polyurethane solution from Jiaxing Puyou used in Example 1 was coated on a liner by the solvent-type applicator under process conditions in Example 1, and finally a polyurethane film having an average thickness of 25 microns was obtained. A suitable amount of the polyurethane film having a width of 1 inch was placed in the clamps of the tensile tester at a clamp distance of 100 mm, and the sample was stretched at a speed of 100 mm/min until it was broken. The maximum tensile strength was recorded as its breaking strength (F1-1).

A hydrocolloid sheet of 0.5 mm was extruded by the method of Example 1. A suitable amount of the hydrocolloid sheet having a width of 1 inch was measured for its breaking strength (F1-2) by the above mentioned method.

The extrusion of the above mentioned hydrocolloid sheet was continued, and at the same time, the above mentioned polyurethane film was laminated onto the hydrocolloid sheet. The sample was wound up.

The sample was crosslinked by gamma ray, and the gamma dosage was set at 10-50 kGy.

Comparative Example 2

A hydrocolloid dressing was prepared by laminating hydrocolloid with a prefabricated film.

First, V-Coat AB5858LV polyurethane solution from Jiaxing Puyou used in Example 2 was coated on a liner by the solvent-type applicator under process conditions in Example 2, and finally a polyurethane film having an average thickness of 30 microns was obtained. A suitable amount of the polyurethane film having a width of 1 inch was placed in the clamps of the tensile tester at a clamp

distance of 100 mm, and the sample was stretched at a speed of 100 mm/min until it was broken. The maximum tensile strength was recorded as its breaking strength (F2-1).

A hydrocolloid sheet of 1 mm was extruded by the method of Example 2. A suitable amount of the hydrocolloid sheet having a width of 1 inch was measured for its breaking strength (F2-2) by the above mentioned method.

The extrusion of the above mentioned hydrocolloid sheet was continued, and at the same time, the above mentioned polyurethane film was laminated onto the hydrocolloid sheet. The sample was wound up.

The sample was crosslinked by gamma ray, and the gamma dosage was set at 20-60 kGy.

Binding force test

A. Peel off test

The binding force between the hydrocolloid layer and the polyurethane film was measured for samples of Examples 1-3 and Comparative Examples 1-2 by the method described below.

1) The polyurethane film side of the sample to be tested was fixed on the plate of an IMASS tensile tester by a double-sided adhesive tape obtained under a series number of 4951 from 3M Co. US, with the hydrocolloid side facing upward;

2) then an adhesive tape obtained under a series number of 2525 from 3M Co. US was affixed onto the surface of the hydrocolloid, and rolled over with a roller of 2 kg back and forth once, respectively, wherein the 2525 tape had the same width as that of the hydrocolloid dressing to be tested, but with excessive portions on both ends;

3) the 2525 tape was folded back at 180° on one end, and fixed by a clamp;

4) the IMASS tensile tester was started to perform peeling off of the sample; the peel force was recorded and the transfer of the hydrocolloid layer was observed, with the ratio of the area of the peeled off portion to the overall area being calculated by the area percentage of the transferred hydrocolloid layer in the hydrocolloid dressing.

Each sample was measured for 3 times, and the test results are shown in Table 3. F1-1, F1-2, F2-1, and F2-2 are also listed in Table 3. The results of the breaking strength and the peel force are averages of three measurements.

Table 3. Test results of peel force and breaking strength of polyurethane film and hydrocolloid

Samples	Area Percentage of Transferred Hydrocolloid	Peel Force (oz/0.5 in)	Breaking Strength of Polyurethane Film (oz/0.5 in)	Breaking Strength of Hydrocolloid (oz/0.5 in)
Example 1	25-50%	112.35	49.63 (F1-1)	4.47 (F1-2)
Comparative Example 1	100%	34.10	49.63 (F1-1)	4.47 (F1-2)
Example 2	25-50%	150.44	50.88 (F2-1)	3.92 (F2-2)
Comparative Example 2	100%	27.55	50.88 (F2-1)	3.92 (F2-2)
Example 3	75%-100%	100.87	-	3.92 (F2-2)

It can be seen from the results in Table 3 that, upon peeling off, the hydrocolloid layers in Example 1 and 2 were destroyed and only 25-50% were transferred, while the hydrocolloid layer in Example 3 was destroyed and 75-100% was transferred. On the other hand, the hydrocolloid layers in Comparative Examples 1 and 2 both remained as a whole and 100% was transferred. Further, the forces for peeling off the two layers were measured for Examples 1, 2, and 3 under the circumstance of the hydrocolloid layer being destroyed, which were higher than the breaking strength of each of the hydrocolloid layer and/or the polymer film layer, while the peel forces of the hydrocolloid layer and the polymer film layer measured for Comparative Examples 1 and 2 were much lower than the peel forces measured for Examples 1-3, and lower than the breaking strength of the polymer film layer.

Thus, the hydrocolloid/film integrations prepared by the method of the present disclosure all have higher binding forces.

B. Soaking test

The binding force between the hydrocolloid and the polymer film in the samples of Examples and Comparative Examples is further evaluated by a soaking test.

A wide necked glass bottle with a cap having a diameter of 1.5 inch was used for the test.

1) The crosslinked hydrocolloid dressing samples prepared in Examples 1, 2, and 3 as well as Comparative Example 1 were cut into a shape corresponding to the bottle opening. Samples were

obtained by placing in an order of the bottle cap, the hydrocolloid dressing, and the rubber washer.

2) A simulated wound effusion was prepared as follows (YY/T 0471.1-2004): 8.298 g of sodium chloride and 0.3689 g of calcium chloride dihydrate were dissolved with deionized water in a volumetric flask and diluted to 1 L. The simulated wound effusion is composed of a solution containing sodium chloride and calcium chloride, including 142 mmol sodium ion and 2.5 mmol calcium ion. The ion content of the solution is comparable to human serum or wound effusion.

3) The samples prepared in the above 1) were placed on bottles containing the simulated wound effusion prepared in the above 2), and the caps were screwed tightly.

4) The bottles were placed upside down so that the hydrocolloid dressing was soaked into the simulated wound effusion, and stood in an oven at 37°C for 24 hours.

5) The samples were taken out after 24 hours for observation (Fig. 3(a) and Fig. 3(b)).

Fig. 3(a) shows the side of the polyurethane film, and Fig. 3(b) shows the side of the hydrocolloid. It can be seen from the figures that obvious "bubbles" appeared in the sample of Comparative Example 1 (a1, b1). The hydrocolloid dressings of Example 1 (a2, b2), Example 2 (a3, b3) and Example 3 (a4, b4), on the other hand, swelled, but no "bubble" appeared. This illustrates that the hydrocolloid/film composites of the Examples still maintained an excellent binding force after a contact with the wound effusion for 24 hours, without separation.

C. Scanning electron microscope test

The cross section of the dressings of Example 1 and Comparative Example 1 were observed by the scanning electron microscope.

Fig. 4(a) shows the sample of Example 1, wherein 1 indicates the polymer film, and 2 indicates the hydrocolloid layer. It can be clearly seen that the hydrocolloid and the polymer film are closely attached to each other, which explains the reasons of the higher binding force between the hydrocolloid and the polymer film.

Fig. 4(b) shows the sample of Comparative Example 1, wherein 1 indicates the polymer film, and 2 indicates the hydrocolloid layer. The boundary between the hydrocolloid and the polymer film is very obvious.

CLAIMS

1. A hydrocolloid dressing, comprising:

a hydrocolloid layer; and

a polymer film layer, disposed on the hydrocolloid layer,

wherein the polymer film layer is formed by coating a polymer solution or a liquid polymer.

2. The hydrocolloid dressing of claim 1, wherein when the hydrocolloid layer and the polymer film layer are peeled off from each other, the ratio of the area of the peeled off portion to the overall area is less than 100%.

3. The hydrocolloid dressing of claim 1, wherein when the hydrocolloid layer and the polymer film layer are peeled off from each other, the ratio of the area of the peeled off portion to the overall area is 100%, and the peel force for peeling the two layers from each other is higher than 60 oz/0.5 in.

4. The hydrocolloid dressing of claim 1, wherein the peel force for peeling off the hydrocolloid layer and the polymer film layer from each other is higher than the breaking strength of the hydrocolloid layer or the polymer film layer.

5. The hydrocolloid dressing of any one of claims 1-4, wherein based on 100 wt% of the weight of the hydrocolloid layer, the hydrocolloid layer comprises 5-55 wt% of a gel forming agent, 10-90 wt% of an adhesive base, and 0-50 wt% of a tackifying resin.

6. The hydrocolloid dressing of claim 5, wherein the gel forming agent is selected from a group consisting of natural hydrophilic polymeric compounds, semisynthetic hydrophilic polymeric compounds, and synthetic hydrophilic polymeric compounds.

7. The hydrocolloid dressing of claim 6, wherein the natural hydrophilic polymeric compounds are selected from a group consisting of polysaccharide-type polymers, protein-type polymers and

polypeptide-type polymers.

8. The hydrocolloid dressing of claim 7, wherein the polysaccharide-type polymers are selected from a group consisting of pectin, gum arabic, guar gum, agar, starch, xanthan gum, and dextran.

9. The hydrocolloid dressing of claim 7, wherein the protein-type polymers or polypeptide-type polymers are selected from a group consisting of gelatin, albumin and casein.

10. The hydrocolloid dressing of claim 6, wherein the semisynthetic hydrophilic polymeric compounds are selected from a group consisting of carboxymethyl cellulose, sodium carboxymethyl cellulose, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, methyl hydroxypropyl cellulose, sodium alginate and carboxymethyl starch.

11. The hydrocolloid dressing of claim 6, wherein the synthetic hydrophilic polymeric compounds are selected from a group consisting of acrylic polymers, polyvinyl alcohol, polyvinyl pyrrolidone, polyethylene glycol and polyvinyl methyl ether.

12. The hydrocolloid dressing of claim 11, wherein the acrylic polymers are polyacrylic acid or polyacrylamide.

13. The hydrocolloid dressing of claim 5, wherein the adhesive base is one or more selected from polymeric elastomers.

14. The hydrocolloid dressing of claim 13, wherein the polymeric elastomers are polyolefins or copolymers comprising at least one olefin polymer block.

15. The hydrocolloid dressing of claim 14, wherein the polyolefins are selected from a group consisting of polyisobutylene, polyisoprene, polybutene and polybutadiene.

16. The hydrocolloid dressing of any one of claims 5-15, wherein the tackifying resin is selected

from a group consisting of aliphatic petroleum resins, alicyclic petroleum resins, aromatic copolymer petroleum resins, terpene resins, terpene-styrene resins, coumarone-terpene resins, rosin resins, and hydrogenates thereof.

17. The hydrocolloid dressing of any one of claims 1-16, wherein the polymer film layer is formed by one or more selected from a group consisting of polyurethanes, polyolefins, polyesters, polyamides, acrylic or acrylate polymers, and olefin copolymers.

18. The hydrocolloid dressing of claim 17, wherein the polymer film layer is formed by one or more selected from a group consisting of polyurethanes, polyethylene, polypropylene, polyesters, and ethylene-vinyl acetate copolymers.

19. The hydrocolloid dressing of claim 17 or 18, wherein the polyurethanes are selected from a group consisting of aliphatic polyether polyurethanes, aliphatic polyester polyurethanes, aromatic polyether polyurethanes, and aromatic polyester polyurethanes.

20. The hydrocolloid dressing of any one of claims 17-19, wherein the polyurethanes are selected from a group consisting of di-cyanate polyether polyurethanes, polycyanate polyether polyurethanes, di-cyanate polyester polyurethanes and polycyanate polyester polyurethanes.

21. The hydrocolloid dressing of claim 20, wherein the di-cyanate or polycyanate is selected from a group consisting of hexamethylene diisocyanate, naphthalene diisocyanate, toluene diisocyanate, diphenylmethane diisocyanate, hydrogenated toluene diisocyanate, hydrogenated diphenylmethane diisocyanate, and isophorone diisocyanate.

22. The hydrocolloid dressing of any one of claims 17-21, wherein the polymer which forms the polymer film layer has a weight average molecular weight of 2,000-1,000,000.

23. The hydrocolloid dressing of any one of claims 1-22, wherein the thickness of the hydrocolloid layer is 10-5000 microns.

24. The hydrocolloid dressing of any one of claims 1-23, wherein the thickness of the polymer film layer is 4-200 microns.

25. The hydrocolloid dressing of any one of claims 1-24, further comprising a protective layer.

26. A method for preparing a hydrocolloid dressing, comprising:

forming a hydrocolloid layer;

coating a polymer solution or a liquid polymer on the hydrocolloid layer; and

drying.

27. The method of claim 26, wherein the hydrocolloid layer is formed by extrusion, hot pressing, or coating process.

28. The method of claim 26 or 27, wherein based on 100 wt% of the weight of the hydrocolloid layer, the hydrocolloid layer comprises 5-55 wt% of a gel forming agent, 10-90 wt% of an adhesive base, and 0-50 wt% of a tackifying resin.

29. The method of any one of claims 26-28, wherein the polymer solution is a solution of one or more selected from a group consisting of polyurethanes, polyolefins, polyesters, polyamides, acrylic polymers, acrylate polymers, and olefin copolymers in a solvent which is selected from a group consisting of water, alcohols, esters, aliphatic hydrocarbons, aromatic hydrocarbons, ketones, and amides, and the liquid polymer is selected from a group consisting of polyurethanes, polyolefins, polyesters, polyamides, acrylic polymers, acrylate polymers, and olefin copolymers.

30. The method of claim 28, wherein the polymer solution is a solution of one or more selected from a group consisting of polyurethanes, polyethylene, polypropylene, polyesters, and ethylene-vinyl acetate copolymers in a solvent which is selected from a group consisting of water, alcohols, esters, aliphatic hydrocarbons, aromatic hydrocarbons, ketones, and amides, and the liquid polymer is selected from a group consisting of polyurethanes, polyethylene, polypropylene, polyesters, and ethylene-vinyl acetate

copolymers.

31. The method of any one of claims 26-30, wherein the polymer solution or the liquid polymer has a Brookfield viscosity of 100-150000 cps at 25°C.

32. The method of any one of claims 26-31, wherein the temperature for drying is 30-300°C.

33. The method of any one of claims 26-32, further comprising performing crosslink after the drying.

34. The method of claim 33, wherein the crosslink is performed by using one or more of gamma radiation, UV radiation, electron beam radiation, or addition of a crosslinking agent.

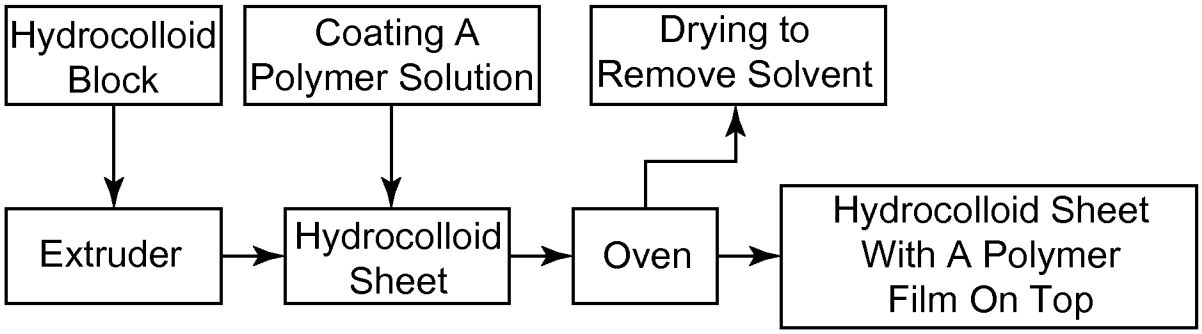
Hydrocolloid Block
Coating A Polymer Solution
Drying to Remove Solvent
Extruder
Hydrocolloid Sheet
Oven
Hydrocolloid Sheet With A Polymer Film On Top

Fig. 1

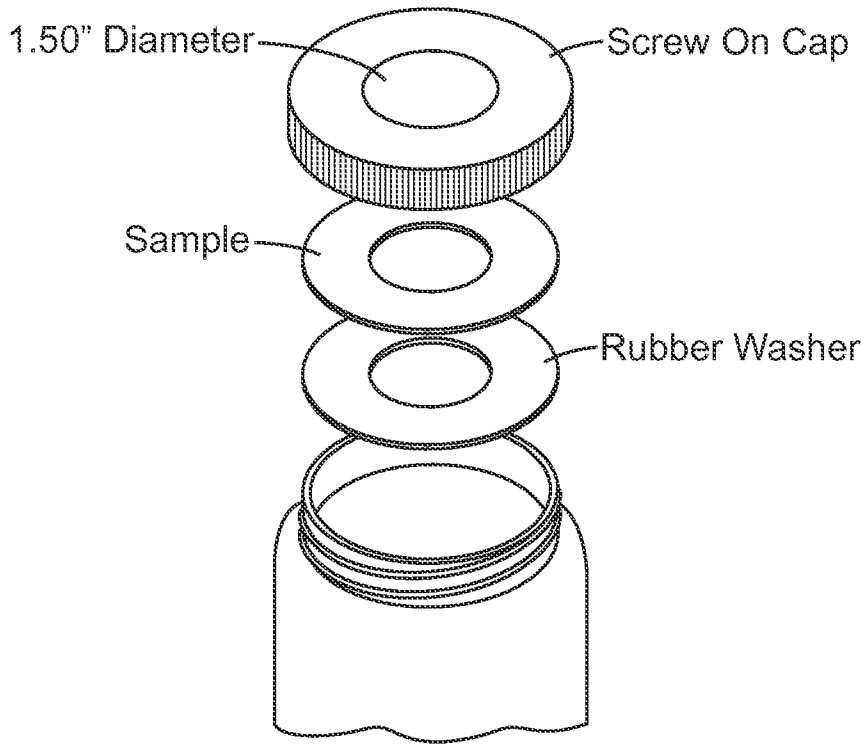
1.50" Diameter
Screw On Cap
Sample
Rubber Washer

Fig. 2

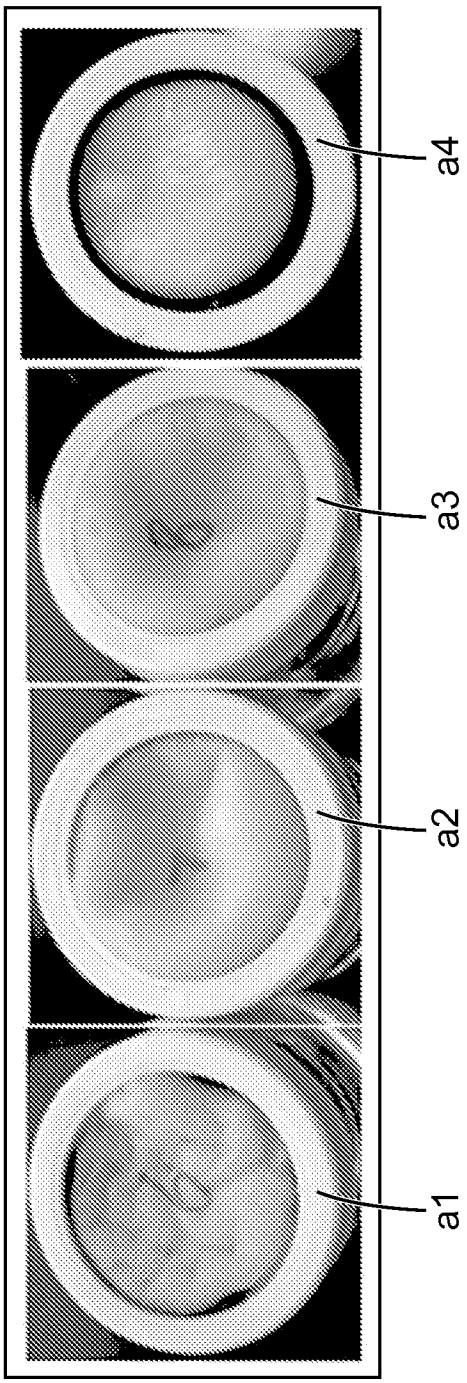

Fig. 3a

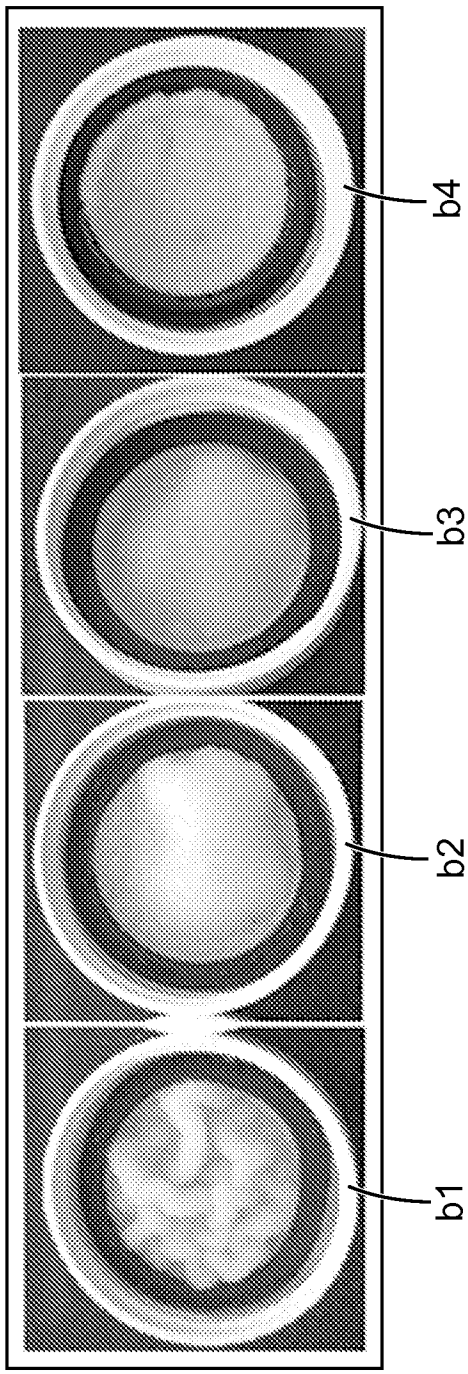

Fig. 3b

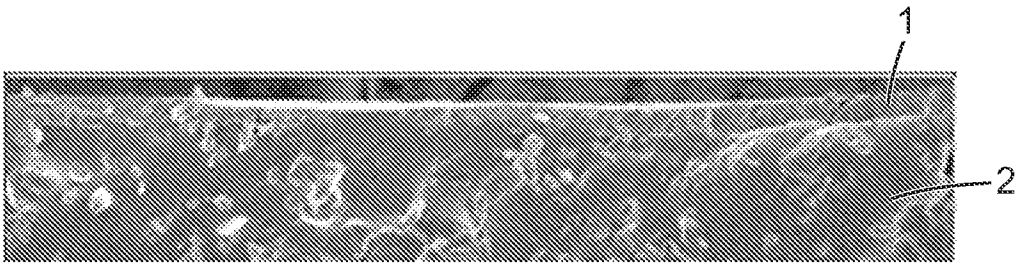

Fig. 4a

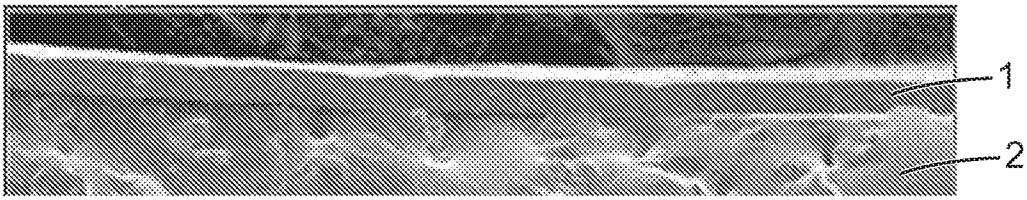

Fig. 4b