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(54) **Titre :** COMPOSITION DE SILICONE COMPATIBLE AVEC LA PEAU
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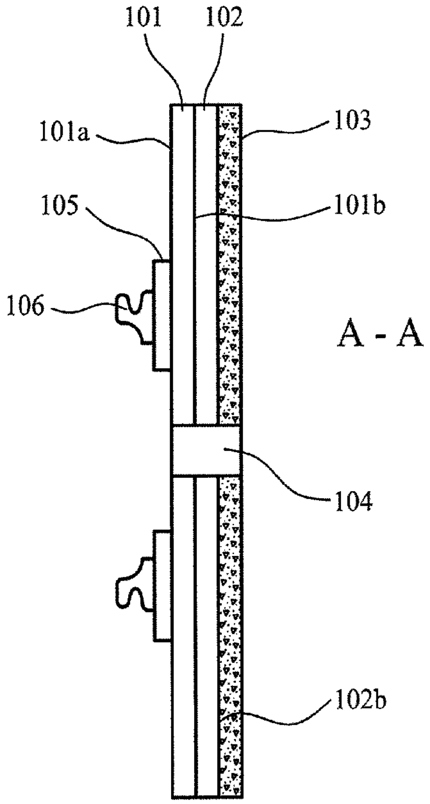

(57) **Abrégé/Abstract:**
A skin compatible component attachable to mammalian skin. The component is formed as a silicone matrix comprising a polyorganosiloxane derived silicone polymer and a moisture control particulate and permeability modifying polymer distributed within the polymer network. The skin compatible component may be utilised as an ostomy wafer or flange to secure an ostomy appliance to the skin and in particular peri-stomal skin.

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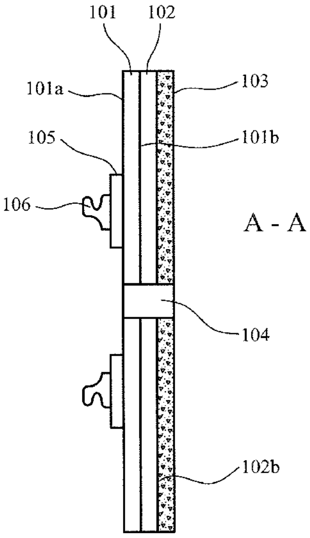

FIG. 2

(57) **Abstract:** A skin compatible component attachable to mammalian skin. The component is formed as a silicone matrix comprising a polyorganosiloxane derived silicone polymer and a moisture control particulate and permeability modifying polymer distributed within the polymer network. The skin compatible component may be utilised as an ostomy wafer or flange to secure an ostomy appliance to the skin and in particular peri-stomal skin.

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# Skin Compatible Silicone Composition

## Field of invention

The present invention relates to an adhesive skin compatible composition and in particular, although not exclusively, to a skin adhesive component suitable for coupling an ostomy appliance to the peristomal skin region of an ostomate.

## Background art

An ostomate having a colostomy, ileostomy or urostomy requires a collection receptacle, such as a bag, be secured around the stoma being an artificial opening exiting through a person's abdomen. Typically, the collection bag is secured to the peristomal skin by means of an adhesive disc that may be required to be changed several times daily. As frequent removal of the adhesive disc causes irritation and damage to the skin, ostomy couplings have been developed in an attempt to increase comfort and improve wellbeing. Ostomy coupling arrangements commonly referred to as '*two-piece*' systems comprise a first coupling part fitted with a ostomy bag to receive stoma discharge and a second coupling part (releasably connectable with the first) provided on a base layer (or wafer) that may be adhered to the peristomal skin. Accordingly, the ostomy bag may be changed readily without having to detach the base layer from the skin. Many different types of coupling arrangements have been proposed to maximise seal strength and minimise undesirable discharge. Example two-piece ostomy bag systems are described in EP 0687166; EP 1959881; US 4,846,798; WO 93/18725 and EP 0334489.

However, as a person is required to wear an ostomy coupling continuously, both two-piece and one-piece coupling arrangements must be completely interchanged at regular periods due to moisture uptake when in contact with the skin that cause erosion and breakdown of the adhesive disc. As will be appreciated, degradation of the coupling wafer will compromise the sealing contact with the skin and hence is very undesirable. Conventionally, the adhesive discs of ostomy appliances comprise hydrocolloids that possess high absorption capacity and are generally benign when in contact with the skin for long periods. However, conventional discs are disadvantageous due to their erosion and breakdown with moisture uptake. Additionally, such systems fail to provide a correct balance of the demands for a secure seal to be maintained around the stoma during attachment whilst allowing the coupling to be detached readily without causing skin irritation. Given the regularity with which even two-piece arrangement require changing, the compromise between adhesion and release is not found via such conventional systems. Accordingly, what is required is a coupling component or arrangement contactable with the skin that facilitates patient security and comfort and maximises wear time.

## Summary of the Invention

It is an objective of the present invention to provide an adhesive skin contactable component and in particular, although not exclusively, an ostomy coupling component or arrangement configured to exhibit enhanced moisture management when mounted in position at the peristomal skin. It is a specific objective to provide a skin attachable component being in particular an ostomy appliance adhesive disc that is resistant to erosion and breakdown in response to moisture so as to extend patient wear time.

The objectives are achieved, by providing a biocompatible silicone based layer, disc or pad positionable in contact with the skin, peri-stomal skin and/or peristomal skin that comprises moisture management characteristics including moisture absorption and breathability. In particular the objectives are achieved via a silicone adhesive layer being a room temperature vulcanisation silicone (RTV silicone) formed from a catalytic, addition cured, two-part system.

The objectives are further achieved specifically via a synthetic silicone gel based adhesive layer formed from a polyorganosiloxane derived silicone polymer network comprising Si-O and Si-C bonds in which a moisture control particulate and a permeability modifying polymer are distributed within the Si network. The present polyorganosiloxane derived material incorporating the superabsorbent (moisture absorbing) particulate and modifying polymer exhibits the desired flexibility and appropriate free internal volume to achieve the desired water vapour transmission rate (WVTR) from the skin and through the matrix and also to accommodate the superabsorbent particulate and the water vapour transmission adjusting polymer additive. Such moisture management: including breathability, absorption, transmission and capillary action provides an ostomy wafer or gasket that may be worn comfortably by an ostomate for significantly longer time periods than is currently available for conventional systems. These moisture-vapour control additives, in the form of particulates and polymers, are selected to achieve the desired substrate adhesion at the skin with low or very low risk of maceration. The synergistic behaviour of the silicone polymer, the absorbent particulate and polymer additive provides the desired balance between moisture absorption (into the silicone matrix) and moisture-vapour transmission without being detrimental to adhesion and the cohesive properties of the wafer. The present base layer is particularly adapted to provide optimised transmission of moisture vapour through the main body and across the full surface area of contact between the wafer and the skin. The present hydrophilic silicone based wafer accordingly maintains its shape profile, does not erode in the presence of moisture and is gas, vapour and moisture permeable.

The term '*particulate*' used herein encompasses polymer species having a micron or submicron size suitable for dispersion within a larger polymer network, gel phase and in particular a silicone polymer network (adapted or suitable to accommodate a superabsorbent particulate (SAP)). The moisture control SAP may be a hydrocolloid including a naturally occurring semi-synthetic or synthetic hydrocolloid.

Naturally-occurring hydrocolloids suitable for use with the subject invention include polysaccharides and cellulosic materials. Example polysaccharide hydrocolloids may comprise plant extracts including gums including in particular xanthan gum or pectin. Example cellulosic materials may comprise cellulose; carboxymethyl cellulose; carboxymethyl β-glucan; cross-linked sodium carboxymethyl cellulose; sodium carboxymethyl cellulose; methylcellulose; hydroxyethylcellulose and hydroxypropyl cellulose.

Semi-synthetic hydrocolloids may comprise starch or cellulose, such as starch-acrylonitrile graft copolymer; a starch polyacrylate salt, and sulfuric acid, vinyl sulfonate, methacrylic acid, vinyl alcohol, vinyl chloride copolymers; guar gums, esterified uronic acid containing polymers such as hyaluronates and alginates, hyaluronate polyvinyl alcohol blends; chitosans formed from partial or complete deacetylation of chitin and/or depolymerisation.

Synthetic hydrocolloids suitable for use with the subject invention may comprise polyvinyl pyrrolidone; carboxyvinyl polymers and polyethylene oxide polymers; polymers of methyl vinyl ether and maleic acid and derivatives; polyvinyl alcohol, high molecular weight polyethylene glycols and polypropylene glycols; or polyethylene oxides.

Preferably, the moisture control SAP comprises sodium polyacrylate. Such a particulate has been found to be compatible with the as-formed addition cured silicone matrix and to absorb moisture released form the skin so as to swell appropriately without destroying the cohesive strength of the matrix hence the skin layer covering. Additionally, a sodium polyacrylate SAP contributes to providing the desired WVTR across the adhesive layer and facilitates the desired wicking action. In particular preferred sodium polyacrylate particulates have excellent water absorption property of the order of 350g/g $H_2O$ and 55g/g 0.9% NaCl. Additionally, such particulates be may configured with a ‘fine’ particle size selected such that a surface area/volume ratio is optimised to maximise the rate of moisture absorption. By way of example, a spherical sodium polyacrylate SAP having a nominal radius of 20 μm has a surface area to volume ratio five times that of an alternative non-sodium polyacrylate particle of nominal radius of 100μm. Additionally, sodium polyacrylate comprises a pH 6-7 and therefore specific/additional neutralisation is not required.

The term '*permeability modifying polymer*' used herein encompasses polymers to affect the hydrophilicity and/or hydrophobicity of the present silicone based skin compatible component and in particular to achieve a desired moisture and vapour permeability/transmission through the silicone polymer matrix. The permeability modifying polymer may be a single polymer or two or more polymer combinations having desired and predetermined molecular weight and size that, in turn, affect the moisture-vapour transmission through the silicone matrix. The polymer additive works synergistically with the superabsorbent particulates to control moisture and vapour flow through the silicone matrix so that the matrix does not swell or absorb water to an undesired extent typically associated with conventional hydrocolloids.

It is preferred that the permeability modifying polymers comprise domains being hydrophilic and domains being hydrophobic that provide an entropic resistance to a perfect dissolution so as to encourage water permeability without becoming absorbent.

According to a first aspect of the present invention there is provided a skin compatible component attachable to mammalian skin comprising: a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride (Si-H) containing crosslinker, in the presence of a metal catalyst; and a superabsorbent particulate distributed within the polymer network configured to absorb moisture from the skin; and a permeability modifying polymer distributed within the polymer network.

Preferably, the superabsorbent particulate has an average particle size of less than 150 μm.

Preferably, the peel adhesion of the present component under standard test conditions according to standard ISO 29862 (standard LTM-01: Self-adhesive tapes – Determination of peel adhesion properties - 180 Degree Peel from Stainless Steel Plate at a constant rate extension of 300mm/min) is in a range 0.2 to 3.0 N/25 mm, 0.5 to 3.0 N/25 0.8 to 3.0 N/25 mm, 1.5 to 3.0 N/25 mm, 1.8 to 3.0 N/25 mm, 2.0 to 3.0 N/25 mm or 2.0 to 4.0 N/25 mm.

In particular, the present silicone adhesive component when incorporated as part of a multicomponent laminate assembly according to the subject invention preferably comprises a peel adhesion, according to ISO 29862 (25 mm strip stainless steel substrate) of 0.2 to 0.8 N or 0.4 to 0.6 N. This is to be contrasted with conventional hydrocolloid skin contactable components that typically comprise a higher peel adhesion of the order of 6 to 9 N (ISO 29862).

Preferably, a component according to the subject invention comprises an adhesive tack in a range 2 to 12 N, 2 to 10 N, 3 to 10 N, 4 to 10 N, 5 to 10 N, 6 to 10 N or 6 to 8 N according to (standard LTM-013: Adhesive tack test – force required to pull a 12 mm diameter stainless steel compression plate at 90° angle from the surface of an adhesive at a constant rate extension of 50 mm/minute).

The present skin compatible component via the polyorganosiloxane derived silicone polymer exhibits high elasticity and low shear strength. The elastic nature of the present silicone adhesive layer provides a coupling assembly configured to retain its shape when stretched below its break point when allowed to relax. The present silicone based components is formed as a silicone gel adhesive composition that also provides a balance of elastic and viscoelastic properties so as to achieve good adhesion of medical appliances to the skin whilst being readily peelable or removable from the skin when desired. Due to the moisture absorption and the moisture vapour transmission rate across the silicone layer, the subject invention provides a device, coupling or appliance attachable to the skin that maintains and promotes skin health. The selection of the particulate described herein and silicone polymer act together to achieve the desired chemical, physical and mechanical properties so as to provide a skin compatible component that does not degrade, erode or breakdown with the uptake of moisture. Accordingly, a skin contactable coupling is provided with considerably longer skin wear times relative to conventional devices.

The vulcanised silicone polymer is obtained by reacting an alkenyl-substituted polydiorganosiloxane, preferably a polydimethylsiloxane having silicon-bonded vinyl, allyl or hexenyl groups, and an organosiloxane containing silicon-bonded hydrogen atom and a catalyst for the reaction of the SiH groups with the Si-alkenyl (SiVi) groups, such as a platinum metal or its compounds or its complexes thereof. The ratio of SiVi:SiH can be 10:1 to 1:10. Preferred ratio of SiVi:SiH is 1:1. Altering the ratio of the reacting silicones from 1:1 ratio can change the adhesive properties of the layer. If a firmer, lower tack gel is required, the SiH component is higher than SiVi, and if a softer layer with higher tack is required, the SiVi component may be higher than SiH. The silicone compositions may be cured at ambient temperatures, but curing times can be reduced by exposure to elevated temperatures, from about 40° C to about 150° C. Non-limiting examples of such silicone polymer precursors include Soft Skin Adhesives SSA MG-7-1010, SSA 7-9900, 7-9950 from Dow Corning Corporation, Silpuran® 2114, 2117, 2122, 2130, 2140, 2142 and combinations thereof, SilGel® 612 from Wacker Chemicals. Hydrophilic group containing silicones, according to the present disclosure, may contain polar groups such as acid, amido, amino, sulfonyl, carboxyl, phosphate, phosphonate, etc., on the polydimethylsiloxane backbone. These groups could be present in an ionic form.

The moisture control particulate having an average particle size of less than 150 μm provides a '*fine*' particle distribution within the polymer network. This is advantageous to provide the moisture management characteristic of the subject invention and in particular to achieve a capillary action moisture transport through the silicone polymer layer such that moisture (water) is readily transported across the silicone polymer layer. Accordingly, the present silicone polymer via the desired particle size of the moisture control particulate is configured to absorb and release moisture when in contact with the skin as the skin compatible component is worn by a patient for example at the peristomal skin. As will be appreciated, the surface area to volume ratio is an important factor in determining the active surface area for absorption of moisture from the skin in that for any given shape of particle, the surface area to volume ratio is inversely proportional to particle size. The present particulate size when incorporated within a polyorganosiloxane derived silicone matrix has been found to act synergistically to achieve the desired performance of the skin compatible component with regard to adhesion, release, absorption and moisture vapour transmission rate. This is achieved in part as the resulting network, formed from the vulcanisation of the two-part system, comprises the desired cross linkage density and open micro-structure that entraps the particulate whilst allowing the particulate to swell in use without destroying the cohesiveness of the silicone layer covering.

A skin compatible component according to the subject invention comprises an optimised water vapour transmission rate so as to provide a component configured to balance transepidermal water loss (TEWL) from the skin with the water vapour transmission rates of the skin compatible component (covering the skin). This is achieved in part by the sodium polyacrylate SAP as detailed herein having the preferred particle size and at the preferred concentration within the mix. According to one aspect, the water vapour transmission rate (WVTR) of the present component may be in a range 100 to 500 $g/m^2.24h$; 150 to 400 $g/m^2.24h$; 200 to 300 $g/m^2.24h$ or 220 to 280 $g/m^2.24h$ using an upright cup method with a layer thickness of 635 μm to 750 μm. Such water vapour transmission rates may be correlated with a layer thickness of the silicone adhesive component having a thickness of 250μm to 1,000 μm; 500 μm to 1,000 μm; or 635 μm to 1,000 μm.

The silicone part of the network formed from the addition curing of a first part and a second part is advantageous to provide the desired physical and mechanical properties of the resulting cured component. In particular, via the choice of the first and second part components the degree of crosslinking may be controlled so as to provide the desired network micro-structure to appropriately entrap the superabsorbent moisture control SAP as immobilised particles within the network. Additionally, the two-part addition cured composition provides the desired viscoelastic properties, adhesive tack, adhesive peel, moisture absorption, cohesive strength and WVTR. As will be appreciated, at least some of these characteristics may be considered contrary with regard to the attachment to mammalian skin and the present component and method of manufacture provides a balance of these considerations so as to optimise the component for moisture management at the skin.

Accordingly, the present component exhibits enhanced wear times relative to conventional hydrocolloid based components whilst providing the desired adhesion (adhesive tack) and adhesive peel so as to avoid problems of skin maceration and '*stripping*' on release. Additionally, the cohesive strength of the component is optimised via the two-part addition curing adhesive so as to maintain the integrity of the adhesive skin covering in response to moisture absorption/swelling of the skin covering for extended continuous wear times in excess of 70 hours and up to or beyond 400 hours. In particular, the two-part addition cured component provides a desired WVTR that is configured specifically to complement the skin TEWL. In particular, the present two-part addition cured system may be considered advantageous over conventional one-part pressure sensitive adhesives (PSAs) that do not comprise the same crosslinking density and cohesive strength.

Preferably, the superabsorbent particulate comprises an average particle size in the range 10 to 40 μm, 15 to 35 μm or 20 to 30 μm. Preferably, the superabsorbent particulate is distributed within the polymer network at a concentration in the range 5 to 45 wt%, 10 to 40 wt%, 15 to 35 wt% or 20 to 30 wt%. The particle size according to the subject invention is advantageous to achieve the desired rate and speed of moisture absorption from the skin. Additionally, such a configuration provides the required rate of moisture transmission across the adhesive layer due to wicking. In particular, a volume of moisture absorbed from the skin is appropriately transported across the silicone adhesive layer (and away from the skin) to avoid skin maceration, undesirable moisture welling and hence lifting/peeling of the silicone layer in use. The particle size also provides homogeneity and uniform distribution of the superabsorbent particulate (SAP) within the silicone matrix that enhances the cohesive strength. In one aspect, the superabsorbent SAP and preferably the sodium polyacrylate (SAP) may comprise an absorption of 350 $g.g^{-1}$ (deionised water) or 55 $g.g^{-1}$ (0.9 weight% by volume of saline solution).

Preferably, an organosilicone resin is included in the first or second part prior to addition curing. Preferably, the organosilicone resin is an MQ resin. The organosilicone resin and in particular the MQ resin is advantageous to provide the desired balance between adhesive tack and peel/release characteristics. Optionally, the MQ resin has at least one reactive group such as hydroxyl, alkoxy, hydride, or vinyl functionalities. The silicone resin may comprise a cage-like oligosiloxane with the general formula of $R_nSiX_mO_y$, where R is a non-reactive substituent, usually Me or Ph, and X is a functional group H, OH, vinyl, or OR. These groups are further condensed to enhance or contribute to the resulting crosslinked polysiloxane network. Non-limiting examples of commercially available MQ resins are MQ-RESIN POWDER 803 TF from Wacker Chemical Corporation; VQM-135, VQM-146, HQM-105, HQM-107, SQO-299, and SQD-255 from Gelest Inc., Prosil 9932, MQOH-7 from SiVance, LLC.

Preferably, a cohesive strengthening agent is including in the first part or the second part prior to addition curing. Optionally, the cohesive strengthening agent comprises any one or a combination of the set of: fumed silica, fumed alumina, colloidal silica, nanoclays, silicates, silane treated organic polymers, polymeric metal oxides, and non-polymeric metal oxides. Preferably, the cohesive strengthening agent comprises fumed silica. The strengthening agent contributes to the cohesive strength characteristics of the component and assists with maintaining integrity of the silicone adhesive layer in response to moisture absorption by the SAP and the moisture-vapour transition management of the permeability modifying polymer additive. In particular, the cohesive strengthening agent is further advantageous to minimise and eliminate layer residue once released from the skin. The strengthening agent is further advantageous to facilitate distribution of the SAP and the permeability modifying polymer additive within the matrix. Furthermore, the cohesive strengthening agent further improves the integrity and cohesive strength at the perimeter edge of the silicone layer so as to reduce '*edge bleed*'. Non-limiting examples of cohesive strengthening agents of the present disclosure include silica, which could be fumed or precipitated silica such as AEROSIL® and SIPERNAT® grades, respectively, from Evonik Industries. The silica powders could be hydrophilic or hydrophobic, such as AEROSIL® 300, AEROSIL® 255, AEROSIL® R 812, AEROSIL® R 812 S, SIPERNAT® 120, SIPERNAT® 218, etc. Other non-limiting examples of cohesive strengthening agents include fumed alumina, colloidal silica, nanoclays, silicates, silane treated organic polymers, polymeric metal oxides, non-polymeric metal oxides, and the like.

Preferably the permeability modifying polymer is adapted to alter the moisture management characteristics of the silicone based material by increasing the moisture vapour transmission alternatively characterised by the transepidermal water loss (TEWL) of the silicone material when the material is wet, dry or in between these two extremes as may be typically encountered during use when the material is positioned in contact with the skin and worn for extend periods (typically over one hour).

Preferably, the permeability modifying polymer is a water soluble polymer. Preferably, such polymer comprises hydrophobic domains and may comprise hydrophilic domains. Such domains contribute to the moisture management characteristics of the polymer.

Preferably, the permeability modifying polymer is not chemically bonded to the silicone polymer network. The polymer additive may be configured to sit between the strands of the silicone matrix forming a semi-interpenetrating polymer network to modulate the permeability of the bulk material. Accordingly, the moisture management polymer additive and the superabsorbent particulate may be considered identifiable and separate species relative to the interconnected silicone network that results from the catalyzed cross linking of the vinyl functionalized silane polymer and the silicon hydride containing cross linker.

Optionally, the permeability modifying polymer is any one of a combination of the following set of: polyvinyl alcohol (PVA), polyvinyl chloride (PVC), a poloxamer, a polyester, polyvinyl pyrrolidone (PVP). Optionally, the permeability modifying polymer may comprise poly(2-vinylpyridine); poly-acrylonitrile; polymethylmethacrylate(PMMA); or polybutadiene.

Preferably, the permeability modifying polymer comprises a poloxamer and optionally poloxamer 407 (alternatively termed poloxamer F127 ($EO_{100}PO_{65}EO_{100}$)) or poloxamer P123 ($EO_{19}PO_{69}EO_{19}$). Such poloxamers within the silicone matrix may form micelle structures. Such structures may comprise a core of PPO blocks and corona of PEO blocks. Optionally, the permeability modifying polymer is a polyester that comprises polycaprolactone (PCL), being optionally polycaprolactone diol; polyhydroxialkanoate (PHA); polyglycolide or plolyglycolic acid (PGA); polylactic acid (PLA); polyhydroxybutyrate (PHB); polyethylene adipate (PEA); polybutylene succinate (PBS); poly(3-hydroxybutyrate-co-3-hyrdoxyvalerate) (PHBV); polyethylene terephthalate (PBT); polytrimethylene terephthalate (PTT); polyethylene naphthalate (PEN); polybutylene succinate adipate (PBSA); polybutylene adipate (PBA); or polybutylene adipate terephthalate (PBAT).

Optionally, the permeability modifying polymer is PVA and comprises a molecular weight in a range 50,000 to 150,000; 60,000 to 120,000; 70,000 to 100,000; or 80,000 to 90,000.

Optionally, the permeability modifying polymer is PVP and comprises a molecular weight in a range 5,000 to 50,000; 10,000 to 40,000; 15,000 to 35,000; or 20,000 to 30,000.

Optionally, the permeability modifying polymer is PVC and comprises a molecular weight in a range 50,000 to 100,000 or 70,000 to 90,000.

Optionally, the permeability modifying polymer is PCL and comprises a molecular weight in a range 200 to 1,000; 200 to 800; 300 to 700; 400 to 700; 500 to 600; or 500 to 580.

The polymer molecular weights mentioned herein may be the number average molar mass (mn), mass average molar mass (mw), or the Z average molar mass (mz).

Optionally, the permeability modifying polymer is included within the skin compatible component at 0.1 to 5.0 wt%; 0.1 to 4.0 wt%; 0.1 to 3.0 wt%; 0.1 to 2.0 wt%; 0.2 to 1.8 wt%; 0.2 to 1.6 wt%; 0.2 to 1.2 wt%; 0.2 to 1.0 wt%; 0.2 to 0.8 wt%; 0.2 to 0.4 wt%; or 0.6 to 1.0 wt%. Optionally, the permeability modifying polymer may be included at 5.0 to 10.0 wt%. However, it is preferred that the permeability modifying polymer is included as a minor additive (less than 5 wt%) to adjust the moisture management characteristics. Such relatively low concentrations of the permeability modifying polymer are not detrimental to the other desired physical and mechanical characteristics of the material including in particular the viscoelastic properties, adhesive tack, adhesive peel, cohesive strength etc. In particular, it is important the polymer additive does not increase adhesive tack to an extent that would otherwise provide skin maceration and '*stripping*' on release.

According to a second aspect of the present invention there is provided an ostomy coupling comprising: a moisture and gas permeable support layer; an ostomy appliance or ostomy appliance connection provided at a first surface of the support layer; and a skin compatible component attached to a second surface of the support layer.

Optionally, the polyurethane layer comprises a thickness in the range 0.02 to 0.08 mm. The polyurethane layer may comprise a moisture vapour transmission rate of greater than 10,000 or 15,000 or an MVTR in the range 15,000 to 20,000 or 1700 to 18,000 or an MVTR of 17,500 $g.m^{-2}.24h^{-1}$ using an inverted cup method (as described herein). The polyurethane layer may comprise a tensile strength of 40 to 50 MPa and an elongation of 500%. Preferably, the support layer may be regarded as porous so as to allow transmission of moisture, water vapour and gas through the support layer and hence provide a fully '*breathable*' skin adhesive covering pad or disc.

Preferably, the silicone matrix layer is protected by a release liner configured for quick and convenient removal prior to mounting of the silicone layer in direct contact with the skin. Optionally, the release liner may comprise a thermoformable material, a fluoropolymer treated film, LDPE, polyethylene terephthalate (PET) or a polycarbonate based material.

Optionally, the support layer comprises any one or a combination of the set of: a breathable silicone layer; a polyethylene block amide polymer; a polytetrafluoroethylene polymer; an acrylic latex polymer; or a polyolefin based layer. Preferably, the support layer comprises polyurethane.

Optionally, the ostomy appliance comprises a bag or pouch attached to the support layer directly or via an intermediate layer. Optionally, the intermediate layer may comprise polyethylene or may comprise any one or a combination of the set of: a polyester disc; a non-woven polyester; a non-woven polyethylene; a polypropylene disc; a non-woven polypropylene. Optionally, the intermediate layer may be a single or double sided adhesive annular ring capable of adhering to one or more components forming part of the assembly. Such a configuration would avoid a requirement to weld the intermediate layer to other components for example via RF or sonic welding.

Preferably, the ostomy appliance connection comprise a first part of a two-part bag or pouch connection assembly (as are known within the art) in which a second part of the connection assembly is mounted at a bag or pouch, the first part and the second part capable of releasable mating to detachably secure the bag or pouch to the coupling.

Optionally, the coupling comprises an opening extending through the support layer and the skin compatible component. Optionally, the ostomy appliance comprises a bag or pouch attached to the support layer directly or via an intermediate layer. Optionally, the intermediate layer comprises polyethylene. Optionally, the intermediate layer comprises any one or a combination of the set of: a polyester disc; a polyester gauze; a polyethylene gauze; a polypropylene disc; a polypropylene gauze. Such materials may be configured as single or doubled sided adhesive rings or pads capable of adhering to other components within the assembly.

Optionally, the ostomy appliance connection comprises a first part of a bag or pouch connection assembly in which a second part of the connection assembly is mounted at a bag or pouch, the first part and the second part capable of releasable mating to detachably secure the bag or pouch to the coupling.

To further enhance the moisture management and vapour transmission of the present coupling (and in turn avoid skin maceration and the like) the coupling may further comprise an additional skin contact layer positioned at the skin facing side of the skin compatible component. Preferably, the additional skin contact layer is a silicone based adhesive component extending over selected regions of a skin facing side or surface of the skin compatible component.

Preferably the additional skin contact layer is formed non-continuously over the skin compatible component so as to provide exposed areas of the skin compatible component that are devoid of the additional skin contact layer. Accordingly, with the material in contact with the skin, adhesion is provided firstly via the additional skin contact layer and secondly by the exposed surface area regions of the skin compatible component (not covered by the additional skin contact layer). Such a configuration improves the skin friendliness of the present material during use by enhancing the breathability of the silicone layer and allowing moisture to be readily removed from the skin without causing irritation.

Preferably, the additional skin contact layer is a silicone adhesive layer provided on the skin facing surface of the skin compatible component and intended to be positioned in contact with the skin to adhere to the skin, the additional skin contact layer being non-continuous over the skin facing surface of the skin compatible component such that areas of said surface are not concealed by the additional skin contact layer, said areas capable of positioning directly adjacent and/or in contact with the skin.

Optionally, the additional skin contact layer comprises a two-part catalysed, silicone elastomer. Optionally, the additional skin contact layer may comprise a composite of a plurality of different silicones and/or silicone based materials.

Optionally, the additional skin contact layer comprises the same material as the skin compatible component. Optionally, the additional skin contact layer comprises the same material as the skin compatible component but without the superabsorbent particulate. That is, the additional skin contact layer may comprise a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker, in the presence of a metal catalyst.

Optionally, the additional skin contact layer may be formed as lines or dots on the skin facing surface of the skin compatible component. In such a configuration, the skin compatible component may be regarded as a substrate. Where the additional skin contact layer is formed as individual dots, flecks or marks, the pattern created by these dots may be uniform across the skin facing surface of the substrate. Alternatively, the pattern may change over the substrate surface and the material may comprise different patterns at different regions over the substrate. Where the additional skin contact layer comprises lines or ridges extending over the substrate, these lines may extend in different directions where the spacing between the lines or ridges is the same or variable across the substrate surface. Optionally, the lines may create a square, rectangular or circular grid pattern. Optionally, the lines or ridges are distributed at the skin facing surface to create geometric shapes. Preferably, the additional skin contact layer is bonded to the substrate and takes the form of concentric circles extending around a central aperture extending through the substrate and/or the multilayer coupling.

According to a third aspect of the present invention there is provided a method of manufacturing a skin compatible component attachable to mammalian skin comprising: mixing a first part including a vinyl functionalized siloxane polymer with a second part including a silicon hydride (Si-H) containing crosslinker to form a mix; incorporating within the mix a superabsorbent particulate; incorporating within the mix a permeability modifying polymer; and curing the mix via a metal catalyst; wherein the superabsorbent particulate and the permeability modifying polymer are distributed within the resulting addition cured silicone polymer network.

Preferably, the first part or the second part further comprise an organosilicone resin. Preferably, the organosilicone resin comprises an MQ resin. Preferably, the organosilicone resin is a silicic acid, trimethylsilylester with silanol functionality. Preferably, the organosilicone resin is included in the mix at 0.2 to 10 wt%, 1 to 9 wt%, 2 to 8 wt%; 3 to 7 wt% or 4 to 6 wt%.

Preferably, the first or second part further comprises a cohesive strengthening agent. Preferably, the cohesive strengthening agent comprises fumed silica. Preferably, the fumed silica comprises a bulk density of 0.4 to 0.8 g/mL and a Brunauer-Emmitt-Teller (BET) specific surface area of 200 to 320 $mm^2/g$, 210 to 310 $mm^2/g$, 230 to 300 $mm^2/g$ or

230 to 290 mm$^2$/g. Preferably, the fumed silica is included within the mix at 0.2 to 2.0 wt%, 0.3 to 2.0 wt%, 0.5 to 1.5 wt% or 0.8 to 1.2 wt%.

Preferably, the superabsorbent particulate and preferably the sodium polyacrylate particulate comprises a particle size in a range 10 to 40 µm, 15 to 35 µm or 20 to 30 µm. Preferably, the superabsorbent particulate and preferably the sodium polyacrylate particulate is included within the mix at 5 to 45 wt%, 15 to 35 wt%, 20 to 30 wt% or 22 to 28 wt%.

Preferably, the vinyl functionalized siloxane polymer comprises a vinyl-terminated polydimethylsiloxane (PDMS). Preferably, the silicon hydride (Si-H) containing crosslinker comprises a hydride-terminated polydimethylsiloxane (PDMS).

Preferably, the vinyl-terminated polydimethylsiloxane (PDMS) comprises a first vinyl-terminated PDMS having a mass average of 10,000 to 20,000 and a second vinyl-terminated PDMS having a mass average of 70, 000 to 100,000. These mass average polymer distributions provide a resulting cured silicone matrix with the desired crosslinking density, porosity and cohesive strength to withstand the swelling of the layer during use and not to degrade which would otherwise result in failure of the covering.

Preferably, the vinyl functionalized siloxane polymer comprises a vinyl-terminated polydimethylsiloxane (PDMS) and the silicon hydride (Si-H) containing crosslinker comprises a hydride-terminated polydimethylsiloxane (PDMS).

Preferably, the first part is included within the mix at 30 to 40 wt% or 31 to 35 wt% and the second part is included within the mix at 30 to 40 wt% or 33 to 37 wt%.

Preferably, the superabsorbent particulate is included within the mix at 20 to 30 wt% or 22 to 28 wt%. Preferably, an MQ resin included in the mix at 2 to 8 wt% or 3 to 7 wt%. Preferably, fumed silica included within the mix at 0.2 to 2.0 wt%, 0.5 to 1.5 wt% or 0.8 to 1.2 wt%.

Preferably, the first part further comprises an organoplatinum catalyst and a silicone-vinyl containing inhibitor and the second part further comprises a vinyl-terminated polydimethylsiloxane (PDMS) and preferrably the superabsorbant particulate is sodium polyacrylate.

According to a fourth aspect of the present invention there is provided a skin compatible component attachable to mammalian skin.

According to a further aspect of the present invention there is provided a method of manufacturing an ostomy coupling comprising: applying a polyorganosiloxane derived silicone polymer mix to a moisture and gas permeable support layer; curing the organosiloxane derived silicone polymer at the support layer; attaching an ostomy appliance or ostomy appliance connection to a part of the support layer.

## Brief description of drawings

A specific implementation of the present invention will now be described, by way of example only, and with reference to the accompanying drawings in which:

Figure 1 is a plan view of an ostomy appliance coupling according to a specific implementation of the present invention;

Figure 2 is a cross sectional view through A-A of the ostomy coupling of figure 1;

Figure 3 is a plan view of an ostomy appliance coupling according to a further specific implementation of the present invention;

Figure 4 is a cross sectional view through B-B of the ostomy coupling of figure 3;

Figure 5A is a cross section through an ostomy coupling of the type of figure 1 and 2 according to a further embodiment having an additional adhesive layer at the skin contact face of the coupling that is discontinuous over the skin contact face;

Figure 5B is a cross section through an ostomy coupling of the type of figure 3 and 4 according to a further embodiment having an additional adhesive layer at the skin contact face of the coupling that is discontinuous over the skin contact face.

## Detailed description of preferred embodiment of the invention

A silicone polymer based skin compatible component according to the subject invention is particularly adapted for placement on mammalian skin to have a desired adhesion characteristic so as to remain in secure attachment to the skin (as the skin moves) when worn by a person whilst having the desired release characteristics to allow the component to be removed from the skin. The silicone based component is accordingly a hydrophilic humectant configured to absorb moisture into the silicone matrix without detriment to adhesion, cohesive properties and peel characteristics. The subject component enables transmission of moisture vapour through the body of the matrix so as to allow the skin (in contact with the component) to breathe. Accordingly, the present silicone wafer, due in part, to the composition of the silicone matrix and additives (in the form of SAPs and moisture management polymer species) is advantageous to balance moisture absorption with moisture and water vapour transmission to avoid skin maceration.

The subject invention is particularly suitable to secure medical appliances or devices to mammalian skin and in particular peri-stomal skin and peristomal skin. Such devices may include but are not limited to catheters, intravenous feeding lines, securement devices, wound dressings, therapeutic devices, drug delivery devices, ostomy appliances and the like.

The subject invention will now be described with reference to a specific implementation in which the moisture absorbing particulate silicone based matrix forms a component part of an ostomy appliance coupling referred to as a '*base plate*' of a '*two-piece*' system.

However, the subject invention may be utilised within a '*one-piece*' ostomy appliance as will be appreciated. Referring to figures 1 and 2, a coupling assembly 100 comprises a moisture and water vapour permeable '***breathable***' substrate layer 101 having a first surface 101a and a second surface 101b. According to the specific implementation, layer 101 comprises a polyurethane having a moisture vapour transmission rate (MVTR) of greater than 700 $g.m^{-2}.24h^{-1}$ and preferably a MVTR of 700 to 950 $g.m^{-2}.24h^{-1}$ using an upright cup method. According to the specific implementation, the polyurethane layer has an MVTR of 875 $g.m^{-2}.24h^{-1}$ using an upright cup method. A polyethylene disc 105 is secured to substrate first layer 101a via RF or ultrasonic welding or using an adhesive. The polyethylene disc 105 provides a mount for a first part 106 of an ostomy appliance coupling mechanism to releasably engage with a second part of the coupling mechanism provided at an ostomy appliance, in particular an ostomy bag. Coupling first part 106 is preferably formed as an annular flange capable of frictionally integrating and releasably locking with the second part of the coupling mechanism so as to provide a sealed coupling between an ostomy bag (not shown) and the coupling arrangement 100 of figures 1 and 2. According to the specific implementation, the first part 106 of the coupling mechanism (being any form of connection as will be appreciated and recognised by those skilled in the art) is secured to layer 105 via RF or ultrasonic welding. However, according to further implementations layer 105 may be a double sided adhesive tape (annular ring) suitable to bond to surface 101a and component part 106.

A silicone polymer matrix layer 102 is applied to substrate second surface 101b by coating second surface 101b with a homogenous liquid phase non-cured silicone polymer mix that is then cured (i.e., room temperature vulcanised) in position at substrate 101. The silicone polymer layer 102 is coated and protected by a release liner 103. Release liner 103 according to the specific implementation comprises a fluoropolymer treated film. Liner 103 is releasably positioned over the silicone layer 102 and is removed prior to mounting of the coupling assembly 100 onto the skin of a person via mating contact with the silicone polymer layer surface 102b.

Layers 101, 102 are annular having a generally circular or oval disc shape profile. A through bore 104 extends through layers 101, 102 and is dimensioned to comprise an internal diameter slightly greater than an external diameter of a stoma with layers 101 and 102 having a generally circular outer perimeter 107 so that the present coupling may be regarded as a generally annular disc. Accordingly, coupling assembly 100 is configured for mounting in close fitting and sealing contact with the peristomal skin as is conventional with both one-piece and two-piece stoma appliances.

According to the specific implementation, polyurethane substrate 101 comprises a layer thickness of 20 μm to 50 μm and the silicone polymer layer 102 comprises a thickness of approximately 400 to 900 μm. Polyethylene disc105 comprises a thickness of 80 to 150 μm and release liner 103 comprises a thickness in the range 40 to 150 μm.

Figures 2 to 4 illustrate an ostomy appliance coupling according to a second embodiment being a variation of the embodiment described with reference to figures 1 to 2. According to the further embodiment, the breathable polyurethane layer 101, the silicone polymer layer 102 and the release liner 103 are as described for the first embodiment. However, in place of the polyethylene disc 105 a weldable non-woven layer 200 is secured to polyurethane first surface 101a. Non-woven layer 200 is also annular and comprises internal and external diameters corresponding to layers 101, 102 so as to form a welded extension of layers 101, 102 in the plane B-B. According to the specific implementation, a thickness of the non-woven layer 200 is 30 to 600 μm. The first part 106 of the appliance coupling mechanism is then welded to non-woven layer 200 via RF or ultrasonic welding.

A specific embodiment of the polymer layer 102 will now be described by reference to the following examples. Polymer layer 102 is formed as a silicone polymer matrix derived from the addition curing of a first part and a second part. Supplementary components are included within the first and/or second parts to achieve the desired physical and mechanical characteristics of the resulting silicone network in addition to achieving the desired balance of viscoelastic properties, adhesive tack, adhesive peel, moisture absorption, cohesive strength and water vapour transmission rate (WVTR).

The two-part components may be cured/vulcanised at ambient temperatures (or elevated temperatures including in the range 30° to 150°). Curing/vulcanisation times may vary depending upon relative concentrations and components within the first and second parts.

*Examples*

| **Component** | **Concentration %w/w** | **Purpose** | **Supplier** |
|---|---|---|---|
| Silicone Silpuran® 2122 part A | 31-35 | Part A silicone + catalyst | Wacker Chemie |
| Silicone Silpuran® 2122 part B | 33-37 | Part B silicone cross-linker | Wacker Chemie |
| Aquakeep™ Sodium Polyacrylate | 22-27 | Moisture control, moisture transmission through silicone adhesive network | Sumitomo Seika Chemicals Co., Ltd |
| MQ Silanol Resin | 3-7 | Tackifier | Milliken™ SiVance LLC |
| Aerosil™ (Fumed silica) | 0.5-1.5 | Cohesive strengthener | Evonik Industries AG |
| Permeability modifying polymer | 0.1-2.0 | Modify permeability | Sigma Oldridge Polymer Laboratories |

*Table 1 – starting materials of liquid phase non-cured mix*

The following examples were prepared using different permeability modifying polymers forming part of the starting materials identified in table 1. The permeability modifying polymer is preferably included in the part B silicone composition but may be included in part A.

| **Example** | **Permeability Modifying Polymer** | **Concentration** |
|---|---|---|
| 1 | Poly(2-vinylpyridine); mw/mn 1.15 | 0.8 |
| 2 | Poly(vinylalcohol); mw 86,000 | 0.8 |
| 3 | Poly(vinylchloride); mw 83,500 | 0.8 |
| 4 | Poly(vinylpyrrolidone); mw 24,000 | 0.8 |
| 5 | Poly(vinylpyrrolidone); mw 10,000 | 0.8 |
| 6 | Poloxamer F127 ($EO_{100}PO_{65}EO_{100}$) | 0.8 |
| 7 | Polycaprolacetone diol mw 530 | 0.4 |
| 8 | Poly(vinylpyrrolidone) mw 24,000 | 0.4 |
| 9 (Comparative) | no permeability modifying polymer | - |
| 10 (Comparative) | Hydrocolloid MED 5094 H | - |

*Table 2 – example permeability modifying polymers incorporated within the starting materials of table 1 where mw is molecular weight.*

*Manufacture Method*

The Silpuran® based parts A and B were weighed and the other components, of the examples added at their respective concentrations. The components were mixed thoroughly to ensure complete dispersal of the components and in particular the SAPs (i.e., sodium polyacrylate) and permeability modifying polymer within the mix. This is advantageous to provide a complete heterogeneous dispersion of the components and in particular the complete distribution of the SAPs and permeability modifying polymer within the silicone matrix. In particular, thorough mixing reduces the risk of the SAPs and/or the permeability modifying polymer agglomerating which would be detrimental to the moisture-vapour management (absorption and transmission) characteristics across the full surface area of the skin compatible component. The above components were mixed using a medium to low shear mixing technique either by centrifusion or dispersal at 1000 to 3000 rpm. Surplus heat energy was removed by active cooling. Vacuum phase mixing was used as a final stage to provide a liquid phase non-cured silicone formulation. The laminate assembly 100 of figures 1 to 4 was manufactured by layering the liquid phase silicone formulation onto the polyurethane layer surface 101b followed by room temperate vulcanisation (RTV) under controlled conditions. The release liner 103, the polyethylene disc 105 and the coupling first part 106 was then attached to form the multi component assembly 100.

*TEWL Performance and Results*

The present silicone adhesive is advantageous to provide a '*soft*' atraumatic release from the skin so as to reduce the potential for skin stripping/damage. Additionally, the present adhesive comprises the desired cohesive strength and tack adhesion so as to be maintained in position for extended wear times of the order of over 400 hours without degradation and loss of moisture absorption and transmission at the adhesive layer. The present invention provides a balance of wear performance characteristics for skin compatibility including in particular edge lift, adhesion during wear, adhesion on removal, moisture control, skin condition after wear, skin trauma on removal and skin residue on removal. The present silicone adhesive is advantageous so as to be capable of being worn continuously during low, modest and high physical activity levels and movement as a wearer engages in such physical activity. The present skin adhesive is further advantageous to satisfy other ergonomic factors such as comfort during wear and conformity to skin/body topography.

Transepidermal water loss (TEWL) or the equivalent moisture vapour transmission rate (MVTR) are well established techniques to determine water and vapour transmission across a material. These characteristics are particularly important for a material composition attached to the skin. In accordance with the subject invention, it is important that the present silicone material does not leach SAPs, monomers or polymers, adheres to the skin appreciably but not to a significant extent that would otherwise damage the skin on removal (i.e. skin peeling or skin stripping). The example silicone base materials were assessed to determine relative TEWL ratings in both a '*dry*' and a '*wet*' environment to understand how permeability of the present silicone materials would perform as a dressing applied to the skin that may be, between two extremes i.e., dry and wet. It is important that the present silicone based materials have a degree of permeability and a moisture vapour transmission without being excessively absorbent. The addition of the permeability modifying polymer therefore provides a means of controlling hydrophilicity and hydrophobicity of the material to improve/enhance permeability of the silicone layer without contributing significantly or enhancing significantly the absorbent characteristics of the material (as this may be controlled by variation of the concentration and/or type and configuration of the SAPs).

Without being bound by theory, it is believed that the present permeability modifying polymers (added in relatively small quantities) sits between the silicone matrix forming a semi-interpenetrating polymer network and thereby modulating the permeability of the bulk material. It is important that this additive should not be too hydrophilic as this will encourage the bulk material to swell and absorb moisture. Accordingly, the permeability modifying polymers were selected to comprise hydrophobic domains causing entropic resistance to perfect dissolution and encouraging water permeability without becoming absorbent.

TEWL testing was undertaken to determine the moisture vapour transmission across the silicone materials of examples 1 to 8 in addition to the comparative examples 9 and 10. Comparative 9 is a silicone material comprising the components of table A without a permeability modifying polymer and comparative 10 is the silicone material comprising the components of table A with addition of a hydrocolloid.

*Equipment*

A Heidolph Hei-Toeque 100 was used for high speed stirring of silicone resins. The draw down bar (1000 micron thickness) was used to spread the silica across a PU film. TEWL values were recorded on a Delfin Technologies Vapometer (Serial SWL5316) equipped with room sensor S/N RHD1236.

*Recording Sample TEWL*

Silicone matrix samples were prepared from the materials of tables 1 and 2 and the mix spread across a PU film and then incubated for 10 minutes and incubated at 100 °C. The water permeability of coatings was measured with a handheld device calibrated to measure the TEWL of skin and surfaces in relation to the ambient temperature and humidity. Coating measurements were not carried out in a specifically air-regulated room although in all cases the ambient temperature was 22-24 °C and the sample was heated to 32 °C to mimic the temperature at the skins surface. Room humidity varied from 40 to 49% and an anova comparison of the data found there was no significant correlation between the room humidity and the TEWL observed.

To measure the TEWL of adhesive materials it was not possible to directly connect the vapometer to the adhesive. Instead, to mimic the application of these in medical dressings, the TEWL was measured through a sandwich design with the adhesive contained between two barrier sheets. The upper PU Film to mimic the protective layer on the medical dressing and the lower to separate the adhesive from moisture sources. The lower barrier layer was tested with both PU film and Wattman filter paper, to compare different occlusive materials. Below the lower barrier layer a standard piece of tissue paper was used, either wet or dry, in an experimental design created to mimic the skin surface where a high moisture content is separated from the adhesive by a thin dermal barrier. Samples were incubated at 32 °C with a wet/dry tissue for 1 hour to ensure they were fully acclimatised to their environment, and the samples were measured immediately upon removal from the incubating oven. In most cases the TEWL was measured on 4 different points in each surface, and each material was repeated 4 times, giving us an n = 16 to determine sample variation. This experimental design also allowed us to compare the changing TEWL of the material in both dry and wet conditions – as it will be important for adhesives not to decrease their TEWL as the relative moisture level increases, as this kind of occlusive behaviour has identified as being detrimental to the wearer.

*Samples*

Small quantities of the permeability modifying polymer (0.8 %) were included in the mixture of table 1 for testing. Examples 7 and 8 were variations on examples 1 to 6 in that

0.4 w/w% of the permeability modifying polymer was added to the mixture of table 1 not 0.8 w/w%.

*Results*

The results of the TEWL testing are shown in table 3

| Example | | Dry TEWL | Wet TEWL | % change dry/wet | % change from original |
|---|---|---|---|---|---|
| 1 | Poly(2-vinylpyridine) mw/mn 1.15 | 7.09 | 8.5 | + 20 | + 33 |
| 2 | Poly(vinylalcohol) mw 86,000 | 10.32 | 11.82 | + 15 | + 93 |
| 3 | Poly(vinylchloride) mw 83,500 | 8.27 | 10.86 | + 31 | + 55 |
| 4 | Poly(vinylpyrrolidone) mw 24,000 | 9.61 | 12.46 | + 30 | + 80 |
| 5 | Poly(vinylpyrrolidone) mw 10,000 | 9.94 | 12 | + 21 | + 86 |
| 6 | Poloxamer F127 ($EO_{100}PO_{65}EO_{100}$) | 9.23 | 12.94 | + 40 | + 73 |
| 7 | Polycaprolacetone Diol mn 530 | 7.19 | 10.04 | + 40 | + 35 |
| 8 | Poly(vinylpyrrolidone) mw 24,000 | 5.71 | 8.44 | + 48 | + 7 |
| 9 | Without permeability modifying polymer | 5.34 | 7.53 | + 41 | 0 |
| 10 | MED 5094 H (Hydrocolloid) | 2.10 | 1.73 | - 17.6 | 0 |

*Table 3 – TEWL testing of examples 1 to 10 where mw is molecular weight.*

The results confirm that incorporating a permeability modifying polymer increases the transepidermal water loss as a measure of the moisture vapour transmission rate across the silicone matrix relative to a silicone material without a permeability modifying polymer (comparative example 9). The examples 1 to 8 all exhibit an increase in the moisture vapour transmission in both dry and wet conditions. As indicated, it is believed the silicone matrix permeability is modified due to the incorporation of the relatively small amounts of modifying polymer to change the bulk hydrophilicity of the material.

### *Further embodiments*

Further embodiments of the present invention are illustrated referring to figures 5A and 5B, with figure 5A being a variation of the embodiment of figure 1 and 2 and figures 5B being a variation of the embodiment of figure 3 and 4 with all embodiments comprising the silicone matrix with SAP and polymer additive according to any of examples 1 to 8 herein. According to both further embodiments, an additional skin contact layer 300 is adhered to and positioned at surface 102b of silicone polymer matrix layer 102. The additional skin contact layer 300 is preferably formed from the same material as layer 102. However, different materials may be used such as silicones or hydrocolloid based materials. In a preferred embodiment layer 300 comprises the silicone polymer matrix formed from the components of table 1 but without the SAP and the permeability modifying polymer.

The additional skin contact layer 300 may be regarded as an additional adhesive layer formed from narrow ridges that are discontinuous over surface 102b such that additional skin contact layer 300 does not coat completely the surface 102b and there is provided regions 301 that are devoid of additional skin contact layer 300 with regions 301 being exposed surface areas of the silicone polymer matrix layer 102.

According to embodiments of figure 5A the pattern of the additional skin contact layer 300 at surface 102b is a rectangular grid pattern or concentric circles formed by uniform ridges extending across surface 102b. The spaces between the ridges may be equal in the respective directions across surface 102b.

The embodiment of Figure 5B comprises the additional skin contact layer 300 formed as a regular repeating array of nodes or bumps. The bumps may be separated from one another by a regular or uniform discreet separation distance such that the skin contact surface 102b of the silicone polymer matrix layer 102 is exposed at spacings 301 between the bumps 300.

According to a specific embodiment the additional skin contact layer 300 at surface 102b is formed as a series of concentric circles extending radially between central bore 104 and outer perimeter 107. The concentric circles (or other polygonal (i.e., rectangular) or non-polygonal (i.e., oval) shapes) may be spaced apart from one another in the radial direction to be formed as discreet ridges separated by regions of exposed surface 102b. Such an embodiment is further beneficial to increase the strength and integrity of the moisture seal of the present coupling and reduce the risk of fluid leakage from under the coupling between the surface 102b and the skin.

Claims

1. A skin compatible component attachable to mammalian skin comprising:

a silicone polymer network derived from the addition curing of a first part including a vinyl functionalised siloxane polymer and a second part including a silicon hydride containing crosslinker, in the presence of a metal catalyst;

a superabsorbent particulate distributed within the polymer network configured to absorb moisture from the skin;

characterised by:

a permeability modifying polymer being a polyester distributed within the polymer network and having hydrophobic and hydrophilic domains.

2. The component as claimed in claim 1 wherein the superabsorbent particulate has an average particle size less than 150 μm.

3. The component as claimed in claim 1 wherein the superabsorbent particulate comprises an average particle size in the range 10 to 40 μm, 15 to 35 μm or 20 to 30 μm.

4. The component as claimed in claims 1 or 3 wherein the superabsorbent particulate is distributed within the polymer network at a concentration in the range 5 to 45 wt%, 10 to 40 wt%, 15 to 35 wt% or 20 to 30 wt%.

5. The component as claimed in any one of claims 1 to 4 wherein the superabsorbent particulate comprises any one or a combination of the set of:

- a naturally occurring hydrocolloid;
- a semi-synthetic hydrocolloid; or
- a synthetic hydrocolloid.

6. The component as claimed in any one of claims 1 to 5 wherein the superabsorbent particulate comprises any one or a combination of:

- a polysaccharide;
- a cellulose;

- hydroxyethylcellulose;
- carboxymethylcellulose; or
- hydroxypropylcellulose.

7. The component as claimed in any one of claims 1 to 6 wherein the superabsorbent particulate comprises any one or a combination of:
    - carboxymethyl β-glucan;
    - cross-linked sodium carboxymethyl cellulose;
    - sodium carboxymethyl cellulose; or
    - methylcellulose.

8. The component as claimed in any one of claims 1 to 4 wherein the superabsorbent particulate comprises sodium polyacrylate.

9. The component as claimed in any one of claims 1 to 8 wherein an organosilicone resin is included in the first or second part prior to addition curing.

10. The component as claimed in claim 9 wherein the organosilicone resin is an MQ resin.

11. The component as claimed in any one of claims 1 to 10 wherein a cohesive strengthening agent is included in the first part or the second part prior to addition curing.

12. The component as claimed in claim 11 wherein the cohesive strengthening agent comprises any one or a combination of the set of: fumed silica, fumed alumina, colloidal silica, nanoclays, silicates, silane treated organic polymers, polymeric metal oxides, and non-polymeric metal oxides.

13. The component as claimed in any one of claims 1 to 12 wherein the permeability modifying polymer is not chemically bonded to the silicone polymer network.

14. The component as claimed in any one of claims 1 to 13 wherein the polyester comprises polycaprolactone diol.

15. The component as claimed in any one of claims 1 to 14 comprising the permeability modifying polymer at 0.1 to 5.0 wt%; 0.1 to 4.0 wt%; 0.1 to 3.0 wt%; 0.1 to 2.0 wt%; 0.2 to 1.8 wt%; 0.2 to 1.6 wt%; 0.2 to 1.2 wt%; 0.2 to 1.0 wt%; 0.2 to 0.8 wt%; 0.2 to 0.4 wt%; or 0.6 to 1.0 wt%.

16. An ostomy coupling comprising:

a moisture and gas permeable support layer;

an ostomy appliance or ostomy appliance connection provided at a first surface of the support layer; and

a skin compatible component as claimed in any one of claims 1 to 15 attached to a second surface of the support layer.

17. The coupling as claimed in claim 16 wherein the support layer comprises polyurethane.

18. The coupling as claimed in claim 16 wherein the support layer comprises any one or a combination of the set of:

- a breathable silicone layer;
- a polyethylene block amide polymer;
- a polytetrafluoroethylene polymer;
- an acrylic latex polymer; or
- a polyolefin based layer.

19. The coupling as claimed in any one of claims 16 to 18 wherein the ostomy appliance comprises a bag or pouch attached to the support layer directly or via an intermediate layer.

20. The coupling as claimed in claim 19 wherein the intermediate layer comprises polyethylene.

21. The coupling as claimed in claim 20 wherein the intermediate layer comprises any one or a combination of the set of:

- a polyester disc;
- a polyester gauze;
- a polyethylene gauze;
- a polypropylene disc; or
- a polypropylene gauze.

22. The coupling as claimed in any one of claims 16 to 21 wherein the ostomy appliance connection comprises a first part of a bag or pouch connection assembly in which a second part of the connection assembly is mounted at a bag or pouch, the first part and the second part capable of releasable mating to detachably secure the bag or pouch to the coupling.

23. The coupling as claimed in any one of claims 16 to 22 wherein the coupling comprises an opening extending through the support layer and the skin compatible component.

24. The coupling as claimed in any one of claims 16 to 23 further comprising an additional skin contact layer positioned at a skin facing side of the skin compatible component, the additional skin contact layer being non-continuous over the skin facing side of the skin compatible component such that areas of the skin facing side of the skin compatible component are not concealed by a silicone adhesive layer, the areas capable of positioning directly adjacent and/or in contact with the skin.

25. The coupling as claimed in claim 24 wherein the additional skin contact layer is formed as lines, dots, flecks or marks on the skin facing side of the skin compatible component.

26. The coupling as claimed in claim 25 wherein the lines, dots, flecks or marks create a pattern on a skin facing surface of the skin compatible component that is substantially uniform across the skin facing surface.

27. The coupling as claimed in claim 26 wherein the additional skin contact layer is formed as lines or ridges extending over a skin facing surface of the skin compatible component.

28. The coupling as claimed in claim 27 wherein the lines or ridges are distributed at the skin facing surface to create geometric shapes.

29. The coupling as claimed in claim 27 wherein the lines or ridges are distributed at the skin facing surface to define concentric circles extending around a central aperture extending through the coupling.

30. A method of manufacturing a skin compatible component attachable to mammalian skin comprising:

mixing a first part including a vinyl functionalized siloxane polymer with a second part including a silicon hydride containing crosslinker to form a mix;

incorporating within the mix a superabsorbent particulate;

incorporating within the mix a permeability modifying polymer being a polyester having hydrophobic and hydrophilic domains; and

curing the mix via a metal catalyst;

wherein the superabsorbent particulate and the polyester are distributed within the resulting addition cured silicone polymer network.

31. The method as claimed in claim 30 wherein the superabsorbent particulate comprises any one or a combination of the set of:

- a naturally occurring hydrocolloid;
- a semi-synthetic hydrocolloid; or
- a synthetic hydrocolloid.

32. The method as claimed in claim 30 wherein the superabsorbent particulate comprises any one or a combination of:

- a polysaccharide;
- a cellulose;
- hydroxyethylcellulose;
- carboxymethylcellulose; or
- hydroxypropylcellulose.

33. The method as claimed in claim 30 wherein the superabsorbent particulate comprises any one or a combination of:

- carboxymethyl β-glucan;
- cross-linked sodium carboxymethyl cellulose;
- sodium carboxymethyl cellulose; or
- methylcellulose.

34. The method as claimed in claim 30 wherein the superabsorbent particulate comprises sodium polyacrylate.

35. The method as claimed in any one of claims 30 to 34 wherein the first part or the second part further comprise an organosilicone resin.

36. The method as claimed in claim 35 wherein the organosilicone resin comprises an MQ resin.

37. The method as claimed in claim 35 wherein the organosilicone resin is included in the mix at 0.2 to 10 wt%, 1 to 9 wt%, 2 to 8 wt%; 3 to 7 wt% or 4 to 6 wt%.

38. The method as claimed in any one of claims 30 to 37 wherein the first or second part further comprises a cohesive strengthening agent.

39. The method as claimed in claim 38 wherein the cohesive strengthening agent comprises fumed silica.

40. The method as claimed in claim 39 wherein the fumed silica comprises a bulk density of 0.4 to 0.8 g/mL and a Brunauer-Emmitt-Teller (BET) specific surface area of 200 to 320 $mm^2/g$, 210 to 310 $mm^2/g$, 230 to 300 $mm^2/g$ or 230 to 290 $mm^2/g$.

41. The method as claimed in any one of claims 39 to 40 wherein the fumed silica is included within the mix at 0.2 to 2.0 wt%, 0.3 to 2.0 wt%, 0.5 to 1.5 wt% or 0.8 to 1.2 wt%.

42. The method as claimed in any one of claims 30 to 41 wherein the superabsorbent particulate has a particle size in a range 10 to 40 µm, 15 to 35 µm or 20 to 30 µm.

43. The method as claimed in claim 42 wherein the superabsorbent particulate is included within the mix at 5 to 45 wt%, 15 to 35 wt% or 20 to 30 wt%.

44. The method as claimed in any one of claims 30 to 43 wherein the vinyl functionalized siloxane polymer comprises a vinyl-terminated polydimethylsiloxane (PDMS).

45. The method as claimed in any one of claims 30 to 43 wherein the silicon hydride containing crosslinker comprises a hydride-terminated polydimethylsiloxane (PDMS).

46. The method as claimed in claim 45 wherein the vinyl-terminated polydimethylsiloxane (PDMS) comprises a first vinyl-terminated PDMS having a mass average of 10,000 to 20,000 and a second vinyl-terminated PDMS having a mass average of 70, 000 to 100,000.

47. The method as claimed in claim 30 wherein the vinyl functionalized siloxane polymer comprises a vinyl-terminated polydimethylsiloxane (PDMS) and the silicon hydride containing crosslinker comprises a hydride-terminated polydimethylsiloxane (PDMS).

48. The method as claimed in claim 47 wherein the first part is included within the mix at 30 to 40 wt% or 31 to 35 wt% and the second part is included within the mix at 30 to 40 wt% or 33 to 37 wt%.

49. The method as claimed in claim 48 wherein the superabsorbent particulate is included within the mix at 20 to 30 wt% or 22 to 28 wt%.

50. The method as claimed in claim 49 further comprising an MQ resin included in the mix at 2 to 8 wt% or 3 to 7 wt%.

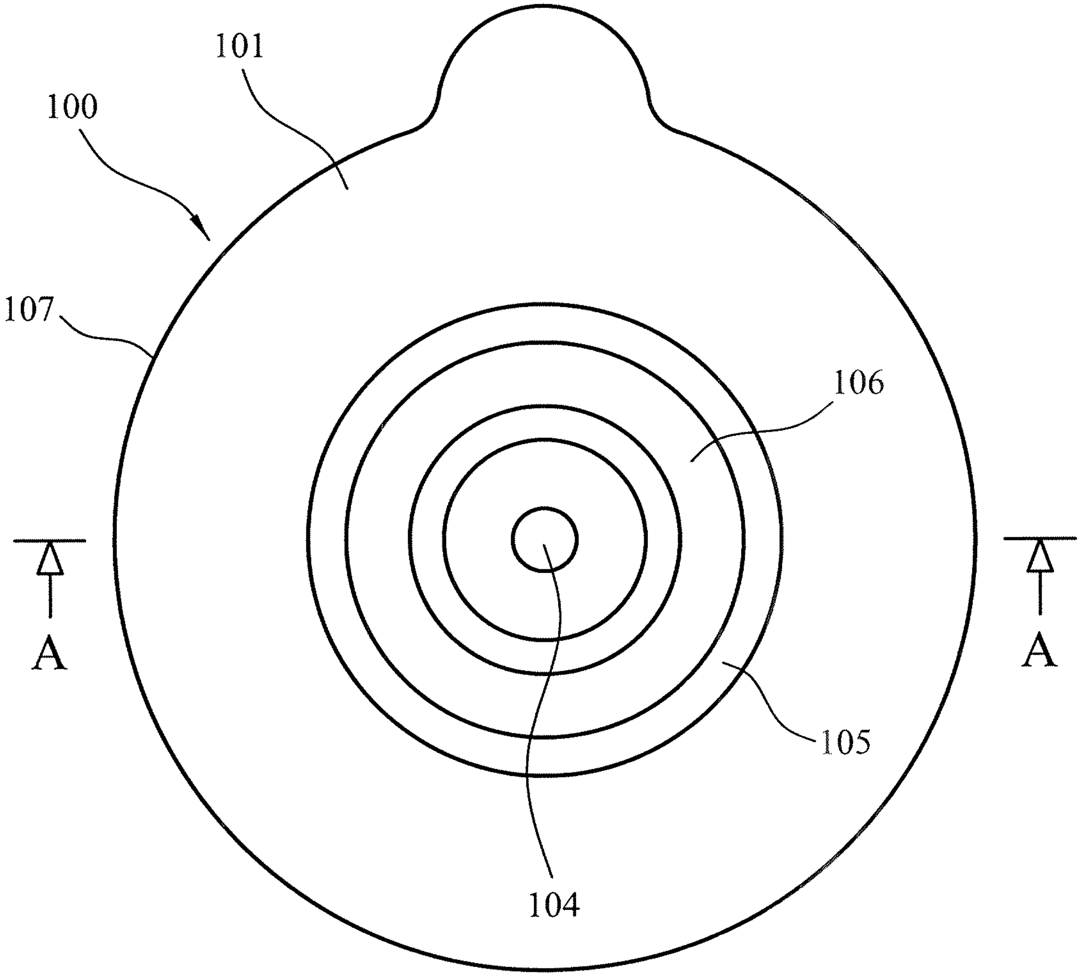
51. The method as claimed in claim 50 further comprising fumed silica included within the mix at 0.2 to 2.0 wt%, 0.5 to 1.5 wt% or 0.8 to 1.2 wt%.

52. The method as claimed in claim 51 wherein the first part further comprises an organoplatinum catalyst and a silicone-vinyl containing inhibitor and the second part further comprises a vinyl-terminated polydimethylsiloxane (PDMS) and wherein the superabsorbant particulate is sodium polyacrylate.

53. The method as claimed in any one of claims 30 to 52 wherein the polyester comprises polycaprolactone diol.

54. The method as claimed in claim 53 wherein the polycaprolactone diol is incorporated within the mix at 0.1 to 5.0 wt%; 0.1 to 4.0 wt%; 0.1 to 3.0 wt%; 0.1 to 2.0 wt%; 0.2 to 1.8 wt%; 0.2 to 1.6 wt%; 0.2 to 1.2 wt%; 0.2 to 1.0 wt%; 0.2 to 0.8 wt%; 0.2 to 0.4 wt%; or 0.6 to 1.0 wt%.

55. A skin compatible component attachable to mammalian skin manufactured by the method of any one of claims 30 to 54.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100
107
106
A
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105
104

FIG. 1

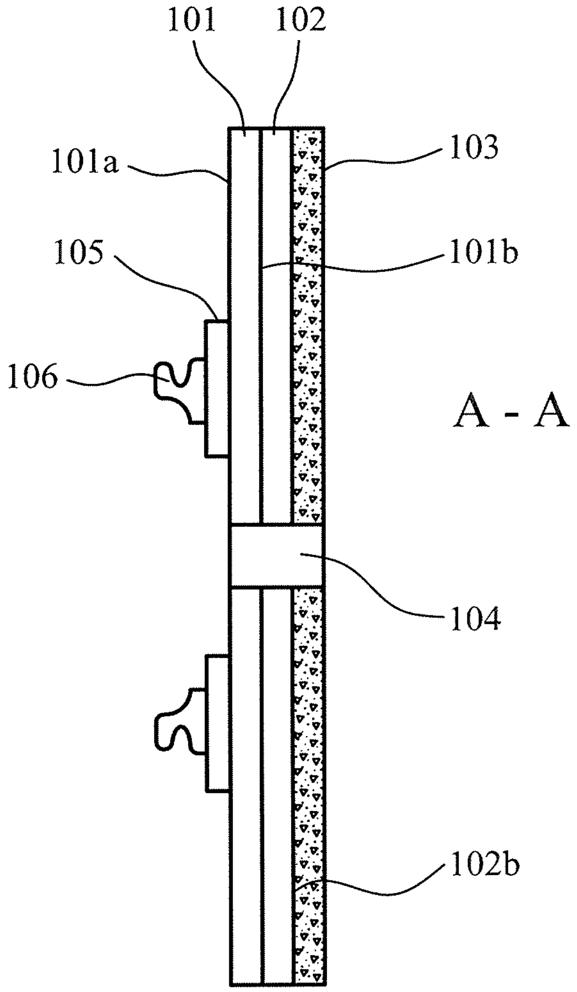
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FIG. 2

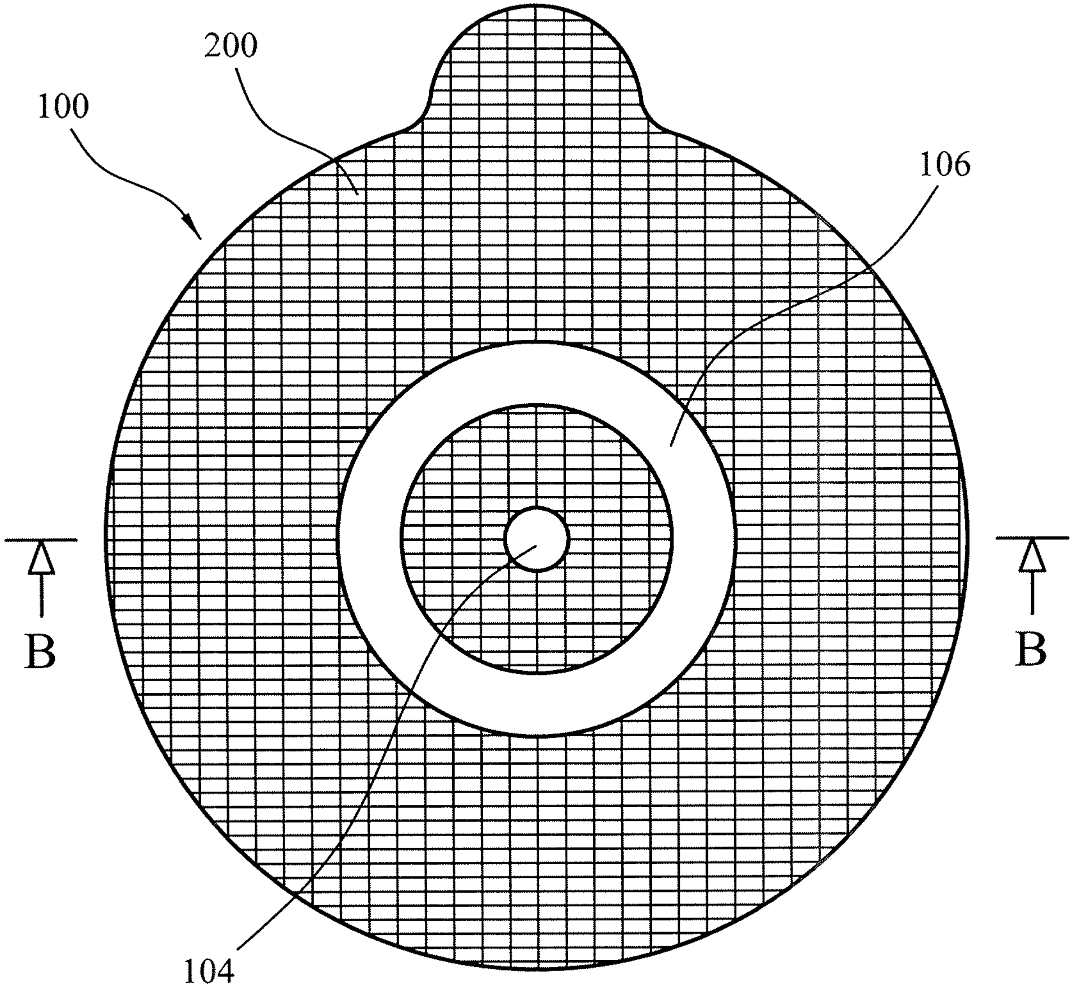


FIG. 3

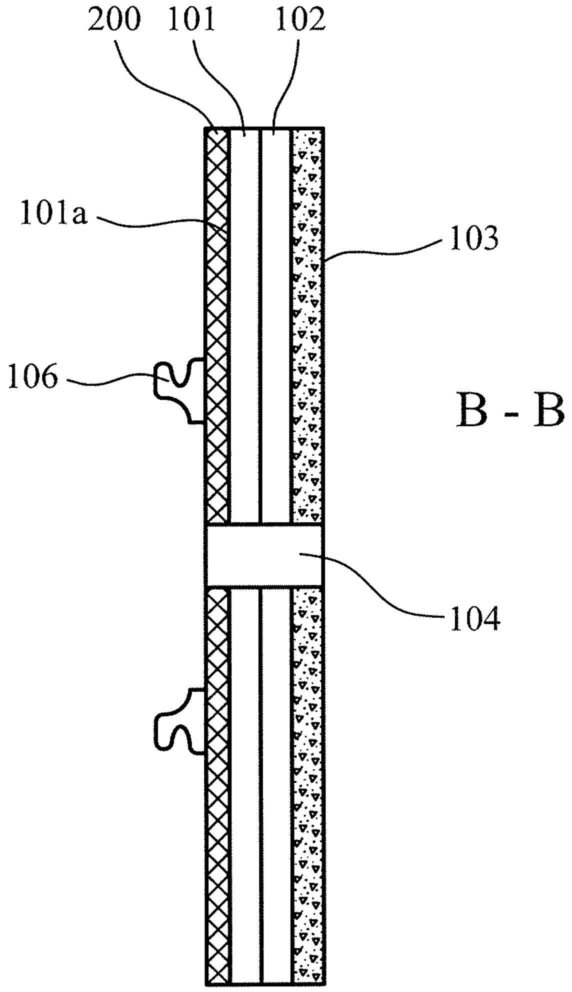
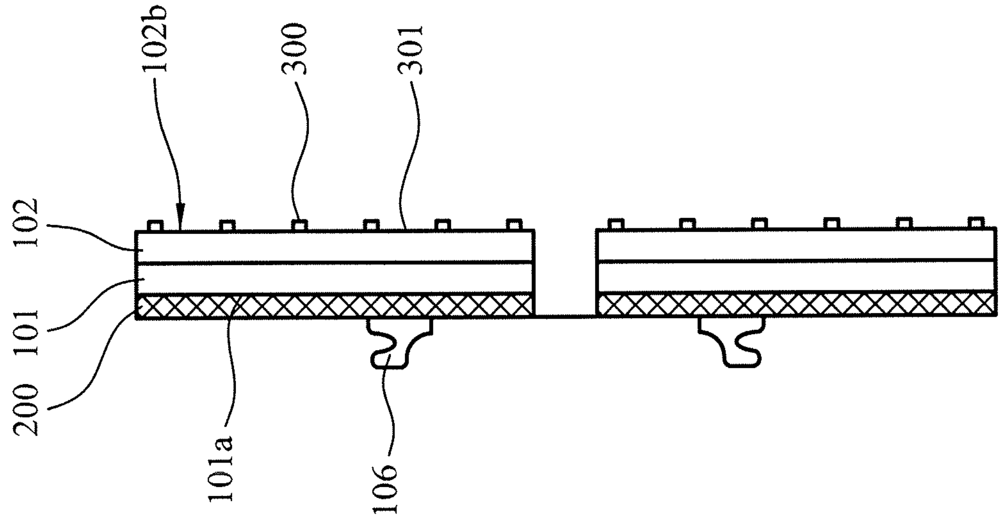


FIG. 4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106

FIG. 5A

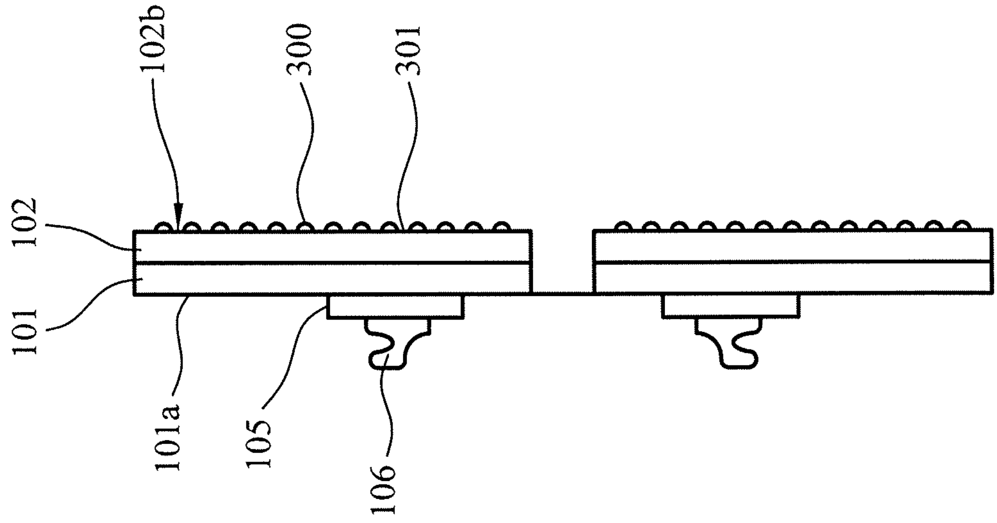
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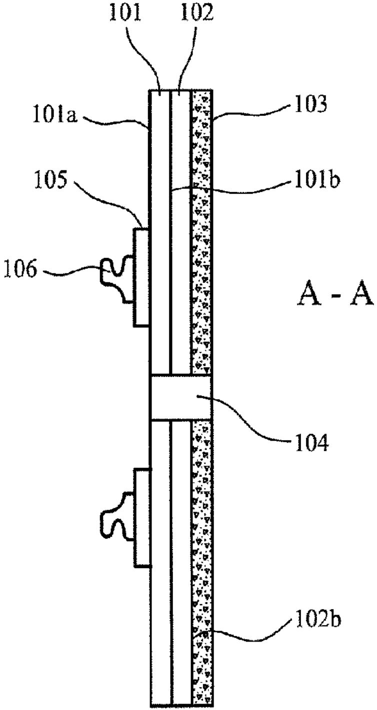
FIG. 5B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102
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102b