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DESCRIPTION

[0001] The present invention provides an elastomer based adhesive composition that is conformable and flexible. The composition is used as a dressing for the treatment of wounds. The advantages provided by the composition produce a wound dressing that is particularly suitable for the treatment of blisters, especially blisters on the foot, as well as corns and calluses. Notable features of the composition include translucent clarity, minimal antioxidant content, and the use of a non-polar oily extender, preferably mineral oil, that is substantially non-irritating to the skin.

[0002] Hydrocolloid adhesive compositions, as well as wound dressings and ostomy products formed from these adhesive compositions, have been known for many years. Typically, these compositions comprise a blend of a polymer matrix, such as a rubbery elastomer like polyisobutylene, in combination with one or more water-soluble or water-swellaable hydrocolloids, such as a dry powdered mixture of pectin, gelatin and carboxymethylcellulose. When included in a wound dressing or ostomy seal, the adhesive composition is usually coated on at least one surface of a water-insoluble film. See e.g., U.S. Pat. Nos. 3,980,084, 3,877,431, 3,532,679, and 3,339,546.

[0003] A major problem with many conventional hydrocolloid adhesive compositions is their susceptibility to breakdown upon exposure to wound exudate and body fluids (i.e. their lack of structural integrity after being hydrated). Another problem with many conventional hydrocolloid adhesive compositions is their initial lack of tack at room temperature. In many cases, the applied dressing must be warmed for several minutes by placing a hand tightly over the dressing before adequate adhesion is achieved. When the compositions are used as skin barriers, e.g., as a dressing for blisters, some absorption of fluid is desirable, but excessive swelling causes the composition to lose its moisture seal with the skin. Leakage occurs and the barrier must be replaced more often than is desirable. Such problems of conventional hydrocolloid adhesive compositions result in product failure.

[0004] A number of attempts have been made to improve the integrity of hydrocolloid adhesive compositions, and thereby improve the resulting wound dressings and ostomy products. U.S. Pat. No. 4,496,357 describes the incorporation of fumed silica into hydrocolloid compositions to control swelling. U.S. Pat. No. 4,551,490 describes a hydrocolloid adhesive composition of a homogenous blend of mineral oil, one or more polyisobutylenes alone or in combination with an elastomer such as butyl rubber, styrene radial or block copolymers, water-soluble hydrocolloid gums, water-swellaable cohesive strengthening agents, and a tackifier. Both the elastomer and water-swellaable agents are said to add cohesive strength to the composition, while the styrene radial or block copolymers are said to provide extensibility and recovery from modular strains associated with hydration. See also U.S. Pat. Nos. 4,204,540, 4,192,785, and 4,166,051.

[0005] U.S. Pat. No. 4,952,618 discloses a hydrocolloid adhesive composition formed from a rubbery elastomeric base having hydrocolloid particles, at least some of which are polycationic, dispersed therein. The composition is said to exhibit improved integrity attributable to the polycationic particles contained in the compositions, particularly when combined with anionic hydrocolloid particles, either alone, or further mixed with neutral hydrocolloid particles.

[0006] U.S. Pat. Nos. 4,538,603 and 4,728,442 disclose a granular wound packing that is covered with a separate occlusive dressing. In general, the occlusive dressing component can include a variety of hydrocolloid materials in combination with one or more pressure sensitive adhesive elastomers, such as polyisobutylene, and one or more thermoplastic elastomers, such as butyl rubber and styrene copolymers.

[0007] Another manner of addressing lack of structural integrity is to provide hydrocolloid adhesive compositions where one or more of the polymeric components are chemically or physically cross-linked. For example, U.S. Pat. No. 4,768,503 provides an adhesive composition of one or more chemically cross-linked hydrophilic polymers in combination with a support matrix of a high molecular weight hydrophobic polymer.

[0008] U.S. Pat. Nos. 4,477,325 and 4,738,257 describe incorporating into a hydrocolloid composition a mixture of a copolymer resin of ethylene and vinyl acetate (EVA). After mixing and moulding, the composition is subjected to ionizing radiation to form cross-linked polymer networks of the EVA or EVA with another cross-linkable resin. The cross-linked matrix is said to provide controlled swelling.

[0009] U.S. Pat. No. 4,231,369 discloses various hydrocolloid materials dispersed within a physically cross-linked gel-like phase. In general, the gel-like phase is comprised of elastomeric materials, such as A-B-A block copolymers, as well as certain ethylene/propylene copolymers, that are said to be physically cross-linked due to phase separation and reformation of the materials after melt processing. The use of elastomeric materials, such as A-B-A block copolymers, is also disclosed by U.S. Pat.

Nos. 4,367,732, 4,369,284, 4,867,748 and 5,508,334.

[0010] EP-A-0 591 898 discloses wound dressings representing the most relevant state of the art. The difference between the compositions of the present application and those of EP-A-0 591 898 is that the elastomer in the latter is a homopolymer, whereas the elastomer in the present application is a styrene-olefin-styrene block copolymer, in particular an S-I-S polymer such as Kraton™ D1107. For that reason it would not be obvious for a person skill in the art from the teachings of the EP publication to provide a wound dressing composition comprising a styrene-olefin-styrene block copolymer elastomer to obtain an improved wound dressing composition.

[0011] In general, a wound dressing composition of the present invention has desirable elastic, adhesive, absorptive and expansion properties as well as a high conformability. The present invention provides a gel-like wound dressing that is comfortable and flexible. The flexibility provides a composition that has the ability to conform to the curvature of body parts while retaining its adhesive properties. The high initial tack at room temperature provides for easy application. While the wound dressing of the present invention is suitable in general for the treatment of wounds that produce exudate, it is particularly suitable for treatment of blisters of the foot, as well as corns and calluses.

[0012] The composition consists of 10 to 35 weight percent of an elastomer, wherein the elastomer is a styrene-olefin-styrene block co-polymer, 20 to 60 weight percent of a hydrocolloid, 25 to 55 weight percent of a hydrocarbon resin tackifier, 2 to 60 weight percent of a non-polar oily extender, no more than 0.1 weight percent, preferably about 0.06 weight percent, of an antioxidant, based on the total weight of the composition.

[0013] The elastomer is 10 to 35 weight percent of the composition, based on the total weight of the composition. Preferably the elastomer is 11 to 18 weight percent of the composition, more preferably 12 to 16 weight percent of the composition. In one preferred embodiment, the elastomer is about 14 weight percent of the composition. In an alternative preferred embodiment, the elastomer is about 20 weight percent of the composition. In another preferred embodiment, the elastomer is about 30 weight percent of the composition.

[0014] Suitable elastomers are thermoplastic elastomers designed for use without vulcanization, such as styrene-olefin-styrene block copolymers. Preferred elastomers are block polymers having either a block of an unsaturated rubber, such as styrene-isoprene-styrene (S-I-S), styrene-butadiene-styrene (S-B-S) or a block of a saturated rubber, such as styrene-ethylene/butylene-styrene (S-E/B-S) or styrene-ethylene/propylene-styrene (S E/P-S). Preferably, the elastomer is a polymer chosen from the group consisting of Kraton™ D 1107 (Shell Chemicals), Kraton™ D 1100, Kraton™ D1102, Kraton™ 4000, Kraton™ G1600, Kraton™ G4600 and mixtures thereof. More preferably, the elastomer is a S-I-S polymer such as Kraton™ D1107 (Shell Chemicals).

[0015] The hydrocarbon resin tackifier is 25 to 55 weight percent of the composition, more preferably 30 to 50 weight percent of the composition. In one preferred embodiment, the hydrocarbon resin tackifier is 40 weight percent of the composition.

[0016] The hydrocarbon resin tackifier is suitably a hydrogenated tackifier resin that is compatible with styrene. Preferably the hydrocarbon resin tackifier has high initial tack, high clarity, is oxidation resistant and has no adhesive properties when wet. More preferably, the hydrocarbon resin tackifier is a low crystalline hydrogenated tackifier resin. Low crystalline hydrogenated resin tackifiers have been found to impart desirable and useful characteristics to the composition, making a more conformable and flexible wound dressing.

[0017] Suitable hydrocarbon resin tackifiers include Wingtack 95 (Goodyear), Wingtack 10 (Goodyear), Wingtack Plus (Goodyear), Wingtack Extra (Goodyear), Wingtack 86 (Goodyear), Foral AX (Hercules, Wilmington, DE), Foral 85 (Hercules, Wilmington, DE), Foral 105(Hercules, Wilmington, DE), Escorez 1000 (Exxon Chemical), Escorez 5300(Exxon Chemical), Escorez 40105 (Exxon Chemical). Preferred hydrogenated resin tackifiers are Wingtack 86 and Foral 85. Most preferred is Foral 85.

[0018] The composition generally includes a hydrocolloid, but in some specific embodiments the hydrocolloid can be omitted. Compositions formulated without hydrocolloid are especially suitable for applications such as holding breast prostheses or ostomy apparatus in place. Adhesives formulated without hydrocolloid have the advantage that they can be washed and reactivated.

[0019] In embodiments containing a hydrocolloid, the hydrocolloid is 20 to 60 weight percent of the composition, based on the total weight of the composition. Preferably the hydrocolloid is 25 to 55 weight percent of the composition, more preferably 30 to 50 weight percent of the composition. In one preferred embodiment, the hydrocolloid is 40 weight percent of the composition.

[0020] The hydrocolloid used in the present invention may be synthetically prepared or naturally occurring. Varieties of hydrocolloids within the scope of the present invention include synthetic polymers prepared from single or multiple monomers,

naturally occurring hydrophilic polymers or chemically modified naturally occurring hydrophilic polymers.

[0021] Non-limiting examples of such hydrocolloids include polyhydroxyalkyl acrylates and methacrylates, polyvinyl lactams, polyvinyl alcohols, polyoxyalkylenes, polyacrylamides, polyacrylic acid, polystyrene sulfonates, natural or synthetically modified polysaccharides, alginates, xanthan gums, guar gums, and cellulose.

[0022] When used in medical applications, the hydrocolloid must also be dermatologically acceptable and non-reactive with the skin of the patient or other components of the composition.

[0023] Suitable hydrocolloids include synthetic polymers that may be either linear or cross-linked. Non-limiting examples of synthetic hydrocolloids include polymers prepared from N-vinyl lactams, e.g. N-vinyl-2-pyrrolidone, 5-methyl-N-vinyl-2-pyrrolidone, 5-ethyl-N-vinyl-2-pyrrolidone, 3,3-dimethyl-N-vinyl-2-pyrrolidone, 3-methyl-N-vinyl-2-pyrrolidone, 3-ethyl-N-vinyl-2-pyrrolidone, 4-methyl-N-vinyl-2-pyrrolidone, 4-ethyl-N-vinyl-2-pyrrolidone, N-vinyl-2-valerolactam, and N-vinyl-2-caprolactam.

[0024] Other monomers useful to prepare a synthetic hydrocolloid include hydroxyalkyl acrylates and methacrylates, (such as 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, 2-hydroxypropyl acrylate, 2-hydroxypropyl methacrylate, 2,3-dihydroxypropyl methacrylate), acrylic acid, methacrylic acid and a tertiary aminomethacrylimide, (e.g. trimethylamino-methacrylimide), crotonic acid, and pyridine. Additional monomers useful to prepare a synthetic hydrocolloid include water soluble amides, (such as N-(hydroxymethyl)acrylamide and -methacrylamide, N-(3-hydroxypropyl)acrylamide, N-(2-hydroxyethyl) methacrylamide, N-(1,1-dimethyl-3-oxabutyl)acrylamide, N-[2-(dimethylamino)ethyl]acrylamide and -methacrylamide, N-[3-(dimethylamino)-2-hydroxypropyl]methacrylamide, and N-[1,1-dimethyl-2-(hydroxymethyl)-3-oxabutyl]acrylamide); water-soluble hydrazine derivatives, (such as trialkylamine methacrylimide, and dimethyl-(2-hydroxypropyl)amine methacrylimide); mono-olefinic sulfonic acids and their salts, (such as sodium ethylene sulfonate, sodium styrene sulfonate and 2-acrylamido-2-methylpropanesulfonic acid); and the following monomers containing nitrogen in the non-cyclic or cyclic backbone of the monomer: 1-vinyl-imidazole, 1-vinyl-indole, 2-vinyl imidazole, 4(5)-vinyl-imidazole, 2-vinyl-1-methyl-imidazole, 5-vinyl-pyrazoline, 3-methyl-5-isopropenyl-pyrazole, 5-methylene-hydantoin, 3-vinyl-2-oxazolidone, 3-methacrylyl-2-oxazolidone, 3-methacrylyl-5-methyl-2-oxazolidone, 3-vinyl-5-methyl-2-oxazolidone, 2- and 4-vinylpyridine, 5-vinyl-2-methyl-pyridine, 2-vinyl-pyridine-1-oxide, 3-isopropenyl-pyridine, 2- and 4-vinyl-piperidine, 2- and 4-vinyl-quinoline, 2,4-dimethyl-6-vinyl-s-triazine, and 4-acrylyl-morpholine.

[0025] Other hydrocolloidal polymers, either naturally occurring or synthetically prepared, are useful in the present invention. These materials include polyvinyl alcohol, polyoxyalkylenes, and such naturally occurring or synthetically modified hydrocolloidal materials as polysaccharides, gums, and modified celluloses.

[0026] Representative polysaccharides include starch, glycogen, hemicelluloses, pentosans, gelatin, celluloses, pectin, chitosan, and chitin. Representative gums include Arabic, Locust Bean, Guar, Agar, Carrageenan, Xanthan, Karaya, alginates, tragacanth, Ghatti, and Furcelleran gums. Representative modified celluloses include methyl cellulose, hydroxypropyl methyl cellulose, carboxymethylcellulose, and hydroxypropyl cellulose.

[0027] Cross-linking of the linear polymer chains of the hydrocolloid may be desired to improve cohesive properties of the gel dispersed in the pressure sensitive adhesive matrix. When such Cross-linking is desired for polymers made from vinyl monomers discussed above, a multi-ethylenically unsaturated compound with the ethylenic groups being vinyl, allyl, or methallyl groups bonded to nitrogen, oxygen or carbon atoms can be used.

[0028] Non-limiting examples of cross-linking agents for vinyl containing polymers include divinyl, diallyl, or dimethallyl esters (e.g. ethylene glycol dimethacrylate, divinyl succinate, divinyl adipate, divinyl maleate, divinyl oxalate, divinyl malonate, divinyl glutarate, diallyl itaconate, diallyl maleate, diallyl fumarate, diallyl diglycolate, diallyl oxalate, diallyl adipate, diallyl succinate, diallyl azelate, diallyl malonate, diallyl glutarate, dimethallyl maleate, dimethallyl oxalate, dimethallyl malonate, dimethallyl succinate, dimethallyl glutarate, and dimethallyl adipate); divinyl, diallyl or dimethallyl ethers (e.g. diethyleneglycol divinyl ether, butane diol divinyl ether, ethylene glycol divinyl ether, ethylene glycol diallyl ether, diethylene glycol diallyl ether, butane diol diallyl ether, ethylene glycol dimethallyl ether, diethylene glycol dimethallyl ether, and butane diol dimethallyl ether); divinyl, diallyl or dimethallyl amides including bis(N-vinyl lactams), (e.g., 3,3'-ethylene bis(N-vinyl-2-pyrrolidone) and methylene-bis-acrylamide); and divinyl, diallyl and dimethallyl ureas.

[0029] Preferable cross-linking agents include ethylene glycol dimethacrylate, methylene-bis-acrylamide, diallyl maleate, and 3,3'-ethylidene bis (N-vinyl-2-pyrrolidone). For n-vinyl lactams, the preferred cross-linking agents are diallyl maleate and 3,3'-ethylidene bis (N-vinyl-2-pyrrolidone). For acrylates and methacrylates, the preferred cross-linking agents are ethylene glycol dimethacrylate and methylene-bis-acrylamide.

[0030] Preferred hydrocolloids for the present invention include polysaccharides including starch, glycogen, hemicelluloses, pentosans, gelatin, celluloses, modified celluloses, pectin, chitosan, and chitin. Modified celluloses include methyl cellulose, hydroxypropyl methyl cellulose, carboxymethylcellulose, and hydroxypropyl cellulose. A most preferred hydrocolloid is a water soluble or swellable hydrocolloid chosen from the group consisting of polyvinyl alcohols, powdered pectin, gelatin, methyl cellulose, hydroxypropyl methyl cellulose, carboxymethylcellulose, hydroxypropyl cellulose and mixtures thereof. In one preferred embodiment, the hydrocolloid is carboxymethylcellulose (CMC).

[0031] The non-polar oily extender is 2 to 60 weight percent of the composition, based on the total weight of the composition. Oils that are polar plasticizers are not suitable for use as the oily extender of the composition of the present invention. Preferably the non-polar oily extender is 2 to 24 weight percent of the composition, more preferably 4 to 10 weight percent of the composition. In one preferred embodiment, the non-polar oily extender is 6 weight percent of the composition.

[0032] It must be noted that, as used in this specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a tackifier" includes a mixture of two or more such compounds, reference to "an oily extender" includes mixtures of two or more oily extenders, and the like.

Example 1: Formulation of Composition A

[0033] Composition A was formulated from the components listed in Table 1.

Table 1: Formulation of Composition A

Component	Weight Percent of Total
Elastomer (Kraton-D1107)	14
Non-polar oily extender (mineral oil)	6
Hydrocolloid (CMC)	40
Hydrocarbon resin tackifier (Foral-85)	40

[0034] The elastomer, hydrocarbon resin tackifier and non-polar oily extender were heated to 120 degrees Celsius with mixing to form a substantially homogeneous admixture. The hydrocolloid was added to the admixture and mixing was continued until the resulting composition was substantially homogeneous. The composition was formed as desired and allowed to cool. Typically the composition was formed into a slab about 0.5 mm thick that was covered on both upper and lower surfaces by release sheets. The properties of Composition A were compared to a commercially available product, Composition B (Compeed(R), Coloplast).

Example 2: Water absorption

[0035] The water absorption of the compositions was tested as follows. Disks about 2.54 cm (1 inch) in diameter were cut from slabs of Composition A, Composition B or sterilized Composition A using a circular die. The release sheets were removed and the mass in grams was determined by weighing the disk initially (m_0) and after 2, 24, 48 and 72 hours immersion in a 0.9 % NaCl saline solution. At each time T, the disk was removed from saline, excess fluid was removed using a paper towel, and the disk was weighed to determine m_T . The percent water absorption at each time T was calculated as $((m_T - m_0)/m_0) \times 100$. Alternatively, the water absorption was expressed as multiples of the original starting mass of the disk, $((m_T - m_0)/m_0)$.

[0036] The water absorption of Composition A, Composition A sterilized by irradiation by beta or gamma rays or Composition B was measured. The results are presented in Table 2, below. Composition A showed greater capacity for water absorption than either the commercially available Composition B or sterilized Composition A.

Table 2: Water absorption by compositions (Multiples of initial mass of disk)

Time (Hours)	0	2	4	6	24	48	120	144
Composition A	0	0.78	0.91	1.03	3.07	7.26	10.19	10.69
Composition B	0	0.34	0.39	0.61	2.43	5.10	6.76	6.93
Sterile Composition A	0	0.51	0.82	1.02	2.18	2.02		

Example 3: Moisture vapour transfer rate

[0037] Disks about 2.54 cm (1 inch) in diameter (an area of about 5cm²) were cut from slabs of Composition A, Composition B or sterilized Composition A using a circular die as described in Example 2. The release sheets were removed and the disks were equilibrated in 0.9 % NaCl solution, and then placed in air at room temperature. The disks were weighed at intervals as described in Example 2, above. The results are presented in Table 3, below.

[0038] Both Composition A and sterilized Composition A demonstrated a good ability to transfer water vapour. In contrast, the commercially available product, Composition B showed little good ability to transfer water vapour.

Table 3: Moisture vapour transfer rate (Water, loss, grams)

Time (Hours)	0	2	4	6	24	48	120	144
Composition A	202.3	202.4	202.4	202.4	202.0	201.0	197.5	196.5
Sterile Composition A	201.9		201.9	201.9	201.6	200.8		
Composition B	204.2	204.2	204.2	204.2	204.2	204.1	204	203.9

[0039] These results, and those of Example 2, demonstrate the ability of Composition A to absorb moisture from a oozing or fluid-filled wound, such as a blister, compared to Composition B. These results also show the ability of Composition A to transfer absorbed moisture away from the wound due to its relatively high vapour transfer rate.

Example 4: Measurement of cold flow

[0040] Disks about 2.54 cm (1 inch) in diameter were cut from slabs of Composition A, Composition B or sterilized Composition A using a circular die as described in Example 2. The release sheets were removed and the disks were stacked on top of each other, adhering each disk to the next until the height of the stack of disks reached about 0.5 inch. The stack of disks was then placed into a cold flow gauge and the weight was placed on the top of the stack of disks. The initial height of the stack was measured using a micrometer. The height was measured at thirty minute intervals until there was no further change in stack height.

[0041] The final percent change in height of the stack of disks after 24 hours was taken as a measure of cold flow. The results were 7.2 % for Composition A, and 0.6 % for Composition B. The cold flow of Composition A corresponds its greater flexibility relative to Composition B. Methods of maintaining high flexibility and high cohesion of an adhesive dressing by incorporation of a meshwork of polymeric filaments are disclosed in U.S. Patent No. 5,571,080.

Example 5: Skin peel test

[0042] Strips 2.54 cm (one inch) wide were cut from slabs of wound dressing Composition A or Composition B. A strip of adhesive tape (Scotch™ 3M, Minneapolis, MN) to prevent stretching of the samples. The samples were taped to a clamp. The skin of the test volunteer was prepared by washing the underside of the forearm with diluted 20 soap and allowing the skin to dry. The adhesive side of the sample was placed on the prepared skin and the clamp was attached to the hook of the testing device, a Chatillon TCD 200 tensile strength meter. The forearm was placed on the base of the testing device, taking care to keep the end of the sample directly under the clamp. The forearm was kept still while the tensile strength tester was activated to pull the adhesive up at the rate of 12.5 inches per minutes. The peak performance was recorded and any residue left on the skin was noted. The results were: 1.53 lb min /inch for Composition A, and 0.69 lb min /inch for Composition B. The results demonstrate that the composition of the present invention, in an embodiment exemplified by Composition A, has superior adhesiveness compared to the commercially available Composition B.

REFERENCES CITED IN THE DESCRIPTION

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Patentkrav

1. Sårforbindings sammensætning bestående af:
10 til 35 vægtprocent af en elastomer, baseret på den totale vægt af sammensætningen, hvor elastomeren er en styren-olefin-styren-blokcopolymer;
5 25 til 55 vægtprocent af et carbonhydridharpiks-klæbemiddel, baseret på den totale vægt af sammensætningen;
2 til 60 vægtprocent af en ikke-polært olieagtigt strækkemiddel, baseret på den totale vægt af sammensætningen;
10 ikke mere end 0,1 vægtprocent af en antioxidant, baseret på den totale vægt af sammensætningen, og
20 til 60 vægtprocent af et hydrokolloid.
2. Sammensætning ifølge krav 1, hvor styren-olefin-styren-blokcopolymeren er 12-16
15 vægtprocent af en styren-isopren-styren-blokcopolymer, baseret på den totale vægt af sammensætningen.
3. Sammensætning ifølge krav 1, hvor styren-olefin-styren-blokcopolymer er omkring
20 14 vægtprocent af en styren-isopren-styren-blokcopolymer, baseret på den totale vægt af sammensætningen.
4. Sammensætning ifølge krav 1, hvor styren-olefin-styren-blokcopolymer er ca. 20
25 vægtprocent af en styren-isopren-styren-blokcopolymer, baseret på den totale vægt af sammensætningen.
5. Sammensætning ifølge krav 1, hvor styren-olefin-styren-blokcopolymer er omkring
30 30 vægtprocent af en styren-isopren-styren-blokcopolymer, baseret på den totale vægt af sammensætningen.
- 30 6. Sammensætning ifølge krav 1, hvor det ikke-polære olieagtige strækkemiddel er omkring 6 vægtprocent mineralolie, baseret på den totale vægt af sammensætningen.
7. Sammensætning ifølge krav 1, hvor hydrokolloidet er carboxymethylcellulose.
- 35 8. Sammensætningen ifølge krav 1, hvor carbonhydridharpiks-klæbemidlet er en lavkrystallinsk strukturharpiks.