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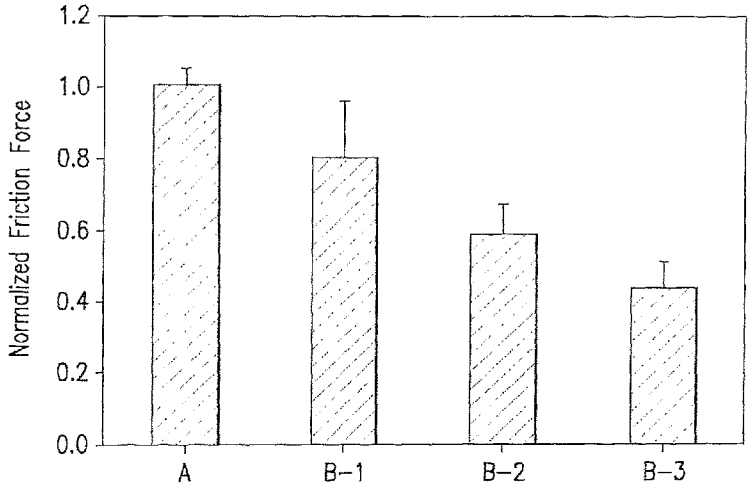

FIG. 1

(57) Abstract: Contact lenses, such as hydrogel contact lenses, are described. The present contact lenses include a lens body that is the reaction product of a polymerizable composition. The polymerizable composition includes one or more monomers and a crosslinker that crosslinks the one or more monomers during polymerization. The polymerization of the one or more monomers occurs in the presence of at least two forms of polyvinyl pyrrolidone, each of the at least two forms of polyvinyl pyrrolidone having a different average molecular weight. The at least two forms of polyvinyl pyrrolidone are associated with the first polymer component in the lens body such that a form of polyvinyl pyrrolidone is released from the lens body for at least eight hours based on *in vitro* release testing. The present invention also relates to packaging systems for use with such lenses and methods of producing such lenses.

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POLYMERIZABLE CONTACT LENS FORMULATIONS AND CONTACT LENSES OBTAINED THEREFROM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Patent Application No. 61/020,843, filed January 14, 2008, the entire contents of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to compositions useful for making contact lenses, such contact lenses, packaging systems including same, and methods of producing same. More particularly, the invention relates to contact lens-forming polymerizable compositions containing at least two forms of polyvinyl pyrrolidone, hydrogel contact lenses produced from such compositions, packaging systems for use with the lenses, and methods of producing the lenses.

BACKGROUND

[0003] Hydrophilic contact lenses can be formed from cross-linked polymers based on hydrophilic derivatives of acrylic or methacrylic acid, hydrophilic vinylic monomers such as vinylpyrrolidone, and the like. When hydrated, these hydrophilic cross-linked polymers can be referred to as hydrogels and include relatively large quantities of water without dissolving. Such polymers may include polymeric units derived from less hydrophilic, or even hydrophobic, monomers to confer mechanical strength and other useful properties.

[0004] End of the day discomfort is a condition reported by many hydrogel contact lens wearers. Discomfort associated with hydrogel contact lenses may be related to changes in water content or dehydration, changes in lubricity of a surface of the contact lens, or lens design, among other factors.

SUMMARY

[0005] New contact lenses, such as hydrogel contact lenses, polymeric compositions useful for making such lenses, packaging systems for use with such lenses and methods of producing such lenses, have been discovered. The present contact lenses have relatively low surface friction

and are able to release hydrophilic polymers present in the contact lenses for prolonged periods of time. The present contact lenses are soft contact lenses that are able to absorb and retain water in an equilibrium state. Thus, the present contact lenses can be understood to be hydrogel contact lenses.

[0006] The present contact lenses comprise a lens body. The lens body is the reaction product of a polymerizable composition comprising one or more monomers, and a crosslinker that crosslinks the monomers during a polymerization reaction to form a first polymer component. The polymerizable composition also comprises a hydrophilic polymer component, which is substantially unreactive during the polymerization. The resulting lens body thus includes a first polymer component formed from the monomers present in the polymerizable composition and a second polymer component, the hydrophilic polymer component that is physically entangled with the first polymer component in the lens body. In an embodiment, the hydrophilic polymer component included in the polmerizable composition which becomes the second hydrophilic polymer in the lens body comprises at least two forms of polyvinyl pyrrolidone, each having a different average molecular weight. In this embodiment, the polymerization of the polymerizable composition takes place in the presence of the least two forms of polyvinyl pyrrolidone each having a different average molecular weight. The at least two forms of polyvinyl pyrrolidone are associated with the first polymer component in the lens body that is formed such that a form of polyvinyl pyrrolidone (PVP) is released from the lens body for extended periods of time. The extended release of PVP from the lens body can be demonstrated, for example, by *in vitro* release testing.

[0007] The lens bodies in accordance with the present invention can exhibit one or more of the following characteristics and properties. In embodiments, the at least two forms of polyvinyl pyrrolidone are associated with the lens body such that a form of polyvinyl pyrrolidone used in the lens body is released from the contact lens for at least about eight hours, or at least about 16 hours, based on *in vitro* release testing. In other embodiments, the release of a form of polyvinyl pyrrolidone from the lens body has a biphasic or multiphasic release profile. In one embodiment, the release profile of a form of polyvinyl pyrrolidone from the lens body plots as total polyvinyl pyrrolidone released versus time with a slope that is greater than 1 for between about 0 hours and about 4 hours, and less than 1 for between about 4 hours and about 16 hours, based on *in vitro* release testing. In other embodiments, the surface friction of the lens body is at least about 10%

less, or at least about 20% less, or at least about 30% less, or at least about 35% less than a surface friction of a second contact lens comprising the reaction product of an identical polymerizable composition without the at least two forms of polyvinyl pyrrolidone. In other embodiments, the sessile drop contact angle of the lens body is at least about 5% less, or at least about 15% less, or at least about 30% less than the second contact lens as described above. The sessile drop contact angle is an in vitro measure of contact lens surface wettability, where a lower contact angle is indicative of a more wettable lens surface compared to a greater contact angle. It has been found that the addition of a mixture of at least two forms of polyvinyl pyrrolidone each with different average molecular weights can have a greater impact on the contact angle as compared to a single form of PVP. In additional embodiments, the viscosity of the polymerizable composition is at least 30% less, or at least about 40% less, or at least 50% less than a viscosity of an identical polymerizable composition with a single form of polyvinyl pyrrolidone of the same average molecular weight as a highest average molecular weight form of polyvinyl pyrrolidone in the mixture when the single form of PVP is present at the same concentration as the highest average molecular weight form of PVP present in the composition containing the mixture. This considerable reduction in monomer viscosity that can be provided with polymerizable compositions containing the at least two forms of polyvinyl pyrrolidone each with different average molecular weights over single PVP formulations is significant from a manufacturing standpoint.

[0008] In another aspect, contact lens packaging systems are provided which comprise a lens body and a packaging solution. The lens body is the reaction product of a polymerizable composition, the polymerizable composition comprising one or more monomers and at least one crosslinker that crosslinks the one or more monomers during polymerization, wherein the polymerization takes place in the presence of at least two forms of polyvinyl pyrrolidone each with different average molecular weights. The packaging solution comprises an aqueous solution containing an additional at least one form of polyvinyl pyrrolidone. In an embodiment, the PVP concentration in the packaging solution is between about 10 ppm and about 5000 ppm. In another embodiment, the PVP concentration in the packaging solution is between about 10 ppm and about 1000 ppm. In another embodiment, the PVP concentration in the packaging solution is between about 500 ppm to about 3000 ppm. By including an additional at least one form of PVP in the packaging solution used to package the lens in addition to the at least two forms of PVP

present in the polymerizable composition used to produce the lens, an increased duration of release of a form of PVP can be achieved. The form of PVP can be released from the lens body and/or the polymerized formulation. The form of PVP released can comprise one or more of the at least two forms of PVP present in the polymerizable composition, one or more of the at least one form of PVP present in the packaging solution, and combinations thereof.

[0009] In an embodiment, a container also can be provided for holding the contact lens and the packaging solution. The container can comprise a base member with a cavity configured to hold the contact lens and the packaging solution. Additionally, the container can comprise a seal configured to maintain the lens and packaging solution in a sterile condition for the duration of the shelf life of the contact lens. Such base members and seals are readily known to those of ordinary skill in the art.

[0010] In yet another aspect, methods for producing contact lenses are provided. Such methods comprise providing a polymerizable composition comprising one or more monomers, at least one crosslinker, and at least two forms of polyvinyl pyrrolidone each having a different average molecular weight, and polymerizing the polymerizable composition, to provide a lens body. In embodiments, the at least two forms of polyvinyl pyrrolidone are associated with the lens body made by the method such that a form of polyvinyl pyrrolidone is released from the lens body for at least eight hours, or at least about 16 hours, based on *in vitro* release testing. The polymerizing step can occur in a contact lens mold.

[0011] Additional aspects and details of the present invention are also described by the following detailed description, examples, drawings, and appended claims.

[0012] Various embodiments of the present invention are described in detail in the detailed description and additional disclosure below. Any feature or combination of features described herein are included within the scope of the present invention provided that the features included in any such combination are not mutually inconsistent as will be apparent from the context, this specification, and the knowledge of one of ordinary skill in the art. In addition, any feature or combination of features may be specifically excluded from any embodiment of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a graph illustrating a reduction in surface friction force of contact lenses that are the reaction product of polymerizable contact lens formulation containing monomers, a crosslinker reactive with the monomers, and a substantially unreactive hydrophilic polymer.

[0014] FIG. 2 is a graph illustrating the release profile of the substantially unreactive hydrophilic polymer from contact lenses prepared from formulation B-2.

[0015] FIG. 3 is a graph illustrating the release profile of the substantially unreactive hydrophilic polymer from contact lenses prepared from formulation B-3.

[0016] FIG. 4 is a graph illustrating a reduction in surface friction force of contact lenses that are the reaction product of polymerizable contact lens formulations containing monomers, a crosslinker reactive with the monomers, and another substantially unreactive hydrophilic polymer that is different than FIG. 1.

[0017] FIG. 5 is a graph illustrating the release profile of the substantially unreactive hydrophilic polymer from contact lenses prepared from formulation C-4.

[0018] FIG. 6 is a graph illustrating the sessile drop contact angle of contact lenses prepared from formulation C-1, a control contact lens prepared from formulation A, and a contact lens prepared from formulation C-1B.

[0019] FIG. 7 is a graph illustrating the surface friction force of a control contact lense E and contact lenses prepared from formulations D-1 to D-6.

[0020] FIG. 8 is a graph illustrating monomer viscosities, measured at 4°, 15° and 25°, for a control contact lense E and formulations D-3 to D-6.

[0021] FIG. 9 is a graph illustrating the surface friction force of a control contact lense G and contact lenses prepared from formulations F-1 to F-4.

[0022] FIG. 10 is a graph illustrating the surface friction force of a control contact lense G and contact lenses prepared from formulations F-5 to F-7.

[0023] FIG. 11 is a graph illustrating the amount of polyvinyl pyrrolidone (PVP) released (μg) over time from contact lenses prepared from formulations H-1 to H-3, as determined by *in vitro* release testing via GPC analysis.

[0024] FIG. 12 is a graph illustrating the amount of PVP released (μg) over time from contact lenses prepared from formulations H-4 to H-6, as determined by *in vitro* release testing via GPC analysis.

[0025] FIG. 13 is a graph illustrating the amount of PVP released (μg) over time from contact lenses prepared from formulations H-7 to H-9, as determined by *in vitro* release testing via GPC analysis.

[0026] FIG. 14 is a graph illustrating the amount of PVP released (μg) over time from contact lenses prepared from formulation H-10, and sample H-10B (H-10 lens stored in 500 ppm PVP (K-90) packaging solution), and H-10C (H-10 lens stored in 1000 ppm PVP (K-90) packaging solution), as determined by *in vitro* release testing via GPC analysis.

DETAILED DESCRIPTION

[0027] Unique contact lens formulations and contact lenses are provided. The present contact lenses have relatively low surface friction and are able to release hydrophilic polymers present in the contact lenses for prolonged periods of time. The present contact lenses are soft contact lenses that are able to absorb and retain water in an equilibrium state. Thus, the present contact lenses can be understood to be hydrogel contact lenses.

[0028] As used herein, a polymer refers to a compound with a molecular weight of at least 1,000 daltons that is formed of linked monomeric units, and includes homopolymers, copolymers, terpolymers, and the like, as understood by persons of ordinary skill in the art. As understood in the art, a copolymer refers to a polymer formed of two or more different monomeric units.

[0029] As used herein, the term "hydrogel" refers to a network or matrix of polymer chains, some or all of which may be water-soluble, and which may contain high percentages of water. Hydrogels refer to polymeric materials, including contact lenses, that are water swellable or water swelled. Thus, a hydrogel may be unhydrated and be water swellable, or a hydrogel may be partially hydrated and swollen with water, or a hydrogel may be fully hydrated and swollen with water.

[0030] In one aspect of the present invention, contact lenses are provided comprising a lens body suitable for placement on an eye of a contact lens wearer. The lens body has an anterior surface and a posterior surface which is oriented toward the corneal epithelium of the eye when the lens is worn by the lens wearer. The lens body of the present contact lenses is the reaction product or polymerized product of a polymerizable composition or formulation.

[0031] In certain embodiments of the present contact lenses, the polymerizable composition, from which the lens body is formed, comprises one or more monomers and a crosslinker that crosslinks the one or more monomers during polymerization to form a first polymer component. The polymerizable composition also comprises a hydrophilic polymer component. The polymerization takes place or occurs in the presence of the hydrophilic polymer component. The hydrophilic polymer component is associated with the first polymer component in the lens body such that the hydrophilic polymer component is released from the lens body over prolonged periods of time. The hydrophilic component can be released over time periods such as, for example, for at least about eight (8) hours, or at least about sixteen (16) hours based on *in vitro* release testing.

[0032] The hydrophilic polymer component is unreactive or substantially unreactive during the polymerization process. Thus, the resulting hydrogel lens body can be understood to comprise a network of a first polymeric component and a hydrophilic polymer component, in which the hydrophilic polymer component is substantially physically entrapped by the first polymer component. Although there may be some small amounts of reactivity of the hydrophilic polymer component, the reactivity is not sufficient to prevent leaching of the hydrophilic polymer from the lens body. The present contact lenses can be understood to comprise an interpenetrating polymer network (IPN) where the formation of the first polymer component occurs in the presence of the polymer component. However, as discussed herein, in the present contact lenses, it is possible for the hydrophilic polymer component to be released from the lens body even though it is entrapped by the first polymer component.

[0033] The polymerizable composition may also comprise other agents and additives. For example, the polymerizable composition may comprise a polymerization initiator. The polymerization initiator may be a thermal initiator, an ultraviolet initiator, or other initiator. In addition or alternatively, the polymerizable composition may also comprise a tinting agent, an ultraviolet absorbing agent, a colorant, an antimicrobial agent, and the like and mixtures thereof.

[0034] In certain embodiments of the present lenses, the polymerizable lens formulation comprises a plurality of monomers, and the first polymer component is a polymer of the plurality of monomers. The hydrophilic polymer component is sufficiently unreactive to prevent copolymerization of the hydrophilic polymer component with the first polymer component.

[0035] In the polymerizable compositions, the hydrophilic polymer component is provided to provide a combination of hydrophilic polymers physically entrapped in the hydrogel lens body. The hydrophilic polymer component comprises at least two forms of polyvinyl pyrrolidone (e.g., two forms, three forms, four forms or more), each with a different average molecular weight. By including at least two different hydrophilic polymers in the polymerizable composition, it is possible to provide different release profiles of the hydrophilic polymer component from the lens body compared to contact lenses that include only one hydrophilic polymer component in the polymerizable lens composition.

[0036] In various embodiments, the monomers that can be used in preparing the first polymer component contain at least one hydrophilic monomeric component including, but not limited to, 2-hydroxyethyl methacrylate (HEMA), 2-(3-phenyl-3-methylcyclobutyl)-2-hydroxyethyl methacrylate (PC-HEMA), 2-methacryloyloxyethyl phosphorylcholine (MPC) 2-hydroxyethyl acrylate, 2-hydroxypropyl methacrylate, 2-hydroxypropyl methacrylate, 2-hydroxypropyl acrylate, 3-hydroxypropyl methacrylate, glycerol mono-acrylate, glycerol mono-methacrylate, n-vinylpyrrolidone, acrylamide, and the like and mixtures thereof. In a preferred embodiment, a major proportion (i.e., >50% by weight) of the first polymer component is derived from one or more of the above-indicated monomeric component(s), such as HEMA alone or in combination with one or more other such monomers. In various embodiments, the at least one hydrophilic monomeric component, such as HEMA alone or in combination with one or more other reactive hydrophilic monomers, can be included, for example, in total amounts of about 50 wt% to about 97 wt%, or about 65 wt% to about 90 wt%, or about 70 wt% to about 85 wt%, by weight of the polymerizable composition. As indicated, the polymerizable composition includes the reactive monomer mixture used to prepare the first polymer component, and the hydrophilic polymer component. Other amounts of the HEMA and/or other hydrophilic monomers also may be used. The first polymer component also can contain at least one polymerizable phospholipid monomer, such as 2-methacryloyloxyethyl phosphorylcholine (MPC). The phospholipid monomer can be included, for example, in amounts of up to about 20 wt%, or about 1 wt% to about 15 wt%, or about 10 wt% to about 20 wt%, by weight of the polymerizable composition. Other amounts of the phospholipid monomer also may be used. Optionally, and although not required in the present contact lenses, small amounts of other monomers (e.g., about 1 to about 5 wt%), such as methacrylic acid, can be included, which can

be used to influence the amount of water that the hydrophilic polymeric material absorbs at equilibrium.

[0037] A cross-linking monomeric component preferably is also included in the reactive monomer mixture used for preparing the first polymer component of the polymerized formulation. Examples of useful cross-linking monomeric component agents or components include, but are not limited to, ethylene glycol dimethacrylate (EGDMA), trimethylolpropane trimethacrylate (TMPTMA), glycerol trimethacrylate, polyethylene glycol dimethacrylate (wherein the polyethylene glycol has a molecular weight up to, for example, about 5000), other polyacrylate and polymethacrylate esters, end-capped polyoxyethylene polyols containing two or more terminal methacrylate moieties, and the like and mixtures thereof. The cross-linking monomer is used in an amount effective to produce a desired degree of crosslinking of the first polymer component. The cross-linking monomer can be used in an amount, e.g., from about 0.05 wt% to about 5.0 wt%, or about 0.1 wt% to about 2.0 wt%, or about 0.5 wt% to about 3.0 wt%, by weight of the polymerizable composition. Other amounts of the cross-linking monomer also may be used.

[0038] As indicated, polymerization initiators can be used in the polymerizable composition. Thermal initiators that may be used include, but are not limited to, azo compounds, such as those having a half-life at the polymerization temperature of at least 20 minutes. Useful azo compounds include, but are not limited to, 2,2'-azo-bis-isobutyro-nitrile, 2, 2'-azo-bis(2,4-dimethylvaleronitrile), 1,1'-azo-bis(cyclohexane carbonitrile), 2,2'azo-bis(2,4-dimethyl-4-methoxy-valeronitrile) and the like and mixtures thereof. Redox initiators also may be used, which include, but are not limited to, ammonium persulfate-sodium thiosulfate, potassium sulfate-Mohr's salt, and one or more peroxides with reducing agents such as sodium thiosulfate. UV (ultraviolet light)-activated initiators include, but are limited to, photoinitiaters such as diethoxyacetophenone, 1-hydroxycyclohexyl phenyl ketone, 2,2-dimethoxy-2-phenylacetophenone, phenothiazine, diisopropylxanthogen disulfide, benzoin, benzoin methyl ether, other benzoin derivatives, 2,2'-azo-bis-isobutyro-nitrile and the like and mixtures thereof. Other free radical generating mechanisms can be employed, such as X-rays, electron-beams, and the like. An effective amount of the initiator used can vary depending on factors such as the type of initiator, the reactive monomer composition, and so forth. In general, the amount of initiator

used may be, for example, up to about 2 wt%, or about 0.005 wt% to about 1 wt%, or about 0.1 to about 0.75 wt%, by weight of the polymerizable composition.

[0039] Tinting agents, if used, may be any agent that imparts a visibility to the otherwise clear hydrogel lens body. The tinting agent may be a water soluble dye, or particles of pigment, or combinations thereof. Some examples of tinting agents include copper phthalocyanine blue, VAT Blue 6, Reactive Blue 4, and the like. An effective amount of the tinting agent used can vary depending on factors such as the type of tinting agent, the reactive monomer composition, the non-reactive polymers present, and so forth. In general, the amount of tinting agent used may be, for example, up to about 15 wt%, or about 0.0005 wt% to about 2 wt%, or about 1 wt% to about 10 wt%, or about 3 wt% to about 8 wt%, by weight of the polymerizable composition.

[0040] Some of the present polymerizable compositions, including those that contain PVP, may include water in addition to the other components. The amount of water can be up to about 10 wt%, or about 0 to about 7 wt%, or about 0 to about 5 wt%, by weight of the polymerizable composition.

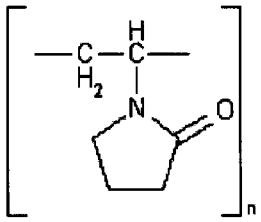
[0041] In certain embodiments of the present contact lenses, including those described in the examples herein, the polymerizable composition comprises 2-hydroxyethyl methacrylate (HEMA), an ethyleneglycol dimethacrylate crosslinker, 2-methacryloyloxyethyl phosphorylcholine (MPC), a polymerization initiator, at least two forms of PVP each with different average molecular weights and, optionally, a VAT Blue 6 tinting agent in addition to the hydrophilic polymer component. In certain embodiments, the polymerizable composition can further comprise a polymer of 2-methacryloyloxyethyl phosphorylcholine such as, for example a copolymer of 2-methacryloyloxyethyl phosphorylcholine and n-butylmethacrylate , which can be present in the composition in an amount from about 1% (wt/wt) to about 6% (wt/wt), in certain embodiments.

[0042] In various embodiments of the present contact lenses, the second hydrophilic polymer component comprises polyvinyl pyrrolidone. In certain embodiments of the present contact lenses, the second hydrophilic polymer component comprises at least two forms of polyvinyl pyrrolidone each having a different average molecular weight. In these embodiments, the polymerization of the polymerizable composition, which includes the reactive monomers and crosslinker, takes place in the presence of the at least two forms of polyvinyl pyrrolidone having a different average molecular weight. In the resulting lens body, the at least two forms of

polyvinyl pyrrolidone are associated with the first polymer component in the lens body such that a form of polyvinyl pyrrolidone is released from the lens body for extended periods of time, such as at least eight hours or more, based on *in vitro* release testing.

[0043] In other embodiments, polyvinyl pyrrolidone can be contained in at least two forms (e.g., based on average molecular weight) in the polymerizable composition where at least one additional form of polyvinyl pyrrolidone is separately added to a packaging solution used in storage of the contact lens made with the polymerizable composition containing the at least two forms of polyvinyl pyrrolidone. This arrangement also can provide an increased duration of release of a form of polyvinyl pyrrolidone from the polymerized formulation and/or the lens body. The form of polyvinyl pyrrolidone released from the polymerized formulation and/or the lens body can comprise one or more of the at least two forms of PVP present in the polymeriziable composition, one or more of the at least one additional form of PVP present in the packaging solution, and combinations thereof.

[0044] Polyvinyl pyrrolidone (PVP) is a water-soluble polymer made from the monomer N-vinylpyrrolidone. PVP can be represented by the formula:



wherein the coefficient "n" has a positive value of least 2 or greater.

[0045] The molecular weights of PVP are designated herein by (kilo)daltons or by "K-value." The K-value is Fikentscher's value of viscosity characteristics which represents a viscosity index relating to molecular weight. The K-value is calculated by the following formula:

$$K = \frac{(1.5 \log \eta - 1) / (0.15+0.003c) + (300c \log \eta + (c+1.5c\log \eta)^2)^{1/2}}{(0.15c+0.003c^2)}$$

where η is the relative viscosity of aqueous PVP solution to water and c is the weight percent of PVP in aqueous solution.

[0046] The PVP can have an average molecular weight, either a number average molecular weight or a weight average molecular weight, of at least 10,000 daltons. Typically, the PVP has a number average molecular weight or a weight average molecular weight between about 10,000 daltons and about 1,500,000 million daltons. In certain embodiments, the PVP has a number average molecular weight or a weight average molecular weight of at least 300,000 daltons. In one aspect, when combinations of at least two forms of PVP are included in the polymerizable compositions, at least two forms of PVP with a relatively wide range of polydispersity or non-uniformity in average molecular weight are included. With wider molecular weight ranges, it is possible to provide contact lenses with *in vitro* release profiles that demonstrate that the different forms of PVP can be released at different rates.

[0047] In certain embodiments, where the polymerizable composition used in making the lens body comprises at least two forms of polyvinyl pyrrolidone having a different average molecular weight, the first of the at least two forms of polyvinyl pyrrolidone has an average molecular weight in the range of about 10 kilodaltons to about 50 kilodaltons, such as about 45 kilodaltons, and a second of the at least two forms of polyvinyl pyrrolidone has an average molecular weight in the range of about 800 kilodaltons to about 1,200 kilodaltons, such as about 1,000 kilodaltons. In another embodiment, a first of the at least two forms of polyvinyl pyrrolidone has an average molecular weight below 10 kilodaltons, such as about 1 to about 9 kilodaltons, and a second of the at least two forms of polyvinyl pyrrolidone has an average molecular weight of about 900 to about 1,100 kilodaltons, such as about 1,000 kilodaltons. In other embodiments, a first of the at least two forms of polyvinyl pyrrolidone has a K-value based on Fikentscher's value of viscosity characteristics equation in the range of about 10 to about 50 and a second of the at least two forms of polyvinyl pyrrolidone has a K-value in the range of about 80 to about 120. The polyvinyl pyrrolidone can comprise a PVP mixture of about 20 wt% to about 40 wt%, or about 25 wt% to about 35 wt% of a polyvinyl pyrrolidone having a K-value of about 10 to about 50, such as about 30, based on Fikentscher's value of viscosity characteristics equation, in combination with about 60 wt% to about 80 wt%, or about 65 wt% to about 75 wt% of a polyvinyl pyrrolidone having a K value of about 80 to about 120, such as about 90. The PVP mixture also may comprise about 30 wt% by weight of a polyvinyl pyrrolidone having a K-value of about 30 based on Fikentscher's value of viscosity

characteristics equation, and about 70 wt% by weight of a polyvinyl pyrrolidone having a K-value of about 90.

[0048] Where the polymerizable composition comprises at least two forms of polyvinyl pyrrolidone having a different average molecular weight, the combined amount of PVP present in the polymerizable composition can be up to 20%, or about 0.005% to about 20%, or about 0.01% to about 10%, or about 0.01% to about 6%, or about 1% to about 5%, or about 2% to about 4%, or about 3% by weight of the polymerizable composition. Amounts above or below any one of these ranges can be used.

[0049] The at least two forms of polyvinyl pyrrolidone having different molecular weights are associated with the polymerized formulation and/or the lens body such that polyvinyl pyrrolidone of at least one of the forms present is released from the contact lens for at least eight hours, or at least 16 hours, based on *in vitro* release testing. Methods for monitoring and quantifying the release of PVP from a contact lens formulation over an extended period of time are illustrated, for example, in examples included with this application. In certain embodiments, "a form of polyvinyl pyrrolidone" is intended to cover either of conditions a) and b), where a) at least one of the forms of PVP is released from the lens formulation over a time period of, for example, about an eight (8) hour time period (hours 0-8) based on *in vitro* release testing, and b) a first one of the forms of PVP is released from the lens formulation is released only over an initial time period such as, a first, for example, about four (4) hour time period (hours 0-4) and a second PVP form is released over a second time period, for example, during the remainder of the monitoring period such as the next about five hour time period (hours 3-8) based on *in vitro* release testing, such that neither individual form of PVP is released over the entire 0-8 hour time period in b) but one or the other form of PVP present is being released over the entire period. Release profiles where the two different forms of PVP have overlapping, but non-identical, *in vitro* release profiles can also be provided to effectively extend the time period in which some form of PVP is released from the formulation. The form of polyvinyl pyrrolidone also can have a biphasic or multiphasic release profile (e.g., a release profile in which the slope of the release plot is greater than a certain value for a number of initial time points, and then the slope of the release plot is less than a certain value but is greater than zero for a number of later time points) based on *in vitro* release testing. In other embodiments, the form of polyvinyl pyrrolidone used in the lens body has a release profile which plots as total polyvinyl pyrrolidone release versus

time with a slope that is greater than 1 for between about 0 hours and about 4 hours, and less than 1 for between about 4 hours and about 16 hours, based on *in vitro* testing.

[0050] In other embodiments, the surface friction of a lens body formed with a polymerizable composition including such different forms of polyvinyl pyrrolidone is at least about 10% less, or at least about 20% less, or at least about 30% less, or at least about 35% less than a surface friction of a second contact lens comprising the reaction product of an identical polymerizable composition without the at least two forms of polyvinyl pyrrolidone, based on *in vitro* testing.

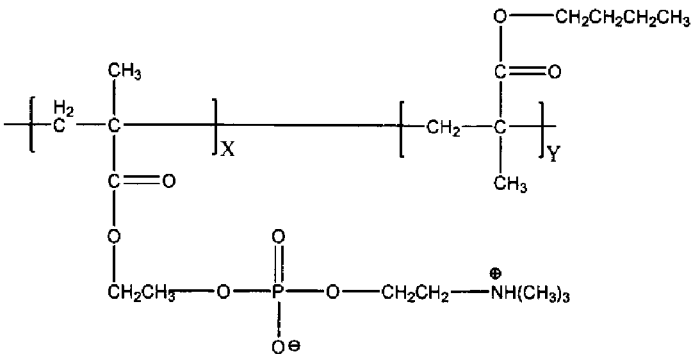
[0051] The wettability of a contact lens can be evaluated *in vitro* by measuring the contact angle of a lens surface, such as by the sessile drop contact angle measurement technique, which is conventionally known by persons of ordinary skill in the art. In other embodiments, the sessile drop contact angle of the lens body is at least about 5% less, or least about 15% less, or at least about 30% less than the second contact lens as described above. In view of test results such as described herein, the addition of a mixture of at least two forms of polyvinyl pyrrolidone with different molecular weights to the polymerizable composition also can have a greater impact on the contact angle as compared to the addition of a single form of PVP.

[0052] In additional embodiments, the viscosity of the polymerizable composition containing at least two forms of PVP is at least 30% less, or at least 40% less, or at least 50% less than a viscosity of an identical polymerizable composition with a single form of polyvinyl pyrrolidone of the same molecular weight as a highest molecular weight form of polyvinyl pyrrolidone in the mixture where the single form is present in the composition at the same concentration as the highest molecular weight form. This considerable reduction in monomer viscosity that can be provided with polymerizable compositions containing at least two forms of polyvinyl pyrrolidone with different molecular weights over single PVP formulations is significant from a manufacturing standpoint.

[0053] In various embodiments of the present contact lenses, other suitable hydrophilic polymers can be used in addition to the at least two forms of polyvinyl pyrrolidone as long as the desired properties are achieved. An additional hydrophilic polymer component that can be used in addition to the at least two forms of PVP used in the lens formulation includes, for example, a polymer of 2-methacryloyloxyethyl phosphorylcholine (MPC), poly-2-ethyl-2-oxazoline, poly(4-vinylpyridine N-oxide), polyglycerol methacrylate, polyvinyl-pyrrolidone-iodine complex,

polyvinyloxazolidone, polyvinylmethyloxazolidone, polyacrylamide and N-substituted polyacrylamides, polymethacrylamide and N-substituted polymethacrylamides, poly(N-acrylylglycinamide), poly(N-methacrylylglycinamide), and polyvinyl urethane, and the like and mixtures thereof. To the extent any of these polymers have an amphiphilic character, they are considered hydrophilic polymers for purposes of this discussion.

[0054] A polymer of 2-methacryloyloxyethyl phosphorylcholine (MPC) can be selected, for example, from the group consisting of a homopolymer of 2-methacryloyloxyethyl phosphorylcholine (PMPC), a copolymer of 2-methacryloyloxyethyl phosphorylcholine and n-butylmethacrylate (MPC/BMA), a copolymer of 2-methacryloyloxyethyl phosphorylcholine and methacryloyloxyethyl ethylene oxide and methacryloyloxyethyl propylene oxide (MPC/PMEP)and combinations of these or other polymers of MPC. A copolymer of 2-methacryloyloxyethyl phosphorylcholine and n-butylmethacrylate (MPC/BMA) is represented by Formula I below:



where X is about 1,600 to about 2,400 and Y is about 400 to about 600, or X is about 1,800 to about 2,200 and Y is about 450 to about 550, or X is about 1,900 to about 2,100 and Y is about 475 to about 525. A MPC/ BMA copolymer is commercially available under the tradename of LIPIDURE-PMB® (NOF Corporation, Japan). LIPIDURE-PMB® also is abbreviated herein as "LIP." LIP is represented by Formula I described herein where X is about 2000 and Y is about 500. As indicated, other values for X and Y may be used.

[0055] As indicated, in addition to the prolonged release of polyvinyl pyrrolidone, the lens bodies of embodiments of the present contact lenses have a reduced surface friction and increased surface wettabilities as indicated by *in vitro* testing.

[0056] Methods also are provided for producing a lens body with the polymerizable composition comprising providing a polymerizable composition comprising one or more monomers, at least one crosslinker, and at least two different forms of polyvinyl pyrrolidone each having a different average molecular weight, and polymerizing the polymerizable composition, to provide a lens body. In embodiments, the at least two forms of polyvinyl pyrrolidone are associated with the lens body made by the method such that a form of polyvinyl pyrrolidone is released from the polymerized formulation and/or lens body for at least eight hours based on *in vitro* release testing. The polymerizing step can occur in a contact lens mold.

[0057] The present contact lenses can be lathed contact lenses, spincast contact lenses, or cast molded contact lenses. It can be appreciated that these types of contact lenses can have different physical features resulting from their method of manufacture. In certain embodiments, including the embodiments of the examples, each of the contact lenses is a cast molded contact lens. In other words, it is a contact lens obtained from a contact lens mold assembly formed from two contact lens mold members (e.g. male and female contact lens mold members) in contact with each other to form a contact lens shaped cavity.

[0058] In certain embodiments, the present contact lenses are daily disposable contact lenses (i.e., a contact lens that is worn on a person's eye only once and then discarded). Other embodiments of the present contact lenses are daily wear lenses (i.e., a lens that is worn on a person's eye, and is then cleaned and is worn on the person's eye for at least one additional time). It can be appreciated that daily disposable contact lenses are physically different, chemically different, or both compared to daily wear contact lenses. For example, formulations used to make daily wear contact lenses are different than formulations used to make daily disposable contact lenses due to the economic and commercial factors in making substantially larger volumes of daily disposable contact lenses.

[0059] The lens bodies of the present contact lenses can have spherical surfaces, aspherical surfaces, toric surfaces, or combinations thereof. The present contact lenses can be understood to be monofocal contact lenses, multifocal contact lenses, including bifocal contact lenses, toric contact lenses, or combinations thereof.

[0060] The present contact lenses can be provided in packages. The contact lens packaging systems can include the lens body in a packaging solution containing one or more wetting agents or surfactants. The lens body is the reaction product of a polymerizable composition as described

herein, wherein the polymerization takes place in the presence of at least two forms of polyvinyl pyrrolidone each having a different average molecular weight. The packaging solution comprises an aqueous solution containing an additional at least one form of polyvinyl pyrrolidone. A container also can be provided for holding the contact lens and the packaging solution. Lens bodies packaged with the additional at least one form of polyvinyl pyrrolidone added to the packaging solution can provide increased duration of release of a form of PVP from the polymerized formulation and/or lens body, including lens formulations made with at least two forms of PVP each having different average molecular weights. In certain embodiments, the packaging solution may be an aqueous solution that contains an additional form of polyvinyl pyrrolidone which has a similar or different average molecular weight than any of the forms of PVP provided in the contact lens formulation. The additional at least one form of polyvinyl pyrrolidone present in the packaging solution can be at a concentration of at least 10 parts per million, or at least 50 parts per million, or at least 100 parts per million, or at least 250 parts per million, or at least 500 parts per million, or at least 3,000 parts per million, or at least 5,000 parts per million. In other aspects, the additional at least one form of polyvinyl pyrrolidone is present in the packaging solution at a concentration of about 10 to about 5,000 parts per million, or about 10 to about 1,000 parts per million, or about 500 to about 3,000 parts per million. The contact lens package can comprise a container having a cavity for holding the contact lens and packaging solution. A seal can be provided surrounding the cavity in a conventional manner to maintain the contact lens in a sterile environment.

[0061] The present lenses are placed on a patient's eye such that the posterior surface of the lens contacts the corneal epithelium of the eye of the patient.

[0062] In embodiments of the present invention, a contact lens can be formed by polymerizing the at least one monomer present in the polymerizable composition to form a first polymer. As, in accordance with the present invention, a pre-formed hydrophilic polymer comprising at least two forms of PVP is also present in the polymerizable composition, an IPN can be created by polymerizing the at least one monomer to form a first polymer, where the first polymer is formed in the presence of a second polymer, the pre-formed hydrophilic polymer (e.g., at least two forms PVP). The IPN is not considered a co-polymer of the first and second polymers. The water retention is not the same for a co-polymer where the reactants are all polymerized together versus where a pre-formed polymer is present upon the polymerization of

at least one monomer to form the first hydrophilic polymer component and thereby form the overall interpenetrating network. Further, the present invention does not form a modified form of PVP, but instead takes a hydrophilic polymer that is pre-formed, such as at least two forms of PVP, and polymerizes the at least one monomer in the presence of this pre-formed hydrophilic polymer such that the pre-formed hydrophilic polymer interpenetrates the first polymer once the first polymer is formed from the polymerization. The present invention is preferably not a simultaneous formation of an IPN which, again, is different from the interpenetrating polymer network preferably formed in the present invention.

[0063] For purposes of the present invention, an IPN material can be understood to be a material containing a mixture of two or more different polymers in which the polymers are entangled or entrapped in the material with little or no covalent bonds between the different polymers. Thus, an IPN is considered a different class of polymeric material having a different chemical structure and material morphology compared to chemically cross-linked materials where the polymers forming the cross-linked material, such as copolymers, including block copolymers and graft copolymers, are connected to each other through covalent bonds. An IPN material is chemically different than a chemically cross-linked polymeric material, such as a copolymer material, in which different polymers are covalently bonded to each other. As explained above, an IPN is a physical blend of two polymers, wherein one polymer physically interpenetrates, or is entrapped with, another polymer. Unlike IPNs, a chemically cross-linked material or copolymer material described above is not a physical blend of two polymers but, instead, the two polymers are covalently bonded together through chemical bonding. Thus, chemically speaking, the IPN would be chemically different from the cross-linked polymeric material since the two polymers forming the cross-linked polymeric material have been chemically altered through the formation of covalent bonds between the different polymers to ultimately create the cross-linked polymeric material, and since the IPN material does not include covalent bonds linking the different polymers. Contact lenses that are formed of an IPN material also have different properties compared to contact lenses that are formed of a chemically cross-linked material in which multiple polymers are covalently bonded to each other. As described in more detail herein, polyvinylpyrrolidone (PVP) is an example of one polymer that can be included in a chemical formulation with other reactive monomers and cross-linking agents that can be used to form an IPN material. In the production of a PVP-containing

IPN, the PVP is basically inert or does not form covalent bonds with the other polymer component of the IPN. PVP is basically inert or not chemically reactive because, in its native form, PVP does not include any functional groups or is chemically unreactive (e.g., does not form covalent bonds). If PVP is modified to include functional or reactive groups, then the PVP reacts with other monomers and the like in the formulation during polymerization processes.

[0064] In the present invention, the PVP used is not preferably functionalized, and therefore, the use of "peroxy"-containing agents, which functionalize the PVP and cause it to react and become covalently bonded to the other lens materials is avoided. Similarly, the present invention preferably does not use peroxide compounds in the formulations or the described polymerization with the PVP so as to not form copolymer materials. For example, the following is preferably not present: a) a t-butyl perbenzoate catalyst without any cross-linking agent, b) a crosslinking agent with benzoyl peroxide and N,N-dimethyl-p-toluidine, c) graft polymerization between PVP and a methacrylate, d) di-secondary butyl peroxy dicarbonate (Lupersol 225), e) catalysts that are included in the formulations, such as t-butyl peroctoate, benzoyl peroxide, isopropyl percarbonate, 2,4-dichloro-benzyoyl peroxide, methyl ethyl ketone peroxide, cumene hydroperoxide, and dicumyl peroxide, f) a catalyst like isopropyl peroxydicarbonate, g) graft copolymers that include PVP, h) a peroxy compound, or h) where the PVP has been modified or functionalized to form a copolymer material with the other ingredients.

[0065] Hydrogel contact lenses can be made by a variety of manufacturing techniques. A manufacturing process which employs a lathe to cut away portions of a polymerized cylindrical rod to form a lathed contact lens is referred to as lathing. A manufacturing process which employs two mold members, in which one of the mold members has a concave lens forming surface (e.g., front surface mold) and the other of the mold members has a convex lens forming surface (e.g., a back surface mold) are assembled together to form a mold assembly that includes a contact lens shaped cavity between the two mold members, is referred to as a cast molding process and results in a cast molded contact lens. Unlike a lathed contact lens, a cast molded contact lens is in the shape of a contact lens when it is removed from the mold. In contrast, in a lathing process, the polymerized product that is removed from the mold is a cylindrical rod that needs to be machined to produce a contact lens. While lathed contact lenses and cast molded contact lenses are produced by different processes, lathed contact lenses and cast molded contact lenses are also chemically and physically different from each other. For example, lathed contact

lenses have been shown to have more rough lens surfaces, reduced water wettability, polarity, and critical surface tension, and different surface chemical content than cast molded contact lenses. Thus, although both lathed contact lenses and cast-molded contact lenses can be hydrogel contact lenses, the different types of contact lenses have different chemical and structural properties that distinguish them from each other. In the present invention, preferably, a cast-molded process to form cast-molded contact lenses is used.

[0066] A "lathable lens formulation" would not be expected to produce an acceptable cast molded contact lens if the lathable lens formulation was used in a cast molding system without changes to the formulation or manufacturing processes. The properties of the polymerized products are dependent on the types and amounts of chemical ingredients present in the polymerizable lens formulations. In a cast molding process, the polymerized product has a maximum thickness (the distance between the anterior surface of the lens and the posterior surface of the lens) on the order of hundreds of micrometers (for example, a spherical correction contact lens may have a maximum thickness of about 100 micrometers, and a toric contact lens with a prism ballast may have a maximum thickness of about 400 to 500 micrometers). In comparison, in a lathing process, the polymerized product has a maximum thickness substantially greater than a cast molded contact lens (for example, the polymerized product may have a thickness from about 1 centimeter to about 30 centimeters (about 1 foot). In a lathing process, the properties at different regions of the polymerized product are different (for example, an end of a polymerized rod may have had a greater oxygen exposure than a central region of the polymerized rod). These different properties affect the chemical and physical properties of the polymerized material, and the effects become more apparent with longer polymerized rods. Lathable lens formulations are made to address these differences, which are not as apparent, if at all, in a cast molded material due to the thin nature of the polymerized product, and to minimize the negative effects that the differences might have. In addition, in a cast molding system, the contact lens mold assembly has a cross-sectional distance, such as a diameter, that is substantially greater than the thickness of the contact lens (for example, a contact lens mold assembly may have a diameter of about 20 millimeters where the contact lens has a thickness of about 100 micrometers). Slight variations in the closure of the two mold members can cause substantial amounts of variability in the shape of the contact lens based on these relative differences (for example, if the mold closure is not symmetrical, the polymerized contact lens

product can have undesired varying thicknesses or be associated with undesired prisming). The cast molding process, such as the mold filling steps (the step where the formulation is placed on the front surface mold), the mold closing steps, the curing steps, and the mold separation steps, will likely need to be adjusted to produce an acceptable cast molded contact lens. These considerations are not necessary when making a lathed contact lens. In addition, differences exist between curing profiles of lathable lens formulations and cast molded lens formulations. For example, certain lathable lens formulations cannot be used in a cast molding process because the formulation begins to polymerize or cure almost immediately upon placement in the cylindrical mold.

[0067] With the present invention, it is possible to have a controlled release or a sustained release of the second hydrophilic polymer (e.g., one or more forms of PVP, and, if present, a polymer of MPC) from the polymerized formulation and/or the lens body over a period of time. When the hydrophilic polymer in the polymerizable composition comprises at least two forms of PVP, the release rate of the hydrophilic polymers will be slower (i.e., more sustained) than the release rate of a similar polymer comprising only one form of PVP. When the hydrophilic polymer comprises at least two forms of PVP, each with different average molecular weights, the release rate of a form of PVP will be slower (i.e., more sustained) than the release rate of a similar polymer with at least two forms of PVP, each with similar average molecular weights. When the hydrophilic polymer comprises at least one polymer of MPC in addition to at least two forms of PVP, the release rate of a form of PVP will be slower (e.g., more sustained) than the release rate of a similar polymer without the at least one polymer of MPC in addition to at least two forms of PVP. When the hydrophilic polymer comprises at least two forms of PVP, and the polymerized formulation has been equilibrated in a packaging solution comprising at least one form of PVP, the release rate will be slower (i.e., more sustained) than the release rate of a similar polymerized formuation with the at least two forms of PVP that has not been equilibrated in a packaging solution comprising at least one one form of PVP.

[0068] The controlled release or sustained release of the hydrophilic polymers can be over a period of time such as 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, 9 hours, 10 hours, 11 hours, 12 hours, 13 hours, 14 hours, 15 hours, 16 hours, 17 hours, 18 hours, or more. The release can be constant (e.g., within +/- 20 % or +/- 10 %) over the period of time or can have a variable release rate, for instance where the wt% of release rate over time is front

heavy or back heavy. For example, the release can be such where the amount of polymer released is greater in the first several hours (e.g., in the first hour, second hour, third hour) or can be less. The release can be such that at least 5 wt% of the releaseable amount of polymer available (e.g. PVP amount) occurs in the first 0 to 4 hours, or 0 to 8 hours. The at least 5 wt% can be from 5 wt% to 99 wt%, or 10 wt% to 95 wt%, or 15 wt% to 90 wt%, or 20 wt% to 85 wt% or 25 wt% to 80 wt%, or 30 wt% to 75 wt%, or 35 wt% to 70 wt%, or 40 wt% to 65 wt%, or 45 wt% to 65 wt% or 50 wt% to 65 wt% or 55 wt% to 75 wt%, or at least 10 wt%, at least 15 wt% or at least 20 wt% or at least 25 wt% or at least 40 wt% or at least 50 wt%. As an option, the release can be such that at least 5 wt% of the releaseable amount of polymer available (e.g. PVP amount) occurs in the period of 4 to 8 hours, or 4 to 12 hours or 4 to 16 hours, or 5 to 12 hours, or 5 to 16 hours. In this embodiment, the at least 5 wt% can be from 5 wt% to 99 wt%, or 10 wt% to 95 wt%, or 15 wt% to 90 wt%, or 20 wt% to 85 wt% or 25 wt% to 80 wt%, or 30 wt% to 75 wt%, or 35 wt% to 70 wt%, or 40 wt% to 65 wt%, or 45 wt% to 65 wt% or 50 wt% to 65 wt% or 55 wt% to 75 wt%, or at least 10 wt%, at least 15 wt% or at least 20 wt% or at least 25 wt% or at least 40 wt% or at least 50 wt%. The time periods provided are a reference to when the polymer material (e.g., IPN) of the present invention is first subjected to an environment that permits the release of the hydrophilic polymer (e.g., a form of PVP), such as the eye, in lens solution, in a liquid environment, and the like.

[0069] As described herein, the present contact lenses exhibit improvements in surface friction, or wettability, or both. For example, the present contact lenses exhibit a reduced surface friction, a reduced contact angle, or both, compared to control contact lenses. In addition, embodiments of the present contact lenses have the reduced surface friction, reduced contact angle, or both, while maintaining a flexural modulus, water content, or both similar to contact lenses that do not include a second hydrophilic polymer component.

[0070] In certain embodiments, the present contact lenses that include a second hydrophilic polymer component have (i) a surface friction that is at least 30% less than an identical contact lens without the second hydrophilic polymer component (the control lens); (ii) a contact angle that is at least 10% less than the contact angle of the control lens; (iii) or both (i) and (ii), while having (iv) a flexural modulus that is within about 50% of the flexural modulus of the control lens; (v) an equilibrium water content that is within about 2% of the equilibrium water content of the control lens; or (vi) both (iv) and (v). In certain preferred embodiments of the present contact

lenses, the contact lenses have features (iii) and (vi) above. In additional embodiments of the foregoing contact lenses, the tensile strength is within about 60% of the tensile strength of the control lens.

[0071] As one example, which is provided for purposes of illustration only, a control contact lens may have a normalized surface friction force of about 1, a contact angle of about 90 degrees, a flexural modulus of about 0.5 Mpa, and an equilibrium water content of about 60%. An embodiment of the present contact lenses described herein would accordingly have a normalized surface friction force of about 0.7 or less, a contact angle of about 81 degrees or less, a flexural modulus from about 0.2 to about 0.8 Mpa, and an equilibrium water content from about 58% to about 62%.

[0072] As another example, which is provided for purposes of illustration only, a control contact lens may have a normalized surface friction force of about 1, a contact angle of about 84 degrees, a flexural modulus of about 0.3 Mpa, and an equilibrium water content of about 60%. An embodiment of the present contact lenses described herein would accordingly have a normalized surface friction force of about 0.7 or less, a contact angle of about 76 degrees or less, a flexural modulus from about 0.1 to about 0.5 Mpa, and an equilibrium water content from about 58% to about 62%.

[0073] In additional embodiments, the surface friction of the present contact lenses is between about 30% and about 80% less than the control contact lens, for example, the surface friction of the present contact lenses may be about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75% less than the control contact lens.

[0074] In any of these embodiments, or all of the embodiments, the contact angle is between about 10% and 60% less than the contact angle of the control lens. In further embodiments, the contact angle is between about 20% and about 50% less than the contact angle of the control lens. In still further embodiments, the contact angle is between about 25% and about 45% less than the contact angle of the control lens.

[0075] In any of these embodiments, or all of the embodiments, the flexural modulus of the lens of the present invention differs from the flexural modulus of the control lens within a range of about 10% to about 60%. In further embodiments, the flexural modulus of the lens differs from the control lens within a range of about 20% to about 50%. In still further embodiments, the flexural modulus differs within a range of about 25% to about 45%.

[0076] In any of these embodiments, or all of the embodiments, the water content of the lens of the present invention differs from the water content of the control lens within a range of about 0% to about 20%. In further embodiments, the water content of the lens of the present invention differs from the water content of the control lens within a range of between about 0% and about 10%. In still further embodiments, the water content differs in a range of between about 0.5% and about 5%.

EXAMPLES

[0077] The following Examples illustrate certain aspects and advantages of the present invention, which should be understood not to be limited thereby. All parts, percentages and ratios are by weight unless indicated otherwise.

EXAMPLE 1

Preparation of Contact Lenses

[0078] Polymerizable lens formulations were prepared by mixing monomers, a crosslinker that is reactive with the monomers, an initiator, and a tinting agent, with a substantially non-reactive hydrophilic polymer. Some of the polymerizable lens formulations contained 5% water.

[0079] Contact lens molds were injection molded from polypropylene resin using conventional injection molding techniques and equipment. Each contact lens mold included a female mold member that includes a concave optical quality surface for forming the front surface of the contact lens, and a male mold member that includes a convex optical quality surface for forming the back surface of the contact lens. The female mold member can be understood to be a front surface mold, and the male mold member can be understood to be a back surface mold.

[0080] An amount (60μl) of the polymerizable lens formulation was placed on the concave surface of the female mold member. The male mold member was placed in contact with the female mold member such that the polymerizable lens formulation was located in a contact lens shaped cavity formed between the concave surface of the female mold member and the convex surface of the male mold member. The male mold member was held in position by an interference fit between a peripheral region of the female and male mold members.

[0081] The contact lens mold containing the polymerizable lens formulation was then placed in an oven where the polymerizable lens formulation was cured at a temperature of about 100° C for about 30 minutes. After curing, the contact lens mold contained a polymerized contact lens product within the contact lens shaped cavity.

[0082] The contact lens mold was removed from the oven and allowed to cool to room temperature (about 20° C). The contact lens mold was mechanically demolded to separate the male and female mold members from each other. The polymerized contact lens product remained attached to the male mold member.

[0083] The polymerized contact lens product was then mechanically delensed from the male mold member to separate the contact lens product from the male mold member.

[0084] The separated contact lens product was then placed in a borate buffered saline (BBS) solution in a contact lens blister package, which was then sealed with a foil covering, to form a packaged hydrated contact lens. The lenses in the blister were sterilized by autoclaving.

[0085] The measurements and testing described below were performed on these packaged contact lenses.

EXAMPLE 2

Measurement of friction force on contact lens surfaces

[0086] Atomic Force Microscopy (AFM) was used to measure the friction force on hydrated contact lenses. A Veeco Digital Instruments CP-II AFM was used to measure the friction force of the fully hydrated contact lens surface under phosphate buffered saline (PBS). Contact mode images were taken with silicon nitride V-shaped cantilevers with a 12μm diameter borosilicate glass sphere tip and a spring constant of 0.03N/m. Normal force applied to the tip was 1.0nN. Scan rate was 0.8Hz and scan area was 30x30μm. 3 areas per lens and 3 lenses per study were measured.

EXAMPLE 3

Measurement of contact lens *in vitro* release profiles

[0087] Release profile of the substantially unreactive hydrophilic polymer was measured by using the gel permeation chromatography (GPC) method. For each sample, 1 lens was blotted (with lens paper) to remove excess packaging solution, placed in a clean vial with 400μl phosphate buffered saline (PBS) solution (pH=7) and kept at 35° C on a 300 rpm shaker for the desired releasing time interval. The extract was removed from the vial, placed in a GPC autosampler vial and then analyzed on a Waters GPC system (Waters 1525 Binary HPLC pump, Waters Corporation, Milford, MA) with refractive index detection. Triplicate samples were tested at each time point. Detailed GPC method parameters are as follows: Ultrahydrogel 250 (300 x 7.80 mm) with Ultrahydrogel gard column, mobile phase 20% MeOH/80% H_2O, flow rate 0.8ml/min, injection volume 50μl, Waters 2414 refractive index detector.

EXAMPLE 4

Hydrogel contact lenses containing LIP

[0088] Contact lenses were prepared as described in Example 1. Four batches (A (control), B-1, B-2, and B-3 in Table 1) of hydrogel contact lenses were prepared. The polymerizable lens formulations are shown in Table 1, where the amounts of each ingredient are in unit parts. In Table 1, the chemical abbreviations are defined as follows: MPC: 2-methacryloyloxyethyl phosphorylcholine (NOF Corporation, Tsukuba, Japan); HEMA: 2-hydroxyethyl methacrylate (Degussa Corp., Piscataway, NJ, USA); EGDMA: ethylene glycol dimethacrylate (Esstech Inc., Essington, Pennsylvania, USA); Initiator: 2,2'-azobisisobutyronitrile (AIBN) (Sigma-Aldrich, St. Louis, MO, USA); VB6: HEMA coated pigment of Vat Blue 6 (tinting agent) (Bioedge Research, La Jolla, CA, USA); LIP: a copolymer of 2-methacryloyloxyethyl phosphorylcholine and n-butyl methacrylate, obtained as LIPIDURE-PMB®, in powder form, from NOF Corporation, Tsukuba, Japan. As indicated, LIP is represented by Formula I described herein where X is about 2000 and Y is about 500. MPC can also be obtained from companies such as Biocompatibles Limited (Great Britain), or can be produced, such as described in U.S. Pat. Nos. 5,981,786; 6,420,453; and 6,423,761.

[0089] Total parts of each formulation A and B-1 to B-3 is based on the combined parts of MPC, HEMA, EGDMA, Initiator, VB6 and LIP. For purposes of these examples, the unit amount can be converted to weight percentages by determining the sum of all of the unit parts in the table and dividing the respective unit part by the sum of all of the unit parts.

Table 1

Formulation ID	Composition Ingredients (Unit Parts)					
	MPC	HEMA	EGDMA	Initiator	VB6	LIP
A (control)	14.7	77.9	0.7	0.46	7.5	0
B-1	14.29	81.89	0.7	0.46	1.68	1
B-2	14.00	81.89	0.7	0.46	0.00	3
B-3	14.7	77.9	0.7	0.46	7.5	5

[0090] Batches of contact lenses which were the reaction product of these four lens formulations were examined for a number of properties shown in Table 2. All of these

measurements were performed using conventional methods and equipment. Table 2 demonstrates that contact lenses resulting from lens formulations containing 5 unit parts of LIP as LIPIDURE-PMB® (Formulation B-3), or less, exhibited substantially similar diameters, base curves, center thicknesses (CT), Transmittance (T), modulus, water content, and sessile drop contact angles to control lenses that contained no LIP as LIPIDURE-PMB®.

Table 2

Formulation ID	LIP amount (Unit Parts)	Properties								
		Diameter (mm)	Base Curve (mm)	CT (μm)	T (%)	Modulus (MPa)	Elongation (%)	Tensile Strength (MPa)	Water Content (%)	Contact Angle (degrees)
A (control)	0	13.84	8.49	84.0	97.1	0.379	111.6	0.274	60.0	97.4
B-1	1	13.76	8.36	88.7	97.1	0.368	116.5	0.281	59.5	99.2
B-2	3	13.90	8.30	83.2	96.7	0.342	263.3	0.648	60.9	100.7
B-3	5	13.98	8.20	91.0	96.4	0.392	283.0	0.677	62.7	94.3

[0091] As shown in FIG. 1, the presence of LIP in the polymerizable lens formulations resulted in hydrogel contact lenses with reduced surface friction compared to controls. The reduction in surface friction was dose dependent in that the surface friction of the contact lenses decreased as the amount of LIP increased. The reduced surface friction is indicative of enhanced lubricity of the surfaces of the contact lenses.

[0092] In addition, as shown in FIG. 2 and FIG. 3, contact lenses containing LIP, which is believed to be physically entrapped in the polymer matrix of the contact lens, released LIP from the contact lens in a prolonged manner during in *vitro* release testing. In contact lenses obtained from formulations containing 3 parts LIP (FIG. 2), LIP was released for at least 8 hours from the contact lens into the surrounding liquid environment. In contact lenses obtained from formulations containing 5 parts LIP (FIG. 3), LIP was released for at least 8 hours from the contact lens into the surrounding liquid environment. The release appears to have plateaued between about 8 and about 16 hours.

[0093] Among other things, these data demonstrate that including a substantially non-reactive hydrophilic polymer in a polymerizable lens formulation can result in contact lenses

with reduced surface friction and prolonged release of the substantially non-reactive hydrophilic polymer from the contact lens over the course of several hours.

EXAMPLE 5

Hydrogel contact lenses containing polyvinyl pyrrolidone

[0094] Contact lenses were prepared as described in Example 1. Five batches (C-1, C-2, C-3, C-4, and C-5 in Table 3) of hydrogel contact lenses were prepared. The polymerizable lens formulations are shown in Table 3, where the amounts of each ingredient are in unit parts. In Table 3, the chemical abbreviations are the same as Table 1, except for PVP which is the abbreviation for polyvinyl pyrrolidone. PVP (number average molecular weight of 360 kilodaltons) was obtained from Sigma-Aldrich and BASF, New Jersey, USA. Total parts of each formulation C-1 to C-5 is based on the combined parts of PVP, MPC, HEMA, EGDMA, Initiator, VB6 and water.

Table 3

Formulation ID	PVP (Parts)	MPC (Parts)	HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	VB6 (Parts)	Water (Parts)
C-1	1	14.7	77.9	0.7	0.46	7.5	5
C-2	2						
C-3	3						
C-4	4						
C-5	5						

[0095] Batches of contact lenses which were the reaction product of these five lens formulations were examined for a number of properties shown in Table 4. All of these measurements were performed using conventional methods and equipment. Table 4 demonstrates that contact lenses that result from lens formulations containing up to 5 unit parts of PVP (Formulation C-5), exhibited substantially similar diameters, base curves, center thicknesses (CT), transmittance (T), and water content (WC), to control lenses that contained no PVP (see Formulation A of Table 1).

Table 4

Formulation ID	Sessile drop contact angle (deg.)	Diameter (mm)	BC (mm)	CT (μm)	T (%)	Modulus (MPa)	Elongation (%)	Tensile strength (MPa)	WC (%)
C-1	36.8	13.82	8.45	90	98.7	0.474	260.4	0.748	58.5
C-2	32.7	13.76	8.38	91	98.5	0.469	230.5	0.579	58.7
C-3	37.8	13.82	8.41	85	98.5	0.401	281.3	0.673	59.4
C-4	33.7	13.81	8.43	86	98.7	0.432	214.2	0.535	59.5
C-5	37.2	13.86	8.45	82	98.8	0.500	259.3	0.713	59.5

[0096] However, as shown in FIG. 4, the presence of PVP in the polymerizable lens formulations resulted in hydrogel contact lenses with reduced surface friction compared to controls. The reduction in surface friction was dose dependent in that the surface friction of the contact lenses decreased as the amount of PVP increased. This reduced surface friction is indicative of enhanced lubricity of the surfaces of the contact lenses.

[0097] In addition, as shown in FIG. 5, contact lenses containing PVP, which is believed to be physically entrapped in the polymer matrix of the contact lens, released PVP from the contact lens in a prolonged manner during *in vitro* release testing. In contact lenses obtained from formulations containing 4 parts PVP (FIG. 5), a form of PVP was released for at least 8 hours from the contact lens into the surrounding liquid environment. The release appears to have plateaued between 8 and 16 hours.

[0098] In addition, as shown in FIG. 6, including PVP in the polymerizable lens formulation under the present manufacturing methods, resulted in a substantial reduction in sessile drop contact angle, as shown by Formulation C-1 in comparison to Formulation A. Furthermore, using a higher molecular weight PVP (Formulation C-1B; number average molecular weight of 440 kilodaltons) did not result in a significant change in sessile drop contact angle values compared to Formulation C-1).

[0099] Among other things, these data demonstrate that including a substantially non-reactive hydrophilic polymer in a polymerizable lens formulation can result in contact lenses with reduced surface friction and prolonged release of the substantially non-reactive hydrophilic polymer from the contact lens over the course of several hours.

EXAMPLE 6

Hydrogel contact lenses containing polyvinyl pyrrolidone

[00100] Contact lenses were prepared as described in Example 1 with the following alterations. Batches (D-1 to D-6 in Table 5) of hydrogel contact lenses were prepared. The formulations contained 3% be weight PVP of various molecular weights and combinations. The polymerizable lens formulations are shown in Table 5, where the amounts of each ingredient are in unit parts. Lenses were made using single molecular weights of PVP (K-17, K-30, K-60, K-80, K-90) in formulations D-1 to D-5, and a mixture of two forms of PVP each with different K-values (K-30 and K-90) in formulation D-6. It should be noted that only K-30 & K-90 grades of PVP were USP certified. with the following concentrations of LIP and PVP (a mixture of (30% K-30 and 70% K-90). The polymerization initiator used for formulations D1 to D-5 was ammonium persulfate (APS), and VAZO® 64 (azo-bis-isobutyronitrile azonitrile, E.I. DuPont De Nemours & Co., Wilmington, DE, USA) was used as an initiator for formulation D-6. Total parts used in each formulation D-1 to D-6 is based on the combined parts of PVP (total), HEMA, PC-HEMA, EGDMA, Initiator, and water.

Table 5

Formulation ID	PVP (K-value)	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
D-1	K-17	3	77.2	14.6	0.7	0.50 (APS)	5
D-2	K-30	3	77.2	14.6	0.7	0.50 (APS)	5
D-3	K-60	3	77.2	14.6	0.7	0.50 (APS)	5
D-4	K-80	3	77.2	14.6	0.7	0.50 (APS)	5
D-5	K-90	3	77.2	14.6	0.7	0.50 (APS)	5
D-6	30% K-30, 70% K-90	3	77.2	14.6	0.7	0.50 (VAZO 64)	5

[00101] Lenses were made manually with the formulations by filling dry molds with 50 μL of monomer mix. They were subsequently closed and sealed manually and then thermally cured at 100 °C for 30 minutes. All lenses were de-molded and de-lensed manually, then packaged with 1.2 mL of BBS buffer solution and autoclaved. The resulting lenses were tested to determine their modulus, tensile strength, contact angle (sessile drop method), and friction force. The instruments and/or standard tests used to determine these properties were the following: modulus and tensile strength: Instron 3342 (Instron Industrial Products, 825 University Ave, Norwood, MA, USA); contact angle: DSA 100 (kruss Inc., 1020 Crews Road, Suite K, Matthews, NC, USA), and friction force: AFM CP II (Veeco Instrument Inc., 112 Robin Hill Road, Santa Barbara, CA, USA. The results in Table 6 for modulus, tensile strength and water content are the average of results measured for five individual lenses, and the contact angle value is based on the average of three individual lenses. Table 7 shows the percentage change in modulus, contact angle, tensile strength, and water content for formulations D-1 to D-6 as compared to a control. As a control (E), ProClear® lenses (CooperVision, Fairport, NY, USA) were used. The viscosity of selected monomer mixes was measured for comparison at 4, 15, & 25 °C. The instrument and/or standard tests used to determine the viscosity was the following: Brookfield DV-II+ programmable viscometer (Brookfield Engineering Laboratories, Inc., 11 Commerce Boulevard, Middleboro, MA, USA).

Table 6

Formulation ID	PVP (K-Value)	Modulus (MPa)	Contact Angle (°)	Tensile Strength (MPa)	Water Content (%)
E (Control)	0	0.494 ± 0.01	90.3 ± 4.6	0.760 ± 0.11	59.8 ± 0.5
D-1	K-17	0.556 ± 0.03	66.6 ± 0.7	0.723 ± 0.20	59.3 ± 0.4
D-2	K-30	0.557 ± 0.02	50.3 ± 7.8	0.722 ± 0.10	59.7 ± 0.3
D-3	K-60	0.565 ± 0.03	46.4 ± 2.8	0.656 ± 0.12	59.8 ± 0.3
D-4	K-80	0.561 ± 0.02	44.9 ± 2.1	0.466 ± 0.04	59.7 ± 0.3
D-5	K-90	0.550 ± 0.02	42.1 ± 5.0	0.517 ± 0.10	59.5 ± 0.3
D-6	30% K-30 70% K-90	0.504 ± 0.06	58.6 ± 1.9	0.749 ± 0.24	58.5 ± 0.6

Table 7

Formulation ID	PVP (K-value)	% Change in Modulus over Control	% Change in Contact Angle over Control	% Change in Tensile Strength over Control	% Change in Water Content over Control
D-1	K-17	+13	-26	-5	-1
D-2	K-30	+13	-44	-5	0
D-3	K-60	+14	-49	-14	0
D-4	K-80	+14	-50	-39	0
D-5	K-90	+11	-53	-32	-1
D-6	30% K-30 70% K-90	+2	-35	-1	-2

[00102] The friction force measured for the Control E (ProClear® lenses) and formulations D-1 to D-6 are shown in FIG. 7. The monomer viscosities, as measured at 4, 15, and 25 °C, for the Control E (ProClear® lenses) and formulations D-3, D-4, D-5 and D-6 are shown in FIG. 8.

[00103] The addition of the mixture of two forms of PVP to the lens formulation decreased the contact angle over the control by at least 30%. The decrease in contact angle observed for the mixture of two forms of PVP with different K-values was less than the decrease in contact angle that would be predicted based on the results for the single forms of PVP.

[00104] While the addition of a single form of PVP to the lens formulation resulted in a decrease in the friction force of at least 50% as compared to the ProClear® control lenses, the addition of the mixture of two forms of PVP with different K-values produced lenses with a somewhat higher friction force than that of the single form of PVP formulations, and which was higher than would be predicted based on the results for the single forms of PVP. The reduction in friction force for the mixture of two forms of PVP was significant compared to the ProClear® control lenses.

[00105] The monomer viscosity of the formulations containing a single form of PVP increased with increasing K-value of the form of PVP. However, the monomer viscosity for the formulation containing the mixture of two forms of PVP with different K-values showed significantly lower values than would be predicted based on the results for the single forms of PVP.

[00106] For the lens properties evaluated (modulus, contact angle, tensile strength, friction force and monomer viscosity), the results for the mixture of two forms of PVP with different K-

values were significantly different from what would be predicted based on the results of the formulations containing single forms of PVP, and did not follow the trends in the data for the single forms of PVP. While the formulation containing the mixture of two forms of PVP with different K-values had slightly lower reductions in contact angle and friction force as formulations with a single form of PVP, the significant reduction in monomer viscosity over the single PVP formulations is an important trait and makes these formulations particularly useful from a manufacturing perspective.

EXAMPLE 7

Hydrogel contact lenses containing polyvinyl pyrrolidone

[00107] Contact lenses were made with the following proportions of PVP (M_p = of 360,000), and other components, as formulations F-1 to F-4 described in Table 8. Contact lenses also were made with the following proportions of PVP (as a mixture of 30% K-30 and 70% K-90), and other components, as formulations F-5 to F-7 described in Table 9. The initiator used in these formulations was VAZO® 64 (azo-bis-isobutyronitrile azonitrile, E.I. DuPont De Nemours & Co., Wilmington, DE, USA). Total parts of each formulation F-1 to F-7 is based on the combined parts of PVP (total), HEMA, PC-HEMA, EGDMA, Initiator, and water.

Table 8

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
F-1	1	77.2	14.6	0.7	0.50	5
F-2	2	77.2	14.6	0.7	0.50	5
F-3	3	77.2	14.6	0.7	0.50	5
F-4	4	77.2	14.6	0.7	0.50	5

Table 9

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
F-5	1	77.2	14.6	0.7	0.50	5
F-6	2	77.2	14.6	0.7	0.50	5
F-7	3	77.2	14.6	0.7	0.50	5

[00108] Lenses were made manually with the formulations by filling dry molds with 50 μL of monomer mix. They were subsequently closed and sealed manually and then thermally cured at 100 °C for 30 minutes. All lenses were de-molded and de-lensed manually, then packaged with 1.2 mL of BBS solution and autoclaved. The resulting lenses were tested to determine their modulus, contact angle (sessile drop method), tensile strength, water content and friction force, and the results were compared to a control. The results in Table 10 for modulus, tensile strength and water content are the average of results measured for five individual lenses, and the contact angle value is based on the average of three individual lenses. As a control (G), ProClear® lenses were used. These results are set forth in Tables 10 and 11.

Table 10

Formulation ID	PVP (Parts)	Modulus (MPa)	Contact Angle (°)	Tensile Strength (MPa)	Water Content (%)
G (Control)	0	0.340 ± 0.03	83.5 ± 3.5	0.492 ± 0.07	60.5 ± 0.3
F-1	1	0.397 ± 0.04	84.9 ± 2.3	0.608 ± 0.07	58.6 ± 0.6
F-2	2	0.370 ± 0.03	83.9 ± 3.6	0.574 ± 0.08	58.7 ± 0.4
F-3	3	0.393 ± 0.01	75.8 ± 2.3	0.452 ± 0.10	58.5 ± 0.5
F-4	4	0.342 ± 0.04	73.8 ± 4.0	0.642 ± 0.19	58.5 ± 0.4
F-5	1	0.353 ± 0.04	75.0 ± 2.7	0.392 ± 0.07	58.8 ± 0.4
F-6	2	0.513 ± 0.02	70.1 ± 1.7	0.533 ± 0.19	59.3 ± 0.5
F-7	3	0.504 ± 0.06	58.6 ± 1.9	0.749 ± 0.24	58.5 ± 0.6

Table 11

Formulation ID	PVP (Parts)	% Change in Modulus over Control	% Change in Contact Angle over Control	% Change in Tensile Strength over Control	% Change in Water Content over Control
F-1	1	+17	+2	+2	-3
F-2	2	+9	0	0	-3
F-3	3	+16	-9	-9	-3
F-4	4	+1	-12	-12	-3
F-5	1	+4	-10	-10	-3
F-6	2	+51	-16	-16	-2
F-7	3	+48	-30	-30	-3

[00109] The normalized friction forces for the Control G (ProClear® lenses) and formulations F-1 to F-4 are shown in FIG. 9. The normalized friction forces for the Control G (ProClear® lenses) and formulations F-5 to F-7 are shown in FIG. 10.

[00110] The addition of the single form of PVP at low concentrations (1 or 2 parts) had little if any effect on the contact angle of the lenses, but at higher concentrations (3 or 4 parts) the effect was at least a 10% reduction in contact angle. However, the effect of the mixture of two forms of PVP on the contact angle was much greater- the lower concentration (1 part) showed approximately the same level of reduction in contact angle as did the higher concentrations (3 or 4 parts) for the single form of PVP, while the formulations with 2 or 3 parts of the mixture of two forms of PVP showed significantly higher reductions in contact angle. Thus, the addition of the mixture of two forms of PVP appears to have a greater impact on the contact angle as compared to the single form of PVP.

[00111] For the formulations containing the single form of PVP, the lower concentrations (1 and 2 parts) showed lowered friction forces of between about 0.6 and about 0.5, and the higher concentrations (3 and 4 parts) showed even lower friction forces of about 0.4. The friction forces for all the formulations containing the mixture of two forms of PVP were between about 0.6 and 0.5, indicating that the addition of more of the mixture of PVPs did not have as significant of an effect on the reduction in friction force.

EXAMPLE 8

Hydrogel contact lenses containing polyvinyl pyrrolidone

[00112] Contact lenses were made with the following formulations and molecular weight(s) of PVP. Contact lenses were made with the following proportions of PVP (M_p = of 360,000), and other components, as formulations H-1 to H-3 described in Table 12. Contact lenses also were made with the following proportions of PVP (K-90), and other components, as formulations H-1 to H-3 described in Table 13. Contact lenses also were made with the following proportions of PVP (as a mixture of 30% K-30 and 70% K-90), and other components, as formulations H-7 to H-9 described in Table 14. Contact lenses also were made with the following proportions of PVP (K-80), and other components, as formulation H-10 described in Table 15. The initiator used in these formulations was VAZO® 64. Total parts of each formulation H-1 to H-10 is based on the combined parts of PVP (total), HEMA, PC-HEMA, EGDMA, Initiator, and water.

Table 12

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
H-1	1	77.2	14.6	0.7	0.50	5
H-2	3	77.2	14.6	0.7	0.50	5
H-3	5	77.2	14.6	0.7	0.50	5

Table 13

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
H-4	1	77.2	14.6	0.7	0.50	5
H-5	2	77.2	14.6	0.7	0.50	5
H-6	3	77.2	14.6	0.7	0.50	5

Table 14

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
H-7	1	77.2	14.6	0.7	0.50	5
H-8	2	77.2	14.6	0.7	0.50	5
H-9	3	77.2	14.6	0.7	0.50	5

Table 15

Formulation ID	PVP (Parts)	HEMA (Parts)	PC-HEMA (Parts)	EGDMA (Parts)	Initiator (Parts)	DI Water (Parts)
H-10	3	77.2	14.6	0.7	0.50	5

[00113] Lenses were made manually with the formulations H-1 to H-10 by filling dry molds with 50 μL of monomer mix. They were subsequently closed and sealed manually and then thermally cured at 100 °C for 30 minutes. All lenses were de-molded and de-lensed manually, then packaged with 1.2 mL of BBS buffer solution, and autoclaved. For formulation H-10, separate lenses also were packaged in a solution containing 500 ppm PVP (K-90), as formulation H-10B, and also packaged in a solution containing 1000 ppm PVP (K-90) as formulation H-10C. Once the lenses had fully hydrated and equilibrated, the resulting lenses were taken out of the package, excess packaging solution was surface blotted dry using lens

paper, and the lenses were placed into a glass vial containing 0.4 mL PBS. Each vial was placed into a shaker rotating at 300 rpm at 35 °C. Time points are taken at 1, 2, 4, 8, and 16 hours unless indicated otherwise. The amount of released PVP (μg) present in the solution was determined via GPC analysis. The results of *in vitro* release testing of the lenses are shown in FIGS. 11-14. Each time point represents an average of 3 individual lenses.

[00114] As shown by the results, for all the formulations containing a single form of PVP, the *in vitro* release of PVP reached a maximum at about 4 hours, with the release staying at a plateau for the later timepoints. However, for the formulations containing the mixture of two forms of PVP with different molecular weights, the *in vitro* PVP release continued to increase over all the timepoints measured. The release from the formulations containing two forms of PVP with different K-values appeared to bi-phasic, with the release plot having a slope greater than 1 from about 0 hours to about 4 hours, and the release plot having a slope of less than 1 from about 4 hours to about 16 hours.

[00115] The addition of a form of PVP to the packaging solution resulted in a significant increase in the duration of release of PVP from the formulation. The formulation packaged without PVP showed release of PVP plateauing after about 4 hours, while the formulations packaged with 500 ppm and 1000 ppm PVP continued to release PVP over all the timepoints evaluated. Thus, the addition of at least one form of PVP to the packaging solution results in a lens formulation containing a single form of PVP releasing PVP over a period of at least 16 hours. Additionally, the amount of PVP released in the presence of 500 ppm PVP and 1000 PVP was essentially the same, indicating that using a packaging solution containing 500 ppm of a form of PVP is unexpectedly superior.

[00116] In reference to the disclosure herein, when an amount, concentration, or other value or parameter is given as either a range, preferred range, or a list of upper preferable values and lower preferable values, this is to be understood as specifically disclosing all ranges formed from any pair of any upper range limit or preferred value and any lower range limit or preferred value, regardless of whether ranges are separately disclosed. Where a range of numerical values is recited herein, unless otherwise stated, the range is intended to include the endpoints thereof, and all integers and fractions within the range. It is not intended that the scope of the invention be limited to the specific values recited when defining a range.

[00117] Other embodiments of the present invention will be apparent to those skilled in the art from consideration of the present specification and practice of the present invention disclosed herein. It is intended that the present specification and examples be considered as exemplary only with a true scope and spirit of the invention being indicated by the following claims and equivalents thereof.

What is claimed is:

1. A contact lens, comprising:

a lens body which is the reaction product of a polymerizable composition, the polymerizable composition comprising one or more monomers and a crosslinker that crosslinks the one or more monomers during polymerization to form a first polymer component, and said polymerization taking place in the presence of at least two forms of polyvinyl pyrrolidone, each of the at least two forms of polyvinyl pyrrolidone having a different average molecular weight;

wherein the at least two forms of polyvinyl pyrrolidone are associated with the first polymer component in the lens body such that a form of polyvinyl pyrrolidone is released from the lens body for at least eight hours based on *in vitro* testing.

2. The contact lens of claim 1, wherein the at least two forms of polyvinyl pyrrolidone are present in the polymerizable composition in a total amount from about 1% to about 5% by weight.

3. The contact lens of claim 1, wherein a first of the at least two forms of polyvinyl pyrrolidone has an average molecular weight in the range of about 10 kilodaltons to about 50 kilodaltons and a second of the at least two forms of polyvinyl pyrrolidone has an average molecular weight in the range of about 800 kilodaltons to about 1,200 kilodaltons.

4. The contact lens of claim 1, wherein the at least two forms of polyvinyl pyrrolidone comprise two forms of polyvinyl pyrrolidone, and a first of the two forms of polyvinyl pyrrolidone has a K-value based on Fikentscher's value of viscosity characteristics equation of about 10 to about 50 and a second of the two forms of polyvinyl pyrrolidone has a K-value of about 80 to about 120.

5. The contact lens of claim 1, wherein the form of polyvinyl pyrrolidone is released from the lens body for at least 16 hours based on *in vitro* testing.

6. The contact lens of claim 1, wherein the form of polyvinyl pyrrolidone has a biphasic release profile over a period of about 16 hours based on *in vitro* testing.

7. The contact lens of claim 1, wherein the at least two forms of polyvinyl pyrrolidone comprise a higher molecular weight form of polyvinyl pyrrolidone and a lower molecular weight form of polyvinyl pyrrolidone, and the higher molecular weight form is present in the polymerizable composition in a greater amount than the lower molecular weight form.

8. The contact lens of claim 1 wherein the at least two forms of polyvinyl pyrrolidone comprise a lower molecular weight form of polyvinyl pyrrolidone and a higher molecular weight form of polyvinyl pyrrolidone, and the lower molecular weight form and the higher molecular weight form are present in the polymerizable composition in a mixture of about 20 to about 40% of the lower molecular weight form and about 60 to about 80% of the higher molecular weight form, and are present in the polymerizable composition in a total amount of between about 1% and about 5% by weight.

9. The contact lens of claim 8, wherein the mixture of the lower molecular weight form and the higher molecular weight form of polyvinyl pyrrolidone is present in the polymerizable composition in a total amount of about 2% to about 4% by weight.

10. The contact lens of claim 1, wherein a surface friction of the lens body is at least 30% less than a surface friction of a second contact lens comprising the reaction product of an identical polymerizable composition without the at least two forms of polyvinyl pyrrolidone.

11. The contact lens of claim 1, wherein a sessile drop contact angle of the lens body is at least 30% less than a sessile drop contact angle of a second contact lens comprising the reaction product of an identical polymerizable composition without the at least two forms of polyvinyl pyrrolidone.

12. The contact lens of claim 1, wherein a viscosity of the polymerizable composition is at least 30% less than a viscosity of an identical polymerizable composition with a single form of polyvinyl pyrrolidone of the same molecular weight as a highest molecular weight form of PVP in the mixture and is present at a concentration that is the same as a concentration of the highest molecular weight form in the mixture.

13. The contact lens of claim 1, wherein a viscosity of the polymerizable composition is at least 50% less than a viscosity of an identical polymerizable composition with a single form of polyvinyl pyrrolidone of the same molecular weight as a highest molecular weight form of PVP in the mixture and is present at a concentration that is the same as a concentration of the highest molecular weight form in the mixture.

14. A contact lens package comprising:

a contact lens body, wherein the lens body is the reaction product of a polymerizable composition comprising one or more monomers, at least one crosslinker that crosslinks the one or more monomers during polymerization to form a first polymer component,

said polymerization taking place in the presence of a first at least one form of polyvinyl pyrrolidone; and

a packaging solution, wherein the packaging solution comprises an aqueous solution containing an additional at least one form of polyvinyl pyrrolidone.

15. The package of claim 14, wherein the first at least one form of polyvinyl pyrrolidone present in the polymerizable composition comprises at least two forms of polyvinyl pyrrolidone, wherein each of the at least two forms of polyvinyl pyrrolidone has a different average molecular weight.

16. The package of claim 14, wherein the additional at least one form of polyvinyl pyrrolidone present in the packaging solution is the same as the first at least one form of polyvinyl pyrrolidone present in the polymerizable composition.

17. The package of claim 14, wherein the additional at least one form polyvinyl pyrrolidone present in the packaging solution is different from the polyvinyl pyrrolidone present in the polymerizable composition.

18. The package of claim 14, wherein the additional at least one form of polyvinyl pyrrolidone is present in the packaging solution at a concentration of at least 500 parts per million.

19. The package of claim 14, wherein the at least two forms of polyvinyl pyrrolidone in the polymerizable composition are associated with the first polymer component in the lens body such that a form of polyvinyl pyrrolidone is released from the lens body for at least eight hours based on *in vitro* release testing.

20. The package of claim 14, wherein the package further comprises a base member with a cavity configured to hold the contact lens and the packaging solution, and a seal attached to the base member configured to maintain the contact lens and the packaging solution in a sterile condition for a duration equivalent to a shelf life of the contact lens.

20. A method for producing a contact lens comprising:

providing a polymerizable composition comprising one or more monomers, at least one crosslinker, and at least two forms of polyvinyl pyrrolidone, each of the at least two forms of polyvinyl pyrrolidone having a different average molecular weight; and

polymerizing the polymerizable composition, providing a lens body.

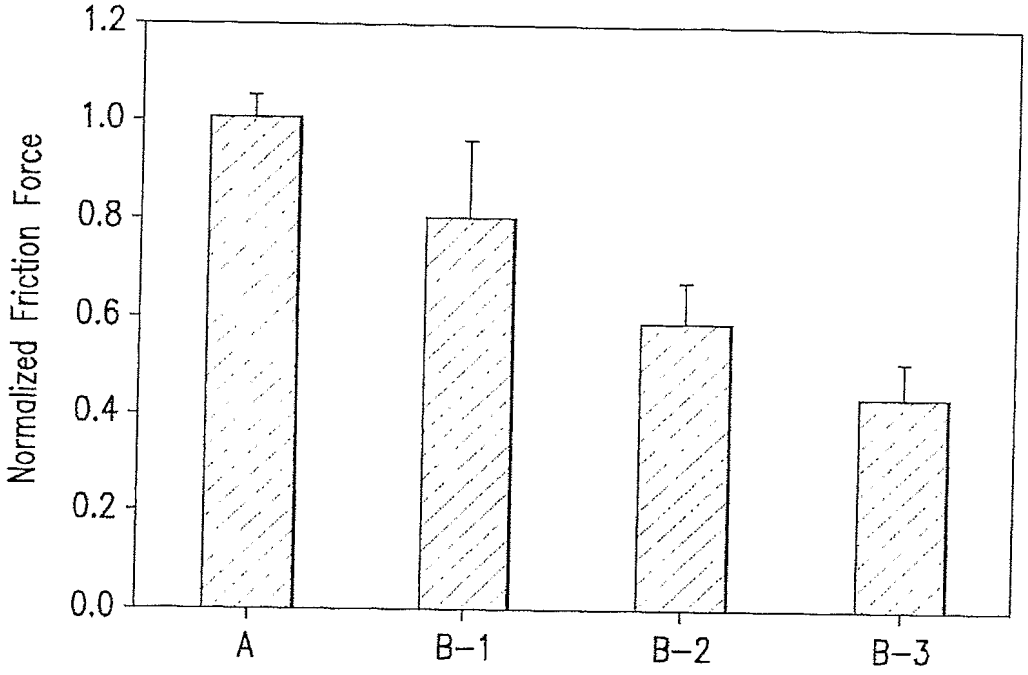


FIG. 1

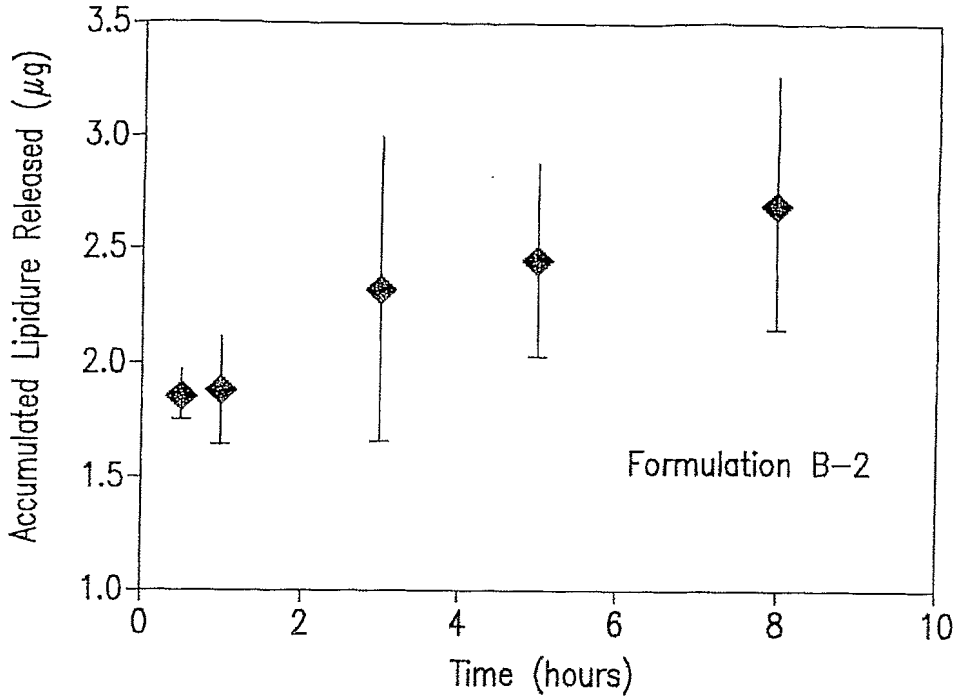

Accumulated Lipidure Released (μg)
3.5
3.0
2.5
2.0
1.5
1.0
0
2
4
6
8
10
Time (hours)
Formulation B-2

FIG.2

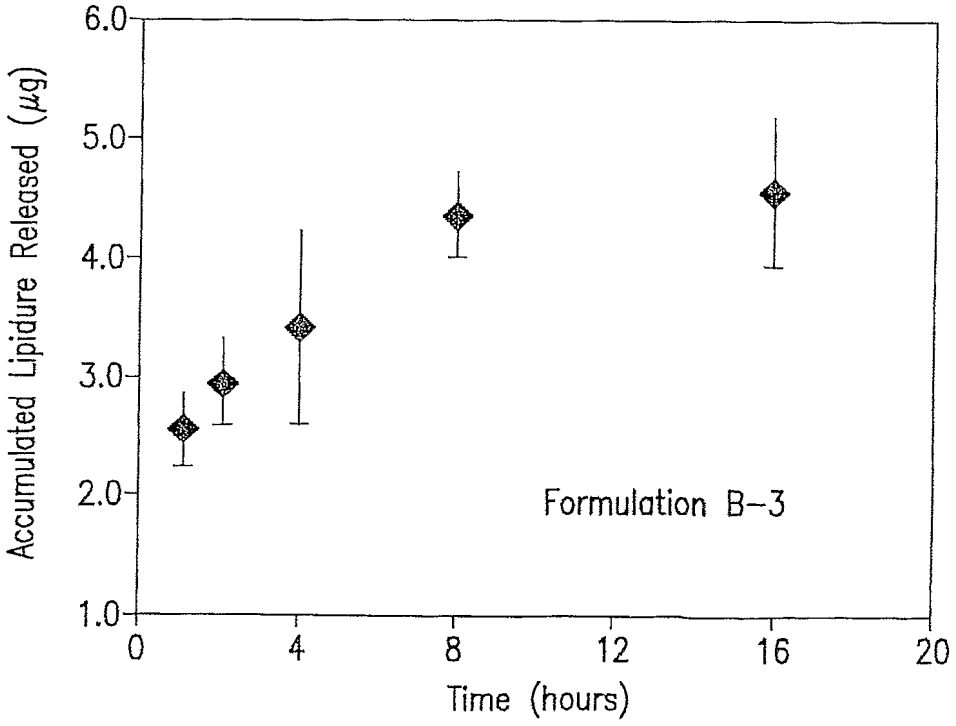

Accumulated Lipidure Released (μg)
6.0
5.0
4.0
3.0
2.0
1.0
0
4
8
12
16
20
Time (hours)
Formulation B-3

FIG.3

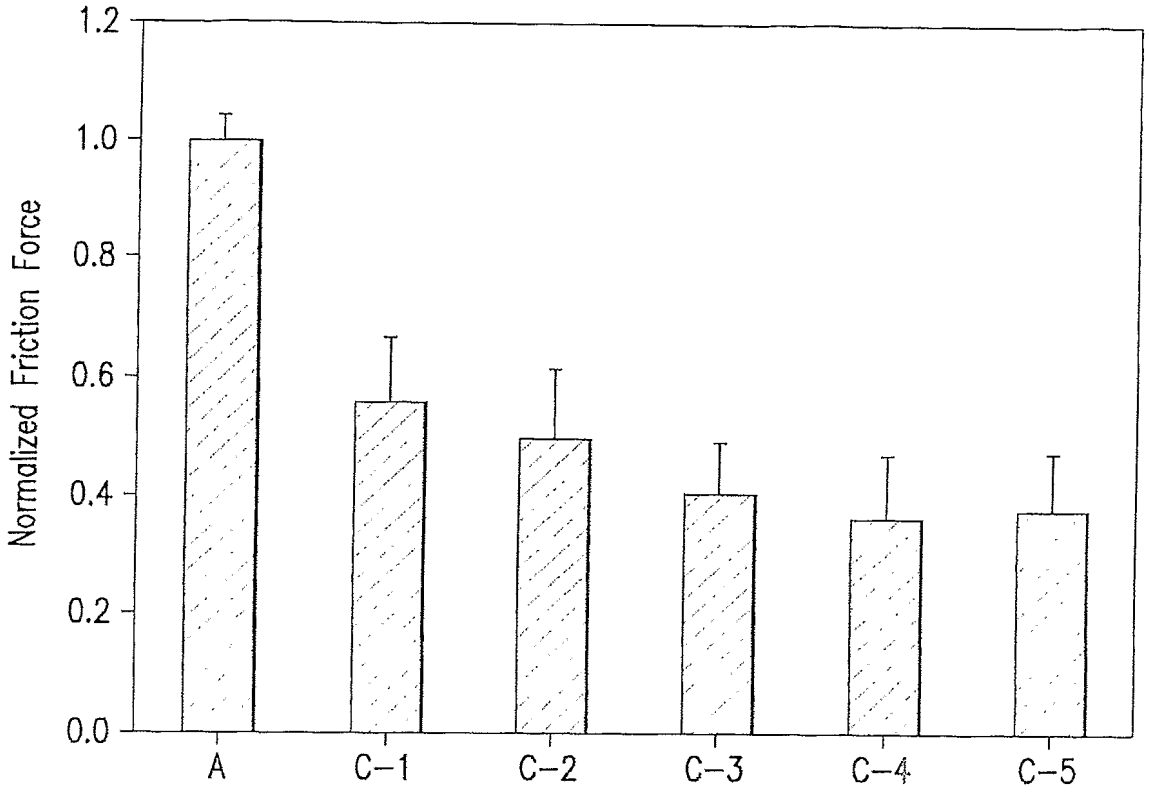


FIG.4

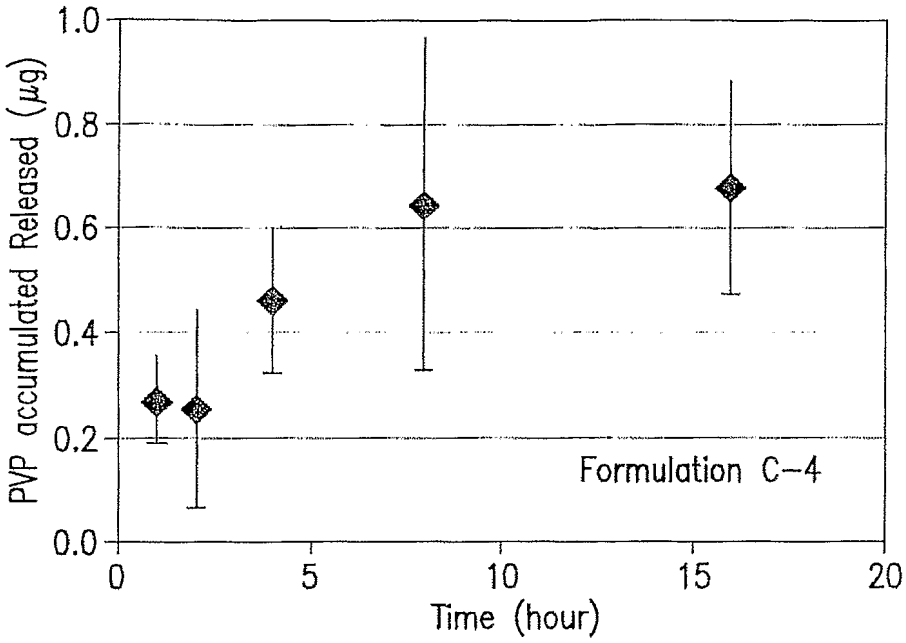

PVP accumulated Released (μg)
1.0
0.8
0.6
0.4
0.2
0.0
0
5
10
15
20
Time (hour)
Formulation C-4

FIG.5

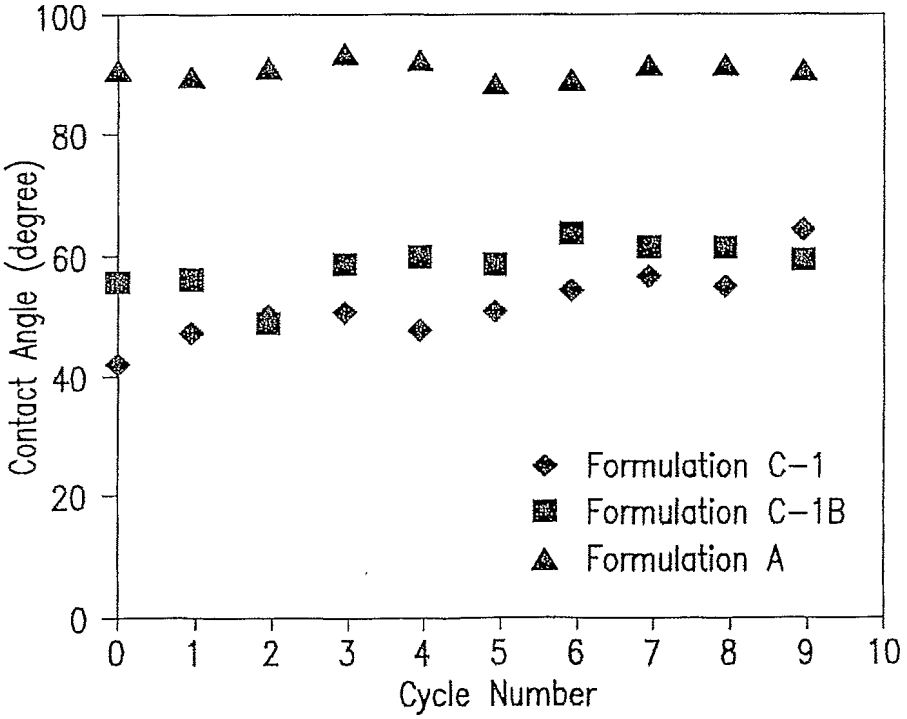

Contact Angle (degree)
100
80
60
40
20
0
0
1
2
3
4
5
6
7
8
9
10
Cycle Number
Formulation C-1
Formulation C-1B
Formulation A

FIG.6

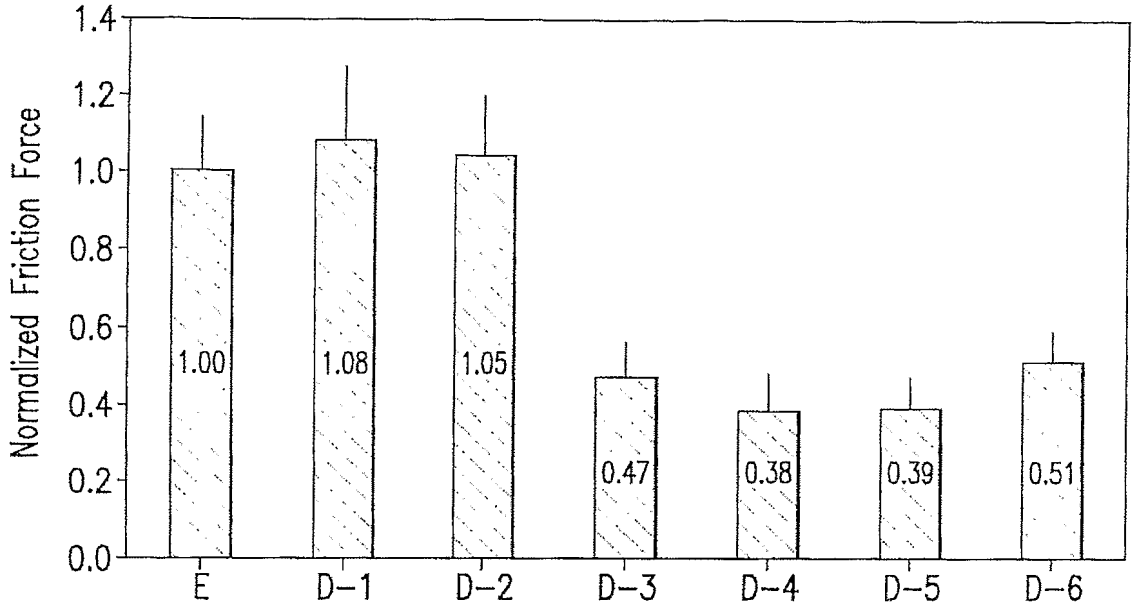

Normalized Friction Force
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
1.00
1.08
1.05
0.47
0.38
0.39
0.51
E
D-1
D-2
D-3
D-4
D-5
D-6

FIG. 7

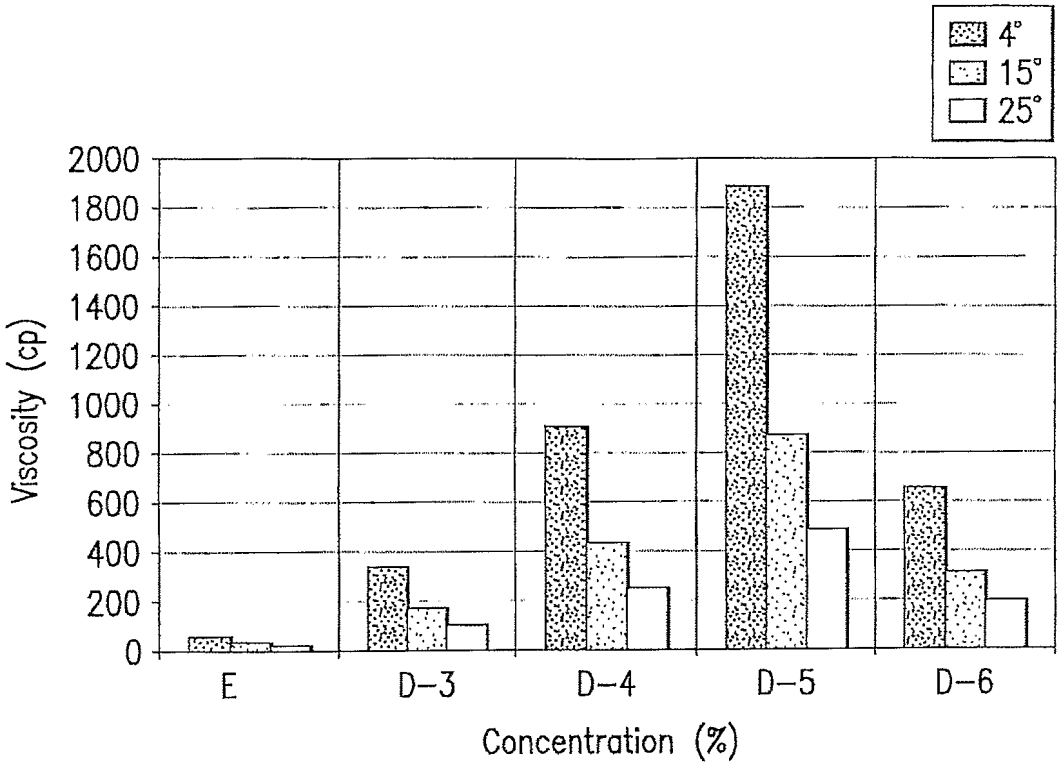

4°
15°
25°
2000
1800
1600
1400
1200
1000
800
600
400
200
0
Viscosity (cp)
E
D-3
D-4
D-5
D-6
Concentration (%)

FIG.8

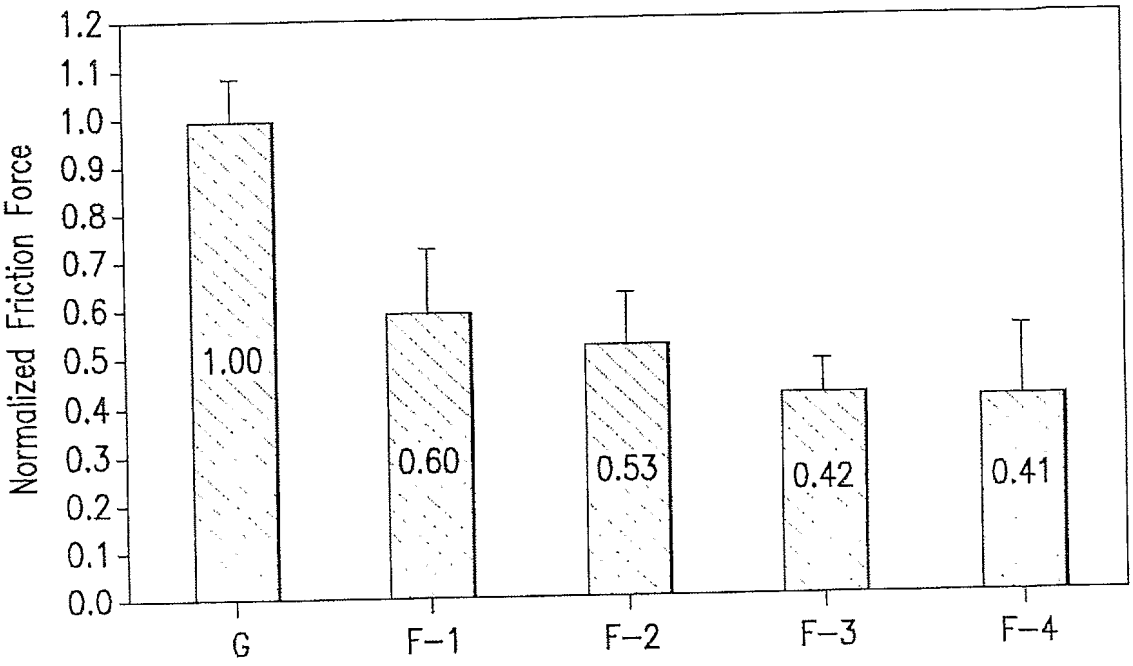

Normalized Friction Force
1.2
1.1
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
1.00
0.60
0.53
0.42
0.41
G
F-1
F-2
F-3
F-4

FIG.9

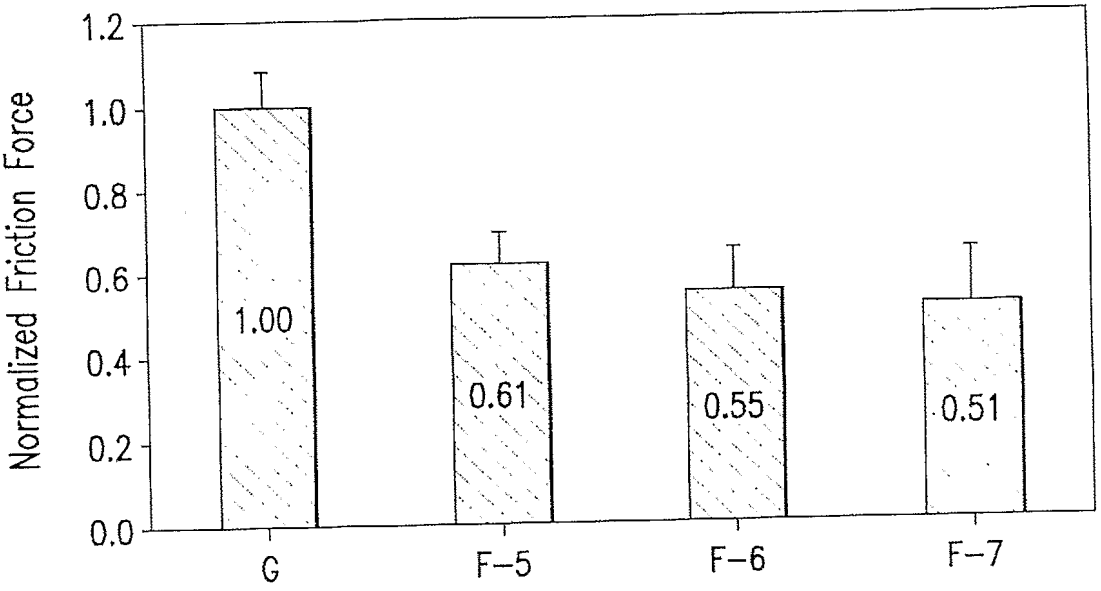

Normalized Friction Force
1.2
1.0
0.8
0.6
0.4
0.2
0.0
1.00
0.61
0.55
0.51
G
F-5
F-6
F-7

FIG.10

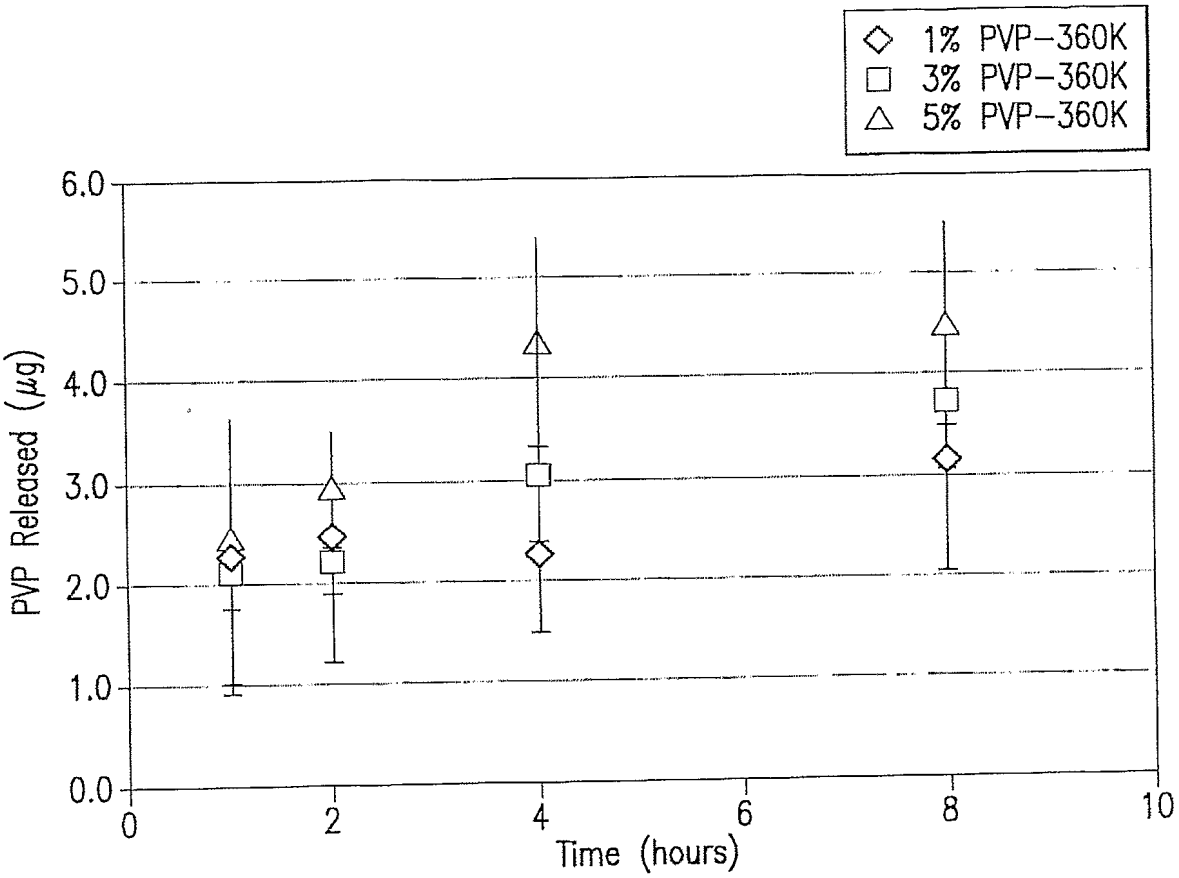

1% PVP-360K
3% PVP-360K
5% PVP-360K
PVP Released (μg)
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
Time (hours)

FIG.11

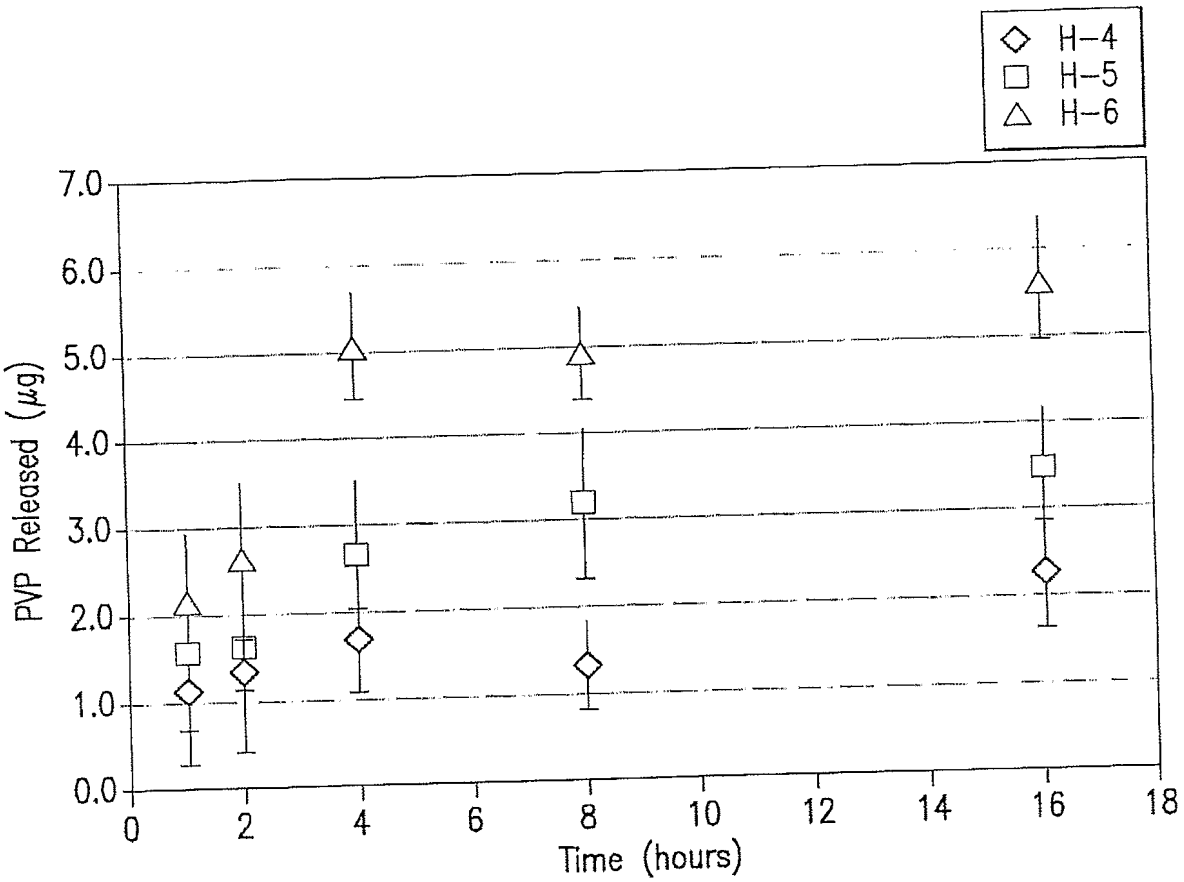

H-4
H-5
H-6
PVP Released (μg)
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
12
14
16
18
Time (hours)

FIG. 12

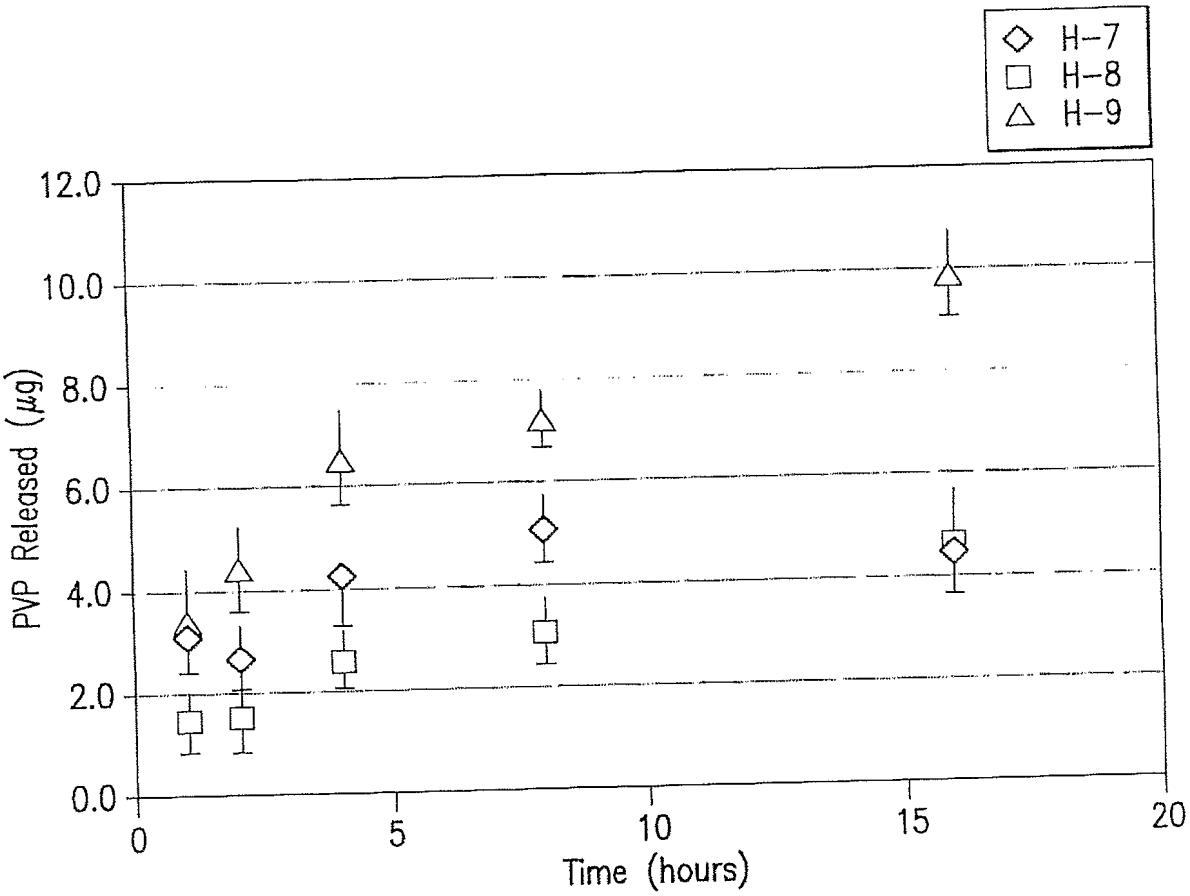

H-7
H-8
H-9
12.0
10.0
8.0
6.0
4.0
2.0
0.0
PVP Released (μg)
0
5
10
15
20
Time (hours)

FIG.13

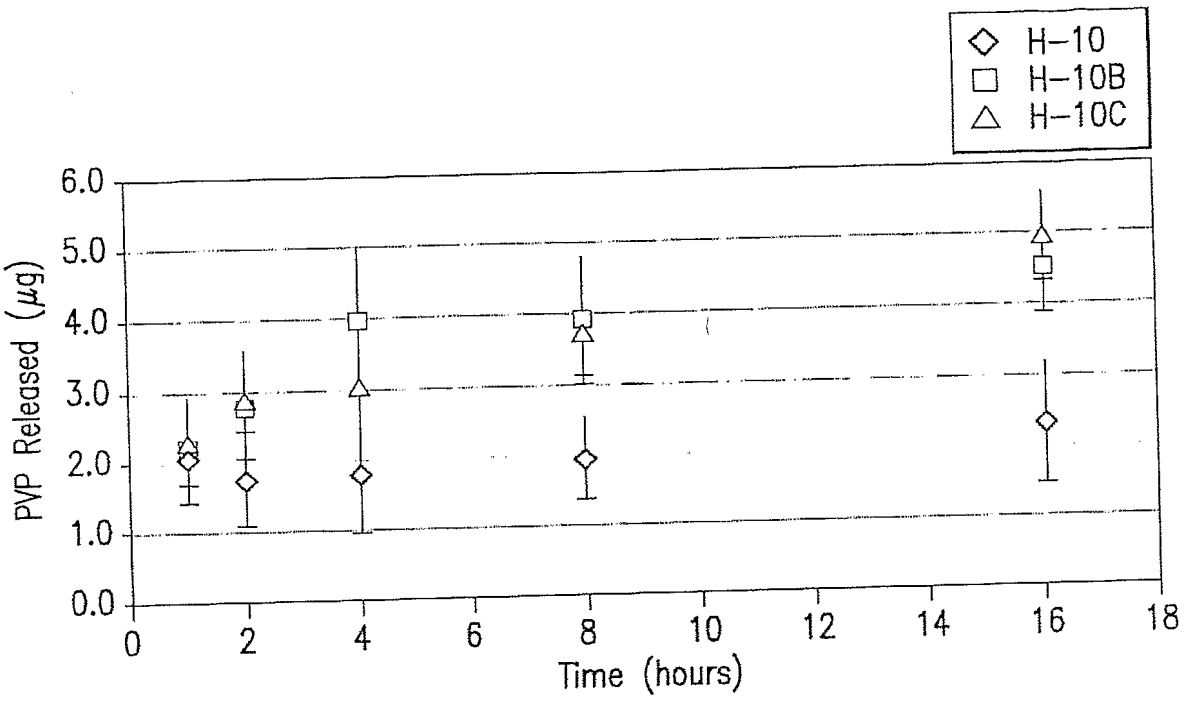

H-10
H-10B
H-10C
PVP Released (μg)
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0
2
4
6
8
10
12
14
16
18
Time (hours)

FIG.14