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(54) **PACKAGING SOLUTIONS**

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(57) **ABSTRACT**

The present invention is directed to new and improved packaging systems for storing ophthalmic devices such as contact lenses and to methods for packaging such ophthalmic devices with solutions to improve the comfort of the lenses during wear. In particular, the present invention is directed to a packaging system for storing an ophthalmic device in an aqueous packaging solution comprising hyaluronic acid or a salt thereof. Such solutions are retained on the surface of an unused lens for extended periods of time, resulting in surface modification that persists in the eye, which may provide significant improvement in the wetting properties of fresh contact lenses used for the first time and, moreover, even several hours after lens insertion, thereby preventing dryness and improving lubricity.

PACKAGING SOLUTIONS

BACKGROUND OF THE INVENTION

[0001] 1. Technical Field

[0002] The present invention generally relates to packaging solutions for ophthalmic devices such as contact lenses.

[0003] 2. Description of Related Art

[0004] Blister-packs and glass vials are typically used to individually package each soft contact lens for sale to a customer. Saline or deionized water is commonly used to store the lens in the blister-packs, as mentioned in various patents related to the packaging or manufacturing of contact lenses. Because lens material may tend to stick to itself and to the lens package, packaging solutions for blister-packs have sometimes been formulated to reduce or eliminate lens folding and sticking. For this reason, polyvinyl alcohol (PVA) has been used in contact-lens packaging solutions.

[0005] It has been stated that if a lens is thoroughly cleaned before insertion, lacrimal fluid can adequately wet the lens. Furthermore, the difficulties of adding a surfactant to a packaging solution, including the possibility of lowering shelf-life and/or adverse reactions during heat sterilization, have further limited the use of surfactants in a packaging solution for the purpose of providing any possible or marginal effect on lens comfort. It is only after a lens has been worn, when proteins or other deposits have formed on the surface of the lens, that surfactants have been used in standard lens-care solutions.

[0006] It is highly desirable that contact lens be as comfortable as possible for wearers. Manufacturers of contact lenses are continually working to improve the comfort of the lenses. Nevertheless, many people who wear contact lenses still experience dryness or eye irritation throughout the day and particularly towards the end of the day. An insufficiently wetted lens at any point in time will cause significant discomfort to the lens wearer. Although wetting drops can be used as needed to alleviate such discomfort, it would certainly be desirable if such discomfort did not arise in the first place.

[0007] U.S. Pat. No. 5,882,687 ("the '687 patent") discloses a package containing a contact lens suitable for immediate use which comprises (a) a solution comprising a soluble polyanionic component and having a viscosity of less than 50 cps at 25° C., an osmolality of at least about 200 mOsm/kg and a pH in the range of about 6 to about 9; (b) at least one contact lens, and (c) a container for holding the solution and contact lens sufficient to preserve the sterility of the solution and contact lens, wherein the solution contains no additional disinfectant component. However, the '687 patent nowhere provides any disclosure of the use of hyaluronic acid in a packaging solution.

[0008] Accordingly, it would be desirable to provide an improved packaging system for an ophthalmic lens such that the lens would be comfortable to wear in actual use and allow for extended wear of the lens without irritation or other adverse effects to the cornea.

SUMMARY OF THE INVENTION

[0009] In accordance with one embodiment of the present invention, a method of preparing a package comprising a storable, sterile ophthalmic device is provided comprising:

[0010] (a) immersing an ophthalmic device in an aqueous packaging solution comprising hyaluronic acid or a salt thereof, wherein the solution has an osmolality of at least about 200 mOsm/kg and a pH in the range of about 4 to about 9;

[0011] (b) packaging the solution and the device in a manner preventing contamination of the device by microorganisms; and

[0012] (c) sterilizing the packaged solution and device.

[0013] In accordance with a second embodiment of the present invention, a method for packaging and storing a contact lens is provided comprising, prior to delivery of the contact lens to the customer-wearer, immersing the contact lens in an aqueous packaging solution inside a package and heat sterilizing the solution, wherein the aqueous packaging solution comprises a sterile ophthalmically safe aqueous solution comprising hyaluronic acid or a salt thereof, wherein the solution has an osmolality of at least about 200 mOsm/kg and a pH of about 4 to about 9.

[0014] In accordance with a third embodiment of the present invention, a packaging system for the storage of an ophthalmic device is provided comprising a sealed container containing one or more unused ophthalmic devices immersed in an aqueous packaging solution comprising hyaluronic acid or a salt thereof, wherein the solution has an osmolality of at least about 200 mOsm/kg, a pH of about 4 to about 9 and is heat sterilized.

[0015] In accordance with a fourth embodiment of the present invention, a packaging system for the storage of an ophthalmic device is provided comprising:

[0016] (a) an aqueous packaging solution comprising hyaluronic acid or a salt thereof, wherein the solution has an osmolality of at least about 200 mOsm/kg and a pH in the range of about 4 to about 9;

[0017] (b) at least one ophthalmic device; and

[0018] (c) a container for holding the solution and ophthalmic device sufficient to preserve the sterility of the solution and ophthalmic device, wherein the solution does not contain an effective disinfecting amount of a disinfecting agent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

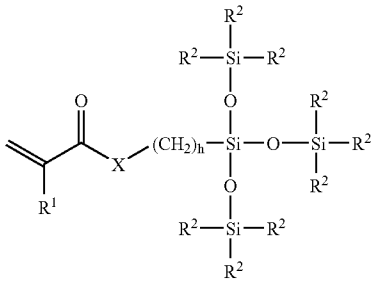
[0019] The present invention provides a packaging system for the storage of ophthalmic devices intended for direct contact with body tissue or body fluid. As used herein, the term "ophthalmic device" refers to devices that reside in or on the eye. These lenses can provide optical correction, wound care, drug delivery, diagnostic functionality or cosmetic enhancement or effect or a combination of these properties. Representative examples of such devices include, but are not limited to, soft contact lenses, e.g., a soft, hydrogel lens; soft, non-hydrogel lens and the like, hard contact lenses, e.g., a hard, gas permeable lens material and the like, intraocular lenses, overlay lenses, ocular inserts, optical inserts and the like. As is understood by one skilled in the art, a lens is considered to be "soft" if it can be folded back upon itself without breaking. Any material known to produce an ophthalmic device including a contact lens can be used herein.

[0020] It is particularly useful to employ biocompatible materials herein including both soft and rigid materials commonly used for ophthalmic lenses, including contact lenses. The preferred substrates are hydrogel materials, including silicone hydrogel materials. Particularly preferred materials include vinyl functionalized polydimethylsiloxanes copolymerized with hydrophilic monomers as well as fluorinated

methacrylates and methacrylate functionalized fluorinated polyethylene oxides copolymerized with hydrophilic monomers. Representative examples of substrate materials for use herein include those disclosed in U.S. Pat. Nos. 5,310,779; 5,387,662; 5,449,729; 5,512,205; 5,610,252; 5,616,757; 5,708,094; 5,710,302; 5,714,557 and 5,908,906, the contents of which are incorporated by reference herein.

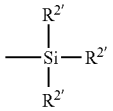
[0021] A wide variety of materials can be used herein, and silicone hydrogel contact lens materials are particularly preferred. Hydrogels in general are a well-known class of materials that comprise hydrated, cross-linked polymeric systems containing water in an equilibrium state. Silicone hydrogels generally have a water content greater than about 5 weight percent and more commonly between about 10 to about 80 weight percent. Such materials are usually prepared by polymerizing a mixture containing at least one silicone-containing monomer and at least one hydrophilic monomer. Typically, either the silicone-containing monomer or the hydrophilic monomer functions as a crosslinking agent (a crosslinker being defined as a monomer having multiple polymerizable functionalities) or a separate crosslinker may be employed. Applicable silicone-containing monomeric units for use in the formation of silicone hydrogels are well known in the art and numerous examples are provided in U.S. Pat. Nos. 4,136,250; 4,153,641; 4,740,533; 5,034,461; 5,070,215; 5,260,000; 5,310,779; and 5,358,995.

[0022] Representative examples of applicable silicon-containing monomeric units include bulky polysiloxanylalkyl (meth)acrylic monomers. An example of a bulky polysiloxanylalkyl(meth)acrylic monomer is represented by the structure of Formula I:



(I)

wherein X denotes —O— or —NR—; each R^1 independently denotes hydrogen or methyl; each R^2 independently denotes a lower alkyl radical, phenyl radical or a group represented by



wherein each $R^{2'}$ independently denotes a lower alkyl or phenyl radical; and h is 1 to 10.

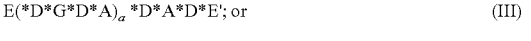
[0023] Examples of bulky monomers are methacryloxypropyl tris(trimethyl-siloxy)silane or tris(trimethylsiloxy) silylpropyl methacrylate, sometimes referred to as TRIS and tris(trimethylsiloxy)silylpropyl vinyl carbamate, sometimes referred to as TRIS-VC and the like.

[0024] Such bulky monomers may be copolymerized with a silicone macromonomer, which is a poly(organosiloxane) capped with an unsaturated group at two or more ends of the molecule. U.S. Pat. No. 4,153,641 discloses, for example, various unsaturated groups such as acryloxy or methacryloxy groups.

[0025] Another class of representative silicone-containing monomers includes, but is not limited to, silicone-containing vinyl carbonate or vinyl carbamate monomers such as, for example, 1,3-bis[4-vinyloxycarbonyloxy)but-1-yl]tetramethyl-disiloxane; 3-(trimethylsilyl)propyl vinyl carbonate; 3-(vinyloxycarbonylthio)propyl-[tris(trimethylsiloxy)silane]; 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate; 3-[tris(trimethylsiloxy)silyl]propyl allyl carbamate; 3-[tris (trimethylsiloxy)silyl]propyl vinyl carbonate; t-butyldimethylsiloxyethyl vinyl carbonate; trimethylsilylethyl vinyl carbonate; trimethylsilylmethyl vinyl carbonate and the like and mixtures thereof.

[0026] Another class of silicon-containing monomers includes polyurethane-polysiloxane macromonomers (also sometimes referred to as prepolymers), which may have hard-soft-hard blocks like traditional urethane elastomers. They may be end-capped with a hydrophilic monomer such as 2-hydroxyethyl methacrylate (HEMA). Examples of such silicone urethanes are disclosed in a variety or publications, including Lai, Yu-Chin, "The Role of Bulky Polysiloxanylalkyl Methacryates in Polyurethane-Polysiloxane Hydrogels," Journal of Applied Polymer Science, Vol. 60, 1193-1199 (1996). PCT Published Application No. WO 96/31792 discloses examples of such monomers, which disclosure is hereby incorporated by reference in its entirety. Further examples of silicone urethane monomers are represented by Formulae II and III:

$$E(*D*A*D*G)_a *D*A*D*E'; \text{ or} \quad \text{(II)}$$



$$E(*D*G*D*A)_a *D*A*D*E'; \text{ or} \quad \text{(III)}$$

wherein:

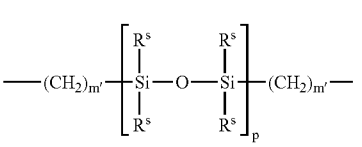
[0027] D independently denotes an alkyl diradical, an alkyl cycloalkyl diradical, a cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 6 to about 30 carbon atoms;

[0028] G independently denotes an alkyl diradical, a cycloalkyl diradical, an alkyl cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 1 to about 40 carbon atoms and which may contain ether, thio or amine linkages in the main chain;

[0029] * denotes a urethane or ureido linkage;

[0030] a is at least 1;

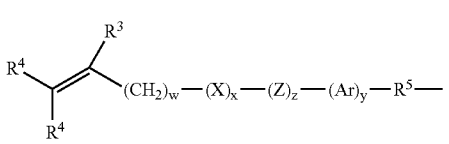
[0031] A independently denotes a divalent polymeric radical of Formula IV:



(IV)

wherein each R^s independently denotes an alkyl or fluoro-substituted alkyl group having 1 to about 10 carbon atoms which may contain ether linkages between the carbon atoms; m' is at least 1; and p is a number that provides a moiety weight of about 400 to about 10,000;

[0032] each of E and E' independently denotes a polymerizable unsaturated organic radical represented by Formula V:



(V)

wherein: R^3 is hydrogen or methyl;

[0033] R^4 is hydrogen, an alkyl radical having 1 to 6 carbon atoms, or a —CO—Y—R^6 radical wherein Y is —O—, —S— or —NH—;

[0034] R^5 is a divalent alkylene radical having 1 to about 10 carbon atoms;

[0035] R^6 is a alkyl radical having 1 to about 12 carbon atoms;

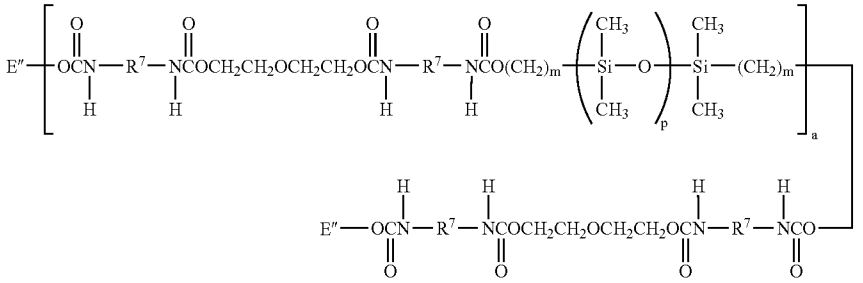
[0036] X denotes —CO— or —OCO—;

[0037] Z denotes —O— or —NH—;

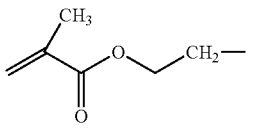
[0038] Ar denotes an aromatic radical having about 6 to about 30 carbon atoms;

[0039] w is 0 to 6; x is 0 or 1; y is 0 or 1; and z is 0 or 1.

[0040] A preferred silicone-containing urethane monomer is represented by Formula VI:



wherein m is at least 1 and is preferably 3 or 4, a is at least 1 and preferably is 1, p is a number which provides a moiety weight of about 400 to about 10,000 and is preferably at least about 30, R^7 is a diradical of a diisocyanate after removal of the isocyanate group, such as the diradical of isophorone diisocyanate, and each E" is a group represented by:



[0041] In another embodiment of the present invention, a silicone hydrogel material comprises (in bulk, that is, in the monomer mixture that is copolymerized) about 5 to about 50 percent, and preferably about 10 to about 25, by weight of one or more silicone macromonomers, about 5 to about 75 percent, and preferably about 30 to about 60 percent, by weight of one or more polysiloxanylalkyl (meth)acrylic monomers, and about 10 to about 50 percent, and preferably about 20 to about 40 percent, by weight of a hydrophilic monomer. In general, the silicone macromonomer is a poly(organosiloxane) capped with an unsaturated group at two or more ends of the molecule. In addition to the end groups in the above structural formulas, U.S. Pat. No. 4,153,641 discloses additional unsaturated groups, including acryloxy or methacryloxy. Fumarate-containing materials such as those disclosed in U.S. Pat. Nos. 5,310,779; 5,449,729 and 5,512,205 are also useful substrates in accordance with the invention. Preferably, the silane macromonomer is a silicon-containing vinyl carbonate or vinyl carbamate or a polyurethane-polysiloxane having one or more hard-soft-hard blocks and end-capped with a hydrophilic monomer.

[0042] Suitable hydrophilic monomers include amides such as dimethylacrylamide and dimethylmethacrylamide, cyclic lactams such as n-vinyl-2-pyrrolidone and poly(alkene glycols) functionalized with polymerizable groups. Examples of useful functionalized poly(alkene glycols) include poly(diethylene glycols) of varying chain length containing monomethacrylate or dimethacrylate end caps. In a preferred embodiment, the poly(alkene glycol) polymer contains at least two alkene glycol monomeric units. Still further examples are the hydrophilic vinyl carbonate or vinyl carbamate monomers disclosed in U.S. Pat. No. 5,070,215, and the hydrophilic oxazolone monomers disclosed in U.S. Pat. No. 4,910,277. Other suitable hydrophilic monomers will be apparent to one skilled in the art.

[0043] In one embodiment, the lens can be a Group II and Group IV lens having a water content greater than about 50% by weight, preferably about 55% to about 80% water. High water content is associated with materials having high oxygen permeability, resulting in the increasing popularity of such lenses, including especially disposable and planned-replacement lenses. Group IV materials include, but are not limited to, bufilcon A, etafilcon A, methafilcon A, ocufilcon C, perfilcon A, phemfilcon A, and vifilcon A. Materials containing methacrylic acid monomers include methafilcon B, ocufilcon D, methafilcon A, and etafilcon A (USAN and the USAP Dictionary of Drug Names). Group II materials include, by way of example only, lidofilcon A or B, alphafilcon A, Sauflon, Hydron, etc., which materials typically contain primarily HEMA and N-vinylpyrrolidone (NVP). DMA (N,N-dimethylacrylamide) is another Group II monomer that may be used in Group II lens materials to provide hydrophilicity.

[0044] The above silicone materials are merely exemplary, and other materials for use as substrates that can benefit by being packaged in the solutions according to the present invention and have been disclosed in various publications and

are being continuously developed for use in contact lenses and other medical devices can also be used. For example, an ophthalmic lens for use herein can be a cationic lens such as a cationic contact lens or fluorinated silicone-containing monomers. Such monomers have been used in the formation of fluorosilicone hydrogels to reduce the accumulation of deposits on contact lenses made therefrom, as disclosed in, for example, U.S. Pat. Nos. 4,954,587; 5,010,141 and 5,079,319. The use of silicone-containing monomers having certain fluorinated side groups, i.e., —(CF_2)—H, have been found to improve compatibility between the hydrophilic and silicone-containing monomeric units. See, e.g., U.S. Pat. Nos. 5,321,108 and 5,387,662.

[0045] In another embodiment, the present invention is also directed to a contact lens for extended-wear or specialty uses, such as for relatively thick lenses. Extended lenses are lenses capable of being worn overnight, preferably capable of being worn for at least one week, most preferably capable of wear for a continuous period of one week to one month. By "capable" is meant lenses approved by one or more governmental regulatory authorities for such consumer use, for example, the U.S. Food & Drug Administration (USFDA) in the U.S. or its equivalent in other countries.

[0046] Extended-wear lenses require relatively high oxygen permeability. The oxygen-permeability is the rate at which oxygen will pass through a material. The oxygen-permeability Dk of a lens material does not depend on lens thickness. Oxygen permeability is measured in terms of barrers which have the following units of measurement:

[0047] On the other hand, the oxygen transmissibility of a lens, as used herein, is the rate at which oxygen will pass through a specific lens. Oxygen transmissibility, Dk/t, is conventionally expressed in units of barrers/mm, where t is the average thickness of the material (in units of mm) over the area being measured. For example, a lens having a Dk of about 90 barrers (oxygen-permeability barrers) and a thickness of about 90 microns (about 0.090 mm) would have a Dk/t or about 100 barrers/mm (oxygen transmissibility barrers/mm).

[0048] Ophthalmic devices such as contact lenses for application of the present invention can be manufactured employing various conventional techniques, to yield a shaped article having the desired posterior and anterior lens surfaces. Spincasting methods are disclosed in U.S. Pat. Nos. 3,408,429 and 3,660,545; preferred static casting methods are disclosed in U.S. Pat. Nos. 4,113,224 and 4,197,266. Curing of the monomeric mixture is often followed by a machining operation in order to provide a contact lens having a desired final configuration. As an example, U.S. Pat. No. 4,555,732 discloses a process in which an excess of a monomeric mixture is cured by spincasting in a mold to form a shaped article having an anterior lens surface and a relatively large thickness. The posterior surface of the cured spincast article is subsequently lathe cut to provide a contact lens having the desired thickness and posterior lens surface. Further machining operations may follow the lathe cutting of the lens surface, for example, edge-finishing operations.

[0049] After producing a lens having the desired final shape, it is desirable to remove residual solvent from the lens before edge-finishing operations. This is because, typically, an organic diluent is included in the initial monomeric mixture in order to minimize phase separation of polymerized products produced by polymerization of the monomeric mixture and to lower the glass transition temperature of the reacting polymeric mixture, which allows for a more efficient curing process and ultimately results in a more uniformly polymerized product. Sufficient uniformity of the initial monomeric mixture and the polymerized product are of particular concern for silicone hydrogels, primarily due to the inclusion of silicone-containing monomers which may tend to separate from the hydrophilic comonomer. Suitable organic diluents include, for example, monohydric alcohols such as C_6-C_{10} straight-chained aliphatic monohydric alcohols, e.g., n-hexanol and n-nonanol; diols such as ethylene glycol; polyols such as glycerin; ethers such as diethylene glycol monoethyl ether; ketones such as methyl ethyl ketone; esters such as methyl enanthate; and hydrocarbons such as toluene. Preferably, the organic diluent is sufficiently volatile to facilitate its removal from a cured article by evaporation at or near ambient pressure. Generally, the diluent is included at about 5 to about 60 percent by weight of the monomeric mixture, with about 10 to about 50 percent by weight being especially preferred.

[0050] Solvent removal can be accomplished by evaporation at or near ambient pressure or under vacuum. An elevated temperature can be employed to shorten the time necessary to evaporate the diluent. The time, temperature and pressure conditions for the solvent removal step will vary depending on such factors as the volatility of the diluent and the specific monomeric components, as can be readily determined by one skilled in the art. According to a preferred embodiment, the temperature employed in the removal step is preferably at least about 50° C., for example, about 60° C. to about 80° C. A series of heating cycles in a linear oven under inert gas or vacuum may be used to optimize the efficiency of the solvent removal. The cured article after the diluent removal step should contain no more than twenty percent by weight of diluent, preferably no more than about 5 percent by weight or less.

[0051] Following removal of the organic diluent, the lens can then be subjected to mold release and optional machining operations. The machining step includes, for example, buffing or polishing a lens edge and/or surface. Generally, such machining processes may be performed before or after the article is released from a mold part. Preferably, the lens is dry released from the mold by employing vacuum tweezers to lift the lens from the mold, after which the lens is transferred by means of mechanical tweezers to a second set of vacuum tweezers and placed against a rotating surface to smooth the surface or edges. The lens may then be turned over in order to machine the other side of the lens

[0052] Next, the lens will be immersed in an aqueous packaging solution and stored in a packaging system according to the present invention. Generally, a packaging system for the storage of an ophthalmic lens according to the present invention includes at least a sealed container containing one or more unused ophthalmic lens immersed in an aqueous packaging solution. Preferably, the sealed container is a hermetically sealed blister-pack, in which a concave well containing a contact lens is covered by a metal or plastic sheet adapted for peeling in order to open the blister-pack. The sealed container may be any suitable generally inert packaging material providing a reasonable degree of protection to the lens, preferably a plastic material such as polyalkylene, PVC, polyamide, and the like.

[0053] Hyaluronic acid, also known as hyalurate or hyaluronan, belongs to the group of glycosaminoglycans. In general, hyaluronic acid is a high molecular weight polysaccha-

ride with an unbranched backbone composed of alternating sequences of β-(1-4)-glucoronic acid and β-(1-3)-N-acetyl glucosamine moieties. Each dimer is referred to as one unit and has a molecular weight of approximately 450 Daltons (D). The hyaluronic acid for use herein can have a number average molecular weight of from about 10,0000 to about 10,000,000, preferably from about 50,000 to about 2,000,000 and most preferably from about 100,000 to about 1,000,000. An example of a salt of hyaluronic acid is hyaluronic acid sodium salt.

[0054] The amount of hyaluronic acid or salt thereof employed is that amount effective to improve the surface properties of the ophthalmic device when combined with a non-ionic polyol. Generally, the concentration of the hyaluronic acid present in the packaging solution of the invention is from about 0.001 to about 1% w/w, preferably from about 0.05 to about 0.5% w/w and most preferably from about 0.1 to about 0.3% w/w.

[0055] The aqueous packaging solutions according to the present invention are physiologically compatible. Specifically, the solution must be "ophthalmically safe" for use with a lens such as a contact lens, meaning that a contact lens treated with the solution is generally suitable and safe for direct placement on the eye without rinsing, that is, the solution is safe and comfortable for daily contact with the eye via a contact lens that has been wetted with the solution. An ophthalmically safe solution has a tonicity and pH that is compatible with the eye and includes materials, and amounts thereof, that are non-cytotoxic according to ISO standards and U.S. Food & Drug Administration (FDA) regulations. The solutions of the present invention will also have a viscosity ranging from at least about 1 cps, preferably at least about 2 cps and most preferably at least about 4 cps. In one embodiment, the solutions of the present invention do not contain a surfactant such as a non-ionic surfactant, e.g., poloxamer.

[0056] The solution of the present invention should also be sterile in that the absence of microbial contaminants in the product prior to release must be statistically demonstrated to the degree necessary for such products. The liquid media useful in the present invention are selected to have no substantial detrimental effect on the lens being treated or cared for and to allow or even facilitate the present lens treatment or treatments. The liquid media are preferably aqueous-based. A particularly useful aqueous liquid medium is that derived from saline, for example, a conventional saline solution or a conventional buffered saline solution.

[0057] The pH of the present solutions should be maintained within the range of about 4 to about 9, and preferably about 6.5 to about 7.8. Suitable buffers may be added, such as boric acid, sodium borate, potassium citrate, citric acid, sodium bicarbonate, tris(hydroxymethy)aminomethane, and various mixed phosphate buffers (including combinations of Na_2HPO_4, NaH_2PO_4 and KH_2PO4) and mixtures thereof. Generally, buffers will be used in amounts ranging from about 0.05 to about 2.5 percent by weight, and preferably from about 0.1 to about 1.5 percent by weight of the solution.

[0058] Typically, the solutions of the present invention are also adjusted with tonicity agents, to approximate the osmotic pressure of normal lacrimal fluids which is equivalent to a 0.9 percent solution of sodium chloride or 2.5 percent of glycerol solution. The solutions are made substantially isotonic with physiological saline used alone or in combination, otherwise if simply blended with sterile water and made hypotonic or made hypertonic the lenses will lose their desirable optical parameters. Correspondingly, excess saline may result in the formation of a hypertonic solution which will cause stinging and eye irritation.

[0059] Examples of suitable tonicity adjusting agents include, but are not limited to, sodium and potassium chloride, dextrose, glycerin, calcium and magnesium chloride and the like and mixtures thereof. These agents are typically used individually in amounts ranging from about 0.01 to about 2.5% w/v and preferably from about 0.2 to about 1.5% w/v. Preferably, the tonicity agent will be employed in an amount to provide a final osmotic value of at least about 200 mOsm/kg, preferably from about 200 to about 400 mOsm/kg, more preferably from about 250 to about 350 mOsm/kg, and most preferably from about 280 to about 320 mOsm/kg.

[0060] If desired, one or more additional components can be included in the packaging solution. Such additional component or components are chosen to impart or provide at least one beneficial or desired property to the packaging solution. Such additional components may be selected from components which are conventionally used in one or more ophthalmic device care compositions. Examples of such additional components include cleaning agents, wetting agents, nutrient agents, sequestering agents, viscosity builders, contact lens conditioning agents, antioxidants, and the like and mixtures thereof. These additional components may each be included in the packaging solutions in an amount effective to impart or provide the beneficial or desired property to the packaging solutions. For example, such additional components may be included in the packaging solutions in amounts similar to the amounts of such components used in other, e.g., conventional, contact lens care products.

[0061] Useful sequestering agents include, but are not limited to, disodium ethylene diamine tetraacetate, alkali metal hexametaphosphate, citric acid, sodium citrate and the like and mixtures thereof.

[0062] Useful viscosity builders include, but are not limited to, hydroxyethyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol and the like and mixtures thereof.

[0063] Useful antioxidants include, but are not limited to, sodium metabisulfite, sodium thiosulfate, N-acetylcysteine, butylated hydroxyanisole, butylated hydroxytoluene and the like and mixtures thereof.

[0064] The method of packaging and storing an ophthalmic lens such as a silicone hydrogel contact lens according to the present invention includes at least packaging a silicone hydrogel contact lens immersed in the aqueous packaging solution described above. The method may include immersing the ophthalmic lens in an aqueous packaging solution prior to delivery to the customer/wearer, directly following manufacture of the contact lens. Alternately, the packaging and storing in the solution of the present invention may occur at an intermediate point before delivery to the ultimate customer (wearer) but following manufacture and transportation of the lens in a dry state, wherein the dry lens is hydrated by immersing the lens in the solution. Consequently, a package for delivery to a customer may include a sealed container containing one or more unused ophthalmic lenses immersed in an aqueous packaging solution according to the present invention.

[0065] In one embodiment, the steps leading to the present ophthalmic lens packaging system includes (1) molding an ophthalmic lens in a mold comprising a posterior and anterior mold portion, (2) removing the lens from the mold and

hydrating the lens, (3) introducing the aqueous packaging solution with the hyaluronic acid or salt thereof into the container with the lens supported therein, and (4) sealing the container. Preferably, the method also includes the step of sterilizing the contents of the container. Sterilization may take place prior to, or most conveniently after, sealing of the container and may be effected by any suitable method known in the art, e.g., by autoclaving of the sealed container and its contents at temperatures of about 120° C. or higher.

[0066] The following examples are provided to enable one skilled in the art to practice the invention and are merely illustrative of the invention. The examples should not be read as limiting the scope of the invention as defined in the claims.

[0067] In the examples, the following abbreviations are used.

[0068] I4D5S4H: Urethane prepolymer derived from isophorone diisocyanate, diethylene glycol, α,ω-bis-hydroxybutyl polydimethylsiloxane of Mn 4,000, and 2-hydroxyethyl methacrylate in the approximate molar ratio of 10:4:5:2

[0069] TRIS: 3-methacryloxypropyltris(trimethylsiloxy) silane

[0070] DMA: N,N-dimethylacrylamide

[0071] HEMA: 2-hydroxyethyl methacrylate

[0072] NVP: N-vinyl-2-pyrrolidone

[0073] HEMAVC: methacryloxyethyl vinyl carbonate

[0074] D1173: 2-hydroxy-2-methyl-1-phenylpropan-1-one (available as Darocur 1173 initiator)

[0075] IMVT: 1,4-bis(4-(2-methacryloxyethyl)phenylamino)anthraquinone

EXAMPLE 1

[0076] Lens casting of a polyurethane-siloxane hydrogel formulation

[0077] Silicone hydrogel lenses were prepared from the monomer mixture set forth below in Table 1. The monomer mixture was filtered, cast between anterior and posterior polypropylene mold parts and then cured under UV for 1 hour. After being released from the molds, the lenses were extracted with isopropanol overnight, and then hydrated in deionized (DI) water.

TABLE 1

Formulation Prepolymer	Example 1
I4D5S4H	53 parts by weight
TRIS	15 parts by weight
DMA	9 parts by weight
HEMA	5 parts by weight
NVP	24 parts by weight
HEMAVC	1.3 parts by weight
n-Hexanol	10 parts by weight
D1173	0.5 parts by weight
IMVT	0.015 parts by weight

EXAMPLE 2

[0078] Surface treatment with hyaluronic acid sodium salt solution.

[0079] An aqueous solution containing 0.5% by weight of hyaluronic acid sodium salt (HA) (hyaluronic acid sodium salt from *Streptococcus equi,* commercially available from Fluka Biochemika, having a total impurity content of less than 1% protein and a solubility of 5 mg/ml in water) was prepared, and the pH was adjusted to 4 using dilute hydrochloric acid. The lenses prepared in accordance with Example 1 were then placed in glass vials, filled with the aqueous treating solution containing 0.5% by weight HA. Next, the lenses were autoclaved for 1 cycle (121° C., 30 minutes) and kept at 45° C. for 24 hours. The lenses were taken out and shaken with large amounts of DI water and then saved in a borate buffer saline for testing. The lenses thus obtained were visually examined and appeared more wettable than the control lens. The lenses were also rubbed between fingers and felt more lubricious than the control lens. The control lens was a lens from Example 1 which was autoclaved in DI water for 1 cycle and stored in a borate buffer saline for testing.

[0080] It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. For example, the functions described above and implemented as the best mode for operating the present invention are for illustration purposes only. Other arrangements and methods may be implemented by those skilled in the art without departing from the scope and spirit of this invention. Moreover, those skilled in the art will envision other modifications within the scope and spirit of the features and advantages appended hereto.

What is claimed is:

1. A method of preparing a package comprising a storable, sterile ophthalmic device, the method comprising:

(a) immersing an ophthalmic device in an aqueous packaging solution comprising hyaluronic acid or salt thereof, wherein the aqueous packaging solution has an osmolality of at least about 200 mOsm/kg and a pH in the range of about 4 to about 9;

(b) packaging the solution and the device in a manner preventing contamination of the lens by microorganisms; and

(c) sterilizing the packaged solution and device.

2. The method of claim **1**, wherein the ophthalmic device is a contact lens.

3. The method of claim **1**, wherein the ophthalmic device is a silicone hydrogel contact lens.

4. The method of claim **1**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 10,000 to about 10,000,000.

5. The method of claim **1**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 50,000 to about 2,000,000.

6. The method of claim **1**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 100,000 to about 1,000,000.

7. The method of claim **1**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.001 to about 1% w/w.

8. The method of claim **1**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.05 to about 0.5% w/w.

9. The method of claim **1**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.1 to about 0.3% w/w.

10. The method of claim **1**, wherein the aqueous packaging solution further comprises a buffering agent.

11. The method of claim **1**, further comprising hermetically sealing the ophthalmic device and the aqueous packaging solution in the package.

12. The method of claim **11**, wherein heat sterilization is performed subsequent to sealing of the package.

13. The method of claim **1**, wherein the aqueous packaging solution does not contain an effective disinfecting amount of a disinfecting agent.

14. The method of claim **1**, wherein the aqueous packaging solution does not contain a germicide compound.

15. The method of claim **1**, wherein the aqueous packaging solution does not contain a surfactant.

16. The method of claim **13**, wherein the aqueous packaging solution further does not contain a surfactant.

17. A packaging system for the storage of an ophthalmic device comprising a sealed container containing one or more unused ophthalmic device immersed in an aqueous packaging solution comprising hyaluronic acid or a salt thereof, wherein the solution has an osmolality of at least about 200 mOsm/kg, a pH of about 4 to about 9 and is heat sterilized.

18. The packaging system of claim **17**, wherein the ophthalmic device is a contact lens.

19. The packaging system of claim **17**, wherein the ophthalmic device is a silicone hydrogel contact lens.

20. The packaging system of claim **17**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 10,000 to about 10,000,000.

21. The packaging system of claim **17**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 50,000 to about 2,000,000.

22. The packaging system of claim **17**, wherein the hyaluronic acid or salt thereof has a number average molecular weight of about 100,000 to about 1,000,000.

23. The packaging system of claim **17**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.001 to about 1% w/w.

24. The packaging system of claim **17**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.05 to about 0.5% w/w.

25. The packaging system of claim **17**, wherein the concentration of the hyaluronic acid or salt thereof in the aqueous packaging solution is about 0.1 to about 0.3% w/w.

26. The packaging system of claim **17**, wherein the aqueous packaging solution further comprises a buffering agent.

27. The packaging system of claim **17**, wherein the package is heat sterilized subsequent to sealing of the package.

28. The packaging system of claim **17**, wherein the aqueous packaging solution does not contain an effective disinfecting amount of a disinfecting agent.

29. The packaging system of claim **17**, wherein the aqueous packaging solution does not contain a germicide compound.

30. The packaging system of claim **17**, wherein the aqueous packaging solution does not contain a surfactant.

31. The packaging system of claim **28**, wherein the aqueous packaging solution further does not contain a surfactant.

32. A method of treating an ophthalmic lens, the method comprising storing the lens in an aqueous packaging solution comprising hyaluronic acid or a salt thereof, wherein the aqueous packaging solution does not contain an effective disinfecting amount of a disinfecting agent.

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