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(54) METHOD FOR TREATING OPHTHALMIC LENSES

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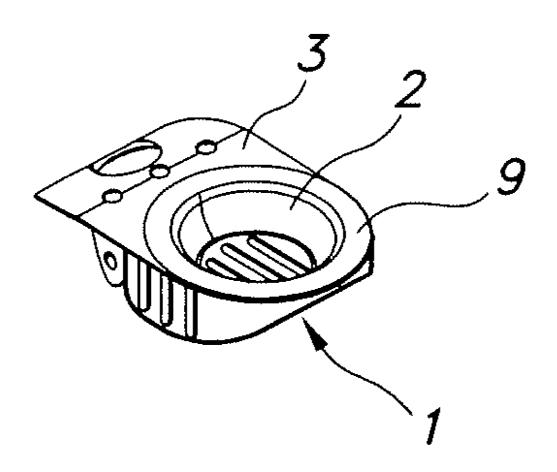
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ABSTRACT (57)

A method of treating an ophthalmic lens in a package involves: placing the lens and an aqueous solution in a recess of package, the solution including an organic surface treatment agent that attaches to anterior and posterior surfaces of the lens; and sealing the recess of the package with lidstock and sterilizing the package contents. The bottom of the recess includes grooves.



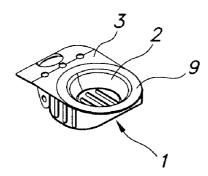


FIG. 1

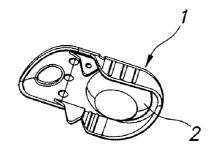


FIG. 2

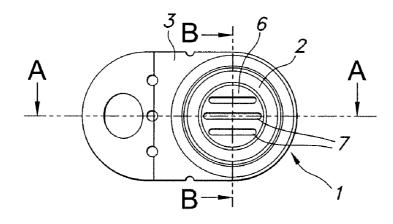
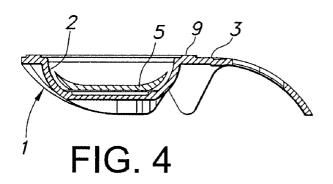


FIG. 3



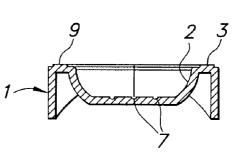
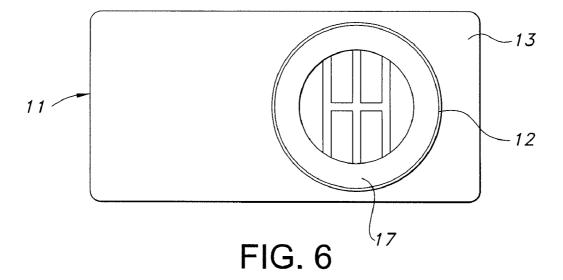


FIG. 5



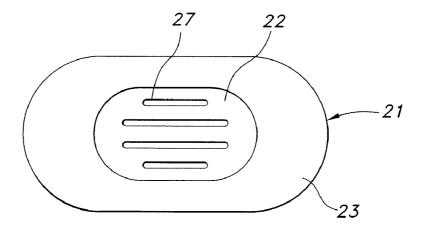


FIG. 7

METHOD FOR TREATING OPHTHALMIC LENSES

BACKGROUND OF THE INVENTION

[0001] This application claims the benefit of provisional patent application No. 61/012,856 filed Dec. 11, 2007 which is incorporated by reference herein.

[0002] This invention provides a method for treating ophthalmic lenses in its package with an organic surface treatment agent.

[0003] It is often desired to improve the surface characteristics of an ophthalmic lens. For example, in the case of intraocular lenses, the surfaces of the lenses may be rendered more biocompatible, for the purpose of reducing or eliminating epithelial cell growth on the lens. Also, intraocular lenses are often placed in the eye with an intraocular lens inserter which has surfaces that contact the lens while it is extruded against these surfaces; the lens surfaces may be modified to become more lubricious so as to lower the coefficient of friction for contacting the lens inserted. In the case of contact lenses, the lens surfaces may be made more wettable by tear film or less resistant to protein and/or lipid deposits from tear film, and more comfortable during wear. With respect to silicon-containing lenses, the lens surfaces have a higher tendency to be hydrophobic with lower wettability, so often a surface treatment is desirable to increase the surface wettability is desired. Various methods of changing the surface characteristics of ophthalmic lenses are known that involve attaching a treatment agent to the lens surfaces.

[0004] A conventional manner of packaging ophthalmic lenses, especially contact lenses, is in a so-called blister package. Such packages include a recess designed to hold an individual lens, which is typically immersed in a saline packaging solution. The packages are then enclosed and sealed with lidstock, the lidstock conventionally being a metallic laminate that can withstand post-packaging heat sterilization conditions. The packaging solution may include various agents. As one example, because the lens material may tend to stick to itself and to the lens package, packaging solutions for blister packages 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. Additionally, U.S. Pat. No. 6,440,366 discloses contact lens packaging solutions comprising polyethylene oxide (PEO)/polypropylene oxide (PPO) block copolymers, especially poloxamers or poloxamines.

[0005] Various blister packages are known. Known blister packages include recesses that are concave, recesses that are flat-bottomed, and recesses that are partially concave with a flat bottom. One specific example is a blister package with a flat bottom having four parallel, longitudinal grooves therein, which is used to package various contact lenses sold by Bausch & Lomb Incorporated (Rochester, N.Y., USA), and has the general configuration illustrated in FIG. 7. Other specific examples may be found in U.S. Pat. Nos. 5,842,325; 5,722,536; 5,467,868; 2004/0031701; 2004/0004008; 2002/0046958; 6,072,172; 5,143,660; and 6,889,825.

SUMMARY OF THE INVENTION

[0006] This invention provides of a method of treating an ophthalmic lens in a package, comprising: placing the lens and an aqueous solution in a recess of package, the solution comprising an organic surface treatment agent that attaches to

anterior and posterior surfaces of the lens; and sealing the recess of the package with lidstock and sterilizing the package contents; wherein a bottom of the recess includes grooves.

[0007] This invention recognized that it may be desirable to effect attachment of the treatment agent to the lens surfaces while the lens is contained in a package, for example, to reduce material handling steps and the accompanying costs associated therewith. And if one employs a solution, containing the treatment agent, that is ophthalmically compatible, this solution may serve as the final packaging solution, and the heat sterilization of the package and its contents can serve to effect chemical attachment of the treatment agent to the lens surfaces.

[0008] However, problems were encountered in that the surfaces of the lens were not uniformly coated with the treatment agent, especially the lens surface in contact with the recess bottom. These problems were overcome by employing packages with recesses including grooves in the bottoms thereof, to ensure better flow of the solution around the lens surfaces.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a top perspective view of a first embodiment of a lens blister package suitable for the method of this invention.

[0010] FIG. 2 is a bottom perspective view of the lens blister package of FIG. 1.

 $[0011]^{1}$ FIG. 3 is a top plan view of the lens blister package of FIG. 1.

[0012] FIG. 4 is a cross-sectional view of the lens blister package of FIG. 1, taken along line A-A of FIG. 3.

[0013] FIG. 5 is a cross-sectional view of the lens blister package of FIG. 1, taken along line B-B of FIG. 3.

[0014] FIG. 6 is a top plan view of a second embodiment of a lens blister package suitable for the method of this invention.

[0015] FIG. 7 is a top plan view of a third embodiment of a lens blister package suitable for the method of this invention.

DETAILED DESCRIPTION OF VARIOUS PREFERRED EMBODIMENTS

[0016] This invention provides a method of treating an ophthalmic lens in a package. The method comprises: placing the lens and an aqueous solution in a recess of package, the solution comprising an organic surface treatment agent that attaches to anterior and posterior surfaces of the lens; and sealing the recess of the package with lidstock and sterilizing the package contents; wherein a bottom of the recess includes grooves.

[0017] The term "ophthalmic lens" means a lens intended for direct contact with ophthalmic tissue, including contact lenses and intraocular lenses. In the following description, the process is discussed with particular reference to silicone hydrogel contact lenses, a preferred embodiment of this invention, but the invention may be employed for surface treating other polymeric biomedical devices.

[0018] Hydrogels comprise a hydrated, crosslinked polymeric system containing water in an equilibrium state. Accordingly, hydrogels are copolymers prepared from hydrophilic monomers. In the case of silicone hydrogels, the hydrogel copolymers are generally prepared by polymerizing a mixture containing at least one lens-forming silicone-containing monomer and at least one lens-forming hydrophilic monomer. Either the silicone-containing monomer or the hydrophilic monomer may function as a crosslinking agent (a

crosslinking agent being defined as a monomer having multiple polymerizable functionalities), or alternately, a separate crosslinking agent may be employed in the initial monomer mixture from which the hydrogel copolymer is formed. (As used herein, the term "monomer" or "monomeric" and like terms denote relatively low molecular weight compounds that are polymerizable by free radical polymerization, as well as higher molecular weight compounds also referred to as "prepolymers", "macromonomers", and related terms.) Silicone hydrogels typically have a water content between about 10 to about 80 weight percent.

[0019] Examples of useful lens-forming hydrophilic monomers include: amides such as N,N-dimethylacrylamide and N,N-dimethylmethacrylamide; cyclic lactams such as N-vinyl-2-pyrrolidone; (meth)acrylated alcohols, such as 2-hydroxyethyl methacrylate, 2-hydroxyethyl acrylate and glyceryl methacrylate; (meth)acrylated poly(ethylene glycol) s; (meth)acrylic acids such as methacrylic acid and acrylic acid; and azlactone-containing monomers, such as 2-isopropenyl-4,4-dimethyl-2-oxazolin-5-one and 2-vinyl-4,4-dimethyl-2-oxazolin-5-one. (As used herein, the term "(meth)" denotes an optional methyl substituent. Thus, terms such as "(meth)acrylate" denotes either methacrylate or acrylate, and "(meth)acrylic acid" denotes either methacrylic acid or acrylic acid.) 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, the disclosures of which are incorporated herein by reference. Other suitable hydrophilic monomers will be apparent to one skilled in the art.

[0020] Applicable silicone-containing monomeric materials 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.

[0021] Examples of applicable silicone-containing monomers include bulky polysiloxanylalkyl (meth)acrylic monomers. An example of such monofunctional, bulky polysiloxanylalkyl (meth)acrylic monomers are represented by the following Formula I:

$$\begin{array}{c}
R_{2} \longrightarrow \\
R_{2} \longrightarrow \\
S_{1} \longrightarrow \\
R_{2} \longrightarrow \\
CCH_{2})_{h} \longrightarrow \\
CCH_{2} \longrightarrow \\
R_{2} \longrightarrow \\
R_{3} \longrightarrow \\
R_{4} \longrightarrow \\
R_{5} \longrightarrow \\
R_{5} \longrightarrow \\
R_{2} \longrightarrow \\
R_{2} \longrightarrow \\
R_{3} \longrightarrow \\
R_{4} \longrightarrow \\
R_{5} \longrightarrow \\
R$$

[0022] wherein:

[0023] X denotes —O— or —NR—;

 $\textbf{[0024]} \quad \text{each } R_1 \text{ independently denotes hydrogen or methyl};$

 $\mbox{\bf [0025]}$ each R_2 independently denotes a lower alkyl radical, phenyl radical or a group represented by

[0026] wherein each R_2^{\prime} independently denotes a lower alkyl or phenyl radical; and h is 1 to 10. One preferred bulky

monomer is 3-methacryloxypropyl tris(trimethyl-siloxy)silane or tris(trimethylsiloxy)silylpropyl methacrylate, sometimes referred to as TRIS.

[0027] Another class of representative silicone-containing monomers includes silicone-containing vinyl carbonate or vinyl carbamate monomers such as: 1,3-bis[4-vinyloxycarbonyloxy)but-1-yl]tetramethyldisiloxane; 1,3-bis[4-vinyloxycarbonyloxy)but-1-yl]polydimethylsiloxane; 3-(trimethylsilyl)propyl vinyl carbonate; 3-(vinyloxycarbonylthio) propyl[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; and trimethylsilylmethyl vinyl carbonate.

[0028] An example of silicone-containing vinyl carbonate or vinyl carbamate monomers are represented by Formula II:

wherein

[0029] Y'_denotes —O—, —S— or —NH—;

[0030] R^{Si} denotes a silicone-containing organic radical;

[0031] R₃ denotes hydrogen or methyl;

[0032] d is 1, 2, 3 or 4; and q is 0 or 1.

[0033] Suitable silicone-containing organic radicals R^{Si} include the following:

$$\hspace{1cm} \underline{\hspace{1cm}} (CH_2)_{n'}Si[(CH_2)_{m'}CH_3]_3; \hspace{1cm} \underline{\hspace{1cm}} (CH_2)_{n'}Si[OSi(CH_2)_{m'}CH_3]_3;$$

wherein:

[0034] R₄ denotes

$$-(CH_2)_{p'}-O$$

wherein p' is 1 to 6;

[0035] R_5 denotes an alkyl radical or a fluoroalkyl radical having 1 to 6 carbon atoms;

[0036] e is 1 to 200; n' is 1, 2, 3 or 4; and m' is 0, 1, 2, 3, 4 or 5

[0037] An example of a particular species within Formula II is represented by Formula III:

$$\begin{array}{c|c} CH_3 & CH_3 & CH_3 & CH_3 \\ \hline \\ CH_2)_4 & Si & O \\ \hline \\ CH_3 & CH_3 & CH_3 \\ \hline \\ CH_3 & CH_3 & CH_2)_4 \\ \hline \\ CH_3 & CH_3 & CH_2)_4 \\ \hline \\ CH_3 & CH_3 & CH_3 \\ \hline \\ C$$

[0038] Another class of silicone-containing monomers includes polyurethane-polysiloxane macromonomers (also sometimes referred to as prepolymers), which may have hardsoft-hard blocks like traditional urethane elastomers. Examples of silicone urethane monomers are represented by Formulae IV and V:

$$E(*D*A*D*G)_{a}*D*A*D*E'; or$$
 (IV)

$$E(*D*G*D*A)_{\sigma}*D*G*D*E';$$
 (V)

wherein:

[0039] D denotes an alkyl diradical, an alkyl cycloalkyl diradical, a cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 6 to 30 carbon atoms;

[0040] G denotes an alkyl diradical, a cycloalkyl diradical, an alkyl cycloalkyl diradical, an aryl diradical or an alkylaryl diradical having 1 to 40 carbon atoms and which may contain ether, thio or amine linkages in the main chain;

[0041] * denotes a urethane or ureido linkage;

[0042] a is at least 1;

[0043] A denotes a divalent polymeric radical of Formula

$$E-(CH_2)_{m'} = \begin{bmatrix} R_s & & & \\ I & & & \\ Si & & O \end{bmatrix} = \begin{bmatrix} R_s & & & \\ I & & & \\ R_s & & & \end{bmatrix}_{p} = \begin{bmatrix} CH_2)_{m'}-E' & & \\ R_s & & & \\ R_s & & & \end{bmatrix}$$

wherein:

[0044] each R_s independently denotes an alkyl or fluorosubstituted alkyl group having 1 to 10 carbon atoms which may contain ether linkages between carbon atoms;

[0045] m' is at least 1; and

[0046] p is a number which provides a moiety weight of 400 to 10,000;

[0047] each of E and E' independently denotes a polymerizable unsaturated organic radical represented by Formula

$$\begin{array}{c} R_{6} \\ R_{7} \\ \hline \\ R_{7} \end{array} (CH_{2})_{w} - (X)_{x} - (Z)_{z} - (Ar)_{y} - R_{8} - \\ \end{array}$$

wherein:

 $\begin{array}{ll} \textbf{[0048]} & R_6 \text{ is hydrogen or methyl;} \\ \textbf{[0049]} & R_7 \text{ is hydrogen, an alkyl radical having 1 to 6 carbon} \end{array}$ atoms, or a —CO—Y—R₉ radical wherein Y is —O—, -S-- or --NH--;

[0050] R_8 is a divalent alkylene radical having 1 to 10 carbon atoms;

[0051] R₉ is a alkyl radical having 1 to 12 carbon atoms;

[0052]X denotes —CO— or —OCO—;

[0053] Z denotes —O— or —NH—;

[0054] Ar denotes an aromatic radical having 6 to 30 carbon atoms;

[0055]w is 0 to 6; x is 0 or 1; y is 0 or 1; and z is 0 or 1.

[0056] A more specific example of a silicone-containing urethane monomer is represented by Formula (VIII):

$$E'' = \begin{bmatrix} O & O & O & O & O & O & CH_3 & CH_3 & CH_3 & CH_2 & CH_$$

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 400 to 10,000 and is preferably at least 30, R₁₀ 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:

[0057] A preferred silicone hydrogel material comprises (based on the initial monomer mixture that is copolymerized to form the hydrogel copolymeric material) 5 to 50 percent, preferably 10 to 25, by weight of one or more silicone macromonomers, 5 to 75 percent, preferably 30 to 60 percent, by weight of one or more polysiloxanylalkyl (meth)acrylic monomers, and 10 to 50 percent, preferably 20 to 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 to Deichert et al. discloses additional unsaturated groups, including acryloxy or methacryloxy. Fumarate-containing materials such as those taught in U.S. Pat. Nos. 5,512,205; 5,449,729; and 5,310,779 to Lai are also useful substrates in accordance with the invention. Preferably, the silane macromonomer is a silicone-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.

[0058] Specific examples of contact lens materials for which the present invention is useful are taught in U.S. Pat. No. 6,891,010 (Kunzler et al.); U.S. Pat. No. 5,908,906 (Kunzler et al.); U.S. Pat. No. 5,710,302 (Kunzler et al.); U.S. Pat. No. 5,710,302 (Kunzler et al.); U.S. Pat. No. 5,708,094 (Lai et al.); U.S. Pat. No. 5,616,757 (Bambury et al.); U.S. Pat. No. 5,610,252 (Bambury et al.); U.S. Pat. No. 5,512,205 (Lai); U.S. Pat. No. 5,449,729 (Lai); U.S. Pat. No. 5,387,662 (Kunzler et al.); U.S. Pat. No. 5,310,779 (Lai); and U.S. Pat. No. 5,260,000 (Nandu et al.), the disclosures of which are incorporated herein by reference.

[0059] Generally, the monomer mixtures may be charged to a mold, and then subjected to heat and/or light radiation, such as UV radiation, to effect curing, or free radical polymerization, of the monomer mixture in the mold. Various processes are known for curing a monomeric mixture in the production of contact lenses or other biomedical devices, including spincasting and static casting. Additionally, the monomer mixtures may be cast in the shape of rods or buttons, which are then lathe cut into a desired shape, for example, into a lens-shaped article.

[0060] Following casting of the lens, the article may be extracted to remove undesired extractables from the device. For example, in the case of contact lenses made from a silicone hydrogel copolymer, extractables include any remaining diluent, unreacted monomers, and oligomers formed from side reactions of the monomers.

[0061] Then, the lens is hydrated, either as part of the extraction process, or in a separate subsequent operation. For example, if an organic solvent is used to extract the lens, then

the lens is hydrated to replace the organic solvent with water or aqueous solution. Hydration may be performed while the lens is held in its package, or prior to placing the lens in the package. In any event, ultimately, the lens is contained in the package with an aqueous packaging solution.

[0062] This invention recognized the desirability of effecting attachment of the treatment agent to the lens surfaces while the lens is contained in a package, in contrast to effecting attachment prior to placing the lens in the package. This offers a reduction in material handling steps and the accompanying costs associated therewith. Also, if the solution containing the treatment agent is ophthalmically compatible, this solution may serve as the final packaging solution, and the heat sterilization of the package and its contents can serve to effect chemical attachment of the treatment agent to the lens surfaces.

[0063] As used herein, "attachment" of the treatment agent to the lens surface, and like terms, denotes that the treatment agent is substantially adhered to the lens surfaces. Thus, after a single rinsing with water of the lens surfaces with the treatment agent attached thereto, at least 50% of the treatment agent will remain adhered to the lens surfaces.

[0064] It is preferred that the surface treatment agent is attached to the lens surfaces by at least one of covalent bonding, ionic attachment, and hydrogen bonding. Covalent bonding denotes that a chemical reaction occurs between the treatment agent and the lens surface, so that covalent bonds are formed therebetween. Ionic attachment denotes that the lens surfaces are ionically charged, and the organic surface treatment agent contains moieties with an opposite, ionic charge. As an example the lens surfaces may be anionic charged, and the treatment agent may be cationic or zwitterionic, that interacts with the anionic lens surface.

[0065] A wide variety of organic surface treatment agents may be employed, including treatment agents known in the

[0066] As a first example, this invention is applicable for the organic surface treatment agents described in U.S. Pat. No. 7,083,646, the entire disclosure of which is incorporated herein by reference. Generally, this method involves surface modification of medical devices, particularly ophthalmic lenses, with one or more reactive, hydrophilic polymers as the surface treatment agent. The reactive, hydrophilic polymers are copolymers of at least one hydrophilic monomer and at least one monomer that contains reactive chemical functionality. The hydrophilic monomers can be aprotic types such as N,N-dimethylacrylamide and N-vinylpyrrolidone, or protic types such as methacrylic acid and 2-hydroxyethyl methacrylate. The monomer containing reactive chemical functionality can be an epoxide-containing monomer, such as glycidyl methacrylate. The hydrophilic monomer and the monomer containing reactive chemical functionality are copolymerized at a desired molar ratio thereof. The hydrophilic monomer serves to render the resultant copolymer hydrophilic. The monomer containing reactive chemical functionality provides a reactive group that can react with the lens surface. In other words, this resultant copolymer contains the reactive chemical functionality that can react with complementary functional groups at or near the lens surface, and form covalent bonds therewith.

[0067] As a second example, this invention is applicable for the organic surface treatment agents described in US 2007/0122540, the entire disclosure of which is incorporated herein

by reference. Generally, this method involves surface modification of medical devices, particularly ophthalmic lenses, where reactive surfactants as the surface treatment agent are covalently bound to the lens surfaces. Preferred reactive surfactants are functionalized poloxamers or functionalized

poloxamines having reactive functionality that is complimentary to surface functionality of the ophthalmic lens. Representative functionalized surfactants are those containing epoxide, methacrylate, or isocyanate functionalities, such as represented below.

1) Phosgene, or Diphosgene in THF

$$O = C = N$$

$$O \longrightarrow O$$

Pluronic F127 Diisocyanate

[0068] For the aforementioned methods where the surface treatment agent is covalently bonded to the lens surface, the reactive groups of the treatment agent are matched with the reactive groups on the lens surface. For example, if the lens surfaces contain carboxylic acid groups, a glycidyl group can be a reactive group of the surface treatment agent. If the lens surfaces contain hydroxy or amino functionality, an isocyanate group or carbonyl chloride group can be a reactive group of the surface treatment agent. A wide variety of suitable combinations of reactive groups will be apparent to those of ordinary skill in the art.

[0069] Examples of suitable lens-forming monomers, providing reactive groups on the lens surface, include those having hydroxy functional groups, such as 2-hydroxyethyl methacrylate, glyceryl methacrylate and 3-hydroxypropyl methacrylamide. Examples of suitable lens-forming monomers providing the lens surfaces with carboxylic acid reactive groups include methacrylic acid, acrylic acid and N-carboxyβ-alanine-N-vinyl ester. Examples of suitable lens-forming monomers providing the lens surface with oxazolinone reactive groups include 2-isopropenyl-4,4-dimethyl-2-oxazolin-5-one, 2-vinyl-4,4-dimethyl-2-oxazolin-5-one, spiro-4'-(2'isopropenyl-2'-oxazolin-5-one)cyclohexane, spiro-4'-(2'vinyl-2'-oxazolin-5'-one)cyclohexane and 2-(1-propenyl)-4, 4-dimethyl-oxazolin-5-one. Examples of suitable lensforming monomers providing the lens surface with anhydride functional groups include methacrylic anhydride, maleic anhydride and acrylic anhydride. An example of a suitable lens-forming monomer providing the lens surfaces with epoxide reactive groups includes glycidyl methacrylate.

[0070] As another example, the surface treatment agent may be one as employed in the method described in U.S. Pat. No. 6,428,839 (Kunzler et al.), the entire disclosure of which is incorporated herein by reference. Generally, this method employs poly(acrylic) acid (PAA) surface complexation. Hydrogel contact lens copolymers containing polymerized hydrophilic lens-forming monomers having relatively strong proton donating moieties, for example DMA or NVP, are treated with water-based solutions containing PAA or PAA co-polymers, acting as wetting agents, to render a lubricious, stable, highly wettable PAA-based surface coating. Alternately, other proton-donating wetting agents besides PAAcontaining agents may be employed, although generally, coating materials containing carboxylic acid functionality are preferred. Surface treatment agents include poly(vinylpyrrolidinone(VP)-co-acrylic acid(AA)), poly(methylvinyletheralt-maleic acid), poly(acrylic acid-graft-ethyleneoxide), poly (AA-co-methacrylic acid), poly(acrylamide-co-AA), poly (AA-co-maleic), and poly(butadiene-maleic Particularly preferred polymers are characterized by acid contents of at least about 30 mole percent, preferably at least about 40 mole percent. The lens, with its surface in contact with the PAA-containing solution, may be heated by autoclaving, or subjected to microwave radiation, to facilitate attachment of the PAA to the lens surface.

[0071] Other organic surface treatment agents will be apparent to one skilled in the art.

[0072] There are various variations of the sequence of steps employed in the methods of this invention.

[0073] As a first example, after placing the lens and the solution containing the treatment agent in the recess of the package, the recess is sealed with the lidstock without removing the solution. In other words, according to this embodiment, this solution also serves as the final packaging solution, and this solution is ophthalmically compatible. Then, when the package contents are heat sterilized, this heat treatment can serve to effect chemical attachment of the treatment agent to the lens surfaces, if needed. Any excess treatment agent, not attached to the lens surfaces, remains in the final packaging solution.

[0074] As a second example, after placing the lens and the solution containing the treatment agent in the recess of the package, this solution is removed with a portion of the organic treatment agent remaining attached to the lens surface. Any excess treatment agent is removed with the solution. If heat treatment is needed to effect chemical attachment of the treatment agent to the lens surfaces, the heat treatment is performed prior to removing this solution from the package recess. Subsequently, after removing this solution, an aqueous packaging solution is added to the recess, followed by sealing the recess with lidstock and sterilizing the package contents.

[0075] The final packaging solution is an aqueous solution, preferably a saline solution. having a pH value within the range of about 6 to about 8, and preferably about 6.5 to about 7.8. Suitable buffers may be included, such as: phosphate; citrate; carbonate; tris-(hydroxymethyl)aminomethane (TRIS); bis(2-hydroxyethyl)-imino-tris-(hydroxymethyl)aminoalcohol (bis-tris); zwitterionic buffers such as N-[2-Hydroxy-1,1-bis(hydroxymethyl)ethyl]glycine (Tricine)and N-[2-Hydroxy-1,1-bis(hydroxymethyl)ethyl] glycine, MOPS; N-(Carbamoylmethyl)taurine (ACES); amino acids and amino acid derivatives; 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. If needed, the solutions of the present invention may be 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. Examples of suitable tonicity adjusting agents include, but are not limited to, sodium and potassium chloride, dextrose, 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 450 mOsm/kg, more preferably from about 250 to about 400 mOsm/kg, and most preferably from about 280 to about 370 mOsm/kg.

[0076] Representative blister packages that may be employed in the method of this invention are illustrated in FIGS. 1 to 7.

[0077] FIGS. 1 to 5 illustrate a first embodiment of a blister package. Package 1 includes a substrate 3 including recess 2 formed therein, recess 2 sized and configured to hold an individual contact lens 5 therein. In the illustrated embodiment, recess 2 is a concave recess with a flat bottom 6. As seen in FIG. 4, the anterior surface of contact lens 5 rests on bottom 6 when the package is oriented as in FIG. 4. This can lead to non-uniform coating of the contact lens, especially this anterior surface of the lens resting on the recess bottom. These problems were overcome by employing packages with recesses including grooves in the bottoms thereof, to ensure better flow of the solution around the lens surfaces. Accordingly, bottom 6 includes three parallel, longitudinal grooves 7 therein. Grooves 7 preferably have a depth of at least 0.2 mm, more preferably at least 0.4 mm.

[0078] After contacting the contact lens with the treatment agent solution, contact lens 5 is contained in recess 2 and immersed in solution. Recess 2 is then sealed with lidstock, i.e., by sealing the lidstock with heat to raised surface 9. The package and its contents may now be sterilized, preferably by heat sterilization such as autoclaving. Recess 2 has a depth greater than a height of the lens, and a sufficiently large volume, that the lens is completely immersed in the final packaging solution.

[0079] FIG. 6 illustrates a second embodiment of a blister package. Package 11 includes a substrate 13 including recess 12 formed therein. In this illustrated embodiment, recess 12 is a concave recess, i.e., a rounded bowl shape. The bottom includes three interconnected, longitudinal grooves 17 therein.

[0080] FIG. 7 illustrates a third embodiment of a blister package. Package 21 includes a substrate 23 including recess 22 formed therein. In this illustrated embodiment, recess 22 has a somewhat oval-shaped flat bottom, and the bottom includes four longitudinal grooves 27 therein.

[0081] Once the package recess contains the contact lens immersed in the final packaging solution, the recess is then sealed with lidstock, i.e., by sealing the lidstock with heat. As an example, the lidstock is sealed to raised surface 9 in FIGS. 1 to 5. The package and its contents may now be sterilized, preferably by heat sterilization such as autoclaving. The recess has a depth greater than a height of the lens, and a sufficiently large volume, that the lens is completely immersed in the final packaging solution. Preferably, the recess is filed with at least 0.5 ml of final packaging solution, more preferably at least 1 ml, and most preferably at least 1.2 ml.

[0082] While there is shown and described herein certain specific structures and compositions and method steps of the

present invention, it will be apparent to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to particular structures herein shown and described except insofar as indicated by the scope of the appended claims.

We claim:

1. A method of treating an ophthalmic lens in a package, comprising:

placing the lens and an aqueous solution in a recess of package, the solution comprising an organic surface treatment agent that attaches to anterior and posterior surfaces of the lens; and

sealing the recess of the package with lidstock and sterilizing the package contents;

wherein a bottom of the recess includes grooves.

- 2. The method of claim 1, wherein the surface treatment agent attaches to the lens surfaces by at least one of covalent bonding, ionic attachment, and hydrogen bonding.
- 3. The method of claim 1, wherein the surface treatment agent attaches to the lens surfaces by covalent bonding.
- **4**. The method of claim **1**, wherein the lens surfaces are ionically charged, and the surface treatment agent has an opposite, ionic charge.
- 5. The method of claim 1, wherein the package contents are sterilized by autoclaving, and autoclaving effects attachment of the surface treatment agent to the lens surfaces.
- 6. The method of claim 1, wherein attachment of the surface treatment agent is effected by heating the solution while in contact with the lens surfaces in the recess.
- 7. The method of claim 1, wherein the anterior surface of the lens contacts a portion of the recess bottom containing the grooves.
- 8. The method of claim 1, wherein the grooves have a depth of at least 0.2 mm.
- 9. The method of claim 8, wherein the grooves have a depth of at least 0.4 mm.
- 10. The method of claim 1, wherein the recess has a depth greater than a height of the lens, and a sufficient volume of solution is placed in the recess so that the lens is completely immersed in the solution.
- 11. The method of claim 10, where the volume of the solution is at least 0.5 ml.
- 12. The method of claim 11, where the volume of the solution is at least 1 ml.
- 13. The method of claim 1, wherein the lens is a hydrogel contact lens.
- 14. The method of claim 1, wherein the lens is a silicone hydrogel contact lens.
- 15. The method of claim 1, wherein after placing the lens and the solution in the recess of the package, the recess is sealed with the lidstock without removing the solution.
- 16. The method of claim 1, wherein after placing the lens and the solution in the recess of the package, the solution is removed with a portion of the surface treatment agent remaining attached to the lens surface, and an aqueous packaging solution is added to the recess prior to sealing the recess with lidstock.

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