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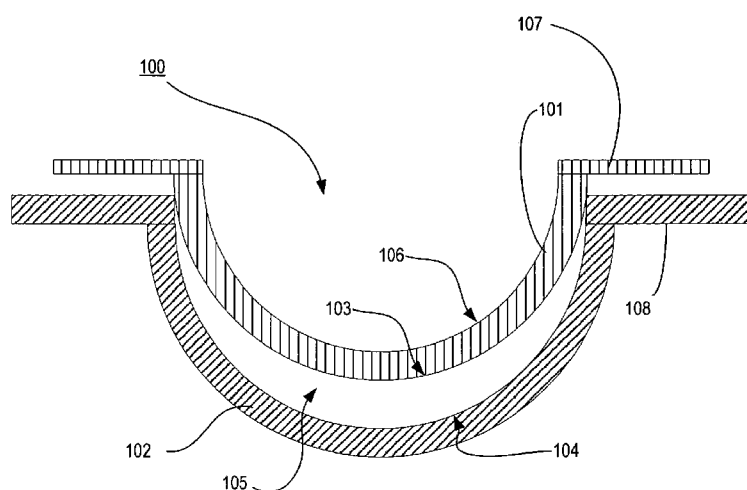


FIG. 1

(57) Abstract: This invention includes methods and systems for processing silicone hydrogel ophthalmic lenses using aqueous solutions which contain dimethyl siloxane as as processing aids to facilitate lens transfer.



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METHODS AND SYSTEMS FOR PROCESSING SILICONE HYDROGEL OPHTHALMIC LENSES FOR IMPROVED LENS TRANSFER

RELATED APPLICATIONS

This application is a non-provisional filing of a provisional application, U.S. Serial No. 61/032,161, filed on February 28, 2008.

FIELD OF THE INVENTION

This invention relates to a process to produce ophthalmic lenses made from silicone hydrogels. More specifically, the present invention relates to methods and systems for processing ophthalmic lenses and providing increased automatic lens inspection yields in mold parts in which the lenses were formed.

BACKGROUND OF THE INVENTION

It is well known that contact lenses can be used to improve vision. Various contact lenses have been commercially produced for many years. Early designs of contact lenses were fashioned from hard materials. Although hard material lenses are still currently used in some applications, they are not suitable for all patients due to issues with comfort and relatively low permeability to oxygen. Later developments in the field gave rise to soft contact lenses, based upon hydrogels.

Currently, silicon hydrogel contact lenses are widely accepted. Soft silicon hydrogel lenses are often more comfortable to wear than contact lenses made of hard materials. Soft contact lenses can be manufactured by forming a lens in a multi-part mold wherein the combined parts form a topography consistent with the desired final lens.

Multi-part molds used to fashion hydrogels into a useful article, such as an ophthalmic lens, can include for example, a first mold portion with a convex surface that corresponds with a back curve of an ophthalmic lens and a second mold portion with a concave surface that corresponds with a front curve of the ophthalmic lens. To prepare a lens, an uncured hydrogel lens formulation is placed between the concave and convex surfaces of the mold portions and subsequently cured. The hydrogel lens

formulation may be cured, for example by exposure to either, or both of, heat and light. The cured hydrogel forms a lens according to the dimensions of the mold.

During ophthalmic lens processing, a lens is typically placed in a lens carrier and exposed to one or more solutions. Following the exposure to solutions, the lenses are transferred from the lens carrier to a package. Consistent placement of each lens within a carrier assists with locating the lens for transfer via automated machinery.

Automated lens inspection systems can be used to visually inspect the lens within a package to determine whether a lens has been properly transferred to the package.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides methods of processing a silicone hydrogel ophthalmic lens which includes lens placement in a carrier or other container facilitated by exposing the lens to an aqueous solution of an effective amount of one or more surfactants with a siloxane backbone with a hydrophilic substituent including a pendent / comb geometry, such as, by way of example: dimethyl siloxane, and in some embodiments, a dimethylsiloxane-ethylene oxide copolymer.

In some embodiments, a neutralizer, such as, for example, sodium borate is included in the aqueous solution.

In addition, the present invention relates generally to ophthalmic lenses fashioned from materials including wettable silicone hydrogels formed from a reaction mixture including at least one high molecular weight hydrophilic polymer and at least one hydroxyl-functionalized silicone-containing monomer. In some embodiments, the ophthalmic lenses are formed from a reaction mixture including a high molecular weight hydrophilic polymer and an effective amount of a hydroxyl-functionalized silicone-containing monomer.

DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a mold assembly apparatus according to some embodiments of the present invention.

FIG. 2 includes a chart that illustrates improved lens yields following lens exposure to a solution including DBE 821.

DETAILED DESCRIPTION OF THE INVENTION

According to the present invention, it has been determined that more efficient processing of the silicone hydrogel ophthalmic lens can be realized by exposing a cured lens to an aqueous solution of an effective amount of dimethyl siloxane, and in some embodiments, a dimethylsiloxane-ethylene oxide copolymer. In particular, in some embodiments, one or more of: dimethyl siloxane and a dimethylsiloxane-ethylene oxide copolymer are included in an aqueous solution to which a contact lens is exposed while the lens is contained in a concave lens carrier. The exposure to the one or more of: dimethyl siloxane and a dimethylsiloxane-ethylene oxide copolymer improve centering the lens in the concave carrier and thereby provide more consistent placement of the lens, which in turn improves transferability of the lens by automated machinery.

Definitions

As used herein, "Leachable Material" includes UCD's, diluents and other material which is not bound to the polymer and may be extracted from the polymer matrix, for example, by leaching with water or an organic solvent. By way of example, in some embodiments, decanoic acid is included as a Leachable Material.

As used herein, a "Leaching Aid" is any compound that if used in an effective amount in an aqueous solution to treat an ophthalmic lens, can yield a lens with a reduced amount of Leachable Materials. Dimethyl siloxane, and in some embodiments, a dimethylsiloxane-ethylene oxide copolymer is included as a Leaching Aid.

As used herein "lens" refers to any ophthalmic device that resides in or on the eye. These devices can provide optical correction or may be cosmetic. For example, the term lens can refer to a contact lens, intraocular lens, overlay lens, ocular insert, optical insert or other similar device through which vision is corrected or modified, or through which eye physiology is cosmetically enhanced (e.g. iris color) without impeding vision. In some embodiments, the preferred lenses of the invention are soft contact lenses are made from silicone elastomers or hydrogels, which include but are not limited to silicone hydrogels, and fluorohydrogels. In various embodiments, a lens can provide optical correction, wound care, drug delivery, diagnostic functionality, cosmetic enhancement or effect or a combination of these properties.

As used herein, the term "lens forming mixture" or "Reactive Mixture" or "RMM"(reactive monomer mixture) refers to a monomer or prepolymer material which can be cured and crosslinked or crosslinked to form an ophthalmic lens. Various embodiments can include lens forming mixtures with one or more additives such as: UV blockers, tints, photoinitiators or catalysts, and other additives one might desire in an ophthalmic lenses such as, contact or intraocular lenses.

As used herein "lens forming surface" means a surface that is used to mold a lens. In some embodiments, any such surface 103-104 can have an optical quality surface finish, which indicates that it is sufficiently smooth and formed so that a lens surface fashioned by the polymerization of a lens forming material in contact with the molding surface is optically acceptable. Further, in some embodiments, the lens forming surface 103-104 can have a geometry that is necessary to impart to the lens surface the desired optical characteristics, including without limitation, spherical, aspherical and cylinder power, wave front aberration correction, corneal topography correction and the like as well as any combinations thereof.

As used herein, the term "mold" refers to a rigid or semi-rigid object that may be used to form lenses from uncured formulations. Some preferred molds include two mold parts forming a front curve mold part and a back curve mold part.

As used herein the term "monomer" is a compound containing at least one polymerizable group and an average molecular weight of about less than 2000 Daltons, as measured via gel permeation chromatography refractive index detection. Thus, monomers can include dimers and in some cases oligomers, including oligomers made from more than one monomeric unit.

As used herein, "released from a mold," means that a lens is either completely separated from the mold, or is only loosely attached so that it can be removed with mild agitation or pushed off with a swab.

As used herein, a "Processing Aid" is a compound or mixture of compounds, excluding organic solvents, which, when combined with water, decreases the surface tension of an ophthalmic lens in a lens receptacle, as compared to a lens in an aqueous solution that does not comprise the Processing Aid. Dimethyl siloxane, and in some embodiments, a dimethylsiloxane-ethylene oxide copolymer are included as Processing Aids.

As used herein, the term "treat" means to expose a cured lens to an aqueous solution including at least one of: a leaching aid and a release aid.

As used herein and also defined above, the term "UCD" means unreacted components and diluents.

Molds

Referring now to Fig. 1, a diagram of an exemplary mold 100 for an ophthalmic lens is illustrated with an energy receiving portion 109. As used herein, the terms a mold includes a form 100 having a cavity 105 into which a lens forming mixture 110 can be dispensed such that upon reaction or cure of the lens forming mixture, an ophthalmic lens of a desired shape is produced. The molds and mold assemblies 100 of this invention are made up of more than one "mold parts" or "mold pieces" 101-102. The mold parts 101-102 can be brought together such that a cavity 105 is formed between the mold parts 101-102 in which a lens can be formed. This combination of mold parts 101-102 is preferably temporary. Upon formation of the lens, the mold parts 101-102 can again be separated for removal of the lens.

At least one mold part 101-102 has at least a portion of its surface 103-104 in contact with the lens forming mixture such that upon reaction or cure of the lens forming mixture 110 that surface 103-104 provides a desired shape and form to the portion of the lens with which it is in contact. The same is true of at least one other mold part 101-102.

Thus, for example, in a preferred embodiment a mold assembly 100 is formed from two parts 101-102, a female concave piece (front piece) 102 and a male convex piece (back piece) 101 with a cavity formed between them. The portion of the concave surface 104 which makes contact with lens forming mixture has the curvature of the front curve of an ophthalmic lens to be produced in the mold assembly 100 and is sufficiently smooth and formed such that the surface of an ophthalmic lens formed by polymerization of the lens forming mixture which is in contact with the concave surface 104 is optically acceptable.

In some embodiments, the front mold piece 102 can also have an annular flange integral with and surrounding circular circumferential edge 108 and extends from it in a plane normal to the axis and extending from the flange (not shown).

A lens forming surface can include a surface 103-104 with an optical quality surface finish, which indicates that it is sufficiently smooth and formed so that a lens surface fashioned by the polymerization of a lens forming material in contact with the molding surface is optically acceptable. Further, in some embodiments, the lens forming surface 103-104 can have a geometry that is necessary to impart to the lens surface the desired optical characteristics, including without limitation, spherical, aspherical and cylinder power, wave front aberration correction, corneal topography correction and the like as well as any combinations thereof.

Mold part 101-102 material can include a polyolefin of one or more of: polypropylene, polystyrene, polyethylene, polymethyl methacrylate, and modified polyolefins.

A preferred alicyclic co-polymer contains two different alicyclic polymers and is sold by Zeon Chemicals L.P. under the trade name ZEONOR. There are several different grades of ZEONOR. Various grades may have glass transition temperatures ranging from 105°C to 160°C. A specifically preferred material is ZEONOR 1060R.

Other mold materials that may be combined with one or more additives to form an ophthalmic lens mold include, for example, Ziegler-Natta polypropylene resins (sometimes referred to as znPP). One exemplary Ziegler-Natta polypropylene resin is available under the name PP 9544 MED. PP 9544 MED is a clarified random copolymer for clean molding as per FDA regulation 21 CFR (c)3.2 made available by ExxonMobile Chemical Company. PP 9544 MED is a random copolymer (znPP) with ethylene group (hereinafter 9544 MED). Other exemplary Ziegler-Natta polypropylene resins include: Atofina Polypropylene 3761 and Atofina Polypropylene 3620WZ.

Still further, in some embodiments, the molds of the invention may contain polymers such as polypropylene, polyethylene, polystyrene, polymethyl methacrylate, modified polyolefins containing an alicyclic moiety in the main chain and cyclic polyolefins. This blend can be used on either or both mold halves, where it is preferred that this blend is used on the back curve and the front curve consists of the alicyclic co-polymers.

In some preferred methods of making molds 100 according to the present invention, injection molding is utilized according to known techniques, however,

embodiments can also include molds fashioned by other techniques including, for example: lathing, diamond turning, or laser cutting.

Typically, lenses are formed on at least one surface of both mold parts 101-102. However, in some embodiments, one surface of a lens may be formed from a mold part 101-102 and another surface of a lens can be formed using a lathing method, or other methods.

Treatment

According to the present invention, treatment can include exposing a cured lens to an aqueous solution which includes a solution with dimethyl siloxane, and in some embodiments, a dimethylsiloxane-ethylene oxide copolymer. Exposing may include, for example, submersion, spraying or flowing the solution into contact with the cured lens.

Additionally, in some embodiments, sodium borate is included in a hydration solution. The sodium borate can be effective to neutralize the hydration solution. Some preferred embodiments can include a hydration solution with a pH of between about 5 and 10 and most preferably between about 7.5 and 9. In some embodiments, sodium borate may be added to a hydration solution in a concentration of between about 0.5% and 5% and most preferably between about 0.8% and 2%.

In various embodiments, treatment can be accomplished, for example, via immersion of the lens in a solution or exposing the lens to a flow of solution. In various embodiments, treatment can also include, for example, one or more of: heating the solution; stirring the solution; increasing the level of release aid in the solution to a level sufficient to cause release of the lens; mechanical agitation of the lens; and increasing the level of leach aid in the solution to a level sufficient to facilitate adequate removal of UCDs from the lens.

By way of non-limiting examples, various implementations can include lens placement that is accomplished by way of a batch process wherein lenses are submerged in a solution contained in a fixed tank for a specified period of time or in a vertical process where lenses are exposed to a continuous flow of a solution that includes at least one of a leach aid and a release aid.

In some embodiments, the solution can be heated with a heat exchanger or other heating apparatus to further facilitate leaching of the lens and release of the lens from a mold part. For example, heating can include raising the temperature of an

aqueous solution to the boiling point while a hydrogel lens and mold part to which the lens is adhered are submerged in the heated aqueous solution. Other embodiments can include controlled cycling of the temperature of the aqueous solution.

In some preferred embodiments, a solution to which a lens is exposed is heated to 90°C or more. In other embodiments an aqueous solution heated to a temperature above the cloud point temperature of a surfactant included in the aqueous solution is preferred. Accordingly, in such embodiments, a temperature of above about 70°C may be preferable.

Some embodiments can also include the application of physical agitation to facilitate leach and release. For example, the lens mold part to which a lens is adhered, can be vibrated or caused to move back and forth within an aqueous solution. Other embodiments may include ultrasonic waves through the aqueous solution.

These and other similar processes can provide an acceptable means of releasing the lens and removing decanoic acid, UCDs or other unwanted material from an ophthalmic lens prior to packaging of the lens, through contact of the lens with dimethylsiloxane-ethylene oxide copolymer.

Processing

According to the present invention, processing of a silicone hydrogel lens is facilitated by exposing the lens to a hydration solution including dimethyl siloxane, and in some embodiments, dimethylsiloxane-ethylene oxide copolymer, combined with water at concentrations effective to facilitate one or both of: leaching the lens and decreasing the surface tension of the hydration solution sufficiently to allow a lens to be placed in a desired position and remain in the position. In some embodiments, the hydration solution includes dimethyl siloxane, such as a dimethylsiloxane-ethylene oxide copolymer, a base and DI water. In some preferred embodiments the hydration solution contains between about 0.05%- 5.0 % dimethylsiloxane-ethylene oxide copolymer and the base ranges in pH from about 7.5 to 9 at a concentration of 0.1% to 1%. Other embodiments can include a hydration solution of between about 0.01%- 10.0 % dimethylsiloxane-ethylene oxide copolymer and with a base range in pH between about 4.5-10 at a concentration of 0.1% to 5%.

The surfactant must have hydrophilic and hydrophobic moieties in which the hydrophilic substituents are pendent/ comb shaped geometries. One preferred exemplary surfactant includes a commercially available compound by Gelest,

available under the trade name DBE, and in particular DBE-821. DBE-821 may be utilized in an aqueous solution as one or both of: a Leach Aid to facilitate extraction; and a Processing Aid to facilitate placement of the lens in a container. When utilized as a Leaching Agent to assist in extraction the surfactant, such as DBE 821 is typically present in a higher concentration than when used as a Processing Aid used at higher concentrations.

A higher surfactant concentration solution will inherently act as a processing aid, whereas if a processing aid is the only desired outcome than the composition can be used, for example, in a solution of between about 0.009 to about 0.0110% dimethylsiloxane-ethylene oxide copolymer.

Aspects of the use of dimethylsiloxane-ethylene oxide copolymer as a processing aid the surfactant solution decreases the surface tension of the solution and thus allows proper placement of the lens ensuring proper transfer throughout the process. The solution may also be used as an extraction aid where at higher concentrations the surfactant increases the rate of diffusion of less water soluble components used in the diluent of the formulation of the lens while inherently acting as a processing aid as described in the previous example.

According to the present invention, extraction and processing of a silicone hydrogel lens is facilitated by exposing the lens to a solution including one or more of: Leaching Aids and Processing Aids combined with water at concentrations effective to remove unwanted material, such as decanoic acid and UCDs from a lens.

For example, in some embodiments, ophthalmic lenses can be subjected to a treatment exposing the lenses to a Leach Aid and a GC Mass Spectrometer can be used to measure the level of one or more UCDs in the ophthalmic lenses. The GC Mass Spectrometer can determine whether treatment with a particular leaching aid is effective to reduce an amount of particular UCDs present in the lenses to a maximum threshold amount.

Accordingly, in some embodiments, a GC Mass Spectrometer can be used to check for a maximum threshold of decanoic acid.

Lens materials

Ophthalmic lenses suitable for use with the current invention include those made from silicone hydrogels. Silicone hydrogels offer benefits to ophthalmic lens

wearers as compared to conventional hydrogels. For example, they typically offer much higher oxygen permeability, Dk , or oxygen oxygen/transmissibility, Dk/l , where l is the thickness of the lens. Such lenses cause reduced corneal swelling due to reduced hypoxia, and may cause less limbal redness, improved comfort and have a reduced risk of adverse responses such as bacterial infections. Silicone hydrogels are typically made by combining silicone-containing monomers or macromers with hydrophilic monomers or macromers.

Examples of silicone containing monomers include SiGMA (2-propenoic acid, 2-methyl-,2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl]propoxy]propyl ester), α,ω -bismethacryloxypropylpolydimethylsiloxane, mPDMS (monomethacryloxypropyl terminated mono-n-butyl terminated polydimethylsiloxane) and TRIS (3-methacryloxypropyltris(trimethylsiloxy)silane).

Examples of hydrophilic monomers include HEMA (2-hydroxyethylmethacrylate), DMA (N,N-dimethylacrylamide) and NVP (N-vinylpyrrolidone).

In some embodiments, high molecular weight polymers may be added to monomer mixes and serve the function of internal wetting agents. Some embodiments can also include additional components or additives, which are generally known in the art. Additives can include, for example: ultra-violet absorbing compounds and monomer, reactive tints, antimicrobial compounds, pigments, photochromic, Processing Aids, combinations thereof and the like.

The silicone monomers and macromers are blended with the hydrophilic monomers or macromers, placed into ophthalmic lens molds, and cured by exposing the monomer to one or more conditions capable of causing polymerization of the monomer. Such conditions can include, for example: heat and light, wherein the light may include one or more of: visible, ionizing, actinic, X-ray, electron beam or ultra violet (hereinafter "UV") light. In some embodiments, the light utilized to cause polymerization can have a wavelength of about 250 to about 700 nm. Suitable radiation sources include UV lamps, fluorescent lamps, incandescent lamps, mercury vapor lamps, and sunlight. In embodiments, where a UV absorbing compound is included in the monomer composition (for example, as a UV block), curing can be

conducted by means other than UV irradiation (such as, for example, by visible light or heat).

In some embodiments a radiation source, used to facilitate curing can be selected from UVA (about 315 – about 400 nm), UVB (about 280-about 315) or visible light (about 400 –about 450 nm), at low intensity. Some embodiments can also include a reaction that mixture includes a UV absorbing compound.

In some embodiments, wherein the lenses are cured using heat then a thermal initiator may be added to the monomer mix. Such initiators can include one or more of: peroxides such as benzoyl peroxide and azo compounds such as AIBN (azobisisobutyronitrile).

In some embodiments, lenses can be cured using UV or visible light and a photoinitiator may be added to the monomer mix. Such photoinitiators may include, for example, aromatic alpha-hydroxy ketones, alkoxybenzoin, acetophenones, acyl phosphine oxides, and a tertiary amine plus a diketone, mixtures thereof and the like. Illustrative examples of photoinitiators are 1-hydroxycyclohexyl phenyl ketone, 2-hydroxy-2-methyl-1-phenyl-propan-1-one, bis(2,6-dimethoxybenzoyl)-2,4,4-trimethylpentyl phosphine oxide (DMBAPO), bis(2,4,6-trimethylbenzoyl)-phenylphosphineoxide (Irgacure 819), 2,4,6-trimethylbenzoyldiphenyl phosphine oxide and 2,4,6-trimethylbenzoyl diphenylphosphine oxide, benzoin methyl ester and a combination of camphorquinone and ethyl 4-(N,N-dimethylamino)benzoate. Commercially available visible light initiator systems include Irgacure 819, Irgacure 1700, Irgacure 1800, Irgacure 819, Irgacure 1850 (all from Ciba Specialty Chemicals) and Lucirin TPO initiator (available from BASF). Commercially available UV photoinitiators include Darocur 1173 and Darocur 2959 (Ciba Specialty Chemicals).

In some embodiments, it may also be useful to include diluents in the monomer mix, for example to improve the solubility of the various components, or to increase the clarity or degree of polymerization of the polymer to be formed. Embodiments can also include secondary and tertiary alcohols as diluents.

Various processes are known for processing the reaction mixture in the production of ophthalmic lenses, including known spincoating and static casting. In some embodiments, a method for producing an ophthalmic lens from a polymer includes molding silicone hydrogels. Silicone hydrogel molding can be efficient and provides for precise control over the final shape of a hydrated lens.

Molding an ophthalmic lens from a silicone hydrogel can include placing a measured amount of monomer mix in a concave mold part. A convex mold part is then placed on top of the monomer and pressed to close and form a cavity that defines a contact lens shape. The monomer mix within the mold parts is cured to form a contact lens. As used herein, curing the monomer mix includes a process or condition which allows or facilitates the polymerization of the monomer mix. Examples of conditions which facilitate polymerization include one or more of: exposure to light and application of thermal energy.

When the mold halves are separated the lens typically adheres to one or the other mold half. It is typically difficult to physically remove the lens from this mold half, and it is generally preferred to place this mold half into a solvent to release the lens. The swelling of the lens that results when the lens absorbs some of this solvent typically facilitates release of the lens from the mold.

Silicone hydrogel lenses may be made using relatively hydrophobic diluents such as 3,7-dimethyl-3-octanol. If one attempts to release such lenses in water, such diluents prevent absorption of water, and do not allow sufficient swelling to cause release of the lens.

Alternatively, silicone hydrogels may be made using relatively hydrophilic and water soluble diluents such as ethanol, t-butanol or t-amyl alcohol. When such diluents are used and the lens and mold are placed into water, the diluent may more easily dissolve and the lens may more easily release in water than if more hydrophobic diluents are used.

Leachable Material

After a lens is cured the polymer formed typically contains some amount of material that is not bound to or incorporated into the polymer. Leachable Material not bound to the polymer may be extracted from the polymer matrix for example by leaching with water or an organic solvent (hereinafter "Leachable Material"). Such Leachable Material may not be favorable to the use of the contact lens in an eye. For example, Leachable Material may slowly be released from a contact lens when the contact lens is worn in an eye and may cause irritation or a toxic effect in the eye of the wearer. In some cases, Leachable Material may also bloom to the surface of a

contact lens where it may form a hydrophobic surface and may attract debris from tears, or may interfere with wetting of the lens.

Some material may be physically trapped in the polymer matrix and may not be able to be removed for example by extracting with water or an organic solvent. As used herein, trapped material is not considered Leachable Material.

Leachable material typically includes most or all of the material included in the monomer mix that does not have polymerizable functionality. For example, a diluent may be a Leachable Material. Leachable material may also include nonpolymerizable impurities which were present in the monomer. As polymerization approaches completion, the rate of polymerization will typically slow and some small amount of the monomer may never polymerize. Monomer that never polymerizes can be included in the material that will be leached from the polymerized lens. Leachable material may also include small polymer fragments, or oligomers. Oligomers can result from the termination reactions early in the formation of any given polymer chain. Accordingly, Leachable Materials can include any or all of a mixture of the above described components, which may vary one to another in their properties such as toxicity, molecular weight or water solubility.

In some specific exemplary embodiments, decanoic acid is a Leachable Material.

High Molecular Weight Hydrophilic Polymer

As used herein, "high molecular weight hydrophilic polymer" refers to substances having a weight average molecular weight of no less than about 100,000 Daltons, wherein said substances upon incorporation to silicone hydrogel formulations, increase the wettability of the cured silicone hydrogels. The preferred weight average molecular weight of these high molecular weight hydrophilic polymers is greater than about 150,000; more preferably between about 150,000 to about 2,000,000 Daltons, more preferably still between about 300,000 to about 1,800,000 Daltons, most preferably about 500,000 to about 1,500,000 Daltons.

Alternatively, the molecular weight of hydrophilic polymers of the invention can be also expressed by the K-value, based on kinematic viscosity measurements. When expressed in this manner, hydrophilic monomers having K-values of greater than about 46 and preferably between about 46 and about 150. The high molecular weight hydrophilic polymers are present in the formulations of these devices in an

amount sufficient to provide contact lenses, which without surface modification remain substantially free from surface depositions during use. Typical use periods include at least about 8 hours, and preferably worn several days in a row, and more preferably for 24 hours or more without removal. Substantially free from surface deposition means that, when viewed with a slit lamp, at least about 70% and preferably at least about 80%, and more preferably about 90% of the lenses worn in the patient population display depositions rated as none or slight, over the wear period.

Suitable amounts of high molecular weight hydrophilic polymer include from about 1 to about 15 weight percent, more preferably about 3 to about 15 percent, most preferably about 5 to about 12 percent, all based upon the total of all reactive components.

Examples of high molecular weight hydrophilic polymers include but are not limited to polyamides, polylactones, polyimides, polylactams and functionalized polyamides, polylactones, polyimides, polylactams, such as DMA functionalized by copolymerizing DMA with a lesser molar amount of a hydroxyl-functional monomer such as HEMA, and then reacting the hydroxyl groups of the resulting copolymer with materials containing radical polymerizable groups, such as isocyanatoethylmethacrylate or methacryloyl chloride. Hydrophilic prepolymers made from DMA or n-vinyl pyrrolidone with glycidyl methacrylate may also be used. The glycidyl methacrylate ring can be opened to give a diol which may be used in conjunction with other hydrophilic prepolymer in a mixed system to increase the compatibility of the high molecular weight hydrophilic polymer, hydroxyl-functionalized silicone containing monomer and any other groups which impart compatibility. The preferred high molecular weight hydrophilic polymers are those that contain a cyclic moiety in their backbone, more preferably, a cyclic amide or cyclic imide. High molecular weight hydrophilic polymers include but are not limited to poly-N-vinyl pyrrolidone, poly-N-vinyl-2-piperidone, poly-N-vinyl-2-caprolactam, poly-N-vinyl-3-methyl-2-caprolactam, poly-N-vinyl-3-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-caprolactam, poly-N-vinyl-3-ethyl-2-pyrrolidone, and poly-N-vinyl-4,5-dimethyl-2-pyrrolidone, polyvinylimidazole, poly-N,N-dimethylacrylamide, polyvinyl alcohol, polyacrylic acid, polyethylene oxide, poly 2 ethyl oxazoline, heparin polysaccharides,

polysaccharides, mixtures and copolymers (including block or random, branched, multichain, comb-shaped or star shaped) thereof where poly-N-vinylpyrrolidone (PVP) is particularly preferred. Copolymers might also be used such as graft copolymers of PVP.

The high molecular weight hydrophilic polymers provide improved wettability, and particularly improved in vivo wettability to the medical devices of the present invention. Without being bound by any theory, it is believed that the high molecular weight hydrophilic polymers are hydrogen bond receivers which in aqueous environments, hydrogen bond to water, thus becoming effectively more hydrophilic. The absence of water facilitates the incorporation of the hydrophilic polymer in the reaction mixture. Aside from the specifically named high molecular weight hydrophilic polymers, it is expected that any high molecular weight polymer will be useful in this invention provided that when said polymer is added to a silicone hydrogel formulation, the hydrophilic polymer (a) does not substantially phase separate from the reaction mixture and (b) imparts wettability to the resulting cured polymer. In some embodiments it is preferred that the high molecular weight hydrophilic polymer be soluble in the diluent at processing temperatures. Manufacturing processes which use water or water soluble diluents may be preferred due to their simplicity and reduced cost. In these embodiments high molecular weight hydrophilic polymers which are water soluble at processing temperatures are preferred.

Hydroxyl-functionalized Silicone Containing Monomer

As used herein a "hydroxyl-functionalized silicone containing monomer" is a compound containing at least one polymerizable group having an average molecular weight of about less than 5000 Daltons as measured via gel permeation chromatography, refractive index detection, and preferably less than about 3000 Daltons, which is capable of compatibilizing the silicone containing monomers included in the hydrogel formulation with the hydrophilic polymer. Hydroxyl functionality is very efficient at improving hydrophilic compatibility. Thus, in a preferred embodiment hydroxyl-functionalized silicone containing monomers of the present invention comprise at least one hydroxyl group and at least one "-Si-O-Si-" group. It is preferred that silicone and its attached oxygen account for more than

about 10 weight percent of said hydroxyl-functionalized silicone containing monomer, more preferably more than about 20 weight percent.

The ratio of Si to OH in the hydroxyl-functionalized silicone containing monomer is also important to providing a hydroxyl functionalized silicone containing monomer which will provide the desired degree of compatibilization. If the ratio of hydrophobic portion to OH is too high, the hydroxyl-functionalized silicone monomer may be poor at compatibilizing the hydrophilic polymer, resulting in incompatible reaction mixtures. Accordingly, in some embodiments, the Si to OH ratio is less than about 15:1, and preferably between about 1:1 to about 10:1. In some embodiments primary alcohols have provided improved compatibility compared to secondary alcohols. Those of skill in the art will appreciate that the amount and selection of hydroxyl-functionalized silicone containing monomer will depend on how much hydrophilic polymer is needed to achieve the desired wettability and the degree to which the silicone containing monomer is incompatible with the hydrophilic polymer.

In some embodiments, reaction mixtures of the present invention may include more than one hydroxyl-functionalized silicone containing monomer. For monofunctional hydroxyl functionalized silicone containing monomer the preferred R' is hydrogen, and the preferred R², R³, and R⁴, are C¹-6alkyl and triC¹-6alkylsiloxy, most preferred methyl and trimethylsiloxy. For multifunctional (difunctional or higher) R¹-R⁴ independently comprise ethylenically unsaturated polymerizable groups and more preferably comprise an acrylate, a styryl, a C₁₋₆alkylacrylate, acrylamide, C₁₋₆alkylacrylamide, N-vinyl lactam, N-vinylamide, C₂₋₁₂alkenyl, C₂₋₁₂alkenylphenyl, C₂₋₁₂alkenyl naphthyl, or C₂₋₆alkenylphenyl C₁₋₆alkyl. In some embodiments R⁵ is hydroxyl, --CH₂OH or CH₂CHOHCH₂OH.

In some other embodiments, R⁶ is a divalent C₁₋₆alkyl, C₁₋₆alkyloxy, C₁₋₆alkyloxyC₁₋₆alkyl, phenylene, naphthalene, C₁₋₁₂ cycloalkyl, C₁₋₆alkoxycarbonyl, amide, carboxy, C₁₋₆ alkylcarbonyl, carbonyl, C₁₋₆alkoxy, substituted C₁₋₆alkyl, substituted C₁₋₆alkyloxy, substituted C₁₋₆alkyloxyC₁₋₆alkyl, substituted phenylene, substituted naphthalene, substituted C₁₋₁₂cycloalkyl, where the substituents are selected from one or more members of the group consisting of C₁₋₆ alkoxycarbonyl, C₁₋₆alkyl, C₁₋₆alkoxy, amide, halogen, hydroxyl, carboxyl, C₁₋₆alkylcarbonyl and formyl. The particularly preferred R⁶ is a divalent methyl (methylene).

In some embodiments, R^7 comprises a free radical reactive group, such as an acrylate, a styryl, vinyl, vinyl ether, itaconate group, a C_{1-6} alkylacrylate, acrylamide, C_{1-6} alkylacrylamide, N-vinyl lactam, N-vinylamide, C_{2-12} alkenyl, C_{2-12} alkenylphenyl, C_{2-12} alkenyl naphthyl, or C_{2-6} alkenylphenyl C_{1-6} alkyl or a cationic reactive group such as vinyl ether or epoxide groups. The particularly preferred R^7 is methacrylate.

In some embodiments, R^8 is a divalent C_{1-6} alkyl, C_{1-6} alkyloxy, C_{1-6} alkyloxy C_{1-6} alkyl, phenylene, naphthalene, C_{1-12} cycloalkyl, C_{1-6} alkoxycarbonyl, amide, carboxy, C_{1-6} alkylcarbonyl, carbonyl, C_{1-6} alkoxy, substituted C_{1-6} alkyl, substituted C_{1-6} alkyloxy, substituted C_{1-6} alkyloxy C_{1-6} alkyl, substituted phenylene, substituted naphthalene, substituted C_{1-12} cycloalkyl, where the substituents are selected from one or more members of the group consisting of C_{1-6} alkoxycarbonyl, C_{1-6} alkyl, C_{1-6} alkoxy, amide, halogen, hydroxyl, carboxyl, C_{1-6} alkylcarbonyl and formyl. The particularly preferred R^8 is C_{1-6} alkyloxy C_{1-6} alkyl.

Examples of hydroxyl-functionalized silicone containing monomer of Formula I include 2-propenoic acid, 2-methyl-2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxy]propoxy]propyl ester (which can also be named (3-methacryloxy-2-hydroxypropyloxy)propylbis(trimethylsiloxy)methylsilane-) 2 . The compound, (3-methacryloxy-2-hydroxypropyloxy)propylbis(trimethylsiloxy)methylsilane can be formed from an epoxide, which produces an 80:20 mixture of the compound shown above and (2-methacryloxy-3-hydroxypropyloxy)propylbis(trimethylsiloxy)methylsilane. In some embodiments of the present invention it is preferred to have some amount of the primary hydroxyl present, preferably greater than about 10 wt % and more preferably at least about 20 wt %.

Other suitable hydroxyl-functionalized silicone containing monomers include (3-methacryloxy-2-hydroxypropyloxy)propyltris(trimethylsiloxy)silane 3 bis-3-methacryloxy-2-hydroxypropyloxypropyl polydimethylsiloxane 4 3-methacryloxy-2-(2-hydroxyethoxy)propyloxy)propylbis(trimethylsiloxy)methylsilane 5 N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)-.alpha.,.omega.-- bis-3-aminopropylpolydimethylsiloxane.

The reaction products of glycidyl methacrylate with amino-functional polydimethylsiloxanes may also be used as a hydroxyl-functional silicone containing monomer. Still additional structures which may be suitable hydroxyl-functionalized silicone containing monomers include those similar to compounds having the

following structure: 6 where $n=1-50$ and R independently comprise H or a polymerizable unsaturated group, with at least one R comprising a polymerizable group, and at least one R, and preferably 3-8 R, comprising H. These components may be removed from the hydroxyl-functionalized monomer via known methods such as liquid phase chromatography, distillation, recrystallization or extraction, or their formation may be avoided by careful selection of reaction conditions and reactant ratios.

Suitable monofunctional hydroxyl-functionalized silicone monomers are commercially available from Gelest, Inc. Morrisville, Pa. Suitable multifunctional hydroxyl-functionalized silicone monomers are commercially available from Gelest, Inc, Morrisville, Pa. or may be made using known procedures.

While hydroxyl-functionalized silicone containing monomers have been found to be particularly suitable for providing compatible polymers for biomedical devices, and particularly ophthalmic devices, any functionalized silicone containing monomer which, when polymerized and/or formed into a final article is compatible with the selected hydrophilic components may be used. Suitable functionalized silicone containing monomers may be selected using the following monomer compatibility test. In this test one gram of each of mono-3-methacryloxypropyl terminated, mono-butyl terminated polydimethylsiloxane (mPDMS MW 800-1000) and a monomer to be tested are mixed together in one gram of 3,7-dimethyl-3-octanol at about 20.degree. C. A mixture of 12 weight parts K-90 PVP and 60 weight parts DMA is added drop-wise to hydrophobic component solution, with stirring, until the solution remains cloudy after three minutes of stirring. The mass of the added blend of PVP and DMA is determined in grams and recorded as the monomer compatibility index. Any hydroxyl-functionalized silicone-containing monomer having a compatibility index of greater than 0.2 grams, more preferably greater than about 0.7 grams and most preferably greater than about 1.5 grams will be suitable for use in this invention.

An "effective amount" or a "compatibilizing effective amount" of the hydroxyl-functionalized silicone-containing monomers of the invention is the amount needed to compatibilize or dissolve the high molecular weight hydrophilic polymer and the other components of the polymer formulation. Thus, the amount of hydroxyl-functional silicone containing monomer will depend in part on the amount of hydrophilic polymer which is used, with more hydroxyl-functionalized silicone

containing monomer being needed to compatibilize higher concentrations of hydrophilic polymer. Effective amounts of hydroxyl-functionalized silicone containing monomer in the polymer formulation include about 5% (weight percent, based on the weight percentage of the reactive components) to about 90%, preferably about 10% to about 80%, most preferably, about 20% to about 50%.

In addition to the high molecular weight hydrophilic polymers and the hydroxyl-functionalized silicone containing monomers of the invention other hydrophilic and hydrophobic monomers, crosslinkers, additives, diluents, polymerization imitators may be used to prepare the biomedical devices of the invention. In addition to high molecular weight hydrophilic polymer and hydroxyl-functionalized silicone containing monomer, the hydrogel formulations may include additional silicone containing monomers, hydrophilic monomers, and cross linkers to give the biomedical devices of the invention.

Additional Silicone Containing Monomers

With respect to the additional silicone containing monomers, useful amide analogs of TRIS can include, 3-methacryloxypropyltris(trimethylsiloxy)silane (TRIS), monomethacryloxypropyl terminated polydimethylsiloxanes, polydimethylsiloxanes, 3-methacryloxypropylbis(trimethylsiloxy)methylsilane, methacryloxypropylpentamethyl disiloxane and combinations thereof are particularly useful as additional silicone-containing monomers of the invention. Additional silicone containing monomers may be present in amounts of about 0 to about 75 wt %, more preferably of about 5 and about 60 and most preferably of about 10 and 40 weight %.

Hydrophilic Monomers

Additionally, reaction components of the present invention may also include any hydrophilic monomers used to prepare conventional hydrogels. For example monomers containing acrylic groups ($\text{CH}_2=\text{C}(\text{R})\text{COX}$, where R is hydrogen or C_1 - C_6 alkyl and X is O or N) or vinyl groups ($-\text{C}(\text{R})=\text{CH}_2$) may be used. Examples of additional hydrophilic monomers are N,N-dimethylacrylamide, 2-hydroxyethyl methacrylate, glycerol monomethacrylate, 2-hydroxyethyl methacrylamide, polyethyleneglycol monomethacrylate, methacrylic acid, acrylic acid, N-vinyl

pyrrolidone, N-vinyl-N-methyl acetamide, N-vinyl-N-ethyl acetamide, N-vinyl-N-ethyl formamide, N-vinyl formamide and combinations thereof.

Aside the additional hydrophilic monomers mentioned above, polyoxyethylene polyols having one or more of the terminal hydroxyl groups replaced with a functional group containing a polymerizable double bond may be used. Examples include polyethylene glycol, ethoxylated alkyl glucoside and ethoxylated bisphenol A, reacted with one or more molar equivalents of an end-capping group such as isocyanatoethyl methacrylate, methacrylic anhydride, methacryloyl chloride, vinylbenzoyl chloride, and the like, produce a polyethylene polyol having one or more terminal polymerizable olefinic groups bonded to the polyethylene polyol through linking moieties such as carbamate, urea or ester groups.

Still further examples include the hydrophilic vinyl carbonate or vinyl carbamate monomers, hydrophilic oxazalone monomers and polydextran.

Additional hydrophilic monomers can include N,N-dimethylacrylamide (DMA), 2-hydroxyethyl methacrylate (HEMA), glycerol methacrylate, 2-hydroxyethyl methacrylamide, N-vinylpyrrolidone (NVP), polyethyleneglycol monomethacrylate, methacrylic acid, acrylic acid and combinations thereof. Additional hydrophilic monomers may be present in amounts of about 0 to about 70 wt %, more preferably of about 5 and about 60 and most preferably of about 10 and 50 weight %.

Crosslinkers

Suitable crosslinkers are compounds with two or more polymerizable functional groups. The crosslinker may be hydrophilic or hydrophobic and in some embodiments of the present invention mixtures of hydrophilic and hydrophobic crosslinkers have been found to provide silicone hydrogels with improved optical clarity (reduced haziness compared to a CSI Thin Lens). Examples of suitable hydrophilic crosslinkers include compounds having two or more polymerizable functional groups, as well as hydrophilic functional groups such as polyether, amide or hydroxyl groups. Specific examples include TEGDMA (tetraethyleneglycol dimethacrylate), TrEGDMA (triethyleneglycol dimethacrylate), ethyleneglycol dimethacrylate (EGDMA), ethylenediamine dimethacrylamide, glycerol dimethacrylate and combinations thereof. Examples of suitable hydrophobic crosslinkers include multifunctional hydroxyl-functionalized silicone containing

monomer, multifunctional polyether-polydimethylsiloxane block copolymers, combinations thereof and the like. Specific hydrophobic crosslinkers include acryloxypropyl terminated polydimethylsiloxane ($n=10$ or 20) (acPDMS), hydroxylacrylate functionalized siloxane macromer, methacryloxypropyl terminated PDMS, butanediol dimethacrylate, divinyl benzene, 1,3-bis(3-methacryloxypropyl)-tetrakis(trimethylsiloxy) disiloxane and mixtures thereof. Preferred crosslinkers include TEGDMA, EGDMA, acPDMS and combinations thereof. The amount of hydrophilic crosslinker used is generally about 0 to about 2 weight % and preferably from about 0.5 to about 2 weight % and the amount of hydrophobic crosslinker is about 0 to about 5 weight %, which can alternatively be referred to in mol % of about 0.01 to about 0.2 mmole/gm reactive components, preferably about 0.02 to about 0.1 and more preferably 0.03 to about 0.6 mmole/gm.

Increasing the level of crosslinker in the final polymer has been found to reduce the amount of haze. However, as crosslinker concentration increases above about 0.15 mmole/gm reactive components modulus may increase above generally desired levels (greater than about 90 psi). Thus, in some embodiments of the present invention the crosslinker composition and amount is selected to provide a crosslinker concentration in the reaction mixture of between about 0.01 and about 0.1 mmoles/gm crosslinker.

Additional components or additives, which are generally known in the art may also be included. Additives include but are not limited to ultra-violet absorbing compounds and monomer, reactive tints, antimicrobial compounds, pigments, photochromic, Processing Aids, combinations thereof and the like.

Additional components include other oxygen permeable components such as carbon-carbon triple bond containing monomers and fluorine containing monomers which are known in the art and include fluorine-containing (meth)acrylates, and more specifically include, for example, fluorine-containing C_2 - C_{12} alkyl esters of (meth)acrylic acid such as 2,2,2-trifluoroethyl (meth)acrylate, 2,2,2,2',2',2'-hexafluoroisopropyl (meth)acrylate, 2,2,3,3,4,4,4-heptafluorobutyl (meth)acrylate, 2,2,3,3,4,4,5,5,6,6,7,7,8,8-pentadecafluorooctyl (meth)acrylate, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9-hexadecafluorononyl (meth)acrylate and the like.

Diluents

The reaction components (hydroxyl-functionalized silicone containing monomer, hydrophilic polymer, crosslinker(s) and other components) are generally mixed and reacted in the absence of water and optionally, in the presence of at least one diluent to form a reaction mixture. The type and amount of diluent used also effects the properties of the resultant polymer and article. The haze and wettability of the final article may be improved by selecting relatively hydrophobic diluents and/or decreasing the concentration of diluent used. As discussed above, increasing the hydrophobicity of a diluent may also allow poorly compatible components (as measured by the compatibility test) to be processed to form a compatible polymer and article. However, as the diluent becomes more hydrophobic, processing steps necessary to replace the diluent with water will require the use of solvents other than water. This may undesirably increase the complexity and cost of the manufacturing process. Thus, it is important to select a diluent which provides the desired compatibility to the components with the necessary level of processing convenience. Diluents useful in preparing some embodiments of the devices of this invention can include ethers, esters, alkanes, alkyl halides, silanes, amides, alcohols and combinations thereof. Amides and alcohols are preferred diluents, and secondary and tertiary alcohols are most preferred alcohol diluents. Examples of ethers useful as diluents for this invention include tetrahydrofuran, tripropylene glycol methyl ether, dipropylene glycol methyl ether, ethylene glycol n-butyl ether, diethylene glycol n-butyl ether, diethylene glycol methyl ether, ethylene glycol phenyl ether, propylene glycol methyl ether, propylene glycol methyl ether acetate, dipropylene glycol methyl ether acetate, propylene glycol n-propyl ether, dipropylene glycol n-propyl ether, tripropylene glycol n-butyl ether, propylene glycol n-butyl ether, dipropylene glycol n-butyl ether, tripropylene glycol n-butyl ether, propylene glycol phenyl ether, dipropylene glycol dimethyl ether, polyethylene glycols, polypropylene glycols and mixtures thereof. Examples of esters useful for this invention include ethyl acetate, butyl acetate, amyl acetate, methyl lactate, ethyl lactate, i-propyl lactate. Examples of alkyl halides useful as diluents for this invention include methylene chloride. Examples of silanes useful as diluents for this invention include octamethylcyclotetrasiloxane.

Examples of alcohols useful as diluents for this invention include those having the formula 7 wherein R, R' and R'' are independently selected from H, a linear, branched or cyclic monovalent alkyl having 1 to 10 carbons which may optionally be substituted with one or more groups including halogens, ethers, esters, aryls, amines, amides, alkenes, alkynes, carboxylic acids, alcohols, aldehydes, ketones or the like, or any two or all three of R, R' and R'' can together bond to form one or more cyclic structures, such as alkyl having 1 to 10 carbons which may also be substituted as just described, with the proviso that no more than one of R, R' or R'' is H.

It is preferred that R, R' and R'' are independently selected from H or unsubstituted linear, branched or cyclic alkyl groups having 1 to 7 carbons. It is more preferred that R, R', and R'' are independently selected from unsubstituted linear, branched or cyclic alkyl groups having 1 to 7 carbons. In certain embodiments, the preferred diluent has 4 or more, more preferably 5 or more total carbons, because the higher molecular weight diluents have lower volatility, and lower flammability. When one of the R, R' and R'' is H, the structure forms a secondary alcohol. When none of the R, R' and R'' are H, the structure forms a tertiary alcohol. Tertiary alcohols are more preferred than secondary alcohols. The diluents are preferably inert and easily displaceable by water when the total number of carbons is five or less. Examples of useful secondary alcohols include 2-butanol, 2-propanol, menthol, cyclohexanol, cyclopentanol and exonorborneol, 2-pentanol, 3-pentanol, 2-hexanol, 3-hexanol, 3-methyl-2-butanol, 2-heptanol, 2-octanol, 2-nonanol, 2-decanol, 3-octanol, norborneol, and the like.

Examples of useful tertiary alcohols include tert-butanol, tert-amyl, alcohol, 2-methyl-2-pentanol, 2,3-dimethyl-2-butanol, 3-methyl-3-pentanol, 1-methylcyclohexanol, 2-methyl-2-hexanol, 3,7-dimethyl-3-octanol, 1-chloro-2-methyl-2-propanol, 2-methyl-2-heptanol, 2-methyl-2-octanol, 2,2-methyl-2-nonanol, 2-methyl-2-decanol, 3-methyl-3-hexanol, 3-methyl-3-heptanol, 4-methyl-4-heptanol, 3-methyl-3-octanol, 4-methyl-4-octanol, 3-methyl-3-nonanol, 4-methyl-4-nonanol, 3-methyl-3-octanol, 3-ethyl-3-hexanol, 3-methyl-3-heptanol, 4-ethyl-4-heptanol, 4-propyl-4-heptanol, 4-isopropyl-4-heptanol, 2,4-dimethyl-2-pentanol, 1-methylcyclopentanol, 1-ethylcyclopentanol, 3-hydroxy-3-methyl-1-butene, 4-hydroxy-4-methyl-1-cyclopentanol, 2-phenyl-2-propanol, 2-

methoxy-2-methyl-2-propanol 2,3,4-trimethyl-3-pentanol, 3,7-dimethyl-3-octanol, 2-phenyl-2-butanol, 2-methyl-1-phenyl-2-propanol and 3-ethyl-3-pentanol, and the like.

A single alcohol or mixtures of two or more of the above-listed alcohols or two or more alcohols according to the structure above can be used as the diluent to make the polymer of this invention.

In certain embodiments, the preferred alcohol diluents are secondary and tertiary alcohols having at least 4 carbons. In particular, some alcohol diluents can include tert-butanol, tert-amyl alcohol, 2-butanol, 2-methyl-2-pentanol, 2,3-dimethyl-2-butanol, 3-methyl-3-pentanol, 3-ethyl-3-pentanol, 3,7-dimethyl-3-octanol.

Diluents can also include: hexanol, heptanol, octanol, nonanol, decanol, tert-butyl alcohol, 3-methyl-3-pentanol, isopropanol, t amyl alcohol, ethyl lactate, methyl lactate, i-propyl lactate, 3,7-dimethyl-3-octanol, dimethyl formamide, dimethyl acetamide, dimethyl propionamide, N methyl pyrrolidinone and mixtures thereof.

In some embodiments of the present invention the diluent is water soluble at processing conditions and readily washed out of the lens with water in a short period of time. Suitable water soluble diluents include 1-ethoxy-2-propanol, 1-methyl-2-propanol, t-amyl alcohol, tripropylene glycol methyl ether, isopropanol, 1-methyl-2-pyrrolidone, N,N-dimethylpropionamide, ethyl lactate, dipropylene glycol methyl ether, mixtures thereof and the like. The use of a water soluble diluent allows the post molding process to be conducted using water only or aqueous solutions which comprise water as a substantial component.

In some embodiments, the amount of diluent can be generally less than about 50 weight % of the reaction mixture and preferably less than about 40% and more preferably between about 10 and about 30%. In some embodiments, diluent may also include additional components such as Processing Aids and can include water soluble and aid in lens deblocking.

Polymerization initiators can include, for example, compounds such as: lauryl peroxide, benzoyl peroxide, isopropyl percarbonate, azobisisobutyronitrile, and the like, that generate free radicals at moderately elevated temperatures, and photoinitiator systems such as aromatic alpha-hydroxy ketones, alkoxyoxybenzoines, acetophenones, acyl phosphine oxides, and a tertiary amine plus a diketone, mixtures thereof and the like. Illustrative examples of photoinitiators are 1-hydroxycyclohexyl phenyl ketone, 2-hydroxy-2-methyl-1-phenyl-propan-1-one, bis(2,6-

dimethoxybenzoyl)-2,4,4-trimethylpentyl phosphine oxide (DMBAPO), bis(2,4,6-trimethylbenzoyl)-phenylphosphineoxide (Irgacure 819), 2,4,6-trimethylbenzoyldiphenyl phosphine oxide and 2,4,6-trimethylbenzoyl diphenylphosphine oxide, benzoin methyl ester and a combination of camphorquinone and ethyl 4-(N,N-dimethylamino)benzoate. Commercially available visible light initiator systems include Irgacure 819, Irgacure 1700, Irgacure 1800, Irgacure 819, Irgacure 1850 (all from Ciba Specialty Chemicals) and Lucirin TPO initiator (available from BASF). Commercially available UV photoinitiators include Darocur 1173 and Darocur 2959 (Ciba Specialty Chemicals). The initiator is used in the reaction mixture in effective amounts to initiate photopolymerization of the reaction mixture, e.g., from about 0.1 to about 2 parts by weight per 100 parts of reactive monomer. Polymerization of the reaction mixture can be initiated using the appropriate choice of heat or visible or ultraviolet light or other means depending on the polymerization initiator used. Alternatively, initiation can be conducted without a photoinitiator using, for example, e-beam. However, when a photoinitiator is used, some embodiments can include a combination of 1-hydroxycyclohexyl phenyl ketone and bis(2,6-dimethoxybenzoyl)-2,4,4-trimethylpentyl phosphine oxide (DMBAPO), and the method of polymerization initiation can include visible light. Other embodiments can include: bis(2,4,6-trimethylbenzoyl)-phenylphosphineoxide (Irgacure 819.RTM.).

A range of the combined silicone-containing monomers (hydroxyl-functionalized silicone-containing and additional silicone-containing monomers) can be from about 5 to 99 weight percent, more preferably about 15 to 90 weight percent, and in some embodiments about 25 to about 80 weight percent of the reaction components. A range of hydroxyl-functionalized silicone-containing monomer can be about 5 to about 90 weight percent, preferably about 10 to about 80, and most preferably about 20 to about 50 weight percent. In some embodiments a range of hydrophilic monomer can be from about 0 to about 70 weight percent, more preferably about 5 to about 60 weight percent, and most preferably about 10 to about 50 weight percent of the reactive components. In other embodiments a range of high molecular weight hydrophilic polymer can be about 1 to about 15 weight percent, or about 3 to about 15 weight percent, or about 5 to about 12 weight percent. . All of the about weight percents are based upon the total of all reactive components.

In some embodiments, a range of diluent is from about 0 to about 70 weight percent, or about 0 to about 50 weight percent, and or about 0 to about 40 weight percent and in some embodiments, between about 10 and about 30 weight percent, based upon the weight all component in the reactive mixture. The amount of diluent required varies depending on the nature and relative amounts of the reactive components.

In some embodiments, the reactive components comprise 2-propenoic acid, 2-methyl-,2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl]propoxy]propyl ester "SiGMA" .about.28 wgt. % of the reaction components); (800-1000 MW monomethacryloxypropyl terminated mono-n-butyl terminated polydimethylsiloxane, "mPDMS" (.about.31 %wt); N,N-dimethylacrylamide, "DMA" (.about.24%wt); 2-hydroxyethyl methacryate, "HEMA" (.about.6%wt); tetraethyleneglycoldimethacrylate, "TEGDMA" (.about.1.5%wt), polyvinylpyrrolidone, "K-90 PVP" (.about.7%wt); with the balance comprising minor amounts of additives and photoinitiators. The polymerization can also be conducted in the presence of about 23% (weight % of the combined monomers and diluent blend) 3,7-dimethyl-3-octanol diluent.

In some embodiments, the polymerizations for the above formulations can be conducted in the presence of tert-amyl-alcohol as a diluent comprising about 29 weight percent of the uncured reaction mixture.

Although the present invention has been described from the aspect of one or more processes, it is to be understood that the present invention also incorporates apparatus and systems, such as, by way of non-limiting example: mold handling machinery, hydration towers, immersion tanks, automated control systems, monomer dispensers, curing tunnels, heat exchangers, and the like, which may be used to implement one or more of the steps described herein.

Examples:

In order to illustrate the invention the following examples are included. These examples do not limit the invention. They are meant only to suggest a method of practicing the invention. Those knowledgeable in contact lenses, as well as other arts, may find other methods of practicing the invention, those methods are deemed to be within the scope of this invention.

Example 1:

Referring now to Fig. 2, a chart illustrates the beneficial effect of including DBE 821 in a solution processing ophthalmic lenses. In the example represented by the chart, silicone hydrogel contact lenses were cast molded according to the processes described above. Lenses were exposed to a one of two sets of heated aqueous solutions.

Solution Set A included a first solution of about 0.45% of sodium borate and 0.0% of DBE-821 heated to about 90°C and a second solution of about 0.45% of sodium borate and 0.0% of DBE-821 heated to between about 70°C and 80°C. Lenses were exposed to the respective first and second solutions for approximately 10 minutes each.

Solution Set B included a first solution of about 0.45% sodium borate and 100 PPM DBE-821 heated to about 90°C and a second solution of about 0.45% sodium borate and 100 PPM DBE-821 heated to between about 70°C and 80°C. Lenses were exposed to the respective first and second solutions for approximately 10 minutes each.

As illustrated by the chart, those lenses processed by Solution Set A 201 had lower transfer yield than those lenses exposed to Solution Set B 202. Transfer yields may be determined, for example, via visual inspection or via an automated lens inspection apparatus.

CLAIMS

What is claimed:

1. A method for processing an ophthalmic lens comprising silicone, the method comprising:
 - forming the ophthalmic lens;
 - placing the lens in a lens carrier;
 - exposing said ophthalmic lens to a first aqueous solution comprising about 0.004% or more of dimethyl siloxane;
 - transferring the lens out of said lens carrier.
2. The method of claim 1 wherein the aqueous solution comprises about 0.01% or more of a dimethylsiloxane-ethylene oxide copolymer.
3. The method of claim 1 wherein the aqueous solution comprises about 0.005% or more of a dimethylsiloxane-ethylene oxide copolymer.
4. The method of claim 1 wherein the aqueous solution comprises between about 0.005% and 5% of a dimethylsiloxane-ethylene oxide copolymer.
5. The method of claim 1 wherein the aqueous solution comprises a pH in the range of about 7.0 to 9.5.
6. The method according to claim 1, wherein the first solution additionally comprises between about 0.40% and 0.50% sodium borate.
7. The method according to claim 4, additionally comprising the step of exposing the lens to a second aqueous solution to rinse away the first aqueous solution.
8. The method according to claim 7, wherein at least one of said first aqueous solution and said second aqueous solution comprises a buffered aqueous solution.

9. The method according to claim 7, wherein the exposure to the first solution continues for a period of five minutes or more.
10. The method according to claim 7, wherein said ophthalmic lens comprises a contact lens comprising from 0 to about 90 percent water.
11. The method according to claim 7, wherein said ophthalmic lens comprises a pattern of colorant.
12. The method of claim 7, wherein the ophthalmic lens is formed from a reaction mixture comprising a high molecular weight hydrophilic polymer and an effective amount of an hydroxyl-functionalized silicone-containing monomer.
13. The method of claim 7, wherein the ophthalmic lens is formed from a reaction mixture comprising about 1% to about 15% high molecular weight hydrophilic polymer.
14. The method of claim 7 additionally comprising the step of forming the ophthalmic lens by curing a monomer comprising of the group consisting of: poly-N-vinyl pyrrolidone, poly-N-vinyl-2-piperidone, poly-N-vinyl-2-caprolactam, poly-N-vinyl-3-methyl-2-caprolactam, poly-N-vinyl-3-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-piperidone, poly-N-vinyl-4-methyl-2-caprolactam, poly-N-vinyl-3-ethyl-2-pyrrolidone, and poly-N-vinyl-4,5-dimethyl-2-pyrrolidone, polyvinylimidazole, poly-N-N-dimethylacrylamide, polyvinyl alcohol, polyacrylic acid, polyethylene oxide, poly 2 ethyl oxazoline, heparin polysaccharides, polysaccharides, mixtures and copolymers thereof.
15. The method of claim 7 wherein the step of rinsing the ophthalmic lens comprises exposing the ophthalmic lens three times to at least 35 ml of deionized water.

16. The method of claim 4 wherein the first aqueous solution is heated to about 90°C or more.
17. The method of claim 4 wherein the step of exposing said ophthalmic lens to a first aqueous solution comprises immersing the lens in the first aqueous solution.
18. The method of claim 4 wherein the step of exposing said ophthalmic lens to a first aqueous solution comprises flowing the first aqueous solution over the lens.
19. The method of claim 1 wherein the exposure of the lens to the first aqueous solution comprising about 0.004% or more of dimethyl siloxane provides an increased lens transfer yield of 5% or more.
20. A method for releasing an ophthalmic lens comprising silicone from a mold part, the method comprising:
 - exposing said ophthalmic lens to a first aqueous solution comprising about 0.01% or more of a surfactant comprising a hydrophobic moiety including a siloxane backbone comprising a hydrophilic substituent comprising a pendent / comb geometry.

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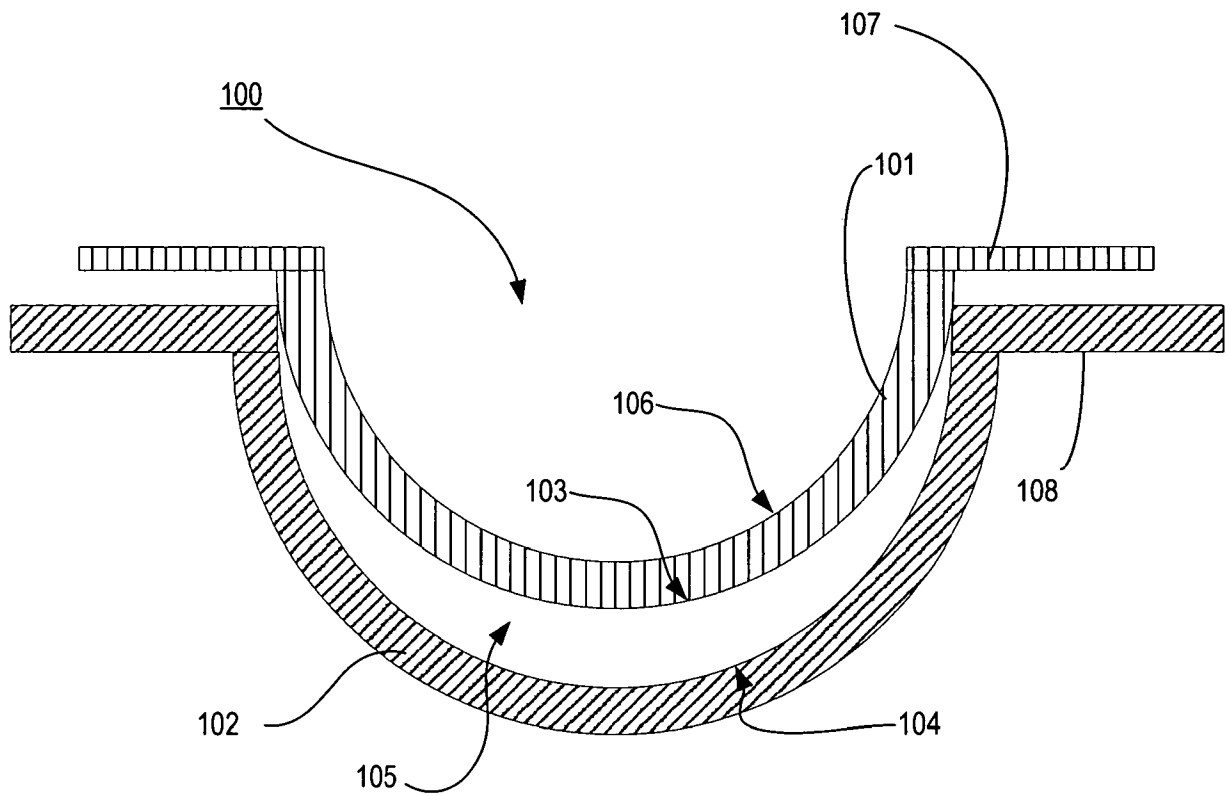
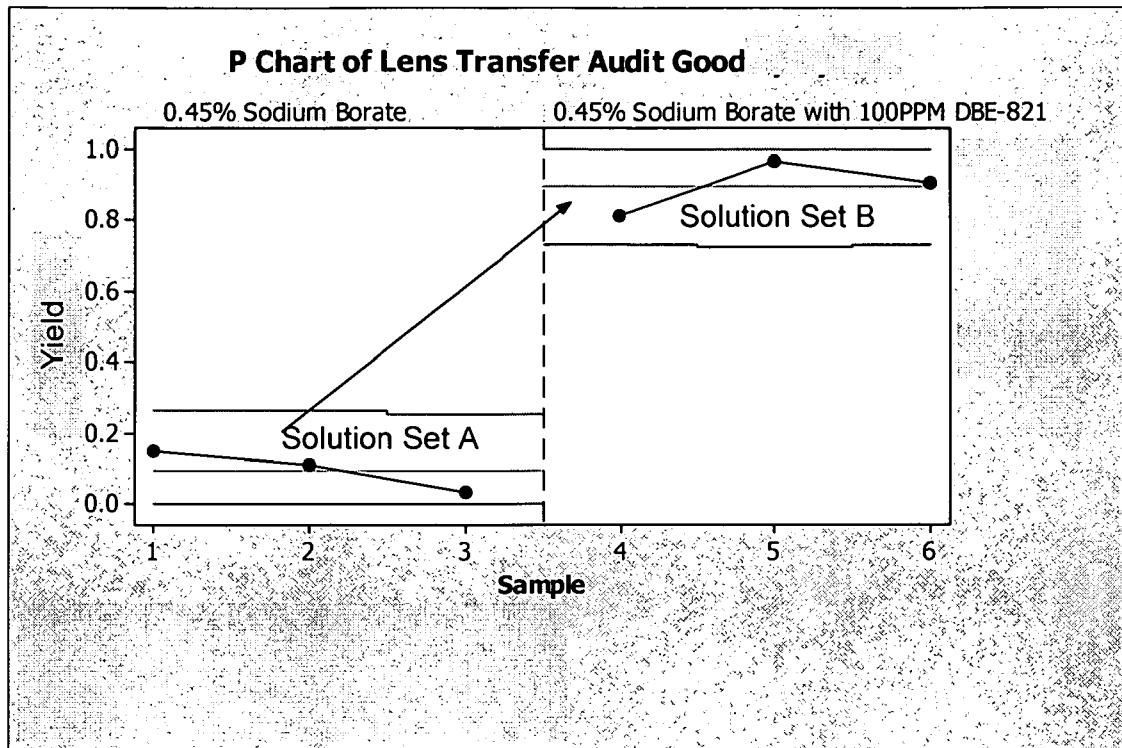


FIG. 1

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FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/001245

A. CLASSIFICATION OF SUBJECT MATTER
INV. B29C33/64 B29D11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B29C B29D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

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☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

9 June 2009

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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