

Method for Making Embedded Silicone Hydrogel Contact Lenses

The present invention generally relates to a method for producing embedded silicone hydrogel contact lenses. In addition, the present invention provides embedded silicone hydrogel contact lenses produced according to a method of the invention.

BACKGROUND

Presbyopia is a well-known disorder in which the eye loses its ability to focus at close distance, affecting more than 2 billion patients worldwide. Extensive research efforts have been contributed to develop multifocal ophthalmic lenses (intraocular lenses or contact lenses) for correcting presbyopia. One of extensive research areas is the development of multifocal diffractive ophthalmic lenses. See, for example, U.S. Pat. Nos. 4210391, 4338005, 4340283, 4637697, 4641934, 4642112, 4655565, 4830481, 4881804, 4881805, 4936666, 4995714, 4995715, 5054905, 5056908, 5076684, 5100226, 5104212, 5114220, 5116111, 5117306, 5120120, 5121979, 5121980, 5229797, 5748282, 5760871, 5982543, 6120148, 6364483, 6536899, 6951391, 6957891, 7025456, 7073906, 7093938, 7156516, 7188949, 7232218, 7891810, 8038293, 8128222, 8142016, 8382281, 8480228, 8556416, 8573775, 8678583, 8755117, 9033494, 9310624, 9320594, 9370416, 10197815, 10209533, 10426599, 10463474, 10524899, 10675146, 10725320, 10932901, and 10945834. Currently, multifocal diffractive intraocular lenses are commercially available for correcting presbyopia.

Multifocal diffractive contact lenses are still not commercially available for correcting presbyopia (see, Pérez-Prados, et al., "Soft Multifocal Simultaneous Image Contact Lenses: Review", Clin. Exp. Optom. 2017, 100: 107-127) probably due to some issues uniquely associated with contact lenses. For example, the standard lens materials have a refractive index of about 1.42 or less, i.e., about 0.04 higher than the refractive index of tear film. With such a small difference in refractive index, a higher diffraction grating height needs to be created on one of the anterior and posterior surfaces of a contact lens. But, contact lenses require smooth anterior and posterior surfaces for wearing comfort. Such a diffraction grating likely causes discomfort to a patient.

U.S. Pat. Appl. Pub. Nos. 2021/0191153 A1, 2021/0191154A1 and 2023/0004023A1 disclose contact lenses with an embedded diffractive optic insert therein for correction of presbyopia. There are challenges for mass production of such multifocal diffractive contact lenses. For example, because there are huge differences in mechanical properties and especially in water-swelling degree between insert material and bulk hydrogel material in which the insert is embedded, embedded silicone hydrogel contact lenses are susceptible to lens distortion or especially delamination during the post-molding processes, including

extraction, hydration and autoclave of the silicone hydrogel contact lenses with inserts embedded therein and during the handling and wearing of the embedded silicone hydrogel contact lens. It would be desirable to extract embedded silicone hydrogel contact lenses with water-based solution and would require a silicone hydrogel ("SiHy") lens-formulation to be substantially free of vinylic monomers which are substantially insoluble in water and/or an ophthalmically compatible solvent (e., 1,2-propylene glycol, polyethyleneglycol with a number average molecular weight (M_n) of about 400 Daltons or less. It would be desirable to produce embedded SiHy contact lenses that have inserts embedded therein and not susceptible to delamination according to a process free of use of ophthalmically-incompatible organic solvent in extraction step.

Therefore, there is still a need for a process for producing embedded SiHy contact lenses that have inserts embedded therein and not susceptible to delamination.

SUMMARY OF THE INVENTION

In some aspects, the invention provides a method for producing embedded SiHy contact lenses, the method of invention comprising the steps of: (1) obtaining a female mold half, a first male mold half and a second male mold half, wherein the female mold half has a first molding surface defining the anterior surface of a contact lens to be molded, wherein the first male mold half has a second molding surface defining the back surface of an insert to be molded, wherein the second male mold half has a third molding surface defining the posterior surface of the contact lens to be molded, wherein the first male mold half and the female mold half are configured to receive each other such that an insert-molding cavity is formed between the second molding surface and a central portion of the first molding surface when the female mold half is closed with the first male mold half, wherein the second male mold half and the female mold half are configured to receive each other such that a lens-molding cavity is formed between the first and third molding surfaces when the female mold half is closed with the second male mold half; (2) dispensing an amount of an insert-forming composition on the central portion of the first molding surface of the female mold half; (3) placing the first male mold half on top of the insert-forming composition in the female mold half and closing the first male mold half and the female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition; (5) separating the first molding assembly obtained in step (4) into the first male mold half and the female mold half with the molded insert that is adhered onto the central portion of the first molding surface; (6) dispensing a lens-forming composition in the female mold half with the molded insert adhered thereon in an amount sufficient for filling

the lens-molding cavity, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the polymerizable composition; (7) placing the second male mold half on top of the lens-forming composition in the female mold half and closing the second male mold half and the female mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity; (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material; (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves; (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half (preferably before the embedded SiHy contact lens precursor is contact with water or any liquid); and (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to obtain an embedded SiHy contact lens.

In another aspects, the invention provides a method for producing embedded SiHy contact lenses, the method of invention comprising the steps of: (1) obtaining a first female mold half, a male mold half and a second female mold half, wherein the first female mold half has a first molding surface defining the front surface of an insert to be molded, wherein the male mold half has a second molding surface defining the posterior surface of a contact lens to be molded and also the back surface of the insert to be molded, wherein the second female mold half has a third molding surface defining the anterior surface of the contact lens to be molded, wherein the first female mold half and the male mold half are configured to receive each other such that an insert-molding cavity is formed between the first molding surface and a central portion of the second molding surface when the first female mold half is closed with the male mold half, wherein the second female mold half and the male mold half are configured to receive each other such that a lens-molding cavity is formed between the second and third molding surfaces when the second female mold half is closed with the

male mold half; (2) dispensing an amount of an insert-forming composition in the first female mold half; (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the male mold half and the first female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition; (5) separating the first molding assembly obtained in step (4) into the first female mold half and the male mold half with the molded insert that is adhered onto the central portion of the second molding surface; (6) dispensing a lens-forming composition in the second female mold half in an amount sufficient for filling the lens-molding cavity, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{\text{OW}})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the polymerizable composition; (7) placing the male mold half with the molded insert that is adhered onto the central portion of the second molding surface on top of the lens-forming composition in the second female mold half and closing the second female mold half and the male mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity; (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material; (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the second female mold half and the male mold halves; (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half (preferably before the embedded SiHy contact lens precursor is contact with water or any liquid); and (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to obtain an embedded SiHy contact lens.

In further aspects, the invention provides an embedded SiHy contact lens, comprising a lens body that comprises an anterior surface, an opposite posterior surface, a

bulk hydrogel material having a first refractive index, and a circular insert embedded in the bulk hydrogel material, wherein the circular insert has a diameter of about 11.0 mm or less and is made of a crosslinked polymeric material having a second refractive index, wherein the circular insert has a front surface and an opposite back surface and is located in a central portion of the embedded SiHy contact lens and concentric with a central axis of the lens body, wherein one of the front and back surfaces of the circular insert merges with one of the anterior and posterior surface of the lens body while the other one of the front and back surfaces of the circular insert is buried within the bulk hydrogel material and designated as buried surface, wherein the buried surface of the circular insert comprises a diffractive structure, wherein the bulk SiHy material comprises at least 92% by weight of repeating units of (a) at least one N,N-dialkylacrylamido monomer which has a 1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{\text{OW}})$ of less than about 0.5, and (c) of at least one polysiloxane acrylic crosslinker, wherein the second refractive index is at least 0.03 higher than the first refractive index, wherein the crosslinked polymeric material comprising repeating units of at least one aryl vinylic monomer and at least one aryl vinylic crosslinker.

These and other aspects of the invention will become apparent from the following description of the presently preferred embodiments. The detailed description is merely illustrative of the invention and does not limit the scope of the invention, which is defined by the appended claims and equivalents thereof. As would be obvious to one skilled in the art, many variations and modifications of the invention may be effected without departing from the spirit and scope of the novel concepts of the disclosure.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 schematically illustrates an embedded SiHy contact lens according to a preferred embodiment of the invention.

Figure 2 schematically illustrates an embedded hydrogel contact lens according to a preferred embodiment of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Generally, the nomenclature used herein and the laboratory procedures are well known and commonly employed in the art. Conventional methods are used for these procedures, such as those provided in the art and various general references. Where a term is provided in the singular, the inventors also contemplate the plural of that term. The

nomenclature used herein and the laboratory procedures described below are those well-known and commonly employed in the art.

"About" as used herein in this application means that a number, which is referred to as "about", comprises the recited number plus or minus 1-10% of that recited number.

"Contact Lens" refers to a structure that can be placed on or within a wearer's eye. A contact lens can correct, improve, or alter a user's eyesight, but that need not be the case. A contact lens can be of any appropriate material known in the art or later developed, and can be a soft lens, a hard lens, or an embedded lens.

A "hydrogel contact lens" refers to a contact lens comprising a hydrogel bulk (core) material. A hydrogel bulk material can be a non-SiHy material or preferably a SiHy material.

A "hydrogel" or "hydrogel material" refers to a crosslinked polymeric material which has three-dimensional polymer networks (i.e., polymer matrix), is insoluble in water, but can hold at least 10% by weight of water in its polymer matrix when it is fully hydrated (or equilibrated).

A "silicone hydrogel" or "SiHy" interchangeably refers to a silicone-containing hydrogel obtained by copolymerization of a polymerizable composition comprising at least one silicone-containing monomer or at least one silicone-containing macromer or at least one crosslinkable silicone-containing prepolymer.

A siloxane, which often also described as a silicone, refers to a molecule having at least one moiety of -Si-O-Si- where each Si atom carries two organic groups as substituents. A polysiloxane refers to a molecule having at least one moiety of $\text{-Si-O-(Si-O)}_n\text{-Si-}$ in which each Si atom carries two organic groups as substituents and n is an integer of 2 or greater.

As used in this application, the term "non-silicone hydrogel" or "non-silicone hydrogel material" interchangeably refers to a hydrogel that is theoretically free of silicon.

An "embedded SiHy contact lens" refers a SiHy contact lens comprising at least one insert which is embedded within the bulk SiHy material of the embedded SiHy contact lens to an extent that at most one of the anterior or posterior surfaces of the insert can be exposed fully or partially. It is understood that the material of the insert is different from the bulk SiHy material of the embedded SiHy contact lens.

An "insert" refers to any 3-dimensional article which has a dimension of at least 5 microns but is smaller in dimension sufficient to be embedded in the bulk material of an embedded SiHy contact lens and which is made of a material (preferably a non-hydrogel material) that is different from the bulk SiHy material.

In accordance with the invention, a non-hydrogel material can be any material that can absorb less than 5% (preferably about 4% or less, more preferably about 3% or less, even more preferably about 2% or less) by weight of water when being fully hydrated.

“Hydrophilic,” as used herein, describes a material or portion thereof that will more readily associate with water than with lipids.

“Hydrophobic” in reference to an insert material or insert that has an equilibrium water content (i.e., water content in fully hydrated state) of less than 5% (preferably about 4% or less, more preferably about 3% or less, even more preferably about 2% or less).

The term “room temperature” refers to a temperature of about 22°C to about 26°C.

The term “soluble”, in reference to a compound or material in a solvent, means that the compound or material can be dissolved in the solvent to give a solution with a concentration of at least about 0.5% by weight at room temperature (i.e., from about 22°C to about 26°C).

The term “insoluble”, in reference to a compound or material in a solvent, means that the compound or material can be dissolved in the solvent to give a solution with a concentration of less than 0.01% by weight at room temperature (as defined above).

A “vinyl monomer” refers to a compound that has one sole ethylenically unsaturated group, is soluble in a solvent, and can be polymerized actinically or thermally.

As used in this application, the term “ethylenically unsaturated group” is employed herein in a broad sense and is intended to encompass any groups containing at least one $>C=CH_2$ group. Exemplary ethylenically unsaturated groups include without limitation (meth)acryloyl ($-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ and/or $-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-CH=CH_2$), allyl, vinyl, styrenyl, or other $C=CH_2$ containing groups.

An “acrylic monomer” refers to a vinyl monomer having one sole (meth)acryloyl group. Examples of acrylic monomers includes (meth)acryloxy [or(meth)acryloyloxy] monomers and (meth)acrylamido monomers.

An “(meth)acryloxy monomer” or “(meth)acryloyloxy monomer” refers to a vinyl monomer having one sole group of $-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-CH=CH_2$.

An “(meth)acrylamido monomer” refers to a vinyl monomer having one sole group of $-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-\overset{\text{CH}_3}{\text{C}}=CH_2$ or $-\overset{\text{O}}{\underset{\text{||}}{\text{C}}}-CH=CH_2$ in which R^0 is H or C_1 - C_4 alkyl.

The term “aryl vinyl monomer” refers to a vinyl monomer having at least one aromatic ring.

The term “(meth)acrylamide” refers to methacrylamide and/or acrylamide.

The term “(meth)acrylate” refers to methacrylate and/or acrylate.

An “N-vinyl amide monomer” refers to an amide compound having a vinyl group ($-CH=CH_2$) that is directly attached to the nitrogen atom of the amide group.

An “ene monomer” refers to a vinyl monomer having one sole ene group.

A “hydrophilic vinyl monomer”, a “hydrophilic acrylic monomer”, a “hydrophilic

(meth)acryloxy monomer", or a "hydrophilic (meth)acrylamido monomer", as used herein, respectively refers to a vinylic monomer, an acrylic monomer, a (meth)acryloxy monomer, or a (meth)acrylamido monomer), which typically yields a homopolymer that is water-soluble or can absorb at least 10 percent by weight of water.

A "hydrophobic vinylic monomer", a "hydrophobic acrylic monomer", a "hydrophobic (meth)acryloxy monomer", or a "hydrophobic (meth)acrylamido monomer", as used herein, respectively refers to a vinylic monomer, an acrylic monomer, a (meth)acryloxy monomer, or a (meth)acrylamido monomer), which typically yields a homopolymer that is insoluble in water and can absorb less than 10% by weight of water.

As used in this application, the term "vinylic crosslinker" refers to an organic compound having at least two ethylenically unsaturated groups. A "vinylic crosslinking agent" refers to a vinylic crosslinker having a molecular weight of 700 Daltons or less.

An "acrylic crosslinker" refers to a vinylic crosslinker having at least two (meth)acryloyl groups.

An "aryl vinylic crosslinker" refers to a vinylic crosslinker having at least one aromatic ring.

The term "acrylic repeating units" refers to repeating units of a polymeric material, each of which is derived from an acrylic monomer or crosslinker in a free-radical polymerization to form the polymeric material.

The term "terminal (meth)acryloyl group" refers to one (meth)acryloyl group at one of the two ends of the main chain (or backbone) of an organic compound as known to a person skilled in the art.

As used herein, "actinically" in reference to curing, crosslinking or polymerizing of a polymerizable composition, a prepolymer or a material means that the curing (e.g., crosslinked and/or polymerized) is performed by actinic irradiation, such as, for example, UV/visible irradiation, ionizing radiation (e.g. gamma ray or X-ray irradiation), microwave irradiation, and the like. Thermal curing or actinic curing methods are well-known to a person skilled in the art.

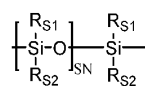
As used in this application, the term "polymer" means a material formed by polymerizing/crosslinking one or more monomers or macromers or prepolymers or combinations thereof.

A "macromer" or "prepolymer" refers to a compound or polymer that contains ethylenically unsaturated groups and has a number average molecular weight of greater than 700 Daltons.

As used in this application, the term "molecular weight" of a polymeric material (including monomeric or macromeric materials) refers to the number-average molecular weight unless otherwise specifically noted or unless testing conditions indicate otherwise. A

skilled person knows how to determine the molecular weight of a polymer according to known methods, e.g., GPC (gel permeation chromatography) with one or more of a refractive index detector, a low-angle laser light scattering detector, a multi-angle laser light scattering detector, a differential viscometry detector, a UV detector, and an infrared (IR) detector; MALDI-TOF MS (matrix-assisted laser desorption/ionization time-of-flight mass spectroscopy); ^1H NMR (Proton nuclear magnetic resonance) spectroscopy, etc.

A "polysiloxane segment" or "polydiorganosiloxane segment" interchangeably refers



to a polymer chain segment (i.e., a divalent radical) of $\left[\begin{array}{c} \text{R}_{\text{S}1} \\ | \\ \text{Si}-\text{O} \\ | \\ \text{R}_{\text{S}2} \end{array} \right]_{\text{SN}} \begin{array}{c} \text{R}_{\text{S}1} \\ | \\ \text{Si}- \\ | \\ \text{R}_{\text{S}2} \end{array}$ in which SN is an integer of 3 or larger and each of $\text{R}_{\text{S}1}$ and $\text{R}_{\text{S}2}$ independent of one another are selected from the group consisting of: C_1 - C_{10} alkyl; phenyl; C_1 - C_4 -alkyl-substituted phenyl; C_1 - C_4 -alkoxy-substituted phenyl; phenyl- C_1 - C_6 -alkyl; C_1 - C_{10} fluoroalkyl; C_1 - C_{10} fluoroether; aryl; aryl C_1 - C_{18} alkyl; $-\text{alk}-(\text{OC}_2\text{H}_4)_{\gamma 1}-\text{OR}^0$ (in which alk is C_1 - C_6 alkylene diradical, R^0 is H or C_1 - C_4 alkyl and $\gamma 1$ is an integer from 1 to 10); a C_2 - C_{40} organic radical having at least one functional group selected from the group consisting of hydroxyl group ($-\text{OH}$), carboxyl group ($-\text{COOH}$), amino group ($-\text{NR}_{\text{N}1}\text{R}_{\text{N}1}'$), amino linkages of $-\text{NR}_{\text{N}1}-$, amide linkages of $-\text{CONR}_{\text{N}1}-$, amide of $-\text{CONR}_{\text{N}1}\text{R}_{\text{N}1}'$, urethane linkages of $-\text{OCONH}-$, and C_1 - C_4 alkoxy group, or a linear hydrophilic polymer chain, in which $\text{R}_{\text{N}1}$ and $\text{R}_{\text{N}1}'$ independent of each other are hydrogen or a C_1 - C_{15} alkyl.

A "polysiloxane vinylic monomer" refers to a compound comprising at least one polysiloxane segment and one sole ethylenically-unsaturated group.

A "polydiorganosiloxane vinylic crosslinker" or polysiloxane vinylic crosslinker" interchangeably refers to a compound comprising at least one polysiloxane segment and at least two ethylenically-unsaturated groups. A "polysiloxane acrylic crosslinker" refers to a compound comprising at least one polysiloxane segment and at least two (meth)acryloyl groups

A "linear polydiorganosiloxane vinylic crosslinker" or "linear polysiloxane vinylic crosslinker" interchangeably refers to a compound comprising a main chain which includes at least one polysiloxane segment and is terminated with one ethylenically-unsaturated group at each of the two ends of the main chain. A "linear polysiloxane vinylic crosslinker" refers to a compound comprising a main chain which includes at least one polysiloxane segment and is terminated with one (meth)acryloyl group at each of the two ends of the main chain.

A "chain-extended polydiorganosiloxane vinylic crosslinker" or "chain-extended polysiloxane vinylic crosslinker" interchangeably refers to a compound comprising at least two ethylenically-unsaturated groups and at least two polysiloxane segments each pair of

which are linked by one divalent radical. A “chain-extended polysiloxane vinylic crosslinker” refers to a compound comprising at least two (meth)acryloyl groups and at least two polysiloxane segments each pair of which are linked by one divalent radical.

The term “fluid” as used herein indicates that a material is capable of flowing like a liquid.

As used in this application, the term “clear” in reference to a polymerizable composition means that the polymerizable composition is a transparent solution or liquid mixture (i.e., having a light transmissibility of 85% or greater in the range between 400 to 700 nm).

The term “monovalent radical” refers to an organic radical that is obtained by removing a hydrogen atom from an organic compound and that forms one bond with one other group in an organic compound. Examples include without limitation, alkyl (by removal of a hydrogen atom from an alkane), alkoxy (or alkoxyl) (by removal of one hydrogen atom from the hydroxyl group of an alkyl alcohol), thiyl (by removal of one hydrogen atom from the thiol group of an alkylthiol), cycloalkyl (by removal of a hydrogen atom from a cycloalkane), cycloheteroalkyl (by removal of a hydrogen atom from a cycloheteroalkane), aryl (by removal of a hydrogen atom from an aromatic ring of the aromatic hydrocarbon), heteroaryl (by removal of a hydrogen atom from any ring atom), amino (by removal of one hydrogen atom from an amine), etc.

The term “divalent radical” refers to an organic radical that is obtained by removing two hydrogen atoms from an organic compound and that forms two bonds with other two groups in an organic compound. For example, an alkylene divalent radical (i.e., alkylene) is obtained by removal of two hydrogen atoms from an alkane, a cycloalkylene divalent radical (i.e., cycloalkylene) is obtained by removal of two hydrogen atoms from the cyclic ring.

In this application, the term “substituted” in reference to an alkyl or an alkylene means that the alkyl or the alkylene comprises at least one substituent which replaces one hydrogen atom of the alkyl or the alkylene and is selected from the group consisting of hydroxyl (-OH), carboxyl (-COOH), -NH₂, sulfhydryl (-SH), C₁-C₄ alkyl, C₁-C₄ alkoxy, C₁-C₄ alkylthio (alkyl sulfide), C₁-C₄ acylamino, C₁-C₄ alkylamino, di-C₁-C₄ alkylamino, and combinations thereof.

A free radical initiator can be either a photoinitiator or a thermal initiator. A “photoinitiator” refers to a chemical that initiates free radical crosslinking/polymerizing reaction by the use of light. A “thermal initiator” refers to a chemical that initiates free radical crosslinking/polymerizing reaction by the use of heat energy.

The intrinsic “oxygen permeability”, Dk_i , of a material is the rate at which oxygen will pass through a material. Oxygen permeability is conventionally expressed in units of barrers, where “barrer” is defined as $[(\text{cm}^3 \text{ oxygen})(\text{mm}) / (\text{cm}^2)(\text{sec})(\text{mm Hg})] \times 10^{-10}$.

The “oxygen transmissibility”, Dk/t , of an insert or material is the rate at which oxygen will pass through a specific insert or material with an average thickness of t [in units of mm] over the area being measured. Oxygen transmissibility is conventionally expressed in units of barrers/mm, where “barrers/mm” is defined as $[(\text{cm}^3 \text{ oxygen})/(\text{cm}^2)(\text{sec})(\text{mm Hg})] \times 10^{-9}$.

The “ion permeability” through a lens correlates with the Ionoflux Diffusion Coefficient. The Ionoflux Diffusion Coefficient, D (in units of $[\text{mm}^2/\text{min}]$), is determined by applying Fick’s law as follows:

$$D = -n' / (A \times dc/dx)$$

where n' = rate of ion transport $[\text{mol}/\text{min}]$; A = area of lens exposed $[\text{mm}^2]$; dc = concentration difference $[\text{mol}/\text{L}]$; dx = thickness of lens $[\text{mm}]$.

The term “modulus” or “elastic modulus” in reference to a contact lens or a material means the tensile modulus or Young’s modulus which is a measure of the stiffness of a contact lens or a material. The modulus can be measured according to the procedures described in Example 1.

A “precursor” refers to an insert or contact lens which is obtained by cast-molding of a polymerizable composition in a mold and has not been subjected to extraction and/or hydration post-molding processes (i.e., having not been in contact with water or any organic solvent or any liquid after molding).

A “male mold half” or “base curve mold half” interchangeably refers to a mold half having a molding surface that is a substantially convex surface and that defines the posterior surface of a contact lens or an insert.

A “female mold half” or “front curve mold half” interchangeably refers to a mold half having a molding surface that is a substantially concave surface and that defines the anterior surface of a contact lens or an insert.

The term “anterior surface”, “front surface”, “front curve surface” or “FC surface” in reference to a contact lens or an insert, as used in this application, interchangeably means a surface of the contact lens or insert that faces away from the eye during wear. The anterior surface (FC surface) is convex.

The “posterior surface”, “back surface”, “base curve surface” or “BC surface” in reference to a contact lens or insert, as used in this application, interchangeably means a surface of the contact lens or insert that faces towards the eye during wear. The posterior surface (BC surface) is concave.

A “central axis” in reference to a contact lens, as used in this application, means an imaginary reference line passing through the geometrical centers of the anterior and posterior surfaces of a contact lens.

A “central axis” in reference to a mold half, as used in this application, means an imaginary reference line passing normally (i.e., normal to the molding surface at the

geometrical center) through the geometrical centers of the molding surface of the mold half.

The term “diameter” in reference to a contact lens or an insert, as used in this application, means the width of the contact lens or the insert from edge to edge.

A corona treatment (aka, so-called a “air plasma”) refers to a surface modification technique that uses a low temperature corona discharge plasma to impart changes in the properties of a surface. The corona plasma is generated by the application of high voltage to an electrode that has a sharp tip.

The term “vacuum UV” refers to ultraviolet radiation with wavelengths below 200 nm.

A “1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ ” refers to a value calculated based on the XlogP3-AA method (Cheng, et al., J. Chem. Inf. Model. 2007, 47(6): 2140-2148).

Figure 1 schematically illustrates a cross-sectional view of an embedded hydrogel contact lens according to an embodiment of the invention. An embedded hydrogel contact lens **100** comprises an anterior surface **110**, an opposite posterior surface **120**, and an insert **150** and has a diameter **105** sufficient large to cover the cornea of a human eye. The insert **150** is made of a polymeric material different from the polymeric material of the remaining part of the embedded hydrogel contact lens **100** and comprises a front surface **160** and an opposite back surface **170**. The insert **150** has a diameter **155** sufficient small so as to be located within the optical zone of the embedded hydrogel contact lens **100**. According to this preferred embodiment, the front surface **160** of the insert **150** substantially merges with the anterior surface **110** of the embedded hydrogel contact lens **100** (excluding any coating on the embedded hydrogel contact lens **100**).

Figure 2 schematically illustrates a cross-sectional view of an embedded hydrogel contact lens according to another embodiment of the invention. An embedded hydrogel contact lens **200** comprises an anterior surface **210**, an opposite posterior surface **220**, and an insert **250** and has a diameter **205** sufficient large to cover the cornea of a human eye. The insert **250** is made of a polymeric material different from the polymeric material of the remaining part of the embedded hydrogel contact lens **200** and comprises a front surface **260** and an opposite back surface **270**. The insert **250** has a diameter **255** sufficient small so as to be located within the optical zone of the embedded hydrogel contact lens **200**. According to this preferred embodiment, the back surface **270** of the insert **250** substantially merges with the posterior surface **220** of the embedded contact lens **200** (excluding any coating on the embedded hydrogel contact lens **200**).

Typically, a SiHy lens formulation (i.e., a polymerizable composition for forming SiHy contact lenses) comprises a siloxane vinylic monomer having a tris(trimethylsilyloxy)silyl or bis(trimethylsilyloxy)silyl group or a polysiloxane segment containing 3 to 15 consecutive dimethylsiloxane units. It is believed that with a bulk group, such a siloxane-containing vinylic monomer in a SiHy lens formulation can function as a compatibilizer of hydrophilic

polymerizable components with hydrophobic polymerizable components and/or as a component for eliminating optical defects (deformations) during manufacturing and handling.

It is observed that when a SiHy lens formulation comprising such a siloxane vinylic monomer is actinically cured (cured with a UV or visible light) to form an embedded SiHy contact lens having a structure schematically illustrated in Figure 1 or 2, resultant embedded SiHy contact lenses are free of delamination but are deformed (no round shape). However, it is also observed that when such a siloxane vinylic monomer is completely substituted with a hydrophilic acrylamido monomer (e.g., N,N-dimethylacrylamide), resultant embedded SiHy contact lenses are rounded (not deformed) but are susceptible to delamination as shown by bubbles observed under microscopy at interfaces between the insert and the bulk SiHy material within the embedded SiHy contact lens after being autoclaved in a packaging solution in a sealed package). Moreover, because of its insolubility in water, embedded SiHy contact lenses made from a lens formulation comprising such a siloxane-containing vinylic monomer cannot be extracted with water or a water-based extraction medium to remove unpolymerized siloxane-containing vinylic monomer.

The invention is partly based on the discovery that the above-described problems can be solved by replacing such a siloxane-containing vinylic monomer with a dialkyl (meth)acrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ around 1.0 (e.g., N,N-diethylacrylamide with $\text{Log}(P_{OW})=1.0$) in the SiHy lens formulation. Such a N,N-dialkylacrylamide has an adequate solubility in water and thereby SiHy lenses obtained from a SiHy lens formulation including such a monomer can be extracted with water, an ophthalmically compatible solvent, or mixtures thereof. Also, because it has sufficient hydrophobicity to be a compatibilizer for hydrophilic components (e.g., N,N-dimethylacrylamide) with hydrophobic components in a SiHy lens formulation. It further has a bulk group and may help in eliminating deformations (optical defects) of resultants lenses from a SiHy lens formulation containing such a monomer.

The present invention provides, in one aspect, a method for producing embedded SiHy contact lenses, comprising the steps of: (1) obtaining a female mold half, a first male mold half and a second male mold half, wherein the female mold half has a first molding surface defining the anterior surface of a contact lens to be molded, wherein the first male mold half has a second molding surface defining the back surface of an insert to be molded, wherein the second male mold half has a third molding surface defining the posterior surface of the contact lens to be molded, wherein the first male mold half and the female mold half are configured to receive each other such that an insert-molding cavity is formed between the second molding surface and a central portion of the first molding surface when the female mold half is closed with the first male mold half, wherein the second male mold half and the female mold half are configured to receive each other such that a lens-molding

cavity is formed between the first and third molding surfaces when the female mold half is closed with the second male mold half; (2) dispensing an amount of an insert-forming composition on the central portion of the first molding surface of the female mold half; (3) placing the first male mold half on top of the insert-forming composition in the female mold half and closing the first male mold half and the female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition; (5) separating the first molding assembly obtained in step (4) into the first male mold half and the female mold half with the molded insert that is adhered onto the central portion of the first molding surface; (6) dispensing a lens-forming composition in the female mold half with the molded insert adhered thereon in an amount sufficient for filling the lens-molding cavity of the female mold half, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% (preferably at least 92%, more preferably at least 94%, even more preferably at least 96%) by weight relative to total amount of all polymerizable components in the polymerizable composition; (7) placing the second male mold half on top of the lens-forming composition in the female mold half and closing the second male mold half and the female mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity; (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material; (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves; (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half (preferably before the embedded SiHy contact lens precursor is contact with water or any liquid); and (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to

obtain an embedded SiHy contact lens.

In a preferred embodiment, a method of the invention further comprises, before step (2), a step of treating a central circular area of the first molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter equal to or smaller than the diameter of the insert to be molded.

It is discovered that when the back surface of a molded insert comprises a diffractive structure, the molded insert would have a great tendency to stick (adhere) to the male mold half during the separation of the insert molding assembly. However, when the molding surface of the female mold has been treated with a corona plasma or a vacuum UV in a central circular area having a diameter equal to or less than the diameter of the insert, the molded insert can consistently adhere to the female mold half during the separation of the insert molding assembly.

In a preferred embodiment, the first male mold half having a molding surface defining back surface of the insert comprise an overflow groove which surrounds the molding surface and receives any excess insert-forming material when the molding assembly is closed. By having such an overflow groove, one can ensure that any flushes formed from the excess insert-forming material during molding of the insert can be stuck on the male mold half during the step of separating the molding assembly, thereby removing the flushes.

In another aspects, the invention provides a method for producing embedded SiHy contact lenses, the method of invention comprising the steps of: (1) obtaining a first female mold half, a male mold half and a second female mold half, wherein the first female mold half has a first molding surface defining the front surface of an insert to be molded, wherein the male mold half has a second molding surface defining the posterior surface of a contact lens to be molded and also the back surface of the insert to be molded, wherein the second female mold half has a third molding surface defining the anterior surface of the contact lens to be molded, wherein the first female mold half and the male mold half are configured to receive each other such that an insert-molding cavity is formed between the first molding surface and a central portion of the second molding surface when the first female mold half is closed with the male mold half, wherein the second female mold half and the male mold half are configured to receive each other such that a lens-molding cavity is formed between the second and third molding surfaces when the second female mold half is closed with the male mold half; (2) dispensing an amount of an insert-forming composition in the first female mold half; (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the male mold half and the first female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the

insert-forming composition; (5) separating the first molding assembly obtained in step (4) into the first female mold half and the male mold half with the molded insert that is adhered onto the central portion of the second molding surface; (6) dispensing a lens-forming composition in the second female mold half in an amount sufficient for filling the lens-molding cavity, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the polymerizable composition; (7) placing the male mold half with the molded insert that is adhered onto the central portion of the second molding surface on top of the lens-forming composition in the second female mold half and closing the second female mold half and the male mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity; (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material; (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the second female mold half and the male mold halves; (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half (preferably before the embedded SiHy contact lens precursor is contact with water or any liquid); and (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to obtain an embedded SiHy contact lens.

In a preferred embodiment, a method of the invention further comprises, before step (2), a step of treating a central circular area of the second molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter equal to or smaller than the diameter of the insert to be molded.

It is discovered that when the front surface of a molded insert comprises a diffractive structure, the molded insert would have a great tendency to stick (adhere) to the female mold half during the separation of the insert molding assembly. However, when the molding surface of the male mold has been treated with a corona plasma or a vacuum UV in a

central circular area having a diameter equal to or less than the diameter of the insert, the molded insert can consistently adhere to the male mold half during the separation of the insert molding assembly.

In a preferred embodiment, the first female mold half having a molding surface defining front surface of the insert comprise an overflow groove which surrounds the molding surface and receives any excess insert-forming material when the molding assembly is closed. By having such an overflow groove, one can ensure that any flushes formed from the excess insert-forming material during molding of the insert can be stuck on the first female mold half during the step of separating the molding assembly, thereby removing the flushes.

Mold halves for making contact lenses (or inserts) are well known to a person skilled in the art and, for example, are employed in cast molding. In general, a molding assembly comprises at least two mold halves, one male half and one female mold half. The male mold half has a first molding (or optical) surface which is in direct contact with a polymerizable composition for cast molding of a contact lens (or an insert) and defines the posterior (back) surface of a molded contact lens (or a molded insert); and the female mold half has a second molding (or optical) surface which is in direct contact with the polymerizable composition and defines the anterior (front) surface of the molded contact lens (or molded insert). The male and female mold halves are configured to receive each other such that a lens- or insert-forming cavity is formed between the first molding surface and the second molding surface.

Methods of manufacturing mold halves for cast-molding a contact lens or an insert are generally well known to those of ordinary skill in the art. The process of the present invention is not limited to any particular method of forming a mold half. In fact, any method of forming a mold half can be used in the present invention. The mold halves can be formed through various techniques, such as injection molding or lathing. Examples of suitable processes for forming the mold halves are disclosed in U.S. Pat. Nos. 4444711; 4460534; 5843346; and 5894002.

Virtually all materials known in the art for making mold halves can be used to make mold halves for making contact lenses or inserts. For example, polymeric materials, such as polyethylene, polypropylene, polystyrene, PMMA, Topas® COC grade 8007-S10 (clear amorphous copolymer of ethylene and norbornene, from Ticona GmbH of Frankfurt, Germany and Summit, New Jersey), or the like can be used.

A diffractive structure is essentially a transmission diffraction grating. As known to a person skilled in the art, a transmission diffraction grating is typically comprised of a plurality of repetitive ridges and/or grooves regularly or periodically spaced and arranged in concentric rings or zones - annular zones (i.e., echelettes) at a respective surface of a lens (i.e., an insert in this application). The periodic spacing or pitch of the ridges and/or

grooves substantially determines the points of destructive and constructive interference at the optical axis of the lens. The shape and height of the ridges and/or grooves control the amount of incident light that is provided at a point of constructive interference by diffraction. The points of constructive interference are generally called diffraction orders or focal points.

The diffractive power is related to the properties of these zones, for instance their number, shape, size and position. Currently used echelettes may typically be defined by a primary zone, a secondary zone between the primary zone and a primary zone of an adjacent echelette, and an echelette geometry. The echelette geometry includes inner and outer diameters and a shaped or sloped profile. Secondary zones may describe the situation where the theoretical primary zone is a discontinuous function, leading to discrete steps in the profile height. Secondary zones may be introduced to solve the manufacturing issue of making sharp corner in a surface, and/or to reduce possible light scatter from sharp corners. The overall profile may be characterized by an echelette height or step height between adjacent echelettes. The relative radial spacing of the echelettes largely determine the power(s) of the lens and the step height of the secondary zones largely determines the light distribution between the different add powers. Together, these echelettes define a diffractive profile, often saw-toothed or stepped, on one of the surfaces of the lens.

The diffractive profile (Z_{diff}) (or so-called sag profile) can be given by Equation 1

$$Z_{\text{diff}} = \frac{m \lambda \phi(x)}{R_{I2} - R_{I1}} x^2 \quad (1)$$

in which m is the diffraction order (typically 0 for the distance focus and 1 for the ADD order), λ is the design wavelength (typically 550nm), x is radial position (i.e., the radial distance from the center), and $\phi(x)$ is a phase function in the radial x direction.

The radial position x of the diffractive transitions is a function of the diffractive optical power to be added to the system or Add power and the wavelength:

$$Zone(i) = \sqrt{\frac{2i\lambda}{Add}} \quad (2)$$

And the height of the diffractive transition is given by:

$$Height(i) = \left| \frac{m\lambda}{R_{I2} - R_{I1}} \right| \quad (3)$$

It is understood that any phase function known to a person skilled in the art can be used in creating a desired diffractive profile. Exemplary phase functions can be a modulo 2π kinoform design which would function as a Fresnel lens, an apodized bifocal lens design similar to ReSTOR or a Quadrafocal design similar to PanOptix which would result in a trifocal lens.

The central area of the molding surface of the female mold half can be treated with a corona plasma and a vacuum UV according to any techniques known to a person skilled in the art. For example, the molding surface can be covered with a mask having a circular

opening which limits the area of the molding surface of the female mold half to be treated with a corona plasma or a vacuum UV.

In accordance with the invention, the central area to be treated on the molding surface of the female mold half has a diameter equal to or smaller than the diameter of the insert. In some preferred embodiment, the diameter of the central area to be treated is about 90% or smaller, preferably about 75% or smaller, more preferably about 60% or smaller, even more preferably about 45% or smaller of the diameter of the insert.

An insert-forming composition can be any polymerizable compositions, so long as the crosslinked polymeric materials resulted therefrom have a refractive index that is at least 0.05 higher than the refractive index of the bulk SiHy material.

In various preferred embodiments, the crosslinked polymeric material of the insert has a refractive index of at least 1.47, (preferably at least 1.49, more preferably at least 1.51, even more preferably at least 1.53).

In a preferred embodiment, the insert-forming composition is a polymerizable composition for forming a silicone elastomer. Any silicone elastomer formulations known to a person skilled in the art can be used in this invention.

In other various preferred embodiments, an insert-forming composition comprises at least one aryl vinylic monomer and/or at least one aryl vinylic crosslinker. Aryl vinylic monomers and aryl vinylic crosslinkers can provide resultant insert with a relatively high refractive index.

Examples of preferred aryl vinylic monomers include, but are not limited to: 2-ethylphenoxy acrylate; 2-ethylphenoxy methacrylate; phenyl acrylate; phenyl methacrylate; benzyl acrylate; benzyl methacrylate; 2-phenylethyl acrylate; 2-phenylethyl methacrylate; 3-phenylpropyl acrylate; 3-phenylpropyl methacrylate; 4-phenylbutyl acrylate; 4-phenylbutyl methacrylate; 4-methylphenyl acrylate; 4-methylphenyl methacrylate; 4-methylbenzyl acrylate; 4-methylbenzyl methacrylate; 2-(2-methylphenyl)ethyl acrylate; 2-(2-methylphenyl)ethyl methacrylate; 2-(3-methylphenyl)ethyl acrylate; 2-(3-methylphenyl)ethyl methacrylate; 2-(4-methylphenyl)ethyl acrylate; 2-(4-methylphenyl)ethyl methacrylate; 2-(4-propylphenyl)ethyl acrylate; 2-(4-propylphenyl)ethyl methacrylate; 2-(4-(1-methylethyl)phenyl)ethyl acrylate; 2-(4-(1-methylethyl)phenyl)ethyl methacrylate; 2-(4-methoxyphenyl)ethyl acrylate; 2-(4-methoxy-phenyl)ethyl methacrylate; 2-(4-cyclohexylphenyl)ethyl acrylate; 2-(4-cyclohexylphenyl)ethyl methacrylate; 2-(2-chlorophenyl)ethyl acrylate; 2-(2-chlorophenyl)ethyl methacrylate; 2-(3-chlorophenyl)ethyl acrylate; 2-(3-chlorophenyl)ethyl methacrylate; 2-(4-chlorophenyl)ethyl acrylate; 2-(4-chlorophenyl)ethyl methacrylate; 2-(4-bromophenyl)ethyl acrylate; 2-(4-bromophenyl)ethyl methacrylate; 2-(3-phenylphenyl)ethyl acrylate; 2-(3-phenylphenyl)ethyl methacrylate; 2-(4-phenylphenyl)ethyl acrylate; 2-(4-phenylphenyl)ethyl methacrylate; 2-(4-benzylphenyl)ethyl

acrylate; 2-(4-benzylphenyl)ethyl methacrylate; 2-(phenylthio)ethyl acrylate; 2-(phenylthio)ethyl methacrylate; 2-benzyloxyethyl acrylate; 3-benzyloxypropyl acrylate; 2-benzyloxyethyl methacrylate; 3-benzyloxypropyl methacrylate; 2-[2-(benzyloxy)ethoxy]ethyl acrylate; 2-[2-(benzyloxy)ethoxy]ethyl methacrylate; silicone-containing aryl vinylic monomers (e.g., p-vinylphenyltris(trimethylsiloxy)silane, m-vinylphenyltris(trimethylsiloxy)silane, o-vinylphenyltris(trimethylsiloxy)silane, p-styrylethyltris(trimethylsiloxy)silane, m-styrylethyl-tris(trimethylsiloxy)silane, o-styrylethyltris(trimethylsiloxy)silane); aryl-containing ene monomers; or combinations thereof. The above listed aryl acrylic monomers can be obtained from commercial sources or alternatively prepared according to methods known in the art.

Examples of aryl-containing ene monomers include without limitation vinyl naphthalenes, vinyl anthracenes, vinyl phenanthrenes, vinyl pyrenes, vinyl biphenyls, vinyl terphenyls, vinyl phenyl naphthalenes, vinyl phenyl anthracenes, vinyl phenyl phenanthrenes, vinyl phenyl pyrenes, vinyl phenyl terphenyls, phenoxy styrenes, phenyl carbonyl styrenes, phenyl carboxy styrenes, phenoxy carbonyl styrenes, allyl naphthalenes, allyl anthracenes, allyl phenanthrenes, allyl pyrenes, allyl biphenyls, allyl terphenyls, allyl phenyl naphthalenes, allyl phenyl anthracenes, allyl phenyl phenanthrenes, allyl phenyl pyrenes, allyl phenyl terphenyls, allyl phenoxy benzenes, allyl(phenylcarbonyl)benzenes, allyl phenoxy benzenes, allyl(phenyl carbonyl)benzenes, allyl(phenylcarboxy)benzenes, and allyl(phenoxy carbonyl)benzenes.

Examples of preferred aryl-containing ene monomers include without limitation styrene, 2,5-dimethylstyrene, 2-(trifluoromethyl)styrene, 2-chlorostyrene, 3,4-dimethoxystyrene, 3-chlorostyrene, 3-bromostyrene, 3-vinylanisole, 3-methylstyrene, 4-bromostyrene, 4-tert-butylstyrene, , 2,3,4,5,6-pentanfluorostyrene, 2,4-dimethylstyrene, 1-methoxy-4-vinylbenzene, 1-chloro-4-vinylbenzene, 1-methyl-4-vinylbenzene, 1-(chloromethyl)-4-vinylbenzene, 1-(bromomethyl)-4-vinylbenzene, 3-nitrostyrene, 1,2-vinyl phenyl benzene, 1,3-vinyl phenyl benzene, 1,4-vinyl phenyl benzene, 4-vinyl-1,1'-(4'-phenyl)biphenylene, 1-vinyl-4-(phenyloxy)-benzene, 1-vinyl-3-(phenyloxy)benzene, 1-vinyl-2-(phenyloxy)benzene, 1-vinyl-4-(phenyl-carbonyl)benzene, 1-vinyl-3-(phenylcarboxy)benzene, 1-vinyl-2-(phenoxycarbonyl)benzene, allyl phenyl ether, 2-biphenylallyl ether, allyl 4-phenoxyphenyl ether, allyl 2,4,6-tribromophenyl ether, allyl phenyl carbonate, 1-allyloxy-2-trifluoromethylbenzene, allylbenzene, 1-phenyl-2-prop-2-enylbenzene, 4-phenyl-1-butene, 4-phenyl-1-butene-4-ol, 1-(4-methylphenyl)-3-buten-1-ol, 1-(4-chlorophenyl)-3-buten-1-ol, 4-allyltoluene, 1-allyl-4-fluorobenzene, 1-allyl-2-methylbenzene, 1-allyl-3-methylbenzene, 1-allyl-3-methylbenzene, 2-allylanisole, 4-allylanisole, 1-allyl-4-(trifluoromethyl)benzene, allylpentafluorobenzene, 1-allyl-2-methoxybenzene, 4-allyl-1,2-dimethoxybenzene, 2-allylphenol, 2-allyl-6-methylphenol, 4-allyl-2-methoxyphenol, 2-

allyloxy-anisole, 4-allyl-2-methoxyphenyl acetate, 2-allyl-6-methoxyphenol, 1-allyl-2-bromobenzene, alpha-vinylbenzyl alcohol, 1-phenyl-3-butene-1-one, allylbenzyl ether, (3-allyloxy)propyl-benzene, allyl phenylethyl ether, 1-benzyloxy-4-pentene, (1-allyloxy)ethylbenzene, 1-phenylallyl ethyl ether, (2-methyl-2-(2-propenyloxy)propyl)benzene, ((5-hexenyloxy)methyl)benzene, 1-allyloxy-4-propoxybenzene, 1-phenoxy-4-(3-prop-2-enoxypropoxy)benzene, 6-(4'-Hydroxy-phenoxy)-1-Hexene, 4-but-3-enoxyphenol, 1-allyloxy-4-butoxybenzene, 1-allyloxy-4-ethoxy-benzene, 1-allyl-4-benzyloxybenzene, 1-allyl-4-(phenoxy)benzene, 1-allyl-3-(phenoxy)benzene, 1-allyl-2-(phenoxy)benzene, 1-allyl-4-(phenyl carbonyl)benzene, 1-allyl-3-(phenyl carboxy)-benzene, 1-allyl-2-(phenoxy-carbonyl)benzene, 1,2-allyl phenyl benzene, 1,3-allyl phenyl benzene, 1,4-allyl phenyl benzene, 4-vinyl-1,1'-(4'-phenyl)biphenylene, 1-allyl-4-(phenyloxy)-benzene, 1-allyl-3-(phenyloxy)benzene, 1-allyl-2-(phenyloxy)benzene, 1-allyl-4-(phenyl carbonyl)benzene, 1-allyl-3-(phenyl carboxy)benzene, and 1-allyl-2-(phenoxy-carbonyl)benzene, 1-vinyl naphthylene, 2-vinyl naphthylene, 1-allyl naphthalene, 2-allyl naphthalene, allyl-2-naphthyl ether, 2-(2-methylprop-2-enyl)naphthalene, 2-prop-2-enylnaphthalene, 4-(2-naphthyl)-1-butene, 1-(3-butenyl)naphthalene, 1-allyl naphthalene, 2-allyl naphthalene, 1-allyl-4-naphthyl naphthalene, 2-(allyloxy)-1-bromonaphthalene, 2-bromo-6-allyloxynaphthalene, 1,2-vinyl(1-naphthyl)benzene, 1,2-vinyl(2-naphthyl)benzene, 1,3-vinyl(1-naphthyl)benzene, 1,3-vinyl(2-naphthyl)benzene, 1,4-vinyl(1-naphthyl)benzene, 1,4-vinyl(2-naphthyl)benzene, 1-naphthyl-4-vinyl naphthalene, 1-allyl naphthalene, 2-allyl naphthalene, 1,2-allyl(1-naphthyl) benzene, 1,2-allyl(2-naphthyl)benzene, 1,3-allyl(1-naphthyl)benzene, 1,3-allyl(2-naphthyl)benzene, 1,4-allyl(1-naphthyl)benzene, 1,4-allyl(2-naphthyl)benzene, 1-allyl-4-naphthyl naphthalene, 1-vinyl anthracene, 2-vinyl anthracene, 9-vinyl anthracene, 1-allyl anthracene, 2-allyl anthracene, 9-allyl anthracene, 9-pent-4-enylantracene, 9-allyl-1,2,3,4-tetrachloroanthracene, 1-vinyl phenanthrene, 2-vinyl phenanthrene, 3-vinyl phenanthrene, 4-vinyl phenanthrene, 9-vinyl phenanthrene, 1-allyl phenanthrene, 2-allyl phenanthrene, 3-allyl phenanthrene, 4-allyl phenanthrene, 9-allyl phenanthrene, and combinations thereof.

Preferred aryl vinylic monomers are 2-phenylethyl acrylate; 3-phenylpropyl acrylate; 4-phenylbutyl acrylate; 5-phenylpentyl (meth)acrylate; 2-benzyloxyethyl (meth)acrylate; 3-benzyloxypropyl (meth)acrylate; 2-[2-(benzyloxy)ethoxy]ethyl (meth)acrylate; p-vinylphenyl-tris(trimethylsiloxy)silane; m-vinylphenyltris(trimethylsiloxy)silane; o-vinylphenyl-tris(trimethylsiloxy)silane; p-styrylethyltris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy) silane; o- styrylethyltris(trimethylsiloxy)silane; or combinations thereof. Most preferred are p-vinylphenyltris(trimethylsiloxy)silane; m-vinylphenyltris(trimethylsiloxy)silane; o-vinylphenyl-tris(trimethylsiloxy)silane; p-styrylethyltris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy) silane; o-styrylethyltris(trimethylsiloxy)silane; or combinations thereof.

Any aryl vinylic crosslinkers can be used. Examples of aryl vinylic crosslinkers include without limitation non-silicone aryl vinylic crosslinkers (e.g., divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, etc.), silicone-containing aryl vinylic crosslinkers.

Preferred silicone-containing aryl vinylic crosslinkers are aryl-containing polysiloxane vinylic crosslinkers each of which comprises: (1) a polydiorganosiloxane segment comprising dimethylsiloxane units and aryl-containing siloxane units each having at least one aryl-containing substituent having up to 45 carbon atoms; and (2) ethylenically-unsaturated groups (preferably (meth)acryloyl groups). In a preferred embodiment, the polydiorganosiloxane segment comprises at least 25% by mole of the aryl-containing siloxane units. The preferred aryl-containing polysiloxane vinylic crosslinkers can have a number average molecular weight of at least 1000 Daltons (preferably from 1500 Daltons to 100000 Daltons, more preferably from 2000 to 80000 Daltons, even more preferably from 2500 to 60000 Dalton).

Examples of such preferred aryl-containing polysiloxane vinylic crosslinkers include without limitation vinyl terminated polyphenylmethysiloxanes (e.g., PMV9925 from Gelest), vinylphenylmethyl terminated phenylmethyl-vinylphenylsiloxane copolymer (e.g., PVV-3522 from Gelest), vinyl terminated diphenylsiloxane-dimethylsiloxane copolymers (e.g., PDV-1625 from Gelest), (meth)acryloxyalkyl-terminated polyphenylmethysiloxanes, (meth)acryloxyalkyl-terminated phenylmethyl-vinylphenylsiloxane copolymers, (meth)acryloxyalkyl-terminated diphenylsiloxane-dimethylsiloxane copolymers, ethylenically-unsaturated group-terminated dimethylsiloxane-arylmethylsiloxane copolymers disclosed in U.S. Pat. Appl. Pub. No. 2022/00306810, or combinations thereof.

An insert-forming composition can further comprises one or more hydrophobic acrylic monomers free of aryl group (e.g., silicone-containing acrylic monomers, non-silicone hydrophobic acrylic monomers, vinyl alkanoates, vinyloxyalkanes, or combinations thereof), vinylic crosslinkers free of aryl group (e.g., acrylic crosslinking agents (crosslinkers) as described below, allyl methacrylate, allyl acrylate, triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof), at least one UV-absorbing vinylic monomer (any one of those described later in this application), at least one UV/HEVL-absorbing vinylic monomer (any one of those described later in this application), at least one photochromic vinylic monomer (any one of those described later in this application), or combinations thereof.

Examples of silicone-containing acrylic monomers free of aryl group can be any one of those described below in this application; examples of non-silicone hydrophobic acrylic monomers free of aryl group can be any one of those described below in this application.

Examples of acrylic crosslinkers free of aryl group include without limitation ethylene

glycol di-(meth)methacrylate; 1,3-propanediol di-(meth)acrylate; 2,3-propanediol diacrylate; 2,3-propanediol di-(meth)acrylate; 1,4-butanediol di-(meth)acrylate; 1,5-pentanediol di-(meth)acrylate; 1,6-hexanediol di-(meth)acrylate; diethylene glycol di-(meth)acrylate; triethylene glycol di-(meth)acrylate; tetraethylene glycol di-(meth)acrylate; glycerol 1,3-diglycerolate di-(meth)acrylate, ethylenebis[oxy(2-hydroxypropane-1,3-diyl)] di-(meth)acrylate, bis[2-(meth)acryloxyethyl] phosphate, trimethylolpropane di-(meth)acrylate, 3,4-bis[(meth)acryloyl]-tetrahydrofuran, di(meth)acrylamide, N,N-di(meth)acryloyl-N-methylamine, N,N-di(meth)acryloyl-N-ethylamine, N,N'-methylene bis((meth)acrylamide); N,N'-ethylene bis((meth)acrylamide); N,N'-hexamethylene bis(meth)acrylamide; NN,N'-dihydroxyethylene bis(meth)acrylamide, N,N'-propylene bis(meth)acrylamide, N,N'-2-hydroxypropylene bis(meth)acrylamide, N,N'-2,3-dihydroxybutylene bis(meth)acrylamide, 1,3-bis(meth)acrylamido-propane-2-yl dihydrogen phosphate, piperazine diacrylamide, pentaerythritol triacrylate, pentaerythritol trimethacrylate, trimethylolpropane triacrylate, trimethylolpropane trimethacrylate, tris(2-hydroxyethyl)-isocyanurate triacrylate, tris(2-hydroxyethyl)isocyanurate trimethacrylate, 1,3,5-triacryloxy-hexahydro-1,3,5-triazine, 1,3,5-trimethacryloxyhexahydro-1,3,5-triazine; pentaerythritol tetraacrylate, pentaerythritol tetramethacrylate, di(trimethylolpropane) tetraacrylate, di(trimethylolpropane) tetramethacrylate, or combinations thereof.

In a preferred embodiment, the polymerizable composition for forming hydrophobic insert comprises at least one acrylic crosslinking agent (any one of those described above).

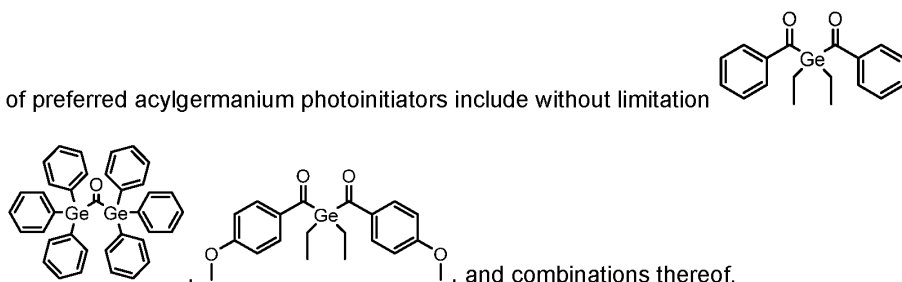
An insert-forming composition can be prepared by mixing all polymerizable materials as described above in the desired proportions, together with one or more polymerization initiators (thermal polymerization initiators or photoinitiators) in the presence or preferably in the absence of a non-reactive organic solvent (i.e., a non-reactive diluent) as described later in this application.

Any thermal polymerization initiators can be used in the invention. Suitable thermal polymerization initiators are known to the skilled artisan and comprise, for example peroxides, hydroperoxides, azo-bis(alkyl- or cycloalkylnitriles), persulfates, percarbonates, or mixtures thereof. Examples of preferred thermal polymerization initiators include without limitation benzoyl peroxide, t-butyl peroxide, t-amyl peroxybenzoate, 2,2-bis(tert-butylperoxy)butane, 1,1-bis(tert-butylperoxy)cyclohexane, 2,5-Bis(tert-butylperoxy)-2,5-dimethylhexane, 2,5-bis(tert-butylperoxy)-2,5-dimethyl-3-hexyne, bis(1-(tert-butylperoxy)-1-methylethyl)benzene, 1,1-bis(tert-butylperoxy)-3,3,5-trimethylcyclohexane, di-t-butyl-diperoxyphthalate, t-butyl hydroperoxide, t-butyl peracetate, t-butyl peroxybenzoate, t-butylperoxy isopropyl carbonate, acetyl peroxide, lauroyl peroxide, decanoyl peroxide, dicetyl peroxydicarbonate, di(4-t-butyl-cyclohexyl)peroxy dicarbonate (Perkadox 16S), di(2-ethylhexyl)peroxy dicarbonate, t-butylperoxy pivalate (Lupersol 11); t-butylperoxy-2-

ethylhexanoate (Trigonox 21-C50), 2,4-pentanedione peroxide, dicumyl peroxide, peracetic acid, potassium persulfate, sodium persulfate, ammonium persulfate, 2,2'-azobis(4-methoxy-2,4-dimethylvaleronitrile) (VAZO 33), 2,2'-Azobis[2-(2-imidazolin-2-yl)propane]dihydrochloride (VAZO 44), 2,2'-azobis(2-amidinopropane) dihydrochloride (VAZO 50), 2,2'-azobis(2,4-dimethylvaleronitrile) (VAZO 52), 2,2'-azobis(isobutyronitrile) (VAZO 64 or AIBN), 2,2'-azobis-2-methylbutyronitrile (VAZO 67), 1,1-azobis(1-cyclohexanecarbonitrile) (VAZO 88); 2,2'-azobis(2-cyclopropylpropionitrile), 2,2'-azobis(methylisobutyrate), 4,4'-Azobis(4-cyanovaleric acid), and combinations thereof. Preferably, the thermal initiator is 2,2'-azobis(isobutyronitrile) (AIBN or VAZO 64).

Suitable photoinitiators are benzoin methyl ether, diethoxyacetophenone, a benzoylphosphine oxide, 1-hydroxycyclohexyl phenyl ketone and Darocur and Irgacur types, preferably Darocur 1173® and Darocur 2959®, acylgermanium photoinitiators (e.g., those described in US7605190). Examples of preferred benzoylphosphine initiators include 2,4,6-trimethylbenzoyldiphenylphosphine oxide; bis-(2,6-dichlorobenzoyl)-4-N-propylphenylphosphine oxide; and bis-(2,6-dichlorobenzoyl)-4-N-butylphenylphosphine oxide. Examples

of preferred acylgermanium photoinitiators include without limitation



In accordance with the invention, a lens-forming composition comprises at least one at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1 (preferably from about 0.7 to about 1.7, more preferably from about 0.8 to about 1.5, even more preferably from about 0.9 to about 1.3).

Examples of preferred N,N-dialkylacrylamides include without limitation N-ethyl-N-methylacrylamide ($\text{Log}(P_{OW}) \sim 0.7$), N,N-diethylacrylamide ($\text{Log}(P_{OW}) \sim 1.0$), N-methyl-N-isopropylacrylamide ($\text{Log}(P_{OW}) \sim 1.1$), N-ethyl-N-isopropylacrylamide ($\text{Log}(P_{OW}) \sim 1.23$), N-methyl-N-propylacrylamide ($\text{Log}(P_{OW}) \sim 1.2$), N-ethyl-N-propylacrylamide ($\text{Log}(P_{OW}) \sim 1.38$), N,N-diisopropylacrylamide ($\text{Log}(P_{OW}) \sim 1.9$), N,N-dipropylacrylamide ($\text{Log}(P_{OW}) \sim 2.1$), and combinations thereof. Preferably, the at least one N,N-dialkylacrylamide comprises N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide, N-ethyl-N-isopropylacrylamide, or combinations thereof.

Any hydrophilic (meth)acrylamido monomers can be used in the invention, so long as they have a $\text{Log}(P_{OW})$ of less than 0.5 (preferably about 0.4 or less, more preferably about

0.3 or less). Examples of preferred hydrophilic (meth)acrylamido monomers include without limitation acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.7$), N-(2-hydroxyethyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.6$), N-(3-aminopropyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.5$), N-(2-aminoethyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.43$), N-(3-hydroxypropyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.2$), N-(2-hydroxypropyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim -0.1$), methacrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.1$), N-methylacrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.13$), N-(4-hydroxybutyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.16$), N-((2-dimethylamino)ethyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.2$), N,N-dimethylacrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.3$), N-(dimethylamino)methyl)acrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.3$), N-(2-hydroxypropyl)methacrylamide ($\text{Log}(P_{\text{OW}}) \sim 0.3$), and combinations thereof. Preferably, said at least one hydrophilic (meth)acrylamido monomer comprises N,N-dimethylacrylamide, acrylamide, N-(2-hydroxyethyl)acrylamide, N-(3-aminopropyl)acrylamide, N-(2-aminoethyl)acrylamide, N-(3-hydroxypropyl)acrylamide, N-(2-hydroxypropyl)acrylamide, or combinations thereof.

In accordance with the invention, any polysiloxane vinylic crosslinkers can be used in this invention. Examples of preferred polysiloxane vinylic crosslinkers include without limitation α,ω -(meth)acryloxy-terminated polydimethylsiloxanes of various molecular weight; α,ω -(meth)acrylamido-terminated polydimethylsiloxanes of various molecular weight; α,ω -vinyl carbonate-terminated polydimethylsiloxanes of various molecular weight; α,ω -vinyl carbamate-terminated polydimethylsiloxane of various molecular weight; bis-3-methacryloxy-2-hydroxypropyloxypropyl polydimethylsiloxane of various molecular weight; N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)- α,ω -bis-3-aminopropyl-polydimethylsiloxane of various molecular weight; the reaction products of glycidyl methacrylate with diamino-terminated polysiloxanes; the reaction products of glycidyl methacrylate with dihydroxyl-terminated polysiloxanes; the reaction products of an azlactone-containing vinylic monomer (any one of those described above) with di-hydroxyl-terminated polydimethylsiloxanes; the reaction products of isocyanatoethyl (meth)acrylate with di-hydroxyl-terminated polydimethylsiloxanes; the reaction products of isocyanatoethyl (meth)acrylate with diamino-terminated polydimethylsiloxanes; polysiloxane-containing macromer selected from the group consisting of Macromer A, Macromer B, Macromer C, and Macromer D described in US 5760100; polysiloxane vinylic crosslinkers disclosed in U.S. Pat. Nos. 4136250, 4153641, 4182822, 4189546, 4259467, 4260725, 4261875, 4343927, 4254248, 4355147, 4276402, 4327203, 4341889, 4486577, 4543398, 4605712, 4661575, 4684538, 4703097, 4833218, 4837289, 4954586, 4954587, 5010141, 5034461, 5070170, 5079319, 5039761, 5346946, 5358995, 5387632, 5416132, 5449729, 5451617, 5486579, 5962548, 5981675, 6039913, 6762264, 7423074, 8163206, 8480227, 8529057, 8835525, 8993651, 9187601, 10081697, 10301451, and 10465047.

One class of preferred polysiloxane vinylic crosslinkers are vinylic crosslinkers which

are prepared by: reacting glycidyl (meth)acrylate or (meth)acryloyl chloride with a di-amino-terminated polydimethylsiloxane or a di-hydroxyl-terminated polydimethylsiloxane; reacting isocyanatoethyl (meth)acrylate with di-hydroxyl-terminated polydimethylsiloxanes; reacting an amino-containing acrylic monomer with di-carboxyl-terminated polydimethylsiloxane in the presence of a coupling agent (a carbodiimide); reacting a carboxyl-containing acrylic monomer with di-amino-terminated polydimethylsiloxane in the presence of a coupling agent (a carbodiimide); or reacting a hydroxyl-containing acrylic monomer with a di-hydroxyl-terminated polydisiloxane in the presence of a diisocyanate or di-epoxy coupling agent.

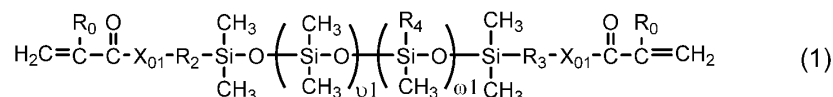
Examples of such preferred polysiloxane vinylic crosslinkers are α,ω -bis[3-(meth)acrylamidopropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-isopropyloxy-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutyloxy-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidoethoxy-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidoisopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidobutyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethyl-amino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-propylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acrylamidoethylamino-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamide-butylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-ethoxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-N-ethylaminopropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-aminopropyl]-polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxy-ethoxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, and combinations thereof.

Another class of preferred polysiloxane vinylic crosslinkers are chain-extended polysiloxane vinylic crosslinkers each of which comprises at least two polysiloxane segments

and can be prepared according to the procedures described in U.S. Pat. Nos. 5034461, 5416132, 5449729, 5760100, 7423074, 8529057, 8835525, 8993651, and 10301451 and in U.S. Pat. App. Pub. No. 2018-0100038 A1.

A further class of preferred polysiloxane vinylic crosslinkers are hydrophilized polysiloxane vinylic crosslinkers that each comprise at least about 1.50 (preferably at least about 2.0, more preferably at least about 2.5, even more preferably at least about 3.0) milliequivalent/gram ("meq/g") of hydrophilic moieties, which preferably are hydroxyl groups (–OH), carboxyl groups (–COOH), amino groups (–NHR_{N1} in which R_{N1} is H or C₁–C₂ alkyl), amide moieties (–CO–NR_{N1}R_{N2} in which R_{N1} is H or C₁–C₂ alkyl and R_{N2} is a covalent bond, H, or C₁–C₂ alkyl), N–C₁–C₃ acylamino groups, urethane moieties (–NH–CO–O–), urea moieties (–NH–CO–NH–), a polyethylene glycol chain of $\left(\text{C}_2\text{H}_4\text{O}\right)_n$ T₁ in which n is an integer of 2 to 20 and T₁ is H, methyl or acetyl or a phosphorylcholin group, or combinations thereof.

Examples of such preferred hydrophilized polysiloxane vinylic crosslinkers are those compounds of formula (1)



in which:

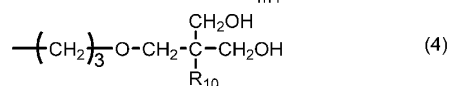
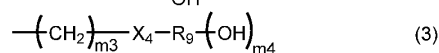
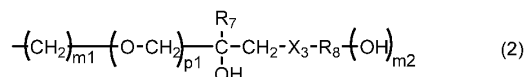
$\omega 1$ is an integer of from 30 to 500 and $\omega 1$ is an integer of from 1 to 75, provided that $\omega 1/\omega 1$ is from about 0.035 to about 0.15 (preferably from about 0.040 to about 0.12, even more preferably from about 0.045 to about 0.10);

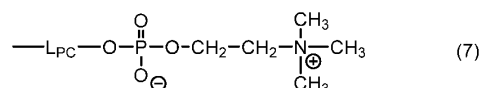
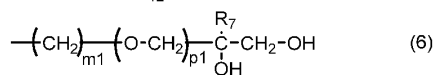
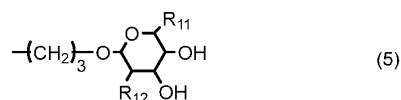
X₀₁ is O or NR_n in which R_n is hydrogen or C₁–C₁₀-alkyl;

R₀ is hydrogen or methyl;

R₂ and R₃ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical or a divalent radical of –R₅–O–R₆– in which R₅ and R₆ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical;

R₄ is a monovalent radical of any one of formula (2) to (7)





p1 is zero or 1; m1 is an integer of 2 to 4; m2 is an integer of 1 to 5; m3 is an integer of 3 to 6; m4 is an integer of 2 to 5;

R7 is hydrogen or methyl;

R8 is a C₂-C₆ hydrocarbon radical having (m2+1) valencies;

R9 is a C₂-C₆ hydrocarbon radical having (m4+1) valencies;

R10 is ethyl or hydroxymethyl;

R11 is methyl or hydromethyl;

R12 is hydroxyl or methoxy;

X₃ is a sulfur linkage of ---S--- or a tertiary amino linkage of $\text{---NR}_{13}\text{---}$ in which R₁₃ is C₁-C₁ alkyl, hydroxyethyl, hydroxypropyl, or 2,3-dihydroxypropyl;

X₄ is an amide linkage of $\text{---NR}_{14}\text{---}\overset{\text{O}}{\parallel}\text{C---}$ or $\text{---}\overset{\text{O}}{\parallel}\text{C---NR}_{14}\text{---}$ in which R₁₄ is hydrogen or C₁-C₁₀ alkyl;

L_{PC} is a divalent radical of $\text{---CH}_2\text{---CHR}_0\text{---R}_{15}\text{---}$, $\text{---C}_3\text{H}_6\text{---O---R}_{16}\text{---}$, $\text{---C}_3\text{H}_6\text{---}\overset{\text{O}}{\parallel}\text{C---C}_2\text{H}_4\text{---}\text{---}_{q1}$, $\text{---C}_3\text{H}_6\text{---}\overset{\text{O}}{\parallel}\text{C---C}_3\text{H}_6\text{---}\text{---}_{q1}$, $\text{---C}_2\text{H}_4\text{---}$ , or $\text{---C}_2\text{H}_4\text{---}$  $\text{---R}_{17}\text{---}$ in which q1 is an integer of 1 to 20, R₁₅ is a linear or branched C₁-C₁₀ alkylene divalent radical, R₁₆ is a linear or branched C₃-C₁₀ alkylene divalent radical, and R₁₇ is a direct bond or a linear or branched C₁-C₄ alkylene divalent radical.

Hydrophilized polysiloxane vinylic crosslinker of formula (1) can be prepared according to the procedures disclosed in U.S. Pat. No. 10081697 and U.S. Pat. Appl. Pub. No. 2022/0251302 A1.

In accordance with the invention, a lens-forming composition comprises at least photoinitiator (any one of those described above), preferably at least one benzoylphosphine initiator, more preferably at least one acylgermanium photoinitiator.

Any solvents can be used as non-reactive diluents in the invention. Examples of suitable solvents include acetone, methanol, cyclohexane, tetrahydrofuran, tripropylene glycol methyl ether, dipropylene glycol methyl ether, ethylene glycol n-butyl ether, ketones (e.g., acetone, methyl ethyl ketone, etc.), 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, ethyl acetate, butyl acetate, amyl acetate, methyl lactate, ethyl lactate, i-propyl lactate, methylene chloride, 2-butanol, 1-propanol, 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, 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, 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, 1-ethoxy-2-propanol, 1-methyl-2-propanol, t-amyl alcohol, isopropanol, 1-methyl-2-pyrrolidone, N,N-dimethylpropionamide, dimethyl formamide, dimethyl acetamide, dimethyl propionamide, N-methyl pyrrolidinone, and mixtures thereof. Preferably, the nonreactive diluents are ethylene glycol butyl ether, propylene glycol, 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, and mixtures thereof.

Preferably, a lens-forming composition comprises at least one UV-absorbing vinylic monomer, at least one UV/high-energy-violet-light ("HEVL") absorbing vinylic monomer, at least visibility tinting agent (a pigment and/or a polymerizable dye), at least one polymerizable photochromic dye, or combinations thereof.

Any suitable UV-absorbing vinylic monomers and UV/HEVL-absorbing vinylic monomers can be used in a polymerizable composition for preparing a preformed SiHy contact lens of the invention. Examples of preferred UV-absorbing and UV/HEVL-absorbing vinylic monomers include without limitation: 2-(2-hydroxy-5-vinylphenyl)-2H-benzotriazole, 2-(2-hydroxy-5-acryloyloxyphenyl)-2H-benzotriazole, 2-(2-hydroxy-3-methacrylamido methyl-5-tert octylphenyl) benzotriazole, 2-(2'-hydroxy-5'-methacrylamidophenyl)-5-chlorobenzotriazole, 2-(2'-hydroxy-5'-methacrylamidophenyl)-5-methoxybenzotriazole, 2-(2'-hydroxy-5'-methacryloxypropyl-3'-t-butyl-phenyl)-5-chlorobenzotriazole, 2-(2'-hydroxy-5'-methacryloxypropylphenyl) benzotriazole, 2-hydroxy-5-methoxy-3-(5-(trifluoromethyl)-2H-

benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-1), 2-hydroxy-5-methoxy-3-(5-methoxy-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-5), 3-(5-fluoro-2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-2), 3-(2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-3), 3-(5-chloro-2H-benzo[d][1,2,3]triazol-2-yl)-2-hydroxy-5-methoxybenzyl methacrylate (WL-4), 2-hydroxy-5-methoxy-3-(5-methyl-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-6), 2-hydroxy-5-methyl-3-(5-(trifluoromethyl)-2H-benzo[d][1,2,3]triazol-2-yl)benzyl methacrylate (WL-7), 4-allyl-2-(5-chloro-2H-benzo[d][1,2,3]triazol-2-yl)-6-methoxyphenol (WL-8), 2-{2'-Hydroxy-3'-*tert*-5'-(3''-(4''-vinylbenzyloxy)propoxy)phenyl}-5-methoxy-2H-benzotriazole, phenol, 2-(5-chloro-2H-benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-ethenyl- (UVAM), 2-[2'-hydroxy-5'-(2-methacryloxyethyl)phenyl]-2H-benzotriazole (2-Propenoic acid, 2-methyl-, 2-[3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl]ethyl ester, Norbloc), 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-2H-benzotriazole, 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-5-methoxy-2H-benzotriazole (UV13), 2-{2'-Hydroxy-3'-*tert*-butyl-5'-[3'-methacryloyloxypropoxy]phenyl}-5-chloro-2H-benzotriazole (UV28), 2-[2'-Hydroxy-3'-*tert*-butyl-5'-(3'-acryloyloxypropoxy)phenyl]-5-trifluoromethyl-2H-benzotriazole (UV23), 2-(2'-hydroxy-5-methacrylamidophenyl)-5-methoxybenzotriazole (UV6), 2-(3-allyl-2-hydroxy-5-methylphenyl)-2H-benzotriazole (UV9), 2-(2-Hydroxy-3-methallyl-5-methylphenyl)-2H-benzotriazole (UV12), 2-3'-*t*-butyl-2'-hydroxy-5'-(3''-dimethylvinylsilylpropoxy)-2'-hydroxyphenyl)-5-methoxybenzotriazole (UV15), 2-(2'-hydroxy-5'-methacryloylpropyl-3'-*tert*-butylphenyl)-5-methoxy-2H-benzotriazole (UV16), 2-(2'-hydroxy-5'-acryloylpropyl-3'-*tert*-butylphenyl)-5-methoxy-2H-benzotriazole (UV16A), 2-Methylacrylic acid 3-[3-*tert*-butyl-5-(5-chlorobenzotriazol-2-yl)-4-hydroxyphenyl]-propyl ester (16-100, CAS#96478-15-8), 2-(3-(*tert*-butyl)-4-hydroxy-5-(5-methoxy-2H-benzo[d][1,2,3]triazol-2-yl)phenoxy)ethyl methacrylate (16-102); Phenol, 2-(5-chloro-2H-benzotriazol-2-yl)-6-methoxy-4-(2-propen-1-yl) (CAS#1260141-20-5); 2-[2-Hydroxy-5-[3-(methacryloyloxy)propyl]-3-*tert*-butylphenyl]-5-chloro-2H-benzotriazole; Phenol, 2-(5-ethenyl-2H-benzotriazol-2-yl)-4-methyl-, homopolymer (9CI) (CAS#83063-87-0). In accordance with the invention, the polymerizable composition comprises about 0.1% to about 3.0%, preferably about 0.2% to about 2.5%, more preferably about 0.3% to about 2.0%, by weight of one or more UV-absorbing vinylic monomers, related to the amount of all polymerizable components in the polymerizable composition.

Examples of preferred photochromic vinylic monomers include polymerizable naphthopyrans, polymerizable benzopyrans, polymerizable indenonaphthopyrans, polymerizable phenanthropyrans, polymerizable spiro(benzindoline)-naphthopyrans, polymerizable spiro(indoline)benzopyrans, polymerizable spiro(indoline)-naphthopyrans, polymerizable spiro(indoline)quinopyrans, polymerizable spiro(indoline)-pyrans, polymerizable naphthoxazines, polymerizable spirobenzopyrans; polymerizable

spirobenzopyrans, polymerizable spirobenzothiopyrans, polymerizable naphthacenediones, polymerizable spirooxazines, polymerizable spiro(indoline)naphthoxazines, polymerizable spiro(indoline)-pyridobenzoxazines, polymerizable spiro(benzindoline)pyridobenzoxazines, polymerizable spiro(benzindoline)naphthoxazines, polymerizable spiro(indoline)-benzoxazines, polymerizable diarylethenes, and combinations thereof, as disclosed in U.S. Pat. Nos. 4929693, 5166345, 6017121, 7556750, 7584630, 7999989, 8158037, 8697770, 8741188, 9052438, 9097916, 9465234, 9904074, 10197707, 6019914, 6113814, 6149841, 6296785, and 6348604.

Any visibility tinting agents known to a person skilled in the art can be used in the invention. Examples of preferred pigments as tinting agent include without limitation copper phthalocyanine. Examples of preferred polymerizable dyes include without limitation Reactive Blue 246, Reactive Blue 247, etc.

In accordance with the invention, a lens-forming composition can further comprise at least one hydrophilic vinylic monomer (other than components (a) and (b)), at least one non-silicone vinylic crosslinker, at least one non-silicone hydrophobic vinylic monomer, or combinations thereof.

Hydrophilic vinylic monomers other than components (a) and (b) have been used in making hydrogel contact lenses, including SiHy contact lenses. Any hydrophilic vinylic monomers other than components (a) and (b) can be used in the invention. Examples of preferred hydrophilic vinylic monomers other than components (a) and (b) include without limitation hydroxyethyl (meth)acrylate, glycerol methacrylate (GMA), (meth)acrylic acid, N-vinylpyrrolidone, N-vinyl-N-methyl acetamide, 1-methyl-3-methylene-2-pyrrolidone, a phosphorylcholine-containing vinylic monomer (any one of those as described later in this application), N-2-hydroxyethyl vinyl carbamate, N-carboxyvinyl- β -alanine (VINAL), N-carboxyvinyl- α -alanine, and combinations thereof.

Examples of phosphorylcholine-containing vinylic monomers include without limitation (meth)acryloyloxyethyl phosphorylcholine, (meth)acryloyloxypropyl phosphorylcholine, 4-((meth)acryloyloxy)butyl-2'-(trimethylammonio)ethylphosphate, 2-[(meth)acryloylamino]ethyl-2'-(trimethylammonio)-ethylphosphate, 3-[(meth)acryloylamino]-propyl-2'-(trimethylammonio)-ethylphosphate, 4-[(meth)acryloylamino]butyl-2'-(trimethylammonio)ethylphosphate, 5-((meth)acryloyloxy)pentyl-2'-(trimethylammonio)ethyl phosphate, 6-((meth)acryloyloxy)hexyl-2'-(trimethylammonio)-ethylphosphate, 2-((meth)acryloyloxy)ethyl-2'-(triethylammonio)ethyl-phosphate, 2-((meth)acryloyloxy)ethyl-2'-(tripropylammonio)ethylphosphate, 2-((meth)acryloxy)-ethyl-2'-(tributylammonio)ethyl phosphate, 2-((meth)acryloyloxy)propyl-2'-(trimethylammonio)-ethylphosphate, 2-((meth)acryloyloxy)butyl-2'-(trimethylammonio)ethylphosphate, 2-((meth)acryloxy)pentyl-2'-(trimethylammonio)ethylphosphate, 2-((meth)acryloyloxy)hexyl-2'-(trimethylammonio)ethyl

phosphate, 2-(vinylloxy)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(allyloxy)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(vinylloxycarbonyl)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(allyloxycarbonyl)ethyl-2'-(trimethylammonio)ethyl-phosphate, 2-(vinylcarbonylamino)ethyl-2'-(trimethylammonio)ethylphosphate, 2-(allyloxycarbonylamino)-ethyl-2'-(trimethylammonio)ethyl phosphate, 2-(butenoyloxy)ethyl-2'-(trimethylammonio)-ethylphosphate, and combinations thereof.

Examples of preferred hydrophobic non-silicone vinylic monomers can be non-silicone hydrophobic acrylic monomers (methyl (meth)acrylate, ethyl (meth)acrylate, propyl (meth)acrylate, isopropyl (meth)acrylate, cyclohexyl (meth)acrylate, 2-ethylhexyl (meth)acrylate, isobornyl (meth)acrylate, (meth)acrylonitrile, etc.), fluorine-containing acrylic monomers (e.g., perfluorohexylethyl-thio-carbonyl-aminoethyl-methacrylate, perfluoro-substituted-C₂-C₁₂ alkyl (meth)acrylates (e.g., 2,2,2-trifluoroethyl (meth)acrylate, tetrafluoropropyl (meth)acrylate, hexafluoro-iso-propyl (meth)acrylate, hexafluorobutyl (meth)acrylate, heptafluorobutyl (meth)acrylate, octafluoropentyl (meth)acrylate, heptadecafluorodecyl (meth)acrylate, pentafluorophenyl (meth)acrylate, and combinations thereof), vinyl alkanoates (e.g., vinyl acetate, vinyl propionate, vinyl butyrate, vinyl valerate, etc.), vinyloxyalkanes (e.g., vinyl ethyl ether, propyl vinyl ether, n-butyl vinyl ether, isobutyl vinyl ether, cyclohexyl vinyl ether, t-butyl vinyl ether, etc.), styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof.

Examples of preferred non-silicone vinylic cross-linking agents include without limitation: acrylic crosslinkers (free of aryl group) as described above, allyl methacrylate, allyl acrylate, N-allyl-methacrylamide, N-allyl-acrylamide, tetraethyleneglycol divinyl ether, triethyleneglycol divinyl ether, diethyleneglycol divinyl ether, ethyleneglycol divinyl ether, triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof.

It is understood that if polymerizable components other than those recited are present in the lens-forming composition, their total amount is about 10% or less by weight (preferably about 8% or less by weight, more preferably about 6% or less by weight, even more preferably about 4% or less by weight) relative the total amount of all polymerizable component in the lens-forming composition.

In a preferred embodiment, the lens-forming composition comprises: from about 10 to about 35 weight part units of at least one N,N-dialkylacrylamide (preferably N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide) having a 1-octanol-water partition coefficient Log(P_{OW}) of from about 0.7 to about 2.1; from about 10 to about 35 weight part units of at least one hydrophilic (meth)acrylamido monomer (preferably N,N-dimethylacrylamide) having a Log(P_{OW}) of less than about 0.5; from about 30 to about 40 weight part units of at least one polysiloxane acrylic crosslinker; and from about 20 to about

30 weight part units of non-reactive diluent (preferably 1-propanol or ethylene glycol butyl ether).

A lens-forming composition or an insert-forming composition can be a solventless clear liquid prepared by mixing all polymerizable components (or materials) and other necessary component(or materials) or a solution prepared by dissolving all of the desirable components (or materials) in any suitable solvent, such as, a mixture of water and one or more organic solvents miscible with water, an organic solvent, or a mixture of one or more organic solvents, as known to a person skilled in the art. The term "solvent" refers to a chemical that cannot participate in free-radical polymerization reaction (any of those solvents as described later in this application).

A solventless SiHy lens formulation (SiHy lens-forming composition) typically comprises at least one blending vinylic monomer as a reactive solvent for dissolving all other polymerizable components of the solventless SiHy lens formulation. Examples of preferred blending vinylic monomers are described later in this application. Preferably, methyl methacrylate is used as a blending vinylic monomer in preparing a solventless SiHy lens formulation.

The insert-forming composition and the lens-forming composition can be introduced into the insert-molding cavity and the lens-molding cavity respectively according to any techniques known to a person skilled in the art.

When the first molding assembly is closed, any excess insert-forming composition is pressed into an overflow groove provided on the first male mold half having a second molding surface defining the back surface of an insert to be molded.

When the second molding assembly is closed, any excess lens-forming composition is pressed into an overflow groove provided on either one of the female mold half and the second male mold half. The overflow groove surrounds the molding surface defining one of the anterior and posterior surfaces of a contact lens to be molded.

The curing of the insert-forming composition within the insert-molding cavity of the closed first molding assembly can be carried out thermally (i.e., by heating) or actinically (i.e., by actinic radiation, e.g., UV radiation and/or visible radiation) to activate the polymerization initiators.

The actinic polymerization of the insert- or lens-forming composition in a molding assembly can be carried out by irradiating the closed molding assembly with the insert- or lens-forming composition therein with an UV or visible light, according to any techniques known to a person skilled in the art.

The thermal polymerization of the insert-forming composition in a molding assembly can be carried out conveniently in an oven at a temperature of from 25 to 120°C and preferably 40 to 100°C, as well known to a person skilled in the art. The reaction time may

vary within wide limits, but is conveniently, for example, from 1 to 24 hours or preferably from 2 to 12 hours. It is advantageous to previously degas the silicone-hydrogel-lens-forming composition and to carry out said copolymerization reaction under an inert atmosphere, e.g., under N₂ or Ar atmosphere.

The step of separating the first molding assembly can be carried out according to any techniques known to a person skilled in the art. It is understood that the molded insert is adhered onto the female mold. As an illustrative example, the first male mold half can be blasted with liquid nitrogen for several seconds and then pinched.

The step of separating the second molding assembly can be carried out according to any techniques known to a person skilled in the art. It is understood that the molded embedded SiHy contact lens can be adhered onto either one of the two mold halves of the second molding assembly.

The embedded SiHy contact lens precursor can be delensed (i.e., removed) from the lens-adhered mold half according to any techniques known to a person skilled in the art.

After the embedded SiHy contact lens precursor is delensed, it typically is extracted with an extraction medium as well known to a person skilled in the art. The extraction liquid medium is water, a buffered saline, 1,2-propylene glycol, a polyethyleneglycol having a number average molecular weight of about 400 Daltons or less, a C₁-C₆ alkylalcohol, or combinations thereof.

The extracted embedded SiHy contact lens can then be hydrated according to any method known to a person skilled in the art.

The hydrated embedded SiHy contact lens can further subject to further processes, such as, for example, surface treatment, packaging in lens packages with a packaging solution which is well known to a person skilled in the art; sterilization such as autoclave at from 118 to 124°C for at least about 30 minutes; and the like.

Lens packages (or containers) are well known to a person skilled in the art for autoclaving and storing a soft contact lens. Any lens packages can be used in the invention. Preferably, a lens package is a blister package which comprises a base and a cover, wherein the cover is detachably sealed to the base, wherein the base includes a cavity for receiving a sterile packaging solution and the contact lens.

Lenses are packaged in individual packages, sealed, and sterilized (e.g., by autoclave at about 120°C or higher for at least 30 minutes under pressure) prior to dispensing to users. A person skilled in the art will understand well how to seal and sterilize lens packages.

In further aspects, the invention provides an embedded SiHy contact lens, comprising a lens body that comprises an anterior surface, an opposite posterior surface, a bulk hydrogel material having a first refractive index, and a circular insert embedded in the

bulk hydrogel material, wherein the circular insert has a diameter of about 11.0 mm or less and is made of a crosslinked polymeric material having a second refractive index, wherein the circular insert has a front surface and an opposite back surface and is located in a central portion of the embedded SiHy contact lens and concentric with a central axis of the lens body, wherein one of the front and back surfaces of the circular insert merges with one of the anterior and posterior surface of the lens body while the other one of the front and back surfaces of the circular insert is buried within the bulk hydrogel material and designated as buried surface, wherein the buried surface of the circular insert comprises a diffractive structure, wherein the bulk SiHy material comprises at least 92% by weight of repeating units of (a) at least one N,N-dialkylacrylamido monomer which has a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, and (c) of at least one polysiloxane acrylic crosslinker, wherein the second refractive index is at least 0.03 higher than the first refractive index, wherein the crosslinked polymeric material comprising repeating units of at least one aryl vinylic monomer and at least one aryl vinylic crosslinker.

The various embodiments and preferred embodiments of inserts, crosslinked polymeric materials of an insert, bulk SiHy materials, N,N-dialkylacrylamido monomers, hydrophilic (meth)acrylamido monomers, and polysiloxane vinyl crosslinkers, and additional polymerizable components are described above and can be used in this aspect of the invention.

In accordance with the invention, the SiHy material of the embedded SiHy contact lens has an equilibrium water content (i.e., in fully hydrated state or when being fully hydrated) of from about 20% to about 70% (preferably from about 20% to about 65%, more preferably from about 25% to about 65%, even more preferably from about 30% to about 60%) by weight, an oxygen permeability of at least about 40 barrers (preferably at least about 60 barrers, more preferably at least about 80 barrers, more preferably at least about 100 barrers), and a modulus (i.e., Young's modulus) of about 1.5 MPa or less (preferably from about 0.2 MPa to about 1.2 MPa, more preferably from about 0.3 MPa to about 1.1 MPa, even more preferably from about 0.4 MPa to about 1.0 MPa).

Although various embodiments of the invention have been described using specific terms, devices, and methods, such description is for illustrative purposes only. The words used are words of description rather than of limitation. As would be obvious to one skilled in the art, many variations and modifications of the invention may be made by those skilled in the art without departing from the spirit and scope of the novel concepts of the disclosure. In addition, it should be understood that aspects of the various embodiments of the invention may be interchanged either in whole or in part or can be combined in any manner and/or

used together, as illustrated below:

1. A method for producing embedded silicone hydrogel contact lenses, comprising the steps of:
 - (1) obtaining a female mold half, a first male mold half and a second male mold half, wherein the female mold half has a first molding surface defining the anterior surface of a contact lens to be molded, wherein the first male mold half has a second molding surface defining the back surface of an insert to be molded, wherein the second male mold half has a third molding surface defining the posterior surface of the contact lens to be molded, wherein the first male mold half and the female mold half are configured to receive each other such that an insert-molding cavity is formed between the second molding surface and a central portion of the first molding surface when the female mold half is closed with the first male mold half, wherein the second male mold half and the female mold half are configured to receive each other such that a lens-molding cavity is formed between the first and third molding surfaces when the female mold half is closed with the second male mold half;
 - (2) dispensing an amount of an insert-forming composition on the central portion of the first molding surface of the female mold half;
 - (3) placing the first male mold half on top of the insert-forming composition in the female mold half and closing the first male mold half and the female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;
 - (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition;
 - (5) separating the first molding assembly obtained in step (4) into the first male mold half and the female mold half with the molded insert that is adhered onto the central portion of the first molding surface;
 - (6) dispensing a lens-forming composition in the female mold half with the molded insert adhered thereon in an amount sufficient for filling the lens-molding cavity of the female mold half, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{\text{OW}})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a

- polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the lens-forming composition;
- (7) placing the second male mold half on top of the lens-forming composition in the female mold half and closing the second male mold half and the female mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity;
 - (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded silicone hydrogel contact lens precursor that comprise a bulk silicone hydrogel material formed from the lens-forming composition and the insert embedded in the bulk silicone hydrogel material;
 - (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded silicone hydrogel contact lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves;
 - (10) removing the embedded silicone hydrogel contact lens precursor from the lens-adhered mold half; and
 - (11) subjecting the embedded silicone hydrogel contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof.
- 2. The method of embodiment 1, wherein the first male mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming material is pressed when the first molding assembly is closed securely, wherein any flushes formed from excess insert-forming material during step (5) can be stuck on the first male mold half during step of separating the first molding assembly, thereby removing the flushes.
 - 3. The method of embodiment 1 or 2, wherein the method further comprises, before step (2), a step of treating a central circular area of the first molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter equal to or smaller than the diameter of the insert to be molded.
 - 4. The method of embodiment 3, wherein the central circular area of the first molding surface is carried out by using a vacuum UV.
 - 5. The method of embodiment 3, wherein the central circular area of the first molding surface is carried out by using a corona plasma.
 - 6. A method for producing embedded SiHy contact lenses, comprising the steps of:

- (1) obtaining a first female mold half, a male mold half and a second female mold half, wherein the first female mold half has a first molding surface defining the front surface of an insert to be molded, wherein the male mold half has a second molding surface defining the posterior surface of a contact lens to be molded and also the back surface of the insert to be molded, wherein the second female mold half has a third molding surface defining the anterior surface of the contact lens to be molded, wherein the first female mold half and the male mold half are configured to receive each other such that an insert-molding cavity is formed between the first molding surface and a central portion of the second molding surface when the first female mold half is closed with the male mold half, wherein the second female mold half and the male mold half are configured to receive each other such that a lens-molding cavity is formed between the second and third molding surfaces when the second female mold half is closed with the male mold half;
- (2) dispensing an amount of an insert-forming composition in the first female mold half;
- (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the male mold half and the first female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;
- (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition;
- (5) separating the first molding assembly obtained in step (4) into the first female mold half and the male mold half with the molded insert that is adhered onto the central portion of the second molding surface;
- (6) dispensing a lens-forming composition in the second female mold half in an amount sufficient for filling the lens-molding cavity, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the polymerizable composition;

- (7) placing the male mold half with the molded insert that is adhered onto the central portion of the second molding surface on top of the lens-forming composition in the second female mold half and closing the second female mold half and the male mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity;
 - (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material;
 - (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the second female mold half and the male mold halves;
 - (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half; and
 - (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to obtain an embedded SiHy contact lens.
- 7. The method of embodiment 6, wherein the first female mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming material is pressed when the first molding assembly is closed securely, wherein any flushes formed from excess insert-forming material during step (5) can be stuck on the first female mold half during step of separating the first molding assembly, thereby removing the flushes.
 - 8. The method of embodiment 6 or 7, wherein the method further comprises, before step (2), a step of treating a central circular area of the second molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter equal to or smaller than the diameter of the insert to be molded.
 - 9. The method of embodiment 8, wherein the central circular area of the second molding surface is carried out by using a vacuum UV.
 - 10. The method of embodiment 8, wherein the central circular area of the second molding surface is carried out by using a corona plasma.
 - 11. The method of any one of embodiments 3 to 5 and 8 to 10, wherein the central circular area has a diameter that is about 90% or smaller of the diameter of the insert.
 - 12. The method of any one of embodiments 3 to 5 and 8 to 10, wherein the central circular area has a diameter that is about 75% or smaller of the diameter of the insert.

13. The method of any one of embodiments 3 to 5 and 8 to 10, wherein the central circular area has a diameter that is about 60% or smaller of the diameter of the insert.
14. The method of any one of embodiments 3 to 5 and 8 to 10, wherein the central circular area has a diameter that is about 45% or smaller of the diameter of the insert.
15. The method of any one of embodiments 1 to 14, wherein the step of (4) curing the insert-forming composition is carried out actinically by using UV and/or visible light.
16. The method of any one of embodiments 1 to 14, wherein the step of (4) curing the insert-forming composition is carried out thermally by heating the first molding assembly in an oven at one or more curing temperature selected from about 40°C to about 100°C.
17. The method of any one of embodiments 1 to 16, wherein the insert-forming composition comprises at least one aryl vinylic monomer and/or at least one aryl vinylic crosslinker.
18. The method of any one of embodiments 1 to 17, wherein the insert-forming composition comprises at least one silicone-containing aryl vinylic monomer and at least one silicone-containing aryl vinylic crosslinker.
19. The method of any one of embodiments 1 to 18, wherein the sum of the amounts of components (a) to (d) is at least 92% by weight relative to total amount of all polymerizable components in the lens-forming composition.
20. The method of any one of embodiments 1 to 18, wherein the sum of the amounts of components (a) to (d) is at least 94% by weight relative to total amount of all polymerizable components in the lens-forming composition.
21. The method of any one of embodiments 1 to 18, wherein the sum of the amounts of components (a) to (d) is at least 96% by weight relative to total amount of all polymerizable components in the lens-forming composition.
22. The method of any one of embodiments 1 to 21, wherein said at least one non-reactive diluent comprises ethylene glycol butyl ether, propylene glycol, 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, or mixtures thereof.
23. The method of any one of embodiments 1 to 22, wherein the embedded silicone hydrogel contact lens precursor is extracted with water, propylene glycol, a mixture of water and propylene glycol, or an aqueous solution.
24. The method of any one of embodiments 1 to 23, wherein the lens-forming composition comprises: (a) from about 10 to about 35 weight part units of at least one N,N-dialkylacrylamide (preferably N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide) having a 1-octanol-water partition coefficient $\text{Log}(P_{ow})$ of from about 0.7 to about 2.1; (b) from about 10 to about 35 weight part units of at least one hydrophilic (meth)acrylamido monomer (preferably N,N-dimethylacrylamide) having a $\text{Log}(P_{ow})$ of

less than about 0.5; and (c) from about 30 to about 40 weight part units of at least one polysiloxane acrylic crosslinker.

25. An embedded SiHy contact lens, comprising a lens body that comprises an anterior surface, an opposite posterior surface, a bulk hydrogel material having a first refractive index, and a circular insert embedded in the bulk hydrogel material, wherein the circular insert has a diameter of about 11.0 mm or less and is made of a crosslinked polymeric material having a second refractive index, wherein the circular insert has a front surface and an opposite back surface and is located in a central portion of the embedded SiHy contact lens and concentric with a central axis of the lens body, wherein one of the front and back surfaces of the circular insert merges with one of the anterior and posterior surface of the lens body while the other one of the front and back surfaces of the circular insert is buried within the bulk hydrogel material and designated as buried surface, wherein the buried surface of the circular insert comprises a diffractive structure, wherein the bulk SiHy material comprises at least 92% by weight of repeating units of (a) at least one N,N-dialkylacrylamido monomer which has a 1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{\text{OW}})$ of less than about 0.5, and (c) of at least one polysiloxane acrylic crosslinker, wherein the second refractive index is at least 0.03 higher than the first refractive index, wherein the crosslinked polymeric material comprising repeating units of at least one aryl vinylic monomer and at least one aryl vinylic crosslinker.
26. The embedded silicone hydrogel contact lens of embodiment 25, wherein the insert comprises a diffractive structure on the buried surface of the insert.
27. The embedded silicone hydrogel contact lens of embodiment 25 or 26, wherein the crosslinked polymeric material is a silicone elastomer.
28. The embedded silicone hydrogel contact lens of embodiment 25 or 26, wherein the crosslinked polymeric material comprises repeating units of at least one aryl vinylic monomer and/or at least one aryl vinylic crosslinker.
29. The embedded silicone hydrogel contact lens of embodiment 28, wherein said at least one aryl vinylic monomer comprises: 2-ethylphenoxy acrylate; 2-ethylphenoxy methacrylate; phenyl acrylate; phenyl methacrylate; benzyl acrylate; benzyl methacrylate; 2-phenylethyl acrylate; 2-phenylethyl methacrylate; 3-phenylpropyl acrylate; 3-phenylpropyl methacrylate; 4-phenylbutyl acrylate; 4-phenylbutyl methacrylate; 4-methylphenyl acrylate; 4-methylphenyl methacrylate; 4-methylbenzyl acrylate; 4-methylbenzyl methacrylate; 2-(2-methylphenyl)ethyl acrylate; 2-(2-methylphenyl)ethyl methacrylate; 2-(3-methylphenyl)-ethyl acrylate; 2-(3-methylphenyl)ethyl methacrylate; 2-(4-methylphenyl)ethyl acrylate; 2-(4-

methylphenyl)ethyl methacrylate; 2-(4-propylphenyl)ethyl acrylate; 2-(4-propylphenyl)-ethyl methacrylate; 2-(4-(1-methylethyl)phenyl)ethyl acrylate; 2-(4-(1-methylethyl)phenyl)-ethyl methacrylate; 2-(4-methoxyphenyl)ethyl acrylate; 2-(4-methoxyphenyl)ethyl methacrylate; 2-(4-cyclohexylphenyl)ethyl acrylate; 2-(4-cyclohexylphenyl)ethyl methacrylate; 2-(2-chlorophenyl)ethyl acrylate; 2-(2-chlorophenyl)ethyl methacrylate; 2-(3-chlorophenyl)ethyl acrylate; 2-(3-chlorophenyl)ethyl methacrylate; 2-(4-chlorophenyl)ethyl acrylate; 2-(4-chlorophenyl)ethyl methacrylate; 2-(4-bromophenyl)ethyl acrylate; 2-(4-bromophenyl)ethyl methacrylate; 2-(3-phenylphenyl)ethyl acrylate; 2-(3-phenylphenyl)ethyl methacrylate; 2-(4-phenylphenyl)ethyl acrylate; 2-(4-phenylphenyl)ethyl methacrylate; 2-(4-benzylphenyl)ethyl acrylate; 2-(4-benzylphenyl)ethyl methacrylate; 2-(phenylthio)ethyl acrylate; 2-(phenylthio)ethyl methacrylate; 2-benzyloxyethyl acrylate; 3-benzyloxypropyl acrylate; 2-benzyloxyethyl methacrylate; 3-benzyloxypropyl methacrylate; 2-[2-(benzyloxy)ethoxy]ethyl acrylate; 2-[2-(benzyloxy)ethoxy]ethyl methacrylate; one or more silicone-containing aryl vinylic monomers; one or more aryl-containing ene monomers; or combinations thereof.

30. The embedded silicone hydrogel contact lens of embodiment 29, wherein said one or more aryl-containing ene monomer comprises: styrene, 2,5-dimethylstyrene, 2-(trifluoromethyl)-styrene, 2-chlorostyrene, 3,4-dimethoxystyrene, 3-chlorostyrene, 3-bromostyrene, 3-vinylanisole, 3-methylstyrene, 4-bromostyrene, 4-tert-butylstyrene, , 2,3,4,5,6-pentanfluorostyrene, 2,4-dimethylstyrene, 1-methoxy-4-vinylbenzene, 1-chloro-4-vinylbenzene, 1-methyl-4-vinylbenzene, 1-(chloromethyl)-4-vinylbenzene, 1-(bromomethyl)-4-vinylbenzene, 3-nitrostyrene, 1,2-vinyl phenyl benzene, 1,3-vinyl phenyl benzene, 1,4-vinyl phenyl benzene, 4-vinyl-1,1'-(4'-phenyl)biphenylene, 1-vinyl-4-(phenyloxy)benzene, 1-vinyl-3-(phenyloxy)benzene, 1-vinyl-2-(phenyloxy)benzene, 1-vinyl-4-(phenyl carbonyl)benzene, 1-vinyl-3-(phenylcarboxy)benzene, 1-vinyl-2-(phenoxycarbonyl)benzene, allyl phenyl ether, 2-biphenylallyl ether, allyl 4-phenoxyphenyl ether, allyl 2,4,6-tribromophenyl ether, allyl phenyl carbonate, 1-allyloxy-2-trifluoromethylbenzene, allylbenzene, 1-phenyl-2-prop-2-enylbenzene, 4-phenyl-1-butene, 4-phenyl-1-butene-4-ol, 1-(4-methylphenyl)-3-buten-1-ol, 1-(4-chlorophenyl)-3-buten-1-ol, 4-allyltoluene, 1-allyl-4-fluorobenzene, 1-allyl-2-methylbenzene, 1-allyl-3-methylbenzene, 1-allyl-3-methylbenzene, 2-allylanisole, 4-allylanisole, 1-allyl-4-(trifluoromethyl)benzene, allylpentafluorobenzene, 1-allyl-2-methoxybenzene, 4-allyl-1,2-dimethoxybenzene, 2-allylphenol, 2-allyl-6-methylphenol, 4-allyl-2-methoxyphenol, 2-allyloxyanisole, 4-allyl-2-methoxyphenyl acetate, 2-allyl-6-methoxyphenol, 1-allyl-2-bromobenzene, alpha-vinylbenzyl alcohol, 1-phenyl-3-butene-1-one, allylbenzyl ether, (3-allyloxy)propyl-benzene, allyl phenylethyl ether, 1-

benzyloxy-4-pentene, (1-allyloxy)ethyl)benzene, 1-phenylallyl ethyl ether, (2-methyl-2-(2-propenyloxy)propyl)benzene, ((5-hexenyloxy)-methyl)benzene, 1-allyloxy-4-propoxybenzene, 1-phenoxy-4-(3-prop-2-enoxypropoxy)-benzene, 6-(4'-Hydroxyphenoxy)-1-Hexene, 4-but-3-enoxyphenol, 1-allyloxy-4-butoxybenzene, 1-allyloxy-4-ethoxybenzene, 1-allyl-4-benzyloxybenzene, 1-allyl-4-(phenoxy)benzene, 1-allyl-3-(phenoxy)benzene, 1-allyl-2-(phenoxy)benzene, 1-allyl-4-(phenyl carbonyl)benzene, 1-allyl-3-(phenyl carboxy)benzene, 1-allyl-2-(phenoxycarbonyl)-benzene, 1,2-allyl phenyl benzene, 1,3-allyl phenyl benzene, 1,4-allyl phenyl benzene, 4-vinyl-1,1'-(4'-phenyl)biphenylene, 1-allyl-4-(phenyloxy)benzene, 1-allyl-3-(phenyloxy)-benzene, 1-allyl-2-(phenyloxy)benzene, 1-allyl-4-(phenyl carbonyl)benzene, 1-allyl-3-(phenyl carboxy)benzene, and 1-allyl-2-(phenoxycarbonyl)benzene, 1-vinyl naphthylene, 2-vinyl naphthylene, 1-allyl naphthalene, 2-allyl naphthalene, allyl-2-naphthyl ether, 2-(2-methylprop-2-enyl)naphthalene, 2-prop-2-enylnaphthalene, 4-(2-naphthyl)-1-butene, 1-(3-butenyl)naphthalene, 1-allyl naphthalene, 2-allyl naphthalene, 1-allyl-4-naphthyl naphthalene, 2-(allyloxy)-1-bromonaphthalene, 2-bromo-6-allyloxynaphthalene, 1,2-vinyl(1-naphthyl)benzene, 1,2-vinyl(2-naphthyl)benzene, 1,3-vinyl(1-naphthyl)benzene, 1,3-vinyl(2-naphthyl)benzene, 1,4-vinyl(1-naphthyl)benzene, 1,4-vinyl(2-naphthyl)benzene, 1-naphthyl-4-vinyl naphthalene, 1-allyl naphthalene, 2-allyl naphthalene, 1,2-allyl(1-naphthyl) benzene, 1,2-allyl(2-naphthyl)benzene, 1,3-allyl(1-naphthyl)benzene, 1,3-allyl(2-naphthyl)benzene, 1,4-allyl(1-naphthyl)benzene, 1,4-allyl(2-naphthyl)benzene, 1-allyl-4-naphthyl naphthalene, 1-vinyl anthracene, 2-vinyl anthracene, 9-vinyl anthracene, 1-allyl anthracene, 2-allyl anthracene, 9-allyl anthracene, 9-pent-4-enylantracene, 9-allyl-1,2,3,4-tetrachloroanthracene, 1-vinyl phenanthrene, 2-vinyl phenanthrene, 3-vinyl phenanthrene, 4-vinyl phenanthrene, 9-vinyl phenanthrene, 1-allyl phenanthrene, 2-allyl phenanthrene, 3-allyl phenanthrene, 4-allyl phenanthrene, 9-allyl phenanthrene, or combinations thereof.

31. The embedded silicone hydrogel contact lens of embodiment 28 or 29, wherein said one or more silicone-containing aryl vinylic monomer comprises: p-vinylphenyl-tris(trimethylsiloxy)silane; m-vinylphenyltris(trimethylsiloxy)silane; o-vinylphenyl-tris(trimethylsiloxy)silane; p-styrylethyltris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy)silane; o- styrylethyltris(trimethylsiloxy)silane; or combinations thereof.
32. The embedded hydrogel contact lens of embodiment 28, wherein said at least one aryl vinylic monomer comprises 2-phenylethyl acrylate; 3-phenylpropyl acrylate; 4-phenylbutyl acrylate; 5-phenylpentyl (meth)acrylate; 2-benzyloxyethyl (meth)acrylate; 3-benzyloxy-propyl (meth)acrylate; 2-[2-(benzyloxy)ethoxy]ethyl (meth)acrylate; p-vinylphenyl-tris(trimethylsiloxy)silane; m-vinylphenyltris(trimethylsiloxy)silane; o-

- vinylphenyl-tris(trimethylsiloxy)silane; p-styrylethyltris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy)silane; o-styrylethyltris(trimethylsiloxy)silane; or combinations thereof.
33. The embedded hydrogel contact lens of embodiment 28, wherein said at least one aryl vinylic monomer comprises p-vinylphenyltris(trimethylsiloxy)silane; m-vinylphenyl-tris(trimethylsiloxy)silane; o-vinylphenyltris(trimethylsiloxy)silane; p-styrylethyl-tris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy)silane; o-styrylethyltris(trimethylsiloxy)silane; or combinations thereof.
34. The embedded hydrogel contact lens of any one of embodiments 28 to 33, wherein said at least one aryl vinylic crosslinker comprises divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, or combinations thereof.
35. The embedded hydrogel contact lens of any one of embodiments 28 to 33, wherein said at least one aryl vinylic crosslinker comprises a silicone-containing aryl vinylic crosslinker.
36. The embedded hydrogel contact lens of any one of embodiments 28 to 33, wherein the crosslinked polymeric material comprises repeating units of at least one silicone-containing aryl vinylic monomer and at least one silicone-containing aryl vinylic crosslinker.
37. The embedded hydrogel contact lens of embodiment 35 or 36, wherein said at least one silicone-containing aryl vinylic crosslinker comprises at least one aryl-containing polysiloxane vinylic crosslinker that comprises: (1) a polydiorganosiloxane segment comprising dimethylsiloxane units and aryl-containing siloxane units each having at least one aryl-containing substituent having up to 45 carbon atoms; and (2) ethylenically-unsaturated groups (preferably (meth)acryloyl groups).
38. The embedded hydrogel contact lens of embodiment 37, wherein the polydiorganosiloxane segment comprises at least 25% by mole of the aryl-containing siloxane units.
39. The embedded hydrogel contact lens of embodiment 37 or 38, wherein said at least one aryl-containing polysiloxane vinylic crosslinker has a number average molecular weight of at least 1000 Daltons (preferably from 1500 Daltons to 100000 Daltons, more preferably from 2000 to 80000 Daltons, even more preferably from 2500 to 60000 Dalton).
40. The embedded hydrogel contact lens of any one of embodiments 37 to 39, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises a vinyl terminated polyphenylmethysiloxane, a vinylphenylmethyl terminated phenylmethyl-vinylphenyl-siloxane copolymer, a vinyl terminated diphenylsiloxane-dimethylsiloxane

copolymer, a (meth)acryloxyalkyl-terminated polyphenylmethysiloxane, a (meth)acryloxyalkyl-terminated phenylmethyl-vinylphenylsiloxane copolymer, a (meth)acryloxyalkyl-terminated diphenylsiloxane-dimethylsiloxane copolymer, an ethylenically-unsaturated group-terminated dimethylsiloxane-arylmethylsiloxane copolymer, or combinations thereof.

41. The embedded hydrogel contact lens of any one of embodiments 37 to 40, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises at least 30% by mole of siloxane units each having at least one phenyl substituent.
42. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises at least 60% by mole of siloxane units each having at least one phenyl substituent.
43. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises at least 90% by mole of siloxane units each having at least one phenyl substituent.
44. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises three or more vinylphenylsiloxane units each having at least one phenyl substituent and one vinyl substituent.
45. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises three or more phenylmethysiloxane units.
46. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one aryl-containing polysiloxane vinylic crosslinker comprises three or more diphenylsiloxane units.
47. The embedded hydrogel contact lens of any one of embodiments 37 to 41, wherein said at least one silicone-containing aryl vinylic monomer comprises p-vinylphenyltris(trimethylsiloxy)-silane; m-vinylphenyltris(trimethylsiloxy)silane; o-vinylphenyltris(trimethylsiloxy)silane; p-styrylethyltris(trimethylsiloxy)silane; m-styrylethyl-tris(trimethylsiloxy)silane; o- styrylethyltris(trimethylsiloxy)silane; or combinations thereof.
48. The embedded hydrogel contact lens of any one of embodiments 25 to 47, wherein the bulk silicone hydrogel material comprises at least 94% by weight of the sum of the repeating units of (a) said at least one N,N-dialkylacrylamido monomer, (b) said at least one hydrophilic (meth)acrylamido monomer, and (c) of said at least one polysiloxane acrylic crosslinker.
49. The embedded hydrogel contact lens of any one of embodiments 25 to 47, wherein the bulk silicone hydrogel material comprises at least 96% (or at least 97%) by weight of

the sum of the repeating units of (a) said at least one N,N-dialkylacrylamido monomer, (b) said at least one hydrophilic (meth)acrylamido monomer, and (c) of said at least one polysiloxane acrylic crosslinker.

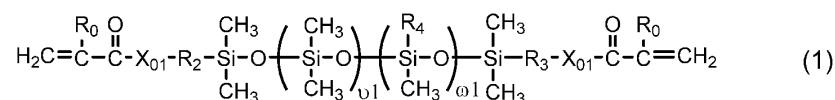
50. The method of any one of embodiments 1 to 24 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 49, wherein said at least one N,N-dialkylacrylamido monomer comprises N-ethyl-N-methylacrylamide, N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide, N-ethyl-N-isopropylacrylamide, N-methyl-N-propylacrylamide, N-ethyl-N-propylacrylamide, N,N-diisopropylacrylamide, N,N-dipropylacrylamide, or combinations thereof.
51. The method of any one of embodiments 1 to 24 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 49, wherein said at least one N,N-dialkylacrylamido monomer comprises N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide, N-ethyl-N-isopropylacrylamide, or combinations thereof.
52. The method of any one of embodiments 1 to 24, 50 and 51 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 51, wherein said at least one hydrophilic (meth)acrylamide monomer comprises acrylamide, N-(2-hydroxyethyl)acrylamide, N-(3-aminopropyl)acrylamide, N-(2-aminoethyl)acrylamide, N-(3-hydroxypropyl)acrylamide, N-(2-hydroxypropyl)acrylamide, methacrylamide, N-methylacrylamide, N-(4-hydroxybutyl)acrylamide, N-((2-dimethylamino)ethyl)acrylamide, N,N-dimethylacrylamide, N-(dimethylamino)methylacrylamide, N-(2-hydroxypropyl)methacrylamide, or combinations thereof.
53. The method of any one of embodiments 1 to 24, 50 and 51 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 51, wherein said at least one hydrophilic (meth)acrylamide monomer comprises N,N-dimethylacrylamide, acrylamide, N-(2-hydroxyethyl)acrylamide, N-(3-aminopropyl)acrylamide, N-(2-aminoethyl)acrylamide, N-(3-hydroxypropyl)acrylamide, N-(2-hydroxypropyl)acrylamide, or combinations thereof.
54. The method of any one of embodiments 1 to 24, 50 and 51 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 51, wherein said at least one hydrophilic (meth)acrylamide monomer comprises N,N-dimethylacrylamide.
55. The method of any one of embodiments 1 to 24 and 50 to 54 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 54, wherein said at least one polysiloxane vinylic crosslinker comprises (1) a vinylic crosslinker which comprises one sole polydiorganosiloxane segment and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups; and/or (2) a chain-extended

polysiloxane vinylic crosslinker which comprises at least two polydiorganosiloxane segment and a covalent linker between each pair of polydiorganosiloxane segments and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups.

56. The method of any one of embodiments 1 to 24 and 50 to 54 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 54, wherein said at least one polysiloxane vinylic crosslinker comprises α,ω -bis[3-(meth)acrylamidopropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxy-isopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutyloxy-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidoethoxy-2-hydroxy-propyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamido-isopropyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamido-butylloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxyethylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxypropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acryloxybutylamino-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acrylamidoethylamino-2-hydroxy-propyloxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamidopropyl-amino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[3-(meth)acrylamide-butylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-ethoxypropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-N-ethylaminopropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyl-aminopropyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxyethoxy-propyl]-terminated polydimethylsiloxane, α,ω -bis[(meth)acryloxyethylamino-carbonyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, or combinations thereof.
57. The method of any one of embodiments 1 to 24 and 50 to 54 or the embedded silicone

hydrogel contact lens of any one of embodiments 25 to 54, wherein said at least one polysiloxane vinylic crosslinker comprises at least one hydrophilized polysiloxane vinylic crosslinker that comprises at least about 1.50 (preferably at least about 2.0, more preferably at least about 2.5, even more preferably at least about 3.0) milliequivalent/gram ("meq/g") of hydrophilic moieties selected from the group consisting of hydroxyl groups (–OH), carboxyl groups (–COOH), amino groups of –NHR_{N1} in which R_{N1} is H or C₁–C₂ alkyl, amide moieties of –CO–NR_{N1}R_{N2} in which R_{N1} is H or C₁–C₂ alkyl and R_{N2} is a covalent bond, H, or C₁–C₂ alkyl, N–C₁–C₃ acylamino groups, urethane moieties of –NH–CO–O–, urea moieties of –NH–CO–NH–, a polyethylene glycol chain of $\text{-(C}_2\text{H}_4\text{O)}_n\text{-T}_1$ in which n is an integer of 2 to 20 and T₁ is H, methyl or acetyl or a phosphorylcholin group, or combinations thereof.

58. The method of any one of embodiments 1 to 24 and 50 to 54 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 54, wherein said at least one polysiloxane vinylic crosslinker comprises a vinylic crosslinker of formula (1)



in which:

$\psi 1$ is an integer of from 30 to 500 and $\omega 1$ is an integer of from 1 to 75, provided that

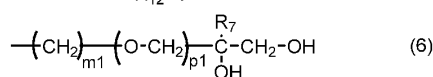
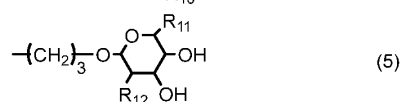
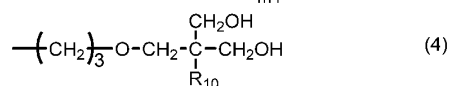
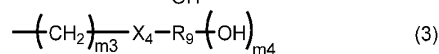
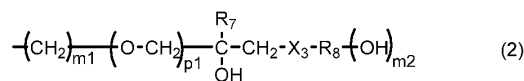
$\omega 1/\psi 1$ is from about 0.035 to about 0.15;

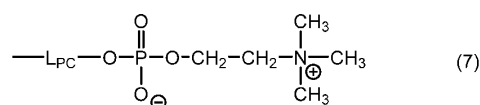
X₀₁ is O or NR_n in which R_n is hydrogen or C₁–C₁₀-alkyl;

R₀ is hydrogen or methyl;

R₂ and R₃ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical or a divalent radical of –R₅–O–R₆– in which R₅ and R₆ independently of each other are a substituted or unsubstituted C₁–C₁₀ alkylene divalent radical;

R₄ is a monovalent radical of any one of formula (2) to (7)





p1 is zero or 1; m1 is an integer of 2 to 4; m2 is an integer of 1 to 5; m3 is an integer of 3 to 6; m4 is an integer of 2 to 5;

R₇ is hydrogen or methyl;

R₈ is a C₂-C₆ hydrocarbon radical having (m2+1) valencies;

R₉ is a C₂-C₆ hydrocarbon radical having (m4+1) valencies;

R₁₀ is ethyl or hydroxymethyl;

R₁₁ is methyl or hydromethyl;

R₁₂ is hydroxyl or methoxy;

X₃ is a sulfur linkage of -S- or a tertiary amino linkage of -NR₁₃- in which R₁₃ is C₁-C₁₀ alkyl, hydroxyethyl, hydroxypropyl, or 2,3-dihydroxypropyl;

X₄ is an amide linkage of -NR₁₄-C(=O)- or -C(=O)-NR₁₄- in which R₁₄ is hydrogen or C₁-C₁₀ alkyl; and

L_{PC} is a divalent radical of -CH₂-CHR₀-R₁₅-, -C₃H₆-O-R₁₆-, -C₃H₆-[O-C₂H₄]_{q1}-,
-C₃H₆-[O-C₃H₆]_{q1}-, -C₂H₄--, or -C₂H₄--R₁₇- in which q1 is an integer of 1 to 20, R₁₅ is a linear or branched C₁-C₁₀ alkylene divalent radical, R₁₆ is a linear or branched C₃-C₁₀ alkylene divalent radical, and R₁₇ is a direct bond or a linear or branched C₁-C₄ alkylene divalent radical.

59. The method of any one of embodiments 1 to 24 and 50 to 58 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 58, wherein said bulk silicone hydrogel material further comprises at least one polymerizable component selected from the group consisting of at least one UV-absorbing vinylic monomer, at least one UV/high-energy-violet-light ("HEVL") absorbing vinylic monomer, at least one polymerizable dye, at least one polymerizable photochromic dye, at least one hydrophilic vinylic monomer other than said at least one N,N-dialkylacrylamide and said at least one hydrophilic (meth)acrylamido monomer, at least one non-silicone vinylic crosslinker, at least one non-silicone hydrophobic vinylic monomer, or combinations thereof.
60. The method or the embedded silicone hydrogel contact lens of embodiment 59, wherein said at least one hydrophilic vinylic monomer comprises hydroxyethyl (meth)acrylate, glycerol methacrylate (GMA), (meth)acrylic acid, N-vinylpyrrolidone, N-vinyl-N-methyl acetamide, 1-methyl-3-methylene-2-pyrrolidone, a phosphorylcholine-containing vinylic monomer (any one of those as described later in this application), N-

2-hydroxyethyl vinyl carbamate, N-carboxyvinyl- β -alanine (VINYL), N-carboxyvinyl- α -alanine, or combinations thereof,

wherein said at least one non-silicone vinylic crosslinker that comprises ethyleneglycol di-(meth)acrylate, diethyleneglycol di-(meth)acrylate, triethyleneglycol di-(meth)acrylate, tetraethyleneglycol di-(meth)acrylate, glycerol di-(meth)acrylate, glycerol 1,3-diglycerolate di-(meth)acrylate, ethylene-bis[oxy(2-hydroxypropane-1,3-diyl)] di-(meth)acrylate, bis[2-(meth)acryloxyethyl] phosphate, diacrylamide, dimethacrylamide, N,N-di(meth)acryloyl-N-methylamine, N,N-di(meth)acryloyl-N-ethylamine, N,N'-methylene bis(meth)acrylamide, N,N'-ethylene bis(meth)acrylamide, N,N'-dihydroxyethylene bis(meth)acrylamide, N,N'-propylene bis(meth)acrylamide, N,N'-2-hydroxypropylene bis(meth)acrylamide, N,N'-2,3-dihydroxybutylene bis(meth)acrylamide, 1,3-bis(meth)acrylamidepropane-2-yl dihydrogen phosphate, piperazine diacrylamide, tetraethyleneglycol divinyl ether, triethyleneglycol divinyl ether, diethyleneglycol divinyl ether, ethyleneglycol divinyl ether, triallyl isocyanurate, or combinations thereof,

wherein said at least one non-silicone hydrophobic acrylic monomers comprises methyl (meth)acrylate, ethyl (meth)acrylate, propyl (meth)acrylate, isopropyl (meth)acrylate, cyclohexyl (meth)acrylate, 2-ethylhexyl (meth)acrylate, isobornyl (meth)acrylate, styrene, 4,6-trimethylstyrene (TMS), t-butyl styrene (TBS), trifluoroethyl (meth)acrylate, hexafluoro-isopropyl (meth)acrylate, hexafluorobutyl (meth)acrylate, or combinations thereof.

61. The method of any one of embodiments 1 to 24 and 50 to 60 or the embedded silicone hydrogel contact lens of any one of embodiments 25 to 60, wherein the silicone hydrogel material that has an equilibrium water content of from about 20% to about 70% by weight, an oxygen permeability of at least 60 barrers, and an elastic modulus of about 1.5 MPa or less.

The previous disclosure will enable one having ordinary skill in the art to practice the invention. Various modifications, variations, and combinations can be made to the various embodiment described herein. In order to better enable the reader to understand specific embodiments and the advantages thereof, reference to the following examples is suggested. It is intended that the specification and examples be considered as exemplary.

Example 1

Oxygen Permeability Measurements

Unless specified, the oxygen transmissibility (Dk/t), the intrinsic (or edge-corrected) oxygen permeability (Dk_i or Dk_e) of an insert and an insert material are determined according

to procedures described in ISO 18369-4.

Delamination

Embedded SiHy contact lenses are examined for possible delamination either using Optimec instrument or Optical Coherence Tomography (OCT).

Regardless of evaluation method, contact lenses are staged for a minimum of 12 hours at room temperature after autoclave run and prior to delamination study.

After meeting required staging time, fully hydrated contact lens is placed in a "V" graticule assembly of Optimec instrument (Model JCF; OPTIMEC England). After the contact lens is settled under the influence of gravity, the front view of the contact lens is inspected carefully for any sign of circular pattern. Delamination displays as circular patterns in Optimec image.

OCT (Spectral Domain Optical Coherence Tomography; Telesto-II; Thorlabs) could also be utilized to study delamination. OCT allows non-invasive imaging of the contact lens to obtain high resolution cross-section image. For this purpose, after meeting the minimum staging requirement, the contact lens is removed from its blister and is soaked into PBS solution for a minimum of 30 min to come to equilibrium. Then a cuvette with a "V" block feature will be filled approximately $\frac{3}{4}$ with fresh PBS solution and the contact lens will be transferred to the cuvette using Q-tips. The lens will be allowed to freely float to the "V" shape at the bottom of the cuvette and the entire contact lens will be scanned in increment of 10 degree. Delamination appears as air pocket in interval surface of insert and carrier in OCT images.

Chemicals

The following abbreviations are used in the following examples: DEA represents N,N-diethylacrylamide; DMA represents N,N-dimethylacrylamide; TRIS-Am represents N-[tris(trimethylsiloxy)-silylpropyl]acrylamide; TRIS-MA represents tris(trimethylsiloxy)silylpropyl methacrylate; CE-PDMS represents a polysiloxane vinylic crosslinker which has three polydimethylsiloxane (PDMS) segments linked via diurethane linkages between two PDMS segments and two urethane linkages each located between one terminal methacrylate group and one PDMS segment and is prepared according to method similar to what described in Example 2 of U.S. Pat. No. 9315669; RI Si-Macromer represents a methacryloxypropyl-terminated polysiloxane of formula (B) in which m~32-34 and n~17-18 as determined by $^{29}\text{Si-NMR}$; Sty-Tris represents p-vinylphenyltris(trimethylsiloxy)silane (aka, 3-(4-ethenylphenyl)1,1,1,5,5,5-hexamethyl-3-[(trimethylsilyl)oxy]trisiloxane); DC 1173 represents a photoinitiator made of 2-hydroxy-2-methyl-1-phenylpropanone; ProOH represents 1-propanol; EGBE represents ethyleneglycol butyl ether; PBS represents a phosphate-buffered saline which has a pH of 7.2 ± 0.2 at 25°C

and contains about 0.044 wt.% $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$, about 0.388 wt.% $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$, and about 0.79 wt.% NaCl and; wt.% represents weight percent.

Example 2

Insert-Forming Compositions

Insert-forming compositions (i.e., Insert formulations) for making diffractive inserts are prepared at room temperature in air by blending all the components (materials) in their desired amounts (weight parts units) to have the composition shown in Table 1.

Table 1		
	Insert formulation 1	Insert Formulation 2
RI Si Macromer	50	50
Sty-Tris	50	50
DC1173	0.5	
CuP dispersion	0.5	0.5
VAZO 67		0.5
Darocur 1173	0.5	

Inserts (a diameter of 6.0 mm and a thickness of 60 μm) molded from the insert-forming compositions prepared above has a refractive index of 1.50 and a modulus of about 20 MPa.

Lens-Forming Compositions

Lens-forming compositions (i.e., SiHy lens formulations) are prepared at room temperature in air by blending all the components (materials) in their desired amounts (weight parts units) to have the composition shown in Table 2.

Table 2				
	2-1 (DMA1)	2-2 (DEA1)	2-3 (DEA2)	2-4 (DEA4)
CE-PDMS	32	32	32	32
TRIS-MA	15	15	15	0
DMA	30	15	0	22.5
DEA	0	15	30	22.5
DC1173	1	1	1	1
PrOH	22	22	22	22

Molds for Making Embedded SiHy Contact Lenses

A set of three mold halves, a female mold half, a first male half and a second male mold half, are made of polypropylene and are used in this Example for preparing embedded diffractive SiHy contact lenses, each of which comprises an insert having a diameter of about 6.0 mm, a thickness of about 60 microns, and a diffractive structure on its back surface.

The female mold half are used twice in the process for preparing an embedded diffractive SiHy contact lens: the first time for molding the insert with the diffractive structure thereon and the second time for molding the embedded SiHy contact lens. The molding

surface of the female mold half defines both the anterior surface of the embedded SiHy contact lens and the front surface of the insert.

The first male mold half has a molding surface defining the back surface of the insert and the diffractive structure. It has an overflow groove into which any excess insert-forming composition can be pressed into during closing of the female mold half and the first male mold half for forming a first molding assembly.

The second male mold half has molding surface defining the posterior surface of the embedded SiHy contact lens.

Example 3

Treatment of Female Mold Halves

The molding surfaces of the female mold halves described in Example 2 are treated with a corona plasma before being used in the production of embedded SiHy diffractive contact lenses.

First male halves (described in Example 2) each with a 2 mm hole drilled in the center are used as masks. The 2mm diameter opening in the mask is used to ensure that the insert is not completely stuck with the front curve side since the overall diameter of the insert is around 6mm. Such a mask can ensure that the insert is attached just enough to remain intact after the insert demolding/flash removal step but not too strong to prevent it from being released after curing with the lens-forming composition.

Each mask is placed on one female mold half (described in Example 2) and closed to form one assembly that is in turn to be treated in a corona treatment instrument (Tantec LabTEC custom corona treater) under the conditions: power applied – 30W; applied voltage – 2kV; duration – 0.5 second. The female mold halves with their molding surface treated with a corona plasma are used later in the production of embedded SiHy contact lenses.

It is understood that any corona treatment instrument can be used in treating the female mold halves.

Preparation of Embedded SiHy Contact Lenses

Insert-forming compositions prepared in Example 2 are used in the preparation of embedded SiHy contact lenses according to either the actinic curing technique or the thermal curing technique described below.

Actinically Curing of Insert-Forming Composition

An insert-forming composition (Insert Formulation 1) prepared in Example 2 is purged with nitrogen at room temperature for 30 to 35 minutes. A specific volume (e.g., ~ 30-90 μ l) of the N₂-purged insert-forming composition is disposed in the center of the molding surface of a female lens mold half that has been treated with a corona plasma above. The female lens mold half with the insert-forming composition therein is closed with a first male

mold half described in Example 2 to form a first molding assembly. The insert-forming composition in the first molding assembly is cured by using a UV LED oven at 2.5 mW/cm² for 45 minutes.

Thermal Curing of Insert-Forming Composition

An insert-forming composition (Insert Formulation 2) prepared in Example 2 is purged with nitrogen at room temperature for 30 to 35 minutes. A specific volume (e.g. ~ 30-90 µl) of the N₂-purged insert-forming composition is disposed in the center of the molding surface of a female lens mold half (described in Example 2) the molding surface of which has been treated with vacuum UV above. The female lens mold half with the insert-forming composition therein is closed with a first male mold half (described in Example 2) to form a first molding assembly.

The oven is configured as follows: a nitrogen supply is connected to the oven through a higher flow capacity controller which can control the flow rate of nitrogen through the oven; at the exhaust line of the oven, vacuum pumps are connected to control the differential pressure of the oven.

The insert-forming compositions in the first molding assemblies are thermally cured in the oven under the following conditions: ramp from room temperature to 55°C at a ramp rate of about 7°C/minute; holding at 55 °C for about 30 minutes; ramp from 55 °C to 80 °C at a ramp rate of about 7°C/minute; holding at 80 °C for about 39 minutes; ramp from 80 °C to 100 °C at a ramp rate of about 7°C/minute; and holding at 100 °C for about 30 minutes. The first molding assemblies are opened, and the molded inserts are adhered onto the central area of the molding surface of the female lens mold halves.

After the curing step, the first male mold half of the first molding assembly is gently blasted with liquid nitrogen for 2 – 5 seconds, then the first male mold half is pinched and released gently. The molded inserts (100%) are adhered onto the central area of the molding surface of the female mold half whereas the insert flash is stuck on the overflow groove of the first male mold half.

A lens-forming composition (lens-forming composition 1) prepared in Example 2 is purged with nitrogen at room temperature for 30 to 35 minutes. A specific volume (e.g., 50-60 mg) of the N₂-purged lens-forming composition is disposed onto the molded insert adhered onto the central portion of the molding surface of the female lens mold half. The female lens mold half with the insert adhered thereonto and with the lens-forming composition is closed with a second male mold half (described in Example 2) to form a second molding assembly.

The lens-forming composition in closed second molding assemblies are irradiated with a UVA (intensities range from 1-15 mW/cm²; both double sided and single sided curing)

for 30 seconds to 10 minutes. The 2nd molding assemblies each with a molded embedded SiHy contact lens precursor therein are mechanically opened. The molded embedded SiHy contact lens precursors adhere to the male mold halves or female mold halves. Molded embedded SiHy contact lens precursors are delensed by use of liquid N₂ spray along the back of the female mold half and mechanical tapping. The delensed embedded SiHy contact lens precursors are immediately placed in deionized water for 0.5-10 hours at 25°C-50°C for extraction and then in room temperature deionized water for hydration. The lenses are subsequently packaged in saline (PBS) and sterilized for 45 minutes at 120°C in an autoclave.

All the resultant embedded SiHy contact lenses obtained from the 4 lens-forming compositions are free of any delamination bubbles under the microscope. But, only the embedded SiHy contact lenses obtained from Formulation 2-4 are not deformed (i.e., having round shape).

All the publications, patents, and patent application publications, which have been cited herein above in this application, are hereby incorporated by reference in their entireties.

What is claimed is:

1. A method for producing embedded silicone hydrogel contact lenses, comprising the steps of:
 - (1) obtaining a female mold half, a first male mold half and a second male mold half, wherein the female mold half has a first molding surface defining the anterior surface of a contact lens to be molded, wherein the first male mold half has a second molding surface defining the back surface of an insert to be molded, wherein the second male mold half has a third molding surface defining the posterior surface of the contact lens to be molded, wherein the first male mold half and the female mold half are configured to receive each other such that an insert-molding cavity is formed between the second molding surface and a central portion of the first molding surface when the female mold half is closed with the first male mold half, wherein the second male mold half and the female mold half are configured to receive each other such that a lens-molding cavity is formed between the first and third molding surfaces when the female mold half is closed with the second male mold half;
 - (2) dispensing an amount of an insert-forming composition on the central portion of the first molding surface of the female mold half;
 - (3) placing the first male mold half on top of the insert-forming composition in the female mold half and closing the first male mold half and the female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;
 - (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition;
 - (5) separating the first molding assembly obtained in step (4) into the first male mold half and the female mold half with the molded insert that is adhered onto the central portion of the first molding surface;
 - (6) dispensing a lens-forming composition in the female mold half with the molded insert adhered thereon in an amount sufficient for filling the lens-molding cavity of the female mold half, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{\text{OW}})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{\text{OW}})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a

- polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the lens-forming composition;
- (7) placing the second male mold half on top of the lens-forming composition in the female mold half and closing the second male mold half and the female mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity;
 - (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded silicone hydrogel contact lens precursor that comprise a bulk silicone hydrogel material formed from the lens-forming composition and the insert embedded in the bulk silicone hydrogel material;
 - (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded silicone hydrogel contact lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves;
 - (10) removing the embedded silicone hydrogel contact lens precursor from the lens-adhered mold half; and
 - (11) subjecting the embedded silicone hydrogel contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof.
2. The method of claim 1, wherein the first male mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming material is pressed when the first molding assembly is closed securely, wherein any flushes formed from excess insert-forming material during step (5) can be stuck on the first male mold half during step of separating the first molding assembly, thereby removing the flushes.
 3. The method of claim 1 or 2, wherein the method further comprises, before step (2), a step of treating a central circular area of the first molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter that is about 90% or smaller of the diameter of the insert to be molded.
 4. The method of claim 3, wherein the central circular area of the first molding surface is carried out by using a vacuum UV.
 5. The method of claim 3, wherein the central circular area of the first molding surface is carried out by using a corona plasma.
 6. A method for producing embedded SiHy contact lenses, comprising the steps of:

- (1) obtaining a first female mold half, a male mold half and a second female mold half, wherein the first female mold half has a first molding surface defining the front surface of an insert to be molded, wherein the male mold half has a second molding surface defining the posterior surface of a contact lens to be molded and also the back surface of the insert to be molded, wherein the second female mold half has a third molding surface defining the anterior surface of the contact lens to be molded, wherein the first female mold half and the male mold half are configured to receive each other such that an insert-molding cavity is formed between the first molding surface and a central portion of the second molding surface when the first female mold half is closed with the male mold half, wherein the second female mold half and the male mold half are configured to receive each other such that a lens-molding cavity is formed between the second and third molding surfaces when the second female mold half is closed with the male mold half;
- (2) dispensing an amount of an insert-forming composition in the first female mold half;
- (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the male mold half and the first female mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;
- (4) curing the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert made of a crosslinked polymeric material formed from the insert-forming composition;
- (5) separating the first molding assembly obtained in step (4) into the first female mold half and the male mold half with the molded insert that is adhered onto the central portion of the second molding surface;
- (6) dispensing a lens-forming composition in the second female mold half in an amount sufficient for filling the lens-molding cavity, wherein the lens-forming composition comprises (a) at least one N,N-dialkylacrylamide having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, (c) at least one polysiloxane acrylic crosslinker, (d) at least one photoinitiator, and (e) at least one non-reactive diluent, wherein the lens-forming composition is free of siloxane-containing vinylic monomer having a tris(trialkylsilyloxy)silyl or bis(trialkylsilyloxy)silyl group or a polysiloxane segment having 3 to 15 consecutive siloxane units, wherein the sum of the amounts of components (a) to (d) is at least 90% by weight relative to total amount of all polymerizable components in the polymerizable composition;

- (7) placing the male mold half with the molded insert that is adhered onto the central portion of the second molding surface on top of the lens-forming composition in the second female mold half and closing the second female mold half and the male mold half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity;
 - (8) actinically curing the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded SiHy contact lens precursor that comprise a bulk SiHy material formed from the lens-forming composition and the insert embedded in the bulk material;
 - (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded SiHy contact lens precursor adhered on a lens-adhered mold half which is one of the second female mold half and the male mold halves;
 - (10) removing the embedded SiHy contact lens precursor from the lens-adhered mold half; and
 - (11) subjecting the embedded SiHy contact lens precursor to post-molding processes including one or more processes selected from the group consisting of extraction, hydration, surface treatment, packaging, sterilization, and combinations thereof to obtain an embedded SiHy contact lens.
7. The method of claim 6, wherein the first female mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming material is pressed when the first molding assembly is closed securely, wherein any flushes formed from excess insert-forming material during step (5) can be stuck on the first female mold half during step of separating the first molding assembly, thereby removing the flushes.
8. The method of claim 6 or 7, wherein the method further comprises, before step (2), a step of treating a central circular area of the second molding surfaces by using a vacuum UV or a corona plasma, wherein the central circular area has a diameter that is about 90% or smaller of the diameter of the insert to be molded.
9. The method of claim 8, wherein the central circular area of the second molding surface is carried out by using a vacuum UV.
10. The method of claim 8, wherein the central circular area of the second molding surface is carried out by using a corona plasma.
11. The method of any one of claims 1 to 10, wherein the insert-forming composition comprises at least one silicone-containing aryl vinylic monomer and at least one silicone-containing aryl vinylic crosslinker.
12. The method of any one of claims 1 to 11, wherein said at least one non-reactive diluent

comprises ethylene glycol butyl ether, propylene glycol, 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, or mixtures thereof.

13. The method of any one of claims 1 to 12, wherein the lens-forming composition comprises: (a) from about 10 to about 35 weight part units of at least one N,N-dialkylacrylamide (preferably N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide) having a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1; (b) from about 10 to about 35 weight part units of at least one hydrophilic (meth)acrylamido monomer (preferably N,N-dimethylacrylamide) having a $\text{Log}(P_{OW})$ of less than about 0.5; and (c) from about 30 to about 40 weight part units of at least one polysiloxane acrylic crosslinker.
14. An embedded SiHy contact lens, comprising a lens body that comprises an anterior surface, an opposite posterior surface, a bulk hydrogel material having a first refractive index, and a circular insert embedded in the bulk hydrogel material, wherein the circular insert has a diameter of about 11.0 mm or less and is made of a crosslinked polymeric material having a second refractive index, wherein the circular insert has a front surface and an opposite back surface and is located in a central portion of the embedded SiHy contact lens and concentric with a central axis of the lens body, wherein one of the front and back surfaces of the circular insert merges with one of the anterior and posterior surface of the lens body while the other one of the front and back surfaces of the circular insert is buried within the bulk hydrogel material and designated as buried surface, wherein the buried surface of the circular insert comprises a diffractive structure, wherein the bulk SiHy material comprises at least 92% by weight of repeating units of (a) at least one N,N-dialkylacrylamido monomer which has a 1-octanol-water partition coefficient $\text{Log}(P_{OW})$ of from about 0.7 to about 2.1, (b) at least one hydrophilic (meth)acrylamido monomer having a $\text{Log}(P_{OW})$ of less than about 0.5, and (c) of at least one polysiloxane acrylic crosslinker, wherein the second refractive index is at least 0.03 higher than the first refractive index, wherein the crosslinked polymeric material comprising repeating units of at least one aryl vinylic monomer and at least one aryl vinylic crosslinker.
15. The embedded silicone hydrogel contact lens of claim 14, wherein the insert comprises a diffractive structure on the buried surface of the insert.
16. The embedded silicone hydrogel contact lens of claim 14 or 15, wherein the crosslinked polymeric material is a silicone elastomer.
17. The embedded silicone hydrogel contact lens of claim 14 or 15, wherein the crosslinked polymeric material comprises repeating units of at least one aryl vinylic monomer and/or at least one aryl vinylic crosslinker.
18. The embedded hydrogel contact lens of claim 14 or 15, wherein the crosslinked

polymeric material comprises repeating units of at least one silicone-containing aryl vinylic monomer and at least one silicone-containing aryl vinylic crosslinker.

19. The method of any one of claims 1 to 13 or the embedded silicone hydrogel contact lens of any one of claims 14 to 18, wherein said at least one N,N-dialkylacrylamido monomer comprises N,N-diethylacrylamide, N-methyl-N-isopropylacrylamide, N-ethyl-N-isopropylacrylamide, or combinations thereof, wherein said at least one hydrophilic (meth)acrylamide monomer comprises N,N-dimethylacrylamide, acrylamide, N-(2-hydroxyethyl)acrylamide, N-(3-aminopropyl)acrylamide, N-(2-aminoethyl)acrylamide, N-(3-hydroxypropyl)acrylamide, N-(2-hydroxypropyl)acrylamide, or combinations thereof.
20. The method of any one of claims 1 to 13 and 19 or the embedded silicone hydrogel contact lens of any one of claims 14 to 19, wherein said at least one polysiloxane vinylic crosslinker comprises (1) a vinylic crosslinker which comprises one sole polydiorganosiloxane segment and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups; and/or (2) a chain-extended polysiloxane vinylic crosslinker which comprises at least two polydiorganosiloxane segment and a covalent linker between each pair of polydiorganosiloxane segments and two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups.