

**28 Claims, 1 Drawing Sheet**

(56)

**References Cited**

## U.S. PATENT DOCUMENTS

4,268,132 A	5/1981	Neefe	6,762,264 B2	7/2004	Kunzler et al.
4,276,402 A	6/1981	Chromeczek	6,851,805 B2	2/2005	Blum et al.
4,327,203 A	4/1982	Deichert et al.	6,867,245 B2	3/2005	Iwata et al.
4,341,889 A	7/1982	Deichert et al.	6,995,192 B2	2/2006	Phelan et al.
4,343,927 A	8/1982	Chang	7,104,648 B2	9/2006	Dahi et al.
4,355,147 A	10/1982	Deichert et al.	7,214,809 B2	5/2007	Zanini et al.
4,401,371 A	8/1983	Neefe	7,423,074 B2	9/2008	Lai et al.
4,444,711 A	4/1984	Schad	7,490,936 B2	2/2009	Blum et al.
4,460,534 A	7/1984	Boehm et al.	7,556,750 B2	7/2009	Xiao et al.
4,486,577 A	12/1984	Mueller et al.	7,584,630 B2	9/2009	Van Gemert
4,543,398 A	9/1985	Bany et al.	7,605,190 B2	10/2009	Mosznier et al.
4,605,712 A	8/1986	Mueller et al.	7,883,207 B2	2/2011	Iyer
4,661,575 A	4/1987	Tom	7,931,832 B2	4/2011	Pugh et al.
4,684,538 A	8/1987	Klemarczyk	7,977,430 B2	7/2011	Devlin et al.
4,703,097 A	10/1987	Wingler et al.	7,999,989 B2	8/2011	Asai et al.
4,833,218 A	5/1989	Lee	8,154,804 B2	4/2012	McGinn et al.
4,837,289 A	6/1989	Mueller et al.	8,158,037 B2	4/2012	Chopra et al.
4,929,693 A	5/1990	Akashi et al.	8,215,770 B2	7/2012	Blum et al.
4,954,586 A	9/1990	Toyoshim et al.	8,324,256 B2	12/2012	Domschke
4,954,587 A	9/1990	Mueller	8,348,424 B2	1/2013	Pugh et al.
5,010,141 A	4/1991	Mueller	8,415,405 B2	4/2013	Maggio et al.
5,034,461 A	7/1991	Lai et al.	8,475,529 B2	7/2013	Clarke
5,039,761 A	8/1991	Ono et al.	8,480,227 B2	7/2013	Qiu et al.
5,070,170 A	12/1991	Robertson et al.	8,529,057 B2	9/2013	Qiu et al.
5,070,215 A	12/1991	Bambury et al.	8,614,261 B2	12/2013	Iwata et al.
5,079,319 A	1/1992	Mueller	8,658,748 B2	2/2014	Liu
5,098,546 A	3/1992	Kawashima et al.	8,697,770 B2	4/2014	Duis et al.
5,156,726 A	10/1992	Nakada et al.	8,741,188 B2	6/2014	Chopra et al.
5,166,345 A	11/1992	Akashi et al.	8,835,525 B2	9/2014	Kuyu et al.
5,346,946 A	9/1994	Yokoyama et al.	8,874,182 B2	10/2014	Etzkorn et al.
5,358,995 A	10/1994	Lai et al.	8,922,898 B2	12/2014	Legerton et al.
5,387,632 A	2/1995	Lai et al.	8,993,651 B2	3/2015	Chang et al.
5,416,132 A	5/1995	Yokoyama et al.	9,052,438 B2	6/2015	Xiao et al.
5,449,729 A	9/1995	Lai	9,097,840 B2	8/2015	Chang
5,451,617 A	9/1995	Lai et al.	9,097,916 B2	8/2015	Chopra et al.
5,486,579 A	1/1996	Lai et al.	9,103,965 B2	8/2015	Chang
5,583,163 A	12/1996	Müller	9,155,614 B2	10/2015	Blum et al.
5,665,840 A	9/1997	Pöhlmann et al.	9,176,332 B1	11/2015	Etzkorn et al.
5,712,356 A	1/1998	Bothe et al.	9,217,813 B2	12/2015	Liu et al.
5,760,100 A	6/1998	Nicolson et al.	9,296,158 B2	3/2016	Pugh et al.
5,843,346 A	12/1998	Morrill	9,465,234 B2	10/2016	Chopra
5,849,841 A	12/1998	Mühlebach et al.	9,475,827 B2	10/2016	Chang
5,894,002 A	4/1999	Boneberger et al.	9,618,773 B2	4/2017	Clarke
5,962,548 A	10/1999	Vanderlaan et al.	9,731,437 B2	8/2017	Pugh et al.
5,981,675 A	11/1999	Valint, Jr. et al.	9,889,615 B2	2/2018	Pugh et al.
6,017,121 A	1/2000	Chateau et al.	9,904,074 B2	2/2018	Duis
6,019,914 A	2/2000	Lokshin et al.	9,977,260 B2	5/2018	Pugh et al.
6,039,913 A	3/2000	Hirt et al.	10,081,697 B2	9/2018	Huang
6,113,814 A	9/2000	Gemert et al.	10,139,521 B2	11/2018	Tran et al.
6,149,841 A	11/2000	Kumar	10,197,707 B2	2/2019	Xiao
6,165,408 A	12/2000	Steinmann	10,203,521 B2	2/2019	Pugh et al.
6,166,236 A	12/2000	Bambury et al.	10,209,534 B2	2/2019	Alli et al.
6,221,303 B1	4/2001	Steinmann	10,301,451 B2	5/2019	Jing
6,296,785 B1	10/2001	Nelson et al.	10,465,047 B2	11/2019	Jing
6,303,687 B1	10/2001	Müller	2004/0141150 A1	7/2004	Roffman et al.
6,348,604 B1	2/2002	Nelson et al.	2009/0091818 A1	4/2009	Haddock et al.
6,472,489 B1	10/2002	Stockinger	2010/0076553 A1	3/2010	Pugh et al.
6,479,587 B1	11/2002	Stockinger et al.	2011/0157544 A1	6/2011	Pugh et al.
6,492,478 B1	12/2002	Steinmann	2012/0140167 A1	6/2012	Blum
			2018/0169905 A1	6/2018	Marullo et al.
			2021/0261581 A1	8/2021	Loccufier
			2021/0292558 A1	9/2021	Bassampour et al.

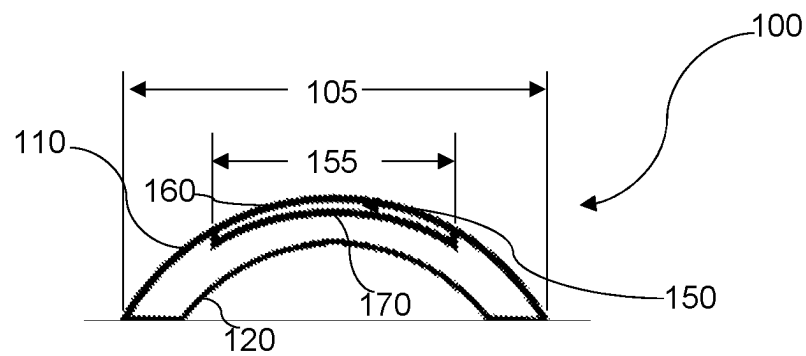


Figure 1

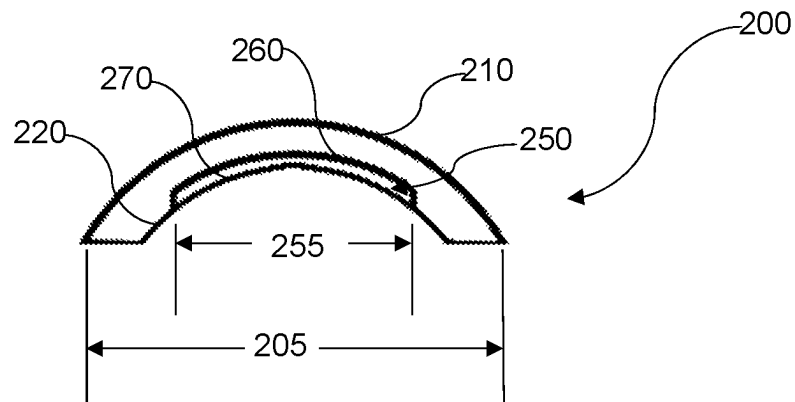


Figure 2

1

## METHOD FOR MAKING EMBEDDED HYDROGEL CONTACT LENSES

This application claims the benefit under 35 USC § 119 (e) of U.S. provisional application No. 63/365,272 filed 25 May 2022, incorporated by reference in its entirety.

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

### BACKGROUND

Hydrogel contact lenses are widely used for correcting many different types of vision deficiencies due to their softness for wearing comfort. They are made of a hydrated, crosslinked polymeric material that contains from about 20% to about 75% by weight of water within the lens polymer matrix at equilibrium. Hydrogel contact lenses generally are produced according to the conventional full cast-molding process. Such a conventional manufacturing process comprises at least the following steps: lens molding (i.e., curing a polymerizable composition in lens molds), demolding (i.e., removing lenses from molds), extracting lenses with an extraction medium, hydrating lenses, packaging and sterilizing the hydrated lenses. During the lens hydration, the hydrogel contact lenses will absorb water and typically can swell significantly in size.

In recent years, it has been proposed that various inserts can be incorporated in hydrogel contact lenses for various purposes, e.g., for corneal health, vision correction, diagnosis, etc. See, for example, U.S. Pat. Nos. 4,268,132, 4,401,371, 5,098,546, 5,156,726, 6,851,805, 7,104,648, 7,490,936, 7,883,207, 7,931,832, 8,154,804, 8,215,770, 8,348,424, 8,874,182, 8,922,898, 9,155,614, 9,176,332, 9,296,158, 9,618,773, 9,731,437, 9,889,615, 9,977,260, 10,203,521, and 10,209,534; and U.S. Pat. Appl. Pub. Nos. 2004/0141150, 2009/0091818, 2010/0076553, 2011/0157544, and 2012/0140167).

Inserts are typically made of a non-hydrogel material that cannot absorb water and is a non-water-swallowable material. One special type of inserts are rigid inserts made of a rigid material (i.e., a highly-crosslinked polymeric material) as rigid center optics for masking astigmatism like a rigid gas permeable (RGP) contact lens. For such inserts, it is expected that there are huge difference in mechanical properties and especially in water-swelling degree between insert material and silicone hydrogel lens material embedding the insert. Due to such huge differences, embedded silicone hydrogel contact lenses are susceptible to lens distortion or especially delamination during the hydration of the 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 have embedded silicone hydrogel contact lenses that have rigid hydrophobic inserts therein and not susceptible to delamination.

U.S. Pat. Appl. Pub. No. 2018/0169905 A1 discloses attempts for reducing distortion during hydration of an embedded contact lens comprising a hydrogel lens body and a non-expandable object embedded therein by selecting the surface energy of the non-expandable object and the modulus of the hydrogel lens body.

U.S. patent Ser. No. 10/139,521 discloses that a silicone elastomer-hydrogel hybrid contact lens that includes a silicone elastomer layer and a hydrogel layer adhered to the silicone elastomer layer by a delamination-resistant bond

2

that is formed by an elastomer-swallowable monomer that is included in the polymerizable composition used to form the hydrogel layer.

U.S. Pat. Appl. Pub. No. 2021/0292558 A1 discloses that when a polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor can be added in a polymerizable composition in cast molding of embedded silicone hydrogel contact lenses each having a rigid insert made of a hydrophobic crosslinked polymeric material, the resultant embedded silicone hydrogel contact lenses are less susceptible to delamination.

### SUMMARY OF THE INVENTION

In one aspect, the invention provides a method for producing embedded hydrogel 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, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (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 thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (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 second free-radical photoinitiator; (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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an

3

embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In other aspects, the invention provides a method for producing embedded hydrogel 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, 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 on the first molding surface of the first female mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the first female mold half and the male mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (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 second free-radical photoinitiator; (7) placing the male mold half with the molded insert adhered thereon on top of the lens-forming composition in the second female mold half and closing the second female mold half and the male mold

4

half to form a second molding assembly comprising the lens-forming composition and the molded insert immersed therein in the lens-molding cavity; (8) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the male and second female mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In a further aspect, the invention provides a method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of: (1) obtaining an insert mold, wherein the insert mold comprises a male insert mold half having a first molding surface and a female insert mold half having a second molding surface are configured to receive each other such that an insert-molding cavity is formed between the first and second molding surfaces when the female insert mold half is closed with the male insert mold half; (2) dispensing an insert-forming composition in the female insert mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (3) closing the female insert mold half with the male insert mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity of the insert mold; (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (5) obtaining a lens mold and a lens-forming composition, wherein the lens mold comprises a male lens mold half having a third molding surface and a female lens mold half having a fourth molding surface are configured to receive each other such that a lens-molding cavity is formed between the third and fourth molding surfaces when the female lens mold half is closed with the male lens mold half, wherein the lens-forming composition comprises at least one second polymerizable material and a second free-radical photoinitiator; (6) in no particular order, placing the insert obtained in step (4) in the female lens mold half at a desired position and dispensing the lens-forming composition in the female lens mold half, wherein the insert is immersed in the lens-forming composition; (7) closing the female lens mold half with the male lens mold half to form a second molding assembly comprising the lens-forming composition and the insert immersed therein in the lens-molding cavity of the lens mold; (8) irradiating, with an UV and/or visible light,

the lens-forming composition and the insert in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the lens mold obtained in step (8) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered onto a lens-adhered lens mold half which is one of the male and female lens mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In other aspect, the invention provides an embedded hydrogel contact lens obtained according to a method of the invention.

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

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

FIG. 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-silicone hydrogel material or preferably a silicone hydrogel material.

A "hydrogel" or "hydrogel material" refers to a cross-linked 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 siloxane, which often also described as a silicone, refers to a molecule having at least one moiety of  $\text{—Si—O—Si—}$  where each Si atom carries two organic groups as substituents.

A "silicone hydrogel" or "SiHy" 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.

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 hydrogel contact lens" refers a hydrogel contact lens comprising at least one insert which is embedded within the bulk hydrogel material of the embedded hydrogel 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 hydrogel material of the embedded hydrogel 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 hydrogel contact lens and which is made of a material (preferably a non-hydrogel material) that is different from the bulk hydrogel material.

In this application, a central axis of an insert (or contact lens) refers to an imaginary line passing through both the centers of the anterior (front) and posterior (back) surface of the insert (or contact lens).

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.

In accordance with the invention, an insert of the invention has a thickness less than any thickness of an embedded hydrogel contact lens in the region where the insert is embedded. An insert can be any object have any geometrical shape and can have any desired functions. Examples of preferred inserts include without limitation thin rigid inserts for providing rigid center optics for masking astigmatism like a rigid gas permeable (RGP) contact lens, multifocal lens inserts, photochromic inserts, cosmetic inserts having color patterns printed thereon, etc.

"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

7

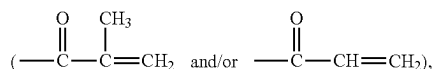
be dissolved in the solvent to give a solution with a concentration of at least about 0.5% by weight at room temperature (i.e., a temperature of about 22° C. to about 26° C.).

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).

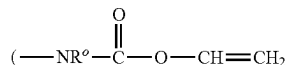
A “vinyl monomer” refers to a compound that has one sole ethylenically unsaturated group, is soluble in a solvent, and can be polymerized actinically or thermally.

A “polymerizable material” refers to a compound, a polymer (soluble in a solvent), or a mixture thereof, each of which comprises at least one ethylenically unsaturated group and can be polymerized actinically or thermally.

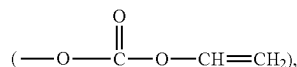
As used in this application, the term “ethylenically unsaturated group” is employed herein in a broad sense and is intended to encompass any groups containing at least one  $>C=CH_2$  group. Exemplary ethylenically unsaturated groups include without limitation (meth)acryloyl



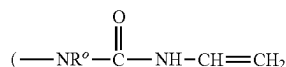
vinylloxycarbonylamino



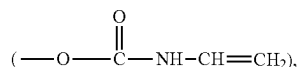
in which  $R^o$  is H or  $C_1$ - $C_4$  alkyl), vinylloxycarbonyloxy



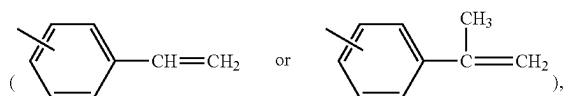
vinylaminocarbonylamino



in which  $R^o$  is H or  $C_1$ - $C_4$  alkyl), vinylaminocarbonyloxy



allyl, vinyl, styrenyl

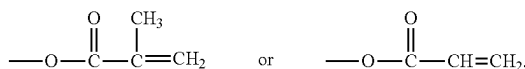


or other  $C=C$  containing groups.

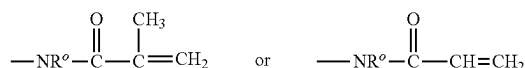
An “acrylic monomer” refers to a vinyl monomer having one sole (meth)acryloyl group. Examples of acrylic monomers includes (meth)acryloxy [or (meth)acryloyloxy] monomers and (meth)acrylamido monomers.

8

An “(meth)acryloxy monomer” or “(meth)acryloyloxy monomer” refers to a vinyl monomer having one sole group



An “(meth)acrylamido monomer” or “(meth)acryloylamino monomer” refers to a vinyl monomer having one sole group of



in which  $R^o$  is H or  $C_1$ - $C_4$  alkyl.

The term “aryl acrylic monomer” refers to an acrylic 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 ( $\text{---CH=CH}_2$ ) 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.

The term “ene group” refers to a monovalent radical of  $\text{CH}_2=\text{CH---}$  or  $\text{CH}_2=\text{CCH}_3\text{---}$  that is not covalently attached to an oxygen or nitrogen atom or a carbonyl 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 vinyl 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 vinyl monomer”, a “hydrophobic acrylic monomer”, a “hydrophobic (meth)acryloxy monomer”, or a “hydrophobic (meth)acrylamido monomer”, as used herein, respectively refers to a vinyl 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 “vinyl crosslinker” refers to an organic compound having at least two ethylenically unsaturated groups. A “vinyl crosslinking agent” refers to a vinyl crosslinker having a molecular weight of 700 Daltons or less.

An “acrylic crosslinker” refers to a vinyl crosslinker having at least two (meth)acryloyl groups.

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.,

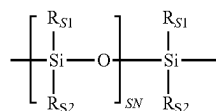
crosslinked and/or polymerized) is performed by actinic irradiation, such as, for example, UV/visible irradiation, ionizing radiation (e.g. gamma ray or X-ray irradiation), microwave irradiation, and the like. Thermal curing or actinic curing methods are well-known to a person skilled in the art.

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);  $^1\text{H}$  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



in which SN is an integer of 3 or larger and each of  $\text{R}_{\text{S1}}$  and  $\text{R}_{\text{S2}}$  independent of one another are selected from the group consisting of:  $\text{C}_1\text{--C}_{10}$  alkyl; phenyl;  $\text{C}_1\text{--C}_4$ -alkyl-substituted phenyl;  $\text{C}_1\text{--C}_4$ -alkoxy-substituted phenyl; phenyl- $\text{C}_1\text{--C}_6$ -alkyl;  $\text{C}_1\text{--C}_{10}$  fluoroalkyl;  $\text{C}_1\text{--C}_{10}$  fluoroether; aryl; aryl  $\text{C}_1\text{--C}_{13}$  alkyl;  $\text{---alk---}(\text{OC}_2\text{H}_4)_{\gamma 1}\text{---OR}^\circ$  (in which alk is  $\text{C}_1\text{--C}_6$  alkylene diradical,  $\text{R}^\circ$  is H or  $\text{C}_1\text{--C}_4$  alkyl and  $\gamma 1$  is an integer from 1 to 10); a  $\text{C}_2\text{--C}_{40}$  organic radical having at least one functional group selected from the group consisting of hydroxyl group ( $\text{---OH}$ ), carboxyl group ( $\text{---COOH}$ ), amino group ( $\text{---NR}_{\text{N1}}\text{R}_{\text{N1}}'$ ), amino linkages of  $\text{---NR}_{\text{N1}}\text{---}$ , amide linkages of  $\text{---CONR}_{\text{N1}}\text{---}$ , amide of  $\text{---CONR}_{\text{N1}}\text{R}_{\text{N1}}'$ , urethane linkages of  $\text{---OCONH---}$ , and  $\text{C}_1\text{--C}_4$  alkoxy group, or a linear hydrophilic polymer chain, in which  $\text{R}_{\text{N1}}$  and  $\text{R}_{\text{N1}}'$  independent of each other are hydrogen or a  $\text{C}_1\text{--C}_{15}$  alkyl; and a photochromic organic radical having a photochromic group.

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 “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 “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.

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, preferably 90% 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 ( $\text{---OH}$ ), carboxyl ( $\text{---COOH}$ ),  $\text{---NH}_2$ , sulfhydryl ( $\text{---SH}$ ),  $\text{C}_1\text{--C}_4$  alkyl,  $\text{C}_1\text{--C}_4$  alkoxy,  $\text{C}_1\text{--C}_4$  alkylthio (alkyl sulfide),  $\text{C}_1\text{--C}_4$  acylamino,  $\text{C}_1\text{--C}_4$  alkylamino, di- $\text{C}_1\text{--C}_4$  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 “oxygen permeability”,  $\text{Dk}_j$ , of a material is the rate at which oxygen will pass through a material and can be measured at about 34-35° C. according to the procedures described in Example 1. 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”,  $\text{Dk}/t$ , 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



11

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 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 “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.

In general, the invention is directed to a method for producing embedded hydrogel contact lenses, each of which comprises a bulk hydrogel material and an insert that is embedded partially or completely within the bulk hydrogel material and is made of a crosslinked polymeric material that is covalently linked to the bulk hydrogel material. This invention is partly based on the discovery that an insert, which made of a crosslinked polymeric material comprising repeating units of the free-radical photoinitiator, can be prepared by thermal curing of a lens-forming composition comprising a thermal free-radical initiator and a free-radical photoinitiator having an ethylenically-unsaturated group. The thermal free-radical initiator is used to initiate the polymerization of the polymerizable materials including the free-radical photoinitiator having an ethylenically-unsaturated group. The free-radical-initiating moiety of the photoinitiator can be preserved and incorporated into the polymer matrix of the insert. They are capable of generating free radicals upon irradiation with an UV and/or visible light and in the presence of polymerizable material, polymer chains can be grafted from repeating units of the free-radical photoinitiator. Such a preformed insert can be photoactive. When it is used in photocuring-based cast-molding of an embedded hydrogel contact lens from a lens-forming composition comprising a free-radical photoinitiator, the bulk hydrogel material formed from the lens-forming composition is covalently linked to the insert at repeating units of the free-radical photoinitiator at and near the surface of the insert.

A method of the invention can offer the following advantages. First, a method of the invention can be easily implemented in an automatic product line for producing embedded hydrogel contact lenses in mass. Furthermore, resultant embedded hydrogel contact lenses can have an improved resistance to delamination due to the presence of the covalent linkages between the bulk hydrogel material and the insert embedded therein.

Such an improved resistance to delamination is especially required for an embedded hydrogel contact lens having a

12

structure shown in FIG. 1 or 2, because only one side of an insert is fully contacted with the bulk hydrogel material of an embedded hydrogel contact lens.

FIG. 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 large than 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 an anterior surface 160 and an opposite posterior 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 anterior surface 160 of the insert 150 has a curvature substantially identical to the curvature of the anterior surface 110 of the embedded hydrogel contact lens, and can substantially merges with the anterior surface 110 of the embedded hydrogel contact lens 100 or be buried beneath the anterior surface 110 of the embedded hydrogel contact lens 100 at a depth of less than 10 microns (preferably excluding any coating on the embedded hydrogel contact lens 100).

FIG. 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 large than 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 an anterior surface 260 and an opposite posterior 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 posterior surface 270 of the insert 250 has a curvature substantially identical to the curvature of the posterior surface 220 of the embedded hydrogel contact lens, and can substantially merges with the posterior surface 220 of the embedded contact lens 200 or be buried beneath the posterior surface 220 of the embedded hydrogel contact lens 200 at a depth of less than 10 microns (preferably excluding any coating on the embedded hydrogel contact lens 200).

In one aspect, the invention provides a method for producing embedded hydrogel 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, wherein the

13

insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (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 thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (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; (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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk hydrogel material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In another aspects, the invention provides a method for producing embedded hydrogel 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, 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

14

molding surfaces when the second female mold half is closed with the male mold half; (2) dispensing an amount of an insert-forming composition on the first molding surface of the first female mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the first female mold half and the male mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity; (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (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; (7) placing the male mold half with the molded insert adhered thereon 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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk hydrogel material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the male and second female mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

In a further aspect, the invention provides a method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of: (1) obtaining an insert mold, wherein the insert mold comprises a male insert mold half having a first molding surface and a female insert mold half having a second molding surface are configured to receive each other such that an insert-molding cavity is formed between the first and second molding surfaces when the female insert mold half is closed with the male insert mold half; (2) dispensing an insert-forming composition in the female insert mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-

unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light; (3) closing the female insert mold half with the male insert mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity of the insert mold; (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator; (5) obtaining a lens mold and a lens-forming composition, wherein the lens mold comprises a male lens mold half having a third molding surface and a female lens mold half having a fourth molding surface are configured to receive each other such that a lens-molding cavity is formed between the third and fourth molding surfaces when the female lens mold half is closed with the male lens mold half, wherein the lens-forming composition comprises at least one second polymerizable material and a second free-radical photoinitiator; (6) in no particular order, placing the insert obtained in step (4) in the female lens mold half at a desired position and dispensing the lens-forming composition in the female lens mold half, wherein the insert is immersed in the lens-forming composition; (7) closing the female lens mold half with the male lens mold half to form a second molding assembly comprising the lens-forming composition and the insert immersed therein in the lens-molding cavity of the lens mold; (8) irradiating, with an UV and/or visible light, the lens-forming composition and the insert in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert embedded in the bulk hydrogel material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator; (9) separating the lens mold obtained in step (8) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered onto a lens-adhered lens mold half which is one of the male and female lens mold halves; (10) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

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.

In a preferred embodiment, the mold half having a molding surface defining one of the anterior (front) and posterior

(back) surfaces 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 mold half having a molding surface defining the anterior (front) or posterior (back) surface of the insert during the step of separating the molding assembly halves, thereby removing the flushes.

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. 4,444,711; 4,460,534; 5,843,346; and 5,894,002.

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.

In accordance with the invention, an insert-forming composition is a polymerizable composition which can be any polymerizable compositions for forming a plastic material, so long as they must comprises a thermal free-radical initiator and a free-radical photoinitiator having an ethylenically unsaturated group.

In accordance with the invention, any thermal free-radical initiators can be used in an insert-forming composition of the invention. Suitable thermal free-radical initiators are known to a skilled artisan and include, for example, peroxides, hydroperoxides, azo-bis(alkyl- or cycloalkylnitriles), persulfates, percarbonates, or mixtures thereof. Examples of preferred thermal free-radical 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-butylcyclohexyl) 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).

In accordance with the invention, any free-radical photoinitiators can be used in an insert-forming composition of the invention, so long as they must comprise an ethylenically-unsaturated group and a free-radical-initiating moiety capable of generating free radicals upon irradiation with an UV and/or visible light. Free-radical-initiating moieties can be a monovalent radical of a benzophenone derivative, an  $\alpha$ -hydroxyketone, an  $\alpha$ -aminoketone, an acylphosphine oxide derivative, or an acylgermanium derivative.

Examples of preferred photoinitiators having an ethylenically-unsaturated group include without limitation: 4-(meth)acryloyloxy benzophenone; 2-(meth)acryloyloxy benzophenone; 4-(meth)acryloyloxyethoxy benzophenone; 2,2-dimethyl-propionic acid 4-benzoyl-2-(1-methyl-allyl)-phenyl ester; 2,2-dimethyl-propionic acid 2-allyl-4-benzoyl-phenyl ester; 2,2-dimethyl-propionic acid 4-benzoyl-2-(2-methyl-allyl)-phenyl ester; 4-allyloxybenzophenone; 4-vinylbenzophenone; 2-(4-benzoylphenoxy)ethyl methacrylate; 4-methallyloxy-benzophenone; 2-methacryloxy-5-methyl benzophenone; 4-(4-benzoylphenoxy)butyl ester; 2-hydroxy-4-(methacryloyloxy)benzophenone; 2-Hydroxy-4-(methacryloyloxy)benzophenone; 2-hydroxy-2-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; (1-hydroxy-2-prop-2-enylcyclohexyl)-phenylmethanone; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; propan-2-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenyl-2-prop-1-en-2-ylphenyl)-2-hydroxy-2-methylpropan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylbutan-1-one; (1-hydroxy-4-prop-1-en-2-ylcyclohexyl)-phenylmethanone; (4-ethenyl-1-hydroxycyclohexyl)-phenylmethanone; 1-[4-(1-hydroxycyclohexanecarbonyl)phenyl]prop-2-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enoylphenyl)propan-1-one; 2-hydroxy-2-methyl-1-phenylhex-5-en-1-one; 2-ethyl-2-hydroxy-1-(4-prop-1-en-2-ylphenyl)hexan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylpropan-1-one; 2-hydroxy-2-methyl-1-(2-prop-1-en-2-ylphenyl)propan-1-one; (4-ethenylphenyl)-(1-hydroxycyclohexyl)methanone; 2-hydroxy-2-methyl-1-phenyl-3-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylpropan-1-one; 2-hydroxy-3-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2,3-dimethyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylbutan-1-one; polymerizable acylphosphine oxides disclosed in U.S. Pat. Appl. Pub. No. 2021/0261581A1; and polymerizable photoinitiators disclosed in U.S. Pat. No. 8,324,256.

In accordance with the invention, an insert-forming composition (i.e., a polymerizable composition) must comprises at least one polymerizable material in addition to the free-radical photoinitiator having an ethylenically unsaturated groups which can comprises one or more vinylic monomers and one or more vinylic crosslinkers known to a person skilled in the art.

In a preferred embodiment, an insert-forming composition is a polymerizable composition for forming a hard plastics, e.g., any one known to a person skilled in the art (preferably a crosslinked polymethylmethacrylate or polystyrene).

In another preferred embodiment, an insert-forming composition is a polymerizable composition for forming a crosslinked silicone polymer (or a silicone rubber or elastomer as known to a person skilled in the art), e.g., any one known to a person skilled in the art. A crosslinked silicone material has three-dimensional polymer networks (i.e., polymer matrix), is insoluble in water, and has an equilibrium

water content of about 5% or less, preferably about 3% or less, more preferably about 2% or less) by weight (i.e., in fully-hydrated state).

In another preferred embodiment, an insert-forming composition is a polymerizable composition for forming a non-silicone hydrogel material (any one of those described later in this application or known to a person skilled in the art).

In another preferred embodiment, an insert-forming composition is a polymerizable composition for forming a silicone hydrogel material (any one of those described later in this application or known to a person skilled in the art).

In another preferred embodiment, an insert-forming composition is a polymerizable composition for forming a rigid gas permeable material (e.g., a material made from fluorosilicone acrylates or known to a person skilled in the art).

In another preferred embodiment, an insert-forming composition comprises at least one polymerizable photochromic compound (i.e., at least one photochromic vinylic monomer), at least one UV-absorbing vinylic monomer, at least one UV/HEVL-absorbing vinylic monomer, a fluorescent vinylic monomer, or combinations thereof.

In another preferred embodiment, an insert-forming composition comprises at least one photochromic dye or pigment, at least one color-filtering material for correcting color blindness, a diffractive material, a high refractive-index material, or combinations.

In another preferred embodiment, an insert-forming composition is a polymerizable composition for forming a hydrophobic crosslinked acrylic material that has an equilibrium water content of less than 5% by weight and comprises at least about 55% (preferably at least about 60%, more preferably at least about 65% even more preferably at least about 70%) by mole of one or more acrylic monomers and/or one or more acrylic crosslinker or crosslinking agent and at least about 6% by mole (preferably at least about 8% by mole, more preferably at least about 10% by mole, even more preferably at least about 12% by mole) of at least one vinylic crosslinking agent.

It is understood that the mole percentages of each of the components of the crosslinked polymeric material of an insert of the invention can be obtained based on the mole percentages of its corresponding polymerizable component (material) in a polymerizable composition for making the insert.

Any hydrophobic acrylic monomers can be used in forming a hydrophobic crosslinked acrylic material of the inventions. Examples of hydrophobic acrylic monomers includes silicone-containing acrylic monomers (any one of those described below in this application), non-silicone hydrophobic acrylic monomers (any one of those described below in this application), fluorine-containing acrylic monomers (any one of those described below in this application), aryl acrylic monomers (any one of those described below in this application), and combinations thereof.

It is also understood that any hydrophobic vinylic monomer can be used as a substitute for a hydrophobic acrylic monomer, so long as it comprises at least one H-bond acceptor such as ester bond, amide bond, carbonate bond, carbamate bond, ether bond, or combinations thereof. Examples of such hydrophobic monomers include vinyl alkanoates (any one of those described above in this application), vinyloxyalkanes (any one of those described above in this application), and combinations thereof.

In accordance with the invention, an insert-forming composition comprises at least one vinylic crosslinker. Any suitable vinyl crosslinkers can be used in the invention.

Examples of preferred vinylic crosslinkers include without limitation: acrylic crosslinkers (any one of those described later in this application), allyl methacrylate, allyl acrylate, an aryl crosslinker (e.g., divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, etc.), triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof. It is understood that vinylic crosslinkers are required for imparting the desired rigidity to the crosslinked polymeric material of the rigid hydrophobic insert.

In a preferred embodiment, an insert-forming composition comprises at least one acrylic crosslinker (any one of those described later in this application).

In another preferred embodiment, an insert-forming composition comprises at least one aryl crosslinker (any one of those described later in this application).

In another preferred embodiment, an insert-forming composition comprises at least one vinyl-functional polysiloxane that comprises at least two vinyl groups each directly attached to one silicon atom and at least 15% by mole of siloxane units each having at least one phenyl substituent.

Examples of such vinyl functional polysiloxanes 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), or combinations thereof. Preferably, the vinyl-functional polysiloxane is vinyl terminated polyphenylmethysiloxanes (e.g., PMV9925 from Gelest), vinylphenylmethyl terminated phenylmethyl-vinylphenylsiloxane copolymer (e.g., PVV-3522 from Gelest), or combinations thereof.

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

Lens-forming compositions (a.k.a., polymerizable compositions) are described in numerous patents and are well known to a person skilled in the art. There are generally two types of lens-forming compositions: the first for forming non-silicone hydrogel contact lenses (i.e., a non-silicone hydrogel bulk material in this application) and the other for forming silicone hydrogel contact lenses (i.e., a silicone hydrogel bulk material in this application).

Typically, a lens-forming composition for forming a non-silicone hydrogel bulk material is either (1) a monomer mixture comprising (a) at least one hydrophilic vinylic monomer (e.g., hydroxyl-containing vinylic monomer, N-vinyl amide monomer, (meth)acrylamido monomer, or combinations thereof), (b) a vinylic crosslinker, and (c) at least one component selected from the group consisting of a hydrophobic vinylic monomer, a free-radical initiator (photoinitiator or thermal initiator), a UV-absorbing vinylic monomer, a high-energy-violet-light ("HEVL") absorbing vinylic monomer, a visibility tinting agent, and combinations thereof; or (2) an aqueous solution comprising one or more water-soluble prepolymers and at least one component selected from the group consisting of hydrophilic vinylic monomer, a vinylic crosslinker, a hydrophobic vinylic monomer, a lubricating agent (or so-called internal wetting agents incorporated in a lens formulation), a free-radical initiator (photoinitiator or thermal initiator), a UV-absorbing vinylic monomer, a HEVL absorbing vinylic monomer, a visibility tinting agent, and combinations thereof.

Examples of water-soluble prepolymers include without limitation: a water-soluble crosslinkable poly(vinyl alcohol) prepolymer described in U.S. Pat. Nos. 5,583,163 and 6,303,687; a water-soluble vinyl group-terminated polyurethane prepolymer described in U.S. Pat. No. 6,995,192; derivatives of a polyvinyl alcohol, polyethyleneimine or polyvinylamine, which are disclosed in U.S. Pat. No. 5,849,841; a water-soluble crosslinkable polyurea prepolymer described in U.S. Pat. Nos. 6,479,587 and 7,977,430; crosslinkable polyacrylamide; crosslinkable statistical copolymers of vinyl lactam, MMA and a comonomer, which are disclosed in U.S. Pat. No. 5,712,356; crosslinkable copolymers of vinyl lactam, vinyl acetate and vinyl alcohol, which are disclosed in U.S. Pat. No. 5,665,840; polyether-polyester copolymers with crosslinkable side chains which are disclosed in U.S. Pat. No. 6,492,478; branched polyalkylene glycol-urethane prepolymers disclosed in U.S. Pat. No. 6,165,408; polyalkylene glycol-tetra(meth)acrylate prepolymers disclosed in U.S. Pat. No. 6,221,303; crosslinkable polyallylamine gluconolactone prepolymers disclosed in U.S. Pat. No. 6,472,489.

Numerous lens-forming compositions for forming non-silicone hydrogel bulk materials (contact lenses) have been described in numerous patents and patent applications published by the filing date of this application and have been used in producing commercial non-silicone hydrogel contact lenses. Examples of commercial non-silicone hydrogel contact lenses include, without limitation, alfilcon A, acofilcon A, deltafilcon A, etafilcon A, focofilcon A, helfilcon A, helfilcon B, hilafilcon B, hioxifilcon A, hioxifilcon B, hioxifilcon D, methafilcon A, methafilcon B, nelfilcon A, neso-filcon A, oculifilcon A, oculifilcon B, oculifilcon C, oculifilcon D, omafilcon A, phemfilcon A, polymacon, samfilcon A, telfilcon A, tetrafilcon A, and vifilcon A. They can be used as a lens-forming composition of the invention.

Preferably, a lens-forming composition for forming a non-silicone hydrogel bulk material comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer, preferably selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, N-2-hydroxyethyl (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl) methyl (meth)acrylamide, vinyl alcohol, allyl alcohol, and combinations thereof, more preferably selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, hydroxyethyl (meth)acrylamide, and vinyl alcohol.

Numerous lens-forming compositions for forming silicone hydrogel contact lenses (bulk materials) have been described in numerous patents and patent applications published by the filing date of this application and have been used in producing commercial SiHy contact lenses. Examples of commercial SiHy contact lenses include, without limitation, asmo-filcon A, balafilcon A, comfilcon A, delefilcon A, efrofilcon A, enfilcon A, fanfilcon A, galyfilcon A, lotrafilcon A, lotrafilcon B, nara-filcon A, nara-filcon B, senofilcon A, senofilcon B, senofilcon C, sma-filcon A, somofilcon A, and stenfilcon A. They can be used as a lens-forming composition of the invention.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material comprises (1) at least one polysiloxane vinylic monomer and/or at least one polysiloxane vinylic crosslinker and (2) at least one hydrophilic vinylic monomer.

Any polysiloxane vinylic monomers can be used in the invention. Examples of preferred polysiloxanes vinylic monomers include without limitation: those of formula (M1) which are described later in this application and can be obtained from commercial suppliers (e.g., Shin-Etsu, Gelest, etc.); those prepared according to procedures described in patents, e.g., U.S. Pat. Nos. 5,070,215, 6,166,236, 6,867,245, 8,415,405, 8,475,529, 8,614,261, and 9,217,813; those prepared by reacting a hydroxyalkyl (meth)acrylate or (meth)acrylamide or a (meth)acryloxypolyethylene glycol with a mono-epoxypropyloxypropyl-terminated polydimethylsiloxane; those prepared by reacting glycidyl (meth)acrylate with a mono-carbinol-terminated polydimethylsiloxane, a mono-aminopropyl-terminated polydimethylsiloxane, or a mono-ethylaminopropyl-terminated polydimethylsiloxane; and those prepared by reacting isocyanatoethyl (meth)acrylate with a mono-carbinol-terminated polydimethylsiloxane according to coupling reactions well known to a person skilled in the art.

Any suitable polysiloxane vinylic crosslinkers can be used in the invention. Examples of preferred polysiloxane vinylic crosslinkers include without limitation: polysiloxane vinylic crosslinkers each comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor (preferably hydroxyl groups); di-(meth)acryloyl-terminated polydimethylsiloxanes; di-vinyl carbonate-terminated polydimethylsiloxanes; di-vinyl carbamate-terminated polydimethylsiloxane; N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)-alpha,omega-bis-3-aminopropyl-polydimethylsiloxane; polysiloxane-containing macromer selected from the group consisting of Macromer A, Macromer B, Macromer C, and Macromer D described in U.S. Pat. No. 5,760,100; polysiloxane-containing macromers disclosed in U.S. Pat. Nos. 4,136,250, 4,153,641, 4,182,822, 4,189,546, 4,343,927, 4,254,248, 4,355,147, 4,276,402, 4,327,203, 4,341,889, 4,486,577, 4,543,398, 4,605,712, 4,661,575, 4,684,538, 4,703,097, 4,833,218, 4,837,289, 4,954,586, 4,954,587, 5,010,141, 5,034,461, 5,070,170, 5,079,319, 5,039,761, 5,346,946, 5,358,995, 5,387,632, 5,416,132, 5,451,617, 5,486,579, 5,962,548, 5,981,675, 6,039,913, and 6,762,264; polysiloxane-containing macromers disclosed in U.S. Pat. Nos. 4,259,467, 4,260,725, and 4,261,875.

One class of preferred polysiloxane vinylic crosslinkers are di-(meth)acryloyl-terminated polysiloxane vinylic crosslinkers each having dimethylsiloxane units and hydrophilized siloxane units each having one methyl substituent and one monovalent C<sub>4</sub>-C<sub>40</sub> organic radical substituent having 2 to 6 hydroxyl groups, more preferably a polysiloxane vinylic crosslinker of formula (G), as described later in this application. They can be prepared according to the procedures disclosed in U.S. patent Ser. No. 10/081,697.

Another class of preferred polysiloxane vinylic crosslinkers are vinylic crosslinkers each of which comprises one sole polydiorganosiloxane segment and two terminal (meth)acryloyl groups, which can be obtained from commercial suppliers; prepared by reacting glycidyl (meth)acrylate (meth)acryloyl chloride with a di-amino-terminated polydimethylsiloxane or a di-hydroxyl-terminated polydimethylsiloxane; prepared by reacting isocyanatoethyl (meth)acrylate with di-hydroxyl-terminated polydimethylsiloxanes prepared by reacting an amino-containing acrylic monomer with di-carboxyl-terminated polydimethylsiloxane in the presence of a coupling agent (a carbodiimide); prepared by reacting a carboxyl-containing acrylic monomer with di-amino-terminated polydimethylsiloxane in the presence of a

coupling agent (a carbodiimide); or prepared by reacting a hydroxyl-containing acrylic monomer with a di-hydroxy-terminated polydisiloxane in the presence of a diisocyanate or di-epoxy coupling agent.

Other classes of preferred polysiloxane vinylic crosslinkers are chain-extended polysiloxane vinylic crosslinkers each of which has at least two polydiorganosiloxane segments linked by a linker between each pair of polydiorganosiloxane segments and two terminal ethylenically unsaturated groups, which can be prepared according to the procedures described in U.S. Pat. Nos. 5,034,461, 5,416,132, 5,449,729, 5,760,100, 7,423,074, 8,529,057, 8,835,525, 8,993,651, 10,301,451, and 10,465,047.

Preferably, a lens forming composition for forming a silicone hydrogel bulk material comprises at least one first polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor (preferably hydroxyl groups).

Any hydrophilic vinylic monomers can be used in the invention. Examples of preferred hydrophilic vinylic monomers are alkyl (meth)acrylamides (as described later in this application), hydroxyl-containing acrylic monomers (as described below), amino-containing acrylic monomers (as described later in this application), carboxyl-containing acrylic monomers (as described later in this application), N-vinyl amide monomers (as described later in this application), methylene-containing pyrrolidone monomers (i.e., pyrrolidone derivatives each having a methylene group connected to the pyrrolidone ring at 3- or 5-position) (as described later in this application), acrylic monomers having a C<sub>1</sub>-C<sub>4</sub> alkoxyethoxy group (as described later in this application), vinyl ether monomers (as described later in this application), allyl ether monomers (as described later in this application), phosphorylcholine-containing vinylic monomers (as described later in this application), N-2-hydroxyethyl vinyl carbamate, N-carboxyvinyl-β-alanine (VINAL), N-carboxyvinyl-α-alanine, and combinations thereof.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can further comprise at least one silicone-containing vinylic monomer having a bis(trialkylsilyloxy)-alkylsilyl group or a tris(trialkylsilyloxy)silyl group. Examples of such preferred silicone-containing vinylic monomers include without limitation those of formula (M2), which are described later in this application and can be obtained from commercial suppliers (e.g., Shin-Etsu, Gelest, etc.) or can be prepared according to procedures described in U.S. Pat. Nos. 5,070,215, 6,166,236, 7,214,809, 8,475,529, 8,658,748, 9,097,840, 9,103,965, and 9,475,827.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprise one or more hydrophobic non-silicone vinylic monomers. 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-C<sub>2</sub>-C<sub>12</sub> alkyl (meth)acrylates described below, etc.), 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, isoputyl vinyl ether,

23

cyclohexyl vinyl ether, t-butyl vinyl ether, etc.), styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof.

Any suitable perfluoro-substituted-C<sub>2</sub>-C<sub>12</sub> alkyl (meth)acrylates can be used in the invention. Examples of perfluoro-substituted-C<sub>2</sub>-C<sub>12</sub> alkyl (meth)acrylates include without limitation 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.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprise one or more non-silicone vinylic crosslinkers.

Examples of preferred non-silicone vinylic crosslinkers are described later in this application.

In accordance with the invention, a lens-forming composition for forming a silicone hydrogel bulk material can also comprises other polymerizable materials, such as, a UV-absorbing vinylic monomer, a UV/high-energy-violet-light ("HEVL") absorbing vinylic monomer, polymerizable photochromic compound, a polymerizable tinting agent (polymerizable dye), or combinations thereof, as known to a person skilled in the art.

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'-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-

24

benzotriazole (UV23), 2-(2'-hydroxy-5-methacrylamidophenyl)-5-methoxybenzotriazole (UV6), 2-(3-allyl-2-hydroxy-5-methylphenyl)-2H-benzotriazole (UV9), 2-(2-Hydroxy-3-methyl-5-methylphenyl)-2H-benzotriazole (UV12), 2-3'-t-butyl-2'-hydroxy-5'-(3"-dimethylvinylsilylpropoxy)-2'-hydroxy-phenyl)-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. 4,929,693, 5,166,345 6,017,121, 7,556,750, 7,584,630, 7,999,989, 8,158,037, 8,697,770, 8,741,188, 9,052,438, 9,097,916, 9,465,234, 9,904,074, 10,197,707, 6,019,914, 6,113,814, 6,149,841, 6,296,785, and 6,348,604.

In accordance with the invention, the formed silicone hydrogel bulk material 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).

In accordance with the invention, a lens-forming composition of the invention must comprise a free-radical photoinitiators. Suitable photoinitiators are benzoin methyl ether, diethoxyacetophenone, a benzoyl-phosphine oxide, 1-hydroxycyclohexyl phenyl ketone and Darocur and Irgacur types, preferably Darocur 1173@ and Darocur 2959@, Germanium-based Norrish Type I photoinitiators (e.g., those



described in U.S. Pat. No. 7,605,190). Examples of benzo-ylphosphine initiators include 2,4,6-trimethylbenzoyldiphenylphosphine oxide; bis-(2,6-dichlorobenzoyl)-4-N-propylphenyl-phosphine oxide; and bis-(2,6-dichlorobenzoyl)-4-N-butylphenylphosphine oxide. Reactive photoinitiators

which can be incorporated, e.g., into a macromer or can be used as a special monomer are also suitable. Examples of reactive photoinitiators are those disclosed in EP632329.

Lens-forming compositions of the invention can be prepared by dissolving or blending all of the desirable components (or materials) in the presence or absence of a non-reactive diluent (solvent) as described later in this application.

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" or "non-reactive diluent" refers to a chemical that cannot participate in free-radical polymerization reaction.

A solventless lens SiHy lens formulation (silicone hydrogel 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.

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. More preferred organic solvents include without limitation methanol, ethanol, 1-propanol, isopropanol, sec-butanol, tert-butyl alcohol, tert-amyl alcohol, acetone, methyl ethyl ketone, methyl isopropyl ketone, methyl propyl ketone, ethyl acetate, heptane, methylhexane (various isomers), methylcyclohexane, dimethylcyclopentane (various isomers), 2,2,4-trimethylpentane, and mixtures thereof.

The insert-forming composition and the lens-forming composition can be introduced into the insert-molding cavity and the lens-molding cavity respectively according 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 insert mold half (i.e., the first male mold half having a second molding surface defining the posterior surface of an insert to be molded or the first female mold half having a first molding surface defining the anterior 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 two mold halves each having a molding surface defining one of the anterior and posterior surfaces of a contact lens to be molded. The overflow groove surrounds the molding surface defining one of the anterior and posterior surfaces of a contact lens to be molded.

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 is carried out thermally (i.e., by heating) to activate the polymerization initiators, as known to a person skilled in the art.

For example, the thermal curing of the insert-forming composition within the insert-molding cavity of the closed first molding assembly can be carried out conveniently in an oven at one or more temperatures 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 insert-forming composition and to carry out said polymerization reaction under an inert atmosphere, e.g., under N<sub>2</sub> or Ar atmosphere.

The curing of the lens-forming compositions within the lens-molding cavity of the closed second molding assembly is carried out actinically (i.e., by actinic radiation, e.g., UV radiation and/or visible radiation) to activate the polymerization initiators, as known to a person skilled in the art.

After the curing step, the steps of opening a mold (i.e., separating the male insert (lens) mold half from the female insert (lens) mold half with the insert (or lens embedded hydrogel lens precursor) attached onto one of the male and female insert (lens) mold halves and delensing (i.e., removing the insert (embedded hydrogel lens precursor) from the insert-adhered or lens-adhered mold half) are carried out according to any techniques known to a person skilled in the art.

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 having a molding defining the anterior surface of a contact lens to be molded (in one



aspect) or onto the male mold have a molding surface defining the posterior surface of a contact lens to be molded (in another aspect). Many techniques are known in the art. For example, the molding surface of the mold half designed to adhere the molded insert can be surface-treated to render the molded insert preferentially adhered to the molding surface of this mold half. Alternatively, a compression force can be applied by using a mold-opening device to non-optical surface (opposite to the molding surface) of the mold half (not adhering the molded insert) of the first molding assembly at a location about the center area of non-optical molding surface at an angle of less than about 30 degrees, preferably less than about 10 degrees, most preferably less than about 5 degrees (i.e., in a direction substantially normal to center area of non-optical molding surface) relative to the axis of the mold to deform the mold half, thereby breaking bonds between the molding surface of the mold half and the molded insert. Various ways of applying a force to non-optical surface of the mold half at a location about the center area of non-optical molding surface along the axis of the mold to deform the mold half which breaks the bonds between the optical molding surface of the mold half and the molded insert. It is understood that the mold-opening device can have any configurations known to a person skilled in the art for performing the function of separating two mold halves from each other.

Similarly, 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 hydrogel contact lens can be adhered onto either one of the two mold halves of the second molding assembly.

The embedded hydrogel 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 hydrogel 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 any solvent capable of dissolving the diluent(s), unpolymerized polymerizable materials, and oligomers in the embedded silicone hydrogel lens precursor. Water, any organic solvents known to a person skilled in the art, or a mixture thereof can be used in the invention. Preferably, the organic solvents used extraction liquid medium are water, a buffered saline, a C<sub>1</sub>-C<sub>3</sub> alkyl alcohol, 1,2-propylene glycol, a polyethyleneglycol having a number average molecular weight of about 400 Daltons or less, a C<sub>1</sub>-C<sub>6</sub> alkylalcohol, or combinations thereof.

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

The hydrated embedded hydrogel 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.

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 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, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light;
- (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 thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;
- (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 second free-radical photoinitiator;

- (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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first cross-linked polymeric material at repeating units of the first free-radical photoinitiator;
  - (9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves;
  - (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and
  - (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.
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 composition is pressed when the first molding assembly is closed securely, wherein any flushes formed from the excess insert-forming composition during step (4) can be stuck on the first male mold half during step of separating the first molding assembly halves, thereby removing the flushes.
  3. The method of embodiment 1 or 2, wherein the front surface of the insert merges with or is buried at a depth of less than about 10 microns beneath the anterior surface of the contact lens, and the curvature of the front surface of the insert is identical to the curvature of a central zone, which has a diameter of the insert, of the anterior surface of the contact lens.
  4. A method for producing embedded hydrogel 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, 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 on the first molding surface of the first female mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethyleneically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light;
- (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the first female mold half and the male mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;
- (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;
- (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 second free-radical photoinitiator;
- (7) placing the male mold half with the molded insert adhered thereon 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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first cross-linked polymeric material at repeating units of the first free-radical photoinitiator;
- (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the male and second female mold halves;
- (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half (preferably before the unprocessed embedded hydrogel contact lens is contact with water or any liquid); and
- (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

## 31

5. The method of embodiment 4, wherein the first female mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming composition is pressed when the first molding assembly is closed securely, wherein any flushes formed from the excess insert-forming material during step (4) can be stuck on the first female mold half during step of separating the first molding assembly halves, thereby removing the flushes.
6. The method of embodiment 4 or 5, wherein the back surface of the insert merges with or is buried at a depth of less than about 10 microns beneath the posterior surface of the contact lens, and the curvature of the back surface of the insert is identical to the curvature of a central zone, which has a diameter of the insert, of the posterior surface of the contact lens.
7. A method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of:
  - (1) obtaining an insert mold, wherein the insert mold comprises a male insert mold half having a first molding surface and a female insert mold half having a second molding surface are configured to receive each other such that an insert-molding cavity is formed between the first and second molding surfaces when the female insert mold half is closed with the male insert mold half;
  - (2) dispensing an insert-forming composition in the female insert mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light;
  - (3) closing the female insert mold half with the male insert mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity of the insert mold;
  - (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;
  - (5) obtaining a lens mold and a lens-forming composition, wherein the lens mold comprises a male lens mold half having a third molding surface and a female lens mold half having a fourth molding surface are configured to receive each other such that a lens-molding cavity is formed between the third and fourth molding surfaces when the female lens mold half is closed with the male lens mold half, wherein the lens-forming composition comprises at least one second polymerizable material and a second free-radical photoinitiator;
  - (6) in no particular order, placing the insert obtained in step (4) in the female lens mold half at a desired position and dispensing the lens-forming composition in the female lens mold half, wherein the insert is immersed in the lens-forming composition;
  - (7) closing the female lens mold half with the male lens mold half to form a second molding assembly comprising the lens-forming composition and the insert immersed therein in the lens-molding cavity of the lens mold;
  - (8) irradiating, with an UV and/or visible light, the lens-forming composition and the insert in the lens-

## 32

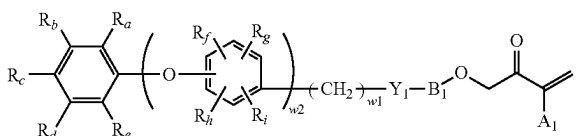
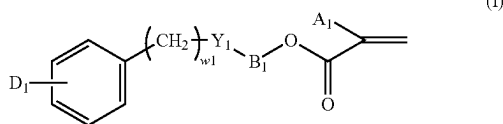
- molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprise a bulk hydrogel material formed from the lens-forming composition and the insert embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator;
- (9) separating the lens mold obtained in step (8) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered onto a lens-adhered lens mold half which is one of the male and female lens mold halves;
- (10) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half (preferably before the embedded hydrogel lens precursor is contact with water or any liquid); and
- (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.
8. The method of any one of embodiments 1 to 7, wherein the photoinitiator-moiety of the first free-radical photoinitiator is a monovalent radical of a benzophenone derivative, an  $\alpha$ -hydroxyketone, an  $\alpha$ -aminoketone, an acylphosphine oxide derivative, or an acylgermanium derivative.
9. The method of any one of embodiments 1 to 7, wherein the first free-radical photoinitiator is selected from the group consisting of 4-(meth)acryloyloxy benzophenone; 2-(meth)acryloyloxy benzophenone; 4-(meth)acryloyloxyethoxy benzophenone; 2,2-dimethyl-propionic acid 4-benzoyl-2-(1-methyl-allyl)-phenyl ester; 2,2-dimethyl-propionic acid 2-allyl-4-benzoyl-phenyl ester; 2,2-dimethyl-propionic acid 4-benzoyl-2-(2-methyl-allyl)-phenyl ester; 4-allyloxybenzophenone; 4-vinyloxybenzophenone; 2-(4-benzoylphenoxy)ethyl methacrylate; 4-methallyloxy-benzophenone; 2-methacryloxy-5-methyl benzophenone; 4-(4-benzoylphenoxy)butyl ester; 2-hydroxy-4-(methacryloyloxy) benzophenone; 2-Hydroxy-4-(methacryloyloxy) benzophenone; 2-hydroxy-2-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; (1-hydroxy-2-prop-2-enylcyclohexyl)-phenylmethanone; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; propan-2-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenyl-2-prop-1-en-2-ylphenyl)-2-hydroxy-2-methylpropan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylbutan-1-one; (1-hydroxy-4-prop-1-en-2-ylcyclohexyl)-phenylmethanone; (4-ethenyl-1-hydroxycyclohexyl)-phenylmethanone; 1-[4-(1-hydroxycyclohexanecarbonyl)phenyl]prop-2-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enoylphenyl)propan-1-one; 2-hydroxy-2-methyl-1-phenylhex-5-en-1-one; 2-ethyl-2-hydroxy-1-(4-prop-1-en-2-ylphenyl)hexan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylpropan-1-one; 2-hydroxy-2-methyl-1-(2-prop-1-en-2-ylphenyl)propan-1-one; (4-ethenylphenyl)-(1-hydroxycyclohexyl)methanone; 2-hydroxy-2-methyl-1-phenyl-3-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylpropan-1-one; 2-hydroxy-3-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2,3-dimethyl-1-

- phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylbutan-1-one; polymerizable acylphosphine oxide; and combinations thereof.
10. The method of any one of embodiments 1 to 9, wherein said at least one first polymerizable material comprises at least one polymerizable photochromic compound (i.e., photochromic vinylic monomer), at least one UV-absorbing vinylic monomer, at least one UV/HEVL-absorbing vinylic monomer, at least one fluorescent vinylic monomer, or combinations thereof.
  11. The method of any one of embodiments 1 to 10, wherein the insert-forming composition further comprises at least one color-filtering material for correcting color blindness, a diffractive material, a high refractive-index material, or combinations.
  12. The method of any one of embodiments 1 to 11, wherein the insert-forming composition is a polymerizable composition for forming a crosslinked polymethylmethacrylate, wherein said at least one first polymerizable material comprises methyl methacrylate and at least one vinylic crosslinker.
  13. The method of any one of embodiments 1 to 11, wherein the insert-forming composition is a polymerizable composition for forming a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight.
  14. The method of embodiment 13, wherein the crosslinked silicone polymer has an equilibrium water content of about 3% or less (preferably about 2% or less) by weight.
  15. The method of any one of embodiments 1 to 11, wherein the insert-forming composition is a polymerizable composition for forming a rigid gas permeable material.
  16. The method of any one of embodiments 1 to 11, wherein the insert-forming composition is a polymerizable composition for forming a hydrophobic crosslinked acrylic material that has an equilibrium water content of less than 5% by weight, and comprises at least 55% by mole of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of at least one vinylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.
  17. The method of embodiment 16, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 4% or less by weight.
  18. The method of embodiment 16, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 3% or less by weight.
  19. The method of embodiment 16, wherein the hydrophobic crosslinked acrylic material has an equilibrium water content of about 2% or less by weight.
  20. The method of any one of embodiments 16 to 19, wherein the insert-forming composition comprises at least about 60% by mole of said one or more acrylic monomers and/or said one or more acrylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.
  21. The method of any one of embodiments 16 to 19, wherein the insert-forming composition comprises at least about 65% by mole of said one or more acrylic monomers and/or said one or more acrylic crosslinker,

- relative to the total amount of said at least one first polymerizable material and other polymerizable materials.
22. The method of any one of embodiments 16 to 19, wherein the insert-forming composition comprises at least about 70% by mole of said one or more acrylic monomers and/or said one or more acrylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.
  23. The method of any one of embodiments 16 to 22, wherein the insert-forming composition comprises at least about 20% by mole of said at least one vinylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.
  24. The method of any one of embodiments 16 to 22, wherein the insert-forming composition comprises at least about 30% by mole of repeating units of said at least one vinylic crosslinking agent.
  25. The method of any one of embodiments 16 to 22, wherein the insert-forming composition comprises at least about 35% by mole of repeating units of said at least one vinylic crosslinking agent.
  26. The method of any one of embodiments 16 to 25, wherein said at least one vinylic crosslinker comprises at least one acrylic crosslinker.
  27. The method of embodiment 26, wherein said at least one acrylic crosslinker is ethylene glycol dimethacrylate; ethylene glycol diacrylate; 1,3-propanediol diacrylate; 1,3-propanediol dimethacrylate; 2,3-propanediol diacrylate; 2,3-propanediol dimethacrylate; 1,4-butanediol dimethacrylate; 1,4-butanediol diacrylate; 1,5-pentanediol dimethacrylate; 1,5-pentanediol diacrylate; 1,6-hexanediol dimethacrylate; 1,6-hexanediol diacrylate; diethylene glycol dimethacrylate; diethylene glycol diacrylate; triethylene glycol dimethacrylate; triethylene glycol diacrylate; tetraethylene glycol dimethacrylate; tetraethylene glycol diacrylate; N,N'-methylene bis(acrylamide); N,N'-methylene bis(methacrylamide); N,N'-ethylene bis(acrylamide); N,N'-ethylene bis(methacrylamide); N,N'-hexamethylene bisacrylamide; N,N'-hexamethylene bismethacrylamide; pentaerythritol triacrylate, pentaerythritol trimethacrylate, trimethyloxypropane triacrylate, trimethyloxypropane trimethacrylate, tris(2-hydroxyethyl) isocyanurate triacrylate, tris(2-hydroxyethyl) isocyanurate trimethacrylate, 1,3,5-triacryloylhexahydro-1,3,5-triazine, 1,3,5-trimethacryloylhexahydro-1,3,5-triazine; pentaerythritol tetraacrylate, pentaerythritol tetramethacrylate, di(trimethyloxypropane) tetraacrylate, di(trimethyloxypropane) tetramethacrylate, or combinations thereof.
  28. The method of embodiment 26, wherein said at least one acrylic crosslinker is allyl (meth)acrylate, pentaerythritol tetra(meth)acrylate, Neopentyl glycol di(meth)acrylate, an aryl crosslinking agent, triallyl isocyanurate, 2,4,6-triallyloxy-1,3,5-triazine, 1,2,4-trivinylcyclohexane, or combinations thereof.
  29. The method of any one of embodiments 16 to 28, wherein said at least one vinylic crosslinker comprises divinylbenzene, 2-methyl-1,4-divinylbenzene, bis(4-vinylphenyl)methane, 1,2-bis(4-vinylphenyl)ethane, or combinations thereof.

35

30. The method of any one of embodiments 16 to 29, wherein said at least one first polymerizable material comprises at least one silicone-containing acrylic monomer.
31. The method of any one of embodiments 16 to 30, wherein said at least one first polymerizable material comprises at least one fluorine-containing acrylic monomer.
32. The method of embodiment 31, wherein said at least one fluorine-containing acrylic monomer is perfluoro-hexylethyl-thio-carbonyl-aminoethyl-methacrylate, 2,2,2-trifluoroethyl (meth)acrylate, tetrafluoropropyl (meth)acrylate, hexafluoro-iso-propyl (meth)acrylate, hexafluorobutyl (meth)acrylate, heptafluorobutyl (meth)acrylate, octafluoropentyl (meth)acrylate, hepta-decafluorodecyl (meth)acrylate, pentafluorophenyl (meth)acrylate, or combinations thereof.
33. The method of any one of embodiments 16 to 32, wherein said at least one first polymerizable material comprises at least one polysiloxane vinylic crosslinker.
34. The method of any one of embodiments 16 to 33, wherein said at least one first polymerizable material comprises at least one aryl acrylic monomer of formula (I) or (II)



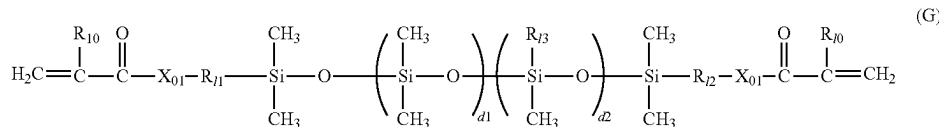
- wherein A<sub>1</sub> is H or CH<sub>3</sub> (preferably H); B<sub>1</sub> is (CH<sub>2</sub>)<sub>m1</sub> or [O(CH<sub>2</sub>)<sub>2</sub>]<sub>z1</sub> in which m1 is 2-6 and z1 is 1-10; Y<sub>1</sub> is a direct bond, O, S, or NR' in which R' is H, CH<sub>3</sub>, C<sub>n</sub>H<sub>2n+1</sub> in which n=1-10, iso-OC<sub>3</sub>H<sub>7</sub>, C<sub>6</sub>H<sub>5</sub>, or CH<sub>2</sub>C<sub>6</sub>H<sub>5</sub>; R<sub>a</sub>, R<sub>b</sub>, R<sub>c</sub>, R<sub>d</sub>, R<sub>e</sub>, R<sub>f</sub>, R<sub>g</sub>, R<sub>h</sub>, and R<sub>i</sub> independent of one another are H, C<sub>1</sub>-C<sub>12</sub> alkyl, or C<sub>1</sub>-C<sub>12</sub> alkoxy (preferably all are H); w<sub>1</sub> is 0-6, provided that m<sub>1</sub>+w<sub>1</sub> ≤ 8; w<sub>2</sub> is an integer from 1 to 3; and D<sub>1</sub> is H, Cl, Br, C<sub>1</sub>-C<sub>4</sub> alkyl, C<sub>1</sub>-C<sub>4</sub> alkoxy, C<sub>6</sub>H<sub>5</sub>, or CH<sub>2</sub>C<sub>6</sub>H<sub>5</sub>.
35. The method of embodiment 34, wherein said at least one aryl acrylic monomer is selected from the group consisting of 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 methacry-

36

- late; 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, and combinations thereof.
36. The method of any one of embodiments 16 to 35, wherein said at least one hydrophobic vinylic monomer selected from the group consisting of a vinyl alkanoate, a vinyloxyalkane, styrene, vinyl toluene, vinyl chloride, vinylidene chloride, 1-butene, and combinations thereof.
37. The method of any one of embodiments 16 to 36, wherein the hydrophobic insert is rigid.
38. The method of any one of embodiments 1 to 37, wherein the lens-forming composition comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer.
39. The method of embodiment 38, wherein said at least one hydroxyl-containing vinylic monomer is selected from the group consisting of hydroxyethyl (meth)acrylate, glycerol (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, N-2-hydroxyethyl (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, vinyl alcohol, allyl alcohol, and combinations thereof.
40. The method of any one of embodiments 1 to 37, wherein the lens-forming composition comprises (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.
41. The method of embodiment 40, wherein the lens-forming composition comprises at least one hydrophilized polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor.
42. The method of embodiment 41, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one hydroxyl groups.
43. The method of embodiment 41 or 42, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises a di-(meth)acryloyloxy-terminated polysiloxane vinylic crosslinker having dimethylsiloxane units and hydrophilized siloxane units each having one methyl substituent and one monovalent C<sub>4</sub>-C<sub>40</sub> organic radical substituent having 2 to 6 hydroxyl groups.

37

44. The method of any one of embodiments 41 to 43, wherein said at least one hydrophilized polysiloxane vinylic crosslinker comprises a vinylic crosslinker of formula (G)



in which:

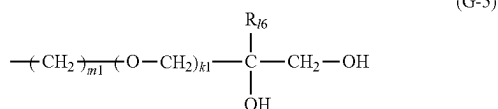
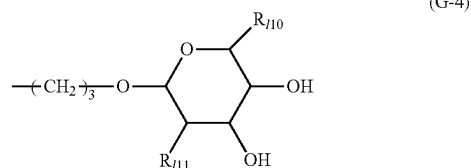
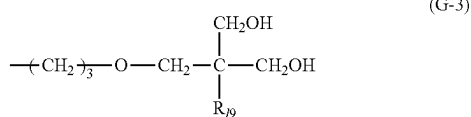
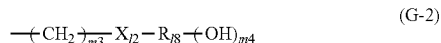
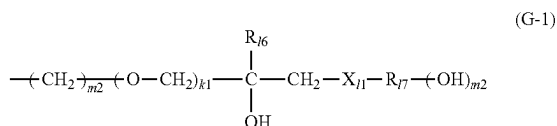
d1 is an integer of from 30 to 500 and d2 is an integer of from 1 to 75, provided that d2/d1 is from about 0.035 to about 0.15;

X<sub>01</sub> is O or NR<sub>13</sub> in which R<sub>13</sub> is hydrogen or C<sub>1</sub>-C<sub>10</sub>-alkyl;

R<sub>10</sub> is hydrogen or methyl;

R<sub>11</sub> and R<sub>12</sub> independently of each other are a substituted or unsubstituted C<sub>1</sub>-C<sub>10</sub> alkylene divalent radical or a divalent radical of —R<sub>14</sub>—O—R<sub>15</sub>— in which R<sub>14</sub> and R<sub>15</sub> independently of each other are a substituted or unsubstituted C<sub>1</sub>-C<sub>10</sub> alkylene divalent radical;

R<sub>13</sub> is a monovalent radical of any one of formula (G-1) to (G-5)



k1 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;

R<sub>16</sub> is hydrogen or methyl;

R<sub>17</sub> is a C<sub>2</sub>-C<sub>6</sub> hydrocarbon radical having (m2+1) valencies;

R<sub>18</sub> is a C<sub>2</sub>-C<sub>6</sub> hydrocarbon radical having (m4+1) valencies;

R<sub>19</sub> is ethyl or hydroxymethyl;

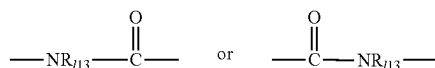
R<sub>110</sub> is methyl or hydromethyl;

R<sub>111</sub> is hydroxyl or methoxy;

38

X<sub>11</sub> is a sulfur linkage of —S— or a tertiary amino linkage of —NR<sub>12</sub>— in which R<sub>12</sub> is C<sub>1</sub>-C<sub>1</sub> alkyl, hydroxyethyl, hydroxypropyl, or 2,3-dihydroxypropyl; and

X<sub>12</sub> is an amide linkage of



in which R<sub>13</sub> is hydrogen or C<sub>1</sub>-C<sub>10</sub> alkyl.

45. The method of any one of embodiments 40 to 44, wherein the lens-forming composition comprises: a di-(meth)acryloyl-terminated polydimethylsiloxane, a di-vinyl carbonate-terminated polydimethylsiloxane; a di-vinyl carbamate-terminated polydimethylsiloxane; N,N,N',N'-tetrakis(3-methacryloxy-2-hydroxypropyl)-alpha,omega-bis-3-aminopropyl-polydimethylsiloxane, or a combination thereof.

46. The method of any one of embodiments 40 to 45, wherein the lens-forming composition 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 two terminal ethylenically-unsaturated groups selected from the group consisting of (meth)acryloyloxy groups, (meth)acryloylamino groups, vinyl carbonate groups, vinylcarbamate groups.

47. The method of any one of embodiments 40 to 45, wherein the lens-forming composition 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-isopropoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω-bis[3-(meth)acryloxybutyloxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω-bis[3-(meth)acrylamidoethoxy-2-hydroxypropyloxy-propyl]-terminated polydimethylsiloxane, α,ω-bis[3-(meth)acrylamidopropoxy-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane, α,ω-bis[3-(meth)acrylamidoisopropoxy-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,  $\alpha,\omega$ -bis[3-(meth)acryloxypropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[3-(meth)acryloxybutylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acrylamidoethylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[3-(meth)acrylamidopropylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[3-(meth)acrylamidebutylamino-2-hydroxypropyloxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxy-2-hydroxypropyloxy-ethoxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxy-2-hydroxypropyl-N-ethylaminopropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxy-2-hydroxypropyl-aminopropyl]-polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxyethylamino-carbonyloxy-ethoxypropyl]-terminated polydimethylsiloxane,  $\alpha,\omega$ -bis[(meth)acryloxyethylamino-carbonyloxy-(polyethylenoxy)propyl]-terminated polydimethylsiloxane, or combinations thereof.

48. The method of any one of embodiments 40 to 47, wherein said at least one hydrophilic vinylic monomer comprises: (1) an alkyl (meth)acrylamide selected from the group consisting of (meth)acrylamide, N,N-dimethyl (meth)acrylamide, N-ethyl (meth)acrylamide, N,N-diethyl (meth)acrylamide, N-propyl (meth)acrylamide, N-isopropyl (meth)acrylamide, N-3-methoxypropyl (meth)acrylamide, and combinations thereof; (2) a hydroxyl-containing acrylic monomer selected from the group consisting of N-2-hydroxyethyl (meth)acrylamide, N,N-bis(hydroxyethyl) (meth)acrylamide, N-3-hydroxypropyl (meth)acrylamide, N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihydroxypropyl (meth)acrylamide, N-tris(hydroxymethyl)methyl (meth)acrylamide, 2-hydroxyethyl (meth)acrylate, 3-hydroxypropyl (meth)acrylate, 2-hydroxypropyl (meth)acrylate, glycerol methacrylate (GMA), di(ethylene glycol) (meth)acrylate, tri(ethylene glycol) (meth)acrylate, tetra(ethylene glycol) (meth)acrylate, poly(ethylene glycol) (meth)acrylate having a number average molecular weight of up to 1500, poly(ethylene glycol)ethyl (meth)acrylamide having a number average molecular weight of up to 1500, and combinations thereof; (3) a carboxyl-containing acrylic monomer selected from the group consisting of 2-(meth)acrylamidoglycolic acid, (meth)acrylic acid, ethylacrylic acid, 3-(meth)acrylamidopropionic acid, 5-(meth)acrylamidopentanoic acid, 4-(meth)acrylamidobutanoic acid, 3-(meth)acrylamido-2-methylbutanoic acid, 3-(meth)acrylamido-3-methylbutanoic acid, 2-(meth)acrylamido-2methyl-3,3-dimethyl butanoic acid, 3-(meth)acrylamidohexanoic acid, 4-(meth)acrylamido-3,3-dimethylhexanoic acid, and combinations thereof; (4) an amino-containing acrylic monomer selected from the group consisting of N-2-aminoethyl (meth)acrylamide, N-2-methylaminoethyl (meth)acrylamide, N-2-ethylaminoethyl (meth)acrylamide, N-2-dimethylaminoethyl (meth)acrylamide, N-3-aminopropyl (meth)acrylamide, N-3-methylaminopropyl (meth)acrylamide, N-3-dimethylaminopropyl (meth)acrylamide, 2-aminoethyl (meth)acrylate, 2-methylaminoethyl (meth)acrylate, 2-ethylaminoethyl (meth)acrylate, 3-aminopropyl (meth)acrylate, 3-meth-

ylaminopropyl (meth)acrylate, 3-ethylaminopropyl (meth)acrylate, 3-amino-2-hydroxypropyl (meth)acrylate, trimethylammonium 2-hydroxy propyl (meth)acrylate hydrochloride, dimethylaminoethyl (meth)acrylate, and combinations thereof; (5) an N-vinyl amide monomer selected from the group consisting of N-vinylpyrrolidone (aka, N-vinyl-2-pyrrolidone), N-vinyl-3-methyl-2-pyrrolidone, N-vinyl-4-methyl-2-pyrrolidone, N-vinyl-5-methyl-2-pyrrolidone, N-vinyl-6-methyl-2-pyrrolidone, N-vinyl-3-ethyl-2-pyrrolidone, N-vinyl-4,5-dimethyl-2-pyrrolidone, N-vinyl-5,5-dimethyl-2-pyrrolidone, N-vinyl-3,3,5-trimethyl-2-pyrrolidone, N-vinyl piperidone (aka, N-vinyl-2-piperidone), N-vinyl-3-methyl-2-piperidone, N-vinyl-4-methyl-2-piperidone, N-vinyl-5-methyl-2-piperidone, N-vinyl-6-methyl-2-piperidone, N-vinyl-6-ethyl-2-piperidone, N-vinyl-3,5-dimethyl-2-piperidone, N-vinyl-4,4-dimethyl-2-piperidone, N-vinyl caprolactam (aka, N-vinyl-2-caprolactam), N-vinyl-3-methyl-2-caprolactam, N-vinyl-4-methyl-2-caprolactam, N-vinyl-7-methyl-2-caprolactam, N-vinyl-7-ethyl-2-caprolactam, N-vinyl-3,5-dimethyl-2-caprolactam, N-vinyl-4,6-dimethyl-2-caprolactam, N-vinyl-3,5,7-trimethyl-2-caprolactam, N-vinyl-N-methyl acetamide, N-vinyl formamide, N-vinyl acetamide, N-vinyl isopropylamide, N-vinyl-N-ethyl acetamide, N-vinyl-N-ethyl formamide, and mixtures thereof; (6) a methylene-containing pyrrolidone monomer selected from the group consisting of 1-methyl-3-methylene-2-pyrrolidone, 1-ethyl-3-methylene-2-pyrrolidone, 1-methyl-5-methylene-2-pyrrolidone, 1-ethyl-5-methylene-2-pyrrolidone, 5-methyl-3-methylene-2-pyrrolidone, 5-ethyl-3-methylene-2-pyrrolidone, 1-n-propyl-3-methylene-2-pyrrolidone, 1-n-propyl-5-methylene-2-pyrrolidone, 1-isopropyl-3-methylene-2-pyrrolidone, 1-isopropyl-5-methylene-2-pyrrolidone, 1-n-butyl-3-methylene-2-pyrrolidone, 1-tert-butyl-3-methylene-2-pyrrolidone, and combinations thereof; (7) an acrylic monomer having a  $C_1$ - $C_4$  alkoxyethoxy group and selected from the group consisting of ethylene glycol methyl ether (meth)acrylate, di(ethylene glycol) methyl ether (meth)acrylate, tri(ethylene glycol) methyl ether (meth)acrylate, tetra(ethylene glycol) methyl ether (meth)acrylate,  $C_1$ - $C_4$ -alkoxy poly(ethylene glycol) (meth)acrylate having a number average molecular weight of up to 1500, methoxy-poly(ethylene glycol)ethyl (meth)acrylamide having a number average molecular weight of up to 1500, and combinations thereof; (8) a vinyl ether monomer selected from the group consisting of ethylene glycol monovinyl ether, di(ethylene glycol) monovinyl ether, tri(ethylene glycol) monovinyl ether, tetra(ethylene glycol) monovinyl ether, poly(ethylene glycol) monovinyl ether, ethylene glycol methyl vinyl ether, di(ethylene glycol) methyl vinyl ether, tri(ethylene glycol) methyl vinyl ether, tetra(ethylene glycol) methyl vinyl ether, poly(ethylene glycol) methyl vinyl ether, and combinations thereof; (9) an allyl ether monomer selected from the group consisting of ethylene glycol monoallyl ether, di(ethylene glycol) monoallyl ether, tri(ethylene glycol) monoallyl ether, tetra(ethylene glycol) monoallyl ether, poly(ethylene glycol) monoallyl ether, ethylene glycol methyl allyl ether, di(ethylene glycol) methyl allyl ether, tri(ethylene glycol) methyl allyl ether, tetra(ethylene glycol) methyl allyl ether, poly(ethylene glycol) methyl allyl ether, and combinations thereof; (10) a phosphorylcho-

41

line-containing vinylic monomer selected from the group consisting of (meth)acryloyloxyethyl phosphor-  
ylcholine, (meth)acryloyloxypropyl phosphorylcho-  
line, 4-((meth)acryloyloxy)butyl-2'-(trimethylam-  
monio)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'-(trimethyl-  
ammonio)-ethylphosphate, 2-((meth)acryloyloxy)  
ethyl-2'-(triethylammonio)ethylphosphate, 2-((meth)  
acryloyloxy)ethyl-2'-(tripropylammonio)  
ethylphosphate, 2-((meth)acryloyloxy)ethyl-2'-  
(tributylammonio)ethyl phosphate, 2-((meth)  
acryloyloxy)propyl-2'-(trimethylammonio)-  
ethylphosphate, 2-((meth)acryloyloxy)butyl-2'-  
(trimethylammonio)ethylphosphate, 2-((meth)  
acryloyloxy)pentyl-2'-(trimethylammonio)  
ethylphosphate, 2-((meth)acryloyloxy)hexyl-2'-  
(trimethylammonio)ethyl phosphate, 2-(vinyloxy)  
ethyl-2'-(trimethylammonio)ethylphosphate,  
2-(allyloxy)ethyl-2'-(trimethylammonio)ethylphos-  
phate, 2-(vinyloxycarbonyl)ethyl-2'-(trimethylam-  
monio)ethyl phosphate, 2-(allyloxycarbonyl)ethyl-2'-  
(trimethylammonio)-ethylphosphate, 2-(vinylcarbonylamino)ethyl-2'-(trimethylammonio)  
ethylphosphate, 2-(allyloxycarbonylamino)ethyl-2'-  
(trimethylammonio)ethyl phosphate, 2-(butenoyloxy)  
ethyl-2-(trimethylammonio)ethylphosphate, and  
combinations thereof; (11) allyl alcohol; (12) N-2-  
hydroxyethyl vinyl carbamate; (13) N-carboxyvinyl- $\beta$ -  
alanine (VINAL); (14) N-carboxyvinyl- $\alpha$ -alanine; (15)  
or combinations thereof.

49. The method of any one of embodiments 40 to 47,  
wherein said at least one hydrophilic vinylic monomer  
comprises N-vinylpyrrolidone, N-vinyl-N-methyl acet-  
amide, or combinations thereof.

50. The method of any one of embodiments 40 to 49,  
wherein said at least one hydrophilic vinylic monomer  
comprises at least one (meth)acrylamido monomer  
selected from the group consisting of (meth)acrylam-  
ide, N,N-dimethyl (meth)acrylamide, N-ethyl (meth)  
acrylamide, N,N-diethyl (meth)acrylamide, N-propyl  
(meth)acrylamide, N-isopropyl (meth)acrylamide,  
N-3-methoxypropyl (meth)acrylamide, N-2-hydroxy-  
ethyl (meth)acrylamide, N,N-bis(hydroxyethyl) (meth)  
acrylamide, N-3-hydroxypropyl (meth)acrylamide,  
N-2-hydroxypropyl (meth)acrylamide, N-2,3-dihy-  
droxypropyl (meth)acrylamide, N-tris(hydroxymethyl)  
methyl (meth)acrylamide, 2-(meth)acrylamidoglycolic  
acid, 3-(meth)acrylamidopropionic acid, 5-(meth)acry-  
lamidopentanoic acid, 4-(meth)acrylamidobutanoic  
acid, 3-(meth)acrylamido-2-methylbutanoic acid,  
3-(meth)acrylamido-3-methylbutanoic acid, 2-(meth)  
acrylamido-2-methyl-3,3-dimethyl butanoic acid,  
3-(meth)acrylamidohexanoic acid, 4-(meth)acry-  
lamido-3,3-dimethylhexanoic acid, N-2-aminoethyl  
(meth)acrylamide, N-2-methylaminoethyl (meth)acry-  
lamide, N-2-ethylaminoethyl (meth)acrylamide, N-2-  
dimethylaminoethyl (meth)acrylamide, N-3-aminopro-  
pyl (meth)acrylamide, N-3-methylaminopropyl (meth)  
acrylamide, N-3-dimethylaminopropyl (meth)  
acrylamide, methoxy-poly(ethylene glycol)ethyl  
(meth)acrylamide having a number average molecular  
weight of up to 1500, and combinations thereof.

42

51. The method of any one of embodiments 40 to 49,  
wherein said at least one hydrophilic vinylic monomer  
comprises (meth)acrylamide, N,N-dimethyl (meth)  
acrylamide, N-ethyl (meth)acrylamide, N,N-diethyl  
(meth)acrylamide, N-propyl (meth)acrylamide, N-iso-  
propyl (meth)acrylamide, N-3-methoxypropyl (meth)  
acrylamide, N-2-hydroxyethyl (meth)acrylamide, or  
combinations thereof.

52. The method of any one of embodiments 40 to 51,  
wherein said at least one hydrophilic vinylic monomer  
comprises 2-hydroxyethyl (meth)acrylate, 3-hydroxy-  
propyl (meth)acrylate, 2-hydroxypropyl (meth)acry-  
late, glycerol methacrylate (GMA), di(ethylene glycol)  
(meth)acrylate, tri(ethylene glycol) (meth)acrylate, tetra-  
(ethylene glycol) (meth)acrylate, poly(ethylene gly-  
col) (meth)acrylate having a number average molecular  
weight of up to 1500, or combinations thereof.

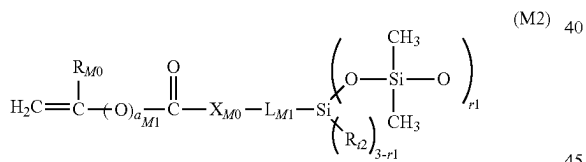
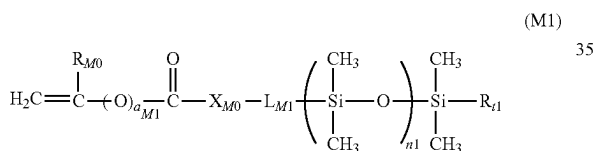
53. The method of any one of embodiments 40 to 52,  
wherein the lens-forming composition comprises at  
least one polysiloxane vinylic monomer selected from  
the group consisting of  $\alpha$ -(meth)acryloxypropyl termi-  
nated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethylsi-  
loxane,  $\alpha$ -(meth)acryloxy-2-hydroxypropyloxypropyl  
terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethyl-  
siloxane,  $\alpha$ -(2-hydroxyl-methacryloxypropyloxypro-  
pyl)- $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl-decamethylpentasiloxane,  $\alpha$ -[3-  
(meth)acryloxyethoxy-2-hydroxypropyloxypropyl]-  
terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -[3-(meth)acryloxy-propy-  
loxy-2-hydroxypropyloxypropyl]-terminated  $\omega$ -C<sub>1</sub>-  
C<sub>4</sub>-alkyl terminated polydimethylsiloxane,  $\alpha$ -[3-(meth)  
acryloxyisopropoxy-2-hydroxypropyloxypropyl]-  
terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -[3-(meth)acryloxybutyloxy-  
2-hydroxypropyloxypropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl  
terminated polydimethylsiloxane,  $\alpha$ -[3-(meth)acry-  
loxyethylamino-2-hydroxypropyloxypropyl]-  
terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -[3-(meth)acryloxypropy-  
lamino-2-hydroxypropyloxypropyl]-terminated  $\omega$ -C<sub>1</sub>-  
C<sub>4</sub>-alkyl terminated polydimethylsiloxane,  
 $\alpha$ -[3-(meth)acryloxy-butylamino-2-hydroxypropy-  
loxypropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -[3-(meth)acryloxy(polyethyl-  
enoxy)-2-hydroxypropyloxypropyl]-terminated  
 $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethylsiloxane,  
 $\alpha$ -[(meth)acryloxy-2-hydroxypropyloxy-ethoxypro-  
pyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydim-  
ethylsiloxane,  $\alpha$ -[(meth)acryloxy-2-hydroxypropyl-N-  
ethylaminopropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl  
terminated polydimethylsiloxane,  $\alpha$ -[(meth)acryloxy-  
2-hydroxypropyl-aminopropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-  
alkyl terminated polydimethylsiloxane,  $\alpha$ -[(meth)acry-  
loxy-2-hydroxypropyloxy-(polyethylenoxy)propyl]-  
terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -(meth)acryloylamidopropy-  
loxypropyl terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated  
polydimethylsiloxane,  $\alpha$ -N-methyl-(meth)acryloy-  
lamidopropyloxypropyl terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl  
terminated polydimethylsiloxane,  $\alpha$ -[3-(meth)acry-  
lamidoethoxy-2-hydroxypropyloxy-propyl]-terminated  
 $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl polydimethylsiloxane,  $\alpha$ -[3-(meth)  
acrylamidopropoxy-2-hydroxypropyloxypropyl]-termi-  
nated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethylsi-  
loxane,  $\alpha$ -[3-(meth)acrylamidoisopropoxy-2-  
hydroxypropyloxypropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl  
terminated polydimethylsiloxane,  $\alpha$ -[3-(meth)acry-



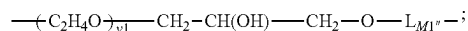
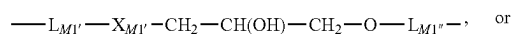
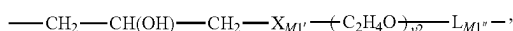
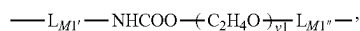
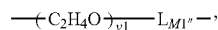
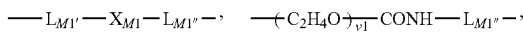
43

lamidobutyloxy-2-hydroxypropyloxypropyl]-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethylsiloxane,  $\alpha$ -[3-(meth)acryloylamido-2-hydroxypropyloxypropyl] terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl polydimethylsiloxane,  $\alpha$ -[3-[N-methyl-(meth)acryloylamido]-2-hydroxypropyloxypropyl] terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl terminated polydimethylsiloxane, N-methyl-N'-(propyltetra(dimethylsiloxy)dimethylbutylsilane) (meth)acrylamide, N-(2,3-dihydroxypropane)-N'-(propyltetra(dimethylsiloxy)dimethylbutylsilane) (meth)acrylamide, (meth)acryloylamidopropyltetra(dimethylsiloxy)dimethylbutylsilane,  $\alpha$ -vinyl carbonate-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl-terminated polydimethylsiloxanes,  $\alpha$ -vinyl carbamate-terminated  $\omega$ -C<sub>1</sub>-C<sub>4</sub>-alkyl-terminated polydimethylsiloxane, or a mixture thereof.

54. The method of any one of embodiments 40 to 53, wherein the lens-forming composition comprises at least one silicone-containing vinylic monomer selected from the group consisting of a vinylic monomer having a bis(trialkylsilyloxy)alkylsilyl group, a vinylic monomer having a tris(trialkylsilyloxy)silyl group, a polysiloxane vinylic monomer, 3-methacryloxy propylpentamethylsiloxane, t-butyl dimethyl-siloxyethyl vinyl carbonate, trimethylsilylethyl vinyl carbonate, and trimethylsilylmethyl vinyl carbonate, and combinations thereof.
55. The method of any one of embodiments 40 to 53, wherein the lens-forming composition comprises at least one silicone-containing vinylic monomer of formula (M1) or (M2)



in which:  $a_{\text{M1}}$  is zero or 1;  $\text{R}_{\text{M0}}$  is H or methyl;  $\text{X}_{\text{M0}}$  is O or  $\text{NR}_{\text{M1}}$ ;  $\text{L}_{\text{M1}}$  is a C<sub>2</sub>-C<sub>8</sub> alkylene divalent radical or a divalent radical of



$\text{L}_{\text{M1}'}$  is a C<sub>2</sub>-C<sub>8</sub> alkylene divalent radical which has zero or one hydroxyl group;  $\text{L}_{\text{M1}''}$  is C<sub>3</sub>-C<sub>8</sub> alkylene divalent radical which has zero or one hydroxyl group;  $\text{X}_{\text{M1}}$  is O,  $\text{NR}_{\text{M1}}$ ,  $\text{NHCOO}$ ,  $\text{OCONH}$ ,  $\text{CONR}_{\text{M1}}$ , or  $\text{NR}_{\text{M1}}\text{CO}$ ;  $\text{R}_{\text{M1}}$  is H or a C<sub>1</sub>-C<sub>4</sub> alkyl having 0 to 2 hydroxyl group;

44

$\text{R}_{t1}$  and  $\text{R}_{t2}$  independent of each other are a C<sub>1</sub>-C<sub>6</sub> alkyl;  $\text{X}_{\text{M1}'}$  is O or  $\text{NR}_{t1}$ ;  $v1$  is an integer of 1 to 30;  $m2$  is an integer of 0 to 30;  $n1$  is an integer of 3 to 40; and  $r1$  is an integer of 2 or 3.

56. The method of any one of embodiments 40 to 55, wherein the lens-forming composition comprises tris(trimethylsilyloxy)silylpropyl (meth)acrylate, [3-(meth)acryloxy-2-hydroxypropyloxy]propylbis(trimethylsiloxy)methylsilane, [3-(meth)acryloxy-2-hydroxypropyloxy]propylbis(trimethylsiloxy)butylsilane, 3-(meth)acryloxy-2-(2-hydroxyethoxy)-propyloxy]propylbis(trimethylsiloxy)methylsilane, 3-(meth)acryloxy-2-hydroxypropyloxy]propyltris(trimethylsiloxy)silane, N-[tris(trimethylsiloxy)silylpropyl]-(meth)acrylamide, N-(2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)propyl)-2-methyl (meth)acrylamide, N-(2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)-propyl) (meth)acrylamide, N-(2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl)-2-methyl acrylamide, N-(2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl) (meth)acrylamide, N-[tris(dimethylphenylsiloxy)-silylpropyl] (meth)acrylamide, N-[tris(dimethylethylsiloxy)-silylpropyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)-propyloxy)propyl]-2-methyl (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(bis(trimethylsilyloxy)methylsilyl)propyloxy)-propyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)-propyl]-2-methyl (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(tris(trimethylsilyloxy)silyl)propyloxy)propyl] (meth)acrylamide, N-[2-hydroxy-3-(3-(t-butyl dimethylsilyl)propyloxy)-propyl]-2-methyl (meth)acrylamide, N-[2-hydroxy-3-(3-(t-butyl dimethylsilyl)propyloxy)-propyl] (meth)acrylamide, N,N-bis[2-hydroxy-3-(3-(t-butyl dimethylsilyl)propyloxy)propyl]-2-methyl (meth)acrylamide, N-2-(meth)acryloxyethyl-O-(methyl-bis-trimethylsiloxy-3-propyl)silyl carbamate, 3-(trimethylsilyl)propylvinyl carbonate, 3-(vinylloxycarbonylthio)-propyl-tris(trimethyl-siloxy)silane, 3-[tris(trimethylsiloxy)silyl]propylvinyl carbamate, 3-[tris(trimethylsiloxy)silyl] propyl allyl carbamate, 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbonate, or a combination thereof.

57. The method of any one of embodiments 40 to 56, wherein the lens-forming composition comprises at least one non-silicone vinylic crosslinker.

58. The method of embodiment 57, wherein said at least one non-silicone vinylic crosslinker comprises ethyleneglycol di-(meth)acrylate, diethyleneglycol di-(meth)acrylate, triethyleneglycol di-(meth)acrylate, tetraethyleneglycol di-(meth)acrylate, glycerol di-(meth)acrylate, 1,3-propanediol di-(meth)acrylate, 1,3-butanediol di-(meth)acrylate, 1,4-butanediol 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, and 3,4-bis[(meth)acryloyl]tetrahydrofuran, 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)acrylam-

ideopropane-2-yl dihydrogen phosphate, piperazine diacrylamide, tetraethyleneglycol divinyl ether, triethyleneglycol divinyl ether, diethyleneglycol divinyl ether, ethyleneglycol divinyl ether, triallyl isocyanurate, triallyl cyanurate, trimethylopropane trimethacrylate, pentaerythritol tetramethacrylate, bisphenol A dimethacrylate, allylmethacrylate, allylacrylate, N-allyl-methacrylamide, N-allyl-acrylamide, or combinations thereof.

59. The method of any one of embodiments 40 to 58, wherein the lens-forming composition comprises at least one blending vinylic monomer.
60. The method of embodiment 59, wherein said at least one blending vinylic monomer comprises C<sub>1</sub>-C<sub>10</sub> alkyl (meth)acrylate, cyclopentylacrylate, cyclohexylmethacrylate, cyclohexylacrylate, 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 40 to 60, wherein the first and second lens-forming compositions comprise at least one polymerizable material selected from the group consisting of a UV-absorbing vinylic monomer, a UV/HEVL-absorbing vinylic monomer, a photochromic vinylic monomer, a polymerizable dye, and combinations thereof.
62. The method of any one of embodiments 40 to 61, wherein the bulk hydrogel material is a silicone hydrogel material that has an equilibrium water content (i.e., in fully hydrated state or when being fully hydrated) of from about 20% to about 70% by weight, an oxygen permeability of at least about 40 barrers, and a modulus (i.e., Young's modulus) of from about 0.2 MPa to about 1.5 MPa.

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<sub>i</sub> or Dk<sub>e</sub>) of an insert and an insert material are determined according to procedures described in ISO 18369-4.

##### Equilibrium Water Content

The equilibrium water content (EWC) of contact lenses is determined as follows.

Amount of water (expressed as percent by weight) present in a hydrated hydrogel contact lens, which is fully equilibrated in saline solution, is determined at room temperature. Quickly stack the lenses, and transfer the lens stack to the aluminum pan on the analytical balance after blotting lens in a cloth. The number of lenses for each sample pan is typically five (5). Record the pan plus hydrated weight of the lenses. Cover the pan with aluminum foil. Place pans in a laboratory oven at 100±2° C. to dry for 16-18 hours. Remove pan plus lenses from the oven and cool in a desiccator for at least 30 minutes. Remove a single pan from the desiccator, and discard the aluminum foil. Weigh the pan plus dried lens sample on an analytical balance. Repeat for

all pans. The wet and dry weight of the lens samples can be calculated by subtracting the weight of the empty weigh pan. Elastic Modulus

- The storage modulus (Young's modulus) of inserts is determined using a TA RSA-G2 DMA (Dynamic Mechanical Analyzer). The insert is cut into a 3.08 mm wide strip using Precision Concept dry lens cutter. Five thickness values are measured within 6.5 mm gauge length. The strip is mounted on the instrument with metal grips. Oscillation temperature ramp test with a linear ramping rate at 2° C./minute from 10° C.~50° C. is applied on the insert, the material response to increasing temperature is monitored at a constant frequency of 1 Hz, constant amplitude of 0.5% deformation and sampling rate of 10.0 pts/s. Storage modulus (E'), loss modulus (E'') and tan δ data are calculated by TRIOS software.

The elastic modulus of a silicone hydrogel material or contact lens is determined using a MTS insight instrument. The contact lens is first cut into a 3.12 mm wide strip using Precision Concept two stage cutter. Five thickness values are measured within 6.5 mm gauge length. The strip is mounted on the instrument grips and submerged in PBS (phosphate buffered saline) with the temperature controlled at 21±2° C. Typically 5N Load cell is used for the test. Constant force and speed is applied to the sample until the sample breaks. Force and displacement data are collected by the TestWorks software. The elastic modulus value is calculated by the TestWorks software which is the slope or tangent of the stress vs. strain curve near zero elongation, in the elastic deformation region.

##### Delamination

Embedded hydrogel 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.

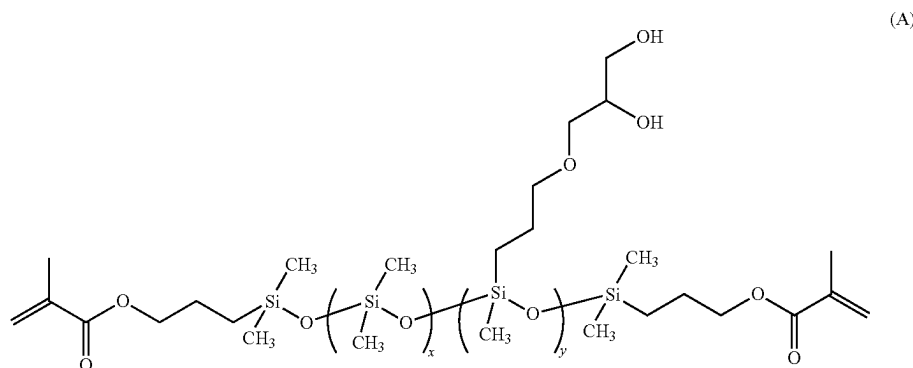
- OCT (Spectral Domain Optical Coherence Tomography; Telesto-II; Thorlabs) could also be utilized to study delamination. OCT allows non-invasive imaging of the contact lens to obtain high resolution cross-section image. For this purpose, after meeting the minimum staging requirement, the contact lens 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 ¾ 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: PEA represent phenylethyl acrylate; DMS-R11 represents amethacryloxypropyl-terminated polydimethylsiloxane (Mw~900-1000 Daltons); VAZO 67 represents 2,2'-azobis(2-methylbutyronitrile); Omnirad 1173 represents 2-hydroxy-2-methyl-1-phenyl-1-propanone; BPA represents 4-benzoylphenyl acrylate; DMA represents N,N-dimethyl acrylamide; MMA represent methyl methacrylate; EGBE

47

represents ethylene glycol butyl ether; PBS represents a phosphate-buffered saline which has a pH of  $7.2 \pm 0.2$  at  $25^\circ\text{C}$ . 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. %  $\text{NaCl}$  and; wt. % represents weight percent; TRIS-MA represents 3-[tris(trimethylsiloxy)silyl]propyl methacrylate; "HA" macromer represents a di-methacryloyloxypropyl-terminated polysiloxane ( $M_n \sim 7450\text{-}8150$  g/mol, OH content  $\sim 1.25\text{-}1.55$  meq/g) of formula (A) shown below; "H4" macromer represents a di-methacryloyloxypropyl-terminated polysiloxane ( $M_n \sim 11.3\text{K}\text{-}12.3\text{K}$  g/mol, OH content  $\sim 1.82\text{-}2.01$  meq/g) of formula (A) shown below.



Example 2

## Inserts

Rigid hydrophobic Inserts are prepared by thermal cast-molding of an insert-forming composition shown in Table 1.

TABLE 1

Insert-forming	Components (weight part units)			
Composition	PEA	DMS-R11	Vazo 67	BPA
IST-1	70	30	0.5	
IST-2	70	30	0.5	5

## Lens-Forming Compositions

Two lens-forming composition (i.e., SiHy lens formulation) are prepared at room temperature in air by blending all the components (materials).

The first lens-forming composition (LNS-1) has the following components: HA (32 weight unit parts); TRIS-MA (21 weight unit parts); DMA (24 weight unit parts); EGBE (22 weight unit parts); Omnicrad 1173 (1 weight unit part).

The second lens-forming composition (LNS-2) has the following components: H4 (40 weight unit parts); DMA (20 weight unit parts); MMA (15 weight unit parts); EGBE (34 weight unit parts); Omnicrad 1173 (1 weight unit part).

Example 3

## Preparation of Embedded Silicone Hydrogel Contact Lenses

An insert-forming composition prepared in Example 2 is purged with nitrogen at room temperature for 30 to 35 minutes. A specific volume (e.g., 30-40 mg) of the  $\text{N}_2$ -purged insert-forming composition is disposed in the center of the molding surface of a female lens mold half that is made of polypropylene and the molding surface defines the anterior surface of a contact lens to be molded. The

48

female lens mold half with the insert-forming composition therein is closed with a male insert mold half which is made of polypropylene and designed to have an overflow groove into which any excess insert-forming composition is pressed during closing for forming a first molding assembly. The male insert mold half has a molding surface defining the posterior surface of an insert to be molded. 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: purging the oven with  $\text{N}_2$  for about 30 minutes; ramp from room temperature to  $55^\circ\text{C}$ . at a ramp rate of about  $7^\circ\text{C./minute}$ ; holding at  $55^\circ\text{C}$ . for about 40 minutes; ramp from  $55^\circ\text{C}$ . to  $80^\circ\text{C}$ . at a ramp rate of about  $7^\circ\text{C./minute}$ ; holding at  $80^\circ\text{C}$ . for about 40 minutes; ramp from  $80^\circ\text{C}$ . to  $100^\circ\text{C}$ . at a ramp rate of about  $7^\circ\text{C./minute}$ ; and holding at  $100^\circ\text{C}$ . for about 40 minutes. The first molding assemblies are opened manually and the molded inserts are adhered onto the central area of the molding surface of the female lens mold halves.

A lens-forming composition 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  $\text{N}_2$ -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 male lens mold half which is made of polypropylene and designed to have an overflow groove into which any excess lens-forming composition is pressed during closing for forming a second molding assembly. The male lens mold half has a molding surface defining the posterior surface of a contact lens to be molded.

The lens-forming compositions in the second molding assemblies are cured actinically by using a Mercury lamp-based UV box at an intensity of approximately  $3\text{ mW/cm}^2$  for about 60 minutes to form embedded hydrogel lens precursors. The molding assemblies are opened manually and the molded embedded hydrogel lens precursors are adhere to the male mold halves or female mold halves.

The unprocessed embedded silicone hydrogel contact lenses molded from the lens forming composition LNS-1 are delensed by using liquid nitrogen. The delensed unprocessed embedded hydrogel lens precursors (molded from lens-

forming composition LBS-1) are subjected to the following extraction/hydration, coating, autoclave processes as follows. The unprocessed embedded hydrogel lens precursors are soaked in a bath containing deionized water for about 60 minutes, then in a bath containing an aqueous solution of polyacrylic acid (PAA, Mw 450K) at a concentration of ca. 0.1% by weight at room temperature for about 120 minutes, then in a bath containing a PBS solution at room temperature for about 60 minutes, then packed/sealed in polypropylene lens packaging shells (or blisters) (one lens per shell) with 0.65 mL of an in-package-coating packaging saline which is prepared according to the procedure described in Example 19 of U.S. Pat. No. 8,480,227, and finally autoclaved for about 45 minutes at 121° C. The resultant embedded SiHy contact lenses each have a hydrogel coating thereon.

The unprocessed embedded silicone hydrogel contact lenses molded from the lens forming composition LNS-2 are delensed by float-off (immersing in an extraction medium). The delensed unprocessed embedded hydrogel lens precursors (molded from lens-forming composition LBS-2) are subjected to the following extraction/hydration, coating, autoclave processes as follows. The unprocessed embedded hydrogel lens precursors are soaked in a bath containing an aqueous solution of Tween 80 (1% by weight) for about 60 minutes, then in a bath containing an aqueous solution of polyacrylic acid (PAA, Mw 450K) at a concentration of ca. 0.1% by weight at room temperature for about 120 minutes, then in a bath containing a PBS solution at room temperature for about 60 minutes, packed/sealed in polypropylene lens packaging shells (or blisters) (one lens per shell) with 0.65 mL of an in-package-coating packaging saline which is prepared according to the procedure described in Example 19 of U.S. Pat. No. 8,480,227, and finally autoclaved for about 45 minutes at 121° C. The resultant embedded SiHy contact lenses each have a hydrogel coating thereon.

Four groups of embedded SiHy contact lenses are obtained as shown in Table 2.

TABLE 2

Embedded SiHy Contact Lens	A	B	C	D
Insert-Forming Composition	IST-1	IST-2	IST-1	IST-2
Lens-Forming Composition	LNS-1	LNS-1	LNS-2	LNS-2

Embedded SiHy lenses A (inserts free of grafted photoinitiating moieties) are observed to have inserts peeling off after extraction and PAA-dip coating processes and also after autoclave.

Embedded SiHy lenses B (inserts comprising grafted photoinitiating moieties) are observed to have delamination bubbles, flat top but free of peeling off after extraction and PAA-dip coating processes, but have peeling off after autoclave.

Embedded SiHy lenses C (inserts free of grafted photoinitiating moieties) are observed to have inserts peeling off after extraction and PAA-dip coating processes and also after autoclave.

Embedded SiHy lenses D (inserts comprising grafted photoinitiating moieties) are observed to have no delamination bubbles, no flat top, no peeling off after extraction and PAA-dip coating processes, but have peeling off and no peeling off after autoclave.

The results indicates that the benzophenone photoinitiating moieties grafted onto inserts can improve the adhesion of the hydrogel bulk material to the insert embedded partially therewithin.

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 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, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethylenically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light;

(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 thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;

(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 at least one second polymerizable material and a second free-radical photoinitiator;

(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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprises a bulk hydrogel material formed from the lens-forming composition

51

and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator;

(9) separating the second molding assembly obtained in step (8) into the second male mold half and the female mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the female and second male mold halves;

(10) removing the embedded hydrogel lens precursor from the lens-adhered mold half; and

(11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

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 composition is pressed when the first molding assembly is closed securely, wherein any flushes formed from the excess insert-forming composition during step (4) can be stuck on the first male mold half during step of separating the first molding assembly halves, thereby removing the flushes.

3. The method of claim 1, wherein the front surface of the insert merges with or is buried at a depth of less than about 10 microns beneath the anterior surface of the contact lens, and the curvature of the front surface of the insert is identical to the curvature of a central zone, which has a diameter of the insert, of the anterior surface of the contact lens.

4. The method of claim 3, wherein the photoinitiator-moiety of the first free-radical photoinitiator is a monovalent radical of a benzophenone derivative, an  $\alpha$ -hydroxyketone, an  $\alpha$ -aminoketone, an acylphosphine oxide derivative, or an acylgermanium derivative.

5. The method of claim 4, wherein the first free-radical photoinitiator is selected from the group consisting of 4-(meth)acryloyloxy benzophenone; 2-(meth)acryloxy benzophenone; 4-(meth)acryloyloxyethoxy benzophenone; 2,2-dimethyl-propionic acid 4-benzoyl-2-(1-methyl-allyl)-phenyl ester; 2,2-dimethyl-propionic acid 2-allyl-4-benzoyl-phenyl ester; 2,2-dimethyl-propionic acid 4-benzoyl-2-(2-methyl-allyl)-phenyl ester; 4-allyloxybenzophenone; 4-vinyloxybenzophenone; 2-(4-benzoylphenoxy)ethyl methacrylate; 4-methallyloxy-benzophenone; 2-methacryloxy-5-methyl benzophenone; 4-(4-benzoylphenoxy)butyl ester; 2-hydroxy-4-(methacryloyloxy) benzophenone; 2-Hydroxy-4-(methacryloyloxy)benzophenone; 2-hydroxy-2-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; (1-hydroxy-2-prop-2-enylcyclohexyl)-phenylmethanone; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; propan-2-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenyl-2-prop-1-en-2-ylphenyl)-2-hydroxy-2-methylpropan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylbutan-1-one; (1-hydroxy-4-prop-1-en-2-ylcyclohexyl)-phenylmethanone; (4-ethenyl-1-hydroxycyclohexyl)-phenylmethanone; 1-[4-(1-hydroxycyclohexanecarbonyl)-phenyl]prop-2-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl)propan-1-one; 2-hydroxy-2-methyl-1-phenylhex-5-en-1-one; 2-ethyl-2-hydroxy-1-(4-prop-1-en-2-ylphenyl)hexan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylpropan-1-one; 2-hydroxy-2-methyl-1-(2-prop-1-en-2-ylphenyl)propan-1-one; (4-ethenylphenyl)-(1-hydroxy-cyclohexyl)methanone;

52

2-hydroxy-2-methyl-1-phenyl-3-(4-prop-1-en-2-ylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylpropan-1-one; 2-hydroxy-3-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2,3-dimethyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl)propan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylbutan-1-one; polymerizable acylphosphine oxide; and combinations thereof.

6. The method of claim 4, wherein the insert-forming composition is a polymerizable composition for forming a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight.

7. The method of claim 6, wherein the insert-forming composition is a polymerizable composition for forming a hydrophobic crosslinked acrylic material that comprises at least 55% by mole of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of at least one vinylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.

8. The method of claim 7, wherein said at least one first polymerizable material comprises at least one silicone-containing acrylic monomer, at least one fluorine-containing acrylic monomer; at least one polysiloxane vinylic crosslinker; or combinations thereof.

9. The method of claim 6, wherein the lens-forming composition comprises (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.

10. A method for producing embedded hydrogel 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, 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 on the first molding surface of the first female mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethyleneically-unsaturated group and a photoinitiator-moiety capable of generating free radicals upon irradiation by an UV and/or visible light;
- (3) placing the male mold half on top of the insert-forming composition in the first female mold half and closing the first female mold half and the male mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity;

- (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;
- (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 at least one second polymerizable material and a second free-radical photoinitiator;
- (7) placing the male mold half with the molded insert adhered thereon 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) irradiating, with an UV and/or visible light, the lens-forming composition in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprises a bulk hydrogel material formed from the lens-forming composition and the insert completely or partially embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator;
- (9) separating the second molding assembly obtained in step (8) into the second female mold half and the male mold half, with the embedded hydrogel lens precursor adhered on a lens-adhered mold half which is one of the male and second female mold halves;
- (10) removing the embedded hydrogel lens precursor from the lens-adhered mold half; and
- (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

11. The method of claim 10, wherein the first female mold half comprise an overflow groove which surrounds the molding surface and into which any excess insert-forming composition is pressed when the first molding assembly is closed securely, wherein any flushes formed from the excess insert-forming material during step (4) can be stuck on the first female mold half during step of separating the first molding assembly halves, thereby removing the flushes.

12. The method of claim 11, wherein the back surface of the insert merges with or is buried at a depth of less than about 10 microns beneath the posterior surface of the contact lens, and the curvature of the back surface of the insert is identical to the curvature of a central zone, which has a diameter of the insert, of the posterior surface of the contact lens.

13. The method of claim 12, wherein the photoinitiator-moiety of the first free-radical photoinitiator is a monovalent radical of a benzophenone derivative, an  $\alpha$ -hydroxyketone, an  $\alpha$ -aminoketone, an acylphosphine oxide derivative, or an acylgermanium derivative.

14. The method of claim 13, wherein the first free-radical photoinitiator is selected from the group consisting of 4-(meth)acryloyloxy benzophenone; 2-(meth)acryloxy ben-

zophenone); 4-(meth)acryloyloxyethoxy benzophenone; 2,2-dimethyl-propionic acid 4-benzoyl-2-(1-methyl-allyl)-phenyl ester; 2,2-dimethyl-propionic acid 2-allyl-4-benzoyl-phenyl ester; 2,2-dimethyl-propionic acid 4-benzoyl-2-(2-methyl-allyl)-phenyl ester; 4-allyloxybenzophenone; 4-vinylxybenzophenone; 2-(4-benzoylphenoxy)ethyl methacrylate; 4-methallyloxy-benzophenone; 2-methacryloxy-5-methyl benzophenone; 4-(4-benzoylphenoxy)butyl ester; 2-hydroxy-4-(methacryloyloxy) benzophenone; 2-Hydroxy-4-(methacryloyloxy)benzophenone; 2-hydroxy-2-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; (1-hydroxy-2-prop-2-enylcyclohexyl)-phenylmethanone; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; propan-2-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; 1-(4-ethenyl-2-prop-1-en-2-ylphenyl)-2-hydroxy-2-methylpropan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylbutan-1-one; (1-hydroxy-4-prop-1-en-2-ylcyclohexyl)-phenylmethanone; (4-ethenyl-1-hydroxycyclohexyl)-phenylmethanone; 1-[4-(1-hydroxycyclohexanecarbonyl)-phenyl]prop-2-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enoylphenyl) propan-1-one; 2-hydroxy-2-methyl-1-phenylhex-5-en-1-one; 2-ethyl-2-hydroxy-1-(4-prop-1-en-2-ylphenyl) hexan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylpropan-1-one; 2-hydroxy-2-methyl-1-(2-prop-1-en-2-ylphenyl) propan-1-one; (4-ethenylphenyl)-(1-hydroxy-cyclohexyl) methanone; 2-hydroxy-2-methyl-1-phenyl-3-(4-prop-1-en-2-ylphenyl) propan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylpropan-1-one; 2-hydroxy-3-methyl-1-phenyl-pent-4-en-1-one; 2-hydroxy-2,3-dimethyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl) propan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylbutan-1-one; polymerizable acylphosphine oxide; and combinations thereof.

15. The method of claim 13, wherein the insert-forming composition is a polymerizable composition for forming a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight.

16. The method of claim 15, wherein the insert-forming composition is a polymerizable composition for forming a hydrophobic crosslinked acrylic material that comprises at least 55% by mole of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of at least one vinylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.

17. The method of claim 16, wherein said at least one first polymerizable material comprises at least one silicone-containing acrylic monomer, at least one fluorine-containing acrylic monomer; at least one polysiloxane vinylic crosslinker; or combinations thereof.

18. The method of claim 15, wherein the lens-forming composition comprises (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.

19. A method for producing embedded hydrogel contact lenses, the method of invention comprising the steps of:

- (1) obtaining an insert mold, wherein the insert mold comprises a male insert mold half having a first molding surface and a female insert mold half having a second molding surface that are configured to receive each other such that an insert-molding cavity is formed

55

- between the first and second molding surfaces when the female insert mold half is closed with the male insert mold half;
- (2) dispensing an insert-forming composition in the female insert mold half, wherein the insert-forming composition comprises (i) at least one first polymerizable material, (ii) a thermal free-radical initiator, and (iii) a first free-radical photoinitiator that comprises an ethyleneically-unsaturated group and a photoinitiator moiety capable of generating free radicals upon irradiation by an UV and/or visible light;
  - (3) closing the female insert mold half with the male insert mold half to form a first molding assembly comprising the insert-forming composition within the insert-molding cavity of the insert mold;
  - (4) curing thermally the insert-forming composition in the insert-molding cavity of the first molding assembly to form a molded insert that is made of a first crosslinked polymeric material that comprises repeating units of the first free-radical photoinitiator;
  - (5) obtaining a lens mold and a lens-forming composition, wherein the lens mold comprises a male lens mold half having a third molding surface and a female lens mold half having a fourth molding surface are configured to receive each other such that a lens-molding cavity is formed between the third and fourth molding surfaces when the female lens mold half is closed with the male lens mold half, wherein the lens-forming composition comprises at least one second polymerizable material and a second free-radical photoinitiator;
  - (6) in no particular order, placing the insert obtained in step (4) in the female lens mold half at a desired position and dispensing the lens-forming composition in the female lens mold half, wherein the insert is immersed in the lens-forming composition;
  - (7) closing the female lens mold half with the male lens mold half to form a second molding assembly comprising the lens-forming composition and the insert immersed therein in the lens-molding cavity of the lens mold;
  - (8) irradiating, with an UV and/or visible light, the lens-forming composition and the insert in the lens-molding cavity of the second molding assembly to form an embedded hydrogel lens precursor that comprises a bulk hydrogel material formed from the lens-forming composition and the insert embedded in the bulk material, wherein the bulk hydrogel material is a second crosslinked polymeric material that is covalently linked to the first crosslinked polymeric material at repeating units of the first free-radical photoinitiator;
  - (9) separating the lens mold obtained in step (8) into the male and female lens mold halves, with the embedded hydrogel lens precursor adhered onto a lens-adhered lens mold half which is one of the male and female lens mold halves;
  - (10) removing the embedded hydrogel lens precursor from the lens-adhered lens mold half; and
  - (11) subjecting the embedded hydrogel lens precursor to post-molding processes including a hydration process and one or more other processes selected from the group consisting of extraction, surface treatment, packaging, sterilization, and combinations thereof to form the embedded hydrogel contact lens.

20. The method of claim 19, wherein the photoinitiator moiety of the first free-radical photoinitiator is a monovalent

56

radical of a benzophenone derivative, an  $\alpha$ -hydroxyketone, an  $\alpha$ -aminoketone, an acylphosphine oxide derivative, or an acylgermanium derivative.

21. The method of claim 20, wherein the first free-radical photoinitiator is selected from the group consisting of 4-(meth)acryloyloxy benzophenone; 2-(meth)acryloxy benzophenone; 4-(meth)acryloyloxyethoxy benzophenone; 2,2-dimethyl-propionic acid 4-benzoyl-2-(1-methyl-allyl)-phenyl ester; 2,2-dimethyl-propionic acid 2-allyl-4-benzoyl-phenyl ester; 2,2-dimethyl-propionic acid 4-benzoyl-2-(2-methyl-allyl)-phenyl ester; 4-allyloxybenzophenone; 4-vinylloxybenzophenone; 2-(4-benzoylphenoxy)ethyl methacrylate; 4-methallyloxy-benzophenone; 2-methacryloxy-5-methyl benzophenone; 4-(4-benzoylphenoxy)butyl ester; 2-hydroxy-4-(methacryloyloxy) benzophenone; 2-Hydroxy-4-(methacryloyloxy)benzophenone; 2-hydroxy-2-methyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; (1-hydroxy-2-prop-2-enylcyclohexyl)-phenylmethanone; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; propan-2-one; 2-hydroxy-2-methyl-1-(4-prop-1-en-2-ylphenyl) propan-1-one; 1-(4-ethenyl-2-prop-1-en-2-ylphenyl)-2-hydroxy-2-methylpropan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylbutan-1-one; (1-hydroxy-4-prop-1-en-2-ylcyclohexyl)-phenylmethanone; (4-ethenyl-1-hydroxycyclohexyl)-phenylmethanone; 1-[4-(1-hydroxycyclohexanecarbonyl)-phenyl]prop-2-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl) propan-1-one; 2-hydroxy-2-methyl-1-phenylhex-5-en-1-one; 2-ethyl-2-hydroxy-1-(4-prop-1-en-2-ylphenyl) hexan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylpropan-1-one; 2-hydroxy-2-methyl-1-(2-prop-1-en-2-ylphenyl) propan-1-one; (4-ethenylphenyl)-(1-hydroxy-cyclohexyl) methanone; 2-hydroxy-2-methyl-1-phenyl-3-(4-prop-1-en-2-ylphenyl) propan-1-one; 1-(4-ethenylphenyl)-2-hydroxy-2-methylpropan-1-one; 2-hydroxy-3-methyl-1-phenyl-pent-4-en-1-one; 2-hydroxy-2,3-dimethyl-1-phenylpent-4-en-1-one; 2-hydroxy-2-methyl-1-(4-prop-2-enylphenyl) propan-1-one; 1-(4-ethenylphenyl)-2-methoxy-2-methylbutan-1-one; polymerizable acylphosphine oxide; and combinations thereof.

22. The method of claim 20, wherein the insert-forming composition is a polymerizable composition for forming a crosslinked silicone polymer that has three-dimensional polymer networks, is insoluble in water, and has an equilibrium water content of about 5% or less by weight.

23. The method of claim 22, wherein the insert-forming composition is a polymerizable composition for forming a hydrophobic crosslinked acrylic material that comprises at least 55% by mole of one or more acrylic monomers and/or one or more acrylic crosslinker and at least about 6% by mole of at least one vinylic crosslinker, relative to the total amount of said at least one first polymerizable material and other polymerizable materials.

24. The method of claim 23, wherein said at least one first polymerizable material comprises at least one silicone-containing acrylic monomer, at least one fluorine-containing acrylic monomer; at least one polysiloxane vinylic crosslinker; or combinations thereof.

25. The method of claim 22, wherein the lens-forming composition comprises at least 50% by mole of at least one hydroxyl-containing vinylic monomer.

26. The method of claim 22, wherein the lens-forming composition comprises (a) at least one polysiloxane vinylic monomer and/or at least one first polysiloxane vinylic crosslinker and (b) at least one hydrophilic vinylic monomer.

57

27. The method of claim 26, wherein the lens-forming composition comprises at least one hydrophilized polysiloxane vinylic crosslinker comprising hydrophilized siloxane units each having one methyl substituent and one organic radical including at least one H-bond donor. 5

28. The method of claim 26, wherein the bulk hydrogel material is a silicone hydrogel material that has an equilibrium water content of from about 20% to about 70% by weight, an oxygen permeability of at least about 40 barrers, and a modulus of from about 0.2 MPa to about 1.5 MPa. 10

\* \* \* \* \*

58