

POLYSILSESQUIOXANE CONTAINING POLYMERIC COMPOSITIONS

Field of the Invention:

The present invention relates to polymeric compositions useful in the manufacture of biocompatible medical devices. More particularly, the present invention relates to the use of reactive polyhedral oligomeric silsesquioxanes with definite structures as reinforcing agents for silicone compositions having desirable physical characteristics and refractive indices for use in the manufacture of ophthalmic implants.

Background of the Invention:

Since the 1940's optical devices in the form of intraocular lens (IOL) implants have been utilized as replacements for diseased or damaged natural ocular lenses. In most cases, an intraocular lens is implanted within an eye at the time of surgically removing the diseased or damaged natural lens, such as for example, in the case of cataracts. For decades, the preferred material for fabricating such intraocular lens implants was poly(methyl methacrylate), which is a rigid, glassy polymer.

Softer, more flexible IOL implants have gained in popularity in more recent years due to their ability to be compressed, folded, rolled or otherwise deformed. Such softer IOL implants may be deformed prior to insertion thereof through an incision in the cornea of an eye. Following insertion of the IOL in an eye, the IOL returns to its original pre-deformed shape due to the memory characteristics of the soft material. Softer, more flexible IOL implants as just described may be implanted into an eye through an incision that is much smaller, i.e., less than 4.0 mm, than that necessary for more rigid IOLs, i.e., 5.5 to 7.0 mm. A larger incision is necessary for more rigid IOL implants because the lens must be inserted through an incision in the cornea slightly larger than the diameter of the inflexible IOL optic portion. Accordingly, more rigid IOL implants have become less popular in the market since larger incisions have been found to be associated with an increased incidence of postoperative complications, such as induced astigmatism.

With recent advances in small-incision cataract surgery, increased emphasis has been placed on developing soft, foldable materials suitable for use in artificial IOL implants. In general, the materials of current commercial IOLs fall into one of three categories: silicones, hydrophilic acrylics and hydrophobic acrylics.

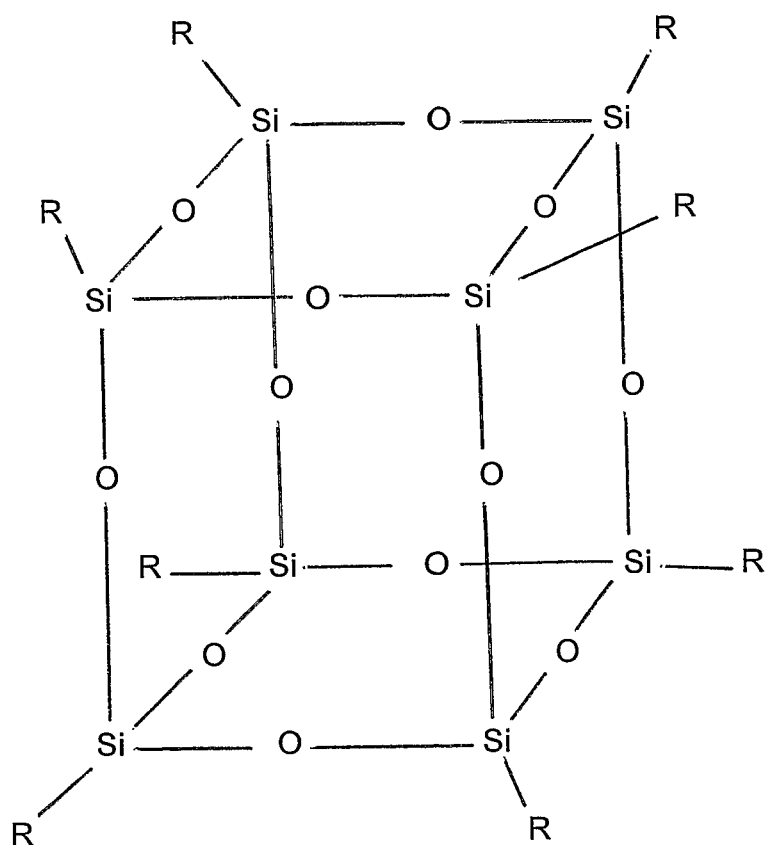
In general, high water content hydrophilic acrylics, or "hydrogels," have relatively low refractive indices, making them less desirable than other materials with respect to minimal incision size. Low refractive index materials require a thicker IOL optic portion to achieve a given refractive power. Silicone elastomers are usually fabricated from the hydrosilation of a vinyl-containing polysiloxane and a hydrosilane-containing polysiloxane. Elastomers so produced are rather weak mechanically, unless a reinforcing agent, typically a silica, is included in the formulation. Silicone elastomers that include such a reinforcing agent are currently used and commercially available through such products as the SilsoftTM contact lens (Bausch & Lomb Incorporated, Rochester, New York) and the ChiroflexTM intraocular lens (Bausch & Lomb Incorporated, Rochester, New York). Low glass transition temperature hydrophobic acrylic materials are desirable because they typically have a high refractive index and unfold more slowly and more controllably than silicone materials. Unfortunately, low glass transition temperature hydrophobic acrylic materials, which contain little or no water initially, may absorb pockets of water *in vivo* causing light reflections or "glistenings." Furthermore, it may be difficult to achieve ideal folding and unfolding characteristics due to the temperature sensitivity of some acrylic polymers.

Because of the noted shortcomings or difficulties associated with current polymeric materials available for use in the manufacture of ophthalmic devices, there is a need for stable, biocompatible polymeric materials having desirable physical characteristics and refractive indices.

Summary of the Invention:

Soft, foldable, high elongation, polymeric compositions of the present invention are synthesized through hydrosilation, epoxy reaction, urethane/urea formation, free radical copolymerization or other types of reactions. Production processes of the present invention using reactive polyhedral oligomeric silsesquioxanes (POSS) with definite structures as reinforcing agents, produce polymeric compositions having desirable physical properties for use in the manufacture of ophthalmic devices. The polymeric compositions of the present invention are transparent and have relatively high strength for durability during surgical manipulation, relatively high elongation and relatively high refractive index. The subject polymeric compositions are particularly well suited for use in the manufacture of ophthalmic devices such as intraocular lens (IOL) implants, keratoprotheses, corneal rings, corneal inlays and the like.

Preferred reactive polyhedral oligomeric silsesquioxanes for use as a reinforcing agent in the production of the polymeric compositions of present invention have a structure generally represented by Formula 1 below:



Formula 1

wherein the R groups may be the same or different with at least one of the R groups being a reactive group, R reactive groups may be the same or different selected from the group consisting of hydrogen, hydroxy, alkoxy, amine, chlorine, epoxide, isocyanate, methacrylate, acrylate, methacrylamine, acrylamide, nitrile, norbornenyl, vinyl, styrenyl and thiol; R nonreactive groups may be the same or different selected from the group consisting of C₁₋₃₀ alkyl and C₆₋₃₀ aryl.

As illustrated by the structure of Formula 1, all eight silicone atoms together form a cubic cage or a "T8" structure. T8 is used to describe the subject structure wherein the "T" refers to three oxygen atoms connecting to each silicon atom and "8" refers to eight silicone atoms forming a cage. If one silicone atom is removed from the T8 structure to leave an "open position", the open position of the remaining T7 structure is replaced with an R group as defined above.

Accordingly, it is an object of the present invention to provide transparent, biocompatible polymeric compositions having desirable physical characteristics and relatively high refractive indices.

Another object of the present invention is to provide polymeric compositions having relatively high elasticity and good clarity.

Another object of the present invention is to provide polymeric compositions suitable for use in the manufacture of ophthalmic devices.

Another object of the present invention is to provide polymeric compositions suitable for use in the manufacture of intraocular lens implants.

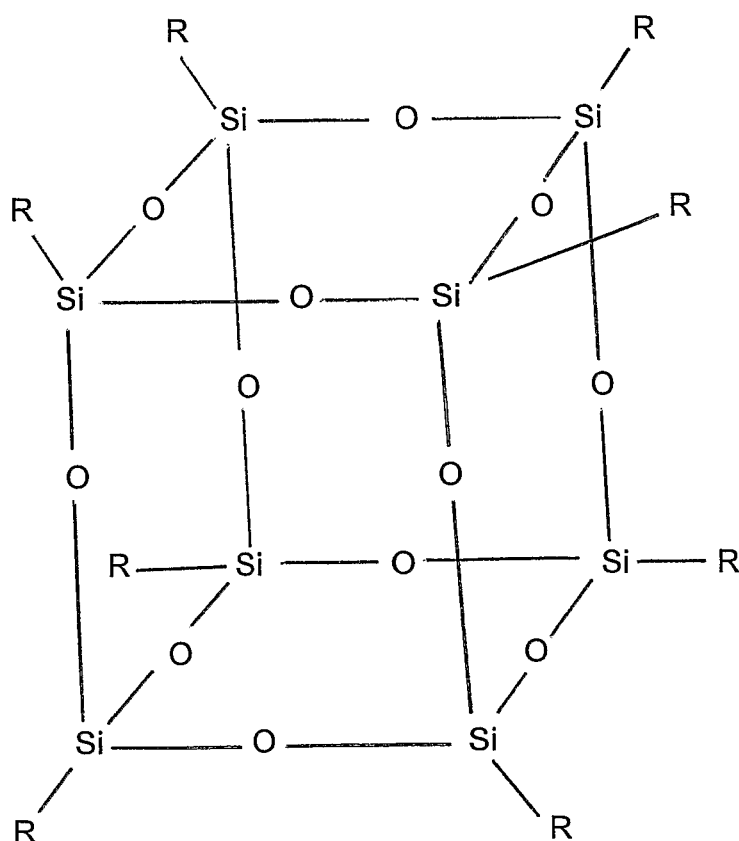
Still another object of the present invention is to provide polymeric compositions that are economical to produce.

These and other objectives and advantages of the present invention, some of which are specifically described and others that are not, will become apparent from the detailed description and claims that follow.

Detailed Description of the Invention:

Silicone elastomers are usually fabricated from the hydrosilation of a vinyl-containing polysiloxane and a hydrosilane-containing polysiloxane. Elastomers so produced are rather weak mechanically, unless a reinforcing agent, typically a silica, is included in the formulation. Accordingly, the present invention relates to the use of reactive polyhedral oligomeric silsesquioxanes (POSS) with definite structures as reinforcing agents for silicone elastomers. Each POSS molecule has at least one reactive group. The POSS of the present invention are useful as reinforcing agents in polymeric compositions suitable for use in the manufacture of ophthalmic devices such as but not limited to intraocular lenses, corneal inlays and corneal rings. The preferred reactive

POSS molecules of the present invention are represented generally by Formula 1 below:



Formula 1

wherein the R groups may be the same or different with at least one of the R groups being a reactive group, R reactive groups may be the same or different selected from the group consisting of hydrogen, hydroxy, alkoxy, amine, chlorine, epoxide, isocyanate, methacrylate, acrylate, methacrylamine, acrylamide, nitrile, norbornenyl, vinyl, styrenyl and thiol; R nonreactive groups may be the same or different selected from the group consisting of C₁₋₃₀ alkyl and C₆₋₃₀ aryl.

The subject POSSes with definite structures are reliably reproducible, which differs significantly from the indefinite structures of silicone resin. Examples of suitable POSSes with definite structures of the present invention include but are not limited to the following molecules, most of which are T8 structures with one to eight reactive sites or T7 structures with three reactive sites.

OH-containing: An OH-containing POSS for example, but not to be limited thereto, is octahydroxypropyldimethylsilyl-POSS.

Alkoxy-containing: Alkoxy-containing POSSes include for example but are not limited to diethoxymethylsilylethyl-cyclohexyl-POSS, diethoxymethylsilylethyl-isobutyl-POSS, diethoxymethylsilylpropyl-cyclohexyl-POSS, diethoxymethylsilylpropyl-isobutyl-POSS, ethoxydimethylsilylethyl-

cyclohexyl-POSS, ethoxydimethylsilylethyl-isobutyl-POSS, ethoxydimethylsilylpropyl-cyclohexyl-POSS, ethoxydimethylsilylpropyl-isobutyl-POSS, diethoxymethylsilylethyl- cyclohexyl-POSS, triethoxysilylethyl-isobutyl-POSS, triethoxysilylpropyl-cyclohexyl-POSS and triethoxysilylpropyl-isobutyl-POSS, with ethoxydimethylsilylethyl-isobutyl-POSS and ethoxydimethylsilylpropyl- isobutyl-POSS as the preferred.

Amine-containing: Amine-containing POSSes include for example but are not limited to aminopropyl cyclohexyl-POSS, aminopropyl isobutyl-POSS, aminopropyl isooctyl-POSS and octaaminophenyl POSS, with aminopropyl isobutyl-POSS as the preferred.

Chlorosilane-containing: Chlorosilane-containing POSSes include for example but are not limited to monochlorocyclohexyl-POSS, monochlorocyclopentyl-POSS, monochloroisobutyl-POSS, chlorodimethylsilylethyl isobutyl-POSS, chlorodimethylsilylpropyl isobutyl-POSS, chlorodimethylsilylpropyl cyclohexyl-POSS, dichloromethylsilylethyl isobutyl-POSS, dichloromethylsilylpropyl isobutyl-POSS, dichloromethylsilylpropyl cyclohexyl-POSS, trichlorosilylethyl isobutyl-POSS, trichlorosilylpropyl isobutyl-POSS, trichlorosilylpropyl cyclohexyl-POSS and octa(chlorodimethylsilylethyl)-POSS with chlorodimethylsilylpropyl isobutyl-POSS as the preferred.

Epoxide-containing: Epoxide-containing POSSes include for example but are not limited to epoxypropyl isobutyl-POSS, epoxypropyl cyclopentyl-POSS, glycidyl cyclohexyl-POSS, glycidyl isobutyl-POSS, glycidyl isooctyl-POSS, glycidyl phenyl-POSS, octaepoxycyclohexyldimethylsilyl-POSS, octaglycidyl dimethylsilyl-POSS, triglycidyl cyclohexyl-POSS, triglycidyl cyclopentyl-POSS, triglycidyl isobutyl-POSS and triglycidyl ethyl-POSS, with epoxypropyl isobutyl-POSS, glycidyl isobutyl-POSS, and triglycidyl isobutyl-POSS as preferred.

Isocyanate-containing: Isocyanate-containing POSSes include for example but are not limited to isocyanatopropyldimethylsiloxy cyclohexyl -POSS and isocyanatopropyldimethylsiloxy isobutyl -POSS with isocyanatopropyldimethylsiloxy isobutyl -POSS as the preferred.

Acrylate/methacrylate -containing : Acrylate/methacrylate-containing POSSes include for example but are not limited to acryloxypropyl cyclohexyl-POSS, acryloxypropyl cyclopentyl-POSS, acryloxypropyl isobutyl-POSS, methacryloxypropyl cyclohexyl-POSS, methacryloxypropyl cyclopentyl-POSS, methacryloxypropyl isobutyl-POSS, methacryloxypropyl ethyl-POSS, methacryloxypropyl isooctyl-POSS, methacryloxypropyl phenyl-POSS, octa-methacryloxypropyl -POSS, methacryloxypropyldimethylsilyl cyclopentyl-POSS and methacryloxypropyl-dimethylsilyl cyclopentyl-POSS with acryloxypropyl isobutyl-POSS, methacryloxypropyl isobutyl-POSS and methacryloxypropyl-dimethylsilyl cyclopentyl-POSS as the preferred.

Acrylamide/methacrylamide-containing: Acrylamide/methacrylamide-containing POSSes include for example but are not limited to acrylamidopropyl cyclohexyl-POSS, acrylamidopropyl cyclopentyl-POSS, acrylamidopropyl cyclohexyl-POSS, methacrylamidopropyl cyclohexyl-POSS, methacrylamidopropyl cyclopentyl-POSS, methacrylamidopropyl cyclohexyl-POSS, with acrylamidopropyl cyclohexyl-POSS as the preferred.

Nitrile-containing: Nitrile-containing POSSes include for example but are not limited to cyanopropyl cyclohexyl-POSS, cyanopropyl cyclopentyl-POSS, cyanopropyl isobutyl-POSS, cyanoethyl cyclohexyl-POSS, cyanoethyl cyclopentyl-POSS and cyanoethyl isobutyl-POSS with cyanopropyl isobutyl-POSS and cyanoethyl isobutyl-POSS as preferred.

Noebornenyl- containing: Noebornenyl-containing POSSes include for example but are not limited to norbornenylethyl cyclohexyl-POSS, norbornenylethyl cyclopentyl-POSS, norbornenylethyl isobutyl-POSS, trisnorbornenylethyldimethylsilyl cyclopentyl-POSS, trisnorbornenylethyldimethylsilyl cyclohexyl- POSS and trisnorbornenylethyldimethylsilyl isobutyl-POSS with norbornenylethyl isobutyl-POSS and trisnorbornenylethyldimethylsilyl isobutyl-POSS as the preferred.

Vinyl-containing: Vinyl-containing POSSes include for example but are not limited to allyl cyclohexyl-POSS, allyl cyclopentyl-POSS, allyl butyl-POSS, allyldimethylsilylcyclopentyl-POSS, cyclohexenylethyl cyclopentyl-POSS, vinyl dimethylsilyl cyclopentyl-POSS, vinyl diphenylsilyl cyclopentyl-POSS, vinyl cyclopentyl-POSS, vinyl cyclohexyl-POSS, vinyl isobutyl-POSS, tris-vinyl dimethyl cyclohexyl-POSS, tris-vinyl dimethyl cyclopentyl-POSS, tris-vinyl dimethyl isobutyl-POSS and octavinyl dimethyl-POSS with allyl butyl-POSS, vinyl isobutyl-POSS and octavinyl dimethylsilyl-POSS as preferred.

Hydrogen-containing: Hydrogen-containing POSSes include for example but are not limited to dimethylhydrosilyl cyclohexyl-POSS, dimethylhydrosilyl cyclopentyl-POSS, dimethylhydrosilyl isobutyl-POSS, monohydro cyclohexyl-POSS, monohydro isobutyl-POSS, octadimethylhydrosilyl-POSS, trisdimethylhydrosilyl cyclohexyl-POSS and trisdimethylhydrosilyl isobutyl-POSS with dimethylhydrosilyl isobutyl-POSS, monohydro isobutyl-POSS and trisdimethylhydrosilyl isobutyl-POSS as the preferred.

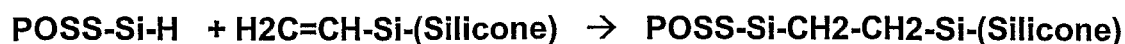
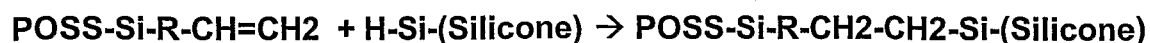
Thiol-containing: Thiol-containing POSSes include for example but are not limited to mercaptopropyl cyclohexyl-POSS, mercaptopropyl cyclopentyl-POSS and mercaptopropyl isobutyl-POSS.

Silanol-containing: Silanol-containing POSSes include for example but are not limited to monohydroxy cyclohexyl-POSS, monohydroxy cyclopentyl-POSS, monohydroxy isobutyl-POSS, trishydroxy cyclohexyl-POSS, trishydroxy cyclopentyl-POSS, trishydroxy isobutyl-POSS, trishydroxy isooctyl-POSS, trishydroxy ethyl-POSS and trishydroxy phenyl-POSS with monohydroxy isobutyl-POSS, trishydroxy isobutyl-POSS and trishydroxy isooctyl-POSS as the preferred.

Styrene-containing: Styrene-containing POSSes include for example but are not limited to p-Styryl cyclohexyl-POSS, p-styryl cyclopentyl-POSS and p-styryl isobutyl-POSS.

Some reactive POSSes having multiple reactive sites have different reactive groups that are not reactive toward each other. Such POSSes are also useful as reinforcing agents in accordance with the present invention. Some examples of such POSSes are norbornylethyldimethylsilyldihydroxy isobutyl-POSS and methacryloxypropylsilylihydroxy isobutyl-POSS.

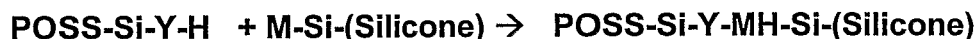
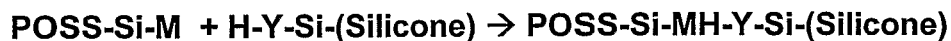
Polysilsesquioxanes reinforcing agents of the present invention may be incorporated into known polymeric compositions, especially silicone-containing formulations useful in the manufacture of intraocular lenses. The method of incorporation can be different depending on the reactive groups of the POSS. Also, the polymer composition to be reinforced with POSSes should have functional groups reactive with one or more reactive groups of the POSS. For POSSes having Si – H or vinyl groups, the POSSes are incorporated into the polymeric composition through a hydrosilation reaction between the POSS and other components with Si-vinyl or Si-H groups in the formulation as set forth in Scheme 1 below. In Scheme 1 below, “silicone” means siloxane moieties in a formulation of interest, and the vinyl group can be an ethylenically unsaturated group such as vinyl, allyl, norbornenyl, fumarate, melete, acrylate, methacrylate, acrylamide, methacrylamide or styrenyl. Also in Scheme 1 below, “R” represents an nonreactive connecting spacer between the Si atom and the reactive vinyl group.



Scheme 1

For POSSes having acrylic and/or styrene groups attached to Si, the polysilsesquioxanes are incorporated into the polymeric composition through a typical free radical copolymerization reaction.

For POSSes having alcohol, amine, thiol, epoxy and isocyanate groups attached to Si, the POSSes are incorporated into the polymeric composition through the typical epoxy or urethane resin reactions as set forth in Scheme 2 below wherein "silicone" means siloxane moieties in a formulation of interest, "Y" can be O, S or NH and "M" is an epoxy group or an isocyanate group.



Scheme 2

POSSes having acid or acid chloride groups can be incorporated into a formulation of interest through an ester/amide synthesis reaction with a molecule having OH, SH or NH groups.

Silicone containing formulations reinforced with the reactive POSSes of the present invention, including reactive polysiloxanes with reactive groups capable of reacting with the reactive groups of the POSSes of the present invention, may include for example but are not limited to polysiloxane-based prepolymers with polymerizable groups such as acrylate, methacrylate, acrylamide, methacrylamide, fumarate, maleate, norbornenyl and styrene groups, and polysiloxanes with multiple reactive groups such as hydrogen, hydroxy, alkoxy, amine, chlorine, epoxide, isocyanate, nitrile, vinyl and thiol groups. Some specific examples of such polysiloxanes include vinyl-terminated or methacrylate-terminated polydimethyl-co-diphenyl siloxanes and polydimethyl-co-methylhydro-siloxanes.

Durable IOLs having thin optic portions are critical in enabling a surgeon to minimize surgical incision size. Keeping the surgical incision size to a minimum reduces intraoperative trauma and postoperative complications. A thin IOL optic portion is also critical for accommodating certain anatomical locations in the eye such as the anterior chamber and the ciliary sulcus. IOLs may be placed in the anterior chamber for increasing visual acuity in both aphakic and phakic eyes and placed in the ciliary sulcus for increasing visual acuity in phakic eyes.

The polymeric compositions with reinforcing agents of the present invention have the durability and flexibility required to allow ophthalmic devices manufactured from the same to be folded or deformed for insertion into an eye through the smallest possible surgical incision, i.e., 3.0 mm or smaller.

One or more suitable ultraviolet light absorbers may optionally be added in the manufacture of the subject polymeric compositions with polysilsesquioxane reinforcing agents. Such ultraviolet light absorbers include for example but are not limited to β -(4-benzotriazolyl-3-hydroxyphenoxy) ethyl acrylate, 4-(2-acryloxyethoxy)-2-hydroxybenzophenone, 4-methacryloxy-2-hydroxybenzophenone, 2-(2'-methacryloxy-5'-methylphenyl)benzotriazole, 2-(2'-hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole, 2-[3'-tert-butyl-2'-hydroxy-5'-(3"-methacryloyloxypropoxy)phenyl]-5-chlorobenzotriazole, 2-[3'-tert-butyl-5'-(3"-dimethylvinylsilylpropoxy)-2'-hydroxyphenyl]-5-methoxybenzotriazole, 2-(3'-allyl-2'-hydroxy-5'-methylphenyl)benzotriazole, 2-[3'-tert-butyl-2'-hydroxy-5'-(3"-methacryloyloxypropoxy)phenyl]-5-methoxybenzotriazole, and 2-[3'-tert-butyl-2'-hydroxy-5'-(3"-methacryloyloxypropoxy)phenyl]-5-chlorobenzotriazole. The choice of ultraviolet light absorber depends on the level of UV blockage desired and the type of polymerizable groups present, i.e., the type of reaction, for curing to occur.

Soft, foldable, relatively high refractive index of approximately 1.45 or greater, relatively high elongation of approximately 100 percent or greater polymeric compositions of the present invention with one or more POSS reinforcing agents are described in still greater detail in the examples that follow.

EXAMPLE 1 - Preparation of polymeric composition with norbornenylethyl isobutyl-POSS:

A glass vial is charged with 2.3 grams (2.45 millimole of vinyl) of norbornenylethyl isobutyl-POSS (Hybrid Plastics, Fountain Valley, CA) and 15 mL of tetrahydrofuran. The mixture was stirred until all POSS powder is dissolved. Then 0.7 grams (4.45 millimole of Si-H) of methylhydrosiloxane-dimethylsiloxane (50/50) of Mn around 1050 (Gelest Inc., Tullytown, PA) and 7.0 grams (0.254 millimole of vinyl) of vinyl-terminated diphenylsiloxane-dimethylsiloxane copolymer (15-17 %) of Mn 55,000 (Gelest Inc., Tullytown, PA) are added and well mixed. The solvent is then removed under reduced pressure. Then 1.0 mg of Platinum(0)-cyclovinyldimethylsiloxane complex (Gelest Inc., Tullytown, PA) is added into the silicone mixture and mixed well prior to degassing. The mixture is then cast between two silane-treated glass plates and cured at 100 °C for two hours. The cured film is optically clear.

EXAMPLE 2 - Preparation of polymeric composition with trisnorbornenylethyl isobutyl-POSS:

The procedure is the same as that of Example 1 except that 1.8 grams (4.07 millimole of vinyl) trisnorbornenylethyl-POSS (Hybrid Plastics, Fountain Valley, CA) is used to replace norbornenylethyl isobutyl-POSS and 1.2 gram (7.64 millimole of Si-H) methylhydrosiloxane-dimethylsiloxane (50/50) copolymer is used. The cured film is optically clear.

EXAMPLE 3 - Preparation of polymeric composition with tris(vinyldimethyl)isobutyl-POSS:

The procedure is the same as that of Example 1 except that 1.8 grams (5.17 millimole of vinyl) of tris(vinyldimethyl)isobutyl-POSS (Hybrid Plastics, Fountain Valley, CA) is used rather than norbornenylethyl isobutyl-POSS and 1.2 gram (7.64 millimole of Si-H) methylhydrosiloxane-dimethylsiloxane (50/50) copolymer is used. The cured film is optically clear.

EXAMPLE 4 - Preparation of polymeric composition with methacryloxypropyl -POSS:

The procedure is the same as that of Example 1 except that 1.2 grams (7.41 millimole of vinyl) of tris(vinyldimethyl)isobutyl-POSS (Hybrid Plastics, Fountain Valley, CA) is used to replace norbornenylethyl isobutyl-POSS and 1.8 gram (11.45 millimole of Si-H) of methylhydrosiloxane-dimethylsiloxane (50/50) copolymer is used. The cured film is optically clear.

EXAMPLE 5 - Preparation of polymeric composition with vinyl-POSS cage mixture:

The procedure is the same as that of Example 1 except that vinyl-POSS cage mixture (Hybrid Plastics, Fountain Valley, CA) in the amount of 1.1 grams (7.52 millimole of vinyl) is used to replace norbornenylethyl isobutyl-POSS and 1.9 gram (12.1 millimole of Si-H) of methylhydrosiloxane-dimethylsiloxane (50/50) copolymer is used. The cured film is optically clear.

Medical devices produced using the polymeric compositions with reinforcing agents of the present invention may be manufactured in accordance with methods known to those skilled in the art of the specific ophthalmic device being produced. For example, if an intraocular lens is to be produced, the same may be manufactured by methods known to those skilled in the art of intraocular lens production.

Ophthalmic devices such as but not limited to IOLs and corneal inlays manufactured using the polymeric compositions with reinforcing agents of the present invention can be of any design capable of being rolled or folded for implantation through a relatively small surgical incision, i.e., 3.0 mm or less. For example, intraocular implants such as IOLs comprise an optic portion and one or

more haptic portions. The optic portion reflects light onto the retina and the permanently attached haptic portions hold the optic portion in proper alignment within an eye. The haptic portions may be integrally formed with the optic portion in a one-piece design or attached by staking, adhesives or other methods known to those skilled in the art in a multipiece design.

The subject ophthalmic devices, such as for example IOLs, may be manufactured to have an optic portion and haptic portions made of the same or differing materials. Preferably, in accordance with the present invention, both the optic portion and the haptic portions of the IOLs are made of the same polymeric composition with one or more reinforcing agents of the present invention. Alternatively however, the IOL optic portion and haptic portions may be manufactured from different materials and/or different formulations of the polymeric compositions with one or more reinforcing agents of the present invention, such as described in detail in U.S. Patent Numbers 5, 217,491 and 5,326,506, each incorporated herein in their entirety by reference. Once the material(s) are selected, the same may be cast in molds of the desired shape or cast in the form of rods and lathed or machined into disks. If cast in the form of rods and lathed or machined into disks, the disks may then be lathed or

machined at a relatively low temperature below that of the glass transition temperature of the material(s) to produce IOLs. The IOLs whether molded or machined are then cleaned, polished, packaged and sterilized by customary methods known to those skilled in the art.

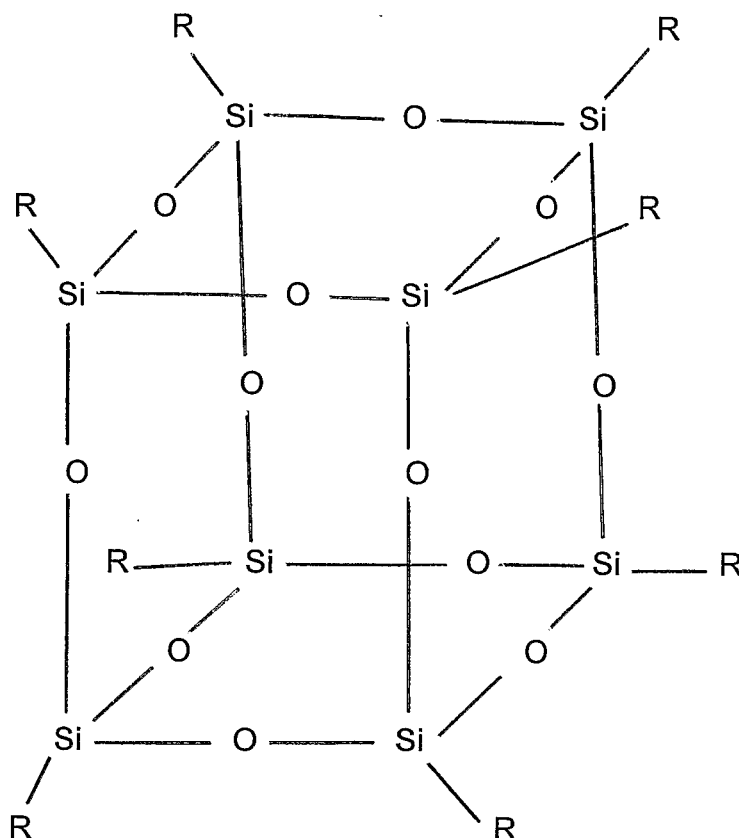
In addition to IOLs, the polymeric compositions with one or more reinforcing agents of the present invention are also suitable for use in the production of other ophthalmic devices such as contact lenses, keratoprotheses, capsular bag extension rings, corneal inlays, corneal rings and like devices.

Ophthalmic devices manufactured using the unique polymeric compositions with one or more reinforcing agents of the present invention are used as customary in the field of ophthalmology. For example, in a surgical cataract procedure, an incision is placed in the cornea of an eye. Through the corneal incision the cataractous natural lens of the eye is removed (aphakic application) and an IOL is inserted into the anterior chamber, posterior chamber or lens capsule of the eye prior to closing the incision. However, the subject ophthalmic devices may likewise be used in accordance with other surgical procedures known to those skilled in the field of ophthalmology.

While shown and described herein certain reinforcing agents, polymeric compositions with one or more reinforcing agents, methods of producing the reinforcing agents and polymeric compositions with one or more reinforcing agents and ophthalmic devices made from the subject polymeric compositions with one or more reinforcing agents in accordance with the present invention, it will be manifest to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to particular structures herein shown and described except insofar as indicated by the scope of the appended claims.

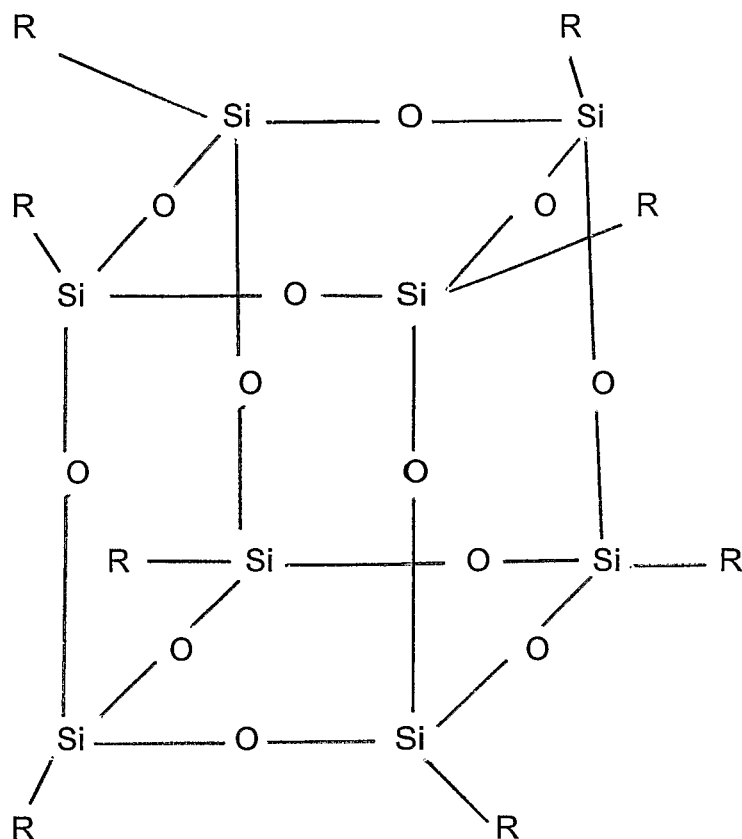
We claim:

1. A reinforcing agent useful in the manufacture of ophthalmic implants comprising:



wherein the R groups may be the same or different with at least one of the R groups being a reactive group, R reactive groups may be the same or different selected from the group consisting of hydrogen, hydroxy, alkoxy, amine, chlorine, epoxide, isocyanate, methacrylate, acrylate, methacrylamine, acrylamide, nitrile, norbornenyl, vinyl, styrenyl and thiol; R nonreactive groups may be the same or different selected from the group consisting of C₁₋₃₀ alkyl and C₆₋₃₀ aryl.

2. A polymeric composition useful in the manufacture of ophthalmic implants polymerized with one or more reinforcing agents, said reinforcing agents comprising:



wherein the R groups may be the same or different with at least one of the R groups being a reactive group, R reactive groups may be the same or different selected from the group consisting of hydrogen, hydroxy, alkoxy, amine, chlorine, epoxide, isocyanate, methacrylate, acrylate, methacrylamine, acrylamide, nitrile, norbornenyl, vinyl, styrenyl and thiol; R nonreactive groups may be the same or different selected from the group consisting of C₁₋₃₀ alkyl and C₆₋₃₀ aryl.

3. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a vinyl group.
4. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a hydrogen group.
5. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a hydroxy group.
6. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is an amine group.
7. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is an alkoxy group.
8. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is an isocyanate group.
9. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a styrenyl group.

10. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is an epoxide or a nitrile group.
11. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a norbornenyl group.
12. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is an acid group.
13. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a methacrylate group, an acrylate group, a methacrylamide group or an acrylamide group.
14. The reinforcing agent of claim or the polymeric composition of claim 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13 wherein at least one of said R groups is an aryl group.

15. The reinforcing agent of claim 1 or the polymeric composition of claim 2 wherein at least one of said R groups is a chlorosilane group.
16. A method of manufacturing the polymeric composition of claim 2 comprising:
 - incorporating one or more reinforcing agents with Si-H or vinyl groups into a polymeric composition through a hydrosilation reaction.
17. A method of manufacturing the polymeric composition of claim 2 comprising:
 - incorporating one or more reinforcing agents with acrylic or styrene groups into a polymeric composition through a free radical copolymerization reaction.
18. A method of manufacturing the polymeric composition of claim 2 comprising:
 - incorporating one or more reinforcing agents with alcohol, amine, thiol, epoxy or isocyanate groups into a polymeric composition through an epoxy or urethane resin reaction.

19. A method of manufacturing the polymeric composition of claim 2 comprising:
- incorporating one or more reinforcing agents with acid or acid chloride groups into a polymeric composition with OH, SH or NH groups through an ester/amide synthesis reaction.
20. A method of producing an ophthalmic device using the polymeric composition produced using the method of claim 16, 17, 18 or 19 comprising:
- casting said polymeric composition in the form of a rod;
 - lathing or machining said rod into disks; and
 - lathing or machining said disks into an ophthalmic device.
21. A method of using the ophthalmic device produced through the method of claim 20 or 22 comprising:
- making an incision in the cornea of an eye; and
 - implanting said ophthalmic device.

22. A method of producing an ophthalmic device using the polymeric composition produced using the method of claim 16, 17, 18 or 19 comprising:
- pouring said polymeric composition prior to curing into a mold;
 - curing said polymeric composition; and
 - removing said polymeric composition from said mold following curing thereof.
23. A method of using the ophthalmic device produced through the method of claim 20 or 22 comprising:
- making an incision in the cornea of an eye;
 - removing the natural lens; and
 - implanting said ophthalmic device.
24. A reactive polyhedral oligomeric silsesquioxane useful as a reinforcing agent in the manufacture of ophthalmic implants.