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(54) Title: A HEMOCOMPATIBLE COATED POLYMER AND RELATED ONE-STEP METHODS

(57) Abstract: A polymer with a hemocompatible film or coating is manufactured by a one-step method comprising polymerizing monomer droplets comprising at least one crosslinking agent to form a polymer and simultaneously coating the resulting polymer using at least one dispersing agent to thereby form a hemocompatible coated polymer.

A HEMOCOMPATIBLE COATED POLYMER AND RELATED ONE-STEP METHODS

BACKGROUND OF THE INVENTION:

FIELD OF THE INVENTION:

The present invention relates to a polymer with a hemocompatible coating comprising at least one crosslinking agent for making the polymer and at least one dispersing agent whereby the dispersing agent forms a hemocompatible surface coating on the polymer. More specifically, the present invention relates to a hemocompatible coated polymer manufactured by a method comprising simultaneously polymerizing and coating with at least one crosslinking agent for making the polymer and using at least one dispersing agent to form a hemocompatible coated polymer.

DESCRIPTION OF RELATED ART:

It has been known and practiced in the art of suspension polymerization to manufacture polymers with a hemocompatible coating using a two-step process. In the first step of the two-step process, polymeric beads are manufactured by polymerizing monomer droplets using suspension polymerization. In the second step of the process, a hemocompatibilizing film is applied onto the exterior surface of the polymer to provide the hemocompatible coating. Unlike the prior art, the polymers of the present invention have aqueous and organic phases where the organic phase is immiscible in the aqueous phase, and the dispersing agent used in the aqueous phase forms a hemocompatible surface on the polymer.

SUMMARY OF THE INVENTION:

The present invention provides for hemocompatible coated polymer system comprising an organic phase and an aqueous phase. In one embodiment, the organic phase comprises polymerizable monomers and at least one initiator and the aqueous phase comprises at least one dispersing agent, at least one free radical inhibitor and at least one buffering agent. In another embodiment, the organic phase of the system of the present invention is immiscible in the aqueous phase, and the dispersing agent forms a hemocompatible surface on the polymer.

In still another embodiment, the monomer is a monofunctional monomer, and the monofunctional monomer is selected from a group consisting of styrene, ethylstyrene, acrylonitrile, butyl methacrylate, octyl methacrylate, butyl acrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinyltoluene, vinylnaphthalene, vinylbenzyl alcohol, vinylformamide, methyl methacrylate, methyl acrylate and mixtures thereof.

In yet another embodiment, the monomer is a polyfunctional monomer, and the polyfunctional monomer is selected from a group consisting of divinylbenzene, trivinylbenzene, divinylnaphthalene, trivinylcyclohexane, divinylsulfone, trimethylolpropane trimethacrylate, trimethylolpropane dimethacrylate, trimethylolpropane triacrylate, trimethylolpropane diacrylate, pentaerythritol dimethacrylate, pentaerythritol trimethacrylate, pentaerythritol tetramethacrylate, pentaerythritol diacrylate, pentaerythritol triiacrylate, pentaerythritol tetraacrylate, dipentaerythritol dimethacrylate, dipentaerythritol trimethacrylate, dipentaerythritol tetramethacrylate, dipentaerythritol diacrylate, dipentaerythritol triacrylate, dipentaerythritol tetraacrylate, divinylformamide and mixtures thereof.

In still yet another embodiment, the initiator of the system of the present invention is selected from a group consisting of diacyl peroxides, ketone peroxides, peroxyesters, dialkyl peroxides, peroxyketals, azoalkylnitriles, peroxydicarbonates and mixtures thereof. In a further embodiment, the

dispersing agent is selected from a group consisting of poly(N-vinylpyrrolidinone), hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly- (dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly- (diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), and salts of poly(acrylic acid) and mixtures thereof.

In still a further embodiment, the free radical inhibitor is selected from a group consisting of p-nitrosophenoxide salts, sodium nitrate, N-hydroxy-N-methylglucamine, N-nitroso-N-methylglucamine and mixtures thereof. In yet a further embodiment, the buffering agent is selected from a group consisting of carbonate salts, bicarbonate salts, boric acid salts, salts of phosphoric acid and mixtures thereof. In still yet a further embodiment, the organic phase further comprises at least one porogen, and the porogen is selected from a group consisting of aliphatic hydrocarbons, dialkyl ketones, aliphatic carbinols and mixtures thereof. In another further embodiment, the polymer is a porous polymer.

In still another further embodiment, the present invention relates to a hemocompatible surface coated polymer system comprising an organic phase and an aqueous phase, the system being manufactured by a method comprising: forming the organic phase comprising polymerizable monomers and at least one initiator; forming the aqueous phase comprising at least one dispersant agent, at least one free radical inhibitor, and at least one buffering agent; dispersing the organic phase into the aqueous phase to thereby form organic phase droplets; and polymerizing the organic phase droplets coated with the dispersing agent to thereby form the hemocompatible surface coating on the polymer. In yet another further embodiment, the polymerization of the organic phase is formed by heating a mixture of the organic and aqueous phases.

In still yet another further embodiment, the present invention relates to a method of manufacturing a hemocompatible surface coated polymer system comprising an organic phase and

an aqueous phase, the method comprising: forming the organic phase comprising polymerizable monomers and at least one initiator; forming the aqueous phase comprising at least one dispersant agent, at least one free radical inhibitor, and at least one buffering agent; dispersing the organic phase into the aqueous phase by agitation to form a suspension of organic droplets; and polymerizing the organic phase by heating the suspension of the organic phase droplets coated with the dispersing agent to thereby form the hemocompatible surface coating on the polymer.

In another embodiment, the present invention relates to a polymer with a hemocompatible coating comprising at least one crosslinking agent for making the polymer and at least one dispersing agent whereby the dispersing agent forms a hemocompatible surface on the polymer.

In another embodiment, the biocompatibilizing polymer comprises poly(N-vinylpyrrolidinone). In still another embodiment, the biocompatibilizing polymer is selected from a group consisting of poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(dimethylaminoethyl methacrylate), salts of poly(acrylic acid), salts of poly(methacrylic acid), poly(diethylaminoethyl methacrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(N-vinylpyrrolidinone), poly(vinyl alcohol) and mixtures thereof. In another embodiment, the salts may be sodium and potassium salts and in still another embodiment, the salts are water-soluble salts.

In yet another embodiment, the dispersing agent is selected from a group consisting of hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly(dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly(diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), and salts of poly(acrylic acid) and mixtures thereof.

In still another embodiment, the crosslinking agent is selected from a group consisting of divinylbenzene, trivinylbenzene, divinylnaphthalene, trivinylcyclohexane, divinylsulfone,

trimethylolpropane trimethacrylate, trimethylolpropane dimethacrylate, trimethylolpropane triacrylate, trimethylolpropane diacrylate, pentaerythrital tetra-, tri-, and dimethacrylates, pentaerythritol tetra-, tri- and diacrylates, dipentaerythritol tetra, tri-, and dimethacrylates, dipentaerythritol tetra-, tri-, and diacrylates, divinylformamide, and mixtures thereof.

In still yet another embodiment, the crosslinking agent comprises divinylbenzene. In a further embodiment, the crosslinking agent comprises trivinylcylohexane. In yet a further embodiment, the crosslinking agent comprises trivinylbenzene.

In still a further embodiment, the crosslinking agent comprises copolymers of divinylbenzene with comonomers being selected from a group consisting of styrene, ethylstyrene, acrylonitrile, butyl methacrylate, octyl methacrylate, butyl acrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinyltoluene, vinylnaphthalene, vinylbenzyl alcohol, vinylformamide, methyl methacrylate, methyl acrylate and mixtures thereof.

In still yet a further embodiment, the polymer with the hemocompatible surface is a porous polymer. In another further embodiment, the polymer with the hemocompatible surface is an ion exchange polymer. In a further embodiment, the polymer is an affinity polymer. In yet another further embodiment, the biocompatibilizing polymer becomes grafted to the surface of the polymer to provide a polymer with the hemocompatible surface. For purposes of this invention, the term "grafting" is defined as chemically bonded with potential entanglement such that the dispersing agent is physically restricted from leaving the surface of the polymer.

In another embodiment, the present invention relates to a polymer manufactured by a process comprising: simultaneously polymerizing and coating with at least one crosslinking agent for making the polymer and using at least one dispersing agent to form a hemocompatible coated polymer.

For purposes of this invention, the term "hemocompatibility" is defined as a condition whereby a material, when placed in contact with whole blood and blood components or

physiological fluids, results in clinically acceptable physiological changes. In another embodiment, the dispersing agent is a biocompatibilizing polymer. A "biocompatibilizing polymer" is defined as a polymer, which forms a surface over a non-biocompatible material, making the polymeric system compatible with physiological fluids and tissues. The term "crosslinking agent" is defined as a linking agent such as a polyfunctional monomer that links two or more polymer chains or segments of the same polymer chain together. The term "dispersing agent" is defined as a substance that imparts a stabilizing effect upon a finely divided array of immiscible particles suspended in a fluidizing medium. The immiscible particles can be a solid, liquid or gas and the fluidizing medium can be a liquid or a gas.

In another embodiment, the crosslinking agent is polymerized with at least one vinyl monomer. In a further embodiment, the dispersing agent forms a hemocompatible coating on a surface of the polymer. In yet a further embodiment, the coating of the polymer is equivalent to the surface of the polymer.

In still a further embodiment, the polymer is processed in non-pyrogenic water. For purposes of this invention, "non-pyrogenic" shall be defined by U.S.P. 25, Monograph (151) Pyrogenic Test, U.S. Pharmacopeia National Formulary.

In still yet another embodiment, the polymer of the present invention is prepared by suspension polymerization. For purposes of the invention, suspension polymerization is defined as the polymerization of monomer droplets dispersed in an immiscible liquid. Based upon an Elemental Analysis of the Polymer's Surface by X-Ray Photoelectron Spectroscopy (XPS), the dispersing agent becomes chemically grafting onto the surface of the polymer as the monomer droplets are transformed into polymeric beads. Polymers coated with poly(N-vinylpyrrolidinone) have been found to be biocompatible and hemocompatible. The hemocompatible polymers of the present invention pass the Lee White clotting tests and the tests for the hemolysis of red blood cells.

In another embodiment, the polymer of the present invention is a porous polymer. The term "porous polymer" is defined as a polymer particle having an internal pore structure with a porosity resulting from voids or holes throughout the polymer matrix. In still another embodiment, the polymer is an ion exchange resin or polymer. An ion exchange resin or polymer is a resin or polymer carrying ionogenic groups that are capable of exchanging ions or of sequestering ions. The ion exchange polymers of the present invention are beneficial when used with blood for removing and isolating varying ions and ionogenic molecules.

In still yet another embodiment, the present invention relates to a polymer with a hemocompatibilizing surface coating. In a further embodiment, the coated polymer is manufactured by a one step process comprising: simultaneously coating and polymerizing monomer droplets in a suspension polymerization procedure with at least one dispersing agent having encapsulated the droplets with a hemocompatible coating to thereby form a polymer with a hemocompatible surface-coating grafted onto the surface of the polymer beads.

In another embodiment, the present invention relates to a method of manufacturing a biocompatible and hemocompatible surface coated polymer. In still another embodiment, the method comprises: polymerizing monomer droplets comprising at least one crosslinking agent and simultaneously coating the resulting polymer beads using at least one dispersing agent to form a biocompatible surface coated polymer. In still another embodiment, the coated polymers are hemocompatible. In yet another embodiment, the polymer is formed using a suspension polymerization procedure. In another embodiment, the polymer is formed using an emulsion polymerization procedure followed by growing the particles with additional monomer feed.

In still another embodiment, the present invention relates to an application of use whereby the hemocompatible surface coated polymers of the present invention are utilized for medical applications. In another embodiment, the hemocompatible polymers of the present invention may be used to isolate and/or remove target substances from blood and physiological fluids and for specific

treatments. In a further embodiment, the hemocompatible polymers of the present invention may be used in preserving organs. In yet another embodiment, the present invention relates to an apparatus for isolating blood components and for purifying blood using the hemocompatible surface coated polymers of the present invention. In one embodiment, the apparatus comprises a cartridge containing the hemocompatible polymers of the present invention.

In yet a further embodiment, the present invention relates to a polymer with a hemocompatible surface coating, the polymer being manufactured by a method comprising: polymerizing monomer droplets comprising at least one crosslinking agent to form a polymer and developing a surface coating on the polymer by using at least one dispersing agent carrying hydroxyl groups followed by a reaction of hydroxyl groups with a vinyl monomer or polymer to thereby form the hemocompatible surface coating on the polymer.

In still yet a further embodiment, the present invention also relates to a method of manufacturing a hemocompatible surface coated polymer using a one step process, the method comprising: polymerizing monomer droplets comprising at least one crosslinking agent to form a polymer and developing a surface coating on the polymer by using at least one dispersing agent carrying hydroxyl groups followed by a reaction of hydroxyl groups with a vinyl monomer or polymer to thereby form the hemocompatible surface coating on the polymer.

In another embodiment, the present invention relates to a polymer having a hemocompatible-coated surface, the polymer being manufactured by a two-step process comprising: polymerizing monomer droplets comprising at least one crosslinking agent and at least one dispersing agent to form a polymer; and coating the surface of the polymer by crosslinking a monovinyl monomer and a polyfunctional monomer mixture over the surface of the polymer bead to thereby form the hemocompatible coating on the surface of the polymer.

In a further embodiment, the present invention relates to a method comprising: polymerizing monomer droplets comprising at least one crosslinking agent and at least one dispersing agent to

form a polymer; and coating the surface of the polymer by crosslinking a monovinyl monomer and a polyfunctional monomer mixture over the surface of the polymer bead to thereby form the hemocompatible coating on the surface of the polymer.

In another embodiment, the present invention relates to a hemocompatible system comprising an organic phase and an aqueous phase, wherein the organic phase composed of the polymerizable monomers and the porogen are dispersed into a slurry of droplets by agitation throughout the aqueous phase which is formulated to effect the stability of the droplets by the water-miscible dispersant and to quench polymer growth in the aqueous phase by carrying a water-soluble free radical inhibitor.

DETAILED DESCRIPTION OF THE INVENTION:

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various forms. The figures are not necessary to scale, some features may be exaggerated to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention.

The specific example below will enable the invention to be better understood. However, they are given merely by way of guidance and do not imply any limitation.

EXAMPLE 1

The first polymer synthesis was targeted at an aqueous to organic volume ratio of 1.0. Table 1 below illustrates the targeted dispersion mixture designed for Example 1 using a fifty (50) liter reaction.

TABLE 1:

Dispersion Mixture Desires for 50 Liters

Aqueous/Organic Volume Ratio	1.0
Volume of Organic Phase, ml	25,000.0
Volume of Aqueous Phase, ml	25,000.0
Density of Organic Phase, g/ml	0.83490
Weight of Organic Phase, g	20,872.5
Density of Aqueous Phase, g/ml	1.005
Weight of Aqueous Phase, g	25,125.0
Polymerizable Monomers, DVB plus EVB, g	8766.45
Total Volume of Organic & Aqueous Phases, ml	50,000.0
Total Weight of Organic & Aqueous Phases, g	45,997.5

The procedure for the polymerization in Example 1 is initiated by the preparation of an aqueous phase and an organic phase. Table 2 and 3 below illustrate the components of the aqueous phase composition for the polymer synthesis by weight percent (%) and by quantity of the components in grams (g), respectively.

TABLE 2

Aqueous Phase Composition

Ultrapure Water, wt. %	98.089
Water from Aqueous 45% Solution of Poly (N-vinylpyrrolidinone), wt. %	0.611
Poly(N-vinylpyrrolidinone) Pure, wt. %	0.500
Sodium Carbonate, wt. %	0.500
Sodium Nitrite, wt. %	0.300

Other dispersants, such as poly(vinyl alcohol) have been used as a substitute for the poly(N-vinylpyrrolidinone).

TABLE 3

Aqueous Phase Charges

Ultrapure Water, g	24,644.83
Water from Aqueous 45% Solution of Poly(N-vinylpyrrolidinone), g	(153.542)
Poly(N-vinylpyrrolidinone) Pure, g	(125.625)
Aqueous Poly(N-vinylpyrrolidinone) Solution, 45 wt. %, g	279.167
Sodium Carbonate, g	125.625
Sodium Nitrite, g	75.375

Weights in parenthesis are part of other charged materials

Total Weight of Aqueous Phase, g	25,124.997

Table 4 and 5 illustrate the components of the organic phase composition for the polymer synthesis by weight percent (5) and by quantity of the components in grams (g), respectively.

TABLE 4

Organic Phase Composition

Divinylbenzene (DVB),wt.%	26.998
Ethylvinylbenzene (EVB), wt. %	15.0024
Inerts, wt. %	0.41567
Toluene,wt. %	27.134
Isooctane,wt.%	30.450
Benzoyl Peroxide, wt. % of polymerizable monomers	1.03

Other immiscible porogens such as isooctane, cyclohexane and nonane have been substituted, both singularly and in combination with one another, for the mixture of toluene and isooctane.

TABLE 5

Organic Phase Charges

Divinylbenzene, Pure, g	(5635.069)
Ethylvinylbenzene, Pure, g	(3131.381)
Commercial DVB, Dow 63.5%, g	8853.211
Inerts, g	(86.761)
Toluene, g	5663.613
Isooctane, g	6355.676
Weights in parenthesis are part of commercial DVB	
Total Weight of Organic Phase, g (excluding BPO)	20,872.50
Benzoyl Peroxide, BPO, Pure, g	90.294
75 weight percent BPO, g	120.393
97 weight oercent BPO, g	93.087

Upon preparation of the aqueous and organic phases, the aqueous phase is introduced into the reactor. The reactor is set at an agitation rate sufficient to produce droplet slurry throughout the reaction volume. The aqueous phase is then heated to 65 degrees Celsius with agitation and a nitrogen sweep through the headspace in order to displace oxygen from the reactor space. The

organic phase is then introduced into the reactor by pouring or pumping the organic phase onto the aqueous phase under agitation at a stirring rate of at least 86 revolutions per minute. The droplet dispersion is then stirred at 86 revolutions per minute for at least fifteen (15) minutes to set the droplet size and allow the droplet slurry to equilibrate as the temperature is raised from about 65 degrees to about 70 degrees Celsius. Once the droplet dispersion is homogenous throughout the reaction volume, the slurry is then heated to about 75 plus or minus 2.0 degrees Celsius and held at that temperature for ten (10) hours.

The slurry is cooled to about 70 degrees Celsius and the stirrer is turned off, and the polymer beads are allowed to collect at the top of the fluid bed. The mother liquor is then removed from the bottom of the reactor via a pump until the bead bed approaches within about one (1) inch from the bottom of the reactor. The mother liquor is discarded.

A sufficient amount of ultrapure water at ambient temperature is added to fluidize the bead bed and the slurry is heated to 60%. The quantity of water needed to wash the beads will be approximately one (1) bed volume or about 25 liters of water. Upon adding the water, the stirrer is then restarted and agitated at a stir rate of 106 revolutions per minute for about thirty (30) minutes while being heated to 60%. The stirring is stopped and the beads are allowed to collect at the top of the fluid bed.

The liquor is then drained from the bottom of the reactor via a pump until the bead bed approaches within about one (1) inch from the bottom of the reactor. The wash liquor is discarded. The beads are then washed with the 60 degree Celsius ultrapure water for at least five (5) washes or until the bulk fluid is transparent and free of junk polymer (a clear liquor is achieved). The water-wet bead slurry is transferred to a column that is fitted with a solid-liquid separator at the bottom of the column. The separator may be a mesh or screen made from Teflon, nylon, polypropylene, stainless steel, or glass with pore openings in the size from about 100 to about 300 microns.

The porogen mixture is displaced from the beads by a downflow treatment with ten (10) bed volumes of isopropyl alcohol at a flow rate of one (1) bed volume per hour. The isopropyl alcohol is displaced from the beads with water at a downflow treatment with ten (10) bed volumes of ultrapure water (pyrogen and endotoxin free) at a flow rate of one (1) bed volume per hour. The polymer beads are then transferred from the column into plastic containers for transport to the thermal steam-flux cleaner.

Alternatively, the porogen is displaced from the beads by a thermal-gas-flux treatment in which the porogen filled beads are heated from about 150 degrees to about 180 degrees Celsius under an upflow gas flux for approximately six (6) hours. The hot gas flux can be either super heated stream or hot nitrogen gas. The dried, cleaned, porogen free beads are wetted out with an aqueous solution of isopropyl alcohol in water for further handling prior to being packed into containers.

EXAMPLE 2

Other experimental procedures were conducted to make the polymeric beads manufactured by similar polymerization procedures described in Example 1 and under the variations identified in the Table of Inputs (Table 6) with the resulting responses tabulated in the Tables of responses (Table 7). Tables 6 & 7 are set forth below:

Experimental Program: Input TABLE 6

LDM	Sample ID 02-001	Sample ID 02-004	Sample ID 02-006	Sample ID 02-008	Sample ID 02-010	Sample ID 02-012	Sample ID 02-015	Sample ID 02-016	Sample ID 02-017	Sample ID 02-022	Sample ID 02-025
Organic Phase Composition											
Monomer (DVB & EVB) Wt. %	42.0	42.0	42.0	42.0	40.7	50.0	40.0	40.0	45.0	45.0	45.0
Porogen Wt. %	58.0	58.0	58.0	58.0	59.3	50.0	60.0	60.0	55.0	55.0	55.0
Porogen/Monomer Ratio	1.3810	1.3810	1.3810	1.3810	1.457	1.000	1.500	1.500	1.222	1.222	1.222
Benzoyl Peroxide (BPO) Wt.%	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03
Porogen Composition											
Isooctane, Wt.%	52.5	52.5	52.5	52.5	53.5	60.0	99.327	99.327	99.174	99.174	99.274
Toluene, Wt.%	46.769	46.769	46.769	46.769	45.81	38.99	0	0	0	0	0
Inerts, Wt %	0.731	0.731	0.731	0.731	0.693	1.010	0.6734	0.6734	0.826	0.826	0.726
Toluene, plus Inerts, Wt. %	47.5	47.5	47.5	47.5	46.5	40.0	"	"	"	"	"
Isooctane/Toluene plus Inerts Ratio	1.105	1.105	1.105	1.105	1.1505	1.500	"	"	"	"	"
Aqueous Phase Composition											
Sodium Carbonate, Wt. %	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500
Sodium Nitrite, Wt.%	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300
Poly (N-Vinylpyrrolidone), Wt.%	0.500	0.500	0.450	0.400	0.400	0.400	0.100	0.400	0.500	0.500	1.000
PVP K 30, 45-55 Kdaltons, Wt%	0	0	0	0	0	0	0	0	0	0.250	1.000
PVP K 60, 400-500 Kdaltons, Wt.%	0.500	0.500	0.450	0.400	0.400	0.400	0.100	0.400	0.500	0.250	0
Poly (Vinyl alcohol), Wt.%	0.01	0.01	0.05	0.100	0.100	0.100	0.400	0.100	0	0	0
Molecular Size, Kdaltons	88.0	88.0	95.0	95.0	95.0	95.0	95.0	95.0	"	"	"
Amount Hydrolized, %	85	85	95	95	95	95	95	95	"	"	"
Aqueous/Organic Phase Volume Ratio	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.1	1.1

Experimental Program: Input

TABLE 6 (CONT.)

LDM	Sample ID 02-028	Sample ID 02-029	Sample ID 02-030	Sample ID 02-031	Sample ID 02-032	Sample ID 02-033	Sample ID 02-034	Sample ID 02-036	Sample ID 02-038	Sample ID 02-040	Sample ID 02-042	Sample ID 02-044
Organic Phase Composition												
Monomer (DVB & EVB) Wt. %	45.0	45.0	45.0	45.0	45.0	50.0	55.0	55.0	55.0	55.0	55.0	55.0
Porogen Wt. %	55.0	55.0	55.0	55.0	55.0	50.0	45.0	45.0	45.0	45.0	45.0	45.0
Porogen/Monomer Ratio	1.222	1.222	1.222	1.222	1.222	1.000	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182
Benzoyl Peroxide (BPO) Wt.%	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03
Porogen Composition												
Isooctane, Wt.%	99.274	99.274	99.274	99.274	99.274	99.112	98.915	98.915	98.915	98.915	98.915	98.915
Toluene, Wt.%	0	0	0	0	0	0	0	0	0	0	0	0
Inerts, Wt %	0.726	0.726	0.726	0.726	0.726	0.8878	1.085	1.085	1.085	1.085	1.085	1.085
Toluene, plus Inerts, Wt. %	..	..	..	..	..	..	..	..	..	..	..	..
Isooctane/Toluene plus Inerts Ratio	..	..	..	..	..	..	..	..	..	..	..	..
Aqueous Phase Composition												
Sodium Carbonte, Wt. %	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500
Sodium Nitrite, Wt.%	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300
Poly (N-Vinylpyrrolidone), Wt.%	0.700	0.900	1.000	1.000	1.500	1.000	0.500	1.300	1.100	1.000	0.200	0.300
PVP K 30, 45-55 Kdaltons, Wt.%	0.700	0.900	1.000	1.000	1.500	0.9	0	1.000	1.000	0.800	0	0
PVP K 60, 400-500 Kdaltons, Wt.%	0	0	0	0	0	0.100	0.500	0.300	0.100	0.200	0.200	0.300
Poly (Vinyl alcohol), Wt.%	0	0	0	0	0	0	0	0	0	0	0	0
Molecular Size, Kdaltons	..	..	..	..	..	..	..	..	..	..	..	..
Amount Hydrolized, %	..	..	..	..	..	..	..	..	..	..	..	..
Aqueous/Organic Phase Volume Ratio	**1.2**	**1.2**	**1.145**	**1.2**	**1.2**	**1.1**	**1.1**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**

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Experimental Program: Input

TABLE 6 (CONT.)

LDM	Sample ID 02-047	Sample ID 02-049	Sample ID 02-050	Sample ID 02-052	Sample ID 02-054	Sample ID 02-055	Sample ID 02-059	Sample ID 02-061	Sample ID 02-073	Sample ID 02-074	Sample ID 02-075	Sample ID 02-079
Organic Phase Composition												
Monomer (DVB & EVB) Wt. %	55.0	55.0	55.0	55.0	55.0	55.0	55.0	55.0	55.0	55.0	55.0	55.0
Porogen Wt. %	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0
Porogen/Monomer Ratio	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182	0.8182
Benzoyl Peroxide (BPO) Wt.%	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03	1.03
Porogen Composition												
Isooctane, Wt.%	98.915	98.915	98.915	98.915	98.915	98.915	98.915	98.915	98.915	98.915	98.915	98.915
Toluene, Wt.%	0	0	0	0	0	0	0	0	0	0	0	0
Inerts, Wt %	1.085	1.085	1.085	1.085	1.085	1.085	1.085	1.085	1.085	1.085	1.085	1.085
Toluene, plus Inerts, Wt. %	..	..	..	..	..	..	..	..	..	..	..	..
Isooctane/Toluene plus Inerts Ratio	..	..	..	..	..	..	..	..	..	..	..	..
Aqueous Phase Composition												
Sodium Carbonte, Wt. %	0.300	0.100	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500
Sodium Nitrite, Wt.%	0.300	0.100	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300
Poly (N-Vinylpyrrolidone), Wt.%	0.010	0.010	0	0.05	0	0	0	0	0	0	0	0
PVP K-30, 45-55 Kdaltons, Wt.%	0.010	0.010	0	0.05	0	0	0	0	0	0	0	0
PVP K 60, 400-500 Kdaltons, Wt.%	0	0	0	0	0	0	0	0	0	0	0	0
Poly (Vinyl alcohol), Wt.%	0.250	0.400	0	0	0	0	0	0.300	0.300	0.300	0.300	0.300
Molecular Size, Kdaltons	95	95	..	..	..	..	170	170	170	170	170	170
Amount Hydrolized, %	95	95	..	..	..	..	88	88	88	88	88	88
Natrosol Plus, Wt. %	0	0	0.500	0.300	0.300	0.300	0	0	0	0	0.05	0
Aqueous/Organic Phase Volume Ratio	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**

TABLE 6 (cont.)

Experimental Program: Input

LDM	Sample ID 02-082	Sample ID 02-083	Sample ID 02-086	Sample ID	Sample ID	Sample ID	Sample ID	Sample ID	Sample ID	Sample ID	Sample ID
Organic Phase Composition											
Monomer (DVB & EVB) Wt. %	55.0	55.0	55.0								
Porogen Wt. %	45.0	45.0	45.0								
Porogen/Monomer Ratio	0.8182	0.8182	0.8182								
Benzoyl Peroxide (BPO) Wt.%	1.03	1.03	1.03								
Porogen Composition											
Isooctane, Wt.%	98.915	98.915	98.915								
Toluene, Wt.%	0	0	0								
Inerts, Wt %	1.085	1.085	1.085								
Toluene plus Inerts, Wt. %	"	"	"								
Isooctane/Toluene plus Inerts Ratio	"	"	"								
Aqueous Phase Composition											
Sodium Carbonte, Wt. %	0.500	0.500	0.500								
Sodium Nitrite, Wt.%	0.300	0.300	0.300								
Poly (N-Vinylpyrrolidione), Wt.%	0	0	0								
PVP K-30, 45-55 Kdaltons, Wt.%	0	0	0								
PVP K-60, 400-500 Kdaltons, Wt.%	0	0	0								
Poly (Vinyl alcohol), Wt.%	0.300	0.300	0.3								
Molecular Size, Kdaltons	170	88	170								
Amount Hydrolized, %	88	85	88								
Natrosol Plus, Wt. %	0	0	0								
Aqueous/Organic Phase Volume Ratio	1.0	1.0	1.0								

Experimental Programs: Response

TABLE 7

LDM	Sample ID 02-001	Sample ID 02-004	Sample ID 02-006	Sample ID 02-008	Sample ID 02-010	Sample ID 02-017	Sample ID 02-025	Sample ID 02-034	Sample ID 02-036	Sample ID 02-038
Surface Characteristics										
SEM; description (smooth, nodes present, open or closed pore structure)	nodes, closed	nodes, closed	nodes, closed	nodes, closed	nodes, closed	no nodes, open	no nodes, open	no nodes, open	no nodes, open	nodes, closed
Internal Pore Stucture (Dry Beads)										
BET Surfrace Area, $\overline{S}$, m^2g^{-1}	563.5	652.8	615.7	614.4	661.4	520.9	540.0	537.2	556.6	556.6
Porosity, Pwt in $ml.g^{-1}$	0.9210	1.5370	1.53085	1.7245	1.7722	1.1241	1.3899	1.9069	1.9588	1.8754
Pore modes greater than 100 Å diameter from Desorption Isotherm. List each	150	250, 400	250 500	430 550	490	250,390,495 640,920 1400, 1900	320, 440 550, 750 1200, 2900	380, 490 620, 930	210, 280 380, 500, 650	210, 280,380 500, 650, 930
Pore modes range in Å greater than 100 Å diameter, Desorption Isotherm.	100-250	100-500	100-600	100-700	100-600	100-2300	100-2900	100-1600	100-1600	100-1600
Cytochrome C Sorption Static Assesment 500 mg/Liter Conc.										
Mg Cyto C sorbed/g dry polymer at 3hr contact	15.2	43.35	42.95	63.05	79.7	135.0	155.8	86.6	82.0	54.8
% of Cyto C removed from solution at 3 hr contact	19.42	53.80	51.46	66.22	73.78	82.64	82.49	85.12	85.26	57.82
Serum Albumin Sorption										
% removed from solution with a concentration of 35,000 mg/l of serum albumin						6.1	4.15	4.38		4.9
Mg BSA (or HSA) sorbed/g dry polymer at 3 hr contact						681.6	488.22	301.46		311.96
Coating Assesment ESCA Measurements for Surface Components, Atom Fraction on surface										
C	0.8702	0.8722	0.8917	0.8881	0.8855	0.8613	0.8520	0.8981	0.8682	0.8901
O	0.0784	0.0758	0.0682	0.0729	0.0860	0.1106	0.1480	0.0778	0.0935	0.0771
N	0.0514	0.0520	0.0401	0.0390	0.0284	0.0281	none detected	0.0241	0.0383	0.0328

Experimental Programs: Response

TABLE 7 (CONT.)

LDM	Sample ID 02-040	Sample ID 02-044	Sample ID 02-054	Sample ID 02-055A	Sample ID 02-075	Sample ID 02-079	Sample ID 02-082	Sample ID 02-083	Sample ID 02-086
Surface Characteristics									
SEM; description (smooth, nodes present, open or closed pore structure)	nodes, closed	nodes, closed	nodes, closed	nodes, closed	nodes, closed		nodes, closed		
Internal Pore Stucture (Dry Beads)									
BET Surface Area, $\overline{S}$ m^2g^{-1}	549.6	545.4	536.8	525.2	531.5		528.9		
Porosity, Pwt in $ml.g^{-1}$	1.8356	1.6420	1.6567	1.6957	1.5232		1.3708		
Pore modes greater than 100 Å diameter from Desorption Isotherm. List each	300;390; 500;650; 950	250;310; 450;550; 790;1200	280;350; 460;600; 810;1900	290;390; 500;640; 990	200;310; 410;530; 740;900;1200		210;280; 380;490;620; 900;1300		
Pore modes range in Å greater than 100 Å diameter, Desorption Isotherm.	100-1600	100-2000	100-2900	100-1700	100-2400		100-2400		
Cytochrome C Sorption Static Assesment 500 mg/Liter Conc.									
Mg Cyto C sorbed/g dry polymer at 3hr contact	57.7	61.7	73.9	57.8	32.8		61.1		
% of Cyto C removed from solution at 3 hr contact	61.43	65.55	79.83	63.63	39.00		74.89		
Serum Albumin Sorption									
% removed from solution with a concentration of 35,000 mg/l of serum albumin	3.07	4.12							
Mg BSA (or HSA) sorbed/g dry polymer at 3 hr contact	192.10	257.96							
Coating Assesment ESCA Measurements for Surface Components, Atom Fraction on surface									
C	0.8586	0.8748	0.8238	0.7924	0.8441		0.8830		
O	0.0982	0.0897	0.1745	0.2076	0.1559		0.1170		
N	0.0432	0.355	none detected	none detected	none detected		none detected		

Numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the attendant claims attached hereto, this invention may be practiced otherwise than as specifically disclosed herein.

CLAIMS:

What Is Claimed Is:

1. A hemocompatible-coated polymer comprising at least one crosslinking agent and at least one dispersing agent whereby said dispersing agent forms a hemocompatible surface on said polymer.

2. The polymer of Claim 1 wherein said dispersing agent comprises a biocompatibilizing polymer.

3. The polymer of Claim 2 wherein said biocompatibilizing polymer comprises poly(N-vinylpyrrolidinone).

4. The polymer of Claim 2 wherein said biocompatibilizing polymer is selected from a group consisting of poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(dimethylaminoethyl methacrylate), salts of poly(acrylic acid), salts of poly(methacrylic acid), poly(diethylaminoethyl methacrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(N-vinylpyrrolidinone), poly(vinyl alcohol) and mixtures thereof.

5. The polymer of Claim 1 wherein said dispersing agent is selected from a group consisting of hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly- (dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly-(diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), and salts of poly(acrylic acid) and mixtures thereof.

6. The polymer of Claim 1 wherein said crosslinking agent is selected from a group consisting of divinylbenzene, trivinylbenzene, divinylnaphthalene, trivinylcyclohexane, divinylsulfone, trimethylolpropane trimethacrylate, trimethylolpropane dimethacrylate, trimethylolpropane triacrylate, trimethylolpropane diacrylate, pentaerythrital dimethacrylates, pentaerythrital trimethacrylates, pentaerythrital tetramethacrylates, pentaerythritol diacrylates, pentaerythritol triiacrylates, pentaerythritol tetraacrylates, dipentaerythritol dimethacrylates, dipentaerythritol trimethacrylates, dipentaerythritol tetramethacrylates, dipentaerythritol diacrylates, dipentaerythritol triacrylates, dipentaerythritol tetraacrylates, divinylformamide and mixtures thereof.

7. The polymer of Claim 1 wherein said crosslinking agent comprises divinylbenzene.

8. The polymer of Claim 1 wherein said crosslinking agent comprises trivinylcylohexane.

9. The polymer of Claim 1 wherein said crosslinking agent comprises trivinylbenzene.

10. The polymer of Claim 1 wherein said crosslinking agent comprises copolymers of divinylbenzene with comonomers being selected from a group consisting of styrene, ethylstyrene, acrylonitrile, butyl methacrylate, octyl methacrylate, butyl acrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinyltoluene, vinylnaphthalene, vinylbenzyl alcohol, vinylformamide, methyl methacrylate, methyl acrylate and mixtures thereof.

11. The polymer of Claim 1 wherein said hemocompatible surfaced polymer is a porous polymer.

12. The polymer of Claim 1 wherein said hemocompatible surfaced polymer is an ion exchange polymer.

13. The polymer of Claim 2 wherein said biocompatibilizing polymer becomes grafted to a surface of said polymer to provide said hemocompatible surfaced polymer.

14. A biocompatible coated polymer manufactured by a method comprising:

polymerizing monomer droplets comprising at least one crosslinking agent to form a polymer and simultaneously coating said resulting polymer using at least one dispersing agent to thereby form a biocompatible coated polymer.

15. The polymer of Claim 14 wherein said crosslinking agent is polymerized with at least one vinyl monomer.

16. The polymer of Claim 14 wherein said dispersing agent forms a hemocompatible coating on a surface of said polymer.

17. The polymer of Claim 14 wherein said dispersing agent comprises a biocompatibilizing polymer.

18. The polymer of Claim 17 wherein said biocompatibilizing polymer is poly (N-vinylpyrrolidinone).

19. The polymer of Claim 17 wherein said biocompatibilizing polymer is poly(vinyl alcohol).

20. The polymer of Claim 17 wherein said biocompatibilizing polymer is selected from a group consisting of poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(dimethylaminoethyl methacrylate), salts of poly(acrylic acid), salts of poly- (methacrylic acid), poly(diethylaminoethyl methacrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(N-vinylpyrrolidinone), poly(vinyl alcohol) and mixtures thereof.

21. The polymer of Claim 14 wherein said dispersing agent is selected from a group consisting of hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly(dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly(diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), and salts of poly(acrylic acid) and mixtures thereof.

22. The polymer of Claim 14 wherein said crosslinking agent is selected from a group consisting of divinylbenzene, trivinylbenzene, divinylnaphthalene, trivinylcyclohexane, divinylsulfone, trimethylolpropane trimethacrylate, trimethylolpropane dimethacrylate, trimethylolpropane triacrylate, trimethylolpropane diacrylate, pentaerythrital dimethacrylates, pentaerythrital trimethacrylates, pentaerythrital tetramethacrylates, pentaerythritol diacrylates, pentaerythritol triiacrylates, pentaerythritol tetraacrylates, dipentaerythritol dimethacrylates, dipentaerythritol trimethacrylates, dipentaerythritol tetramethacrylates, dipentaerythritol diacrylates, dipentaerythritol triacrylates, dipentaerythritol tetraacrylates, divinylformamide and mixtures thereof.

23. The polymer of Claim 14 wherein said crosslinking agent comprises divinylbenzene.

24. The polymer of Claim 14 wherein said crosslinking agent comprises trivinylcylohexane.

25. The polymer of Claim 14 wherein said crosslinking agent comprises trivinylbenzene.

26. The polymer of Claim 14 wherein said crosslinking agent comprises copolymers of divinylbenzene with comonomers being selected from a group consisting of styrene, ethylstyrene, acrylonitrile, butyl methacrylate, octyl methacrylate, butyl acrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinyltoluene, vinylnaphthalene, vinylbenzyl alcohol, vinylformamide and mixtures thereof.

27. The polymer of Claim 14 wherein said hemocompatible coated polymer is a porous polymer.

28. The polymer of Claim 14 wherein said hemocompatible coated polymer is an ion exchange polymer.

29. The polymer of Claim 17 wherein said biocompatibilizing polymer becomes grafted to a surface of said polymer to provide said hemocompatible coated polymer.

30. The polymer of Claim 14 wherein said polymer is processed in non-pyrogenic water.

31. A polymer with a hemocompatible surface coating, said polymer being manufactured by a one step process comprising:

simultaneously coating and polymerizing monomer droplets in a suspension polymerization procedure with at least one dispersing agent having encapsulated said droplets with a hemocompatible

coating to thereby form a polymer with a hemocompatible surface-coating grafted onto the surface of said polymer, said dispersing agent being a biocompatibilizing polymer.

32. The polymer of Claim 31 wherein said monomer droplets is selected from a group consisting of divinylbenzene, styrene, ethylstyrene, acrylonitrile, butyl acrylate, butyl methacrylate, vinyltoluene, vinylnaphthalene, octyl methacrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinylbenzyl alcohol, vinylformamide andmixtures thereof.

33. The polymer of Claim 31 wherein said biocompatibilizing polymer is selected from a group consisting of poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(dimethylaminoethyl methacrylate), salts of poly(acrylic acid), salts of poly(methacrylic acid), poly(diethylaminoethyl methacrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(N-vinylpyrrolidinone), poly(vinyl alcohol) and mixtures thereof.

34. The polymer of Claim 31 wherein said dispersing agent is selected from a group consisting of hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly(dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly(diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), salts of poly(acrylic acid) and mixtures thereof.

35. A method of manufacturing a biocompatible coated polymer, said method comprising:

polymerizing monomer droplets comprising at least one crosslinking agent to form a polymer and simultaneously coating said resultant polymer using at least one dispersing agent to thereby form a biocompatible coated polymer.

36. The method of Claim 35 wherein said polymer is formed using a suspension polymerization procedure.

37. The method of Claim 35 wherein said polymer is formed using emulsion polymerization procedure.

38. The method of Claim 35 wherein said dispersing agent comprises a biocompatibilizing polymer.

39. The method of Claim 35 wherein said biocompatibilizing polymer is poly(N-vinylpyrrolidinone).

40. The method of Claim 35 wherein said biocompatibilizing polymer is poly(vinyl alcohol).

41. The method of Claim 35 wherein said biocompatibilizing polymer is selected from a group consisting of poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(dimethylaminoethyl methacrylate), salts of poly(acrylic acid), salts of poly (methacrylic acid), poly(diethylaminoethyl methacrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(N-vinylpyrrolidinone), poly(vinyl alcohol) and mixtures thereof.

42. The method of Claim 35 wherein said dispersing agent is selected from a group consisting of hydroxyethyl cellulose, hydroxypopyl cellulose, poly(hydroxyethyl methacrylate), poly(hydroxyethyl acrylate), poly(hydroxypropyl methacrylate), poly(hydroxypropyl acrylate), poly(dimethylaminoethyl methacrylate), poly(dimethylaminoethyl acrylate), poly(diethylamimoethyl methacrylate), poly(diethylaminoethyl acrylate), poly(vinyl alcohol), salts of poly(methacrylic acid), and salts of poly(acrylic acid) and mixtures thereof.

43. The method of Claim 35 wherein said crosslinking agent comprises copolymers of divinylbenzene with comonomers being selected from a group consisting of styrene, ethylstyrene, acrylonitrile, butyl methacrylate, octyl methacrylate, butyl acrylate, octyl acrylate, cetyl methacrylate, cetyl acrylate, ethyl methacrylate, ethyl acrylate, vinyltoluene, vinylnaphthalene, vinylbenzyl alcohol, vinylformamide and mixtures thereof.

44. The method of Claim 35 wherein said crosslinking agent is hydrophobic prior to coating and said external surface of said polymer is rendered hydrophilic and biocompatible after coating.

45. The method of Claim 38 wherein said biocompatibilizing polymer becomes grafted to a surface of said hemocompatible coated polymer.

46. The method of Claim 35 wherein said polymer is processed in non-pyrogenic water.

47. The method of Claim 35 wherein said crosslinking agent is polymerized with at least one vinyl monomer.