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(54) **Contact lens of high water content and high water balance**

Weiche Kontaktlinsen mit hohem Wassergehalt und hohem Wassergleichgewicht

Lentille de contact à haute teneur en eau et à bilan hydrique élevé

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DescriptionBACKGROUND OF THE INVENTION5 Field of the Invention

[0001] The present invention relates to a contact lens formed from a polymer based on 2,3-dihydroxypropyl methacrylate (GMA) that has high water content and high water balance. The present invention also relates to methods of making and using such contact lenses. The present invention also relates to polymers and hydrogels of GMA and to methods of making and using such polymers.

Description of the Related Art

[0002] The literature teaches that high water content lenses are susceptible to dimensional changes during wear because they tend to lose a higher percent of water (dehydrate) relative to lenses of lower water content. Further, the ability to regain the lost water (rehydrate) is important to the dimensional stability of a contact lens. If a lens material absorbs water more rapidly, then the lens will more closely return to a water-saturated state during each blink, when the lens is bathed in tear fluid. Therefore, as a lens begins to dehydrate, a characteristic of rapid rehydration is extremely advantageous for maintaining saturation and maximum stability.

[0003] Unfortunately, conventional contact lens development either has ignored the effect of rehydration rate upon lenses or has constructed lenses of materials with a less than optimal rate of rehydration.

[0004] U.S. Patent No. 5,532,289, hereby incorporated by reference in its entirety, describes a family of copolymers useful for making contact lenses. The copolymers have improved ability to remain near their water saturated state during wear. In this patent, the inventors of the present invention describe a method for making contact lenses with improved dimensional stability based on copolymers of 2,3-dihydroxypropyl methacrylate (GMA) and 2-hydroxyethyl methacrylate (HEMA). The polymers contain between 20 and 90 mole percent of GMA and have a water content from about 40 to about 70% by weight. The dimensional stability of these lenses results from the ability of these hydrogels to strongly bind water.

[0005] In the '289 patent, lenses made from this family of materials were shown, under in-vitro conditions, to be slow to dehydrate and fast to rehydrate, relative to all other soft lens materials. The times it took a lens to dehydrate to 10% of its water weight and rehydrate back to saturation were combined into a factor called "water balance". This "water balance" value can be used to compare commercial lens materials, regardless of water content and as a guideline, by practitioners, in selecting an appropriate lens material for a patient. This patent also emphasizes the ability to remain near or at saturation as a key to dimensional stability in a soft lens.

[0006] Clinical studies by Businger in Contact Lens Spectrum, August 1995, pp. 19-25 and Die Kontaktlinsen 7-8, 4 (1997) support the laboratory findings on water retention and lens stability. These studies report that lenses made from hioxifilcon A (p-GMA/HEMA, 59% water) were preferred by the largest margin of test subjects because of comfort and visual acuity. These lenses showed the highest dimensional stability and the best of both low-contrast and high-contrast visual acuity during wear cycles of 14 hours, over a period of 30 days, over other conventional contact lenses irrespective of water content.

[0007] The literature teaches that the water content of GMA/HEMA copolymers increases, from an initial 38% for p-HEMA, with increasing concentration of GMA. See, Yasuda, et. al., Journal of Polymer Science: Part A1, 4, 2913-27 (1966) and Macret et. al., Polymer, 23(5) 748-753 (1982), which describes hydrogels based on HEMA and GMA.

[0008] Refojo, Journal of Applied Polymer Science, 9, 3161-70 (1965), describes hydrogels of high water content made from GMA. The polymer are made by polymerization in bulk or in water solution. Also, high water content hydrogels of copolymers of GMA and glycidyl methacrylate are described.

[0009] Wichterle, et. al., UK Patent GB 2196973A, reported the use of hydrophilic solvents, such as glycerol, dimethylformamide, and dimethylsulfoxide, in 2-HEMA blends primarily for the centrifugal casting of contact lenses.

50 Summary of the Invention

[0010] The literature is significantly void of examples of p-GMA homopolymer and copolymers where the GMA content exceeds 80 mole percent, for use in contact lens application. While some of the literature described above discusses hydrogels based on GMA polymers, the literature fails to suggest to fabricate contact lenses from polymer of high GMA content; and certainly none of the literature suggests that contact lenses formed from polymers of at least 80 mole percent GMA could exhibit the outstanding and unexpected properties, including slow dehydration and fast rehydration, i.e., a high water balance, discovered by the present inventors.

[0011] Since polymers that contain 2,3-dihydroxypropyl methacrylate (GMA) show improved water retention capability

(See Pescossolido et al., Contactologia, 15D, 64-7 (1993) and Benz et al., Contact Lens Spectrum July 1997, pp.40-46), the present inventors conceived that a polymer composed mostly of GMA should yield a contact lens with extraordinary dimensional stability and water retention. Overall lens performance, with respect to stability and water retention, should surpass any commercial available lens material. However, to date, the art has failed to suggest contact lenses formed

of polymers having at least 80 mol percent GMA or method of making such lenses.

[0012] Accordingly, it is an object of the present invention to provide contact lenses formed from a material primarily composed of GMA.

[0013] It is also an object of the invention to provide methods of making and using such contact lenses.

[0014] Another object of the invention is to provide polymers with improved machining, useful for a spheric contact lens, a toric contact lens, a multifocal contact lens, and a bandage contact lens.

[0015] Another object of the invention is to provide a spheric contact lens, a toric contact lens, a multifocal contact lens, and a bandage contact lens with superior dimensional stability.

[0016] Another object of the invention is to provide a spheric contact lens, a toric contact lens, a multifocal contact lens and a bandage contact lens with superior water retention and water balance.

[0017] Another object of the invention is to provide a spheric contact lens, a toric contact lens, a multifocal contact lens and a bandage contact lens suitable for daily wear and extended wear modalities.

[0018] It is also an object of the invention to provide blanks for contact lenses, and finished and unfinished contact lenses having improved characteristics, such as high water content and high water balance.

[0019] A method for producing a contact lens satisfying at least the first-mentioned object is defined in claim 1. The further claims define preferred executions and a contact lens blank obtained by the method.

[0020] Accordingly, it is provided a contact lens formed from a homopolymer of 2,3-dihydroxypropyl methacrylate, wherein the polymer has a water content of at least 60%, and a water balance of greater than about 8 relative to that of p-HEMA.

[0021] There is also provided in accordance with the present invention a method of making a polymer including more than 90 mol percent of units from 2,3-dihydroxypropyl methacrylate, comprising polymerizing 2,3-dihydroxypropyl methacrylate in the presence of a polar aprotic diluent.

[0022] There is also provided a method of making a contact lens, comprising polymerizing GMA and a comonomer in the presence of a polar aprotic diluent to form a copolymer, and forming the copolymer into a contact lens.

Furthermore, the invention relates to the following:

[0023] A hydrogel, contact lens blank or a contact lens formed from a copolymer, the copolymer of the contact lens characterized in that the copolymer comprises: more than 80 mole percent of incorporated 2,3-dihydroxypropyl methacrylate and from about 0.05 to 20 mole percent of incorporated alkoxyalkyl methacrylate having the formula R_1-O-R_2-MA , wherein R_1 and R_2 are independently selected alkyl groups having 1 to 6 carbon atoms, and MA is methacrylate.

[0024] Further objects, features, and advantages of the present invention will become apparent from the detailed description of preferred embodiments that follows.

[0028] The polymers of the present invention can be formed into hydrogels, contact lens blanks, semi-finished contact lenses, or finished contact lenses. The contact lenses can be of any type including spheric, toric, multifocal, and bandage contact lenses.

5 [0029] The present inventors have found that alkoxyalkylmethacrylates of formula R_1-O-R_2-MA , wherein R_1 and R_2 are independently alkyl groups of 1 to 6 carbon atoms, and MA is methacrylate; and reactive pyrrolidones, such as N-vinyl pyrrolidone are especially useful comonomers.

10 [0030] The polymers of GMA can be prepared using polymerization techniques well known to those in the art. Any desired crosslinking agents or initiators can be used in result-effective amounts. Useful crosslinking agents include ethylene glycol dimethacrylate. Crosslinkers are generally used in amounts of less than 5 weight percent, generally less than 2 weight percent, based on the weight of the polymer. Useful initiators include the azo initiators such as used in the examples. Polymerization can take place at any temperature, but preferably above room temperature, for example, above 30°C or above about 40°C.

15 [0031] Due to the fact that concentrated GMA solutions are highly viscous, the present inventors have also developed a procedure for preparing polymers having a high content of GMA. As with glycerol, GMA's high viscosity results in part because of the vicinal -OH groups leading to a tight (hydrogen-bond) network, which greatly influence polymerization because molecular motion is greatly restricted.

20 [0032] The effect of GMA on viscosity can be seen in Figure 1. Figure 1 shows the contrasting effect on the viscosity of 2-HEMA when blended with monomers like GMA and NVP. Addition of GMA increases the viscosity of the HEMA blend, while NVP has the opposite effect. NVP reduces the viscosity of HEMA blends, in part, because it contains no hydroxyl groups (i.e., is aprotic) and disrupts the internal H-bond network since the lactam nitrogen is a weaker hydrogen-bonding moiety. When GMA is polymerized in the presence of NVP, the disruption of the intermolecular H-bond network of the GMA, reduces viscosity and improves the polymerization conditions and consistency. During the initial phase of the polymerization with GMA, the NVP comonomer acts as a reactive diluent improving the mobility of the di-hydroxy containing comonomer and allowing a higher level of polymerization prior to gel.

25 [0033] Thus, the present invention relates to method of preparing GMA polymers by polymerizing in the presence of a reactive polar aprotic diluent, such as N-vinyl pyrrolidone and/or a non-reactive polar aprotic diluent. Protic diluents can be used in combination with the aprotic diluents. Generally, at least 50% by weight of the total diluent should be an aprotic polar diluent, which is reactive or unreactive.

30 [0034] As discussed above, the present invention relates to GMA homopolymers and copolymers, useful in contact lenses. The homopolymers and copolymers are discussed below.

GMA Homopolymer:

35 [0035] To obtain a GMA homopolymer, the GMA is combined with one or more non-reactive polar aprotic diluents or blend of such diluents with a protic diluent and polymerized. Non-reactive diluents are ones that do not copolymerize with the GMA, thus ensuring that a homopolymer or GMA is formed. The non-reactive polar diluent (s) act to disrupt the intra-intermolecular H-bond network of the GMA monomer and to reduce the viscosity of the blend, thereby increasing reactant mobility and allowing a more desirable and random polymerization. Diluent selection is important because it should be inert, should improve the polymerization process, and should be effectively removed during hydration.

40 [0036] Two fundamental types of diluent that can be used in polymerizations are protic and aprotic diluents. An aprotic diluent is used in the methods of the present invention. Polar aprotic diluents alone or in combination with protic diluents, such as water can be used.

45 [0037] Figures 2 and 3 show the viscosity of GMA with various diluents. Protic diluents are diluents with hydroxyl groups available for H-bonding, and include water, ethylene glycol (EG), and blends thereof. These diluents modify viscosity and affect the GMA hydrogen bond network but can also strongly contribute to the H-bond network. Aprotic diluents are diluents without hydrogen moieties available for H-bonding, such as N-methyl pyrrolidone (NMP), N,N-dimethylformamide (DMF), tetrahydrofuran (THF), and the like. The aprotic diluents are preferably polar. The aprotic diluents can more effectively disrupt the hydrogen bond network while contributing weakly to the network and reducing the viscosity of the GMA monomer. Thus, polar aprotic diluents, such as NMP, are used in the present invention. But again, protic diluents can be combined with the aprotic diluents. In addition to NMP and NVP, any alkyl, or alkenyl N-substituted lactam can be used as polar aprotic diluent.

50 [0038] Figures 2 and 3 show the reduction in GMA viscosity, over a range of temperatures, brought about by blending the GMA monomer with both non-reactive diluents, such as NMP and EG, and reactive polar diluents, such as HEMA and NVP. Figures 2 and 3 also show that, as expected, differences in the viscosity of the blends decrease with temperature. To approach a viscosity range (< 20 cps) like that for HEMA, at room temperature, diluent amounts greater than 15 weight% are generally needed. However, at temperatures above 45°C the differences in viscosity of the various blends decrease allowing for lower concentration of diluent.

GMA Copolymers & Terpolymers:

[0039] In addition to GMA homopolymer, the present invention relates to GMA copolymers and terpolymers. The inventors have developed an approach to achieve a high water content in a hydrogel primarily composed of GMA. This approach is to combine the GMA with either a monomer or blend of monomers that also act as a diluent during polymerization to change the intra-intermolecular H-bond network of the GMA monomer and modify the viscosity of the mixture to allow a high degree of cure prior to gel. The copolymer or terpolymers generally have more than about 80 mol percent of GMA, preferably more than 90 mol percent GMA, for example, they are composed of 90 to 99 mole% GMA. The comonomers can be present in amounts of up to 20 mol percent, for example from 0.05 to 20 mol percent, or from 0.5 to 10 mol percent or 1 to 8 mole%.

[0040] Any comonomer or mixture of comonomers polymerizable with GMA can be used, so long as the resulting copolymer/terpolymer has physical, optical and machining characteristics suitable for contact lenses. The term copolymers means polymers of at least two monomers, including terpolymers of three monomers, and polymers formed from more than three monomers.

[0041] Useful comonomers include pyrrolidone derivative like NVP (N-vinyl pyrrolidone) and alkoxy alkyl methacrylates of the formula R_1-O-R_2-MA , where R_1 is an alkyl group having 1 to 6, preferably 1-4, carbon atoms such as methyl, ethyl, n-propyl, n-butyl and R_2 is an alkyl group having 1 to 6, preferably 1-4, carbon atoms such as ethyl and propyl, and MA is methacrylate.

[0042] Additions of N-vinylpyrrolidone (NVP) and alkoxyalkyl-methacrylates like ethoxy ethyl methacrylate (EOEMA) provide improved machinability while maintaining the high water content and water balance values of the copolymers. During polymerization to produce the copolymers, the viscosity of the monomer blends can be further optimized by the inclusion of protic or aprotic diluents such as NMP, EG, or water. During polymerization, a reactive and/or non-reactive aprotic diluent should be used. NMP and NVP modify the viscosity and enhance the mixture reactivity (See Kloosterboer et. al., Phillips Tech. Rev., 40, 298 (1982)). The EOEMA also modifies the viscosity of the blend improving reactant mobility.

[0043] Contact lens blanks, semi-finished lenses, and contact lenses can be prepared from the GMA homo- and copolymers of the present invention using techniques well know to those in art. See, for example, U.S. Patent No. 5,532,2890, herein incorporated by reference in its entirety.

[0044] The contact lenses of the present invention have low protein build-up, a high water balance (low rate of water evaporation and high rate of rehydration) and substantially less tendency to desiccate the cornea of extended wear soft lens patients. Due to the use of a polar aprotic diluent(s) during polymerization, water contents of above 70% or above 72 or 74% can be obtained. UV absorbing monomer (s) and tint-forming pigment(s) can be used in manufacturing the contact lens as would be understood by those in the art. The invention is illustrated by the following examples, which illustrate the invention, but do not limit it.

EXAMPLE 1Preparation of GMA Homopolymer with 74% Water Content

[0045] 91.7 grams of GMA were mixed with 8.2 grams of NMP and 0.03 grams of cyclohexanecarbonitrile, 1,1'-azobis initiator. The total diester concentration was adjusted to 0.07% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens buttons (blanks). The mechanical formation process comprised cutting the polymer into cylinders of 0.5 to 0.65 inches (1.27 to 1.65 cm.) in diameter and 0.1 to 0.2 inches (0.25 to 0.51 cm.) in thickness. The blanks were further cured at 100°C for 5 hours. After curing, the flat parallel faces of the buttons (blanks) were ground perpendicular to the cylinder walls with the desired dimensions.

EXAMPLE 2Preparation of GMA/NVP Copolymer with 69% Water Content

[0046] 91.8 grams of GMA were mixed with 3.4 grams of NVP and 4.8 grams of water. To the mixture, 0.03 grams of 2, 2'-azobis (2, 4-dimethylvaleronitrile) were added and the total diester concentration adjusted to 0.3% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 30°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks. The mechanical formation process included cutting the polymer into cylinders of 0.5 to 0.65 inches (1.27 to 1.65 cm.) in diameter and 0.1 to 0.2 inches (0.25 to 0.51 cm.) in thickness. The blanks were further cured at 100°C for 5 hours. The polymer was then removed from the molds

and formed into contact lens blanks as described previously.

EXAMPLE 3

5 Preparation of GMA/NVP Copolymer with 74% Water Content

[0047] 90.1 grams of GMA were mixed with 3.3 grams of NVP and 6.5 5 grams of NMP. To the mixture 0.03- grams of cyclohexanecarbonitrile, 1,1'-azobis were added. The total diester concentration was adjusted to 0.08% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described in Example 1.

EXAMPLE 4

15 Preparation of GMA/NVP Copolymer

[0048] 90.1 grams of GMA were mixed with 3.3 grams of NVP and 6.5 grams of DMF. To the mixture 0.03 grams of cyclohexanecarbonitrile, 1,1'-azobis were added. The total diester concentration was adjusted to 0.07% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described in Example 1.

EXAMPLE 5

25 Preparation of GMA/NVP Copolymer

[0049] 90.1 grams of GMA were mixed with 3.3 grams of NVP and 6.5 grams of ethylene glycol. To the mixture 0.03 grams of cyclohexanecarbonitrile, 1,1'-azobis were added. The total diester concentration was adjusted to 0.07% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cure at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described in Example 1.

EXAMPLE 6

35 Preparation of GMA/EOEMA Copolymer with 72% Water Content

[0050] 89.6 grams of GMA were mixed with 4.6 grams of EOEMA and 5.7 grams of NMP. To the mixture 0.03 grams of cyclohexanecarbonitrile, 1,1'-azobis were added and the total diester concentration adjusted to 0.07% by weight with ethylene glycol dimethacrylate (EGDMA) . The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described in Example 1.

EXAMPLE 7

45 Preparation of GMA/NVP Copolymer with 74% Water Content

[0051] 90.1 grams of GMA were mixed with 3.3 grams of NVP and 6.5 grams of NMP. To the mixture, 0.03 grams of cyclohexanecarbonitrile, 1,1'-aczbis were added. The total diester concentration was adjusted to 0.07% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described in Example 1.

EXAMPLE 8

55 Preparation of GMA/NVP/EOEMA Terpolymer with 73% Water Content

[0052] 87.0 grams of GMA were mixed with 3.3 grams of NVP, 2.0 grams of EOEMA and 6.5 grams of NMP. To the mixture, 0.03 grams of cyclohexanecarbonitrile, 1,1'-azobis were added and the total diester concentration was adjusted

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to 0.08% by weight with ethylene glycol dimethacrylate (EGDMA). The mixture was degassed while applying vigorous stirring. The mixture was dispensed into cylindrical molds, polymerized at 50°C for 10 hours, and post-cured at 100°C for 5 hours. The polymer was then removed from the molds and formed into contact lens blanks as described previously. **[0053]** The formulations for Examples 1-8 are summarized in Table 1. The properties are set out in Table 2.

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TABLE 1

Chemical Composition in Weight Percent								
	EXAMPLE 1	EXAMPLE 2	EXAMPLE 3	EXAMPLE 4	EXAMPLE 5	EXAMPLE 6	EXAMPLE 7	EXAMPLE 8
2,3-DHPMA (GMA)	91.7	91.8	90.1	90.1	90.1	89.6	90.1	87
EOEMA	--	--	--	--	--	4.6	--	2
NVP	--	3.4	3.3	3.3	3.3	--	3.3	3.3
Initiator VAZO 52/64/88	0.03	0.03	0.03	0.03	0.03	0.03	0.03	.003
EGPMA	0.07	--	0.08	0.07	0.07	0.08	0.07	0.08
NON-REACTIVE DILUENTS								
Protic	--	4.8 DI-H ₂ O	--	--	6.5 EG	--	--	--
Aprotic	8.2 NMP	--	6.5 NMP	6.5 DMF	--	5.7 NMP	6.5 NMP	6.5 NMP

TABLE 2

Material Properties								
PROPERTY	EXAMPLE 1	EXAMPLE 2	EXAMPLE 3	EXAMPLE 4	EXAMPLE 5	EXAMPLE 6	EXAMPLE 7	EXAMPLE 8
Water Content (%)	74	69	74	Not Measured	Not Measured	72	74	73
Water Balance (Relative to 2 -HEMA)	15	8	11	Not Measured	Not Measured	Not Measured	8	8.5
Linear Expansion	1.612	1.541	1.624,	Not Measured	Not Measured	Not Measured	1.628	1.617
Radial Expansion	1.620	1.541	1.628	Not Measured	Not Measured	Not Measured	1.628	1.619
Hardness (Shore D)	87	76	87	70	64	85	85	88
Transmission (%) at 600 nm	>96	>97	>98	Not Measured	Not Measured	Not Measured	>98	>98
<p>Water content and residuals were determined using a gravimetric method that records the wet and dry weights of a number of sample discs through 2 hydration and drying cycles.</p> <p>Expansion coefficients (radial and linear) were determined using uniform thickness, approximately 0.1 mm, lenses. Both linear and radial dimensions of the lens are measured in the dry state, followed by lens hydration and repeat of the linear and radial dimension measurements. The coefficients are obtained from the ratios of wet and dry.</p> <p>Shore D Hardness was obtained using a Shore D durometer (Serial No. 9075) with a calibrated reference block D34.</p> <p>% Transmission was measured by placing a hydrated lens in a cuvette that contains saline solution. The cuvette is then place in an UV-visible spectrophotometer and scanned from 700 nm to 250 nm wavelength range. The transmission value at 600 nm is recorded, a subtracted from saline (vaseline) and the value reported as % Transmission.</p>								

[0054] The Water Balance was determined as follows

1. **Purpose:** The purpose of this test was to determine the water balance capability of the hydrogel lenses using gravimetric techniques. Water balance is defined as the ratio of the time it takes a lens to dehydrate by 10% of its water weight and the time it takes to return to saturation. Values are reported relative to p-HEMA (Polymacon, 38%), used as a control.

It is important that ambient conditions for the test be maintained accurately, and that all samples be measured under the same controlled conditions. The specified conditions are $21^{\circ} \pm 2^{\circ}\text{C}$ and $40 \pm 5\%$ RH.

2. **Test Equipment:** High precision, calibrated balance (such as Sartorius, Mettler, etc.) with 0.0001 gram capability. The balance should be placed in a controlled temperature and relative humidity environment of $21^{\circ}\text{C} \pm 2^{\circ}$ and $40 \pm 5\%$ relative humidity.

3. **Fabrication of Sample Lenses:** For each material, uniform thickness lenses were based on expansion factors to yield a final wet (uniform) thickness lens of 0.1mm. Finished dry lenses were cleaned and hydrated overnight in buffered saline solution. BENZ buffered saline solution is composed of 8.01 grams NaHBO_3 , 2.47 grams of H_3BO_3 , and 0.14 grams $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$ in 1 liter of distilled water, with a pH = 7.26 and an osmolarity of 295 mOs at 22.5°C .

4. **Lens Dehydration Procedure.** Remove a clean sample lens from saline vial, secure lens on wire holder and blot gently with a lint free paper. Hang the wire holder on a balance scale, weigh and record weight. Dehydrate the lens by 10% of its total water weight, recording the weight and cumulative time every 20 seconds until the 10% weight loss is achieved. After the test is complete, return the lens to the saline flask, allow the lens to rehydrate back to saturation and repeat the drying procedure at least 2 more times to obtain an average weight loss.

5. **Lens Rehydration Procedure.** Remove a clean sample lens from saline vial, secure lens on wire holder and blot gently with a lint free paper. Hang the wire holder on the balance scale and weigh the lens to determine the weight of the saturated lens. Record the weight. Allow the lens to dehydrate 10% of its water weight (saturated weight x water content x 10%) Record weight. Remove wire-holder from the scale and submerge the lens in buffered saline for 10 seconds. Remove the lens from the saline, blot gently with a lint free paper and weigh the lens. Record the weight and time hydrated. After weight is recorded, re-submerge the lens 10 more seconds. Blot and record the weight and cumulative time hydrated. Continue this procedure until the saturated weight of the lens is achieved. Repeat complete procedure 3 times to obtain an average weight gain.

6. **Results:** The water balance ratio of a material is obtained by dividing the time (in minutes) to dehydrate 10% from saturation by the time (in minutes) to rehydrate from 90% of saturation. This ratio value is the compared to p-HEMA control.

[0055] With the exception of Example 2 (69%), all examples show a water content higher than 70% and relative water balance values higher than p-GMA/2-HEMA (69% water described in U.S. Patent No. 5,532,289).

[0056] The contact lenses of the present invention have unexpectedly high water balance, i.e., of greater than about 8. This high water balance was quite unexpected and found by the present inventors only after fabrication of contact lenses from the described GMA materials. Contact lenses formed from the materials of the invention offer numerous improvements, including: high water balance, high water content, reduction of opacity in the lenses, ease of lenses machining, and increased material strength.

Claims

1. A method of forming a contact lens blank, comprising:

polymerizing a mixture of monomers in the presence of a non-reactive aprotic polar diluent to produce a polymer, wherein the polymer comprises an incorporated crosslinking agent and greater than 99 mole percent of incorporated 2,3-dihydroxypropyl methacrylate; and mechanically forming the contact lens blank from the polymer.

2. The method of forming a contact lens blank according to claim 1, wherein the mixture of monomers comprises a dimethacrylate monomer.

3. The method of forming a contact lens blank according to claim 1, wherein the non-reactive polar aprotic diluent is

selected from the group consisting of tetrahydrofuran, N,N-dimethylformamide, N-alkyl lactams, and combinations thereof.

- 5 4. The method of forming a contact lens blank according to claim 1, wherein the non-reactive polar aprotic diluent comprises N-methyl pyrrolidone.
5. The method of forming a contact lens blank according to claim 1, wherein the mixture of monomers is polymerized in the presence of a non-reactive polar protic diluent and the non-reactive aprotic polar diluent.
- 10 6. The method of forming a contact lens blank according to claim 5, wherein the non-reactive polar protic diluent comprises water.
7. The method of forming a contact lens blank according to claim 1, wherein the mixture of monomers is polymerized in the presence of a radical initiator.
- 15 8. The method of forming a contact lens blank according to claim 1, wherein the crosslinking agent is ethylene glycol dimethacrylate.
9. The method of forming a contact lens blank according to claim 1, wherein the polymer is a crosslinked homopolymer of 2,3-dihydroxypropyl methacrylate.
- 20 10. A method for forming a contact lens, comprising:
forming the contact lens blank according to claim 1; and mechanically forming the contact lens from the contact lens blank.
- 25 11. A contact lens blank formed according to the method of claim 1.
12. A hydrogel, contact lens blank or a contact lens formed from a copolymer, **characterized in that** the copolymer comprises: more than 80 mole percent of incorporated 2,3-dihydroxypropyl methacrylate and from 0.05 to 20 mole percent of incorporated alkoxyalkyl methacrylate having the formula R_1-O-R_2-MA , wherein R_1 and R_2 are independently selected alkyl groups having 1 to 6 carbon atoms, and MA is methacrylate.
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35 **Patentansprüche**

1. Verfahren zur Herstellung eines Kontaktlinsenrohrlings, enthaltend die Polymerisierung einer Mischung aus Monomeren in der Gegenwart eines nichtreaktiven polaren aprotischen Verdünnungsmittels zur Bildung eines Polymers, wobei das Polymer ein eingebautes Vernetzungsmittel und mehr als 99 Molprozent eingebautes 2,3-Dihydroxypropylmethacrylat enthält; und das mechanische Formen des Kontaktlinsenrohrlings aus dem Polymer.
- 40 2. Verfahren zur Herstellung eines Kontaktlinsenrohrlings nach Anspruch 1, worin die Mischung aus Monomeren ein Dimethacrylat-Monomer beinhaltet.
3. Verfahren zur Herstellung eines Kontaktlinsenrohrlings nach Anspruch 1, worin das nichtreaktive polare aprotische Verdünnungsmittel aus der Gruppe bestehend aus Tetrahydrofuran, N,N-Dimethylformamid, N-Alkylactamen und Kombinationen derselben ausgewählt ist.
- 45 4. Verfahren zur Herstellung eines Kontaktlinsenrohrlings nach Anspruch 1, worin das nichtreaktive polare aprotische Verdünnungsmittel N-Methylpyrrolidon enthält.
- 50 5. Verfahren zur Herstellung eines Kontaktlinsenrohrlings nach Anspruch 1, worin die Mischung aus Monomeren in Gegenwart eines nichtreaktiven polaren protischen Verdünnungsmittels und des nichtreaktiven polaren aprotischen Verdünnungsmittels polymerisiert wird.
- 55 6. Verfahren zur Herstellung eines Kontaktlinsenrohrlings nach Anspruch 5, worin das polare protische Verdünnungsmittel Wasser enthält.

7. Verfahren zur Herstellung eines Kontaktlinsenrohlings nach Anspruch 1, worin die Mischung aus Monomeren in Gegenwart eines Radikalinitiators polymerisiert wird.
- 5 8. Verfahren zur Herstellung eines Kontaktlinsenrohlings nach Anspruch 1, worin das Vernetzungsmittel Ethylenglycoldimethacrylat ist.
9. Verfahren zur Herstellung eines Kontaktlinsenrohlings nach Anspruch 1, worin das Polymer ein vernetztes Homopolymer aus 2,3-Dihydroxypropylmethacrylat ist.
- 10 10. Verfahren zur Herstellung einer Kontaktlinse, enthaltend die Herstellung des Kontaktlinsenrohlings nach Anspruch 1 und das mechanische Formen der Kontaktlinse aus dem Kontaktlinsenrohling.
11. Kontaktlinsenrohling, hergestellt nach dem Verfahren nach Anspruch 1.
- 15 12. Hydrogel, Kontaktlinsenrohling oder Kontaktlinse aus einem Copolymer, **dadurch gekennzeichnet, dass** das Copolymer mehr als 80 Molprozent eingebautes 2,3-Dihydroxypropylmethacrylat und von 0,05 bis 20 Molprozent eingebautes Alkoxyalkylmethacrylat der Formel R_1-Q-R_2-MA enthält, worin R_1 und R_2 unabhängig voneinander ausgewählte Alkylgruppen mit 1 bis 6 Kohlenstoffatomen sind und MA Methacrylat ist.

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Revendications

1. Procédé de fabrication d'une ébauche de lentille de contact, comprenant la polymérisation d'un mélange de monomères en présence d'un diluant aprotique polaire non réactif pour produire un polymère, le polymère comprenant un agent de réticulation incorporé et plus de 99 pour cent molaire de méthacrylate de 2,3-dihydroxypropyle incorporé; et le façonnage mécanique de l'ébauche de lentille de contact à partir du polymère.
- 25 2. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le mélange de monomères comprend un monomère diméthacrylate.
- 30 3. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le diluant aprotique polaire non réactif est choisi parmi le groupe comprenant du tétrahydrofurane, du N,N-diméthyleformamide, des N-alkyle lactames et des combinaisons de ces derniers.
- 35 4. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le diluant aprotique polaire non réactif comprend le N-méthyle pyrrolidone.
5. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le mélange de monomères est polymérisé en présence d'un diluant protique polaire non réactif et du diluant aprotique polaire non réactif.
- 40 6. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 5, où le diluant protique polaire non réactif comprend de l'eau.
7. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le mélange de monomères est polymérisé en présence d'un initiateur de radicaux.
- 45 8. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où l'agent de réticulation est le diméthacrylate d'éthylène glycol.
- 50 9. Procédé de fabrication d'une ébauche de lentille de contact selon la revendication 1, où le polymère est un homopolymère réticulé de méthacrylate de 2,3-dihydroxypropyle.
10. Procédé de fabrication d'une lentille de contact, comprenant la fabrication de l'ébauche de lentille de contact selon la revendication 1 et le façonnage mécanique de la lentille de contact à partir de l'ébauche de lentille de contact.
- 55 11. Ebauche de lentille de contact fabriquée selon le procédé de la revendication 1.
12. Hydrogel, ébauche de lentille de contact ou lentille de contact fabriqué(e) à partir d'un copolymère, **caractérisé(e)**

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en ce que le copolymère comprend plus de 80 pour cent molaire de méthacrylate de 2,3-dihydroxypropyle incorporé et de 0,05 à 20 pour cent molaire de méthacrylate d'alkoxyalkyle ayant la formule R_1-O-R_2-MA , où R_1 et R_2 sont des groupes alkyle indépendamment choisis ayant 1 à 6 atomes de carbone et MA est le méthacrylate.

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FIG. 1

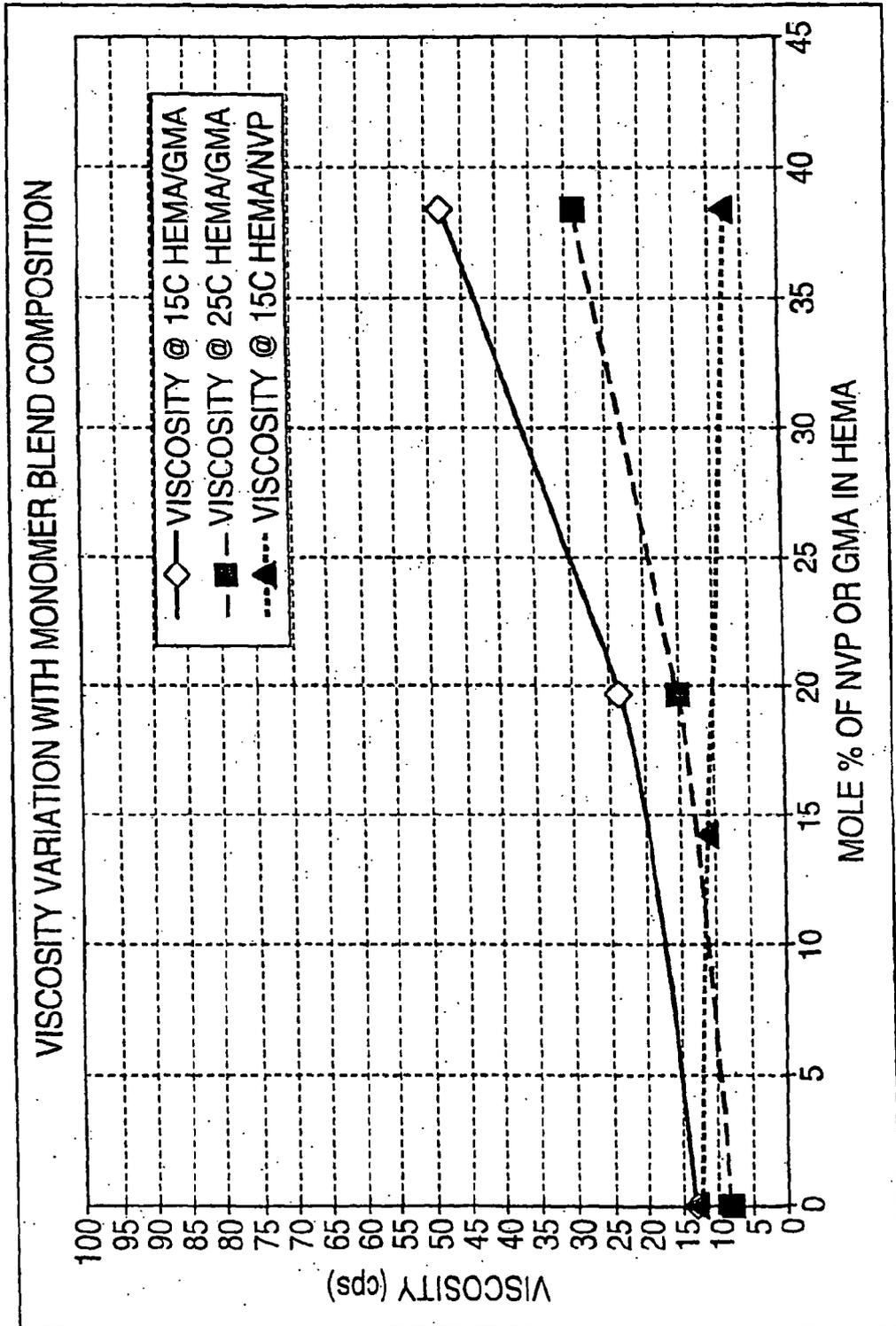


FIG. 2

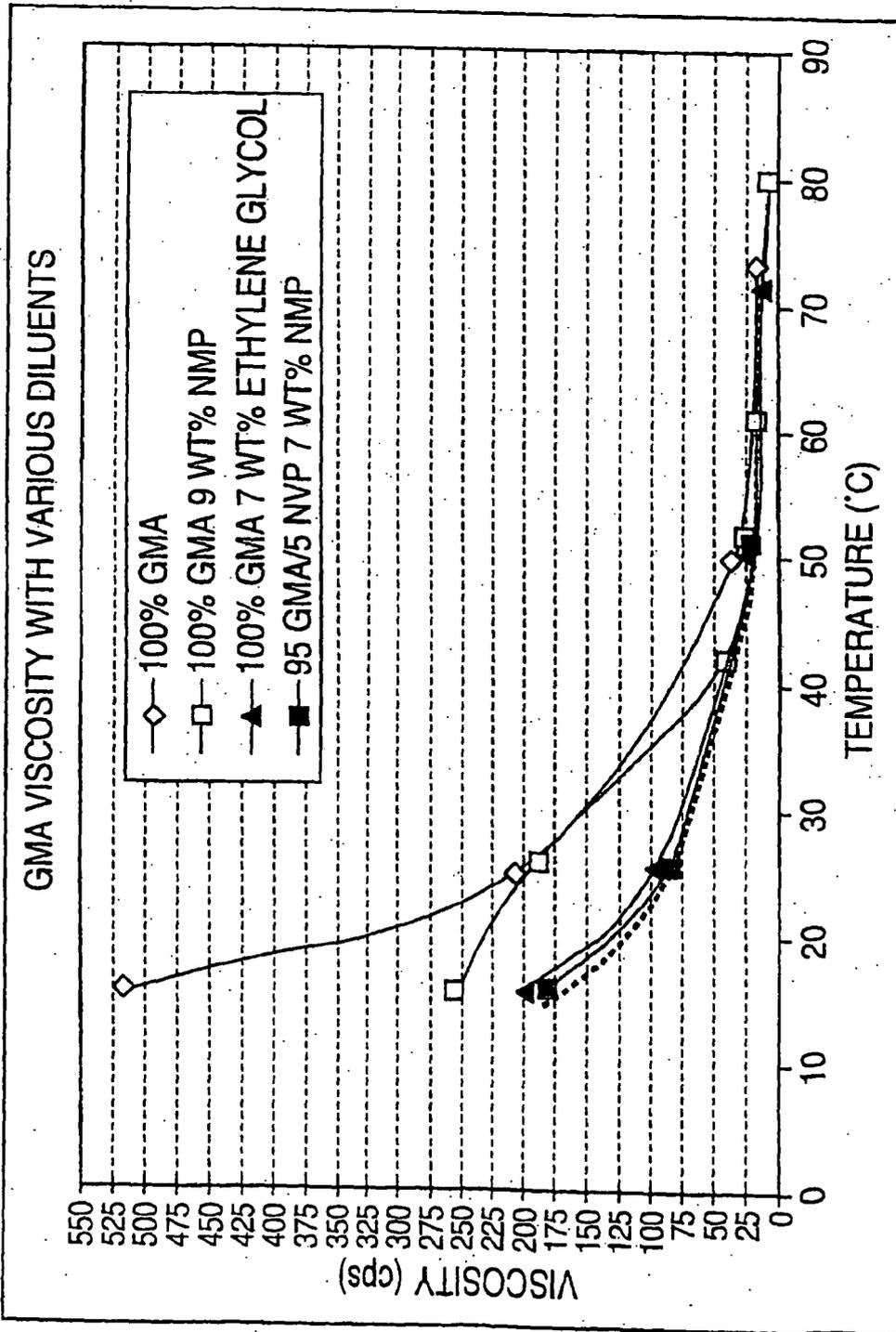
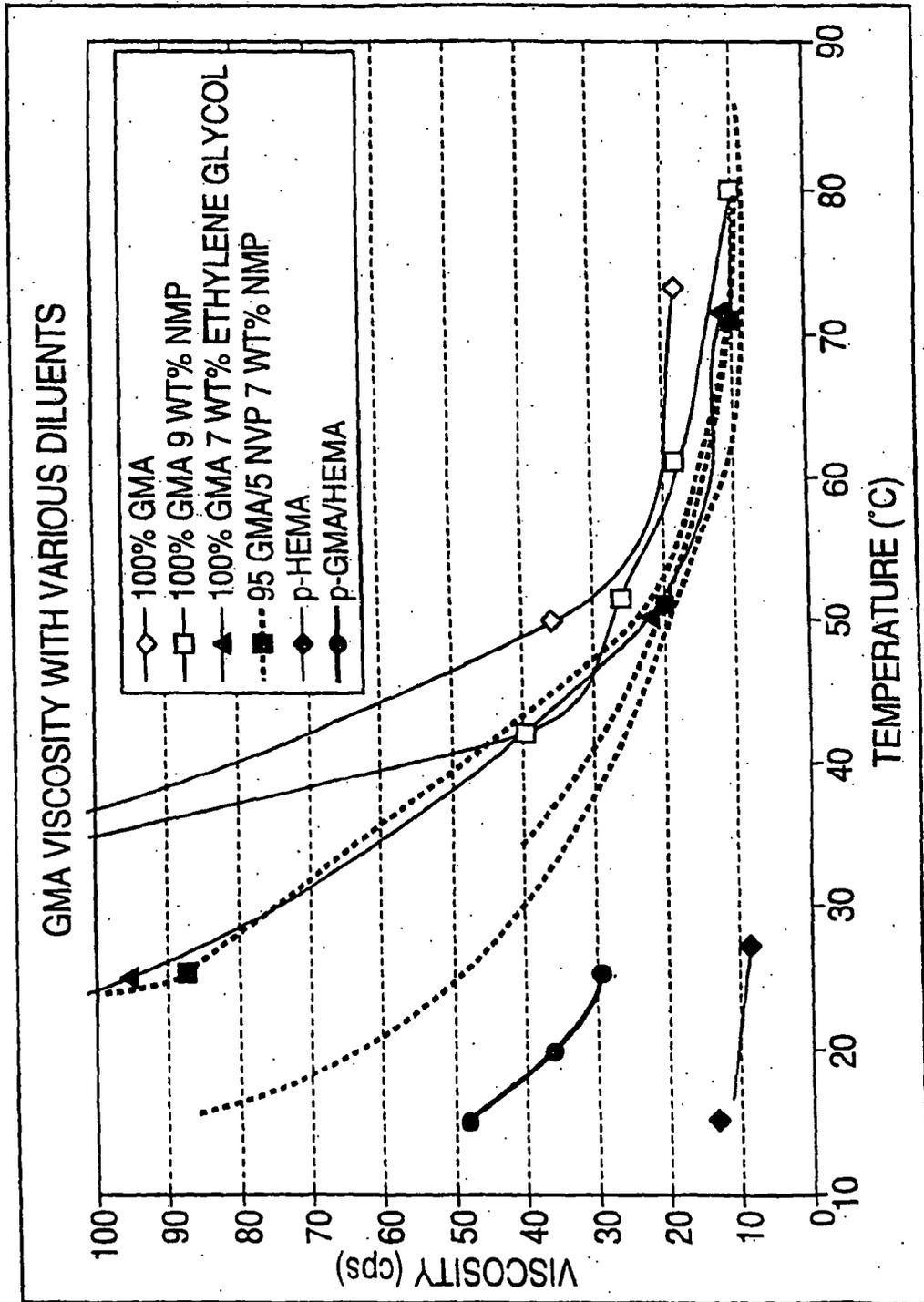


FIG. 3



REFERENCES CITED IN THE DESCRIPTION

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