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(54) **Cleansing composition for optical surfaces and method of cleansing a contact lens.**

(57) Soft and hard contact lenses are freed from deposits by cleansing them with a particulate organic polymer suspended in a carrier, the polymer having a particular size in the range from one micron to 600 microns and a Rockwell hardness in the range of from R120 to M68, or a shore hardness in the range from A15 to D100.

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CLEANSING COMPOSITION FOR OPTICAL SURFACES AND METHOD OF CLEANSING A CONTACT LENS

This invention relates to a cleansing composition for optical surfaces such as contact lenses and similar optic apparatuses.

Cleansing compositions containing various abrasive materials have been used in the past. The abradant material is added to the composition to increase the effectiveness of the composition in removing undesired matter from the surface being cleaned. Heretofore the abradants, even when in fine particle form, were harsh and had a tendency to scratch optical surfaces.

Efficient cleaning of optical surfaces without damaging them when such surfaces become encrusted with foreign matter sometimes presents difficult problems. Contact lenses that have developed heavy proteinaceous or other encrustations present particularly difficult cleaning problems. Encrustations that form on contact lenses may be proteinaceous in nature or may be lipids or other materials foreign to the eye such as lady's mascara which usually is a soap or wax in gelatin. Success in wearing and properly using contact lenses is a function of maintaining them in a clean condition without the buildup of foreign matter, particularly encrustations which physically or chemically attach to the lens surface. Buildup of such material is gradual, but will ultimately render the lens opaque. Even before the lens becomes opaque, however, the presence of encrustations on the lens causes the wearer of the lens increased discomfort and irritation. Hard contact lenses may be buffed to remove encrustations, but such a process requires skill and is not easily done by the user at home without the considerable danger of scratching the lens. The surface of a soft contact lens is particularly prone to develop encrustations and presents particularly difficult cleaning problems since

soft contact lenses cannot be cleaned except by professionals and then only with limited success.

Many different solutions have been formulated for cleaning contact lenses. The compositions, however, are primarily directed to disinfecting lenses and generally do not remove encrustations. Those compositions that have been formulated for the purpose of removing encrustations have met with limited success.

Soft contact lenses may be divided into two broad categories, namely, hydrophilic and hydrophobic lenses. Hydrophobic contact lenses are usually based on elastic and flexible silicone rubber (polysiloxane), and are generally made from cross-linked dimethyl polysiloxane.

Hydrophilic soft contact lenses are a hydrated gel, and the ability to absorb water results in swelling to a transparent soft mass of good mechanical strength which is very comfortable to the wearer. Hydrated gel lenses can contain: hydroxyethylmethacrylate (HEMA) or its analogs, ethylene-glycol dimethacrylate (EGMA) or its analogs, polymethylmethacrylate (PMMA) or its analogs, polyvinylpyrrolidone (PVP) or its analogs, monomers, inhibitors, traces of catalysts and water. Hydrophilic groups of these plastic lenses attract and hold large amounts of water in the gel. These virtues, however, lead to difficulties in cleaning and sterilizing the lenses.

Hydrophilic soft lenses may be disinfected by chemical treatment or by boiling. As indicated, neither procedure is entirely successful in removing encrustations. Some chemicals are ineffective in removing proteins, others in removing lipids. Boiling may even denature proteinaceous material on the lenses thereby attaching encrustations all the more firmly to the lenses. United States Patent No. 3,910,296 to

Karageozian et al., discusses a method for removing proteinaceous deposits from contact lenses with the use of a protease. However, lenses may become encrusted and contaminated with other deleterious materials such as lipids which protease enzyme will not remove.

The highly hydrophobic nature of the contact lenses based upon silicone rubber interferes with their uniform and effective cleaning. United States Patent No. 4,127,423 to Rankin discusses a method of cleansing encrusted soft contact lenses including silicone lenses, with aqueous solutions of sodium silicates. Deionized water is required and boiling is required when the lenses are heavily encrusted.

United States Patent No. 3,954,644 to Krezanoski et al. discusses a contact lens cleaning, storing and wetting solution. The solution discussed contains a poly(oxyethylene)-poly(oxypropylene) block copolymer which is the primary wetting and cleaning agent of the composition. Elimination of encrustations from the surface of the lens is not discussed.

A need exists, therefore, for a cleansing composition which can remove foreign deposits and encrustations from both hard and soft surfaces without adversely affecting the surfaces thereof. More particularly, a need exists for a cleansing composition which can clean and remove foreign deposits from both soft and hard contact lenses, and particularly from soft contact lenses.

Accordingly, the present invention provides a cleansing composition for cleaning optical surfaces comprising, a particulate polymer which is an organic polymer, polysiloxane polymer or a mixture thereof wherein the polymer has a particle size in the range of from one micron to six hundred microns and a Rockwell hardness in the range of from R120 to M68,or a Shore hardness in the range from A15 to D100, and a carrier having a viscosity sufficient to keep the particulate polymer in suspension.

particulate polymer is mixed with a carrier containing a thickening agent such as Carbopol (a registered trademark of B.F. Goodrich Chemical Co.), cellulose or polyethylene glycol with a molecular weight distribution of 400 to 4000 to form a suspension. The carrier can be any ocular compatible composition in which the polymeric particulates remain in suspension. Most generally the carrier is water to which various optional ingredients may be added. The end product may be a fluid or may be a thixotropic ointment or gel. A surfactant such as Pluronic, (a registered trademark of Wyanclotte Chemicals Co.), Tween, (a registered trademark of Atlas Powder Company) or tyloxapol may optionally be added to the cleaning composition to increase its effectiveness. Thimerosal (a product of Eli Lilly & Co.), sorbic acid, or ethylenediamintetraacetic acid (EDTA), as preservatives or bactericides, sodium chloride, and purified water may be optionally employed as is known in the art to provide a sterile, buffered, isotonic cleansing composition for contact lenses.

According to the present invention, a suspension is prepared containing a particulate organic polymer or polysiloxane of a particle size of one to six hundred microns and forming 1 to 25 percent by weight of the suspension, a surfactant, and a sufficient amount of a thickener to give the suspension a viscosity of between about 150 and about 1500 cps. The thickener keeps the polymeric particles in suspension and any viscosity suspension that will accomplish this result may be used. The polymeric particles are preferably spherical, have a particle size range preferably between about twenty and about one hundred microns, and preferably form 5 to 20 percent by weight of the suspension. A particle size above and below the twenty to one hundred micron range will function; however, the smaller sized particles will take longer to complete

their cleaning function and larger particles will feel gritty to the user.

Nylon 6 which has the formula $(CH_2\ CH_2\ CH_2\ CH_2\ CH_2\ C\text{-}NH)$, Nylon 11, which has the formula $(CH_2\ (CH_2)_8\text{-}CH_2CN)$, Nylon 12, which has the formula $(CH_2\ (CH_2)_9\ CH_2\ C\text{-}NH)$ or mixtures thereof with Rockwell hardnesses of R80-83, R-108, and R-106, respectively, and particle size ranges of 1 to 80 microns, 1 to 80 microns, and 20 to 45 microns, respectively, all may be used as polymeric particulates. Nylon 11 is a preferred polymer. Polyethylene glycol is a preferred thickener in amounts of between about 20 and about 80 percent by weight of the suspension, preferably between about 25 and about 50 percent by weight. The following polymers with their hardnesses as indicated in TABLE 1 will serve as a suitable particulate polymer.

TABLE I

SUITABLE PARTICULATE POLYMERS*

POLYMER	SHORE HARDNESS	ROCKWELL HARDNESS
acrylonitrile-butadiene-styrene		R75-115
acetal		M94
polymethylmethacrylate (PMMA)		M85-105
methylmethacrylate/styrene copolymer		M75
ethyl cellulose		R50-115
cellulose acetate butyrate		R30-115
cellulose acetate		R85-120
polytetrafluoroethylene	D50-55	
polychlorotrifluorethylene		R75-95
modified poolyethylene-tetrafluoroethylene (PE-TFE)		R50
ionomer (copolymers of ethylene)	D50-65	
fluoro ethylene polymer (FEP) fluoroplastic	D50-65	

Nylon 6	R80-83
Nylon 6/6	
Nylon 11	R108
Nylon 12	R106
polyutadiene	R40
polyarylether	R117
polycarbonate	M70
PBT polyester	M68-78
polyethylene	R50
polypropylene	R80
polysulfone	R88
silicone	A15-65

*ASTM test method D785 applies to the Rockwell Hardness figure given, and ASTM test method D22450 applies to the Shore Hardness figures given.

Pluronic F-127 is a preferred surfactant and is an ethylene oxide-propylene oxide-propylene glycol condensation product sold by Wyandotte Chemical Corporation. The surfactant as a 20% gel by weight in purified water is optionally added to the suspension in an amount of between about 5 to 15 percent by weight of the suspension, preferably between about 8 and about 12 percent by weight.

The particulate polymer, the polyethylene glycol and Pluronic F-127, as a 20% gel in purified water, may be mixed with thimerosal, sorbic acid, EDTA, sodium chloride, and purified water to provide a sterile isotonic cleaning suspension.

To prepare a cleansing suspension polyethylene glycol having a molecular weight range form 400 to 4,000 is melted by suspending a suitable sized container, such as a beaker, containing the glycol in hot water. When the polyethylene glycol is completely melted, the beaker is removed from the heat source. The Pluronic F-127 is added with stirring until the mixture is cooled to room temperature. Upon cooling the particulate polymer is added with stirring. The optional salts and preservative are then added together with the required amount of water to provide a cleansing suspension of the desired viscosity.

For a clearer understanding of the invention, specific examples are set forth below. These examples are merely illustrative, and are not to be understood as limiting the scope and underlying principles of the invention in any way. In the following Examples the particulate polymer, which is commercially purchased, has a range of particle sizes. A certain percentage of the substance may have a particle size below 5 or even 1 micron. Hence, the particle sizes expressed in the Examples will be set forth as a range from between 0 and a size at the larger end of the range.

EXAMPLE I

A mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400 was melted and thoroughly mixed. With stirring 20 grams of a 20% gel in purified water of Pluronic F-127 was added to the polyethylene glycol mix. The resulting mixture was sitrred until cooled to

room temperature. Upon cooling 10 grams of Natural ($10/_{15}$) ES (which is a trademark of Rislan Corporation and is Nylon-11 electrostatic extrude of a particle size range between 0 to 44 microns) was added with stirring to the polyethylene glycol and Pluronic mixture. With stirring 15 ml of purified water was added to the mixture and stirring was continued until a smooth suspension was formed.

EXAMPLE II

As in Example I, 25 grams of Pluronic F-127 20% gel was added with stirring to a melted mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400. The resulting mixture was stirred until cooled to room temperature, whereupon 10 grams of Polymer H0050/80 (which is a trademark of Rislan Corporation and is Nylon-11 of a particle size range between 0 to 80 microns) was added with stirring to the polyethylene glycol and Pluronic mixture. With stirring 10 ml of purified water was added to the mixture and stirring was continued until a smooth suspension was formed.

EXAMPLE III

As in Example I, 35 grams of Pluronic F-127 20% gel was added with stirring to a melted mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400. The resulting mixture was stirred until cooled to room temperature, whereupon 10 grams of French-Naturelle ES (which is a trademark of Rislan Corporation and is Nylon-11 electrostatic extrude of a particle size range between 0 to 80 microns) was added with stirring to the polyethylene glycol and Pluronic mixture. Stirring of the mixture was continued until a smooth suspension was formed.

EXAMPLE IV

As in Example I, 35 grams of Pluronic F-127 20% gel was added with stirring to a melted mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400. The resulting mixture was stirred until cooled to room temperature, whereupon 10 grams of CAB 381-20 (which is a trademark of Eastman Chemical Co. and is cellulose acetate butyrate of a particle size range between 0 to 120 microns) was added to the polyethylene glycol and Pluronic mixture. Stirring of the mixture was continued until a smooth suspension was formedd

EXAMPLE V

As in Example I, 25 grams of Pluronic F-127 20% gel was added with stirring to a melted mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400. The resulting mixture was stirred until cooled to room temperature, whereupon 12.5 grams of Naturell Fine (which is a trademark of Rislan Corporation and is Nylon-11 of a particle size range between 0 to 45 microns) was added with stirring to the polyethylene glycol and Pluronic mixture. With constant agitation 0.02 grams of a 1.0% aqueous solution of thimerosal and 0.9 grams of sodium chloride were mixed into the glycol-Pluronic-Naturell Fine mixture to form the cleaning composition. After addition of the thimerosal and sodium chloride, with continued stirring purified water was added to bring the total weight of the composition to 100 grams and a smooth suspension was formed.

EXAMPLE VI

As in Example I, 25 grams of Pluronic F-127 20% gel was added with stirring to a melted mixture of 25

grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of approximately 400. The resulting mixture was stirred until cooled to room temperature, whereupon 10.0 grams of polyethylene F-N500 (which is a product of S. Industrial Chemicals and is low density polyethylene of a particle size of less than 20 microns) was added with stirring to the polyethylene glycol and Pluronic mixture. With constant agitation 0.02 grams of an aqueous solution of thimerosal and 0.9 grams of sodium chloride were mixed into the glycol-Pluronic- polyethylene mixture to form the cleaning composition. After the addition of the thimerosal and sodium chloride, with continuous stirring purified water was added to bring the total weight of the composition to 100 grams and a smooth suspension was formed.

EXAMPLE VII

In a beaker 0.8 grams of hydroxy ethyl cellulose having a molecular weight of approximately 15,000 and 0.5 grams Tween 21 is dispersed into about 40 ml of purified water. The mixture then is sterilized by autoclaving at 121°C under a pressure of 18 psi for 1/2 hour. In another beaker 0.6 gram sodium chloride, 0.2 gram boric acid, 0.1 gram EDTA-disodium, 0.25 gram sodium borate qs to pH 7.6 and 0.4 ml of a 1.0% aqueous solution of thimerosal is dissolved and mixed with constant agitation into 40 ml of purified water. This mixture is then pressure filtered into the first mixture using a sterile millipore setup fitted with a 0.2 micron filter. The two mixtures are then homogeneously mixed.

10 grams of French Naturelle beads, sterilized at 121°C at 18 psi for 1/2 hour, are added to the homogeneous mixture with constant agitation. With continuous stirring purified water was added to the latter mixture to bring the total weight of the

composition to 100 grams and to form a smooth suspension.

EXAMPLE VIII

A mixture of 30 grams of polyethylene glycol of a molecular weight of approximately 4000, and 40 grams of polyethylene glycol of a molecular weight of approximately 400 was melted in a beaker by suspending the beaker into hot water. After the polyethylene glycol was completely melted, it was thoroughly mixed with a glass rod to form a smooth ointment base. The ointment base was transferred onto a porcelain tile and was mixed with a spatula with 15 grams of Natural ES (10/15) to form an ointment. With continued stirring purified water was incorporated into the ointment to bring the total weight of the composition to 100 grams and to soften and smooth the resulting cleansing ointment.

EXAMPLE IX

A mixture of 50 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of 400 was melted and mixed as in Example VIII. After mixing and melting, as in Example VIII, the glycol mixture was mixed with 10 grams of Natural ES and further mixed with purified water to bring the total weight of the composition to 100 grams and to provide a soft smooth cleansing ointment.

EXAMPLE X

A mixture of 25 grams of polyethylene glycol of a molecular weight of approximately 4000, and 30 grams of polyethylene glycol of a molecular weight of 400 was melted and mixed as in Example VII. After mixing and melting, 25 grams of a 20% gel in purified water of Pluronic F-127 and 10 grams of polymer H0050/80 were added and mixed into the polyethylene glycol to provide an ointment. With continued mixing purified water was incorporated into the ointment to bring the total weight

of the composition to 100 grams and to soften and smooth the resulting cleansing ointment.

A study was designed to determine the non-abrasive nature of the polymeric cleaner formulation.

Five unused lenses of each of the six brands of contact lenses were selected for the non-abrasive test. The six brands of contact lenses selected were:

Polycon - Syntex
Tesicon - Uricon
TRESOFT - Alcon Laboratories, Inc.
Silicon - Wohlk
CAB - Danker Wohlk
PMMA - Standard Hard Lenses

Prior to starting the study to determine the non-abrasive nature of the polymeric cleaner formulations, all the lenses were viewed through the Bausch & Lomb Optical Microscope under 40X magnification for scratches and/or cuts on lens surface. It was noted that almost all types of lenses had some surface scratches.

Each brand of lenses was then cycled through a cleaning regimen. The lens was rubbed with 2 to 3 drops of polymeric cleaner of Example VIII in the palm of the hand with the index finger for a total of 20 seconds and rinsed with normal saline. This procedure was repeated for a total of fifty cycles on each lens. The lenses were viewed for scratches after 5, 10, 20, 30, 40 and 50 cleaning cycles using the Bausch & Lomb Optical Microscope under 20X and 100X magnifications. Photographs were taken.

The lens photographs indicate no sign of new cuts and/or scratches on the lens surfaces under study.

The efficacy of polymeric cleaner was determined on laboratory deposited as well as human worn soft contact lenses.

In the laboratory, soft contact lenses were

soiled with artificial deposition model solution, containing 0.05 percent by weight lysozyme 3X protein and 0.05% percent by weight mucin type 2 in isotonic solution to pH 7.0. The deposition of clean lenses involved heating the lenses with a 5ml of deposition model solution in stoppered glass vial for one hour at 92°C. The above procedure was repeated two times with fresh depositions model solution to obtain heavier deposits of protein on the lens surface.

The deposited lens was then rubbed with 2 to 3 drops of the polymer cleaner of Example VIII in the palm of the hand with the index finger for a total of 20 seconds (both sides of the lens) and rinsed with normal saline. Depending on the extent of protein deposit on the lens, one to two applicatons of polymeric cleaner of Example VIII was needed to clean the protein from the lens.

In another efficacy study, human worn soft contact lenses having protein encrustations were collected and cleaning efficacy of the polymeric cleaner was determined following a similar cleaning regimen as described above. Six sets of human worn lenses were used for the efficacy study and all the lenses were effectively cleaned, and the protein encrustations were removed.

CLAIMS :

1. A cleansing composition for cleaning optical surfaces comprising, a particulate polymer which is an organic polymer, polysiloxane polymer or a mixture thereof wherein the polymer has a particle size in the range of from one micron to six hundred microns and a Rockwell hardness in the range of from R120 to M68, or a Shore hardness in the range from A15 to D100, and a carrier having a viscosity sufficient to keep the particulate polymer in suspension.

2. A cleansing composition as claimed in Claim 1 wherein the carrier is compatible with ocular tissue.

3. A cleansing composition as claimed in Claim 1 or Claim 2 wherein the carrier comprises water and a thickener wherein the thickener is polyethylene glycol, Carbopol, cellulose, or a mixture thereof.

4. A cleansing composition as claimed in any one of the preceding claims wherein particulate polymer has a Rockwell hardness in the range from R120 to M68.

5. A cleansing composition as claimed in any one of the preceding claims wherein the particulate polymer has a Shore hardness in the range from A15 to D100.

6. A cleansing composition as claimed in any one of the preceding claims the particulate polymer is cellulose-acetate-butyrate, polyethylene, acrylonitrile-butadiene-styrene, acetal, polymethylmethacrylate, methylmethacrylate/styrene copolymer, ethyl cellulose, cellulose acetate, cellulose acetate butyrate polychloro-trifluoroethylene, modified polyethylene-tetrafluorosethylene, Nylon 6, Nylon 6/6, Nylon 11, Nylon 12, polybutadiene, polyarylether, polycarbonate, PBT polyester, polypropylene,

polysulfone, polytetraflourethylene, Ionomer, fluoroethylene polymer, silicone or a mixture thereof.

7. A cleansing composition as claimed in any one of the preceding claims wherein the organic polymer or polysiloxane forms from 1 to 25 percent by weight of the suspension.

8. A cleansing composition as claimed in any one of the preceding claims which has a viscosity in the range of from 150 to 1500 cps.

9. A method of cleansing a contact lens comprising rubbing the contact lens with a cleansing composition as claimed in any one of the preceding claims.