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(73) Proprietor: **BAUSCH & LOMB INCORPORATED**
One Lincoln First Square
PO Box 54
Rochester New York 14601-0054 (US)

(72) Inventor: **Mowrey-McKee, Mary F.**
11 Somerset Lane
Victor, New York 14564 (US)
Inventor: **Proud, David W.**
920 South Avenue
Rochester, New York 14620 (US)
Inventor: **Minno, George E.**
93 Church Street
Victor, New York 14564 (US)

(74) Representative: **Allam, Peter Clerk et al**
LLOYD WISE, TREGEAR & CO.
Norman House
105-109 Strand
London WC2R 0AE (GB)

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Description

This invention relates to a method for cleaning and disinfecting contact lenses and a composition for the same. More specifically, the present invention is directed to a method for simultaneously cleaning and disinfecting contact lenses by contacting the lenses with an aqueous system containing an antimicrobial agent and a proteolytic enzyme. A composition for simultaneously cleaning and disinfecting the lenses is also provided.

In the normal course of wearing contact lenses, tear film and debris consisting of proteinaceous, oily, sebaceous, and related organic matter have a tendency to deposit and build up on lens surfaces. As part of the routine care regimen, contact lenses must be cleaned to remove these tear film deposits and debris. If these deposits are not properly removed, both the wettability and optical clarity of the lenses is substantially reduced causing discomfort for the wearer.

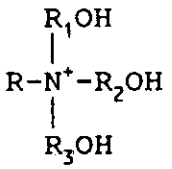
Further, contact lenses, especially those made from hydrophilic materials, must be continuously disinfected to kill any harmful microorganisms that may be present or grow on the lenses. A number of methods for disinfecting contact lenses have been used such as the use of high temperatures, the use of oxidative chemicals, and the use of antimicrobial agents. However, current disinfecting solutions do not exhibit significant cleaning ability for the removal of proteinaceous material.

Conventionally, the cleaning of contact lenses is accomplished with one or both of two general classes of cleaners. Surfactant cleaners, generally known as "daily cleaners" because of their recommended daily use, are effective for the removal of most carbohydrate and lipid derived matter. However, they are not as effective for the removal of proteinaceous matter such as lysozyme. Typically, proteolytic enzymes derived from plant, animal, and microbial sources are used to remove the proteinaceous deposits. These "enzyme" cleaners are recommended for weekly use and are conventionally employed by dissolving enzyme tablets in suitable aqueous solutions.

The process of cleaning and disinfecting contact lenses with enzyme cleaners (as well as daily cleaners) involves two steps. The first step consists of the cleaning phase whereby lenses are conventionally soaked in an enzyme cleaning solution at ambient temperature conditions, i.e, cold soaking for a period of up to 12 hours, to achieve effective removal of proteinaceous deposits. At the conclusion of the cleaning step, the lenses are separately disinfected. Disinfection involves contacting the lenses with a solution containing either an oxidative chemical or an antimicrobial agent at ambient temperatures or exposing the lenses to elevated temperatures for specified periods of time. The latter disinfection technique requires specific electrical disinfecting apparatus.

New methods have been developed which can remove proteinaceous material from contact lenses while disinfecting the lenses. For example, US-A-4,614,549 discloses a single-step method of cleaning and disinfecting contact lenses in aqueous solutions of proteolytic enzymes at temperatures of between 60 °C and 100 °C. This method requires the use of electrical disinfecting apparatus and elevated temperatures. US-B-32672 discloses a method which immerses the lenses in a solution containing peroxide and a peroxide-active enzyme. However, this method requires an additional step for the neutralization of the residual peroxide prior to inserting the lens into the eye.

JP-A-8224526 discloses a method for simultaneously cleaning and disinfecting a soft contact lens using a virtually isotonic aqueous solution containing a protease and a sterilizing agent of the formula:



wherein R is C_{12}-C_{20} alkyl or C_{12}-C_{20} alkenyl and R_1-R_3 are, individually, C_1-C_3 alkyl groups.

WO-A-8911878, which is in the state of the art for certain designated countries by virtue of Article 54(3) EPC, discloses a method for simultaneously cleaning and disinfecting a contact lens using an aqueous solution which contains a protease and a disinfecting agent which may be chlorhexidine.

In order to develop an improved simultaneous cleaning and disinfecting method that does not require neutralization of any oxidative chemical, we tested proteolytic enzymes in tablet form in combination with a disinfecting solution containing hexamethylene biguanide polymers as the antimicrobial agent at ambient conditions. However, subsequent microbicidal efficacy studies revealed that the antimicrobial agent was

rendered less effective for killing certain microorganisms during these initial studies.

However, we have now discovered that the disinfecting ability of certain polymeric antimicrobial agents, particularly at ambient temperatures, can be most effective if suitable osmolality conditions for the agent are employed. However, when the osmotic level of the solution is too high, the antimicrobial agents are rendered less effective for killing certain microorganisms.

More particularly, the present invention provides a method for simultaneously cleaning and disinfecting a contact lens, wherein the lens is contacted with an aqueous system containing a proteolytic enzyme and a disinfecting amount of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, said aqueous system having an osmotic value which is adjusted such that the system is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

The present invention also provides an aqueous composition for cleaning and disinfecting a contact lens, comprising a proteolytic enzyme and a disinfecting amount of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, said aqueous composition having a pH of 6.5-8.5 and an osmotic value which is adjusted so that the composition is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

Thus, according to this invention, proteolytic enzymes can be used in combination with antimicrobial agents to simultaneously clean and disinfect contact lenses. Under ambient temperatures, the disinfection has been found to be most effective at suitable osmotic conditions. The present invention thus provides a less complex and more convenient regimen for cleaning and disinfecting contact lenses without the need for a separate neutralizing step or electrical disinfecting apparatus.

The present invention can be used with all contact lenses such as conventional hard, soft, rigid gas permeable, and silicone lenses but is preferably employed with soft lenses such as those commonly referred to as hydrogel lenses prepared from monomers such as hydroxyethylmethacrylate, hydroxyethylmethyl methacrylate, vinylpyrrolidone, glycerolmethacrylate, methacrylic acid or acid esters and the like. Hydrogel lenses typically absorb significant amounts of water such as from 4 to 80 percent by weight.

The compositions employed herein for the cleaning and disinfecting of contact lenses are composed of at least water, one or more proteolytic enzymes, and one or more antimicrobial agents. Generally, these cleaning and disinfecting systems are prepared by mixing two components, the enzyme and a disinfecting solution containing the antimicrobial agent. However, other methods of combining the active components as well as off the shelf compositions containing all of the active components are contemplated as being within the scope of this invention.

A wide variety of proteolytic enzymes are useful in the present invention such as those derived from plant, animal, and microbial sources. The separation and purification of these enzymes is well known to those skilled in the art with many of these enzymes being commercially available. Moreover, it is anticipated that many of the enzymes can be prepared from new techniques being developed such as those using recombinant DNA techniques and proteolytic enzymes prepared by these techniques are contemplated to be within the scope of the present invention.

The proteolytic enzymes used herein must have at least a partial capability to hydrolyse peptide-amide bonds which reduces the proteinaceous material to smaller water-soluble subunits. Typically, these enzymes will exhibit some lipolytic, amylolytic or related activities associated with the proteolytic activity and may be neutral, acidic or alkaline. In addition, separate lipases or carbohydrases may be used in combination with the proteolytic enzymes.

Examples of suitable proteolytic enzymes include but are not limited to pancreatin, trypsin, chymotrypsin, collagenase, papain, bromelain, aminopeptidase, Aspergillo peptidase, pronase E (from S. graseus) and dispase (from Bacillus , polymyxa). The preferred group of proteolytic enzymes are the microbial derived enzymes such as those derived from Bacillus Streptomyces, and Aspergillus microorganisms. Most preferred are the Bacillus derived alkaline proteases generically called subtilisin enzymes. The subtilisin enzymes include both sub-classes, subtilisin A and subtilisin B. Microbial derived enzymes are disclosed in US-A-4,690,773.

The present invention employs an effective amount of enzyme to clean the lenses. An effective amount is that which removes a substantial portion of the proteinaceous deposits which occur during normal wear in a reasonable time. The precise amount of enzyme required to make an effective cleaner will depend on several factors including the activity of the enzyme, the purity of the enzyme, the amount of proteinaceous matter deposited on the lenses, the desired soaking period, the specific type of lenses, as well as other factors.

It will be appreciated by one skilled in the art, that the enzyme concentrations useful herein are adjusted depending upon the time allowed for removing the proteinaceous material, the other components in the solutions and the factors previously mentioned. Typically, when the enzyme is provided in solid form, it will be present in amounts from 0.01 to 200 milligrams.

Enzyme activity is generally pH dependent and there will be a particular pH range in which any particular enzyme will function best. However, the determination of an optimum pH range can readily be determined by known techniques by those skilled in the art. It is preferred that the enzyme be selected to have substantial activity at a pH from 6.5 to 8.5.

The enzyme may be employed in liquid or solid form usually in combination with additional components. Preferably, the enzymes are provided in solid form such as tablets or powders which are mixed with the aqueous solutions prior to use.

Additional components may be added to or incorporated into the enzyme which do not substantially decrease the activity of the enzyme. For example, components such as effervescing agents, stabilizers, buffering agents, chelating and/or sequestering agents, coloring agents, tonicity adjusting agents, surfactants and the like can be employed. In addition, binders, lubricants, carriers, and other excipients normally used in producing tablets may be incorporated into the enzyme when tablets are employed.

Examples of suitable buffering agents which may be incorporated into the enzyme include, but are not limited to, alkali metal salts such as potassium or sodium carbonates, acetates, borates, phosphates, citrates and hydroxides, and weak acids such as acetic and boric acids. Preferred buffering agents are alkali metal borates such as sodium or potassium borates. Additionally, other pH adjusting agents may be employed such as inorganic acids. For example, hydrogen chloride may be employed in concentrations suitable for ophthalmic uses. Generally, buffering agents are present in amounts from 0.01 to 2.5 percent by weight/volume (w/v).

Effervescing agents are typically employed when the enzyme is provided in solid form. Examples of suitable effervescing agents include, but are not limited to, tartaric or citric acid used in combination with a suitable alkali metal salt such as sodium carbonate.

The disinfecting solutions used with the present invention may contain any of the above-mentioned enzyme components as well as other components but typically will contain water, the antimicrobial agent, one or more of a suitable buffering agent, chelating and/or sequestering agent, tonicity adjusting agent, and surfactant.

The tonicity adjusting agent which may be a component of the disinfecting solution and may optionally be incorporated into the enzyme is employed to adjust the osmotic value of the final cleaning and disinfecting solution to more closely resemble that of human tears and to maintain a suitable level for optimum activity by the antimicrobial agent, as will hereafter be described in more detail. Suitable tonicity adjusting agents include, but are not limited to, sodium and potassium chloride, dextrose, calcium and magnesium chloride, the buffering agents listed above and combinations thereof. The tonicity adjusting agents are generally used in amounts ranging from 0.01 to 2.5% (w/v), and preferably from 0.5 to 1.5% (w/v). Most preferably, the tonicity agent will be employed in an amount to provide a final osmotic value of the cleaning and disinfecting solutions of less than 800 millosmoles/kilogram water (mOsm./kg. water)

Suitable surfactants can be either cationic, anionic, nonionic or amphoteric. Preferred surfactants are neutral or nonionic surfactants which may be present in amounts up to 5% (w/v). Examples of suitable surfactants include, but are not limited to, polyethylene glycol esters of fatty acids, polyoxypropylene ethers of C_{12}-C_{18} alkanes and polyoxyethylene, polyoxypropylene block copolymers of ethylene diamine (i.e. poloxamine).

Examples of preferred chelating agents include ethylenediaminetetraacetic acid (EDTA) and its salts (disodium) which are normally employed in amounts from about 0.025 to about 2.0% (w/v). Other known chelating (or sequestering agents) such as certain polyvinyl alcohols can also be employed.

The disinfecting solutions used with this invention will contain a disinfecting amount of one or more antimicrobial agents which are compatible with and do not precipitate in the presence of the enzymes and which are selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides. As used herein, antimicrobial agents are defined as non-oxidative organic chemicals which derive their antimicrobial activity through a chemical or physiochemical interaction with the organisms. Suitable polymeric quaternary ammonium salts include, but are not limited to, poly[(dimethyliminio)-2-butene-1,4-diyl chloride] and α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]-dichloride (chemical registry number 75345-27-6), generally available as polyquaternium 1® from ONYX Corporation. Suitable polymeric biguanides are polymers of alexidine, chlorhexidine and hexamethylene biguanide. Preferred antimicrobial agents are the polymeric biguanides, with hexamethylene biguanide polymers being most preferred. Generally, the hexamethylene biguanide polymers, also referred to as

polyaminopropyl biguanide (PAPB), have molecular weights of up to about 100,000. Such compounds are known and are disclosed in US-A-4758595 which is incorporated herein by reference.

The amount of antimicrobial agent used is that which will at least partially reduce the microorganism population in the system employed. The test used in this specification to evaluate antimicrobial efficacy (and which, as has been mentioned, is a function of the osmolality of the solution as well as of the amount of antimicrobial agent which is present) is that the system must be capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens. Preferably, the amount of the antimicrobial agent is that which will reduce the microbial burden by one log order in one hour. Most preferably, the amount of the antimicrobial agent is that which will eliminate the microbial burden on a contact lens when used in regimen for the recommended soaking time (FDA Chemical Disinfection Efficacy Test-July, 1985 Contact Lens Solution Draft Guidelines). Typically, such agents are present in concentrations ranging from 0.00001 to 0.5% (w/v), and more preferably, from 0.00003 to 0.05% (w/v).

As mentioned above, it has been found that the polymeric antimicrobial agents of present interest, at simulated commercial concentrations, are rendered less effective in environments having high osmotic values, generally above about 800 mOsm./kg. water at typical commercial concentrations (generally less than about 0.05% (w/v)). This is a particularly important discovery since it is common in the industry to add bulking agents to the active enzyme when used in tablet or powder form. These bulking agents usually increase the osmotic values of the cleaning solutions, often significantly reducing the antimicrobial activity. Further, the various other possible components discussed above may also raise the osmolality of the final formulation.

Moreover, it should also be understood that the particular osmotic value rendering any given antimicrobial agent ineffective will vary from agent to agent. The determination of the suitable osmotic range for any particular antimicrobial agent can be easily determined by routine experimentation by one skilled in the art. However, the generally preferred osmotic values is less than 800 mOsm./kg. water, and more preferably 200 to 600 mOsm./kg. water at antimicrobial agent concentrations of less than 0.05% (w/v).

During practice of this invention, the enzyme formulation, either in solid or liquid form, is typically dissolved in a predetermined amount of disinfecting solution which may be isotonic or hypotonic, to obtain a cleaning and disinfecting solution having the proper osmotic value. This solution is then contacted with lenses at ambient temperatures for a sufficient time to clean and disinfect.

In a preferred embodiment of the invention, an enzyme tablet is dissolved in an aqueous disinfecting solution containing a polymeric biguanide as the antimicrobial agent in order to prepare the cleaning and disinfecting solution. The lenses are then contacted with the cleaning and disinfecting solution, preferably by being immersed therein, and remain in contact with the solution for a sufficient period of time to disinfect the lenses. An effective amount of enzyme agent is used such that the time sufficient to disinfect will also be sufficient to substantially remove the proteinaceous deposits. Typically, the cleaning and disinfecting will take less than eight hours, with from 1 to 4 hours being preferred. Advantageously, the lenses can be removed from the solution and placed directly into the eye without the need for a separate neutralizing step. Preferably, the lenses are rinsed with a suitable isotonic aqueous solution prior to insertion into the eye.

The following detailed examples are presented to illustrate the present invention.

Example 1-18

In order to study the antimicrobial efficacy of the compositions of the present invention, several aqueous solutions were prepared and evaluated for the log kill rate of Serratia marcescens.

Aqueous solutions were prepared having compositions which simulate commercial disinfecting solutions. All percentages indicated throughout these examples are in weight/volume. Each composition had 0.85% boric acid, 0.09% sodium borate, 1.0% Tetronic® 1107 (a poloxamine surfactant purchased from BASF Corporation), simulated commercial concentrations of PAPB and polyquatenium 1^R (purchased from ONYX Corporation) as the antimicrobial agent, respectively, and 0.005% of a proteolytic enzyme (subtilisin-A enzyme purchased from NOVO Laboratories, Inc.). The osmolality was varied using sodium chloride as the tonicity adjusting agents Two separate solutions were tested for each composition. The compositions are shown in Table I.

The microbicidal activity of the above solutions were tested in duplicate by exposing Serratia marcescens at 1.0×10^6 to 1.0×10^7 colony forming units per milliliter (CFU/ml.) to 10 ml. of each solution at room temperature for 1 hour and 4 hour time intervals. An aliquot of each inoculated sample was removed at 1 and 4 hours and diluted in a neutralizing broth (Dey-Engley) and plated with neutralizing agar. The agar plates were incubated for two days and plate counts were determined to calculate reduction in CFU/ml. for the organism. The calculated log order reductions are shown in Table I.

As can be seen from Table I the log order reductions of the antimicrobial agents tested were significantly reduced at high osmotic levels.

TABLE I
DISINFECTING

EXAMPLE	DISINFECTING AGENT	SODIUM CHLORIDE % (w/v)	MEASURED OSMOLALITY (mOsm/kg water)	LOG REDUCTION S. MARCESCENS 1 Hour	4 Hours
1A	PAPB 1.0 ppm	0.20	199	>4.5	>4.5
1B	PAPB 1.0 ppm	0.20	199	4.5	>4.5
2A	PAPB 1.0 ppm	0.53	301	4.2	>4.5
2B	PAPB 1.0 ppm	0.53	301	4.3	>4.5
3A	PAPB 1.0 ppm	0.85	402	3.0	>4.5
3B	PAPB 1.0 ppm	0.85	402	2.8	>4.5
4A	PAPB 1.0 ppm	1.15	501	2.7	>4.5
4B	PAPB 1.0 ppm	1.15	501	2.7	>4.5
5A	PAPB 1.0 ppm	1.47	601	1.9	>4.5
5B	PAPB 1.0 ppm	1.47	601	2.1	>4.5
6A	PAPB 1.0 ppm	2.09	801	0.3	>4.5
6B	PAPB 1.0 ppm	2.09	801	0.2	>4.5
7A	Polyquaternium 1 100 ppm	0.20	200	3.9	>4.5
7B	Polyquaternium 1 100 ppm	0.20	200	4.2	>4.5
8A	Polyquaternium 1 100 ppm	0.53	303	2.4	3.9
8B	Polyquaternium 1 100 ppm	0.53	303	2.3	4.2

TABLE I
DISINFECTING (Continued)

EXAMPLE	DISINFECTING AGENT	SODIUM CHLORIDE % (w/v)	MEASURED OSMOLALITY (mOsm/kg water)	LOG REDUCTION S. MARCESCENS 1 Hour	4 Hours
9A	Polyquaternium 1 100 ppm	0.85	403	0.9	3.1
9B	Polyquaternium 1 100 ppm	0.85	403	0.9	3.0
10A	Polyquaternium 1 100 ppm	1.15	502	0.6	2.6
10B	Polyquaternium 1 100 ppm	1.15	502	0.5	2.4
11A	Polyquaternium 1 100 ppm	1.47	601	0.4	2.1
11B	Polyquaternium 1 100 ppm	1.47	601	0.4	2.1
12A*	Polyquaternium 1 100 ppm	2.09	802	0.4	1.4
12B*	Polyquaternium 1 100 ppm	2.09	802	0.4	1.2

TABLE I
DISINFECTING (Continued)

EXAMPLE	DISINFECTING AGENT	SODIUM CHLORIDE % (w/v)	MEASURED OSMOLALITY (mOsm/kg water)	LOG REDUCTION S. MARCESCENS 1 Hour	LOG REDUCTION S. MARCESCENS 4 Hours
13A*	PAPB 0.5 ppm	0.20	204	0.1	0.2
13B*	PAPB 0.5 ppm	0.20	204	0.0	0.3
4A	PAPB 0.5 ppm	0.53	309	1.0	2.7
14B	PAPB 0.5 ppm	0.53	309	1.1	2.7
5A*	PAPB 0.5 ppm	0.85	402	0.1	1.5
15B*	PAPB 0.5 ppm	0.85	402	0.2	1.5
16A*	PAPB 0.5 ppm	1.15	509	-0.1	0.2
16B*	PAPB 0.5 ppm	1.15	509	-0.1	0.2
17A*	PAPB 0.5 ppm	1.47	607	0.0	-0.1
17B*	PAPB 0.5 ppm	1.47	607	0.0	-0.1
18A*	PAPB 0.5 ppm	2.09	806	-0.1	0.0
18-B*	PAPB 0.5 ppm	2.09	806	0.0	0.0

* Comparative example

Examples 19-20

In order to study the cleaning efficacy of the present invention, several solutions were prepared and evaluated for removal of lysozyme deposits from contact lenses.

The percent light transmission through ten new Bausch & Lomb Soflens® (polymacon) Contact Lenses was read through a uv/vis spectrophotometer at 500 and 280 nanometers (nm). An average transmission value was obtained (Tn) which was used below to calculate percent protein removal. An aqueous solution was prepared containing 0.7% NaCl, 0.22% sodium bicarbonate, 0.17% potassium chloride, 0.0005% calcium chloride and 0.15% lysozyme (3x crystallized from egg white). Five lenses were soaked in the lysozyme solution and heated for about 1 hour at about 90°C. After heating, the lenses were removed, finger rubbed and rinsed with isotonic saline solution to remove any nonbound lysozyme on the lenses. The percent light transmission was taken at 280 and 500 nm (Td).

The lenses were then submerged in 10 ml. of an aqueous solution containing 0.005% of subtilisin-A proteolytic enzyme (from NOVO Laboratories, Inc.) and PAPB (0.5 ppm) or polyquaternium 1® (100 ppm) at osmotic values adjusted to 300 or 600 mOsm./kg. water. The lenses remained in the solution for 1 hour at ambient temperature. The lenses were removed, rubbed and rinsed in an aqueous isotonic solution and soaked in the aqueous isotonic solution for an additional 15 minutes. The percent light transmission was taken at 280 and 500 nm (Te).

The above transmission readings were placed into the following equation at each reading (280 and 500 nm) to determine the percent of lysozyme removed:

$$\% \text{ protein lysozyme removed} = \frac{(Tn-Td) - (Tn-Te)}{(Tn-Td)}$$

The % protein removed at 500 nm (the visual range of light) and at 280 nm (specific for protein) is shown in Table II.

As can be seen from Table II, the present invention removes proteinaceous deposits from contact lenses. It should be mentioned, that the lysozyme deposition technique used herein results in much more severe protein deposition than occurs during normal wear.

TABLE II

CLEANING			
PRESERVATIVE	OSMOLALITY (mOsm/kg. water)	% PROTEIN REMOVED (500 nm)	% PROTEIN REMOVED (280 nm)
19. PAPB			
1	300	64.8	48.4
2		63.9	45.1
3		54.4	29.1
4		41.0	26.7
5		15.8	7.3
Average		48.0	31.3
1	600	50.0	32.9
2		68.0	27.8
3		31.2	31.1
4		66.7	66.4
5		66.0	45.9
Average		56.4	40.8
20. polyquaternium 1®			
1	300	95.9	71.2
2		70.0	42.2
3		85.8	56.7
4		50.9	21.5
5		34.1	26.2
Average		67.3	43.6
1	600	87.5	47.2
2		75.0	45.2
3		89.5	27.1
4		90.2	60.7
5		88.9	30.9
Average		86.2	42.2

Claims

Claims for the following Contracting States : AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE

1. A method for simultaneously cleaning and disinfecting a contact lens, wherein the lens is contacted with an aqueous system containing a proteolytic enzyme and a disinfecting amount of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, said aqueous system having an osmotic value which is adjusted such that the system is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

2. A method according to Claim 1, wherein the antimicrobial agent and the proteolytic enzyme are in an aqueous solution.

3. A method according to Claim 1 or Claim 2, wherein the antimicrobial agent and the proteolytic enzyme are contacted with the lenses at ambient temperatures.

4. A method according to any preceding claim, wherein the aqueous solution contains a tonicity adjusting agent.

5. A method according to any preceding claim, wherein the antimicrobial agent is a polymeric biguanide.

6. A method according to Claim 5, wherein said polymeric biguanide is a hexamethylene biguanide polymer.

7. A method according to any one of Claims 1-4, wherein the antimicrobial agent is α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichloride.

8. A method according to any preceding claim, wherein the osmotic value is less than 800 mOsm./kg. water.

9. A method according to Claim 8, wherein the osmotic value is from 200 to 600 mOsm./kg. water.

10. A method according to any preceding claim, wherein the proteolytic enzyme is in a powder or tablet form and is dissolved in a disinfecting solution containing water and the antimicrobial agent to prepare said aqueous system.

11. A method according to any preceding claim, wherein the aqueous system additionally contains a buffering agent.

12. A method according to any preceding claim, wherein the aqueous system additionally contains a surfactant.

13. An aqueous composition for cleaning and disinfecting a contact lens, comprising a proteolytic enzyme and a disinfecting amount of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, said aqueous composition having a pH of 6.5-8.5 and an osmotic value which is adjusted so that the composition is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

14. A composition according to Claim 13, wherein the composition is prepared by mixing said proteolytic enzyme in a disinfecting solution containing said antimicrobial agent.

15. A composition according to Claim 13 or Claim 14, wherein the antimicrobial agent is a polymeric biguanide.

16. A composition according to Claim 15, wherein said polymeric biguanide is a hexamethylene biguanide polymer.

17. A composition according to Claim 13 or Claim 14, wherein the antimicrobial agent is α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichloride.

18. A composition according to any one of Claims 13-17, wherein the osmotic value of the composition is less than 800 mOsm./kg. water.

19. A composition according to any one of Claims 13-18, wherein a tonicity adjusting agent or a buffering agent, or both, are also present.

20. A composition according to any one of Claims 13-19, wherein a surfactant is also present.

Claims for the following Contracting State : ES

1. An aqueous detergent composition for cleaning and disinfecting a contact lens, comprising from 0.01-200 mg of a proteolytic enzyme, a disinfecting amount, within the range of 0.00001-0.5% w/v, of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, and a surfactant, said aqueous composition having a pH of 6.5-8.5 and an

osmotic value which is adjusted so that the composition is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

2. A composition according to Claim 1, wherein the composition is prepared by mixing said proteolytic enzyme in a disinfecting solution containing said antimicrobial agent.

3. A composition according to Claim 1 or Claim 2, wherein the antimicrobial agent is a polymeric biguanide.

4. A composition according to Claim 3, wherein said polymeric biguanide is a hexamethylene biguanide polymer.

5. A composition according to Claim 1 or Claim 2, wherein the antimicrobial agent is α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichloride.

6. A composition according to any preceding claim, wherein the osmotic value of the composition is less than 800 mOsm./kg. water.

7. A composition according to any preceding claim, wherein a tonicity adjusting agent or a buffering agent, or both, are also present.

8. A method for simultaneously cleaning and disinfecting a contact lens, wherein the lens is contacted with an aqueous detergent system containing from 0.01-200 mg of a proteolytic enzyme, a disinfecting amount, within the range of 0.00001-0.5% w/v, of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, and a surfactant, said aqueous system having an osmotic value which is adjusted such that the system is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

9. A method according to Claim 8, wherein the antimicrobial agent and the proteolytic enzyme are in an aqueous solution.

10. A method according to Claim 8 or Claim 9, wherein the antimicrobial agent and the proteolytic enzyme are contacted with the lenses at ambient temperatures.

11. A method according to any one of Claims 8-10, wherein the aqueous solution contains a tonicity adjusting agent.

12. A method according to any one of Claims 8-11, wherein the antimicrobial agent is a polymeric biguanide.

13. A method according to Claim 12, wherein said polymeric biguanide is a hexamethylene biguanide polymer.

14. A method according to any one of Claims 8-11, wherein the antimicrobial agent is α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichloride.

15. A method according to any one of Claims 8-14, wherein the osmotic value is less than 800 mOsm./kg. water.

16. A method according to Claim 15, wherein the osmotic value is from 200 to 600 mOsm./kg. water.

17. A method according to any one of Claims 8-15, wherein the proteolytic enzyme is in a powder or tablet form and is dissolved in a disinfecting solution containing water and the antimicrobial agent to prepare said aqueous system.

18. A method according to any one of Claims 8-17, wherein the aqueous system additionally contains a buffering agent.

Claims for the following Contracting State : GR

1. A method for simultaneously cleaning and disinfecting a contact lens, wherein the lens is contacted with an aqueous system containing a proteolytic enzyme and a disinfecting amount of an antimicrobial agent selected from ophthalmically-suitable polymeric quaternary ammonium salts and polymeric biguanides, said aqueous system having an osmotic value which is adjusted such that the system is capable of reducing the microbial burden by at least two log orders in four hours when tested against Serratia marcescens.

2. A method according to Claim 1, wherein the antimicrobial agent and the proteolytic enzyme are in an aqueous solution.

3. A method according to Claim 1 or Claim 2, wherein the antimicrobial agent and the proteolytic enzyme are contacted with the lenses at ambient temperatures.

4. A method according to any preceding claim, wherein the aqueous solution contains a tonicity adjusting agent.

5. A method according to any preceding claim, wherein the antimicrobial agent is a polymeric biguanide.

6. A method according to Claim 5, wherein said polymeric biguanide is a hexamethylene biguanide polymer.

7. A method according to any one of Claims 1-4, wherein the antimicrobial agent is α[4-tris(2-hydroxyethyl)ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichloride.

8. A method according to any preceding claim, wherein the osmotic value is less than 800 mOsm./kg. water.

9. A method according to Claim 8, wherein the osmotic value is from 200 to 600 mOsm./kg. water.

10. A method according to any preceding claim, wherein the proteolytic enzyme is in a powder or tablet form and is dissolved in a disinfecting solution containing water and the antimicrobial agent to prepare said aqueous system.

11. A method according to any preceding claim, wherein the aqueous system additionally contains a buffering agent.

12. A method according to any preceding claim, wherein the aqueous system additionally contains a surfactant.

Patentansprüche
Patentansprüche für folgende Vertragsstaaten : AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE

1. Verfahren zur gleichzeitigen Reinigung und Desinfektion einer Kontaktlinse, worin die Linse in Berührung mit einem wässrigen System gebracht wird, welches ein proteolytisches Enzym und eine desinfizierende Menge eines antimikrobiellen Mittels, ausgewählt aus in der Ophthalmologie geeigneten quaternären Polyammoniumsalzen und polymeren Biguaniden, enthält, wobei der osmotische Druck des Systems derart eingestellt ist, daß die mikrobielle Belastung um wenigstens zwei logarithmische Ordnungen innerhalb von vier Stunden bei der Prüfung gegen Serratia marcescens verringert werden kann.

2. Verfahren nach Anspruch 1, worin das antimikrobielle Mittel und das proteolytische Enzym in einer wässrigen Lösung vorliegen.

3. Verfahren nach Anspruch 1 oder 2, worin das antimikrobielle Mittel und das proteolytische Enzym mit den Linsen bei Umgebungstemperatur in Berührung gebracht werden.

4. Verfahren nach einem der vorhergehenden Ansprüche, worin die wässrige Lösung einen isotonisierenden Zusatz enthält.

5. Verfahren nach einem der vorhergehenden Ansprüche, worin das antimikrobielle Mittel ein polymeres Biguanid ist.

6. Verfahren nach Anspruch 5, worin das polymere Biguanid ein Hexamethylenbiguanidpolymer ist.

7. Verfahren nach einem der Ansprüche 1 bis 4, worin das antimikrobielle Mittel α[4-Tris(2-hydroxyethyl)-ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichlorid ist.

8. Verfahren nach einem der vorhergehenden Ansprüche, worin der osmotische Druck geringer als 800 mOsm/kg Wasser ist.

9. Verfahren nach Anspruch 8, worin der osmotische Druck 200 bis 600 mOsm/kg Wasser beträgt.

10. Verfahren nach einem der vorhergehenden Ansprüche, worin das proteolytische Enzym in Form eines Pulvers oder einer Tablette vorliegt und in einer desinfizierenden, Wasser und das antimikrobielle Mittel enthaltenden Lösung zur Herstellung dieses wässrigen Systems gelöst ist.

11. Verfahren nach einem der vorhergehenden Ansprüche, worin das wässrige System zusätzlich einen Puffer enthält.

12. Verfahren nach einem der vorhergehenden Ansprüche, worin das wässrige System zusätzlich ein Tensid enthält.

13. Wässrige Zusammensetzung zur Reinigung und Desinfektion einer Kontaktlinse, enthaltend ein proteolytisches Enzym und eine desinfizierende Menge eines antimikrobiellen Mittels, welches aus in der Ophtamologie geeigneten quaternären Polyammoniumsalzen und polymeren Biguaniden ausgewählt ist, wobei die wässrige Zusammensetzung einen pH-Wert von 6,5 bis 8,5 und einen osmotischen Druck aufweist, der derart eingestellt ist, daß die mikrobielle Belastung um wenigstens zwei logarithmische Ordnungen innerhalb von vier Stunden bei der Prüfung gegen Serratia marcescens verringert werden kann.

14. Zusammensetzung nach Anspruch 13, die durch Vermischen des proteolytischen Enzyms in einer das antimikrobielle Mittel enthaltenden desinfizierenden Lösung hergestellt wird.

15. Zusammensetzung nach Anspruch 13 oder 14, worin das antimikrobielle Mittel ein polymeres Biguanid ist.

16. Zusammensetzung nach Anspruch 15, worin das polymere Biguanid ein Hexamethylbiguanidpolymer ist.

17. Zusammensetzung nach Anspruch 13 oder 14, worin das antimikrobielle Mittel α[4-Tris(2-hydroxyethyl)-ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichlorid ist.

18. Zusammensetzung nach einem der Ansprüche 13 bis 17, worin der osmotische Druck weniger als 800 mOsm/kg Wasser ist.

19. Zusammensetzung nach einem der Ansprüche 13 bis 18 mit einem isotonisierenden Zusatz und/oder einen Puffer.

20. Zusammensetzung nach einem der Ansprüche 13 bis 19 mit einem Tensid.

Patentansprüche für folgenden Vertragsstaat : ES

1. Wässrige Tensidzusammensetzung zur Reinigung und Desinfektion einer Kontaktlinse, enthaltend 0,01 bis 200 mg eines proteolytischen Enzyms, einer desinfizierenden Menge von 0,00001 bis 0,5% G/V

eines anitmikrobiellen Mittels, das aus in der Ophthalmologie geeigneten quaternären Polyammoniumsalzen und polymeren Biguaniden ausgewählt ist, und eines Tensids, wobei die wässrige Zusammensetzung einen pH-Wert von 6,5 bis 8,5 aufweist und der osmotische Druck derart eingestellt ist, daß die mikrobielle Belastung um wenigstens zwei logarithmische Ordnungen innerhalb von vier Stunden bei der Prüfung gegen Serratia marcescens verringert werden kann.

2. Zusammensetzung nach Anspruch 1, die durch Vermischen des proteolytischen Enzyms in einer das antimikrobielle Mittel enthaltenden desinfizierenden Lösung hergestellt wird.

3. Zusammensetzung nach Anspruch 1 oder 2, worin das antimikrobielle Mittel ein polymeres Biguanid ist.

4. Zusammensetzung nach Anspruch 3, worin das polymere Biguanid ein Hexamethylenbiguanidpolymer ist.

5. Zusammensetzung nach Anspruch 1 oder 2, worin das antimikrobielle Mittel α[4-Tris(2-hydroxyethyl)-ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichlorid ist.

6. Zusammensetzung nach einem der vorhergehenden Ansprüche, worin das osmotische Druck geringer als 800 mOsm/kg Wasser ist.

7. Zusammensetzung nach einem der vorhergehenden Ansprüche, worin ein isotonisierender Zusatz und/oder ein Puffer vorhanden ist.

8. Verfahren zur gleichzeitigen Reinigung und Desinfektion einer Kontaktlinse, worin die Linse mit einem wässrigen Detergenzsystem, das 0,01 bis 200 mg eines proteolytischen Enzyms, eine desinfizierende Menge von 0,00001 bis 0,5% G/V eines aus ophthalmologisch geeigneten quaternären Polyammoniumsalzen und polymeren Biguaniden ausgewählten antimikrobiellen Mittels und ein Tensid enthält, wobei der osmotische Druck des Systems derart eingestellt ist, daß die mikrobielle Belastung um wenigstens zwei logarithmische Ordnungen innerhalb von vier Stunden bei der Prüfung gegen Serratia marcescens verringert werden kann.

9. Verfahren nach Anspruch 8, worin das antimikrobielle Mittel und das proteolytische Enzym in wässriger Lösung vorliegen.

10. Verfahren nach Anspruch 8 oder 9, worin das antimikrobielle Mittel und das proteolytische Enzym mit den Linsen bei Umgebungstemperatur in Berührung gebracht werden.

11. Verfahren nach einem der Ansprüche 8 bis 10, worin die wässrige Lösung einen isotonisierenden Zusatz enthält.

12. Verfahren nach einem der Ansprüche 8 bis 11, worin das antimikrobielle Mittel ein polymeres Biguanid ist.

13. Verfahren nach Anspruch 12, worin das polymere Biguanid ein Hexamethylenbiguanidpolymer ist.

14. Verfahren nach einem der Ansprüche 8 bis 11, worin das antimikrobielle Mittel α[4-Tris(2-hydroxyethyl)-ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichlorid ist.

15. Verfahren nach einem der Ansprüche 8 bis 14, worin der osmotische Wert geringer als 800 mOsm/kg Wasser ist.

16. Verfahren nach Anspruch 15, worin der osmotische Druck 200 bis 600 mOsm/kg Wasser ist.

17. Verfahren nach einem der Ansprüche 8 bis 15, worin das proteolytische Enzym in Form eines Pulvers oder einer Tablette vorliegt und in einer desinfizierenden, Wasser und das antimikrobielle Mittel enthaltenden Lösung zur Herstellung des wässrigen Systems gelöst ist.

18. Verfahren nach einem der Ansprüche 8 bis 17, worin das wässrige System zusätzlich einen Puffer enthält.

Patentansprüche für folgenden Vertragsstaat : GR

1. Verfahren zur gleichzeitigen Reinigung und Desinfektion einer Kontaktlinse, worin die Linse in Berührung mit einem wässrigen System gebracht wird, welches ein proteolytisches Enzym und eine desinfizierende Menge eines antimikrobiellen Mittels, ausgewählt aus in der Ophthalmologie geeigneten quaternären Polyammoniumsalzen und polymeren Biguaniden, enthält, wobei der osmotische Druck des Systems derart eingestellt ist, daß die mikrobielle Belastung um wenigstens zwei logarithmische Ordnungen innerhalb von vier Stunden bei der Prüfung gegen Serratia marcescens verringert werden kann.

2. Verfahren nach Anspruch 1, worin das antimikrobielle Mittel und das proteolytische Enzym in einer wässrigen Lösung vorliegen.

3. Verfahren nach Anspruch 1 oder 2, worin das antimikrobielle Mittel und das proteolytische Enzym mit den Linsen bei Umgebungstemperatur in Berührung gebracht werden.

4. Verfahren nach einem der vorhergehenden Ansprüche, worin die wässrige Lösung einen isotonisierenden Zusatz enthält.

5. Verfahren nach einem der vorhergehenden Ansprüche, worin das antimikrobielle Mittel ein polymeres Biguanid ist.

6. Verfahren nach Anspruch 5, worin das polymere Biguanid ein Hexamethylenbiguanidpolymer ist.

7. Verfahren nach einem der Ansprüche 1 bis 4, worin das antimikrobielle Mittel α[4-Tris(2-hydroxyethyl)-ammonio-2-butenyl-ω-tris(2-hydroxyethyl)ammonio]dichlorid ist.

8. Verfahren nach einem der vorhergehenden Ansprüche, worin der osmotische Druck geringer als 800 mOsm/kg Wasser ist.

9. Verfahren nach Anspruch 8, worin der osmotische Druck 200 bis 600 mOsm/kg Wasser beträgt.

10. Verfahren nach einem der vorhergehenden Ansprüche, worin das proteolytische Enzym in Form eines Pulvers oder einer Tablette vorliegt und in einer desinfizierenden, Wasser und das antimikrobielle Mittel enthaltenden Lösung zur Herstellung dieses wässrigen Systems gelöst ist.

11. Verfahren nach einem der vorhergehenden Ansprüche, worin das wässrige System zusätzlich einen Puffer enthält.

12. Verfahren nach einem der vorhergehenden Ansprüche, worin das wässrige System zusätzlich ein Tensid enthält.

Revendications

Revendications pour les Etats contractants suivants : AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE

1. Procédé de nettoyage et désinfection simultanés d'une lentille de contact, dans lequel la lentille est mise en contact avec a système aqueux contenant une enzyme protéolytique et une quantité désinfectante d'un agent anti-microbien sélectionné parmi des sels d'ammonium quaternaire polymères et des biguanides polymères convenant en ophtalmologie, ledit système aqueux ayant une valeur osmotique ajustée de telle sorte que le système est capable de réduire la charge microbienne d'au moins deux ordres logarithmiques en 4 h lorsqu'il est testé contre Serratia marcescens.

2. Procédé selon la revendication 1, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont en solution aqueuse.

3. Procédé selon la revendication 1 ou 2, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont mis en contact avec les lentilles à des températures ambiantes.

4. Procédé selon l'une quelconque des revendications précédentes, dans lequel la solution aqueuse contient un agent d'ajustement de la tonicité.

5. Procédé selon l'une quelconque des revendications précédentes, dans lequel l'agent anti-microbien est un biguanide polymère.

6. Procédé selon la revendication 5, dans lequel ledit biguanide polymère est un polymère hexaméthylène-biguanide.

7. Procédé selon l'une quelconque des revendications 1 à 4, dans lequel l'agent microbien est le dichlorure d'α[4-tris(2-hydroxyéthyl)ammonio-2-butényl-ω-tris(2-hydroxyéthyl)-ammonium].

8. Procédé selon l'une quelconque des revendications précédentes, dans lequel la valeur osmotique est inférieure à 800 mosmoles/kg d'eau.

9. Procédé selon la revendication 8, dans lequel la valeur osmotique est comprise entre 200 et 600 mosmoles/kg d'eau.

10. Procédé selon l'une quelconque des revendications précédentes, dans lequel l'enzyme protéolytique est sous forme de poudre ou de comprimé et on la dissout dans une solution désinfectante contenant de l'eau et l'agent anti-microbien pour préparer ledit système aqueux.

11. Procédé selon l'une quelconque des revendications précédentes, dans lequel le système aqueux contient additionnellement un agent tampon.

12. Procédé selon l'une quelconque des revendications précédentes, dans lequel le système aqueux contient additionnellement un agent tensioactif.

13. Composition aqueuse destinée au nettoyage et à la désinfection d'une lentille de contact, comprenant une enzyme protéolytique et une quantité désinfectante d'un agent anti-microbien sélectionné parmi des sels d'ammonium quaternaire polymères et des biguanides polymères convenant en ophtalmologie, ladite composition aqueuse ayant un pH compris entre 6,5 et 8,5 et une valeur osmotique ajustée de telle sorte que la composition est capable de réduire la charge microbienne d'au moins deux ordres logarithmiques en 4 h lorsqu'elle est testée contre Serratia marcescens.

14. Composition selon la revendication 13, dans laquelle la composition est préparée par mélange de ladite enzyme protéolytique dans une solution désinfectante contenant ledit agent anti-microbien.

15. Composition selon la revendication 13 ou 14, dans laquelle l'agent anti-microbien est un biguanide polymère.

16. Composition selon la revendication 15, dans laquelle ledit biguanide polymère est un polymère hexaméthylène-biguanide.

17. Composition selon la revendication 13 ou 14, dans laquelle l'agent anti-microbien est le dichlorure d'α-[4-tris(2-hydroxyéthyl)ammonio-2-butényl-ω-tris(2-hydroxyéthyl)-ammonium].

18. Composition selon l'une quelconque des revendications 13 à 17, dans laquelle la valeur osmotique de la composition est inférieure à 800 mosmoles/kg d'eau.

19. Composition selon l'une quelconque des revendications 13 à 18, dans laquelle un agent d'ajustement de la tonicité et/ou un agent tampon sont également présents.

20. Composition selon l'une quelconque des revendications 13 à 19, dans laquelle un tensioactif est également présent.

Revendications pour l'Etat contractant suivant : ES

1. Composition détergente aqueuse destinée au nettoyage et à la désinfection d'une lentille de contact, comprenant de 0,01 à 200 mg d'une enzyme protéolytique, une quantité désinfectante, comprise dans la place de 0,00001 à 0,5 % p/v, d'un agent anti-microbien sélectionné parmi des sels d'ammonium quaternaire polymères et des biguanides polymères convenant en ophtalmologie, et un tensioactif, ladite composition aqueuse ayant un pH compris entre 6,5 et 8,5 et une valeur osmotique ajustée de telle sorte que la composition est capable de réduire la charge microbienne d'au moins deux ordres logarithmiques en 4 h lorsqu'elle est testée contre Serratia marcescens.

2. Composition selon la revendication 1, laquelle est préparée par mélange de ladite enzyme protéolytique dans une solution désinfectante contenant ledit agent anti-microbien.

3. Composition selon la revendication 1 ou 2, dans laquelle l'agent anti-microbien est un biguanide polymère.

4. Composition selon la revendication 3, dans laquelle ledit biguanide polymère est un polymère hexaméthylène-biguanide.

5. Composition selon la revendication 1 ou 2, dans laquelle l'agent anti-microbien est le dichlorure d'α[4-tris(2-hydroxyéthyl)ammonio-2-butényl-ω-tris(2-hydroxyéthyl)ammonium].

6. Composition selon l'une quelconque des revendications précédentes, dans laquelle la valeur osmotique de la composition est inférieure à 800 mosmoles/kg d'eau.

7. Composition selon l'une quelconque des revendications précédentes, dans laquelle un agent d'ajustement de la tonicité et/ou un agent tampon sont également présents.

8. Procédé de nettoyage et désinfection simultanés d'une lentille de contact, dans lequel la lentille est mise en contact avec un système détergent aqueux contenant de 0,01 à 200 mg d'une enzyme protéolytique, une quantité désinfectante, comprise dans la plage de 0,00001 à 0,5 % p/v, d'un agent anti-microbien sélectionné parmi des sels d'ammonium quaternaire polymères et des biguanides polymères convenant en ophtalmologie, et un tensioactif, ledit système aqueux ayant une valeur osmotique ajustée de telle sorte que le système est capable de réduire la charge microbienne d'au moins deux ordres logarithmiques en 4 h lorsqu'il est testé contre Serratia marcescens.

9. Procédé selon la revendication 8, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont en solution aqueuse.

10. Procédé selon la revendication 8 ou 9, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont mis en contact avec les lentilles à des températures ambiantes.

11. Procédé selon l'une quelconque des revendications 8 à 10, dans lequel la solution aqueuse contient un agent d'ajustement de la tonicité.

12. Procédé selon l'une quelconque des revendications 8 à 11, dans lequel l'agent anti-microbien est un biguanide polymère.

13. Procédé selon la revendication 12, dans lequel ledit biguanide polymère est un polymère hexaméthylène-biguanide.

14. Procédé selon l'une quelconque des revendications 8 à 11, dans lequel l'agent microbien est le dichlorure d'α[4-tris(2-hydroxyéthyl)ammonio-2-butényl-ω-tris(2-hydroxyéthyl)-ammonium].

15. Procédé selon l'une quelconque des revendications 8 à 14, dans lequel la valeur osmotique est inférieure à 800 mosmoles/kg d'eau.

16. Procédé selon la revendication 15, dans lequel la valeur osmotique est comprise entre 200 et 600 mosmoles/kg d'eau.

17. Procédé selon l'une quelconque des revendications 8 à 15, dans lequel l'enzyme protéolytique est sous forme de poudre ou de comprimé et on la dissout dans une solution désinfectante contenant de l'eau et l'agent anti-microbien pour préparer ledit système aqueux.

18. Procédé selon l'une quelconque des revendications 8 à 17, dans lequel le système aqueux contient additionnellement un agent tampon.

Revendications pour l'Etat contractant suivant : GR

1. Procédé de nettoyage et désinfection simultanés d'une lentille de contact, dans lequel la lentille est mise en contact avec un système aqueux contenant une enzyme protéolytique et une quantité désinfectante d'un agent anti-microbien sélectionné parmi des sels d'ammonium quaternaire polymères et des biguanides polymères convenant en ophtalmologie, ledit système aqueux ayant une valeur osmotique ajustée de telle sorte que le système est capable de réduire la charge microbienne d'au moins deux ordres logarithmiques en 4 h lorsqu'il est testé contre Serratia marcescens.

2. Procédé selon la revendication 1, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont en solution aqueuse.

3. Procédé selon la revendication 1 ou 2, dans lequel l'agent anti-microbien et l'enzyme protéolytique sont mis en contact avec les lentilles à des températures ambiantes.

4. Procédé selon l'une quelconque des revendications précédentes, dans lequel la solution aqueuse contient un agent d'ajustement de la tonicité.

5. Procédé selon l'une quelconque des revendications précédentes, dans lequel l'agent anti-microbien est un biguanide polymère.

6. Procédé selon la revendication 5, dans lequel ledit biguanide polymère est un polymère hexaméthylène-biguanide.

7. Procédé selon l'une quelconque des revendications 1 à 4, dans lequel l'agent microbien est le dichlorure d'α[4-tris(2-hydroxyéthyl)ammonio-2-butényl-ω-tris(2-hydroxyéthyl)-ammonium].

8. Procédé selon l'une quelconque des revendications précédentes, dans lequel la valeur osmotique est inférieure à 800 mosmoles/kg d'eau.

9. Procédé selon la revendication 8, dans lequel la valeur osmotique est comprise entre 200 et 600 mosmoles/kg d'eau.

10. Procédé selon l'une quelconque des revendications précédentes, dans lequel l'enzyme protéolytique est sous forme de poudre ou de comprimé et on la dissout dans une solution désinfectante contenant de l'eau et l'agent anti-microbien pour préparer ledit système aqueux.

11. Procédé selon l'une quelconque des revendications précédentes, dans lequel le système aqueux contient additionnellement un agent tampon.

12. Procédé selon l'une quelconque des revendications précédentes, dans lequel le système aqueux contient additionnellement un agent tensioactif.

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Applicant/Proprietor
BAUSCH & LOMB INCORPORATED, One Lincoln First Square PO Box 54, Rochester New York 14601-0054, United States of America [ADP No. 50326073001]

Inventors
MARY F. MOWREY-MCKEE, 11 Somerset Lane, Victor, New York 14564, United States of America [ADP No. 57747792001]

DAVID W. PROUD, 920 South Avenue, Rochester, New York 14620, United States of America [ADP No. 57747800001]

GEORGE E. MINNO, 93 Church Street, Victor, New York 14564, United States of America [ADP No. 57747818001]

Classified to
A61L

Address for Service
LLOYD WISE, TREGEAR & CO, Norman House, 105-109 Strand, LONDON, WC2R 0AE, United Kingdom [ADP No. 00000117001]

EPO Representative
PETER CLERK ALLAM, LLOYD WISE, TREGEAR & CO. Norman House 105-109 Strand, London WC2R 0AE, United Kingdom [ADP No. 50128842001]

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BAUSCH & LOMB INCORPORATED, One ~~Lincoln~~ First Square PO Box 54, Rochester New York 14601-0054, United States of America

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