

MEDICAL COMPOSITION FOR SOFT CONTACT LENS

TECHNICAL FIELD

[0001]

5 The present invention relates to a medical composition for a soft contact lens, wherein the composition comprises an alkyldiaminoethylglycine and adsorption of the alkyldiaminoethylglycine on the soft contact lens is suppressed.

10

BACKGROUND ART

[0002]

Various medical compositions for a soft contact lens which compositions have the component composition similar to tears
15 have been developed in order to relieve discomfort in wearing a soft contact lens or a hard contact lens. Tears mean a mixture of a lacrimal gland secretion secreted by a main lacrimal gland and four or more substances secreted by an accessory lacrimal gland, and contain inorganic components
20 such as Na, K, Ca and Cl and organic components such as glucose, ascorbic acid, citric acid, urea, ammonia, an amino acid and a protein. Although there are individual differences of the concentration of glucose in tears, the concentration is approximately 0.001 to 0.01 w/v%. On the one hand, glucose may
25 be mixed in an ophthalmic aqueous liquid composition as a nutritional component in a higher concentration than that in tears in some cases. For example, the glucose concentrations in the ophthalmic aqueous liquid compositions described in Patent documents 1 to 4 are approximately 0.1 w/v%. Glucose,
30 however, may promote growth of the bacteria that can

metabolize glucose into pyruvic acid to produce energy. In general, glucose is therefore mixed in a lower concentration than that of tears particularly in the ophthalmic aqueous liquid composition of which content amounts of a preservative agent and a preservative are reduced.

[0003]

Even if the concentration of glucose is reduced, a preservative agent is mixed in a medical composition for preservation. A preservative agent may be possibly associated with an adverse effect, since an ophthalmic solution is directly administered to an eye. For example, it is described in Non-patent documents 1 to 5 that a preservative agent such as benzalkonium chloride impairs a cell and causes irritation to the skin, povidone-iodine has the lowest toxicity, and the toxicity of an alkyldiaminoethylglycine is medium. Patent documents 1 to 4 disclose ophthalmic compositions containing an alkyldiaminoethylglycine hydrochloride.

[0004]

Some ophthalmic solutions contain a monoterpene such as 1-menthol for refreshing feeling (Patent documents 1, 3, 5 to 9).

PRIOR ART DOCUMENT

PATENT DOCUMENT

[0005]

Patent document 1: JP 2001-302518 A

Patent document 2: JP 2001-302545 A

Patent document 3: JP 2009-46480 A

Patent document 4: JP 2005-336153 A

Patent document 5: JP 2011-93888 A

Patent document 6: JP 2011-213729 A

Patent document 7: JP 2007-99643 A

Patent document 8: JP 2014-15417 A

Patent document 9: JP 2015-78248 A

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NON-PATENT DOCUMENT

[0006]

Non-patent document 1: TAKAHASHI Nobuo et al., The Journal of the Japan Ophthalmologists Association, 58: 10, pp. 945-950

10 (1987)

Non-patent document 2: TSUJI Akiyoshi et al., Japanese Journal of Environmental Infections, Vol. 11, No. 3, pp. 207-220 (1996)

Non-patent document 3: AJISAI, Vol. 12, No. 4, pp. 67-73
15 (2003)

Non-patent document 4: NAKASHIMA Keiji et al., Journal of Japanese Society of Hospital Pharmacists, Vol. 40, No. 12, pp. 1559-1562 (2004)

Non-patent document 5: SHIRAISHI Tadashi, The Journal of the Japanese Society of Internal Medicine, Vol. 99, No. 8, pp. 166-172 (2010)
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SUMMARY

PROBLEMS TO BE SOLVED BY THE DISCLOSURE

25 [0007]

The objective of the present disclosure is to provide a medical composition for a soft contact lens, wherein the composition comprises an alkyldiaminoethylglycine and adsorption of the alkyldiaminoethylglycine on the soft contact lens is suppressed.
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MEANS FOR SOLVING THE PROBLEMS

[0008]

The inventor of the present disclosure made extensive
5 studies to solve the above-described problem. As a result, the
inventor completed the present disclosure by finding that when
an alkyldiaminoethylglycine hydrochloride is mixed in a
medical composition for a soft contact lens in a low
concentration, the alkyldiaminoethylglycine tends to adsorb
10 particularly on a soft contact lens and addition of menthol
strengthens the tendency but such adsorption can be suppressed
by mixing taurine.

Hereinafter, the embodiment of the present disclosure is
described.

15 [0009]

[1] In one aspect, there is provided a medical composition for
a soft contact lens, comprising 0.001 w/v% or more and 0.0045
w/v% or less of an alkyldiaminoethylglycine hydrochloride,
menthol and taurine.

20 [2] The medical composition for a soft contact lens according
to the above [1], comprising 0.002 w/v% or more and 0.004 w/v%
or less of the alkyldiaminoethylglycine hydrochloride.

[3] The medical composition for a soft contact lens according
to the above [1] or [2], wherein the menthol is 1-menthol.

25 [4] The medical composition for a soft contact lens according
to any one of the above [1] to [3], comprising 0.0005 w/v% or
more and 0.1 w/v% or less of the menthol.

[5] The medical composition for a soft contact lens according
to any one of the above [1] to [3], comprising 0.001 w/v% or
30 more and 0.035 w/v% or less of the menthol.

[6] The medical composition for a soft contact lens according to any one of the above [1] to [3], comprising 0.001 w/v% or more and 0.02 w/v% or less of the menthol.

5 [7] The medical composition for a soft contact lens according to any one of the above [1] to [6], comprising 0.01 w/v% or more and 1 w/v% or less of the taurine.

[8] The medical composition for a soft contact lens according to any one of the above [1] to [6], comprising 0.05 w/v% or more and 0.5 w/v% or less of the taurine.

10 [9] The medical composition for a soft contact lens according to any one of the above [1] to [8], comprising:

0.002 w/v% or more and 0.004 w/v% or less of the alkyldiaminoethylglycine hydrochloride,

15 0.001 w/v% or more and 0.035 w/v% or less of the menthol, and

0.05 w/v% or more and 0.5 w/v% or less of the taurine.

[10] The medical composition for a soft contact lens according to any one of the above [1] to [9], further comprising a non-ionic surfactant.

20 [11] The medical composition for a soft contact lens according to the above [10], wherein the non-ionic surfactant is one or more non-ionic surfactants selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan long-chain fatty acid monoester, mono long-chain
25 fatty acid and polyoxyethylene-polyoxypropylene block copolymer.

[12] The medical composition for a soft contact lens according to the above [11], wherein the polyoxyethylene hydrogenated castor oil is polyoxyethylene hydrogenated castor oil 60.

30 [13] The medical composition for a soft contact lens according

to any one of the above [10] to [12], comprising 0.001 w/v% or more and 0.5 w/v% or less of the non-ionic surfactant.

[14] The medical composition for a soft contact lens according to any one of the above [10] to [13], comprising 0.001 w/v% or
5 more and 0.1 w/v% or less of the non-ionic surfactant.

[15] The medical composition for a soft contact lens according to any one of the above [10] to [13], comprising 0.005 w/v% or more and 0.05 w/v% or less of the non-ionic surfactant.

[16] The medical composition for a soft contact lens according
10 to any one of the above [1] to [15], further comprising glucose.

[17] The medical composition for a soft contact lens according to the above [16], wherein 0.001 w/v% or more and 0.01 w/v% or less of the glucose.

15 [18] The medical composition for a soft contact lens according to the above [16], wherein 0.002 w/v% or more and 0.008 w/v% or less of the glucose.

[19] The medical composition for a soft contact lens according to any one of the above [1] to [18], further comprising an
20 inorganic salt.

[20] The medical composition for a soft contact lens according to the above [19], wherein the inorganic salt is sodium chloride and/or potassium chloride.

[21] The medical composition for a soft contact lens according
25 to the above [19] or [20], comprising 0.05 w/v% or more and 5 w/v% or less of the inorganic salt.

[22] The medical composition for a soft contact lens according to the above [19] or [20], comprising 0.1 w/v% or more and 2 w/v% or less of the inorganic salt.

30 [23] The medical composition for a soft contact lens according

to any one of the above [1] to [22], further comprising a thickening agent.

[24] The medical composition for a soft contact lens according to the above [23], wherein the thickening agent is

5 hydroxypropyl methylcellulose.

[25] The medical composition for a soft contact lens according to the above [23] or [24], comprising 0.01 w/v% or more and 1 w/v% or less of the thickening agent.

[26] The medical composition for a soft contact lens according
10 to the above [23] or [24], comprising 0.05 w/v% or more and 0.5 w/v% or less of the thickening agent.

[27] The medical composition for a soft contact lens according to any one of the above [1] to [26], further comprising a buffering agent.

15 [28] The medical composition for a soft contact lens according to the above [27], wherein the buffering agent is one or more buffering agents selected from the group consisting of borate buffering agent, phosphate buffering agent, carbonate buffering agent, citrate buffering agent, acetate buffering
20 agent, HEPES buffering agent and MOPS buffering agent.

[29] The medical composition for a soft contact lens according to the above [27] or [28], wherein the buffering agent is boric acid and/or borax.

[30] The medical composition for a soft contact lens according
25 to any one of the above [27] to [29], comprising 0.05 w/v% or more and 5 w/v% or less of the buffering agent.

[31] The medical composition for a soft contact lens according to any one of the above [27] to [29], comprising 0.1 w/v% or more and 1 w/v% or less of the buffering agent.

30 [32] The medical composition for a soft contact lens according

to any one of the above [1] to [31], further comprising a pH adjuster.

[33] The medical composition for a soft contact lens according to any one of the above [1] to [32], wherein pH is 5.5 or more
5 and 8.0 or less.

[34] The medical composition for a soft contact lens according to any one of the above [1] to [32], wherein pH is 6.5 or more and 7.5 or less.

[35] The medical composition for a soft contact lens according
10 to any one of the above [1] to [34], comprising:

0.002 w/v% or more and 0.004 w/v% or less of the alkyldiaminoethylglycine hydrochloride,

0.001 w/v% or more and 0.035 w/v% or less of the menthol,

0.05 w/v% or more and 0.5 w/v% or less of the taurine,

15 0.005 w/v% or more and 0.05 w/v% or less of the non-ionic surfactant,

0.002 w/v% or more and 0.008 w/v% or less of the glucose,

0.1 w/v% or more and 2 w/v% or less of the inorganic salt,

0.05 w/v% or more and 0.5 w/v% or less of the thickening

20 agent, and

0.1 w/v% or more and 2 w/v% or less of the buffering agent.

[36] The medical composition for a soft contact lens according to any one of the above [1] to [35], comprising:

0.002 w/v% or more and 0.004 w/v% or less of the

25 alkyldiaminoethylglycine hydrochloride,

0.001 w/v% or more and 0.035 w/v% or less of the menthol,

0.05 w/v% or more and 0.5 w/v% or less of the taurine,

0.005 w/v% or more and 0.05 w/v% or less of the non-ionic surfactant,

30 0.002 w/v% or more and 0.008 w/v% or less of the glucose,

0.1 w/v% or more and 2 w/v% or less of the inorganic salt,
0.05 w/v% or more and 0.5 w/v% or less of the thickening
agent, and

0.1 w/v% or more and 2 w/v% or less of the buffering agent,
5 wherein pH is 5.5 or more and 7.5 or less.

[37] The medical composition for a soft contact lens according
to any one of the above [1] to [36], further comprising an
amino acid.

[38] The medical composition for a soft contact lens according
10 to the above [37], wherein the amino acid is one or more amino
acids selected from the group consisting of glutamic acid,
aspartic acid, glycine, alanine, arginine, lysine and salts
thereof.

[39] The medical composition for a soft contact lens according
15 to the above [37] or [38], comprising 0.01 w/v% or more and 1
w/v% or less of the amino acid.

[40] The medical composition for a soft contact lens according
to the above [37] or [38], comprising 0.05 w/v% or more and
0.5 w/v% or less of the amino acid.

20 [41] The medical composition for a soft contact lens according
to any one of the above [1] to [40], further comprising a
chelating agent.

[42] The medical composition for a soft contact lens according
to the above [41], the chelating agent is
25 ethylenediaminetetraacetic acid or a salt thereof.

[43] The medical composition for a soft contact lens according
to the above [41] or [42], comprising 0.001 w/v% or more and
0.1 w/v% or less of the chelating agent.

[44] The medical composition for a soft contact lens according
30 to the above [41] or [42], comprising 0.005 w/v% or more and

0.05 w/v% or less of the chelating agent.

[45] The medical composition for a soft contact lens according to any one of the above [1] to [44], comprising:

0.002 w/v% or more and 0.004 w/v% or less of the

5 alkyldiaminoethylglycine hydrochloride,

0.001 w/v% or more and 0.035 w/v% or less of the menthol,

0.05 w/v% or more and 0.5 w/v% or less of the taurine,

0.005 w/v% or more and 0.05 w/v% or less of the non-ionic
surfactant,

10 0.002 w/v% or more and 0.008 w/v% or less of the glucose,

0.1 w/v% or more and 2 w/v% or less of the inorganic salt,

0.05 w/v% or more and 0.5 w/v% or less of the thickening
agent,

0.1 w/v% or more and 2 w/v% or less of the buffering agent,

15 and

0.005 w/v% or more and 0.1 w/v% or less of the chelating
agent.

[46] The medical composition for a soft contact lens according to any one of the above [1] to [45], comprising:

20 0.002 w/v% or more and 0.004 w/v% or less of the

alkyldiaminoethylglycine hydrochloride,

0.001 w/v% or more and 0.035 w/v% or less of the menthol,

0.05 w/v% or more and 0.5 w/v% or less of the taurine,

0.005 w/v% or more and 0.05 w/v% or less of the non-ionic

25 surfactant,

0.002 w/v% or more and 0.008 w/v% or less of the glucose,

0.1 w/v% or more and 2 w/v% or less of the inorganic salt,

0.05 w/v% or more and 0.5 w/v% or less of the thickening
agent,

30 0.1 w/v% or more and 2 w/v% or less of the buffering

agent, and

0.005 w/v% or more and 0.1 w/v% or less of the chelating agent,

wherein pH is 6.5 or more and 7.5 or less.

5 [47] The medical composition for a soft contact lens according to any one of the above [1] to [46], wherein the medical composition is ophthalmic.

[48] The medical composition for a soft contact lens according to any one of the above [1] to [47], wherein the medical
10 composition is an aqueous liquid.

[49] The medical composition for a soft contact lens according to any one of the above [1] to [48], wherein the medical composition is an ophthalmic solution.

[50] Use of taurine for suppressing adsorption of an
15 alkyldiaminoethylglycine on a soft contact lens in a medical composition comprising 0.001 w/v% or more and 0.0045 w/v% or less of the alkyldiaminoethylglycine hydrochloride and menthol.

[51] Use of taurine for producing a medical composition,
20 wherein the medical composition comprises 0.001 w/v% or more and 0.0045 w/v% or less of the alkyldiaminoethylglycine and menthol, and adsorption of the alkyldiaminoethylglycine hydrochloride on a soft contact lens is suppressed in the medical composition.

25 [52] A method for suppressing adsorption of an alkyldiaminoethylglycine on a soft contact lens,

wherein a medical composition for a soft contact lens comprises 0.001 w/v% or more and 0.0045 w/v% or less of an alkyldiaminoethylglycine hydrochloride,

30 the method comprising the step of mixing menthol and

taurine in the medical composition for a soft contact lens.

[53] The method according to the above [52], wherein the medical composition for a soft contact lens comprises 0.002 w/v% or more and 0.004 w/v% or less of the

5 alkyldiaminoethylglycine hydrochloride.

The matters specified in the above [1] to [49] can be applied to the above-described "use of taurine for producing a medical composition, wherein adsorption of an alkyldiaminoethylglycine on a soft contact lens is suppressed
10 in the medical composition" and "method for suppressing adsorption of an alkyldiaminoethylglycine on a soft contact lens".

EFFECT OF THE DISCLOSURE

15 [0010]

The medical composition for a soft contact lens of the present disclosure comprises an alkyldiaminoethylglycine hydrochloride, and the adsorption of the alkyldiaminoethylglycine on a soft contact lens is suppressed.

20

MODE FOR CARRYING OUT THE INVENTION

[0011]

Various medical compositions have been developed as described above, and a preservative agent is mixed in an
25 ophthalmic solution for the preservation stability. The cytotoxicity of an alkyldiaminoethylglycine hydrochloride among preservative agents for a medical composition is relatively lower than that of benzalkonium chloride or the like.

30 [0012]

The inventor of the present invention found that when an alkyldiaminoethylglycine hydrochloride is mixed in a medical composition for a soft contact lens in a relatively low concentration, the alkyldiaminoethylglycine tends to adsorb on the soft contact lens and the tendency becomes further stronger by mixing menthol. The inventor searches the component to suppress such adsorption; and as a result, found that taurine is effective.

[0013]

The medical composition for a soft contact lens of the present invention comprises 0.001 w/v% or more and 0.0045 w/v% or less of an alkyldiaminoethylglycine hydrochloride, menthol and taurine.

Hereinafter, an alkyldiaminoethylglycine is abbreviated as "ADG", and a soft contact lens is abbreviated as "SCL".

[0014]

The "alkyldiaminoethylglycine hydrochloride" has the following chemical structure and has been conventionally used as a component of a preservative agent mainly.

$$\text{R-NH-(CH}_2\text{)}_2\text{-NH-(CH}_2\text{)}_2\text{-NH-CH}_2\text{-CO}_2\text{H}\cdot\text{HCl}$$
wherein R is an alkyl group of C₈H₁₇ to C₁₆H₃₃ and mainly C₁₂H₂₅ and C₁₄H₂₉.

[0015]

The inventor of the present invention adjusted the content amount of the alkyldiaminoethylglycine hydrochloride in the medical composition for a soft contact lens to be relatively low as 0.001 w/v% or more and 0.0045 w/v% or less to provide the medical composition for a soft contact lens having low cytotoxicity. When the concentration is 0.001 w/v% or more, the antiseptic action can be exerted more surely. When the

concentration is 0.0045 w/v% or less, the cytotoxicity can be suppressed more surely. In addition, the inventor experimentally found that when the concentration is 0.0045 w/v% or less, the effect to suppress the adsorption of the alkyldiaminoethylglycine on a soft contact lens is improved. The concentration is more preferably 0.002 w/v% or more and 0.004 w/v% or less.

[0016]

The medical composition for a soft contact lens of the present invention contains menthol from the viewpoint of refreshing feeling. The adsorption of ADG on a soft contact lens is accelerated by mixing menthol, but such adsorption is suppressed by mixing taurine in the present invention. Any one of l-menthol and dl-menthol can be used as the menthol, and l-menthol is preferred.

[0017]

The concentration of menthol in the medical composition for a soft contact lens may be appropriately adjusted and can be adjusted to, for example, 0.0005 w/v% or more and 0.1 w/v% or less. When the concentration is included in the range, appropriate refreshing feeling can be obtained more surely. The concentration is preferably 0.001 w/v% or more, more preferably 0.0015 w/v% or more, even more preferably 0.002 w/v% or more, and preferably 0.035 w/v% or less, more preferably 0.02 w/v% or less, even more preferably 0.01 w/v% or less or 0.009 w/v% or less.

[0018]

The "taurine" is an alternate name for 2-aminoethylsulfonic acid [$\text{H}_2\text{N}-(\text{CH}_2)_2-\text{SO}_3\text{H}$] and one of neurotransmitters having a homeostatic function. Taurine reduces elevated blood pressure.

In addition, taurine is expected to activate tissue as the nutrition of eye tissue and promote healing of eye fatigue and ophthalmopathy. The inventor of the present invention experimentally found that a low concentration

5 alkyldiaminoethylglycine in a medical composition tends to adsorb on a soft contact lens, such a tendency is further accelerated by mixing menthol, and such adsorption of an alkyldiaminoethylglycine is suppressed by mixing taurine.

[0019]

10 The concentration of taurine in the medical composition for a soft contact lens may be appropriately adjusted and may be adjusted to, for example, 0.01 w/v% or more and 1 w/v% or less. The concentration is preferably 0.05 w/v% or more, more preferably 0.08 w/v% or more, and preferably 0.5 w/v% or less,
15 more preferably 0.2 w/v% or less.

[0020]

The "non-ionic surfactant" means a surfactant that does not dissociate into an ion even when the surfactant is dissolved in water. In general, the polyoxyethylene chain and the
20 hydroxy group thereof act as a hydrophilic group, and the long-chain alkyl group thereof acts as a hydrophobic group. The non-ionic surfactant contributes to the stability of the ophthalmic solution. An example of the non-ionic surfactant includes one or more non-ionic surfactants selected from the
25 group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan long-chain fatty acid monoester, polyethylene glycol long-chain fatty acid monoester and polyoxyethylene-polyoxypropylene block copolymer.

[0021]

30 The polyoxyethylene hydrogenated castor oil means a

compound obtained by etherifying hydrogenated castor oil with a polyoxyethylene chain. The addition mole number of the ethylene oxide of the polyoxyethylene chain in the polyoxyethylene hydrogenated castor oil may be adjusted to, 5 for example, 5 or more and 100 or less. The addition mole number is preferably 10 or more or 20 or more, more preferably 30 or more, even more preferably 40 or more, and preferably 90 or less, more preferably 80 or less, even more preferably 70 or less. An example of the polyoxyethylene hydrogenated castor oil includes polyoxyethylene hydrogenated castor oil 5, 10 polyoxyethylene hydrogenated castor oil 10 and polyoxyethylene hydrogenated castor oil 60. Polyoxyethylene hydrogenated castor oil 60 is preferably used. The number after the polyoxyethylene hydrogenated castor oil represents the 15 addition mole number of the ethylene oxide.

[0022]

The polyoxyethylene sorbitan long-chain fatty acid monoester is also called as polysorbate and is a polyoxyethylene ether of a sorbitan fatty acid ester. The 20 polyoxyethylene sorbitan long-chain fatty acid monoester can be obtained by reacting sorbitol with a long-chain fatty acid with heating in the presence of an alkali catalyst to produce a sorbitan long-chain fatty acid ester and condensing the sorbitan long-chain fatty acid ester with ethylene oxide. In 25 general, totally about 18 molecules or more and about 22 molecules or less of ethylene oxide is bound to one molecule of the polyoxyethylene sorbitan long-chain fatty acid monoester. The carbon number of the long-chain fatty acid is generally about 10 or more and about 20 or less, and an 30 example of the long-chain fatty acid includes lauric acid,

palmitic acid, stearic acid and oleic acid. For example, polysorbate 20, polysorbate 60, polysorbate 65 and polysorbate 80 can be used as the polyoxyethylene sorbitan long-chain fatty acid monoester, and polysorbate 80 is preferred.

5 [0023]

The polyethylene glycol long-chain fatty acid monoester means an ester of a long-chain fatty acid and polyethylene glycol. An example of the long-chain fatty acid includes stearic acid. For example, the polymerization degree of the polyethylene glycol is about 10 or more and about 60 or less. Polyoxyl 40 stearate is preferred as the polyethylene glycol long-chain fatty acid monoester.

[0024]

The polyoxyethylene-polyoxypropylene block copolymer means a copolymer of propylene oxide and ethylene oxide. An example of the polyoxyethylene-polyoxypropylene block copolymer includes polyoxyethylene (160) polyoxypropylene (30) glycol (Poloxamer 188), polyoxyethylene (196) polyoxypropylene (67) glycol (Poloxamer 407) and Poloxamer 235.

20 [0025]

The concentration of the non-ionic surfactant in the medical composition may be appropriately adjusted and may be adjusted to, for example, 0.001 w/v% or more and 0.5 w/v% or less. When the concentration is included in the range, the effect to stabilize the medical composition is exerted more surely. The concentration is preferably 0.005 w/v% or more, more preferably 0.008 w/v% or more, and preferably 0.1 w/v% or less, more preferably 0.05 w/v% or less, even more preferably 0.02 w/v% or less.

30 [0026]

The "glucose" is represented by the formula of $C_6H_{12}O_6$ and is one of aldohexoses. Natural glucose is D-glucose and is conjugated to an electron transport system to produce a large amount of ATP in an animal having a respiratory system. There is approximately 1 w/v% or more and 5 w/v% or less of glucose in tears.

[0027]

The medical composition for a soft contact lens of the present invention preferably comprises 0.001 w/v% or more and 0.01 w/v% or less of the glucose. When the concentration is 0.001 w/v% or more, a similar effect to the glucose in tears may be exerted. When the concentration is 0.01 w/v% or less, the composition can be stabilized more surely. The concentration is more preferably 0.002 w/v% or more, even more preferably 0.004 w/v% or more, and more preferably 0.008 w/v% or less, more preferably 0.006 w/v% or less.

[0028]

The "inorganic salt" means an inorganic compound corresponding to an inorganic acid of which hydrogen atom is substituted by a metal and is mainly mixed as a tonicity agent. An inorganic salt that can be dissolved in water, which is a solvent of the ophthalmic solution, is preferred. The phrase "can be dissolved in water" means that a material to be tested is powderized so that the material can pass Sieve No. 100 having a mesh size of 150 μm , 1 g of the powderized material is added in water, the mixture is vigorously shaken at 20°C for 30 seconds every 5 minutes, and an amount of water required for dissolution of the material within 30 minutes is less than 10 mL.

[0029]

An example of the inorganic salt includes an alkali metal chloride such as sodium chloride and potassium chloride; a group 2 metal chloride such as calcium chloride and magnesium chloride; an alkali metal carbonate such as sodium carbonate; 5 an alkali metal hydrogencarbonate such as sodium hydrogencarbonate; a group 2 metal sulfate such as magnesium sulfate; an alkali metal sulfite such as sodium sulfite; an alkali metal hydrogensulfite such as sodium hydrogensulfite; an alkali metal thiosulfate such as sodium thiosulfate; an 10 alkali metal hydrogenphosphate such as disodium hydrogenphosphate; and an alkali metal dihydrogenphosphate such as sodium dihydrogenphosphate and potassium dihydrogenphosphate. Sodium chloride and/or potassium chloride is preferably used. A group 2 metal is preferably an alkaline 15 earth metal such as calcium.

[0030]

The concentration of the inorganic salt in the ophthalmic solution may be appropriately adjusted and may be adjusted to, for example, 0.05 w/v% or more and 5 w/v% or less. When the 20 concentration is included in the range, the function as a tonicity agent is exerted more surely. The concentration is preferably 0.1 w/v% or more, more preferably 0.5 w/v% or more, and preferably 2 w/v% or less, more preferably 1 w/v% or less. Only one metal chloride may be used alone, or two or more 25 metal chlorides may be used in combination. When two or more metal chlorides are used, the above concentration is a total concentrations.

[0031]

The "thickening agent" means a component to increase the 30 viscosity of the medical composition for a soft contact lens

and to contribute to the suppression of the rapid evaporation of the medical composition for a soft contact lens, the improvement of the dripping performance, the suppression of the variation of the dropping quantity and the improvement of the use feeling. Glucose is also used in a medical composition as a tonicity agent and a thickening agent; but glucose is excluded from the category of the thickening agent for the sake of convenience in the present invention.

[0032]

The viscosity of the medical composition for a soft contact lens according to the present invention may be appropriately adjusted and may be adjusted to, for example, 1.0 mPa·s or more and 200 mPa·s or less. The viscosity is preferably 50 mPa·s or less and more preferably 3.0 mPa·s or less.

[0033]

An example of the thickening agent includes hydroxypropyl methylcellulose, carboxyvinyl polymer, hydroxyethyl cellulose, methylcellulose, alginic acid, polyvinyl alcohol and polyvinylpyrrolidone, and hydroxypropyl methylcellulose is preferred.

[0034]

The concentration of the thickening agent in the medical composition for a soft contact lens may be appropriately adjusted and may be adjusted to, for example, 0.01 w/v% or more and 1 w/v% or less. When the concentration is included in the range, the above-described effect by the thickening agent can be exerted more surely. The concentration is preferably 0.05 w/v% or more, more preferably 0.08 w/v% or more, and preferably 0.5 w/v% or less, more preferably 0.2 w/v% or less.

[0035]

The "buffering agent" mainly means a compound to ease the change of pH due to a foreign substance and is exemplified by one or more buffering agents selected from the group consisting of a borate buffering agent, a phosphate buffering agent, a carbonate buffering agent, a citrate buffering agent, an acetate buffering agent, a HEPES buffering agent and a MOPS buffering agent. The buffering agent is preferably a borate buffering agent or a phosphate buffering agent, more preferably a borate buffering agent, and even more preferably boric acid and/or borax. Boric acid and borax are also used as a preservative agent and have a disinfecting effect on the conjunctival sac.

[0036]

The concentration of the buffering agent in the medical composition for a soft contact lens may be appropriately adjusted and may be adjusted to, for example, 0.05 w/v% or more and 5 w/v% or less. When the concentration is included in the range, the buffering effect by the buffering agent can be exerted more surely. The concentration is preferably 0.1 w/v% or more, more preferably 0.5 w/v% or more, and preferably 2 w/v% or less, more preferably 1 w/v% or less.

[0037]

The "amino acid" means a compound having a carboxy group and an amino group in one molecule and is mainly 20 kinds of so-called protein-constituting amino acids. The amino acid mainly plays a role of a nutrient component for the eye and contributes to reduction of eye fatigue. An example of the amino acid includes one or more amino acids selected from the group consisting of glutamic acid, aspartic acid, glycine, alanine, arginine, lysine and salts thereof. An example of the

amino acid salt includes an alkali metal salt such as sodium salt and potassium salt.

[0038]

The concentration of the amino acid in the medical composition for a soft contact lens may be appropriately adjusted and may be adjusted to, for example, 0.01 w/v% or more and 1 w/v% or less. When the concentration is included in the range, the effect by the respective amino acid can be exerted more surely. The concentration is preferably 0.05 w/v% or more, more preferably 0.08 w/v% or more, and preferably 0.5 w/v% or less, more preferably 0.2 w/v% or less.

[0039]

The pH of the medical composition for a soft contact lens according to the present invention is adjusted to the range applicable to a living body, especially the eyes. For example, the pH may be adjusted to 5.0 or more and 8.5 or less. The pH is preferably 5.5 or more, more preferably 6.0 or more, even more preferably 6.5 or more, and preferably 8.0 or less, more preferably 7.5 or less. The pH of the medical composition for a soft contact lens may be adjusted by the above-described buffering agent or a pH adjuster.

[0040]

The pH adjuster is not particularly restricted as long as the pH adjuster is applicable to a living body, especially the eyes. An example of the pH adjuster includes an inorganic acid such as hydrochloric acid and boric acid; an organic acid such as acetic acid, glutamic acid and aspartic acid; an inorganic base such as sodium hydroxide, sodium carbonate and sodium hydrogencarbonate; and an organic base such as triethanolamine and monoethanolamine. The kind and the additive amount of the

pH adjuster may be adjusted depending on the pH to be adjusted of the medical composition for a soft contact lens.

[0041]

5 The "chelating agent" means a compound to improve the preservation stability of the ophthalmic solution by sequestering a metal ion such as calcium ion to prevent an insoluble metal salt thereof from being produced. The chelating agent is not particularly restricted as long as the chelating agent is applicable to a living body, especially the
10 eyes, and has the above-described action. An example of the chelating agent includes ethylenediaminetetraacetic acid (edetic acid), ascorbic acid, citric acid and salts thereof. An example of the ethylenediaminetetraacetate salt includes ethylenediaminetetraacetic acid tetrasodium salt and
15 ethylenediaminetetraacetic acid disodium salt.

[0042]

The concentration of the chelating agent in the medical composition for a soft contact lens may be appropriately adjusted and may be adjusted to, for example, 0.001 w/v% or
20 more and 0.2 w/v% or less. When the concentration is included in the range, the stabilizing effect by the chelating agent can be exerted more surely. The concentration is preferably 0.002 w/v% or more, more preferably 0.005 w/v% or more, and preferably 0.1 w/v% or less, more preferably 0.05 w/v% or
25 less, even more preferably 0.02 w/v% or less.

[0043]

A preservative agent or an antiseptic agent may be added in the medical composition for a soft contact lens of the present invention in addition to the alkylldiaminoethylglycine
30 hydrochloride without particular restriction as long as the

effect of the present invention is not impaired. An example of the preservative agent or antiseptic agent includes benzalkonium chloride, benzalkonium bromide, benzethonium chloride, chlorhexidine hydrochloride, chlorhexidine

5 gluconate, chlorhexidine acetate, chlorobutanol, benzyl alcohol, phenethyl alcohol, sorbic acid or a salt thereof, methyl parahydroxybenzoate, ethyl parahydroxybenzoate, propyl parahydroxybenzoate, dehydroacetic acid or a salt thereof, zinc chloride, polidronium chloride, thimerosal,
10 dibutylhydroxytoluene, sodium chlorite, boric acid and borax. Only one of the preservative agent or antiseptic agent may be used alone, or two or more of the preservative agents or antiseptic agents may be used in combination.

[0044]

15 Only one of the above-described each component may be used alone, or two or more of the above-described components may be appropriately used in combination.

[0045]

A soft contact lens is classified into 4 kinds by FDA: Food
20 and Drug Administration. Specifically, a soft contact lens is classified into Group I: water content is less than 50% and material is nonionic, Group II: water content is 50% or more and material is nonionic, Group III: water content is less than 50% and material is ionic, Group IV: water content is 50%
25 or more and material is ionic. The term "ionic" means that the mol% of the monomer having an anion among the constituent monomer of the raw material polymer is 1% or more, and the term "nonionic" means that the mol% is less than 1%. The soft contact lens may be classified into any one of the above-
30 described soft contact lenses, may be ionic or nonionic, and

may be hydrous or may not be hydrous in this disclosure.

[0046]

The "soft contact lens" in this disclosure is exemplified by a soft contact lens mainly composed of 2-hydroxyethyl
5 methacrylate (HEMA), EGDMA, SiMAA2, mPDMS 1000, CE-PDMS, TRIS, EMA, methacryloyloxyethyl phosphorylcholine, Tris VC, MMA, MA, polyethylene glycol monomethacrylate (PEGMA), glycerol methacrylate (GMA), N,N-dimethylacrylamide (DMA), vinyl alcohol (VA), N-vinylpyrrolidone (NVP or VP), methacrylic acid
10 (MAA), fluorine-containing methacrylate compound, silicon-containing methacrylate compound, silicone hydrogel and cycloalkyl methacrylate.

[0047]

The material of the soft contact lens in this disclosure
15 may be any one of the above-described materials. The soft contact lens mainly composed of 2-hydroxyethyl methacrylate (HEMA) is preferably exemplified and is more preferably mainly composed of 2-hydroxyethyl methacrylate (HEMA) and EGDMA or HEMA and methacryloyloxyethyl phosphorylcholine.

20 [0048]

The kind of the soft contact lens is not particularly restricted, and the soft contact lens can be used as any one of a disposable soft contact lens, a periodic replacement soft contact lens, a conventional soft contact lens, a silicone
25 hydrogel soft contact lens and a color contact lens.

[0049]

A silicone hydrogel soft contact lens is made of a silicone hydrogel material.

[0050]

30 The color contact lens means a contact lens that are

colored for the purpose of beauty such as eye decoration and aesthetics. For example, the color of the iris can be changed by wearing a color contact lens. In addition, the pupil can be looked larger by using a contact lens of which larger area
5 than the periphery of the iris is colored. Such a contact lens may be referred to as a circle lens in some cases.

[0051]

Publicly known dye is used as the dye used for coloring a color contact lens, such as inorganic dye and organic dye. An
10 example of such dye includes azo dye, phthalocyanine dye, diketopyrrolopyrrole dye, anthraquinone dye, tripheno dioxane dye, violanthron dye, isoindoline dye, carbazole dye, quinoline dye, metal oxide dye and carbon black. One dye may be used or a plurality of dyes may be used in combination
15 depending on the color or the design of a color contact lens. Any one of substances referred to as pigment or dye can be used by a publically known means in this disclosure. Even a clear contact lens or a soft contact lens other than a color soft contact lens may be colored lightly to the extent that
20 the color is visually easily recognized in the case where the contact lens is immersed in a solution such as a washing solution.

[0052]

The medical composition for a soft contact lens of the
25 present invention can be produced by an ordinary method. For example, each component may be dissolved in water as a solvent. Clear water in which the amount of an impurity, a bacterium, a virus, a fungus or the like is less than the detection limit or sufficiently small, such as distilled
30 water, purified water and sterile water, is used as a solvent.

[0053]

The container for the medical composition for a soft contact lens of the present invention is not particularly restricted and may be a container that has been conventionally
5 used as an eyedropper container. The container may be made of glass or plastic. When the container for the medical composition for a soft contact lens of the present invention is made of plastic, the material of the plastic container is not particularly restricted and is exemplified by any one kind
10 or two or more kinds mixture of polyethylene naphthalate, polyacrylate, polyethylene terephthalate, polybutylene terephthalate, polypropylene, polyethylene and polyimide. The material of the container main body, in other words, the part in which the medical composition for a soft contact lens is
15 contained, is preferably polyethylene terephthalate, polyethylene and polypropylene and more preferably polyethylene terephthalate from the viewpoint to ensure the stability of the medical composition for a soft contact lens.
[0054]

20 Whether the adsorption of an alkylldiaminoethylglycine on a soft contact lens in the medical composition for soft contact lens of the present invention is suppressed or not is evaluated by whether the amount of the alkylldiaminoethylglycine in the medical composition for a soft
25 contact lens after the soft contact lens is immersed in the medical composition is larger or not than the amount of the alkylldiaminoethylglycine in the liquid having a similar composition except that the liquid does not contain taurine after the a soft contact lens is immersed in the liquid. For
30 example, a soft contact lens is immersed in a liquid at 25°C

with shaking the liquid for 24 hours. The amount of an alkyldiaminoethylglycine can be measured by high performance liquid chromatography and absorbance of a light having a wave length of 545 nm, which is characteristic of an

5 alkyldiaminoethylglycine.

[0055]

The medical composition for a soft contact lens of the present invention complements tears and is effective in relieving discomfort, dryness of eyes, eye fatigue and blurred
10 vision in wearing a soft contact lens.

[0056]

The medical composition of the present invention can be used in either an internal form or an external form depending on the purpose. The composition can be provided as a local
15 administration liquid medicinal agent for various application. For example, the composition can be provided for medical application in an internal form and for ophthalmic, dental, ontological and dermatologic applications in an external form. In particular, the composition can be provided for ophthalmic
20 application.

[0057]

The term "ophthalmic medical composition" means a medical composition for ophthalmic application. An example of the medical composition particularly includes an aqueous liquid
25 composition containing water as a solvent. The term "aqueous liquid composition" particularly means a liquid medical composition containing water as a solvent. The aqueous liquid composition can be produced by an ordinary method. For example, the aqueous liquid composition can be produced by
30 dissolving or dispersing each component in water as a solvent.

The aqueous liquid composition may be a solution, a suspension or an emulsion and is preferably a solution.

[0058]

An example of the ophthalmic medical composition includes
5 an ophthalmic solution, an eye wash, an eye ointment, a soft
contact lens fitting liquid and a soft contact lens care
liquid. An ophthalmic solution is exemplified by an ophthalmic
solution usable with wearing a soft contact lens and is also
called as an eye-drop and an ophthalmic agent. An eye wash is
10 exemplified by an eye wash usable with wearing a soft contact
lens and is also called as an eye lotion and an eye wash
agent. An example of a soft contact lens care liquid includes
a cleaning liquid, a preservative solution, a sterilizing
liquid and an antiseptic solution such as a multi-purpose
15 solution. The ophthalmic pharmaceutical composition is
preferably an ophthalmic solution, a soft contact lens fitting
liquid, an eye wash and a soft contact lens care liquid, and
particularly preferably an ophthalmic solution for soft
contact lens care.

20 [0059]

The medical composition of the present invention is
exemplified by an ophthalmic solution usable with wearing a
soft contact lens. In other words, the medical composition of
the present invention can be applied to the eye with wearing a
25 soft contact lens. The kind of a soft contact lens is not
particularly restricted, and the composition can be used for
any one of a disposable soft contact lens, a periodic
replacement soft contact lens, a conventional soft contact
lens, a silicone hydrogel contact lens and a color contact
30 lens. A silicone hydrogel contact lens is made of a silicone

hydrogel material.

[0060]

The administration and dosage of the ophthalmic solution according to the present invention is adjusted depending on
5 the symptom, age or the like of a patient, and one drop or more and 3 drops or less of the ophthalmic solution may be generally instilled into an eye one time or more and 6 times or less per one day.

The container used for the medical composition of the
10 present invention is sterilized by an ordinary method. The sterilization method is not particularly restricted as long as the method is generally used and is exemplified by dry heat sterilization, electron beam sterilization, gamma
sterilization and ethylene gas sterilization. Electron beam
15 sterilization is used as a sterilization method in one embodiment.

[0061]

The present invention also relates to a method for suppressing adsorption of an alkyldiaminoethylglycine on a
20 soft contact lens, the method comprising the step of mixing menthol and taurine in a medical composition for a soft contact lens, wherein a content amount of an alkyldiaminoethylglycine hydrochloride in the medical composition for a soft contact lens is 0.001 w/v% or more and
25 0.0045 w/v% or less. When the content amount of the alkyldiaminoethylglycine hydrochloride in the medical composition for a soft contact lens is 0.002 w/v% or more and 0.004 w/v% or less in the above method, the adsorption of the alkyldiaminoethylglycine is suppressed further effectively.

[0062]

The reason why the content amount of the alkyldiaminoethylglycine hydrochloride in the medical composition for a soft contact lens in the above-described method for suppressing the adsorption is restricted to 0.001 w/v% or more and 0.0045 w/v% or less is that the adsorption rate of the alkyldiaminoethylglycine on a soft contact lens is high in such a low concentration range.

[0063]

The above-described kind and the concentration with respect to the alkyldiaminoethylglycine hydrochloride, menthol, taurine and other optional component of the above-described medical composition for a soft contact lens may be applied alone or in combination to the kind and the concentration of those in the above-described method for suppressing the adsorption. The pH, container or the like of the medical composition can be also similarly applied to the method.

[0064]

The present application claims the benefit of the priority date of Japanese patent application No. 2019-217423 filed on November 29, 2019. All of the contents of the Japanese patent application No. 2019-217423 filed on November 29, 2019, are incorporated by reference herein.

EXAMPLES

[0065]

Hereinafter, the present invention is described in more detail with Examples. The present invention is however not restricted to the following Examples in any way, and it is possible to work the present invention according to the Examples with an additional appropriate change within the

range of the above descriptions and the following descriptions. Such a changed embodiment is also included in the technical scope of the present invention.

[0066]

5 Test example 1: Adsorption test on soft contact lens

The aqueous solution of Example 1 having the composition shown in Table 1 was prepared. Specifically, sodium chloride manufactured by NACALAI TESQUE, sodium dihydrogenphosphate dihydrate manufactured by NACALAI TESQUE and disodium
10 hydrogenphosphate 12 hydrate manufactured by NACALAI TESQUE were dissolved in water (80 mL) so that the concentrations became those shown in Table 1. The obtained aqueous solution was heated to about 70°C, and 1-menthol manufactured by SUZUKI MENTHOL and taurine manufactured by Kasano Kosan were added
15 thereto to be dissolved. Then, the solution was cooled to an atmospheric temperature. Further, 40% alkyldiaminoethylglycine hydrochloride aqueous solution ("LEBON LAG-40" manufactured by Sanyo Chemical) was added thereto to be mixed, the pH was adjusted using 1 mol/L hydrochloric acid or 1 mol/L sodium
20 hydroxide aqueous solution as pH adjusters, and water was added so that the total volume became 100 mL. Alternatively, a geometric multiple aqueous solution was prepared.

In addition, aqueous solutions of Comparative example 1 and Comparative example 2 having the compositions shown in Table 1
25 were prepared in accordance with the above condition. The unit of the numerical values in Table 1 is w/v% except for pH and ADG adsorption rate.

Then, adsorption of the alkyldiaminoethylglycine on a soft contact lens was tested. Each test liquid (3 mL) was
30 respectively taken and added into three vial containers, and a

soft contact lens ("1-DAY ACUVUE MOIST" manufactured by Johnson & Johnson) was immersed into a vial container one by one. The vial container was shaken at 25°C for 24 hours or longer to obtain SCL immersion liquid. Three liquid in which a soft contact lens was not immersed were similarly treated as control test liquid. Next, the content amounts (C) of the alkyldiaminoethylglycine in the SCL immersion liquid and the control test liquid were respectively measured from the total areas of the peaks derived from the alkyldiaminoethylglycine using high speed chromatography (HPLC) in the following condition.

Column: inner diameter 4.6 mm × length 15 cm
cyanopropylsilylated silica gel ("CN12S05-1546WT" manufactured by YMC)

Detector: ultraviolet absorptiometer

Measured wavelength: 210 nm

Mobile phase: water/methanol/phosphoric acid mixed liquid = 750/250/1

Each average value was calculated from the measured content amounts (C) of the alkyldiaminoethylglycine, and the alkyldiaminoethylglycine adsorption rate (%) on a soft contact lens was calculated in accordance with the following formula. The result is shown in Table 1. The "%" of each component in the table means w/v%.

Adsorption rate (%) = $100 - \{[(C_c - C_T) / C_c] \times 100\}$
wherein C_T is the average value (μg/mL) of the alkyldiaminoethylglycine content amount in the SCL immersion liquid, and C_c is the average value (μg/mL) of the alkyldiaminoethylglycine content amount in the control test liquid.

[0067]

Table 1

	Comparative example 1	Comparative example 2	Example 1
NaCl	0.83		
NaH ₂ PO ₄ ·2H ₂ O	0.053		
Na ₂ HPO ₄ ·2H ₂ O	0.60		
ADG hydrochloride	0.0025		
l-Menthol	—	0.035	0.035
Taurine	—	—	0.10
pH adjuster	Appropriate amount		
Purified water	Appropriate amount		
pH	7		
ADG adsorption rate	25.6%	27.6%	21.6%

[0068]

When menthol was mixed in the formulation, the amount of
5 the alkyldiaminoethylglycine adsorbed on a soft contact lens
was increased as the result shown in Table 1.

On the one hand, it was demonstrated that when taurine is
mixed in the formulation in addition to menthol, the
adsorption of the alkyldiaminoethylglycine on a soft contact
10 lens is suppressed.

[0069]

Test example 2: Examination of content amount of
alkyldiaminoethylglycine hydrochloride

The adsorption rate of the alkyldiaminoethylglycine on a
15 soft contact lens was calculated in a similar condition to
Test example 1 with respect to the formulations having the
compositions having various content amounts of the
alkyldiaminoethylglycine hydrochloride shown in Table 2. The
result is shown in Table 2.

20 In addition, the adsorption suppression rate (%) of an
alkyldiaminoethylglycine on a soft contact lens was calculated
in accordance with the following formula using the formulation

having a similar composition except that taurine was not mixed. The result is shown in Table 2. The unit of the numerical value in Table 2 other than pH, ADG adsorption rate and adsorption suppression rate is w/v%.

5 Adsorption suppression rate (%) = $\{[(\text{adsorption rate of formulation not containing taurine}) - (\text{adsorption rate of formulation containing taurine})] / (\text{adsorption rate of formulation not containing taurine})\} \times 100$

[0070]

Table 2

	Comparative example 3	Comparative example 4	Example 2	Comparative example 5	Example 3	Comparative example 6	Example 4	Comparative example 7	Comparative example 8	Example 5
NaCl	0.83									
NaH ₂ PO ₄ ·2H ₂ O	0.053									
Na ₂ HPO ₄ ·2H ₂ O	0.60									
ADG hydrochloride	0.001			0.002		0.004		0.005		
l-Menthol	—	0.035	0.035	—	0.035	—	0.035	—	0.035	0.035
Taurine	—	—	0.10	—	0.10	—	0.10	—	—	0.10
pH adjuster	Appropriate amount									
Purified water	Appropriate amount									
pH	7									
ADG adsorption rate	23.7%	27.4%	25.3%	24.4%	20.7%	19.3%	17.3%	29.8%	28.6%	29.0%
Adsorption suppression rate	—	—	7.7%	—	15.2%	—	10.4%	—	—	-1.4%

[0071]

Though the adsorption amount of an alkyldiaminoethylglycine on a soft contact lens is increased by mixing menthol in the formulation containing 0.001 w/v% or more and 0.004 w/v% or less of an alkyldiaminoethylglycine hydrochloride, the adsorption of an alkyldiaminoethylglycine on a soft contact lens tends to be suppressed by mixing taurine in addition to menthol as the result shown in Table 2.

On the one hand, when the concentration of an alkyldiaminoethylglycine hydrochloride was 0.005 w/v%, such an effect was not shown.

[0072]

Test example 3: Examination of amphoteric surfactant

Since an alkyldiaminoethylglycine is an amphoteric surfactant, lauryl dimethylaminoacetic acid, which is an amphoteric surfactant other than an alkyldiaminoethylglycine, was tested. Specifically, the adsorption rate of an alkyldiaminoethylglycine on a soft contact lens was determined in the same condition as Test example 1 using the formulations having the compositions shown in Table 3 containing lauryl dimethylaminoacetic acid manufactured by FUJIFILM Wako Chemicals in place of an alkyldiaminoethylglycine hydrochloride, and the adsorption suppression rate (%) was calculated in the same condition as Example 2. The result is shown in Table 3. The unit of the numerical value in Table 3 other than pH, ADG adsorption rate and adsorption suppression rate is w/v%.

[0073]

Table 3

	Comparative example 9	Comparative example 10	Comparative example 11
NaCl	0.83		
NaH ₂ PO ₄ ·2H ₂ O	0.053		
Na ₂ HPO ₄ ·2H ₂ O	0.60		
Lauryl dimethylaminoacetic acid	0.001		
l-Menthol	—	0.035	0.035
Taurine	—	—	0.10
pH adjuster	Appropriate amount		
Purified water	Appropriate amount		
pH	7		
ADG adsorption rate	16.8%	17.7%	17.5%
Adsorption suppression rate	—	—	1.1%

[0074]

Even though lauryl dimethylaminoacetic acid and an
5 alkyldiaminoethylglycine are classified into an amphoteric
surfactant, the amount of lauryl dimethylaminoacetic acid
adsorbed on a soft contact lens was small, the adsorption
amount was not significantly increased even by mixing menthol,
and the adsorption amount was not decreased by mixing taurine
10 as the result shown in Table 3.

It was clarified from the results that the adsorption on a
soft contact lens, the increase of the adsorption amount by
menthol and the suppression of the adsorption by mixing
taurine are phenomena peculiar to an alkyldiaminoethylglycine
15 among amphoteric surfactants.

[0075]

Test example 4: Examination of buffering agent

The adsorption rate and the adsorption suppression rate of
an alkyldiaminoethylglycine on a soft contact lens were
20 determined using the formulations having the compositions
shown in Table 4 in the same condition as Test example 2. The
result is shown in Table 4. The unit of the numerical value in

Table 4 other than pH, ADG adsorption rate and adsorption suppression rate is w/v%.

[0076]

Table 4

	Comparative example 12	Example 5	Comparative example 13	Example 6	Comparative example 14	Example 7	Comparative example 15	Comparative example 16	Example 8	Example 9
Sodium chloride	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55
Potassium chloride	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Boric acid	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Borax	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04
Taurine	—	0.1	—	0.1	—	0.1	—	—	0.1	1
Sodium edetate	0.01	0.01	—	—	—	—	—	—	—	—
Menthol	0.035	0.035	0.001	0.001	0.002	0.002	—	0.009	0.009	0.009
Alkyldiaminoethylglycine hydrochloride	0.0025	0.0025	0.001	0.001	0.0025	0.0025	0.004	0.004	0.004	0.004
pH adjuster	Appropriate amount									
Purified water	Appropriate amount									
pH	7									
ADG adsorption rate	27.7%	24.9%	23.4%	22.3%	29.2%	27.8%	27.4%	30.0%	28.0%	28.0%
Adsorption suppression rate	—	10.1%		4.7%	—	4.8%	—	—	6.7%	6.7%

[0077]

The amount of an alkyldiaminoethylglycine adsorbed on a soft contact lens also tended to be increased by mixing menthol but decreased by mixing taurine in addition to menthol in the case where a borate buffering agent was used in place of a phosphate buffering agent as a buffering agent as the result shown in Table 4.

[0078]

Examples 10 to 15

The medical compositions for a soft contact lens having the compositions shown in Table 5 were prepared in accordance with Test example 1. The unit of the numerical value in Table 5 other than pH is w/v%.

[0079]

Table 5

	Example 10	Example 11	Example 12	Example 13	Example 14	Example 15
Sodium chloride	0.55	0.55	0.55	0.55	0.55	0.55
Potassium chloride	0.15	0.15	0.15	0.15	0.15	0.15
Boric acid	0.5	0.5	0.5	0.5	0.5	0.5
Borax	0.04	0.04	0.04	0.04	0.04	0.04
Taurine	1	0.1	0.1	0.2	1	0.5
Sodium edetate	—	0.01	0.01	—	0.005	0.01
Menthol	0.001	0.002	0.03	0.005	0.0025	0.01
Alkyldiaminoethylglycine hydrochloride	0.004	0.0025	0.0035	0.002	0.002	0.004
Polysorbate 80	0.02	—	—	—	—	0.1
Polyoxyethylene hydrogenated castor oil 60	—	0.01	0.1	0.02	0.01	
Glucose	0.01	0.005	—	—	0.002	0.008
pH adjuster	Appropriate amount					
Purified water	Appropriate amount					
pH	7	7	6.5	6.8	7.2	7

CLAIMS

1. A medical composition for a soft contact lens, comprising
0.001 w/v% or more and 0.0045 w/v% or less of an
5 alkyldiaminoethylglycine hydrochloride, menthol and taurine.
2. The medical composition for a soft contact lens according
to claim 1, comprising 0.002 w/v% or more and 0.004 w/v% or
less of the alkyldiaminoethylglycine hydrochloride.
10
3. The medical composition for a soft contact lens according
to claim 1 or 2, comprising 0.0005 w/v% or more and 0.1 w/v%
or less of the menthol.
- 15 4. The medical composition for a soft contact lens according
to any one of claims 1 to 3, comprising 0.01 w/v% or more and
1 w/v% or less of the taurine.
5. The medical composition for a soft contact lens according
20 to any one of claims 1 to 4, comprising:
0.002 w/v% or more and 0.004 w/v% or less of the
alkyldiaminoethylglycine hydrochloride,
0.001 w/v% or more and 0.035 w/v% or less of the menthol,
and
25 0.05 w/v% or more and 0.5 w/v% or less of the taurine.
6. The medical composition for a soft contact lens according
to any one of claims 1 to 5, further comprising a non-ionic
surfactant.
30

7. The medical composition for a soft contact lens according to any one of claims 1 to 6, further comprising glucose.

5 8. The medical composition for a soft contact lens according to any one of claims 1 to 7, further comprising an inorganic salt.

9. The medical composition for a soft contact lens according to any one of claims 1 to 8, further comprising a thickening
10 agent.

10. The medical composition for a soft contact lens according to any one of claims 1 to 9, further comprising a buffering agent.

15

11. The medical composition for a soft contact lens according to any one of claims 1 to 10, comprising:

0.002 w/v% or more and 0.004 w/v% or less of the alkyldiaminoethylglycine hydrochloride,

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0.001 w/v% or more and 0.035 w/v% or less of the menthol,
0.05 w/v% or more and 0.5 w/v% or less of the taurine,
0.005 w/v% or more and 0.05 w/v% or less of the non-ionic surfactant,

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0.002 w/v% or more and 0.008 w/v% or less of the glucose,
0.1 w/v% or more and 2 w/v% or less of the inorganic salt,
0.05 w/v% or more and 0.5 w/v% or less of the thickening agent, and

0.1 w/v% or more and 2 w/v% or less of the buffering agent.

30 12. The medical composition for a soft contact lens according

to any one of claims 1 to 11, wherein pH is 5.5 or more and 8.0 or less.

MEDICAL COMPOSITION FOR SOFT CONTACT LENS

Abstract

5 The objective of the present invention is to provide a medical composition for a soft contact lens, wherein adsorption of an alkyldiaminoethylglycine on the soft contact lens is suppressed. The medical composition for a soft contact lens according to the present invention is characterized in comprising 0.001 w/v% or
10 more and 0.0045 w/v% or less of an alkyldiaminoethylglycine hydrochloride, menthol and taurine.

[No Suitable Figure]