

DESCRIPTION

TITLE OF INVENTION: SKIN COMPOSITION

TECHNICAL FIELD

[0001]

The present invention relates to an external preparation for skin (topical composition) useful for preventing and/or treating acne vulgaris. More specifically, the present invention relates to a skin composition (particularly, a gel) containing benzoyl peroxide having an antibacterial effect, the skin composition being intended to be removed after contact with an affected skin area for a predetermined time.

BACKGROUND ART

[0002]

Acne vulgaris is a skin disease generally referred to as "acne" that commonly occurs on the face, and self-care is generally practiced by applying an external preparation. Benzoyl peroxide is used in many countries for preventing and/or treating acne vulgaris. For example, Patent Documents 1 to 5 disclose external preparations for skin containing benzoyl peroxide as an active ingredient.

CITATION LIST

PATENT DOCUMENT

[0003]

Patent Document 1: JP 2018-538365 A

Patent Document 2: JP 2017-508770 A

Patent Document 3: JP 2005-513146 A

Patent Document 4: JP 2010-513428 A

Patent Document 5: WO 2017/109761

[0004]

Patent Document 1 discloses a composition that is mild to the skin, stable, and free of irritating surfactants, and more specifically discloses a topical pharmaceutical or cosmetic cleansing composition containing an alkyl glucoside derivative surfactant. Patent Document 2 discloses a benzoyl peroxide-containing composition provided in the form of a foam intended for rinse-off topical application, and more specifically discloses a composition containing few or no foaming surfactants. Patent Document 3 discloses a composition containing a retinoid and

benzoyl peroxide, and more specifically discloses limiting a decrease in viscosity over time and maintaining good chemical stability of the two active ingredients by using a specific pH-independent gelling agent. Patent Document 4 discloses a composition containing a retinoid and benzoyl peroxide, and more specifically discloses providing the composition in the form of a cream gel without an emulsifier. Patent Document 5 discloses providing a composition containing benzoyl peroxide, a silicone compound (such as a siloxane), and a zinc compound, the composition being capable of effectively treating acne and simultaneously preventing formation of acne scars and other scars.

SUMMARY OF INVENTION

TECHNICAL PROBLEM

[0005]

None of the above Patent Documents discloses a benzoyl peroxide-containing gel preparation used for treating acne by contact with an affected area for a predetermined time (e.g., 1 to 30 minutes) and subsequent removal (e.g., rinsing off). Since dryness of the skin at the application site has been reported as a side effect of benzoyl peroxide-containing preparations, a preparation intended to be removed after contact with an affected area is preferable for reducing such a side effect. In addition, since benzoyl peroxide is insoluble in water, it exists in a suspended state in the preparation. Since a gel preparation has an appropriate viscosity, it is suitable for uniformly dispersing benzoyl peroxide in the preparation. In order to put such a gel preparation into practical use, it is important to suppress a change in viscosity during storage, thereby preventing a change in appearance and providing a preparation with stable quality.

[0006]

Therefore, an object of the present invention is to provide a benzoyl peroxide-containing skin composition (particularly a gel) that is unlikely to undergo a change in viscosity over time and is easily removable from the skin.

SOLUTION TO PROBLEM

[0007]

As a result of repeated studies to solve the above problem, the inventors have successfully developed a skin composition (particularly a gel) that is unlikely to undergo a change in viscosity over time and is easily removable after application, by using a specific thickener to impart viscosity to a benzoyl peroxide-containing composition and further using a specific surfactant.

[0008]

The composition of the present invention capable of solving the above problem has the following features.

[1]

A skin composition containing:

(A) benzoyl peroxide;

(B) acrylamide/sodium acryloyldimethyltaurate copolymer;

(C) surfactant(s) including at least one selected from the group consisting of the following (c1), (c2), and (c3):

(c1) a combination of sodium lauroyl sarcosinate and at least one anionic surfactant and/or nonionic surfactant;

(c2) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, a polyoxyethylene alkyl ether phosphate salt, a polyoxyethylene alkyl ether sulfate salt, and sodium lauroyl glutamate; and

(c3) a combination of sodium oleate and at least one anionic surfactant and/or nonionic surfactant; and

(D) at least one aqueous solvent selected from water and water-soluble solvents, the skin composition for use by being applied to an affected skin area, left for a predetermined time, and then removed from the affected area.

[2]

The composition according to [1], wherein the at least one anionic surfactant and/or nonionic surfactant set forth in (c1) is at least one surfactant selected from the group consisting of a sodium salt of a sulfate ester of a higher aliphatic alcohol; a polyoxyethylene alkyl ether phosphate salt; a polyoxyethylene alkyl ether sulfate salt; a sodium salt of a long-chain fatty acid; a polyoxyethylene polyoxypropylene glycol; a fatty acid alkanolamide; a polyglycerin fatty acid ester; and a polyoxyethylene alkyl ether.

[3]

The composition according to [1] or [2], wherein the surfactant(s) (C) includes (c1).

[4]

The composition according to any one of [1] to [3], wherein the surfactant(s) (C) contains:

2.0% by weight or less of sodium lauroyl sarcosinate; and

2.0% by weight or less of at least one anionic surfactant and/or nonionic surfactant selected from the following (I) and (II):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium

polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium oleate; and (II) at least one nonionic surfactant selected from the group consisting of a polyoxyethylene polyoxypropylene glycol, lauric acid diethanolamide, decaglyceryl laurate, a polyoxyethylene behenyl ether, and coconut fatty acid diethanolamide.

[5]

The composition according to any one of [1] to [3], wherein the surfactant(s) (C) contains:

1.0% by weight or less of sodium lauroyl sarcosinate; and

1.0% by weight or less of at least one anionic surfactant selected from the following (I):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium oleate.

[6]

The composition according to [1], wherein the surfactant(s) (C) includes (c2).

[7]

The composition according to [1], wherein the surfactant(s) (C) includes (c3).

[8]

The composition according to [1] or [7], wherein the surfactant(s) (C) contains:

2.0% by weight or less of sodium oleate; and

2.0% by weight or less of at least one anionic surfactant and/or nonionic surfactant selected from the following (I) and (II):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium lauroyl sarcosinate; and

(II) at least one nonionic surfactant selected from the group consisting of a polyoxyethylene polyoxypropylene glycol, lauric acid diethanolamide, decaglyceryl laurate, a polyoxyethylene behenyl ether, and coconut fatty acid diethanolamide.

[9]

The composition according to [1] or [7], wherein the surfactant(s) (C) contains:

1.0% by weight or less of sodium oleate; and

1.0% by weight or less of at least one anionic surfactant selected from the following (I):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, and sodium lauroyl sarcosinate.

[10]

The composition according to any one of [1] to [9], containing only benzoyl peroxide as an active ingredient.

[11]

The composition according to any one of [1] to [10], wherein the composition is a gel.

[12]

The composition according to any one of [1] to [11], for use by being applied to the affected skin area, left for 1 to 30 minutes, and then removed from the affected area.

[13]

The composition according to any one of [1] to [12], containing at least one selected from the group consisting of Sepineo P600 (Seppic), SIMULGEL 600 (Seppic), and Acrylamide/sodium acryloyldimethyltaurate copolymer (Alfa Chemistry) as the copolymer (B).

ADVANTAGEOUS EFFECTS OF INVENTION

[0009]

The present invention can provide a benzoyl peroxide-containing skin composition (particularly a gel) that exhibits little change in viscosity over time and is easily removable from the skin.

DESCRIPTION OF EMBODIMENTS

[0010]

A gel generally refers to an external preparation in the form of a gel to be applied to the skin, and is a preparation having an appropriate viscosity in which an active ingredient is dissolved or uniformly dispersed in an aqueous or oily base. The skin composition of the present invention mainly relates to a suspension gel in which benzoyl peroxide is uniformly dispersed in an aqueous base.

[0011]

The composition contains benzoyl peroxide (A) as an active ingredient. Benzoyl peroxide can be prepared by adding aqueous hydrogen peroxide to a sodium hydroxide solution to obtain a sodium peroxide solution, and adding benzoyl chloride thereto. It is also commercially available. Benzoyl peroxide may be coated with a metal oxide layer or the like, but uncoated benzoyl peroxide is more preferable. The content of benzoyl peroxide is preferably

1.0 to 20% by weight, more preferably 1.5 to 15% by weight, particularly preferably 2.0 to 12% by weight, and even more preferably 2.5 to 11% by weight or 5.0 to 10% by weight. Since the composition is intended to be removed from the skin after being applied to the skin and left for a predetermined time, side effects caused by benzoyl peroxide are unlikely to occur even if the composition contains benzoyl peroxide at a high concentration.

[0012]

In the present specification, % by weight, content, or concentration means a proportion by weight of each component based on 100% of the total weight of the composition.

[0013]

The composition preferably contains only benzoyl peroxide as an active ingredient (a component for preventing and/or treating acne). For example, although a combination preparation containing a retinoid such as adapalene and benzoyl peroxide as active ingredients is known as a therapeutic agent for acne, the composition of the present invention preferably contains no retinoid compound (or naphthoic acid compound) such as adapalene.

[0014]

As a result of examining a carboxyvinyl polymer and an acrylamide/sodium acryloyldimethyltaurate copolymer as candidates for a thickener for keeping benzoyl peroxide in a dispersed state, it was confirmed that the acrylamide/sodium acryloyldimethyltaurate copolymer is preferable as the thickener of the present invention, particularly in the case of short-time contact, considering the amount of stratum corneum exfoliation. Therefore, the composition of the present invention contains an acrylamide/sodium acryloyldimethyltaurate copolymer (Acrylamide/Sodium Acryloyldimethyltaurate Copolymer; $(C_3H_5NO.C_7H_{13}NO_4S.Na)_x$) (B). The weight average molecular weight of the copolymer (B) is preferably 2,000,000 to 30,000,000, more preferably 4,000,000 to 20,000,000, more preferably 6,000,000 to 14,000,000, and more preferably 8,000,000 to 12,000,000. The copolymer (B) is commercially available, and for example, products containing this copolymer are sold by Seppic under trade names such as Sepineo P600 and SIMULGEL 600, or by Alfa Chemistry under a trade name of "Acrylamide/sodium acryloyldimethyltaurate copolymer". Sepineo P600 and "Acrylamide/sodium acryloyldimethyltaurate copolymer" are more preferable. These products may be used alone or in combination of two or more, but are preferably used alone.

[0015]

In order to impart an appropriate viscosity to the composition, the content of the copolymer (B) is preferably 0.5 to 4.0% by weight, more preferably 0.7 to 3.5% by weight, and particularly preferably 1.0 to 3.0% by weight. Since a change in viscosity of the composition can be suppressed by using the copolymer (B) in combination with a specific surfactant even if the

amount of the copolymer (B) is small, considering the cost, the content of the copolymer (B) is preferably 0.5 to 2.5% by weight, more preferably 1.0 to 2.0% by weight, and particularly preferably 1.3 to 1.7% by weight.

[0016]

When the composition contains at least one product selected from the group consisting of Sepineo P600 (Seppic), SIMULGEL 600 (Seppic), and "Acrylamide/sodium acryloyldimethyltaurate copolymer" (Alfa Chemistry), the total content thereof is preferably 1.5 to 10% by weight, more preferably 2 to 9% by weight, and particularly preferably 3 to 8% by weight. Considering the cost, the total content of the products is preferably 1.5 to 6.5% by weight, more preferably 2 to 6% by weight, particularly preferably 3 to 5% by weight, and even more preferably 3.5 to 4.5% by weight. Preferred examples of the composition include a composition containing one of the products at any of the above weight percentages.

[0017]

The composition contains specific surfactant(s) (C). As described above, the copolymer (B) can impart an appropriate viscosity to the benzoyl peroxide-containing composition, but this viscosity significantly decreases over time, and as a result, the quality of the preparation cannot be maintained. Furthermore, if the viscosity decreases too much, precipitation of benzoyl peroxide may occur. In contrast, using the specific surfactant(s) can suppress a change in viscosity over time. Furthermore, the action of the surfactant(s) can provide a composition that is easy to wash off from the skin.

[0018]

The total content of the surfactant(s) (C) in the composition is preferably 0.2 to 10% by weight, more preferably 0.3 to 8.0% by weight, more preferably 0.4 to 6.0% by weight, particularly preferably 0.5 to 5.0% by weight, even more preferably 0.7 to 4.0% by weight, and most preferably 1.0 to 2.0% by weight.

[0019]

The surfactant(s) (C) includes at least one selected from the group consisting of the following (c1), (c2), and (c3):

(c1) a combination of sodium lauroyl sarcosinate and at least one anionic surfactant and/or nonionic surfactant;

(c2) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, a polyoxyethylene (POE) alkyl ether phosphate salt (wherein the alkyl group preferably has 10 to 24 carbon atoms; for example, sodium POE oleyl ether phosphate, sodium POE lauryl ether phosphate, sodium POE cetyl ether phosphate, and the like), a polyoxyethylene (POE) alkyl ether sulfate salt (wherein the alkyl group preferably has 10 to 24 carbon atoms; for

example, sodium POE lauryl ether sulfate and the like), and sodium lauroyl glutamate (sodium N-lauroyl-L-glutamate) (wherein an average POE number of each of the surfactants containing POE is preferably 2 to 10); and

(c3) a combination of sodium oleate and at least one anionic surfactant and/or nonionic surfactant.

[0020]

The anionic surfactant(s) and/or nonionic surfactant(s) used in combination with sodium lauroyl sarcosinate in (c1) or sodium oleate in (c3) include the following:

- Examples of the anionic surfactant: a sodium salt of a sulfate ester of a higher aliphatic alcohol (an alcohol having 6 or more carbon atoms, preferably 8 to 24 carbon atoms) (for example, sodium lauryl sulfate, sodium cetyl sulfate, and the like), a POE alkyl ether phosphate salt (wherein the alkyl group preferably has 10 to 24 carbon atoms; for example, sodium POE oleyl ether phosphate, sodium POE lauryl ether phosphate, sodium POE cetyl ether phosphate, and the like), a POE alkyl ether sulfate salt (wherein the alkyl group preferably has 10 to 24 carbon atoms; for example, sodium POE lauryl ether sulfate and the like), and a sodium salt of a long-chain fatty acid (a fatty acid having 12 or more carbon atoms, preferably 14 to 24 carbon atoms) (for example, sodium stearate and the like) (wherein an average POE number of each of the surfactants containing POE is preferably 2 to 10).
- Examples of the nonionic surfactant: a polyoxyethylene polyoxypropylene (POE/POP) glycol (wherein an average POE number is preferably 2 to 200, 4 to 100, 8 to 50, or 10 to 30, and an average POP number is preferably 2 to 100, 4 to 70, 5 to 50, or 10 to 30), a fatty acid alkanolamide (wherein the fatty acid preferably has 6 to 22 carbon atoms, and the alkanol preferably has 2 to 10 carbon atoms; for example, lauric acid diethanolamide, coconut fatty acid diethanolamide, and the like), a polyglycerin fatty acid ester (wherein the fatty acid preferably has 10 to 24 carbon atoms; for example, decaglyceryl laurate), and a polyoxyethylene alkyl ether (wherein the alkyl group preferably has 10 to 24 carbon atoms, and an average POE number is preferably 2 to 30 or 10 to 20; for example, a POE behenyl ether).

[0021]

The surfactant(s) (C) may simultaneously satisfy (c1) and (c2). That is, the surfactant(s) (C) may include a combination of sodium lauroyl sarcosinate and the anionic surfactant(s) set forth in (c2).

[0022]

The surfactant(s) (C) may simultaneously satisfy (c2) and (c3). That is, the surfactant(s) (C) may include a combination of sodium oleate and the anionic surfactant(s) set forth in (c2).
[0023]

The surfactant(s) (C) may simultaneously satisfy (c1) and (c3). That is, the surfactant(s) (C) may include a combination of sodium lauroyl sarcosinate and sodium oleate.
[0024]

The surfactant(s) (C) may satisfy only one of (c1) to (c3).

For example, the surfactant(s) (C) may satisfy only (c1). That is, the surfactant(s) (C) may include:

- a combination of sodium lauroyl sarcosinate and a nonionic surfactant (preferably a POE/POP glycol, lauric acid diethanolamide, decaglyceryl laurate, a POE behenyl ether, or coconut fatty acid diethanolamide); or
- a combination of sodium lauroyl sarcosinate and "an anionic surfactant corresponding to neither the anionic surfactants in (c2) nor sodium oleate in (c3)".

[0025]

The surfactant(s) (C) may satisfy only (c2). That is, the surfactant(s) (C) may include an anionic surfactant selected from (c2), but may be free of sodium lauroyl sarcosinate or sodium oleate. The total content of the anionic surfactant(s) in (c2) is preferably 0.2 to 6.0% by weight, more preferably 0.3 to 5.0% by weight, more preferably 0.5 to 4.0% by weight, more preferably 0.5 to 3.0% by weight, and most preferably 0.5 to 2.0% by weight.

[0026]

The surfactant(s) (C) may satisfy only (c3). That is, the surfactant(s) (C) may include:

- a combination of sodium oleate and a nonionic surfactant (preferably a POE/POP glycol, lauric acid diethanolamide, decaglyceryl laurate, a POE behenyl ether, or coconut fatty acid diethanolamide); or
- a combination of sodium oleate and "an anionic surfactant corresponding to neither the anionic surfactants in (c2) nor sodium lauroyl sarcosinate in (c1)".

[0027]

Sodium lauroyl sarcosinate in (c1) and sodium oleate in (c3) alone cannot sufficiently maintain the viscosity of the composition, but exhibit a high effect of suppressing a change in viscosity by being combined with another anionic or nonionic surfactant (for example, the viscosity of the composition after storage at 40°C for 3 months can be maintained at 50% or more, preferably within a range of 55 to 140%, more preferably 80 to 120%, and particularly preferably 90 to 110% of the initial viscosity).

More specifically, effects were confirmed such as:

- even if another anionic or nonionic surfactant cannot maintain an appropriate viscosity alone, an appropriate viscosity can be maintained by combining it with sodium lauroyl sarcosinate or sodium oleate;
- even if another anionic or nonionic surfactant can maintain an appropriate viscosity at a high concentration but cannot maintain it at a low concentration, an appropriate viscosity can be maintained even at a low concentration by combining it with sodium lauroyl sarcosinate or sodium oleate;
- even if another anionic or nonionic surfactant can maintain an appropriate viscosity alone and at a low concentration, an effect of suppressing a change in viscosity becomes higher by combining it with sodium lauroyl sarcosinate or sodium oleate.

[0028]

When the surfactant(s) (C) satisfies (c1), the content of sodium lauroyl sarcosinate is preferably 0.2 to 3.0% by weight, for example, 0.2 to 2.0% by weight (more preferably 0.2 to 1.5% by weight, particularly preferably 0.3 to 1.2% by weight, and even more preferably 0.4 to 1.0% by weight), and the total content of the anionic surfactant(s) and/or the nonionic surfactant(s) is preferably 0.1 to 3.0% by weight (more preferably 0.1 to 2.0% by weight, particularly preferably 0.3 to 1.5% by weight, and even more preferably 0.4 to 1.5% by weight, 0.4 to 1.0% by weight, or 0.4 to 0.7% by weight). The anionic surfactant(s) may or may not correspond to (c2).

[0029]

Preferred examples of a case where the surfactant(s) (C) satisfies at least (c1) and optionally satisfies (c2) include a combination of:

- sodium lauroyl sarcosinate; and
- at least one anionic surfactant and/or nonionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium POE oleyl ether phosphate, sodium POE lauryl ether phosphate, sodium POE cetyl ether phosphate, sodium POE lauryl ether sulfate, sodium stearate, lauric acid diethanolamide, decaglyceryl laurate, and a POE behenyl ether (it was confirmed that a change in viscosity could be kept within a range of 65 to 130% by combining these with sodium lauroyl sarcosinate), more preferably at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium POE oleyl ether phosphate, and sodium POE lauryl ether sulfate, and particularly preferably at least one anionic surfactant selected from sodium lauryl sulfate and sodium cetyl sulfate.

[0030]

When the surfactant(s) (C) satisfies (c3), the content of sodium oleate is preferably 0.2 to 2.0% by weight, for example, 0.2 to 1.5% by weight (more preferably 0.3 to 1.2% by weight, and particularly preferably 0.4 to 1.0% by weight), and the total content of the anionic surfactant(s) and/or the nonionic surfactant(s) is preferably 0.1 to 2.0% by weight (more preferably 0.3 to 1.5% by weight, particularly preferably 0.4 to 1.2% by weight, 0.4 to 1.0% by weight, or 0.4 to 0.7% by weight). The anionic surfactant(s) may or may not correspond to (c2).

[0031]

Preferred examples of a case where the surfactant(s) (C) satisfies at least (c3) and optionally satisfies (c2) include a combination of:

- sodium oleate; and
- at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium POE oleyl ether phosphate, and sodium POE lauryl ether sulfate.

[0032]

In particular, a tendency was observed that sodium lauroyl sarcosinate in (c1) or sodium oleate in (c3) could effectively suppress a change in viscosity of the composition when used in combination with an anionic surfactant. Therefore, preferred examples of a case of satisfying (c1) or (c3) include a combination of sodium lauroyl sarcosinate or sodium oleate and an anionic surfactant.

[0033]

In particular, sodium lauroyl sarcosinate is expected to improve the skin permeability of benzoyl peroxide from the results of an in vitro hairless mouse skin permeability test. Furthermore, sodium lauroyl sarcosinate also has good compatibility with the copolymer (B). Therefore, preferred examples of the surfactant(s) (C) of the present invention include a combination of sodium lauroyl sarcosinate and an anionic surfactant.

[0034]

The composition contains at least one aqueous solvent (D) selected from water and water-soluble solvents. Preferred examples of the aqueous solvent(s) include water (preferably purified water) and a polyhydric alcohol. Examples of the polyhydric alcohol include a polyhydric alcohol having 3 to 6 carbon atoms. A polyhydric alcohol selected from glycerin, propylene glycol, and 1,3-butylene glycol is more preferable. Any of the above aqueous solvents can be used alone or in combination.

[0035]

The content of the aqueous solvent(s) (D) is preferably 70% by weight or more, more preferably 80% by weight or more, and particularly preferably 85% by weight or more. The upper limit of the content of the aqueous solvent(s) (D) is preferably 95% by weight or less, and more preferably 94% by weight or less. An appropriate range of the content of the aqueous solvent(s) (D) is 70 to 95% by weight, more preferably 80 to 95% by weight, and particularly preferably 85 to 94% by weight.

[0036]

The composition may contain both (d1) a polyhydric alcohol and (d2) water (preferably purified water) as the aqueous solvent(s) (D). For example, the composition may contain 1 to 20% by weight of the polyhydric alcohol(s) and 60% by weight or more of the water, may contain 2 to 10% by weight of the polyhydric alcohol(s) and 70% by weight or more of the water, or may contain 3 to 7% by weight of the polyhydric alcohol(s) and 75% by weight or 80% by weight or more of the water. The weight percentages (% by weight) of (d1) and (d2) above mean the weight percentages based on 100% by weight of the total amount of the composition, not the total amount of the aqueous solvent(s) (D).

[0037]

A lower monohydric alcohol (a monohydric alcohol having 1 to 3 carbon atoms such as ethanol and isopropanol) may be used as the aqueous solvent(s) (D), but since such a lower monohydric alcohol causes skin irritation, the composition of the present invention is preferably essentially free of a lower monohydric alcohol. In the present specification, "essentially free of a lower monohydric alcohol" means that the lower monohydric alcohol(s) is/are not intentionally added during the preparation of the composition, and therefore, the content of the lower monohydric alcohol(s) in the composition is usually less than 1.0% by weight, more preferably less than 0.5% by weight, and particularly preferably 0% by weight.

[0038]

In order to reduce side effects caused by benzoyl peroxide, the composition is used by leaving it in contact with the affected skin area for a predetermined time from application (for example, about 1 to 30 minutes, 2 to 20 minutes, 3 to 15 minutes, or 5 to 10 minutes), and then removing it (for example, washing off or wiping off) from the affected skin area. Therefore, the composition is preferably substantially free of an oily component so that it can be quickly and easily removed from the affected skin area. In the present specification, "substantially free of an oily component" means that the content of the oily component(s) in the total amount of the composition is 4.0% by weight or less, preferably 3.0% by weight or less, and more preferably 2.0% by weight or less.

[0039]

The pH value of the composition is preferably 3 to 7. If the pH is less than 3, it causes skin irritation, and if it exceeds 7, the stability of benzoyl peroxide deteriorates. A more preferable pH value is 3 to 6, and a particularly preferable pH value is 3 to 4.5. Examples of a pH adjuster include diisopropanolamine, triisopropanolamine, triethanolamine, potassium hydroxide, sodium hydroxide, citric acid hydrate, sodium citrate hydrate, phosphoric acid, potassium dihydrogen phosphate, sodium dihydrogen phosphate, tartaric acid, dl-malic acid, glacial acetic acid, and the like. Any of the above pH adjusters can be used alone or in combination.

[0040]

The viscosity of the composition is not particularly limited as long as benzoyl peroxide can be kept in a dispersed state, but is preferably 200 mPa·s or more or 400 mPa·s or more, more preferably 500 mPa·s or more, even more preferably 1,000 mPa·s or more, and particularly preferably 1,300 mPa·s or more. Considering the ease of spreading on the skin, the upper limit of the viscosity is preferably 10,000 mPa·s or less, more preferably 7,000 mPa·s or less or 6,000 mPa·s or less, and particularly preferably 4,000 mPa·s or less or 3,000 mPa·s or less. Examples of an appropriate viscosity range include 500 to 7,000 mPa·s, 800 to 5,000 mPa·s, 900 to 4,000 mPa·s, and 1,000 to 3,000 mPa·s. In the present specification, the viscosity means a viscosity measured with a cone-plate viscometer (modular compact rheometer) at a measurement temperature of 25°C, using a cone plate No. 50-1, at a rotation speed of 10 rpm, 30 seconds after starting rotation.

[0041]

The composition can contain other additive(s) generally used for an external preparation for skin. Examples of the other additive(s) include an antioxidant (ascorbic acid, dibutylhydroxytoluene, dibutylhydroxyanisole, α -tocopherol, tocopherol acetate, propyl gallate, sodium bisulfite, sodium sulfite, sodium pyrosulfite, erythorbic acid, and the like), a stabilizer (sodium edetate hydrate, l-menthol, and the like), a preservative (a paraoxybenzoate ester, phenoxyethanol, and the like), a colorant (titanium oxide, and the like), a wetting agent, a buffer, a solubilizer, and the like, and any combination thereof. The total content of the other additive(s) is preferably 5% by weight or less, more preferably 3% by weight or less, and particularly preferably 2% by weight or less.

[0042]

The composition may be free of a silicone compound (such as a siloxane) and/or a zinc compound. The composition may be free of a hydrophobic phase. The composition may be free of malonic acid and/or an aryl benzoate. The composition may be free of an amphoteric

surfactant. The composition may be free of a cannabinoid, a terpene, and/or a flavonoid. The composition can exert the desired effects even if it does not contain these components.

[0043]

A particularly preferred example of the composition includes a composition (particularly a gel) containing:

(A) benzoyl peroxide;

(B) acrylamide/sodium acryloyldimethyltaurate copolymer;

(C) a combination of sodium lauroyl sarcosinate and at least one anionic surfactant selected from the group consisting of a sodium salt of a sulfate ester of a higher aliphatic alcohol, a POE alkyl ether phosphate salt, a POE alkyl ether sulfate salt, and a sodium salt of a long-chain fatty acid (more preferably at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium POE oleyl ether phosphate, sodium POE lauryl ether phosphate, sodium POE cetyl ether phosphate, sodium POE lauryl ether sulfate, and sodium stearate, particularly preferably at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium POE oleyl ether phosphate, and sodium POE lauryl ether sulfate, and even more preferably at least one anionic surfactant selected from sodium lauryl sulfate and sodium cetyl sulfate); and

(D) aqueous solvents consisting of a polyhydric alcohol and water.

In particular, a composition (particularly a gel) in which the total content of (A) to (D) is 95% by weight or more, 97% by weight or more, or 98% by weight or more is preferable.

Further, in the above particularly preferred example, the content of (A) is preferably 1.0 to 20% by weight (more preferably 1.5 to 15% by weight, particularly preferably 2.0 to 12% by weight, and even more preferably 2.5 to 11% by weight or 5.0 to 10% by weight), the content of (B) is preferably 0.5 to 4.0% by weight (more preferably 0.7 to 3.5% by weight, 1.0 to 3.0% by weight, 1.0 to 2.5% by weight, or 1.0 to 2.0% by weight, and particularly preferably 1.3 to 1.7% by weight), the contents of sodium lauroyl sarcosinate and the anionic surfactant(s) in (C) are each preferably 0.2 to 1.5% by weight (more preferably 0.3 to 1.2% by weight, and particularly preferably 0.4 to 1.0% by weight), and the content of (D) is preferably 70 to 95% by weight (more preferably 80 to 94% by weight, and particularly preferably 85 to 93% by weight).

In the above particularly preferred example, at least one selected from the group consisting of Sepineo P600 (Seppic), SIMULGEL 600 (Seppic), and Acrylamide/sodium acryloyldimethyltaurate copolymer (Alfa Chemistry), which are commercial products containing this copolymer, may be used as the copolymer (B). When the composition contains the commercial product(s), the total content thereof is preferably 2 to 10% by weight (more preferably 2 to 9% by weight, 3 to 8% by weight, 3 to 6% by weight, or 3 to 5% by weight in

total, and particularly preferably 3.5 to 4.5% by weight in total). For example, the composition may contain one of the commercial products at any of the above weight percentages.

[0044]

The composition can be used for the prevention and/or treatment of acne. For example, it can be used for the prevention and/or treatment of acne vulgaris, comedonal acne or polymorphic acne, acne rosacea, nodulocystic acne, acne conglobata, senile acne or secondary acne (for example, solar acne), drug-induced acne, or occupational acne (but is not limited thereto). The application amount and the application frequency may be appropriately adjusted according to the degree of symptoms, the concentration of benzoyl peroxide in the composition, and the like. For example, when used on the face, an amount of the composition covering the affected area is applied once or twice a day to the skin where acne has occurred. Then, after being left in contact with the affected skin area for a predetermined time from application (for example, about 1 to 30 minutes, 2 to 20 minutes, 3 to 15 minutes, or 5 to 10 minutes), the composition is removed (for example, washed off or wiped off) from the affected skin area.

[0045]

In the preceding paragraphs, preferred compound names of essential components and optional components used in the composition of the present invention have been described, but the composition of the present invention also includes a composition obtained by arbitrarily combining these, and a composition obtained by arbitrarily combining the content of each component. Further, numerical ranges regarding viscosity, pH, content, and the like can also be arbitrarily combined, and when a plurality of numerical ranges are described, the upper limit value or the lower limit value of each numerical range can also be arbitrarily combined.

[0046]

Hereinafter, the present invention will be described in more detail with reference to Examples, but the present invention is not limited by the Examples.

[0047]

[Example 1]

Preparation of formulation

A commercial thickener (Sepineo P600; Seppic) containing acrylamide/sodium acryloyldimethyltaurate copolymer was used. Sepineo P600 is a mixed raw material containing acrylamide/sodium acryloyldimethyltaurate copolymer, isohexadecane, polysorbate 80, sorbitan oleate, and water.

Each of the surfactants and a pH adjuster were added to an aqueous solvent (mainly purified water) and were dissolved by stirring until uniform. Sepineo P600 was added to the obtained solutions, and aqueous phases were prepared by stirring until uniform. Benzoyl

peroxide was added to these aqueous phases, and formulations (suspension gels) having the compositions shown in Table 1 were prepared by stirring until uniform.

[0048]

Measurement of viscosity

An appropriate amount of each formulation was sampled, and the viscosity was measured under the following measurement conditions using a modular compact rheometer (n=3). An initial viscosity and a viscosity after storage at 50°C for 2 weeks to 1 month or at 40°C for 1 to 3 months were measured, and a percentage of the viscosity after storage relative to the initial viscosity was calculated.

- Geometry: CP50-1
- Rotation speed: 10 rpm
- Measurement temperature: 25.0°C ± 0.1°C
- Measurement time: 30 seconds

[0049]

The results are shown in Table 1. The numerical value of each component shown in Table 1 is % by weight. "Trace" regarding the pH adjuster(s) in the table is an amount necessary to adjust the pH to about 4, and is less than 1% by weight. The aqueous solvent(s) in the table are purified water and a polyhydric alcohol (mostly purified water), and "q.s." means an amount such that the total amount of the formulation becomes 100% by weight. The percentage relative to the initial viscosity was calculated by dividing the viscosity after storage by the initial viscosity and multiplying the value by 100 (the same applies to other tables).

[0050]

Table 1

Formulation No.	No.1	No.2	No.3	No.4	No.5	No.6	No.7	No.8	No.9	No.10	No.11	No.12	No.13	No.14	No.15
Benzoyl peroxide	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
A*	Sodium lauryl sulfate	0.5	2.0												
	Sodium POE oleyl ether phosphate (8E.O.)			0.3	2.0										
	Sodium POE lauryl ether phosphate (4E.O.)				0.3	2.0									
	Sodium POE cetyl ether phosphate (5E.O.)							1.0	2.0	4.0					
	Sodium POE lauryl ether sulfate (3E.O.)										0.5	1.0	2.5		
	Sodium N-lauroyl-L-glutamate													0.3	0.5
pH adjuster(s)	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity															
50°C, 2 weeks	20%	96%	102%	88%	91%	85%	106%	80%	92%	104%	85%	84%	97%	86%	78%
50°C, 1 month	3%	54%	108%	59%	83%	56%	91%	55%	86%	110%	61%	81%	112%	63%	79%
40°C, 1 month	35%	97%	98%	91%	97%	91%	106%	86%	86%	79%	91%	87%	94%	-	-
40°C, 2 months	13%	88%	115%	86%	93%	82%	106%	80%	82%	87%	76%	85%	116%	-	-
40°C, 3 months	5%	69%	110%	77%	95%	67%	105%	63%	80%	96%	60%	78%	132%	56%	74%

A*: Anionic surfactant

[0051]

As is evident from Table 1, when a formulation containing benzoyl peroxide was thickened with Sepineo P600 (a product containing acrylamide/sodium acryloyldimethyltaurate copolymer), it was in a gel state immediately after preparation, but the viscosity remarkably decreased over time, and it changed from the gel state to a liquid state (see Formulation No. 1). The viscosity after storage at 40°C for 3 months is preferably within the range of 50% to 140% of the initial viscosity, but the viscosity of Formulation No. 1 after 3 months at 40°C was only 5% of the initial viscosity, and the thickening effect by the copolymer almost disappeared.

In contrast, the inventors found that the decrease in viscosity of the gel could be remarkably suppressed by adding the surfactants shown in Table 1 (see Formulation Nos. 2 to 15). A tendency was observed that the effect of suppressing the decrease in viscosity increased when the amount of the surfactants was increased.

[0052]

[Example 2]

Further, the inventors found that the decrease in viscosity of the gel could be more efficiently suppressed by using sodium lauroyl sarcosinate, which is an anionic surfactant, in combination with other anionic or nonionic surfactant(s). Since sodium lauroyl sarcosinate alone could not sufficiently suppress the decrease in viscosity of the gel, this result was unexpected.

[0053]

The types of the surfactants used in combination with sodium lauroyl sarcosinate and the percentage of the viscosity after storage relative to the initial viscosity are shown in Tables 2 and 3. "Unpreparable" in the column of the percentage relative to the initial viscosity in Table 3 indicates that the preparation of the formulation was abandoned without adding benzoyl peroxide because a uniform state was not obtained when the aqueous solvent containing the surfactant and the copolymer was stirred. "-" in the same column indicates that measurement was not performed and there is no data (the same applies to other tables).

[0054]

Table 2

Formulation No.	No.16	No.17	No.18	No.19	No.20	No.21	No.22	No.23	No.24	No.25	No.26	No.27	No.28	No.29	No.30
Benzoyl peroxide	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
A*	Sodium lauroyl sarcosinate	0.5		0.5	0.5		0.3	0.5	1.0	2.0		0.5		0.5	0.5
	Sodium lauryl sulfate		0.5	0.1	0.3										
	Sodium cetyl sulfate					0.5	0.3	0.5	1.0	2.0					
	Sodium POE oleyl ether phosphate (8E.O.)										0.5	0.5			
	Sodium POE lauryl ether phosphate (4E.O.)												0.5	0.3	0.5
pH adjuster(s)	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity															
50°C, 1 month	33%	54%	104%	90%	92%	42%	74%	-	83%	130%	70%	101%	69%	-	-
40°C, 3 months	35%	69%	103%	93%	95%	43%	76%	90%	95%	126%	83%	99%	68%	89%	84%

A*: Anionic

[0055]

Table 3-1

Formulation No.		No.31	No.32	No.33	No.34	No.35	No.36
Benzoyl peroxide		5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600		4.0	4.0	4.0	4.0	4.0	4.0
A *	Sodium lauroyl sarcosinate		0.5		0.5		0.5
	Sodium POE cetyl ether phosphate (5E.O.)	0.5	0.5				
	Sodium POE lauryl ether sulfate (3E.O.)			0.125	0.125		
	Sodium stearate					0.5	0.5
pH adjuster(s)		Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)		q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity							
50°C, 1 month		57%	-	24%	-	Unpreparable	88%
40°C, 3 months		48%	84%	28%	105%		87%

A*: Anionic

Table 3-2

Formulation No.		No. 37	No. 38	No. 39	No. 40	No. 41	No. 42	No. 43	No. 44	No. 45	No. 46
Benzoyl peroxide		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600		4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
Sodium lauroyl sarcosinate			0.5		0.5		0.5		0.5		0.5
N*	POE(20)POP(20) glycol	0.5	0.5								
	Lauric acid diethanolamide			0.5	0.5						
	Decaglyceryl laurate					0.5	0.5				
	POE behenyl ether							0.5	0.5		
	Coconut fatty acid diethanolamide									0.5	0.5
pH adjuster(s)		Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)		q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity											
50°C, 1 month		8%	53%	10%	71%	2%	68%	9%	119%	7%	56%
40°C, 3 months		12%	58%	12%	68%	3%	66%	13%	124%	4%	53%

N*: Nonionic

[0056]

As shown in Tables 2 and 3, when only sodium lauroyl sarcosinate was added in an amount of 0.5% by weight, the viscosity after storage at 40°C for 3 months decreased to 35% of the initial viscosity, and the initial texture could not be maintained (Formulation No. 16). However, when sodium lauroyl sarcosinate and another anionic or nonionic surfactant were used in combination, a change in viscosity could be remarkably suppressed even when the concentrations of both surfactants were low. This effect was observed with both anionic surfactants and nonionic surfactants, but a higher effect was observed particularly when used in combination with anionic surfactants.

[0057]

For example, the viscosity of Formulation No. 8 (concentration of sodium POE cetyl ether phosphate = 1.0% by weight) after storage at 40°C for 3 months was 63% of the initial viscosity, but that of Formulation No. 32 (total concentration of sodium lauroyl sarcosinate + sodium POE cetyl ether phosphate = 1.0% by weight) was 84%. Further, the viscosity of

Formulation No. 12 (concentration of sodium POE lauryl ether sulfate = 1.0% by weight) after storage at 40°C for 3 months was 78% of the initial viscosity, but that of Formulation No. 34 (total concentration of sodium lauroyl sarcosinate + sodium POE lauryl ether sulfate = 0.625% by weight) was 105%. Further, sodium cetyl sulfate could not sufficiently suppress a change in viscosity at any concentration of 0.5, 2.0, 4.0, and 10% by weight (the viscosity after storage at 40°C for 3 months was less than 50% of the initial viscosity at any concentration; data not shown), but the viscosity of Formulation No. 23 (total concentration of sodium lauroyl sarcosinate + sodium cetyl sulfate = 1.0% by weight) was 90%. From these results, it is considered that a change in viscosity can be more efficiently suppressed with a smaller total amount of the surfactants by using sodium lauroyl sarcosinate in combination with an anionic or nonionic surfactant, rather than using the anionic or nonionic surfactant alone.

[0058]

[Example 3]

Further, the inventors found that the decrease in viscosity of the gel could also be more efficiently suppressed by using sodium oleate, which is an anionic surfactant, in combination with another surfactant. Since sodium oleate alone could not even make the aqueous solvent containing the copolymer into a uniform state, this result was unexpected.

[0059]

The types of the surfactants used in combination with sodium oleate and the percentage of the viscosity after storage relative to the initial viscosity are shown in Table 4.

Table 4

Formulation No.		No.47	No.48	No.49	No.50	No.51	No.52	No.53	No.54
Benzoyl peroxide		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600		4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
A*	Sodium oleate	0.5		0.5		0.5		0.5	0.5
	Sodium lauryl sulfate		0.5	0.5					
	Sodium cetyl sulfate				0.5	0.5			
	Sodium POE oleyl ether phosphate (8E.O.)						0.5	0.5	
	Sodium POE lauryl ether sulfate (2E.O.)								0.35
pH adjuster(s)		Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)		q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity									
50°C, 1 month		Unpreparable	54%	81%	42%	67%	70%	88%	85%
40°C, 3 months			69%	80%	43%	68%	83%	91%	87%

A*: Anionic

[0060]

As shown in Table 4, when only sodium oleate was used in an amount of 0.5% by weight, the formulation could not be prepared (Formulation No. 47). However, by using sodium oleate and another surfactant in combination, a change in viscosity could be significantly suppressed. Further, a change in viscosity could be suppressed more by using sodium oleate in combination with the other surfactant, rather than using the other surfactant alone.

[0061]

[Example 4]

Formulations (suspension gels) with different amounts of benzoyl peroxide were prepared, and the percentage of the viscosity after storage relative to the initial viscosity was examined. The results are shown in Table 5.

Table 5

Formulation No.	No.55	No.20	No.56	No.57	No.23	No.58
Benzoyl peroxide	2.5	5.0	10.0	2.5	5.0	10.0
Sepineo P600	4			4		
Sodium lauroyl sarcosinate	0.5			0.5		
Sodium lauryl sulfate	0.5			-		
Sodium cetyl sulfate	-			0.5		
pH adjuster(s)	Trace			Trace		
Aqueous solvent(s)	q.s.			q.s.		
Percentage relative to initial viscosity						
50°C, 1 month	92%	-	-	88%	-	-
40°C, 3 months	95%	95%	91%	91%	90%	82%

[0062]

As shown in Table 5, even when the concentration of benzoyl peroxide was changed, gels exhibiting little change in viscosity were obtained with a small amount of surfactants.

[0063]

As shown in each of the above Examples, by using specific surfactants, the thickening effect of the copolymer (B) on the compositions can be maintained over time. Further, it was also confirmed that each composition can be easily removed from the skin after being applied to the skin and left for a while (1 to 30 minutes). Therefore, the composition of the present invention is suitable for use by applying it to an affected area of the skin, leaving it for a predetermined time, and then removing it from the affected area.

[0064]

[Example 5]

Formulations (suspension gels) were prepared in the same manner as in Example 1 using a commercial product different from Sepineo P600 (trade name "Acrylamide/sodium acryloyldimethyltaurate copolymer" manufactured by Alfa Chemistry: hereinafter referred to as Alfa product), and the same experiment was performed. The Alfa product is a formulation containing 35 to 40% by weight of acrylamide/sodium acryloyldimethyltaurate copolymer, 20 to 25% by weight of isohexadecane, 5 to 10% by weight of polysorbate 80, 0 to 5% by weight of sorbitan oleate, and water. The results are shown in Table 6. In Table 6, the numerical values in

parentheses shown in the column of the Alfa product are the % by weight of the acrylamide/sodium acryloyldimethyltaurate copolymer contained in the Alfa product.

[0065]

Formulation No.		No.59	No.60	No.61	No.62	No.63	No.64
Benzoyl peroxide		5.0	5.0	5.0	5.0	5.0	5.0
Alfa product (Copolymer B)		4.0 (1.4 - 1.6)	4.0 (1.4 - 1.6)	4.0 (1.4 - 1.6)	4.0 (1.4 - 1.6)	4.0 (1.4 - 1.6)	4.0 (1.4 - 1.6)
Anionic	Sodium lauroyl sarcosinate		0.5	0.5	0.5		
	Sodium oleate					0.5	0.5
	Sodium lauryl sulfate			0.5			0.5
Nonionic	Lauric acid diethanolamide				0.5		
pH adjuster(s)		Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)		q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity							
50°C, 1 month		3%	34%	87%	68%	Unpreparable	76%
40°C, 3 months		3%	38%	90%	64%		80%

[0066]

As shown in Table 6, when the Alfa product was used, the same results as with Sepineo P600 were also obtained. Specifically, the benzoyl peroxide-containing product thickened using the Alfa product was in a gel state immediately after preparation, but the viscosity remarkably decreased over time, and after storage at 50°C for 1 month or at 40°C for 3 months, the thickening effect almost disappeared, and the product changed into a liquid state (see Formulation No. 59). Further, when only sodium lauroyl sarcosinate was added (Formulation No. 60), a change in viscosity could not be sufficiently suppressed, and the initial texture could not be maintained. When only sodium oleate was added (Formulation No. 63), benzoyl peroxide could not be uniformly dispersed, and the formulation could not even be successfully prepared.

In contrast, the combination of sodium lauroyl sarcosinate or sodium oleate with sodium lauryl sulfate or lauric acid diethanolamide could significantly suppress a change in viscosity, and the composition could be easily removed from the skin after being applied to the skin and left for a while.

[0067]

[Example 6]

Formulations (suspension gels) with different amounts of Sepineo P600 or the Alfa product were prepared, and the percentage of the viscosity after storage relative to the initial viscosity was examined. The results are shown in Table 7 (the numerical values in parentheses shown in the column of the Alfa product are the % by weight of the acrylamide/sodium acryloyldimethyltaurate copolymer contained in the Alfa product).

Table 7

Formulation No.	No.65	No.66	No.20	No.67	No.68	No.69	No.26	No.70	No.71	No.72	No.61	No.73	No.74	No.75	No.76
Benzoyl peroxide	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Sepineo P600	3.0	3.5	4.0	8.0	3.0	3.5	4.0	8.0							
Alfa product (Copolymer B)									3.0 (1.05 - 1.2)	3.5 (1.23 - 1.4)	4.0 (1.4 - 1.6)	8.0 (2.8 - 3.2)	3.0 (1.05 - 1.2)	3.5 (1.23 - 1.4)	8.0 (2.8 - 3.2)
A*	Sodium lauroyl sarcosinate	0.5	0.5	0.5					0.5	0.5	0.5	0.5			
	Sodium lauryl sulfate	0.5	0.5	0.5					0.5	0.5	0.5	0.5			
	Sodium POE oleyl ether phosphate (8E.O.)				0.5	0.5	0.5	0.5					0.5	0.5	0.5
pH adjuster(s)	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace	Trace
Aqueous solvent(s)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Percentage relative to initial viscosity															
50°C, 1 month	99%	99%	92%	88%	76%	74%	70%	74%	101%	98%	87%	85%	61%	72%	71%
40°C, 3 months	102%	104%	95%	100%	84%	85%	83%	83%	107%	103%	90%	96%	86%	85%	81%

A* : Anionic

[0068]

As shown in Table 7, both Sepineo P600 and the Alfa product could provide gels exhibiting little change in viscosity by being combined with specific surfactants, regardless of their amounts. In particular, the gels containing the combination of sodium lauroyl sarcosinate and an anionic surfactant exhibited little change in viscosity.

CLAIMS

[Claim 1]

A skin composition comprising:

(A) benzoyl peroxide;

(B) acrylamide/sodium acryloyldimethyltaurate copolymer;

(C) surfactant(s) comprising at least one selected from the group consisting of the following (c1), (c2), and (c3):

(c1) a combination of sodium lauroyl sarcosinate and at least one anionic surfactant and/or nonionic surfactant;

(c2) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, a polyoxyethylene alkyl ether phosphate salt, a polyoxyethylene alkyl ether sulfate salt, and sodium lauroyl glutamate; and

(c3) a combination of sodium oleate and at least one anionic surfactant and/or nonionic surfactant; and

(D) at least one aqueous solvent selected from water and water-soluble solvents, the skin composition for use by being applied to an affected skin area, left for a predetermined time, and then removed from the affected area.

[Claim 2]

The composition according to claim 1, wherein the at least one anionic surfactant and/or nonionic surfactant set forth in (c1) is at least one surfactant selected from the group consisting of a sodium salt of a sulfate ester of a higher aliphatic alcohol; a polyoxyethylene alkyl ether phosphate salt; a polyoxyethylene alkyl ether sulfate salt; a sodium salt of a long-chain fatty acid; a polyoxyethylene polyoxypropylene glycol; a fatty acid alkanolamide; a polyglycerin fatty acid ester; and a polyoxyethylene alkyl ether.

[Claim 3]

The composition according to claim 1, wherein the surfactant(s) (C) comprises (c1).

[Claim 4]

The composition according to claim 1, wherein the surfactant(s) (C) comprises:

2.0% by weight or less of sodium lauroyl sarcosinate; and

2.0% by weight or less of at least one anionic surfactant and/or nonionic surfactant selected from the following (I) and (II):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium oleate; and
 (II) at least one nonionic surfactant selected from the group consisting of a polyoxyethylene polyoxypropylene glycol, lauric acid diethanolamide, decaglyceryl laurate, a polyoxyethylene behenyl ether, and coconut fatty acid diethanolamide.

[Claim 5]

The composition according to claim 1, wherein the surfactant(s) (C) comprises:

1.0% by weight or less of sodium lauroyl sarcosinate; and

1.0% by weight or less of at least one anionic surfactant selected from the following (I):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium oleate.

[Claim 6]

The composition according to claim 1, wherein the surfactant(s) (C) comprises (c2).

[Claim 7]

The composition according to claim 1, wherein the surfactant(s) (C) comprises (c3).

[Claim 8]

The composition according to claim 1, wherein the surfactant(s) (C) comprises:

2.0% by weight or less of sodium oleate; and

2.0% by weight or less of at least one anionic surfactant and/or nonionic surfactant selected from the following (I) and (II):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether phosphate, sodium polyoxyethylene cetyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, sodium stearate, and sodium lauroyl sarcosinate; and

(II) at least one nonionic surfactant selected from the group consisting of a polyoxyethylene polyoxypropylene glycol, lauric acid diethanolamide, decaglyceryl laurate, a polyoxyethylene behenyl ether, and coconut fatty acid diethanolamide.

[Claim 9]

The composition according to claim 1, wherein the surfactant(s) (C) comprises:

1.0% by weight or less of sodium oleate; and

1.0% by weight or less of at least one anionic surfactant selected from the following (I):

(I) at least one anionic surfactant selected from the group consisting of sodium lauryl sulfate, sodium cetyl sulfate, sodium polyoxyethylene oleyl ether phosphate, sodium polyoxyethylene lauryl ether sulfate, and sodium lauroyl sarcosinate.

[Claim 10]

The composition according to any one of claims 1 to 9, comprising only benzoyl peroxide as an active ingredient.

[Claim 11]

The composition according to any one of claims 1 to 9, wherein the composition is a gel.

[Claim 12]

The composition according to any one of claims 1 to 9, for use by being applied to the affected skin area, left for 1 to 30 minutes, and then removed from the affected area.

[Claim 13]

The composition according to any one of claims 1 to 9, comprising at least one selected from the group consisting of Sepineo P600 (Seppic), SIMULGEL 600 (Seppic), and Acrylamide/sodium acryloyldimethyltaurate copolymer (Alfa Chemistry) as the copolymer (B).