

Foam stabilizer composition

TECHNICAL FIELD

[0001]

- 5 This invention relates to a composition for sterilization capable of forming persistent and stable foam.

BACKGROUND ART

[0002]

- 10 Various drugs are used as antiseptics for hands, fingers and skin, and povidone-iodine is well known as a disinfectant/antiseptic. The povidone-iodine is used in various sites such as hospitals and homes since the povidone-iodine is known to hardly allow an occurrence of resistant microbe, and to have high disinfection capability on various pathogenic microbes.
- 15 As drug products of povidone-iodine, formulations such as an ointment, a paste, or a powder have been developed and used (see Patent Reference 1 or 2, for example), and a liquid drug is mainly used as a formulation for hands and fingers (see Patent Reference 3, for example). Such a liquid drug is a solution having a blackish color
- 20 derived from iodine and known to have a problem of dripping which has been often pointed out. Particularly, in the liquid drug of cleansing type, dripping and scattering easily occur when dispensing on a hand upon using, and therefore, a part of the drug solution dispensed on a hand is usually wasted. Further, there are many cases where the drug solution is scattered on clothes, floor, and the like, and a considerable time
- 25 is required for washing and cleaning.

[Patent Reference 1] Japanese Patent Examined Publication No. 1-32210

[Patent Reference 2] Japanese Patent No. 3583166

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[Patent Reference 3] Japanese Patent Examined Publication No. 7-2646

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DISCLOSURE OF THE INVENTION

PROBLEMS TO BE SOLVED BY THE INVENTION

5 [0003]

An object of this invention is to provide a composition for sterilization that is prevented from dripping and scattering caused in use and enables effective use of all drug solution dispensed on the hand, with effective disinfection of hands and fingers.

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MEANS FOR SOLVING THE PROBLEMS

[0004]

The inventors have conducted extensive research in order to solve the above problems and as a result, by blending a specific amount of an organosulfate type
15 surfactant with povidone-iodine or further blending a specific amount a nonionic surfactant, it is possible to make a formulation for a stable and persistent foamed drug product and to prevent dripping or the like that is caused in use and, as a result, the inventors have found a composition for sterilization that enables effective use of all the drug solution dispensed on the hand, prevention of smirching of clothes, floor,
20 and the like, and at the same time, effective disinfection of hands and fingers, thereby accomplishing this invention.

That is, this invention is as described below.

25 (1) A composition for sterilization including povidone-iodine and an organosulfate type surfactant.

(2) A composition for sterilization, wherein a nonionic surfactant is further contained in the composition for sterilization according to (1).

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(3) A composition for sterilization, wherein the organosulfate type surfactant described in (1) is nonylphenyl polyoxyethylene ether ammonium sulfate or lauryl polyoxyethylene ether ammonium sulfate.

5 (4) A composition for sterilization, wherein the nonionic surfactant described in (2) is diethanolamide laurate.

(5) A composition for sterilization, wherein a blending amount of the organosulfate type surfactant described in (1) is 0.4 to 10 (W/V)%.

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(6) The composition for sterilization according to (2), wherein a blending ratio between the organosulfate type surfactant described in (1) and the nonionic surfactant described in (2) is from 50:1 to 2:1 and a total of the contents of the two surfactants is 0.4 to 14 (W/V)% with respect to the total amount of the composition
15 for sterilization.

(7) A composition for sterilization, wherein the composition for sterilization described in (5) or (6) has a foaming power of 190 to 270 mm, a foam stability of 140 to 201 mm, and a reduction in foaming power of 30% or less.

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(8) The composition for sterilization according to (6), wherein the dripping time is 5 minutes or more.

EFFECT OF THE INVENTION

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[0005]

A composition for sterilization in this invention enables reliable cleansing and disinfection by preventing dripping and forming persistently stable foam. Further, since the composition for sterilization of this invention does not drip, the complete
30 amount of the composition for sterilization dispensed on the hand is effectively used,

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and it is possible to improve utilization of an effective component as a drug and economic efficiency.

BEST MODE FOR CARRYING OUT THE INVENTION

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[0006]

The composition for sterilization in this invention includes povidone-iodine having a disinfection action and serving as a main component, and an organosulfate type surfactant. Further, as another aspect of this invention, a nonionic surfactant may
10 furthermore be blended to the above composition. If necessary, a pH adjuster, a solvent, and other pharmaceutical additives may be blended.

[0007]

Since the composition for sterilization in this invention is discharged from a pump
15 type container, it is not particularly necessary to limit viscosity insofar as clogging of a filter inside a nozzle of a pump is prevented. Since excessively high viscosity causes clogging, the viscosity of the composition may preferably be 10 mPa·s or less.

[0008]

20 The pH level of the composition for sterilization in this invention may preferably be 3 to 6 in view of stability over time. In this case, it is preferable to adjust the pH of the composition for sterilization with a pH adjuster. As the pH adjuster, sodium hydroxide, hydrochloric acid, or the like may be used.

25 [0009]

The concentration of povidone-iodine in this invention is preferably 4 to 10 (W/V)% or less, more preferably 4 to 7.5 (W/V)% or less with respect to the total amount of the composition, in view of the viscosity.

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[0010]

The organosulfate type surfactant in this invention may particularly preferably be an organosulfate type surfactant of an ammonium salt, and, as specific examples thereof, nonylphenyl polyoxyethylene ether ammonium sulfate or lauryl

- 5 polyoxyethylene ether ammonium sulfate may be used. In the case of blending only the surfactant such as the above organosulfate type surfactants, an amount of the surfactant may preferably be 0.4 to 10 (W/V)% with respect to the total amount of the composition.

10 [0011]

As another aspect of this invention, in the case of blending the nonionic surfactant, it is possible to use diethanolamide laurate. In order to form a persistent foam, the amount of the nonionic surfactant blended may preferably be smaller than that of the organosulfate type surfactant blended in this invention. More specifically, the

- 15 blending ratio of the organosulfate type surfactant and the nonionic surfactant is 50:1 to 2:1, wherein the concentration of the organosulfate type surfactant is 0.4 to 10 (W/V)%, and the concentration of the nonionic surfactant is 0.02 to 1 (W/V)% with respect to the total amount of the composition for sterilization in this invention. More preferably, the concentration of the organosulfate type surfactant is 1 to 4 (W/V)%,
20 and the concentration of the nonionic surfactant is 0.08 to 1 (W/V)%. It is possible to form the persistent foam when the concentrations are within these ranges.

[0012]

The total of the amounts of the organosulfate type surfactant and the nonionic

- 25 surfactant blended may preferably be 0.4 to 14 (W/V)%, more preferably 0.4 to 10.2 (W/V)%, with respect to the total amount of the composition for sterilization in this invention.

[0013]

- 30 The composition for sterilization in this invention has a foaming power of 190 to 270

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mm at 25°C and a foam stability of 140 to 201 mm at 25°C. A composition for sterilization having a reduction in foaming power of 30% or less when the foaming power and the foam stability are as specified above is preferred. Here, “reduction in foaming power” means a value that is obtained by dividing the foam stability (mm) by the foaming power (mm) and expressed as a percentage (%). The composition for sterilization in this invention having such a value forms persistent and stable foam. Testing methods for the foaming power and the foam stability are described in JIS (Japanese Industrial Standards) K3362:1998 (synthetic detergent testing method), and the tests were conducted in accordance with this method. Specifically, by using a foaming power measurement device described in JIS K3362, 50 mL of a sample is charged in an inner cylinder in advance, and 20 mL of the same sample is dropped on a central part of a liquid surface from a height of 900 mm under a temperature condition of 25°C. After dripping the whole sample, the height (mm) of the foam was measured, and the measured value is the foaming power. Furthermore, the height of the foam after 5 minutes had passed was measured, and the measured value is the foam stability.

[0014]

The composition for sterilization in this invention does not cause dripping for 3 minutes or more, and more preferably 5 minutes or more. Here, “Time in which dripping does not occur” means the time elapsed until dripping of liquid droplets from the sieve starts as a result of breakage of the foam when the composition for sterilization which has been filled in the pump type container is discharged by pressing the pump once with a hand on a sieve having a screen number of 16 (1 μ m) which is defined in the Japanese Pharmacopeia. Such time is referred to as the dripping time (min) of the discharged foam. The foam having the dripping time of 3 minutes or more forms sufficiently persistent foam, and the foam having the dripping time of 5 minutes or more is furthermore finer, more persistent, and more preferred in terms of foam properties.

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[0015]

In the composition for sterilization in this invention, it is possible to use a stabilizer such as potassium iodide, a viscosity adjuster such as lauryl pyrrolidone,
5 hydroxyethylcellulose, and concentrated glycerin, flavoring, and the like if necessary.

[0016]

As a solvent used in this invention, any solvent may be used as long as povidone-
10 iodine is completely dissolved in the solvent, and specifically, purified water, or distilled water or the like may be used as the solvent. A temperature for dissolution is not particularly limited, and it is ordinarily preferable to perform the dissolution within a temperature range of from 10°C to 30°C.

15 [0017]

It is possible to produce the composition for sterilization in this invention by a conventional method. For example, povidone-iodine is added to purified water in an amount of from 70% to 90% of the total amount of the composition for sterilization in this invention, followed by sufficient stirring for perfect dissolution, and then the
20 organosulfate type surfactant is added, followed by sufficient stirring for perfect dissolution. A pH level of the solution is adjusted by using the pH adjuster. Purified water is added to the solution after the pH adjustment to achieve the predetermined concentration, whereby producing the composition for sterilization.

25 [0018]

Any container may be used as the pump type container to be charged with the composition for sterilization in this invention insofar as the container is provided with a pump that makes the composition for sterilization into foam without scattering. Therefore, for example, a pump foamer container capable of discharging
30 foam when a nozzle part thereof is pressed down may be used. Further, a mesh filter

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or a porous filter is necessarily attached inside the nozzle of the pump. In the case of using a material subject to solidification easily by drying, such as povidone-iodine, it is more preferable to use the porous filter than to use the mesh filter. As specific examples of products, pump foamer containers E3 type, F5L type, WRT4 type, and the like manufactured by Daiwa Can Company, a non-gas type pump foamer
5 container manufactured by Yoshino Kogyosho Co., Ltd., and a pump foam dispenser PF03F type and the like manufactured by Kohno Jushi Kogyo Group may be used.

[0019]

10 As used herein, the mesh filter means a filter in the form of a mesh. A material is not particularly limited, and it is possible to use PET (polyethyleneterephthalate), PP (polypropylene), and the like. The size of the mesh at the time is not particularly limited, and it is possible to select appropriately in accordance with the purpose. For example, the size may preferably be 100-mesh or more, more preferably 100- to 400-
15 mesh, and further preferably 200- to 350-mesh. The number of filters is not particularly limited and may be selected appropriately in accordance with the purpose. From the viewpoint of improving the foam property, two or more filters may preferably be used for example. Further, a thickness of the filter is not particularly limited and may be selected appropriately in accordance with the
20 purpose. The thickness may preferably be 0.01 to 2 mm.

[0020]

Further, the porous filter means a filter having fine pores. It is possible to define the fine pores by way of the number of cells (density). The number of cells (density) of a
25 porous body may preferably be 10 to 200 cells/25 mm, and more preferably 25 to 175 cells/25mm. A material is not also particularly limited, and CFS (polyphenylene sulfite), urethane, PP (polypropylene), and the like may preferably be used. It is also possible to use filters different in mesh and different materials in combination. Further, a thickness of the filter is not particularly limited and may be selected
30 appropriately in accordance with the purpose. For example, the thickness may

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preferably be 1 to 10 mm. Specifically, the porous body used for such as the pump of WO2006/131980 may be used.

Examples

5 [0021]

Hereinafter, this invention will be described in more detail by way of examples, however, this invention is not limited to the examples and test examples.

[0022]

10 Examples 1 to 3 and Comparative Example 1

To purified water of 25°C, povidone-iodine and nonylphenyl polyoxyethylene ether ammonium sulfate were added based on the blending amount of Table 1, followed by perfect dissolution. A pH level of each of the solutions was adjusted to 4.2, and then
15 purified water was added to each of the solutions to achieve a total amount of 100 mL, thereby obtaining compositions for sterilization in this invention.

In the same manner, Comparative Example 1 was prepared based on the blending amount of Table 1.

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[0023]

Examples 4 to 6 and Comparative Example 2

To purified water of 25°C, povidone-iodine and lauryl polyoxyethylene ether
25 ammonium sulfate were added based on the blending amount of Table 2, followed by perfect dissolution. A pH level of each of the solutions was adjusted to 4.2, and then purified water was added to each of the solutions to achieve a total amount of 100 mL, thereby obtaining compositions for sterilization in this invention.

30 In the same manner, Comparative Example 2 was prepared based on the blending

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amount of Table 2.

[0024]

Examples 7 to 12 and Comparative Examples 3 and 4

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To purified water of 25°C, povidone-iodine and diethanolamide laurate that had been melted were added based on the blending amount of Table 3, followed by mixing.

Furthermore, nonylphenyl polyoxyethylene ether ammonium sulfate was added to the mixture, followed by perfect dissolution. A pH level of each of the solutions was
10 adjusted to 4.2, and then purified water was added to each of the solutions to achieve a total amount of 100 mL, thereby obtaining compositions for sterilization in this invention.

In the same manner, Comparative Examples 3 and 4 were prepared based on the
15 blending amount of Table 3.

[0025]

Examples 13 to 18 and Comparative Examples 5 and 6

20 To purified water of 25°C, povidone-iodine and diethanolamide laurate that had been melted were added based on the blending amount of Table 4, followed by mixing. Further, lauryl polyoxyethylene ether ammonium sulfate was added to the mixture, followed by perfect dissolution. A pH level of each of the solutions was adjusted to 4.2, and then purified water was added to each of the solutions to achieve a total
25 amount of 100 mL, thereby obtaining compositions for sterilization in this invention.

In the same manner, Comparative Examples 5 and 6 were prepared based on the blending amount of Table 4.

[0026]

Test Example 1 Dripping Test

Each of the compositions for sterilization (hereinafter referred to as samples:
5 formulations are shown in Tables 1 to 4) of this invention different in components from one another was charged in a pump type container of 350 mL (E3-08 type manufactured by Daiwa Can Company; discharge volume of 20 cm³). The pump was pressed down once with a hand, and the discharged foam was dropped on a sieve of the Japanese Pharmacopeia sieve number 16 (1 μm) to measure a time elapsed till the
10 foam was deformed to cause droplets to start falling down from the sieve. The time was taken as a dripping time (min) of the discharged foam. The results are shown in Tables 1 to 6. The compositions for sterilization in this invention were capable of maintaining fine foam for 5 minutes or more and preventing from dripping from the sieve in this test, but foams of the compositions within the range outside this
15 invention were rapidly disappeared to cause dripping.

[0027]

Foaming Power Test

20 Foaming power of the samples were measured in accordance with the column “Foaming Power and Foam Stability” described in the synthetic detergent testing method of JIS K3362. Specifically, by using a foaming power measurement device described in JIS K3362, 50 mL of each of the samples was charged in an inner cylinder in advance, and 20 mL of the same sample was dropped on a central part of
25 a liquid surface from a height of 900 mm under a temperature condition of 25°C. After dripping whole of the sample, a height (mm) of the foam was measured, and the measured value was taken as the foaming power. Furthermore, a height of the foam after 5 minutes had passed was measured, and the measured value was taken as the foam stability. This test was conducted for each of the samples in the same
30 manner. The results are shown in Tables 1 to 4.

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[0028]

TABLE 1

		Example			Comparative Example
		1	2	3	1
Blended components	Povidone-iodine (g)	7.5	7.5	7.5	7.5
	Nonylphenyl polyoxyethylene ether ammonium sulfate (g)	0.4	1	10	20
	Sodium hydroxide (g)	Adequate amount	Adequate amount	Adequate amount	Adequate amount
	Purified water	Added so that total amount reaches to 100 ml			
Foaming power (mm)		190	220	210	10
Foam stability (mm)		140	170	160	Out of measurement
Dripping time (min)		5 minutes or more	5 minutes or more	5 minutes or more	One second

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[0029]

TABLE 2

		Example			Comparative Example
		4	5	6	2
Blended components	Povidone-iodine (g)	7.5	7.5	7.5	7.5
	Lauryl polyoxyethylene ether ammonium sulfate (g)	0.4	1	10	20
	Sodium hydroxide (g)	Adequate amount	Adequate amount	Adequate amount	Adequate amount
	Purified water	Added so that total amount reaches to 100 ml			
Foaming power (mm)		215	220	245	135
Foam stability (mm)		172	163	164	84
Dripping time (min)		5 minutes or more	5 minutes or more	5 minutes or more	7 seconds

[0030]

TABLE 3

		Example							Comparative Example		
		7	8	9	10	11	12				
Blended components	Povidone-iodine (g)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	3	4	
	a: Nonylphenyl polyoxyethylene ether ammonium sulfate (g)	0.5	2	1	3.5	1	10	0.5	2.5		
	b: Diethanolamide laurate (g)	0.25	1	0.2	0.25	0.02	0.2	1	5		
	Blending ratio (a:b)	2:1	2:1	5:1	14:1	50:1	50:1	0.5:1	0.5:1		

	Sodium hydroxide (g)	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount
	Purified water (mL)	Added so that total amount reaches to 100 ml								
Foaming power (mm)		245	270	245	245	245	215	205	175	155
Foam stability (mm)		184	201	180	181	163	149	143	120	
Dripping time (min)		5	5	5	5	5	5	5	3	25
		minutes or more	minutes or more	minutes or more	minutes or more	minutes or more	minutes or more	minutes	seconds	seconds

[0031]

TABLE 4

	Example								Comparative Example		
	13	14	15	16	17	18	5	6			
Povidone-iodine (g)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5		
a: Lauryl polyoxyethylene ether ammonium sulfate (g)	0.5	2	1	4	1	10	1.25	2.5	2.5		
b: Diethanolamide laurate (g)	0.25	1	0.1	0.4	0.02	0.2	2.5	5	5		
Blending ratio (a:b)	2:1	2:1	10:1	10:1	50:1	50:1	0.5:1	0.5:1	0.5:1		
Sodium hydroxide (g)	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount	Adequate amount		
Purified water (mL)	Added so that total amount reaches to 100 ml										
Foaming power (mm)	250	270	260	245	245	240	190	160	160		
Foam stability (mm)	195	196	200	196	191	164	150	120	120		

Dripping time (min)	5 minutes or more	5 minutes or more	5 minutes or more	5 minutes or more	5 minutes or more	5 minutes	5 minutes	4 seconds	25 seconds
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INDUSTRIAL APPLICABILITY

[0032]

The composition for sterilization in this invention is excellent in forming a persistent foam and usable for effective disinfection and sterilization.

CLAIMS

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1. A composition for sterilization comprising povidone-iodine and a sulfate type surfactant.
 2. A composition for sterilization according to claim 1, wherein a nonionic
10 surfactant is further contained in the composition for sterilization.
 3. A composition for sterilization according to claim 1 or 2, wherein the sulfate type surfactant is nonylphenyl polyoxyethylene ether ammonium sulfate or lauryl polyoxyethylene ether ammonium sulfate.
 - 15 4. A composition for sterilization according to claim 2, wherein the nonionic surfactant is diethanolamide laurate.
 5. A composition for sterilization according to any preceding claim, wherein the
20 blending amount of the sulfate type surfactant described in claim 1 is 0.4 to 10 (W/V)%.
 6. The composition for sterilization according to claim 2, wherein a blending ratio between the sulfate type surfactant and the nonionic surfactant is from
25 50:1 to 2:1 and the total of the contents of the two surfactants is 0.4 to 14 (W/V)% with respect to the total amount of the composition for sterilization.
 7. A composition for sterilization according to claim 5 or 6, wherein the
30 composition for sterilization has a foaming power of 190 to 270 mm, a foam stability of 140 to 201 mm, and a reduction in foaming power of 30% or less.