事　務　連　絡
平成２７年１１月１１日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬・生活衛生局審査管理課

パーマネント・ウェーブ用剤製造販売承認基準の英訳について

医薬部外品のうち、パーマネント・ウェーブ用剤の製造販売の承認基準については、「パーマネント・ウェーブ用剤製造販売承認基準について」（平成 27 年３月 25 日付け薬食発 0325 第 35 号厚生労働省医薬食品局長通知）により示してきたところであるが、別添のとおり、当該基準の英訳を作成したのでお知らせいたします。

Provisional Translation
from Japanese Original

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The Standards for Marketing Approval of Permanent Wave Agents

1. Scope of the standards

The standards shall apply to external preparations for hair (except leg/arm hair and eyebrow/eyelash) intended to be used for "creating and preserving waves in the hair" or "straightening the frizzy, curly or wavy hairs, and preserving that condition"; these preparations are hereinafter referred to as "permanent wave agents", regardless of ingredients contained therein.

2. Standards

The standards for marketing approval of permanent wave agents (hereinafter referred to as "standards for approval") are as follows.

For permanent wave agents that do not meet the standards, documents regarding its efficacy, safety, and ingredient formulation, purpose, etc. shall be submitted for review.

(1) Types of active ingredients

Active ingredients which are permitted to be used shall be those listed in the attached Table 2 and their corresponding usage classification shall be listed in the attached Table 1.

A. Dual-step Cold or Tepid Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

The preparation shall contain at least one or more active ingredients listed in Column I of the attached Table 2 as the first agent and at least one or more active ingredients listed in either A or B of Column III of the same Table as the second agent.

B. Dual-step Cold or Tepid Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients

The preparation shall contain at least one or more active ingredients listed in Column II of the attached Table 2 as the first agent and at least one or more active ingredients listed in either A or B of Column III of the same Table as the second agent.

C. Single-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

The preparation shall contain at least one or more active ingredients listed in Column I of the attached Table 2.

D. Dual-step Permanent Wave Agents with the first agent containing thioglycolic acid and/or its salt as active ingredients (consisting of components to be mixed at use, generating exothermal reaction)

The preparation shall contain at least one or more active ingredients listed in Column I of the attached Table 2 as the first agent (1), at least one or more active ingredients listed in A of Column III of the same Table as the first agent (2) and at least one or more active ingredients listed in

either A or B of Column III of the same Table as the second agent.

E. Dual-step Cold or Dual-Step Tepid Hair Straightening Agents or Dual-step Cold or Dual-Step Tepid (using a high temperature hair-iron) Hair Straightening Agents containing thioglycolic acid and/or its salt as active ingredients

The preparation shall contain at least one or more active ingredients listed in Column I of the attached Table 2 as the first agent and at least one or more active ingredients listed in either A or B of Column III of the same Table as the second agent.

(2) Amounts of active ingredients

The range and the upper limit of the content of active ingredients and the oxidizing activity per dose per person shall be as shown in the attached Table 2.

(3) Standards of active ingredients

The standards of active ingredients shall be as shown in the attached Table 2.

(4) Types, standards and amounts of additives

A. Types, standards and amounts of additives shall be as specified by the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labor and Welfare.

B. If the first agent of Dual-step Cold Permanent Wave Agents, Dual-step Cold Hair Straightening Agents or Dual-step Cold (using a high temperature hair-iron) Hair Straightening Agents contains the active ingredients listed in Column I of the attached Table 2 with a total amount as thioglcolic acid exceeding 7.0%, it shall contain dithiodiglycolic acid and/or its salt with an amount as dithiodiglycolic acid equal to or more than the excess of the active ingredients as thioglycolic acid.

C. If cysteine, its salt and/or acetylcysteine are contained as additives in preparations with the active ingredients in Column I of the attached Table 2, the total amount of the additives shall be no more than 1.5% as cysteine. In this case, the total reducing power shall not exceed the upper limit of that corresponding to “the reducing substance after boiling under acidic condition”.

D. If thioglycolic acid and/or its salt are contained as additives in preparations with the active ingredients in Column II of the attached Table 2 as additives, the total amount of the additives shall be no more than 1.0% as thioglycolic acid. In this case, the total reducing power shall not exceed the upper limit of that corresponding to “cysteine”.

(5) Each active ingredient listed in the attached Table 2 shall be specified with the standards of the “Japanese Standards of Quasi-Drug Ingredients, Appended Forms I and II” (indicated by “Q” in the Table), the Japan’s Specifications and Standards for Food Additives (indicated by “F” in the Table), and the Japanese Industrial Standards (indicated by “J” in the Table), and the attachment of the aforementioned standards may be omitted.

(6) Product forms

The first agent shall be in liquid, paste, cream or aerosol form etc. The second agent shall be in powder, tablet, liquid, paste, cream or aerosol form etc. They shall not be misidentified to be a medicinal product.

(7) Dosage and administration

Product labels shall clearly indicate the correct dosage and administratiojn, leaving no room for misuse.

(8) Indications

Product indication shall be selected from “for creating and preserving waves in the hair” or “straightening the frizzy, curly or wavy hairs, and preserving that condition” depending on the intended uses.

(9) Standards and testing methods

Preparations shall meet the attached Quality Standards for Permanent Wave Agents.

[Attached Table 1]　Classification of active ingredients of Permanent Wave Agents

Indication	Classification		Column I	Column II	Column III A	Column III B
Permanent wave	Dual-step Cold or Tepid Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients	First agent	○			
		Second agent			○	
	Dual-step Cold or Tepid Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients	First agent		○		
		Second agent			○	
	Single-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients	First agent	○			
	Dual-step Permanent Wave Agents with the first agent containing thioglycolic acid and/or its salt as active ingredients (consisting of components to be mixed at use, generating exothermal reaction)	First agent-(1)	○			
		First agent-(2)			○	
		Second agent			○	
Hair straightening	Dual-step Cold or Dual-step Tepid Hair Straightening Agents or Dual-step Cold or Dual-step Tepid (using a high temperature hair-iron) Hair Straightening Agents containing thioglycolic acid and/or its salt as active ingredients	First agent	○			
		Second agent			○	

[Attached Table 2]　Classification of active ingredients of Permanent Wave Agents

		Standard	Name of Components	First agent: Range of the content (%) Dual-step Cold	Dual-step Tepid	Single-step Cold	Prepare before use	Second agent: Upper limit of the content (%)	Oxidizing activity per dose per person	Remarks
Column I		Q	Thioglycolic acid	2.0-11.0	1.0-5.0	3.0-3.3	Fist agent (1) 8.0-19.0			as thioglycolic acid
		Q	Ammonium thioglycolate solution							
		Q	Monoethanolamine thioglycolate solution							
Column II		Q	L-Cysteine hydrochloride	3.0-7.5	1.5-5.5					as cysteine
		Q	DL-Cysteine hydrochloride							
		Q	L-Cysteine							
		Q	DL-Cysteine							
		F	L-Cysteine Monohydrochloride							
		Q	N-acetyl-L-cysteine							
Column III	A	F	Hydrogen peroxide				Fist agent (2) 2.7-3.0	2.5	0.8-3.0	as hydrogen peroxide
		J								
		Q	Hydrogen peroxide solution							
	B	Q	Sodium perborate						not less than 3.5	as potassium bromate
		Q	Potassium bromate							
		Q	Sodium bromate							

Attachment

Quality Standards for Permanent Wave Agents

1. Dual-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are used at room temperature. They consist of the first agent containing thioglycolic acid and/or its salt and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing thioglycolic acid and/or its salt as active ingredient with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (h). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Measure the pH of this agent at 25°C using a glass electrode pH meter: it is between 4.5 and 9.6.

(b) Alkali

Take exactly 10 mL of a sample in a 100-mL volumetric flask, add purified water (hereinafter referred to as "water") conforming to the Japanese Standards of Quasi-Drug Ingredients (PFSB Notification No. 0331030, March 31, 2006; hereinafter referred to as JSQI) to make 100 mL, and use this solution as the sample solution.

Measure exactly 20 mL of the sample solution, and titrate with 0.1 mol/L hydrochloric acid VS. The amount of the volumetric solution consumed is not more than 7 mL per mL of the sample (Indicator : 2 drops of methyl red TS).

(c) Reducing substance after boiling under acidic condition

Measure exactly 20 mL of the sample solution obtained in (b), add 50 mL of water and 5 mL of 30 % sulfuric acid, and boil for 5 minutes by gentle heating. After cooling, titrate with 0.05 mol/L iodine VS, and designate the amount of 0.05 mol/L iodine VS consumed as A mL (indicator: 3 mL of starch TS).

The content (as thioglycolic acid, %) of the reducing substance after boiling under acidic conditions calculated by the following equation shall be between 2.0 % and 11.0 %.

Content (%)(as thioglycolic acid) of the reducing substance after boiling under acidic condition=0.4606×A

However, when the content of the reducing substance after boiling under acidic conditions is more than 7.0 %, dithiodiglycolic acid or its salt shall becontained as additives in an amount of dithiodiglycolic acid equal to or more than the excess of the reducing substance after boiling under acidic conditions.

(d) Reducing substance other than the reducing substance after boiling under acidic condition

To 50 mL of water and 5 mL of 30 % sulfuric acid in a 200-mL glass-stoppered flask add exactly 25 mL of 0.05 mol/L iodine VS. To this solution add exactly 20 mL of the sample solution obtained

in (b), stopper the flask tightly, shake, allow to stand at room temperature for 15 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as B mL (indicator: 3 mL of starch TS). Separately, take 70 mL of water and 5 mL of 30 % sulfuric acid in a 200-mL glass-stoppered flask, proceed in a similar manner and designate the amount of the volumetric solution consumed as C mL.

The amount per mL of the sample of 0.05 mol/L iodine VS consumed for the reducing substance other than the reducing substance after boiling under acidic condition, which is calculated by the following equation, is not more than 0.6 mL.

Amount (mL) per mL of the sample of 0.05 mol/L iodine VS consumed for the reducing substance other than the reducing substance after boiling under acidic condition
= [(C-B)-A]/2

(e) Reducing substance after reduction

Measure exactly 20 mL of the sample solution obtained in (b), add 30 mL of 1 mol/L hydrochloric acid and 1.5 g of zinc powder (85), stir by a stirrer for 2 minutes with careful attention not to mix air bubbles, and filter the solution under vacuum through a filter paper (4A). Wash the residue with a small amount of water three times, add washing to the filtrate and boil for 5 minutes by gentle heating. After cooling, titrate with 0.05 mol/L iodine VS, and designate the amount of 0.05 mol/L iodine VS consumed as D mL (indicator: 3 mL of starch TS).

Or, measure accurately 10 g of the sample, add 50 mL of sodium lauryl sulfate solutoin (1 in 10) and 20 mL of water and heat to approximately 80°C on a water bath. After cooling, make 100 mL in total, use this solution as the sample solution and proceed in a similar manner.

The content (%) of the reducing substance after reduction calculated by the following equation is not more than 4.0 %.

Content (%) of the reducing substance after reduction = [4.556× (D-A)]/W
W: Amount of the sample (mL or g)

(f) Iron

To 20 mL of the sample in a 300 mL decomposition flask add 20 mL of nitric acid, and heat carefully until the reaction subsides. After cooling, add 5 mL of sulfuric acid, and heat again. To this solution add carefully 2-mL portions of nitric acid, and heat until the solution is clear and colorless or light yellow. After cooling, add 1 mL of perchloric acid, heat until the white fumes of sulfuric acid evolve, and allow to cool. Add 20 mL of a saturated solution of ammonium oxalate, and heat until white fumes evolve. After cooling, add water to make 100 mL, and use this solution as the sample solution.

Separately, prepare a solution with 20 mL of water in the same manner as the sample solution. To 50 mL of this solution add exactly 2.0 mL of Standard Iron Solution, adjust to a pH between 9.5 and 10.0 by adding carefully ammonia water (28) under cooling, and use this solution as the standard matching fluid. Transfer the two solutions to separate Nessler tubes, to each add exactly 1.0 mL of mercaptoacetic acid, and add water to make 100 mL.

Compare the colors of the two solutions: the sample solution has no more color than the standard matching fluid (not more than 2 ppm as iron).

(g) Heavy metals

Take 2.0 mL of the sample and perform the test as directed under the Method 2, the Heavy Metals Limit Test, JSQI General Tests: the limit is not more than 20 ppm. Prepare the control solution with 4.0 mL of Standard Lead Solution.

(h) Arsenic

Perform the test with 2.0 mL of the sample solution obtained in (f) as directed under the Arsenic Limit Test of the JSQI General Tests: the limit is not more than 5 ppm.

(2) Second agent

The second agent should meet the following requirements (a) or (b).

(a) Potassium bromide, sodium bromide, sodium perborate or the mixture of these substances to which a suitable osmotic agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added for maintaining quality or enhancing usefulness of the product.

(i) Clarity and color of solution

For preparations in powder or in tablet form, dissolve an amount of the sample per dose per person in 200 mL of cold or lukewarm water, take in a colorless flat bottomed colorimetric tube, and observe vertically against white paper: no distinct insoluble foreign matters are observable.

(ii) pH

Perform the test as directed in 1-(1)-(a) with the second agent prepared before use in accordance with Dose and Administration: the pH of this solution is between 4.0 and 10.5.

(iii) Heavy metals

To 2.0 mL of the second agent prepared before use in accordance with Dose and Administration add 10 mL of water, then add 1 mL of hydrochloric acid and evaporate on a water bath to dryness. Incinerate the residue at a temperature below 500°C, dissolve in 10 mL of water and 2 mL of dilute acetic acid, add water to make 50 mL and use this solution as the sample solution.

Perform the test with the sample solution as directed under the Method 4, the Heavy Metals Limit Test of the JSQI General Test: the limit is not more than 20 ppm. Prepare the control solution with 4.0 mL of Standard Lead Solution.

(iv) Oxidizing activity

Measure accurately about a tenth of an amount of the second agent prepared before use according to the Dose and Administration in a 200-mL volumetric flask and add water to make 200 mL. Transfer 20 mL of the solution to a glass-stoppered flask, add 10 mL of dilute sulfuric acid, stopper tightly at once, and shake once or twice gently. To this solution, add 10 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 5 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as E mL (indicator: 3 mL of starch TS).

The oxidizing activity per dose per person, calculated by the following equation, is not less than 3.5.

Oxidizing activity per dose per person=0.2783×E

(b) Hydrogen peroxide or hydrogen peroxide to which a suitable osmotic agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added for maintaining quality or enhancing usefulness of the product.

(i) pH

Perform the test as directed in 1-(2)-(a)-(ii): the pH of the solution obtained is between 2.5 and 4.5.

(ii) Heavy metals

Proceed as directed in 1-(2)-(a)-(iii).

(iii) Oxidizing activity

Measure exactly 1 mL of the sample in a 200-mL glass-stoppered flask, add 10 mL of water and 5 mL of 30% sulfuric acid, stopper tightly at once, and shake once or twice gently. To this

solution, add 5 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 30 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as F mL (indicator: 3 mL of starch TS).

The oxidizing activity per dose per person, calculated by the following equation, is between 0.8 and 3.0.

Oxidizing activity per dose per person = 0.001701×F×amount (mL) per dose per person

The content (%) of hydrogen peroxide, calculated by the following equation, is not more than 2.5%.

Content (%) of hydrogen peroxide = 0.1701×F

2. Dual-step Cold Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients

These agents are used at room temperature. They consist of the first agent containing cysteine, its salt and/or acetylcysteine as an active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing cysteine, its salt and/or acetylcysteine as an active ingredient and not containing nonvolatile inorganic alkali. It should meet the following requirements (a) to (g). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 8.0 and 9.5.

(b) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 12 mL per mL of the sample.

(c) Cysteine

(i) Preparation of the sample stock solution

Measure 10 mL of the sample in a suitable reflux apparatus, add 40 mL of water and 20 mL of 5 mol/L hydrochloric acid TS and heat under reflux for 2 hours. After cooling, transfer the solution into a 100-mL volumetric flask, add water to make 100 mL and use this solution as the undiluted sample stock solution.

For the sample which is known to contain no acetylcysteine, take exactly 10 mL of the sample in a 100-mL volumetric flask, add water to make 100 mL and use this solution as the undiluted sample stock solution.

(ii) Preparation of the sample solution

Pass 25 mL of the sample undiluted stock solution through a layer of a column 8 to 15 mm in inside diameter packed with 30 mL of strongly acidic ion-exchange resin (H type) at the flow rate of 2 mL/min. Wash the resin layer with water and discard the eluate and washing. Pass 60 mL of 3 mol/L ammonia water through the resin layer at the flow rate of 2 mL/min, transfer the eluate to a 100-mL volumetric flask, wash the resin layer with water, and to the combined washing and eluate add water to make 100 mL and use this solution as the sample solution.

(iii) Assay of cysteine

Measure exactly 20 mL of the sample solution, neutralized with dilute hydrochloric acid as needed (indicator: methyl orange TS), add 4 g of potassium iodide and 5 mL of dilute

hydrochloric acid and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as G mL (indicator: 3 mL of starch TS).

Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as H mL.

The content (%) of cysteine calculated by the following equation is between 3.0 % and 7.5 %.

Content (%) of cysteine=1.212×2× (H-G)

For "Total reducing power" described in 2-(4)-(d) of the approval standards, "20 mL of the sample solution" in this test method shall be deemed to be replaced with "5 mL of the undiluted sample stock solution".

(d) Reducing substance after reduction

Measure exactly 10 mL of the sample solution obtained in 2-(1)-(b), add 30 mL of 1 mol/L hydrochloric acid TS and 1.5 g of zinc powder (85), stir by a stirrer for 2 minutes with careful attention not to mix air bubbles, and filter the solution under vacuum through a filter paper (4A). Wash the residue with a small amount of water three times and combine washings and filtrate. Add 4 g of potassium iodide and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as I mL (indicator: 3 mL of starch TS). Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as J mL.

Separately, measure exactly 10 mL of the sample solution, neutralized with dilute hydrochloric acid as needed (indicator: methyl orange TS), add 4 g of potassium iodide and 5 mL of dilute hydrochloric acid and dissolve with shaking. To this solution, add exactly 10 mL of 0.05 mol/L iodine solution, stopper tightly, allow to stand in ice water in a dark place for 20 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as K mL (indicator: 3 mL of starch TS). Perform a blank test in a similar manner and designate the amount of the volumetric solution consumed as L mL.

The content (%) of the reducing substance (as cystine) after reduction, calculated by the following equation, is not more than 0.65 %.

Content (%) of the reducing substance (as cystine) after reduction=1.202× {(J-I)-(L-K)}

(e) Iron

Proceed as directed in 1-(1)-(f).

(f) Heavy metals

Proceed as directed in 1-(1)-(g).

(g) Arsenic

Proceed as directed in 1-(1)-(h).

(2) Second agent

Proceed as directed in 1-(2).

3. Dual-step Tepid Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent

containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid.

It should meet the following requirements (a) to (h). A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.5 and 9.3.

(b) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 5 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition

Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing substance after boiling under acidic conditions is between 1.0 % and 5.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition

Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction

Proceed as directed in 1-(1)-(e).

(f) Iron

Proceed as directed in 1-(1)-(f).

(g) Heavy metals

Proceed as directed in 1-(1)-(g).

(h) Arsenic

Proceed as directed in 1-(1)-(h).

(2) Second agent

Proceed as directed in 1-(2)

4. Dual-step Tepid Permanent Wave Agents containing cysteine, its salt and/or acetylcysteine as active ingredients

These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing cysteine, its salt and/or acetylcysteine as an active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent is a liquid containing cysteine, its salt and/or acetylcysteine as an active

ingredient and not containing nonvolatile inorganic alkali. It should meet the following requirements (a) to (g).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.0 and 9.5.

(b) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 9 mL per mL of the sample.

(c) Cysteine

Perform the test as directed in 2-(1)-(c): the content (%) of cysteine is between 1.5 and 5.5 %.

(d) Reducing substance after reduction

Proceed as directed in 2-(1)-(d).

(e) Iron

Proceed as directed in 1-(1)-(f).

(f) Heavy metals

Proceed as directed in 1-(1)-(g).

(g) Arsenic

Proceed as directed in 1-(1)-(h).

(2) Second agent

Proceed as directed in 1-(2)

5. Single-step Cold Permanent Wave Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are used at room temperature. They contain thioglycolic acid and/or its salt as an active ingredient with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. They should meet the following requirements (1) to (8).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(1) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 9.4 and 9.6.

(2) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is between 3.5 and 4.6 mL per mL of the sample.

(3) Reducing substance after boiling under acidic condition

Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing

substance after boiling under acidic condition is between 3.0 % and 3.3 %.

(4) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(5) Reducing substance after reduction
Perform the test as directed in 1-(1)-(e): the content (%) of the reducing substance after reduction is not more than 0.5 %.

(6) Iron
Proceed as directed in 1-(1)-(f).

(7) Heavy metals
Proceed as directed in 1-(1)-(g).

(8) Arsenic
Proceed as directed in 1-(1)-(h).

6. Dual-Step Permanent Wave Agents with the first agent containing thioglycolic acid and/or its salt as active ingredients (consisting of components to be mixed at use, generating exothermal reaction)

These agents consist of the first agent-(1) containing thioglycolic acid and/or its salt as active ingredient, the first agent-(2) containing a amount of hydrogen peroxide smaller than the equivalent amount of thioglycolic acid and/or its salt contained in the first agent-(1) and the second agent containing oxidizing agent. The first agent-(1) and the first agent-(2) are mixed to raise its temperature to about 40°C with an exothermic reaction before use. The quality standards for these agents are as follows.

(1) First agent-(1)
This agent is a liquid containing thioglycolic acid and/or its salt as active ingredient. It should meet the following requirements (a) to (h).
A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.5 and 9.5.

(b) Alkali
Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 10 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition
Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing substance after boiling under acidic condition is between 8.0 % and 19.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Perform the test as directed in 1-(1)-(d): the amount of 0.05 mol/L iodine VS consumed for the reducing substance other than the reducing substance after boiling under acidic condition per mL

of the sample is not more than 0.8 mL. In this test add 50 mL of 0.05 mol/L iodine VS.

(e) Reducing substance after reduction

Perform the test as directed in 1-(1)-(e): the content (%) of the reducing substance after reduction is not more than 0.5 %.

(f) Iron

Proceed as directed in 1-(1)-(f).

(g) Heavy metals

Proceed as directed in 1-(1)-(g).

(h) Arsenic

Proceed as directed in 1-(1)-(h).

(2) First agent-(2)

This agent is a liquid containing a amount of hydrogen peroxide smaller than the equivalent amount of thioglycolic acid and/or its salt contained in the first agent-(1). It should meet the following requirements (a) to (c).

A suitable penetrant, pH adjusting agent, stabilizing agent, moisturizing agent, coloring agent, emulsifying agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 2.5 and 4.5.

(b) Heavy metals

Take 2.0 mL of the sample and proceed as directed in 1-(2)-(a)-(iii).

(c) Hydrogen peroxide

Take exactly 1 mL of the sample in a 200-mL glass-stoppered flask, add 10 mL of water and 5 mL of 30% sulfuric acid, stopper tightly at once, and shake once or twice gently. To this solution, add 5 mL of potassium iodide TS carefully, stopper tightly, allow to stand in a dark place for 30 minutes, titrate with 0.1 mol/L sodium thiosulfate VS, and designate the amount of the volumetric solution consumed as M mL (indicator: 3 mL of starch TS). The content (%) of hydrogen peroxide calculated by the following equation is between 2.7 % and 3.0 %.

Content(%) of hydrogen peroxide=0.1701× M

(3) Mixture of the First Agent-(1) and (2)

This product is a 3:1 mixture (in volume) of the first agent-(1) and (2). It contains thioglycolic acid or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (f). It generates heat on mixing and is warmed to about 40°C before using. In the test, mix one dose per person of the first agent-(1) with one dose per person of the first agent-(2), allow to stand at room temperature for 10 minutes, cool to room temperature and use the solution as the sample solution.

(a) pH

Perform the test as directed in 1-(1)-(a): the pH of the solution obtained is between 4.5 and 9.4.

(b) Alkali

Perform the test as directed in 1-(1)-(b): the amount of 0.1 mol/L hydrochloric acid VS consumed is not more than 7 mL per mL of the sample.

(c) Reducing substance after boiling under acidic condition

Perform the test as directed in 1-(1)-(c): the content (as thioglycolic acid, %) of the reducing substance after boiling under acidic condition is between 2.0 % and 11.0 %.

(d) Reducing substance other than the reducing substance after boiling under acidic condition

Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction

Perform the test as directed in 1-(1)-(e): the content (%) of the reducing substance after reduction is between 3.2 % and 4.0 %.

(f) Temperature rise

Place one dose per person of the first agent-(1) and one dose per person of the first agent-(2) in a thermostat maintained at 25°C, and allow to stand until the temperature of the agents rises to 25°C. Transfer the first agent-(1) to a 100-mL beaker and record temperature (T0) of the solution. To this add the first agent-(2), measure temperature immediately with shaking, and record the highest temperature (T1).

Calculate the temperature rise by deducting T0 from T1: it is between 14°C and 20°C.

(4) Second agent

Proceed as directed in 1-(2)

7. Dual-step Cold Hair Straightening Agents containing thioglycolic acid or its salt as active ingredients

These agents are used at room temperature. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent contains thioglycolic acid and/or its salt as active ingredients, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH

Proceed as directed in 1-(1)-(a).

(b) Alkali

Proceed as directed in 1-(1)-(b).

(c) Reducing substance after boiling under acidic condition

Proceed as directed in 1-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
Proceed as directed in 1-(1)-(e).

(f) Viscosity
Perform the test according to Method 2 under the Viscosity of the JSQI General Tests; the limit is not more than 40,000 mPa·s.

(g) Iron
Proceed as directed in 1-(1)-(f).

(h) Heavy metals
Proceed as directed in 1-(1)-(g).

(i) Arsenic
Proceed as directed in 1-(1)-(h).

(2) Second agent
Proceed as directed in 1-(2)

8. Dual-step Tepid Hair Straightening Agents containing thioglycolic acid and/or its salt as active ingredients

These agents are warmed to a temperature lower than about 60°C before use. They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Proceed as directed in 3-(1)-(a).

(b) Alkali
Proceed as directed in 3-(1)-(b).

(c) Reducing substance after boiling under acidic condition
Proceed as directed in 3-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
Proceed as directed in 1-(1)-(e).

(f) Viscosity
Proceed as directed in 7-(1)-(f).

(g) Iron
Proceed as directed in 1-(1)-(f).

(h) Heavy metals
Proceed as directed in 1-(1)-(g).

(i) Arsenic
Proceed as directed in 1-(1)-(h).

(2) Second agent
Proceed as directed in 1-(2)

9. Dual-Step Cold, Hair Straightening Agents containing thioglycolic acid or its salt as active ingredients using a high temperature hair-iron

For these agents, after treatment with the first agent at room temperature, the first agent is washed with water sufficiently and the moisture is wiped off. The procedure includes the use of a high temperature hair-iron (not more than 180°C). They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient, and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Proceed as directed in 1-(1)-(a).

(b) Alkali
Proceed as directed in 1-(1)-(b).

(c) Reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
Proceed as directed in 1-(1)-(e).

(f) Viscosity
Proceed as directed in 7-(1)-(f).

(g) Iron
Proceed as directed in 1-(1)-(f).

(h) Heavy metals
Proceed as directed in 1-(1)-(g).

(i) Arsenic
Proceed as directed in 1-(1)-(h).

(2) Second agent
Proceed as directed in 1-(2)

10. Dual-Step Tepid, Hair Straightening Agents containing thioglycolic acid or its salt as active ingredients using high temperature hair-iron

These agents are warmed to a temperature lower than about 60°C before use and after treatment with the first agent, the first agent is washed with water sufficiently and the moisture is wiped off. The procedure includes the use of high temperature hair-iron (not more than 180°C). They consist of the first agent containing thioglycolic acid and/or its salt as active ingredient, and the second agent containing an oxidizing agent. The quality standards for the first and the second agents are as follows.

(1) First agent

The first agent contains thioglycolic acid and/or its salt as active ingredient, with a total amount of nonvolatile inorganic alkali not exceeding the equivalent amount of thioglycolic acid. It should meet the following requirements (a) to (i).

A suitable alkaline substance, penetrant, moisturizing agent, coloring agent, emulsifying agent, viscous agent, perfume and other substances may be added to this agent in order to maintain quality and to enhance usefulness.

(a) pH
Proceed as directed in 3-(1)-(a).

(b) Alkali
Proceed as directed in 3-(1)-(b).

(c) Reducing substance after boiling under acidic condition
Proceed as directed in 3-(1)-(c).

(d) Reducing substance other than the reducing substance after boiling under acidic condition
Proceed as directed in 1-(1)-(d).

(e) Reducing substance after reduction
Proceed as directed in 1-(1)-(e).

(f) Viscosity

Proceed as directed in 7-(1)-(f).

(g) Iron
Proceed as directed in 1-(1)-(f).

(h) Heavy metals
Proceed as directed in 1-(1)-(g).

(i) Arsenic
Proceed as directed in 1-(1)-(h).

(2) Second agent
Proceed as directed in 1-(2)

11. Reagents, Test Solutions and Standard Solutions
The reagents, test solutions and standard solutions used in the tests in 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 above are shown as follows unless otherwise specified.

(1) Reagents and Test solutions
(a) Zinc powder (85), ammonia solution (28), 1 mol/L hydrochloric acid TS, 5 mol/L hydrochloric acid TS, hydrochloric acid, dilute hydrochloric acid, perchloric acid, dilute acetic acid, ammonium oxalate, nitric acid, starch TS, methyl orange TS, methyl red TS, mercaptoacetic acid, potassium iodide, potassium iodide TS, sodium lauryl sulfate, sulfuric acid and dilute sulfuric acid
As specified in the Reagents and Test Solutions of the JSQI General Tests.

(b) 3 mol/L ammonia solution
To 61 mL of strong ammonia solution (JSQI reagent) add water to make 300 mL.

(c) 30 % Sulfuric acid
Cautiously add 17.1 mL of sulfuric acid (JSQI reagent) to 30 mL of water, cool and dilute with water to make 100 mL.

(2) Standard solution
(a) 0.1 mol/L hydrochloric acid, 0.1 mol/L sodium thiosulfate and 0.05 mol/L iodine solution
As specified in the Standard Solutions for Volumetric Analysis of the JSQI General Tests.

(b) Standard lead solution
As specified in the Standard Solutions of JSQI General Tests.

(c) Standard Iron solution
Dissolve 0.7021 g of ammonium iron (II) sulfate hexahydrate (JSQI reagent), accurately weighed, in 50 mL of water, add 20 mL of sulfuric acid, then add dropwise 0.6% potassium permanganate solution (prepared by dissolving 0.6 g of potassium permanganate (JSQI reagent) in water to make 100 mL) with warming until the pale red color of the solutions persists, cool and add water to make exactly 1000 mL. Take 10 mL of this solution in a 100-mL volumetric flask and add water to make 100 mL.

12. Remarks

(1) "%" and "ppm" used in the standards are defined as follows. In the case of a liquid preparation, "%" and "ppm" denote percent weight in volume and parts per million weight in volume. In the case of a powder or tablet preparation, "%" and "ppm" denote percent weight in weight and parts per million weight in weight. In the case of viscous sample which cannot be measured exactly in a directed volume, it may be measured in equivalent weight. In such case, 1 g is deemed equivalent to 1 mL.

(2) An alternative method for the test method specified in the standards, of which the correctness and accuracy are equal to or greater than that specified, may be used. However, when a questionable result is obtained, the specified method shall be used for the final determination.