

事 務 連 絡
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厚生労働省医薬・生活衛生局審査管理課

「染毛剤製造販売承認基準の英訳について」の一部改正について

医薬部外品のうち、染毛剤の製造販売承認基準の英訳については、「染毛剤製造販売承認基準の英訳について」（平成 27 年 1 月 11 日付け厚生労働省医薬・生活衛生局審査管理課事務連絡）により示してきたところですが、別添のとおり、その一部を改正したのでお知らせいたします。

(別添) 下線部は今般の変更箇所。

Provisional Translation
from Japanese Original

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The Standards for Marketing Approval of Hair Coloring Agents

1. Scope of the standards

These standards are applicable to external preparations for hair intended to be used for hair dyeing, hair dye removal and hair bleaching, excluding those for bleaching of unwanted hair on arms and legs and those for direct hair dyeing by simple physical means (categorized as cosmetics); these preparations are hereinafter referred to as “hair coloring agents”, regardless of ingredients contained therein.

2. Standards

The following standards are applied to hair coloring agents of quasi-drugs.

For hair coloring agents which do not conform to the approval standards, documents regarding its efficacy, safety, and ingredient formulation, purpose, etc. shall be submitted for review for approval.

(1) Active ingredients

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

A. Oxidative hair coloring agents

(a) In the case of three-agent type preparations

The first agent:

If a preparation does not contain any of the active ingredients listed in Column I-C of the attached Table 2, it is possible that the preparation shall contain at least one or more active ingredients listed in Column I-A, and it may also, as necessary, contain an active ingredient listed in Column I-B of the attached Table 2.

If a preparation contains an active ingredient listed in Column I-C of the attached Table 2, the preparation must contain one of the combinations of the active ingredients listed from Column I-A to I-N, and shall also contain at least one or more active ingredients listed in Column II of the attached Table 2-2.

The second agent:

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

The third agent:

The preparation may contain an active ingredient(s) listed in Column IV of the attached Table 2.

(b) In the case of two-agent type preparations

The first agent:

If a preparation does not contain any of the active ingredients listed in Column I-C of the attached Table 2, it is possible that the preparation shall contain at least one or more active ingredients listed in Column I-A, and it may also, as necessary, contain an active ingredient listed in Column I-B or Column IV of the attached Table 2.

If a preparation contains an active ingredient listed in Column I-C of the attached Table 2, the preparation must contain one of the combinations of the active ingredients listed from Column I-A to I-N, and shall also contain at least one or more active ingredients listed in Column II of the attached Table 2-2.

The second agent:

The preparation shall contain at least one or more active ingredients listed in Column II of the attached Table 2. However, for a single item application in which the first agent contains an active ingredient listed in Column II of the attached Table 2, the second agent shall not contain any active ingredient listed in the same column.

(c) In the case of single-agent type preparations

A preparation shall contain at least one or more active ingredients listed in Column I-A of the attached Table 2 and it may also, as necessary, contain active ingredients listed in Column I-B, II, or IV of the attached Table 2.

B. Non-oxidative hair coloring agents

(a) In the case of a two-agent type preparation

The first agent:

A preparation may contain the active ingredients listed in Column III, V-B or V-C of the attached Table 2, as necessary.

The second agent:

A preparation shall contain at least one or more active ingredients listed in Column V-A of the attached Table 2 and it may also, as necessary, contain the active ingredients listed in Column V-B of the attached Table 2.

However, at least one or more active ingredients listed in Column V-B of the attached Table 2 shall be contained into only one of either the first agent or the second agent.

(b) In the case of a single-agent type preparation

A preparation shall contain at least one or more active ingredients of those listed in both Columns V-A and V-B of the attached Table 2 and it may also, as necessary, contain an active ingredients listed in Column V-C of the attached Table 2.

C. Hair bleaching agents/Hair dye removal agents

(a) In the case of a three-agent type preparations

The first agent:

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

The second agent:

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

The third agent:

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

(b) In the case of a two-agent type preparations

The first agent:

A preparation shall contain at least one or more active ingredients listed in Column II, III, or IV of the attached Table 2 and it may also, as necessary, contain an active ingredient listed in Column III or IV of the attached Table 2. However, for single item application, the preparation shall not contain any active ingredients listed in Column II of the attached Table 2.

The second agent:

A preparation may contain at least one or more active ingredients listed in Column II of the attached Table 2 and it may also, as necessary, contain an active ingredient listed in Column IV of the attached Table 2.

(c) In the case of a single-agent type preparation

A preparation may contain at least one or more active ingredients listed in Column II of the attached Table 2 and it may also, as necessary, contain an active ingredient listed in Column III or IV of the attached Table 2.

D. Oxidants of oxidative hair coloring agents, hair bleaching agents, or hair dye removal agents

A preparation may contain at least one or more active ingredients listed in Column II of the attached Table 2 and may also, as necessary, contain an active ingredient listed in Column IV of the attached Table 2.

E. Oxidation aids of oxidative hair coloring agents, hair bleaching agents, or hair dye removal agents

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

(2) Amount of active ingredients

A. For active ingredients listed in the attached Table 2 and Table 2-2 specified by the maximum concentration for use in the Tables, the maximum content shall not exceed the specified value of maximum concentration for use, which is calculated in terms of the concentration for use and listed in the Tables.

B. If at least two or more active ingredients in Column I-A or Column I-C of the attached Table 2 are contained in the agents, the total concentration (%) of active ingredients for use shall not exceed 5.0%.

C. For hydrogen peroxide and hydrogen peroxide solution as listed in Column II of the

attached Table 2, the total concentration of hydrogen peroxide in the product shall not exceed 6.0%.

(3) Standards of active ingredients

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

(4) Types, standards and maximum amount of additives

Types, standards, and maximum amount of additives shall be provided by the notification from the Director of the Evaluation and Licensing Division in Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare.

(5) Each active ingredient listed in the attached Table 2 and Table 2-2 shall be specified with the standards of the “Japanese Standards of Quasi-Drug Ingredients” (indicated by a “Q” in the Tables), the Japanese Pharmacopoeia (indicated by a “P” in the Tables), Japan’s Specifications and Standards for Food Additives (indicated by an “F” in the Tables), or Japanese Industrial Standards (indicated by a “J” in the Tables).

(6) Product forms

The product forms shall be powder, tablet, aerosol, liquid or cream, etc. which shall not be misidentified to be medicinal products.

(7) Dosage and administration

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

(8) Indications

Product indication shall be selected from hair dyeing, hair dye removal and hair bleaching depending on the intended use.

[Attached Table 1]

Classification of Active ingredients

○: Active ingredients which shall be contained
 (○): Active ingredients which may be contained

Indications	Application type	Product forms		Attached Table 2						Table 2-2									
				Column I			Column II	Column III	Column IV	Column V			Column I	Column II					
				A	B	C	Column II	Column III	Column IV	A	B	C	A-N						
Hair Dyeing	Oxidative hair dyeing	Single item application	Three-agent type preparation	First agent (case 1)	○	(○)													
				First agent (case 2)			○							○ (Single type only)		○			
				Second agent				○											
				Third agent Note 1						(○)									
		Two-agent type preparation	First agent (case 1)	○	(○)		(○) Note 2		(○)										
			First agent (case 2)			○			(○)					○ (Single type only)		○			
			Second agent				○												
		Single-agent type preparation		○	(○)		(○)		(○)										
		Separated application	Three-agent type preparation	First agent (case 1)	○	(○)													
	First agent (case 2)					○								○ (Single type only)		○			
	Two-agent type preparation		First agent (case 1)	○	(○)				(○)										
			First agent (case 2)			○			(○)					○ (Single type only)		○			
	Single-agent type preparation																		
	Non-oxidative hair dyeing	Single item application	Two-agent type preparation	First agent					(○)					(○)					
				Second agent							○	○							
			Single-agent type preparation									○	○	(○)					
	Hair bleaching Hair dye removal	Single item application	Three-agent type preparation	First agent					○										
				Second agent				○											
Third agent									○										
Two-agent type preparation (case 1)			First agent					○	(○)										
			Second agent					○	(○)										
Two-agent type preparation (case 2)			First agent						○										
			Second agent					○											
Single-agent type preparation							○	(○)	(○)										

Separated application	Three-agent type preparation	First agent					○						
	Two-agent type preparation (case 1)	First agent					○	(○)					
	Two-agent type preparation (case 2)	First agent				○	(○)						
	Two-agent type preparation (case 3)	First agent						○					
Oxidation agents for oxidative hair coloring agents, hair bleaching agents, and hair dye removal agents							○	(○)					
Oxidation aids for oxidative hair coloring agents, hair bleaching agents, and hair dye removal agents								○					

Note: The following product form shall be applicable for single item application.

- 1) Three-agent type oxidative hair coloring agents having a paste form, third agent of which shall not contain an active ingredient.
- 2) Two-agent type oxidative hair coloring agents which consist of a first agent containing the active ingredients in Column II and a second agent containing a diluent, etc. without active ingredients.

[Attached Table 2]

Active ingredients of hair coloring agents

Classification		Ingredient Standard	Ingredient name	Upper limit of concentration for use (%)
I	A	Q	5-Amino-o-cresol	1.0
		Q	2-Amino-4-nitrophenol	2.5
		Q	2-Amino-5-nitrophenol	1.5
		Q	1-Amino-4-methylaminoanthraquinone	0.5
		Q	3,3'-Iminodiphenol	1.5
		Q	2,4-Diaminophenoxyethanol hydrochloride	0.5
		Q	2,4-Diaminophenol hydrochloride	0.5
		Q	Toluene-2,5-diamine hydrochloride	4.5
		Q	Nitro-p-phenylenediamine hydrochloride	2.0
		Q	p-Phenylenediamine hydrochloride	4.5
		Q	N-phenyl-p-phenylenediamine Hydrochloride	0.5
		Q	m-Phenylenediamine hydrochloride	0.5
		Q	o-Aminophenol	3.0
		Q	N-phenyl-p-phenylenediamine acetate	4.5
		Q	1,4-Diaminoanthraquinone	0.5
		Q	2,6-Diaminopyridine	1.0
		Q	1,5-Dihydroxynaphthalene	0.5
		Q	Toluene-2,5-diamine	2.5
		Q	Toluene-3,4-diamine	0.5
		Q	Nitro-p-phenylenediamine	3.0
		Q	p-Aminophenol	3.0
		Q	p-Nitro-o-phenylenediamine	1.5
		Q	p-Phenylenediamine	3.0
		Q	p-Methylaminophenol	1.0
		Q	Picramic acid	3.0
		Q	Sodium picramate	1.0
		Q	N-N'-bis(4-aminophenyl)-2,5-diamino-1,4-quinonediimine	1.5
		Q	5-(2-Hydroxyethylamino)-2-methylphenol	0.5
		Q	N-Phenyl-p-phenylenediamine	2.0
		Q	m-Aminophenol	2.0
		Q	m-Phenylenediamine	1.0
		Q	5-Amino-o-cresol sulfate	4.5
		Q	2-Amino-5-nitrophenol sulfate	1.5
		Q	o-Aminophenol sulfate	3.0
		Q	o-Chloro-p-phenylenediamine sulfate	1.5
		Q	4,4'-Diaminodiphenylamine sulfate	1.0
Q	2,4-Diaminophenol sulfate	1.0		
Q	Toluene-2,5-diamine sulfate	4.5		
Q	Nitro-p-phenylenediamine sulfate	3.5		
I	A	Q	p-Aminophenol sulfate	4.0
		Q	p-Nitro-o-phenylenediamine sulfate	2.0

		Q	p-Nitro-m-phenylenediamine sulfate	3.0
		Q	p-Phenylenediamine sulfate	4.5
		Q	p-Methylaminophenol sulfate	3.0
		Q	m-Aminophenol sulfate	2.0
		Q	m-Phenylenediamine sulfate	3.0
	B	Q	Catechol	1.5
		Q	Diphenylamine	
		Q	α -Naphthol	
		Q	Hydroquinone	2.5
		Q	Pyrogallol	2.0
		Q	Phloroglucin	
		Q	Gallic acid	4.0
		Q	Resorcin	2.0
	C	Q	2,2'-[(4-aminophenyl)imino]bisethanol sulfate	see Table 2-2
II		Q	Hydrogen peroxide solution	
		F, J	Hydrogen peroxide	
		Q	Sodium percarbonate	
		Q	Sodium perborate	
		Q	Sodium perborate (monohydrate)	
		Q	Sodium bromate	
III		Q	Strong ammonia solution	
		P, J	Ammonia solution	
		Q, F, J	Ammonium carbonate	
		F	Ammonium bicarbonate	
		Q	Sodium carbonate	
		Q	Monoethanolamine	
		J	2-Aminoethanol	
		F, J	Ammonium sulfate	
IV		F	Ammonium persulfate	
		J	Ammonium peroxodisulfate	
		Q	Potassium persulfate	
		J	Potassium peroxodisulfate	
		Q	Sodium persulfate	
V	A	P	Ferrous sulfate hydrate	
		F	Ferrous sulfate	
	B	P	Tannic acid	
		Q	Sodium 2-hydroxy-5-nitro-2',4'-diamino azobenzene-5'-sulfonate	5.0
		Q	Pyrogallol	2.0
	C	Q	Hemateine	
		Q, P, J	Sodium hydrogen sulfite	
	F	Sodium pyrosulfite		
	F	Sodium hydrosulfite		

[Attached Table 2-2]

Active ingredients of hair coloring agents

Classification	Ingredient Standard	Ingredient name	Upper limit of concentration for use (%)
I	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	1.9
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.2
	Q	Toluene-2,5-diamine	0.3
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	1.9
	Q	p-Aminophenol	0.5
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.2
	Q	p-Phenylenediamine	0.5
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1
	Q	Toluene-2,5-diamine sulfate	0.3
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1
	Q	Toluene-2,5-diamine	0.7
	Q	p-Aminophenol	0.2
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1
	Q	Toluene-2,5-diamine	0.4
	Q	p-Phenylenediamine	0.7
	Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	1.1
Q	p-Aminophenol	0.3	
Q	p-Nitro-o-phenylenediamine	0.1	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.5	
Q	p-Aminophenol	0.2	
Q	p-Phenylenediamine	1.2	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1	
Q	p-Aminophenol	0.1	
Q	Toluene-2,5-diamine sulfate	0.6	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	1.9	
Q	p-Aminophenol	0.1	
Q	p-Methylaminophenol sulfate	0.3	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1	
Q	Toluene-2,5-diamine	1.1	
Q	p-Aminophenol	0.3	
Q	p-Phenylenediamine	0.7	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	2.2	
Q	p-Aminophenol	0.3	
Q	p-Nitro-o-phenylenediamine	0.1	
Q	p-Methylaminophenol sulfate	0.2	
Q	2,2'-(4-aminophenyl)iminol]bisethanol sulfate	0.1	
Q	p-Aminophenol	0.1	
Q	p-Phenylenediamine	0.1	
Q	Toluene-2,5-diamine sulfate	0.1	
II	Q	5-Amino-o-cresol	0.6
	Q	2,6-Diaminopyridine	0.1
	Q	2,4-Diaminophenoxyethanol hydrochloride	0.5
	Q	5-(2-Hydroxyethylamino)-2-methylphenol	0.5
	Q	m-Aminophenol	0.4
	Q	α-Naphthol	0.1
	Q	Resorcin	0.9