

**Original: Japanese
Provisional Translation**

Standards for Cosmetics

(Ministry of Health and Welfare Notification No.331 of 2000)

In accordance with the provisions of Article 42, Paragraph 2 of the Pharmaceutical Affairs Law (Law No.145 of 1960), the Standards for Cosmetics are hereby established as follows and shall be applied from April 1, 2001, and the Quality Standards for Cosmetics (Ministry of Health and Welfare Notification No.321 of August 1967) and the Japanese Standards for Cosmetic Ingredients (Ministry of Health and Welfare Notification No.322 of August 1967) shall be abolished on March 31, 2001; provided, however, that any medical drug ingredients which are also cosmetic ingredients that have actually been approved pursuant to Article 14, Paragraph 1 of the said law at the time of application of this notification or which are also cosmetic ingredients listed in the Appendix of the Ministry of Health and Welfare Notification No.15 of February 1961 (Re: Designation of Cosmetic Ingredients that must be Approved for Each Item in Accordance with the Provisions of Article 14, Paragraph 1 of the Pharmaceutical Affairs Law) may, regardless of the provisions of section 2 below, be used as cosmetic ingredients only if used in the amount for which the cosmetic ingredient was approved or the amount of the cosmetic ingredient as listed in the said Appendix, as the case may be; and provided further, that any cosmetics manufactured or imported on or before March 31, 2001, shall be treated as though this notification were not established.

Standards for Cosmetics

1. General provisions

Ingredients of cosmetics, including any impurities contained therein, shall not contain anything that may cause infection or that otherwise makes the use of the cosmetics a potential health hazard.

2. Prohibition of inclusion of ingredients other than preservatives, UV absorbers and tar colors

Cosmetics shall not contain any medical drug ingredients (excluding those used only as additives and those listed in Appendix 2-1 through 4), or any ingredients that do not meet the Standards for Biological Materials (Ministry of Health, Labour and Welfare Notification No.210 of 2003), Class I Specified Chemical Substances provided in the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. Article 2, Paragraph 2 (Law No.117 of 1973), or Class II Specified Substances provided in the same law Article 2, paragraph 3 or the materials that are determined by the Minister of Health, Labour and Welfare and have property similar to these substances, or any of the materials listed in Appendix 1.

3. Limitation on inclusion of ingredients other than preservatives, UV absorbers and tar colors

If any of the materials listed in the section of ingredient names of Appendix 2 is

incorporated in a cosmetic, the amount of such ingredient contained shall be under the values in the column of maximum amount of ingredient per 100 g of the said Appendix.

4. Limitation on inclusion of preservatives, UV absorbers and tar colors

Any and all preservatives (meaning materials incorporated in cosmetics for the purpose of inhibiting growth of microorganisms in such cosmetics) incorporated in cosmetics shall be among those listed in Appendix 3.

Any and all UV absorbers (meaning materials that specifically absorb ultraviolet rays and that are incorporated in cosmetics for the purpose of protecting skin or hair from adverse effects of ultraviolet rays) incorporated in cosmetics shall be among those listed in Appendix 4.

The provisions of Article 3 of the Ministerial Ordinance for the Designation of Tar Colors That May Be Used in Medical Drugs, Etc. (Ministry of Health and Welfare Ordinance No.30 of 1966) shall be applied *mutatis mutandis* to tar colors incorporated in cosmetics; provided, however, that Red No.219 and Yellow No.204 may be incorporated only in cosmetics applied to hair and nails.

5. Glycerin mixed with cosmetics should contain diethylene glycol less than 0.1g per 100g glycerin.

Appendix 1

1. 6-Acetoxy-2,4-dimethyl-m-dioxane
2. Antihistamines except those of aminoether type (such as diphenhydramine)
3. Hormones and those derivatives except estradiol, estrone and ethinylestradiol
4. Vinyl chloride monomer
5. Methylene chloride
6. Bismuth compounds other than bismuth oxychloride
7. Hydrogen peroxide
8. Cadmium compounds
9. Sodium perborate
10. Chloroform
11. Progesterone acetate
12. Dichlorophene
13. Mercury and its compounds
14. Strontium compounds
15. Sulfamide and its derivatives
16. Selenium compounds
17. Nitrofurantoin type compounds
18. Hydroquinone monobenzylether
19. Halogenated salicylanilide
20. Vitamin L1 and Vitamin L2
21. Bithionol
22. Pilocarpine
23. Pyrogallol
24. Inorganic fluorine compounds
25. Pregnenolone
26. Local anesthetics such as procaine
27. Hexachlorophen
28. Boric acid
29. Formalin
30. Methyl alcohol

Appendix 2

1. The ingredients restricted in all types of cosmetics

Ingredient name	Maximum amount of ingredient per 100 g
Aluminum chlorhydroxy allantoinate	1.0 g
Cantharides tincture, ginger tincture or capsicum tincture	1.0 g as total
Phenyl salicylate	1.0 g
Polyoxyethylene laurylether (8-10E.O.)	2.0 g

2. The ingredients restricted according to types or intended purposes of cosmetics

Ingredient name	Maximum amount of ingredient per 100 g
Aerosol agents Zirconium	Prohibited
Cosmetics to be washed away immediately after use such as soap or shampoo Thiram	0.50 g
Cosmetics other than those washed away immediately after use such as soap or shampoo Undecylenic acid monoethanolamide Thiram Zinc <i>p</i> -phenolsulfonate 2-(2-Hydroxy-5-methylphenyl) benzotriazole Sodium lauroyl sarcosinate	Prohibited 0.30g 2.0 g 7.0 g Prohibited
Hair setting agent to be washed away used in only hair. Cysteamine Hydrochloride	8.63 g
Cosmetics other than hair setting agent to be washed away used in only hair. Cysteamine Hydrochloride	Prohibited
Cosmetics used in cephalic, mucosa part or the oral cavity, and cosmetics used in other parts, containing lower aliphatic monoalcohols (exclude those containing the said alcohols added to dissolve ingredients in the said cosmetics) Estradiol, estrone and ethinylestradiol	20000 IU as total
Cosmetics other than those used in cephalic, mucosa part or the oral cavity, containing no lower aliphatic monoalcohols (include those containing the said alcohols added to dissolve ingredients in the said cosmetics) Estradiol, estrone and ethinylestradiol	50000 IU as total
Cosmetics used in only cephalic part Aminoether type antihistamines	0.010 g
Cosmetics other than those used only in cephalic part Aminoether type antihistamines	Prohibited
Toothpaste Diethylene glycol	Prohibited 0.50 g

Sodium lauroyl sarcosinate	
Compounds to be used with the purpose of emulsifying beeswax or white beeswax Sodium pyroborate	0.76 g (limited not to greater than 1/2 amount of beeswax and white beeswax)
Compounds to be used for purposes other than emulsifying beeswax or white beeswax Sodium pyroborate	Prohibited

3. The ingredients restricted according to types of cosmetics (*1)

Ingredient name	Maximum amount (g) of ingredient per 100 g		
	Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
Jujube Extract (*2)	○	○	5.0
Thioctic acid	0.01	0.01	
Ubidecarenone	0.03	0.03	

(*1) Blank indicates that it is prohibited to be used, and ○ indicates that there is no upper limit for the amount of ingredient.

(*2) It extracted from " Jujube" defined in Japanese pharmacopoeia with 30% (w/v) ethanol water solution.

Appendix 3

1. The ingredients restricted in all types of cosmetics

Ingredient name	Maximum amount (g) of ingredient per 100 g
Benzoic acid	0.2
Benzoate	1.0 as total
Alkyldiaminoethylglycine hydrochloride	0.20
Photosensitizing dyes	0.0020 as total
Chlorocresol	0.50
Chlorobutanol	0.10
Salicylic acid	0.20
Salicylate	1.0 as total
Sorbic acid and sorbate	0.50 as total
Dehydroacetic acid and dehydroacetate	0.50 as total
Trichlorohydroxydiphenylether (Triclosan)	0.10
<i>p</i> -Oxybenzoic acid esters and their sodium salts	1.0 as total
Phenoxyethanol	1.0
Phenol	0.10
Sodium lauryldiaminoethylglycine	0.030
Resorcin	0.10

2. The ingredients restricted according to types of cosmetics (*1)

Ingredient name	Maximum amount (g) of ingredient per 100g		
	Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
Zinc, ammonia and silver substituted zeolite ^(*4)	1.0	1.0	
Pantothenyl ethylether benzoate	○	0.30	0.30
Isopropylmethylphenol	○	0.10	0.10
Cetylpyridinium chloride	5.0	1.0	0.010
Benzalkonium chloride	○	0.050	0.050
Benzethonium chloride	0.50	0.20	
Chlorhexidine hydrochloride	0.10	0.10	0.0010
<i>o</i> -Phenyl phenol	○	0.30	0.30
Sodium <i>o</i> -phenylphenate	0.15	0.15	
Silver-Copper Zeolite ^(*5)	0.5	0.5	
Chlorhexidine gluconate	○	0.050	0.050
Cresol	0.010	0.010	
Chloramine T	0.30	0.10	
Chlorxylenol	0.30	0.20	0.20
Chlorphenesin	0.30	0.30	
Chlorhexidine	0.10	0.050	0.050
1,3-Dimethylol-5, 5-dimethylhydantoin	0.30		
Alkylisoquinolinium bromide	○	0.050	0.050
Thianthol	0.80	0.80	
Thymol	0.050	0.050	○ ^(*2)
Trichlorocarbanilide	○	0.30	0.30
<i>p</i> -Chlorphenol	0.25	0.25	
Halocarban	○	0.30	0.30
Hinokitiol	○	0.10	0.050
Zinc pyrithione	0.10	0.010	0.010
Piroctone olamine	0.05	0.05	
Iodopropynyl butylcarbamate ^(*6)	0.02	0.02	0.02
Polyaminopropyl biguanide	0.1	0.1	0.1
Methyl isothiazolinone	0.01	0.01	
Methylchloro isothiazolinone and methyl isothiazolinone solution ^(*3)	0.10		
N,N''-Methylenebis[N'-(3-hydroxymethyl-2,5-dioxo-4-imidazolidinyl)urea]	0.30		
<i>p</i> -Dimethylaminostyryl heptyl methyl thiazolium iodide	0.0015	0.0015	

(*1) Blank indicates that it is prohibited to be used, and ○ indicates that there is no upper limit for the amount of ingredient.

(*2) It can be contained in cosmetics used for mucosa and only for oral cavity.

(*3) It indicates the aqueous solution containing 1.0 - 1.3% of 5-chloro-2-methyl-4-isothiazolin-3-one and 0.30 - 0.42% of 2-methyl-4-isothiazolin-3-one.

(*4) It indicates the compound containing 0.2 - 4.0% as silver and 5.0 - 15.0% as zinc when it is exposed to strong heat.

(*5) It indicates the compound containing 2.7 - 3.7% as silver and 4.9 - 6.3% as copper when it is exposed to strong heat.

(*6) It is prohibited to be contained in aerosol agents.

Appendix 4

1. The ingredients restricted in all types of cosmetics

Ingredient name	Maximum amount (g) of ingredient per 100g
Homomenthyl salicylate	10
2-Cyano-3,3-diphenyl prop-2-enoic acid 2-ethylhexyl ester (octocrylene)	10
Glyceryl mono-2-ethylhexanoate di- <i>p</i> -methoxycinnamate	10
Tris-Biphenyl Triazine	10.0
<i>p</i> -Aminobenzoic acid and its esters	4.0 as total
4- <i>tert</i> -Butyl-4'-methoxy dibenzoylmethane	10

2. The ingredients restricted according to types of cosmetics (*1)

Ingredient name	Maximum amount (g) of ingredient per 100g		
	Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
4- (2-β-glucopyranosiloxy) propoxy-2-hydroxybenzophenone	5.0	5.0	
Octyl salicylate	10	10	5.0
Methyl-2, 5-diisopropylcinnamate	10	10	
2-[4-(diethylamino)-2-hydroxybenzyl] benzoic acid hexylester	10.0	10.0	
Cinoxate	○	5.0	5.0
Dihydroxydimethoxybenzophenone	10	10	
Sodium dihydroxydimethoxybenzophenone disulfonate	10	10	
Dihydroxybenzophenone	10	10	
Dimethicodiethyl-benzal malonate	10.0	10.0	10.0
1- (3, 4-dimethoxyphenyl)-4, 4-dimethyl-1, 3-pentanedione	7.0	7.0	
Dimethoxybenzylidenedioxo-imidazolidine 2-ethylhexyl propionate	3.0	3.0	
Tetrahydroxybenzophenone	10	10	0.050
Terephthalylidene dicamphor sulfonic acid	10	10	
2,4,6-Tris [4-(2-ethylhexyloxy)carbonyl] anilino] -1,3,5-triazine	5.0	5.0	
Methylbis(trimethylsiloxy)silyl isopentyl trimethoxycinnamate	7.5	7.5	2.5
Drometizole trisiloxane	15.0	15.0	
Amyl <i>p</i> -dimethylaminobenzoate	10	10	
2-Ethylhexyl <i>p</i> -dimethylaminobenzoate	10	10	7.0
Isopropyl <i>p</i> -methoxycinnamate and diisopropyl cinnamate ester mixture(*2)	10	10	
2-Ethylhexyl <i>p</i> -methoxycinnamate	20	20	8.0
2,4-Bis-[{4-(2-ethylhexyloxy)-2-hydroxy }-phenyl]-6-(4-methoxyphenyl)-1,3,5-triazine	3.0	3.0	
2-Hydroxy-4-methoxybenzophenone	○	5.0	5.0
Hydroxymethoxybenzophenone sulfonate and its trihydrate	10(*3)	10(*3)	0.10(*3)
Sodium hydroxymethoxybenzophenone sulfonate	10	10	1.0
Phenylbenzimidazole sulfonic acid	3.0	3.0	
Ferulic acid	10	10	
2,2'-methylenebis(6-(2H-benzotriazole-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	10.0	10.0	
2-Methylphenyl 4-methoxycinnamate	10.0	10.0	

(*1) Blank indicates that it is prohibited to be used, and ○ indicates that there is no upper limit for the amount of ingredient.

(*2) It indicates the compound containing 72.0 - 79.0% of isopropyl *p*-methoxycinnamate, 15.0 - 21.0% of ethyl 2,4-diisopropyl cinnamate and 3.0 - 9.0% of methyl 2,4-diisopropyl cinnamate.

(*3) It is calculated as the total amount of hydroxymethoxybenzophenone sulfonate.

Pharmaceutical Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare