

Guideline
on
Cosmetics Category

Definition of terms according to the Cosmetics Act B.E.2535

<p>Cosmetics means</p> <ol style="list-style-type: none">1. Preparations designed for use by applying, rubbing, powdering, spraying, or otherwise applying to any part of the body to cleanse or beautify, including skin-care products but excluding ornaments and clothing.2. Substances intended for use as admixtures in the manufacture of cosmetics.3. Other substances designated specifically by the ministerial regulation as cosmetics.	<p>“Manufacture” means process of admixture, transformation, production, dividing and changing containers.</p> <p>“Importation” means bringing or ordering into the Kingdom.</p> <p>“Distribution” means sell, disposal, or exchange for commercial purpose and includes availability for sale.</p>
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Products that fall into the cosmetics category must be intended for use to cleanse or beautify. Other products with other purposes such as therapy, relief, healing or products have medicine as chemical components and product that have to be ingested are not counted as cosmetics.

In order to protect public health, the Minister of Public Health, by virtue of Section 5 of the Cosmetics Act B.E.2535, has specified specially controlled cosmetics, controlled cosmetics, cosmetics that has been forbidden to manufacture, import or distribute, admixture that has been forbidden to manufacture, substances which may be used as admixtures in the manufacture of cosmetics, and also classified cosmetics.

Category of Cosmetics according to the Cosmetics act B.E. 2535

1. Specially-Controlled Cosmetics
2. Controlled Cosmetics
3. Other cosmetics besides specially-controlled cosmetics or controlled cosmetics which are designated as General Cosmetics

Specially-Controlled Cosmetics means cosmetics containing substances that may be harmful if not used properly. Therefore, the manufacturers and/or importers must apply for registration, and if approved, the applicant must pay an annual fee before manufacture or import of specially-controlled cosmetics. Substances that might harm consumers' health have been announced to be specially-controlled substances. The Notifications of Ministry of Public Health that designated specially-controlled substances are

1. Notification of Ministry of Public Health No. 3 (B.E. 2535)
2. Notification of Ministry of Public Health (No. 16) B.E. 2537 has been repealed according to Notification of Ministry of Public Health (No. 22) B.E. 2538
3. Notification of Ministry of Public Health (No.18) B.E. 2537
4. Notification of Ministry of Public Health (No. 22) B.E. 2538
5. Notification of Ministry of Public Health (No. 24) B.E. 2539

In the total of 5 Notifications there are 26 specially-controlled substances that have been announced up to the present. In these Notifications, there are name, category, maximum level allowed and condition of specially-controlled substances. The specially-controlled cosmetics can be grouped by type as followed

<i>Type</i>	<i>Specially-controlled substances</i>	<i>Maximum Level/ allowed</i>
1. Products for use on scalp hair	<ul style="list-style-type: none"> - oxalic acid including esters and alkaline salts of oxalic acid - resorcinol - hydrogen peroxide, including other peroxides except sodium peroxide 	<ul style="list-style-type: none"> - not more than 5.0% - not more than 0.5% - not more than 12.0%
2. Hair Perming Products	<ul style="list-style-type: none"> - thioglycolic acid and its salts - thioglycolic acid esters - thiolactic acid 	<ul style="list-style-type: none"> - not more than 11.0% at pH 7-9.5 calculated in form of thioglycolic acid - not more than 11.0% at pH 6-9.5 calculated in form of thioglycolic acid - not more than 8.5% at pH not more than 9.5
3. Hair Straightening	- thioglycolic acid and its salts	- not more than 11.0% at pH

Products	<ul style="list-style-type: none"> - thioglycolic acid esters - potassium hydroxide or sodium hydroxide 	<p>7-9.5 calculated in form of thioglycolic acid</p> <ul style="list-style-type: none"> - not more than 11.0% at pH 6-9.5 calculated in form of thioglycolic acid - not more than 2.0% calculated in form of sodium hydroxide
4. Hair dyeing Products	<ul style="list-style-type: none"> - diaminophenols - hydroquinone - methylphenylenediamines including N-substituted derivatives and their salts (except 4-methyl-m-phenylenediamine and its salts) - m- or p-phenylenediamines including N-substituted derivatives and their salts and N-substituted derivatives of o-phenylenediamines - resorcinol 	<ul style="list-style-type: none"> - not more than 10.0% - not more than 2.0% - not more than 10.0% - not more than 6.0% - not more than 5.0%
5. Hair Blackening Cream	<ul style="list-style-type: none"> - lead acetate - silver nitrate 	<ul style="list-style-type: none"> - Calculated in the form of lead not more than 0.6% (equal to lead acetate not more than 0.94% or equal to lead acetate trihydrate not more than 1.1%) - not more than 5.0%
6. Anti- dandruff products	<ul style="list-style-type: none"> - aluminium pyrithione 	<ul style="list-style-type: none"> - not more than 2.0%
7. Hair Bleaching Products	<ul style="list-style-type: none"> - persulfates of ammonium or potassium or sodium 	<ul style="list-style-type: none"> - not more than 45% calculated in the form of persulfate and when mixed with hydrogen peroxide must

		not be more than 20.0%
8. Toothpaste	<ul style="list-style-type: none"> - chlorates of the alkali metals - salts and derivatives of fluoride 	<ul style="list-style-type: none"> - not more than 5.0% - not more than 0.11% (active fluoride ion not more than 1,100 ppm.)
9. Dental Floss	<ul style="list-style-type: none"> - salts and derivatives of fluoride 	<ul style="list-style-type: none"> - not more than 0.11% (active fluoride ion not more than 1,100 ppm.)
10. Mouth wash	<ul style="list-style-type: none"> - formaldehyde - hydrogen peroxide including other peroxide (except sodium peroxide) - salts and derivatives of fluoride - cetylpyridinium chloride 	<ul style="list-style-type: none"> - not more than 0.1% - not more than 0.5% - not more than 0.11% (active fluoride ion not more than 1,100 ppm.) - not more than 0.06%
11. Oral Refresher Spray	<ul style="list-style-type: none"> - cetylpyridinium chloride 	<ul style="list-style-type: none"> - not more than 0.06%
12. Depilatory products	<ul style="list-style-type: none"> - calcium sulfide - calcium thioglycolate - strontium sulfide - thioglycolic acid and its salts - zinc sulfide 	<ul style="list-style-type: none"> - not more than 30.0% - not more than 9.0% at pH 9-12.5 - not more than 20.0% - not more than 5.0 at pH 7-12.7 (Calculate in form of thioglycolic acid) - not more than 40.0%
13. Skin Hair Lightening Products	<ul style="list-style-type: none"> - hydrogen peroxide including other peroxide (except sodium peroxide) 	<ul style="list-style-type: none"> - not more than 4.0%
14. Manicure Product	<ul style="list-style-type: none"> - formaldehyde - hydrogen peroxide including other peroxide except sodium peroxide - potassium hydroxide or sodium hydroxide used as solvent in nail 	<ul style="list-style-type: none"> - not more than 5.0% - not more than 2.0% - not more than 5.0% calculate in form of sodium hydroxide

	products	
15. Deodorant products	- zinc p-phenolsulfonate	- not more than 6.0%
16. Spray products	- 1,1,1-trichloroethane or solvent methylchloroform	- not more than 35.0%
17. Other products besides toothpaste	- chorates of alkali metals	- not more than 3.0%

Manufacturing or Importing Specially-Controlled Cosmetics for Distributing

Following procedure must be complied with

1. Notify an officer at Cosmetic Control Division, the Thai-FDA, or Provincial Public Health where the informant resides, not less than 15 days before the manufacturing or importing of a sample-for-registration of specially-controlled cosmetics. After an officer has inspected and approved the application, the Thai-FDA will issue notification of manufacturing and importing of specially-controlled to the informant.
2. Registration of special-controlled cosmetics enclosed with required documents to an officer at Cosmetics Control Division, the Thai-FDA, or Provincial Public Health Office where place of manufacturing or importing is located.
3. Inform the manufacture or import of specially-controlled cosmetics all registered products must inform the manufacturing or importation of specially-controlled cosmetics.
4. Pay an Annual Fee In case of new registration and repay annual fee every year.

Controlled Cosmetics means cosmetics which cause harm to the health of users but less harm than Specially-Controlled Cosmetics. The manufactures and importers of cosmetics in this category must notify details of controlled cosmetics and pay an annual fee before manufacture or importation of the cosmetics.

Type of Controlled Cosmetics

<i>Type</i>	<i>Controlled substance</i>	<i>Volume Not exceed</i>	<i>condition</i>	<i>Notification of Minister of Public Health</i>
1. Sanitary Napkins	-	-	- Those for external use must be made cleanly and hygienically - Those for internal use must be sterilized	(No. 10) B.E. 2536
2. Refreshing towel/ paper	-	-	- must be made cleanly and hygienically	(No. 11) B.E. 2536
3. Talcum Powder	-	-	- Children talcum powder must not contain boric acid, borate, menthol and/or camphor - Talcum powder contains - Boric acid or sodium borate not more than 1.0% - Menthol not to exceed 1.0% - Camphor not to exceed 1.5%	(No. 12) B.E. 2536

4. Liquid powder	-	-	<p>- pH between 5.5-8.0</p> <p>- children liquid powder must not contain boric acid, borate, menthol and/or camphor</p> <p>- Liquid Powder contains</p> <ul style="list-style-type: none"> - Boric acid or sodium borate not more than 1.0% - Menthol not to exceed 1.0% - Camphor not to exceed .5% 	<p>(No. 13)</p> <p>B.E. 2536</p>
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5. Products containing UV protection	1. Benzyl Salicylate	1.00%		(No. 8) B.E. 2536
	2. Ethyl diethylaminobenzoate	1.0%		
	3. Ethyl p-dimethyl-amino benzoate	1.0%		
	4. p-Aminobenzoic acid	5.0%		
	5. Oxybenzone	10.0%		
	6. Octyl Dimethyl PABA	8.0%		
	7. Ethylhexyl p-methoxycinnamate	10.0%		
	8. Homosalate	10.0%		
	9. Phenylbenzimidazole Sulfonic acid and its potassium, sodium and triethanolamine salts	8.0%		
	10. Dihydroxyacetone	5.0%		
	11. Ethyl N-dihydroxypropyl PABA	5.0%		
	12. Glycerol-1, 4-anubibebziate (free from benzocain)	3.0%		
	13. Menthyl antranilate	5.0%		
	14. 2-Ethylhexyl Salicylate	5.0%		
	15. Sulisobenzone	10.0%		
	16. Dioxybenzone	3.0%		
	17. Digalloyl trioleate	5.0%		
	18. Lawsone with Dihydroxyacetone	0.25% and 3.0%		
	19. 2-Ethylhexyl-2-cyano-3, 3-diphenyl-acrylate	10.0%		

6. Hair Product that contain anti-dandruff substances	1. Zinc Pyrithione	2.0%	Use in rinse-off products	(No. 19) B.E. 2537
		0.5%	Use in leave-on products	(No. 19) B.E. 2537
	2. Piroctone Olamine	1.0%	Use in rinse-off products	(No. 19) B.E. 2537
		0.1%	Use in leave-on products	(No. 19) B.E. 2537
	3. Climbazole	2.0%	Use in rinse-off products	(No. 26) B.E. 2537
			Use in leave-on products	(No. 26) B.E. 2537
		0.5%	Use in rinse-off products	(No. 26) B.E. 2537
			Use in leave-on products	(No. 26) B.E. 2537

Manufacturing or Importing Controlled Cosmetics for Distributing

Must follow procedures set out below

1. Notify details of controlled cosmetics to an officer at Cosmetics Control Division, the Thai-FDA, or Provincial Public Health Office where the informant resides not less than 15 days before manufacturing or importing controlled cosmetics.
2. Pay an Annual Fee In case of new registration and repay an annual fee every year.

General Cosmetic means Cosmetics which are not specially-Controlled Cosmetics and Controlled Cosmetics such as soaps, shampoos, hair conditioners, lotions, perfumes, face make up etc. which have been checked that their formulas do not contain specially-controlled substances, or as controlled cosmetics.

In case of Manufacturing of General Cosmetics

There is no need to apply for permission but

1. Must provide Thai label as announced in Notification of Cosmetics Committee No. 1 (2536)
2. Must not contain forbidden substances, specially-controlled substances or controlled cosmetics
3. Must use colour as prescribed in Notification of Ministry of Public Health (No. 20) B.E. 2538

In case of Importing General Cosmetics

Procedures as follows

1. Provide notice of importation to an officer at Cosmetics Control Division, the Thai- FDA
2. Must provide correct Thai label as announced in Notification of Cosmetics Committee No. 1 (2536) within 30 days from the day that the officer inspects and give permission to import. The message on the label must be the same as of manufacturing but has to contain manufacturers' name, country of origin and name and location of importer.
3. Must not contain forbidden substances, specially-controlled substances or as controlled cosmetics
4. Must use colour as prescribed in Notification of Ministry of Public Health (No. 20) B.E. 2538