HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

Revised May 2017

GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

The information in this Guideline shall be updated or revised from time-to-time. For any new, addition, amendments or deletion made to this Guideline, please refer to the latest version in our website www.hsa.gov.sg.

HSA
Health Sciences Authority

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1 INTRODUCTION

These guidelines provide information for the trade in the dealing with Cosmetic Products in Singapore. The information provided in these guidelines serves to supplement understanding and application of the following legislation and is not at any time meant to supersede or replace any of the legislation:

- Health Products Act
- Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations

Singapore has implemented the ASEAN Cosmetic Directive (ACD) from 1 January 2008. Companies dealing with cosmetic products are responsible for the safety and quality of the cosmetic products they are dealing with. They have to ensure that the cosmetic product is safe for human use when applied under normal or reasonably foreseeable conditions of use. Under the current regulatory control, person responsible (refer to section 5) must inform the Health Sciences Authority (HSA) before the supply and/or sale of the cosmetic product. The person responsible has to ensure the product label of the cosmetic product comply with regulatory requirements, maintain supply records and report to the Health Sciences Authority (HSA) of product defects and adverse effects caused by their products.

Under the Regulations, there are ingredients that are prohibited in the formulation of cosmetic products as well as ingredients that are only allowed to be used with certain restrictions. This list of ingredients is aligned to that adopted by the European Union (EU).

Manufacturers and importers of cosmetic products do not require manufacturer's or importer's licence.

The information in these guidelines does not apply to a cosmetic product that is:

- Imported into Singapore solely for re-export;
- Manufactured in Singapore solely for export.

2 DEFINITION OF COSMETIC PRODUCT

A “cosmetic product” is defined as any substance or preparation that is intended to be placed in contact with the various external parts of the human body or with the teeth or the mucous membranes of the oral cavity with a view exclusively or mainly to:

- Cleaning
- Perfuming
- Changing appearance
- Correcting body odours
- Protecting
- Keeping in good condition

The area of application of cosmetic products is to one or more of the following sites of application of the external parts of the human body or with the teeth or the mucous membranes of the oral cavity:

- the epidermis (skin, including the vicinity of the eyes)
- the hair system
- the nails
- the lips
- the external genital organs
- the teeth; or
- the mucous membrane of the oral cavity

2.1 Types of Cosmetic Products

Below is a non-exhaustive illustrative list of products that could be considered as cosmetic products:

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)
- Face masks
- Tinted bases (liquids, pastes, powders)
- Make-up powders, after-bath powders, hygiene powders etc
- Toilet soaps, deodorant soaps, etc
- Perfumes, toilet waters and eau de Cologne
- Bath and shower preparations (salts, foams, oils, gels, etc)
- Depilatories
- Deodorants and anti-perspirants
- Hair care products
    - Hair tints and bleaches
    - Products for waving, straightening or fixing
    - Setting products
    - Cleansing products (lotions, powders, shampoos)
    - Conditioning products (lotions, creams, oils)
    - Hairdressing products (lotions, lacquers, brilliantines)
- Shaving products (creams, foams, lotions, etc)
- Products for making-up and removing make-up from the face and the eyes
- Products intended for the application to the lips and around the eyes
- Products for care of the teeth and the mouth
- Products for nail care and make-up (manicure and pedicure products)
- Products for external intimate hygiene
- Sunbathing products
- Products for tanning without sun
- Skin whitening products

- Anti-wrinkle products
- Baby / Facial Wipes

Examples of products that are **not** cosmetic products:

- Oral supplements for beauty purposes
- Injections / injectable products (e.g. mesotherapy)
- Massage oil (e.g.: for relieving stress; removing toxins)
- Essential oils (e.g.: for aromatherapy; diffuser)
- Aesthetic/beauty devices
- Lubricants
- Insect repellants
- Sanitary pads
- Hand sanitizers
- Cream for treatment of eczema / acne / psoriasis / fungal
- Toothbrush
- Dental floss
- Detergent (e.g. dish-washing detergent, laundry detergent)
- Temporary tattoo

If you are not certain if the product you are dealing with is a cosmetic product, you may follow the link below and submit the Health Products Enquiry Form to HSA_Prod_Class@hsa.gov.sg:

http://www.hsa.gov.sg/content/dam/HSA/e-Services/HEALTH%20PRODUCT%20ENQUIRY%20FORM_%2021May13.pdf

3 COSMETIC PRODUCT INGREDIENTS

Companies supplying the cosmetic products are responsible to ensure the product including the ingredients are safe for use.

Cosmetic products shall not contain substances found in Part I of the Regulations. These substances are prohibited for use in cosmetic products.

Substances found in Part II of the Third Schedule of the Regulations, may only be used in cosmetic products provided the specified conditions are met. Depending on the substance, the conditions could be on the maximum concentration allowed to be used or labelling of special warning on the product packaging.

Only colouring agents, preservatives or UV filters found in Parts III, IV and V respectively of the Third Schedule of the Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007 are allowed to be used in cosmetic products. The use of colouring agents, preservatives and UV filters are subject to the conditions specified, if any.

For the latest development on cosmetic ingredients, please refer to HSA website for the latest updates.

4 LABELING REQUIREMENTS

Cosmetic product labels should contain truthful and accurate information about the cosmetic product, its intended purpose and how it is to be used. They are required to be labelled in accordance with the Regulations before they can be sold or supplied in Singapore and to make claims that will NOT mislead the consumer about the product's contents, quality or safety.

Suppliers of cosmetic products, such as wholesalers or retailers, must ensure that the cosmetic products comply with the Regulations before they supply the product. Labels or labeling statements must be in English and legible. The following information must appear on the outer packaging or immediate container of the cosmetic products:

a. Name of the cosmetic product
b. Function of the cosmetic product
c. Instructions for use
d. Full ingredients listing
e. Country of manufacture
f. Contents (weight/volume)
g. Batch number
h. Manufacturing/ expiry date (expiry date is only required for products with less than 30 months durability)
i. Name and address in Singapore of company responsible for placing the product in the market
j. Special precautions, if any (especially those listed in Annex III, VI, VII in the ASEAN Cosmetic Directive)

An explanation of the symbol or code (e.g. colour) used in the label should be provided.

Cosmetic products that bear the label “for professional use only” or similar labelling are restricted for “professional use”.

“Professional use” means the application and use of cosmetic products by persons in the exercise of their professional activity (e.g. in hair salons, nail salons, spa salons, skin clinics etc). It also means that such cosmetic products should not be sold by a professional to the consumer.

A “professional” would have attained a certain level of expertise and experience. Therefore, they are more familiar with the risks associated with the use of the products than the consumer. They would also have the professional expertise in the correct application of the product on a consumer.

4.1 Label Display

The label must be legible, permanent, indelible, prominently and conspicuously displayed on the product at the point of sale. Labels or labeling statements shall appear on the outer packaging of the cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products.

Where the size, shape or nature of the container or package does not permit all the required information to be specified on the container or package, the use of leaflets, pamphlets, hang tags, display panels etc placed together with the product are allowed. However, the name of the cosmetic product and the batch reference must be displayed on the immediate package or container.

4.2 Listing of Ingredients

All cosmetic products must be labelled with all the ingredients contained in the product. The quantity or percentage of each ingredient in the cosmetic product need not be disclosed on the labelling.

The ingredients should be listed in descending order by weight, except for:

a. Ingredients (except colouring agents) in concentrations of less than 1% (by weight) which may be listed in any order after ingredients present in concentration of 1% or more; and

b. Colouring agents which may be listed in any order, after the other ingredients.

Perfume and aromatic compositions and their raw materials may be referred to by the word “perfume”, “fragrance”, “aroma” or any other similar term. Likewise, flavouring may be referred to as “flavour” or any other similar term.

4.3 Nomenclature of Ingredients

The nomenclature used should be based on the most recent edition of the International Cosmetic Ingredient Dictionary, Chemical Abstracts Service, British Pharmacopoeia and United States Pharmacopoeia, or any other approved standard references. Botanicals and extract of botanicals should be identified by its genus and species.

5 PERSON RESPONSIBLE

The person responsible for placing a cosmetic product in the market is defined in the Regulations as a locally registered company who is instrumental in causing the cosmetic product to be available for sale in Singapore which may be an importer, a manufacturer, a distributor or a retailer.

Under the Regulations, the person responsible must inform the Health Sciences Authority (HSA) by submitting a product notification before the supply and/or sale of the cosmetic product. The person responsible also has to keep records of supply of the cosmetic products and report to HSA on product defects and adverse effects of the cosmetic products he is responsible for. As a supplier of cosmetic products, the person responsible is also responsible to ensure that the cosmetic product is safe for human use

when applied under normal conditions of use and that the product labels comply with regulatory requirements.

Key responsibility of person responsible:

1. Submit product notification
2. Ensure product safety
3. Recall unsafe products
4. Report product defects and adverse effects; and
5. Submit safety and technical information when requested by HSA

The table below illustrates a few common scenarios on who should be the "responsible person" be under normal circumstances for submitting notification:

Local manufacturer A manufactures its own brand of products and sells them locally to other distributors	Manufacturer A should submit product notification
Company B engages a local manufacturer to manufacture the products for it to make commercial supply in local market	Company B should submit product notification
Importer C imports the products into Singapore and sell them to other distributors for local supply	Company C should submit product notification
Company D engages another company (e.g. freight forwarder) to import the product for it to supply in the local market	Company D should submit product notification
Company E supplies product as a retailer and wishes to be the person responsible for the products he is retailing	Company E should submit product notification

6 PRODUCT NOTIFICATION

The person responsible must inform Health Sciences Authority (HSA) by submitting product notification using the online Pharmaceutical Regulatory Information System (PRISM) system. Acknowledgement of the notification from HSA must be received before the product can be marketed. Subsequent retention of the notification (re-notification) is required every year if the cosmetic product continues to be supplied in the market.

Cosmetic products are not evaluated by HSA. Sellers of cosmetic products are responsible for the safety and quality of their products. Cosmetic products should not contain adulterants or prohibited substances and they should not breach the limits for specified substances.

On-line notification may be made at the following website:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/Cosmetic_Products_Oral_Dental_Gums.html

More information on the procedure for submitting a product notification may be found at the following document:
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Cosmetic_Products/Product%20Notification%20Procedures%20%2021Aug2017.pdf

A new product notification is required if changes are made to the following:

a. Brand name
b. Product name
c. Product type
d. Formulation
e. Company change of distribution rights

For the changes to manufacturer's name and address, that affect more than one product notification, submission under the "Update to Manufacturer's Name & Address" in PRISM is sufficient to effect the change.

A company may select up to a maximum of 20 affected notifications per amendment submitted.

For changes to be made to the name and/or address of company without change of distribution rights (i.e. no change in Registry of Companies & Businesses or RCB number), the company can effect the change via the "amend company information" under amend@PRISM.

Notification need not be submitted if:

- a cosmetic product that is supplied solely as a sample in connection with any advertising, sponsorship or promotional activity; or
- a cosmetic product that is supplied solely for testing or trial use in connection with any research or development of that product; or
- a cosmetic product that is manufactured by or in accordance with the specifications of a medical practitioner, and supplied solely by that medical practitioner for the use of patients under his care.

Nonetheless, compliance with other requirements such as labeling, safety of ingredients and adverse event reporting is still required.

Product notification is intended for cosmetic products. Products notified with HSA that does not meet the cosmetic product's legal definition found in the First Schedule of the Health Products Act maybe removed without notice.

7 RECORD KEEPING

The person responsible is required to keep records relating to the supply of the cosmetic product. The records shall contain information on the name and notification number of the product, name and address of company supplied, and the batch number, date and quantity of product supplied. The records should be kept for 2 years after the date of supply.

The person responsible is required to produce records of supply, safety or technical information of the cosmetic products upon request by HSA when safety concern on the cosmetic product arises. In addition, companies may be required to submit samples of cosmetic products for laboratory testing when requested by HSA, for example to verify the safety or quality of the products. The expenses incurred in the testing will be borne by the companies.

8 PRODUCT DEFECTS AND ADVERSE EVENT REPORTING

The person responsible must report all serious adverse events or product defects to the HSA whenever there is reasonable suspicion or evidence to suggest that the cosmetic product might be the cause of the reaction

If the serious adverse event or product defect has caused death or is life-threatening, the company must report to HSA within 7 days after the company has become aware of the event. The company is required to submit an adverse event report form within the next 8 days.

For the other serious adverse events or product defects, which have resulted in hospitalisation or any persistent or significant disability or incapacity, the company must submit the adverse report form to HSA within 15 days after the company has become aware of the event.

More information on the adverse event reporting and the reporting form can be found in the "Guide Manual for the Industry – Adverse Event Reporting of Cosmetic Products" on our website or contact HSA at the following:

Adverse Event Management Unit
Vigilance and Compliance Branch
Post-Market Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Tel: 6866 1111

For product defects, please contact Cosmetic Control Unit at the following:

Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01 Helios
Singapore 138667

Tel: 6866 1111
Email: HSA_Cosmetics_Control@hsa.gov.sg

9 ADVERTISEMENT

Cosmetic products are intended for the purposes mentioned in Section 2 of this guideline. Product claims to modify a physiological process or to prevent or treat a disease/medical conditions are not permitted in cosmetic products and on advertisements for cosmetic products. In general, any claims made must be justified by scientific data/evidence and/or by the cosmetic formulation or preparation itself.

All advertising claims must be fully substantiated when requested as per the Singapore Code of Advertising Practices (SCAP). Advertising activities should also comply with the principles and guidelines listed in SCAP.

10 FEES

10.1 Notification Fee

From 1 January 2011, the annual notification fees for cosmetic products are as follows:

1.	**Notification fee for Cosmetic Products deemed to be of higher risk[1]**		
	(a)	Single product	$25
	(b)	Variant	
	(i)	First 3 variants	$25/variant
	(ii)	4th and subsequent variants	$5/variant
2.	**Notification fee for Cosmetic Products deemed to be of lower risk[2]**		
	(a)	Single product	$10
	(b)	Variant	
	(i)	First 3 variants	$10/variant
	(ii)	4th and subsequent variants	$5/variant

[1]Cosmetic Products deemed to be of higher risk are cosmetic products to be applied around the eyes, on the lips, hair dyes containing phenylenediamines and oral and dental care products.
[2]Cosmetic Products deemed to be of lower risk are all other cosmetic products not listed above such as skin whitening products, moisturisers, etc.

For retention on the cosmetic product, the above fee is applicable.

10.2 Updates of Manufacturer's Details

The fee for "Update of Manufacturer's Details" of the above details is $15 per amendment. A company may select up to a maximum of 20 affected notifications per amendment submitted.

10.3 Good Manufacturing Practice (GMP) Certificate

Companies who wish to apply for the GMP certificate may refer to the following link:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Certification_Of_Manufacturers_and_Dealers/Good_Manufacturing_Practice_Certificate.html

The fee for the application of GMP certificate is as follows:

1.	**GMP Certificate (non-mandatory)**		
	(1)	Application for GMP certification (3 years' validity)	$4,000
	(2)	Application for issuance of additional certificate	$200

11 PENALTY

When deemed necessary, the Health Sciences Authority may direct that a cosmetic product be withheld from sale and supply, and withdrawn from the market.

Under Regulation 4(3) of the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007 it is an offence for the person responsible to supply a cosmetic product where no prior notification has been submitted for that product. The person responsible shall be liable, on conviction, to a fine not exceeding $20,000 and/or to an imprisonment for a term not exceeding 12 months.

Under the same regulations, a cosmetic product shall not contain prohibited ingredients and undeclared western medicinal ingredients. Please note that it is an offence under Section 16(1) of the Health Products Act, Cap 122D. Individuals or companies found guilty shall be liable, on conviction, to a fine not exceeding $100,000 and/or to an imprisonment for a term not exceeding 3 years.

12 ENQUIRY

For the latest update on regulation of cosmetic products, please visit HSA website.

Enquiries on cosmetic products should be directed to:

Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Tel: 65 6866 1111
Fax: 65 6478 9754
Email: HSA_Cosmetics_Control@hsa.gov.sg

Information on the ASEAN Cosmetic Directive requirements can be found under the following website link:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Cosmetic_Products/Overview/ASEAN_Cosmetic_Directive.html

More details on regulation of cosmetic products can be found at our frequently-asked-questions (FAQ) page located at the following website link:
www.hsa.gov.sg/pub/Faq/Faq/faqcategory/cosmetic-products.aspx

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact:
Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
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