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SINGAPORE
Republic of Singapore

1. **General**

Summary of Legal Authority

The Health Sciences Authority (HSA), a statutory board of the Singapore Ministry of Health, has the authority for the regulation and licensing of cosmetic products intended for human use in Singapore.

Legal Definitions

The definition of a **cosmetic** is an adaptation of the EU definition:
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 (epidermis, hair system, nails, lips, eyes and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, correcting body odours, protecting them or keeping them in good condition. Cosmetic products include skincare products, make-up colours, bath and shower preparations.

With effect from 1 January 2008, the Health Sciences Authority (HSA) has implemented the ASEAN Cosmetic Directive (ACD) by way of the Health Products (Cosmetic Products - ASEAN Cosmetic Directive) Regulations 2007, which is a Subsidiary Legislation under the Health Products Act for the regulatory control of cosmetic products in Singapore.

2. Product Notification

Singapore has implemented the ASEAN Cosmetic Directive (ACD) from 1 January 2008. Under the ACD, any person who introduces a cosmetic product into the local market must notify the Health Sciences Authority (HSA) before the supply and/or sale of the cosmetic product. The person also has to ensure that the cosmetic product is safe for human use when applied under normal or reasonably foreseeable conditions of use, and does not contain any banned or restricted substances stipulated for cosmetic products as listed in the legislation.

The company or person responsible for placing a cosmetic product in the market must notify the Health Sciences Authority (HSA) using the online Pharmaceutical Regulatory Information System (PRISM). Acknowledgement of the notification from HSA must be received before the product can be marketed. Subsequent re-notification is required every year if the cosmetic product continues to be supplied in the market.

Notification is not required for cosmetic products that are supplied as sample for advertising or promotional activity, supplied for testing or trial use for research and development or supplied by medical practitioners for the use by patients under his/her care. However, compliance with other ACD requirements is necessary e.g. labeling, safety of ingredients and adverse event reporting.

Importers and manufacturers do not need to apply for a manufacturer's or importer's license.

Products

Higher Risk

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.

Lower Risk

Cosmetic Products deemed to be of lower risk are all other cosmetic products not listed above such as skin whitening products, moisturizers, etc.

Sample Testing

Companies are required to submit samples of cosmetic products for laboratory testing when requested by the Health Sciences Authority, for example to verify the safety or quality of the products. The expenses incurred in the testing will be borne by the companies.

Electronic Submission of Notification Submission
On-line notification may be made at the following website:
http://www.hsa.gov.sg/publish/hsaportal/en/services/prism/cosmetics.html

Companies may submit their notifications via their own computers or at Do-It-Yourself (DIY) kiosk available at:
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Tel: 65 6866 3474/75
Fax: 65 6478 9754

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

a) Brand name
b) Product name
c) Product types
d) Intended use
e) Formulation
f) Company change of distribution rights

For the following type of change that affects more than one product notification, one submission under the "Global Update" in the PRISM is sufficient to effect the change:

a) Manufacturer
b) Assembler
c) Importer
d) Store/ warehouse address

For changes to be made on the name and/or address of the 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.

For changes to be made on change of person representing the company, the company can amend the change through the Client Registration and Identification Services (CRIS@hsa).

Record Keeping
The person responsible for placing a cosmetic product in the market is required to keep records on the supply of the cosmetic product. The record shall contain information on

the name and notification number of the product, name and address of person supplied, and the batch number, date and quantity of product supplied. The records should be kept for 2 years after the date of supply.

Product Information File (PIF)
Information about the cosmetic product is also to be kept in a Product Information File (PIF), which is retained for a minimum period of 3 years after the product is last placed in the market. Upon specific requests from the Authorities, PIF should be made available and accessible to the Authorities for audits within an agreed upon timeframe usually 15 to 60 calendar days or shorter, depending on the urgency of the audit. Audits may be conducted routinely or on an ad-hoc basis by the regulatory authority.

Adverse Event Reporting
A company must report all serious adverse events to the health authority at the following address, whenever there is reasonable suspicion or evidence to suggest that the cosmetic product might be the cause of the reaction:

Adverse Event Management Unit
Vigilance Branch
Vigilance, Compliance and Enforcement Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Tel: 68663530/ 68663531

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

Product Information File (PIF)
Companies placing a product on the market are requested to have a Product Information File readily available for Authorities to audit.
For convenience purpose, the PIF may be divided into 4 parts as per the table below. In case of audit, the Part 1 of the PIF must be readily available. Documents from other parts, if requested by the Authorities, will have to be made available within a reasonable and mutually agreed timeframe.

Table -Product Information File for Cosmetics

Product Information File (PIF)	**Information**
Part 1- Administrative Documents and Product Summary	**To be readily available upon request**
A) Administrative Documents	-Copy of the Notification form bearing the acknowledgement receipt from the Authorities; this will include the identity of the product, the address of the manufacturer, assembler, importer and company -Any other relevant administrative documents that may be prescribed by the local Authorities e.g. Certificate of Incorporation of the Company;
B) Qualitative and Quantitative formula of the product (INCI or other ACD approved reference names and corresponding concentrations of the ingredients)	-For fragrance materials, name and code number of the composition and the identity of the supplier
C) Product presentation and label	-Outer and inner labels (photographs and/or drawings will be useful); -Consumer information leaflets and instructions for use if part of the product as sold to the consumer
D) Manufacturing Statement	- A statement by the manufacturer or company that the product was manufactured according to the ASEAN GMP Guidelines or any ACC approved equivalent GMP Guidelines; -Provide the batch coding system/ key of the product

E) Safety Assessment (summary) as per the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product	-Safety statement (signed statement of opinion, including the name and qualifications of the safety assessor)
F) Confirmed undesirable effects on human health (summary)	- Health related consumer complaints recorded
G) On-pack product claim support (summary)	-Summary report of the Efficacy Assessment of the product, based on its composition or on tests performed
Part II: Quality Data of Raw Materials The second part of the PIF should include full technical information on the quality of the raw materials/ ingredients **Part III: Quality Data of Finished Product** The third part of the PIF supplies the detailed technical information on the quality of the finished product **Part IV: Safety and Efficacy Data** The fourth and final part of the PIF provides detailed information on the safety assessment and data of the finished product and also relevant efficacy data to support any claims made on the product	**Upon specific request, any other document should be made available to the Authorities within an agreed timeframe i.e. 15 to 60 calendar days (can be shorter depending on the urgency)**

3. Ingredient Restrictions

The ASEAN Cosmetic Directive contains several technical documents pertaining to cosmetic regulations that are applicable to all products placed in the ASEAN market. One such technical document is a detailed list of ingredients that states whether an ingredient can or cannot be used in cosmetics. There are 5 ingredient annexes:

Annex II is a list of prohibited ingredients i.e. ingredients that must not be added to cosmetic products. They are not allowed beyond "unavoidable traces in Good Manufacturing Practice";
Annex III is a list of ingredients that cannot be used in cosmetic products beyond the limits and/or outside the conditions laid down (also called list of restricted substances);
Annex IV is a list of permitted coloring ingredients (except hair colors) that can be used in cosmetics. Each color is listed with its conditions of use;
Annex VI is a list of preservatives allowed to be used in cosmetics. Each preservative is listed together with limits and conditions of use, as well as warnings to be labeled if required;
Annex VII is a list of UV filters allowed to be used in cosmetic sunscreen products. Each UV filter is listed with limits and conditions of use, as well as warnings to be labeled if required;

4. **Labeling**

General Labeling Requirements
Labeling is required for all cosmetic products. Labels must be in English and be clearly legible. The label must be prominently and conspicuously displayed on the product at the point of sales.
In cases 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, shrink wrap, etc. shall be allowed. However, the name of cosmetic product and the manufacturer's batch number must appear on the container or immediate package.

Table -Labeling Requirements for COSMETICS

	Primary (inner) packaging	Secondary (outer) packaging	Comments
Name of Cosmetic Product and its function, unless it is clear from the presentation of the product.	Yes	Yes	
Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation.	Yes, if there is no outer packaging	Yes	
Full ingredient listing specified using the	Yes, if there is no	Yes	Ingredients in concentrations of less than 1% may be listed in any

nomenclature from the latest edition of standard references. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavor".	outer packaging		order after those of concentration of more than 1%. Coloring agents may be listed in any order after the other ingredients, in accordance with the color index number or denomination adopted in Annex IV. For decorative cosmetic marketed in several color, all coloring agents used in the range may be listed, provided that the terms "may contain" or "+/-"be added.
Country of manufacture	Yes, if there is no outer packaging	Yes	
Name and address of the company or person responsible for placing the product on the market.	Yes, if there is no outer packaging	Yes	
Contents given by weight or volume, in either metric or both metric and imperial system.	Yes, if there is no outer packaging	Yes	
Manufacturer's batch number	Yes	Yes	
Manufacturing or expiry date of the product in clear terms (e.g. month/year) Indication of expiry date shall be mandatory for cosmetic products with minimum durability of which is less than 30 months.	Yes, if there is no outer packaging	Yes	The date shall be clearly expressed and shall consist either of month and year or the day, month and year in that order. It should be preceded by the words "expiry date" or "best before".

Special precautions to be observed in use, especially those listed in the ASEAN Cosmetic Directive Annexes.	Yes, if there is no outer packaging	Yes	

Nomenclature of Ingredient
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 extracts of botanicals should be identified by its genus and species.

Product Claims
A claim can be a word, a sentence, a paragraph or simply an implication. A cosmetic cannot have specific claim for alleviating, treating, curing or preventing a disease or symptoms of a pathological condition. The following guidelines help determine if product will be classified as cosmetics or therapeutic.

a. Composition of Cosmetics
   The product should contain only ingredients that comply with the ASEAN Cosmetic Directive annexes, and does not contain any banned ingredients.

b. Target site of application
   The product should be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity.

   Products that are intended to be ingested, injected or placed in contact with other parts of the human body e.g. the mucous membranes of the nasal passage or the internal genitalia cannot be considered to be cosmetic products.

c. Intended main function of cosmetics
   The product should be applied to the permitted parts of the human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

d. Product presentation of cosmetics
   The product should not be presented as treating or preventing disease in human beings.

e. Physiological effects of cosmetics

Every product that has an effect on the functioning of the body also has an effect on its metabolism. Cosmetic products typically have effects that are not permanent, and have to be used regularly to maintain their effects.

Advertising Claims

All Cosmetics advertisements should be legal, decent, honest, and truthful. The general rule is that marketing & advertising of cosmetic products, texts, name, trademarks, pictures and figurative or other signs cannot be used to imply that the products have characteristics or functions which they do not have.

a. Claims that a product contains ingredients with special properties should be supported by acceptable evidence that the ingredients are beneficial for the purpose referred to.

b. Advertisements should not contain any claim or implication that any preparation will promote rejuvenation (i.e. remove, reverse or retard the physiological and degenerative conditions brought about by or associated with increasing age) of the skin or muscles, or that hormones or vitamins remove or delay the formation of wrinkles.

c. Claims that a cosmetic product has a particular physiological effect should be backed by evidence specifically directed at establishing this within the context of established scientific knowledge. When the effect claimed is of a novel unique kind, such substantiation should include data from practical trials, on human subjects, of adequate rigour in both design and execution.

d. When any specific physiological or biological effect is attributed to the inclusion of a particular ingredient or ingredients in a cosmetic, substantiation should address the need adequately to distinguish between the effect(s) caused by the ingredient(s) concerned and those caused either by other elements in the formulation of the cosmetic, or by its mode of application.

e. It should not be claimed that products which confer a cosmetic benefit through their (partial) absorption by the skin offer any systemic nutritive benefit.

f. No advertisement should contain any claim to provide rejuvenation, that is to prevent, retard or reverse the physiological changes and degenerative conditions brought about by, or associated with, increasing age.

g. Statements relating to changes in the structure or renewal rate of skin cells should not exaggerate the effect of such changes on the general appearance of the skin.

5. **Packaging Restrictions/Requirements**

Standard Sizes

Packaging is regulated generally under the Consumer Protection Act.

There are no specific restrictions on the raw material content of packaging and no requirement to encode the material of construction on the package.

Testing Requirements

Testing of cosmetic products is required from time to time upon request by the Controlling Authority.

6. **Regulatory References**

- Ministry of Health's Drugs Act of 1975;

- Food & Drugs Regulation of 1957, as amended in 1970;

- The Medicines (Cosmetic Products)(Specification and Prohibition) Order of 1996 and its amendments.

- The Medicines (Cosmetic Products) (Licensing) Regulations of 1996;

-The Medicines (Cosmetic Products) (Labeling) Regulations of 1996;

- Poisons Act 1999/Poisons Rules of 1978, as amended in 1980, and revisions,

- Consumer Protection Act of 1987;

- Weights and Measures (Prescribed Quantities of Prepackaged Goods for Sale by Retail) Amendment Order of 1980, and Act 1985, and its revisions.

-Health Products Act (Amendment of First Schedule) (No.2) Order 2007

-Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007

-Health Products (Cosmetic Products – ASEAN Cosmetic Directive) (Amendment) Regulations 2010

Sources of printed information:

Singapore National Printers (LTDSNP)
303 Upper Serangoon Road 97 Obi Avenue 4
Singapore 1334 408754
Phone: (65) 282-0611 8463915
Fax: (65) 382-73607447098
Web site: www.myepb.com
http://www.egazette.com.sg/egazette/welcome.asp

7. **Contacts/Sources of Information**

Government agency in charge of cosmetics

Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01 Helios
Singapore 138667
www.hsa.gov.sg
Tel: 65 6866 3474/65 6866 3475
Fax: 65 6478 9754
Email: HSA_Cosmetics_Control@hsa.gov.sg

Cosmetic Industry Association

The Cosmetic, Toiletry & Fragrance Association of Singapore (CTFAS)
Bukit Batok Central Post Office
PO Box 034
Singapore 916502
Email : regulatory@ctfas.org.sg
www.ctfas.org.sg

Sources of Information on the Internet

Health Sciences Authority

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/cosmetic_products.html