

Cosmetic Product Regulations



The Health Sciences Authority has implemented the ASEAN Cosmetic Directive under the Health Products Act for the regulatory control of cosmetic products, with effect from 1 January 2008. The ACD harmonises all cosmetic regulatory matters in ASEAN countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam). The Cosmetics Control Unit of the HSA is responsible for the administration of the regulations for cosmetic products in Singapore.

The Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007 governs the control of cosmetic products in Singapore.

Generally, any company or person who introduces a cosmetic product into the Singapore market must ensure that the cosmetic product is safe for human use when applied under normal conditions of use, and does not contain any banned or restricted substances as stipulated in the ACD Regulations.

Definition of Cosmetic Products

A cosmetic product is defined as "any substance or preparation that is intended to be placed in contact with the 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, exclusively or mainly for cleansing, perfuming, altering the appearance,

Awards

Ranked Band 1 for Life Sciences
Chambers Global rankings 2014 - 2020

Ranked Band 1 for Intellectual Property
Chambers Global 2009 - 2020

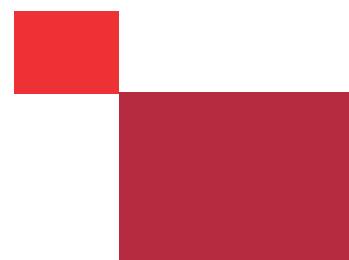
Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2019

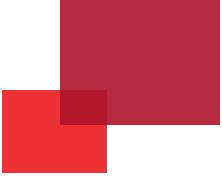
Tier 1 Intellectual Property Firm in Asia
ALB IP Rankings 2018 - 2019

Asia Pacific IP Firm of the Year
Managing IP Asia Pacific Awards 2018 - 2019

Ranked Band 1 for Intellectual Property Firm in Singapore
Chambers Asia Pacific 2010 - 2020

Ranked Tier 1 for Intellectual Property Firm in Singapore
Legal 500 Asia Pacific 2010 - 2019





correcting body odours and protecting or keeping them in good conditions".

The following is a non-exhaustive illustrative list on the types of cosmetic products:

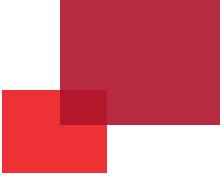
- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.);
- Face masks (with the exception of chemical peeling products);
- Tinted bases (liquids, pastes, powders);
- Make-up powders, after-bath powders, hygiene powders, etc.;
- Toilet soaps, deodorant soaps, etc.;
- Perfumes, toilet waters and eau de cologne;
- Bath and shower preparations (salts, foams, oils, gels, etc.);
- Depilatories;
- Deodorants and antiperspirants;
- Hair care products;
 - Hair tints and bleaches;
 - Products for waving, straightening or fixing;
 - Setting products;
 - Cleaning 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;
- Products for the 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; and
- Anti-winkle products

Product forms and types not listed above should be considered against the definition of a cosmetic product.

Product Notification

The company or person responsible for placing a cosmetic product on the market must notify HSA prior to the product being placed on the market. Acknowledgement of such 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.

However, such notification is not required for cosmetic products that are supplied as samples for advertising or promotional activities, supplied for



testing or trial use for research and development or supplied by a medical practitioner for the use of patients under his care. However, compliance with other ACD Regulations is necessary e.g. labelling, safety of ingredients and adverse event reporting.

Any person who contravenes the above, makes a false statement, or provides misleading information in a notification shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 and/or to imprisonment for a term not exceeding 12 months.

Labelling Requirements

Labelling in English is required for all cosmetic products. The following information must appear on the container or package of the cosmetic products:

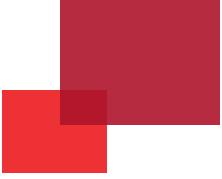
- Name of cosmetic product;
- Function of cosmetic product;
- Instructions for use;
- Full ingredients listing;
- Country of manufacture;
- Contents (weight/volume);
- Batch number;
- Manufacturing/expiry date (expiry date is required for products with less than 30 months durability);
- Name and address in Singapore of company responsible for placing the product in the market; and
- Special precautions, if any.

Record Keeping & Product Information File

The company or person responsible for placing a cosmetic product on the market is required to keep records of the supply of the cosmetic product, including information on the name and notification number of the product, name and address of person supplying the product, and the batch number, date and quantity of product supplied. The records should be kept for 2 years after the date of supply.

Information about the cosmetic product is also to be kept in a Product Information File, which is retained for a minimum period of 3 years after the product is last placed on the market. Upon request from the HSA, the PIF should be made available and accessible for audits within an agreed 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 HSA.

Any person who contravenes the above shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 and/or to imprisonment for a term not exceeding 6 months. Further, any person



who furnishes any record which he knows is false or misleading shall be guilty of an offence, and shall be liable on conviction to a fine not exceeding \$20,000 and/or to imprisonment for a term not exceeding 12 months.

Adverse Event Reporting

The company or person responsible for placing a cosmetic product in the market must report all serious adverse events to HSA whenever there is reasonable suspicion or evidence to suggest that the cosmetic product might be the cause of the reaction. In particular, 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 report form to HSA within 15 days after the company has become aware of the event.

Any person who contravenes the above, makes a false statement, or provides misleading information shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 and/or to imprisonment for a term not exceeding 12 months.

Advertisement of Cosmetic Products

Under the ACD Regulations, no company or person is allowed to, whether expressly or by implication, advertise that a cosmetic product has a therapeutic benefit or can be used for a therapeutic purpose. Further, no claims can be made which would be likely to create an erroneous impression regarding the formulation, composition, quality or safety of the cosmetic product.

Separately, all advertisements for cosmetic products should also comply with the Singapore Code of Advertising Practice. The Code, which is administered by the Advertising Standards Authority of Singapore, regulates local advertising activities in general, and is not aimed at specific industries. The scope of the Code extends to any form of commercial communication for any goods or services, regardless of the medium used, including advertising claims on packs, labels and point of sale material, as well as internet advertisements.

Although the Code does not have statutory force, it should be noted that the ASAS may impose sanctions upon determination of a breach of the Code (including withholding advertising space or time from advertisers, as well as adverse publicity from its investigation reports).

The general principles and/or guidelines of the Code that are commonly applicable to cosmetic products are highlighted below:

- Truthful presentation: Advertisements should not mislead in any way by inaccuracy, ambiguity, exaggeration, omission or otherwise.

- **Claims:** Advertisements should not misuse research results or quotations from technical and scientific publications. Statistics should not be presented so as to imply a greater validity than they really have. Scientific terms should not be misused; scientific jargon and irrelevancies should not be used to make claims appear to have any scientific basis which they do not possess.
- **Matters of fact:** All descriptions, claims and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation.
- **Use of research results:** When a factual claim in an advertisement is said to be supported by the results of independent research, the advertiser and sales promoter should be able to show that those responsible for the research accept the advertisement as an accurate account of the research.
- **Use of testimonials:** Advertisements should not contain or refer to any testimonial or endorsement unless it is genuine and related to the personal experience of the party who provided the testimonial or endorsement. Testimonials or endorsements which are exceptional experiences (i.e. which do not reflect the experience that an average user of the product would ordinarily expect to have) should not be used. Advertisers and advertising agencies are required to show substantiation that such testimonials or endorsements reflect the typical experience of ordinary users.

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