

GUIDELINES FOR REGISTRATION OF COSMETICS IN SRI LANKA

The objective of regulation of cosmetics is to provide safe and quality cosmetics to the people of Sri Lanka, at a standard equal to that of comparable countries. To achieve this, regulators and industry should work together to meet common goals. The purpose of this guideline is to provide guidance and inform marketing authorization holders and consumers on the methods and criteria employed by the regulatory authorities on determining the suitability for registration as a cosmetic, describes the requirements for registration and how applications should be made.

The basis for the regulatory control comes from the Cosmetics, Devices and Drugs Act No. 27 of 1980. All cosmetics marketed in the country whether manufactured here or imported must be registered in compliance with the regulations published under the authority of these laws (Regulation No 38 of 1984).

OBJECTIVE OF REGISTRATION

- To ensure that cosmetic products in Sri Lanka are safe and not injurious to health.
- To prohibit the use of certain toxic substances as ingredients in cosmetic products.
- To ensure that cosmetic products are properly labelled with batch markings and listing of ingredients used.

DEFINITIONS

AMENDMENTS TO THE Definition in the Cosmetics, Devices and Drugs Act No. 27 of 1980

as any substance or preparation or device intended to be applied to the human body for cleansing, improving or altering the complexion, skin, hair, teeth or mucous membranes of the oral cavity without affecting the body's structure or function.

Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, nail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colours, tooth pastes, deodorants and any ingredient intended for use as a component of a cosmetic products and cosmetic devices. Soap products making no label claim of human use are not considered as cosmetics under the law.

PRODUCT

An ingredient(s) in a cosmetic dosage form having a singular identity, composition characteristic and origin

PRODUCT VARIANT

For the purpose of this guideline product variants shall mean "items in a range of cosmetic products which are produced by the same manufacturer that are similar in composition and are intended for the same use but are available in different colours, fragrances or flavours".

- Colour shall mean a substance used as an ingredient of cosmetic product solely to give colour to the product
- Fragrance shall mean a substance used as an ingredient of cosmetic product solely to impart odour to the product and
- Flavour shall mean a substance used as an ingredient of cosmetic product solely to impart taste to the product.

NATURAL PRODUCT COSMETICS

Products formulated from herbs, animal and mineral must be registered with the CDDA if intended to be used as a cosmetic.

WHEN DOES A COSMETIC BECOME A DRUG?

Products that are cosmetics but also exert a therapeutic effect (intended to treat or prevent disease, or affect the structure or functions of the body) will be considered to be a medicine irrespective of whether therapeutic claims are made on the label or in advertising material. Even if a product is intended for marketing as a cosmetic it would be determined to be either "cosmetic" or "medicine" depending on;

- Its Ingredients
- Its route of administration
- Therapeutic claims made on its label / or in advertising

One of the main factors in determining whether a product is a cosmetic or a medicine, is on the claims made for the product. There are also several indicators that a cosmetic product has a proposed therapeutic use. Intended use may be established in a number of ways. Among them are:

- **Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials.** Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells.
- **Consumer perception, which may be established through the product's reputation.** This means asking why the consumer is buying it and what the consumer expects it to do.
- **Ingredients that may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use.** An example is fluoride in toothpaste.

This principal also holds true for essential oils in fragrance products. A fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use.

Such products must comply with both the drug and cosmetic provisions of the law.

REGULATION OF COSMETIC PRODUCTS

The government of Sri Lanka regulates the manufacture, sale and importation of cosmetic products by requiring that all cosmetic products be registered before they can be manufactured, supplied, distributed or sold. The details of the registration procedures can be found under the proceeding topics

WHO SHOULD APPLY FOR A PRODUCT LICENCE

Person(s) who import or manufacture cosmetic products or have products imported or manufactured on their behalf are responsible for applying to the Drug Regulatory Authority (DRA), to have their products registered. The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product

PRODUCTS FROM MULTIPLE SOURCES

Products with the same formulation and the same name but sourced from different manufacturing sites shall be registered separately.

HOW AND WHERE TO FILE

Application forms are available from the DRA. The duly completed application should be submitted in English in a hard cover file in duplicate to the DRA, 120 Norris Canal Road, Colombo 10.

If more than one application is submitted, there shall be no cross reference from one application to another, i.e. information supplied in one application and also required in other applications shall be repeated in those other applications. For products classified under the category “Product Variant” shall be allowed to be registered under one application but with separate fees for each variant.

TEST MARKET SAMPLING OR SAMPLES FOR STUDY PURPOSE

The industry maybe allowed manufacturing or importing unregistered products for the sole purpose of a selective test sampling or clinical studies before its registration. However, prior approval from the DRA must be obtained for such activities.

RESPONSIBILITY OF REGISTRATION HOLDER

The registration holder either manufacturer or importer must in writing declare that they are responsible for ensuring safety quality and efficacy of the registered cosmetic product and that the product complies with all existing regulations. Responsibilities include

- Using raw materials which are safe and at the allowed concentration
- Practicing good manufacturing practices
- Ensuring appropriate packaging material is used to guarantee quality of product
- Executing suitable quality control
- Having effective procedure for handling any adverse effects that may occur with the product when used

VALIDITY OF REGISTRATION

Full Product Registration

Full registration of a cosmetic will be valid for a period of 5 years. Renewal of registration to be done every five years.

Provisional registration

Under certain circumstances provisional registration may be granted for a period of one year. Provisional registration will be granted for a

- New cosmetic product
- New manufacturer
- New formulation of an existing product
- Products which have been suspended due to quality problems will be given provisional registration on reapplication for registration

Applications that do not provide the required documentation as outlined above for registration of a cosmetic product will not be granted provisional registration pending submission. The registration process will be stopped at that moment of time till all documents are furnished

AMMENDMENTS OR CHANGE IN A REGISTERED COSMETIC

Following registration of a cosmetic, the holder of the certificate of registration should notify the authorities of

- any material changes that have been made or that are proposed to be made to the relating to the registered cosmetic product
- any new information regarding the safety of the cosmetic product or active ingredients/ excipients used in the product.

DOCUMENTS WHICH MUST ACCOMPANY APPLICATION FORMS FOR REGISTRATION OF A COSMETIC

The application should contain all the information detailed below in support of their proposal to register a cosmetic product

- Name and address of applicant
- Status of applicant : Manufacturer / Importer
- Name and address of manufacturer
- Name and address of person responsible for marketing the cosmetic
- Name of cosmetic : Brand name / Official or Approved name
- Classification of cosmetic : Controlled / General (Refer Annexure 1)
- Product category of cosmetic: Refer Annexure 11
- Formulation and package content:
- Composition:
- Certificate of analysis from a laboratory acceptable to the DRA Sri Lanka (Refer Annexure).
- Certificate of free sales (CFS) - certificate from the health authority or a recognized body of the country in which the cosmetic is produced confirming that the cosmetic is in use there and the period of use, if not available state reasons.
- Fully packed sample of the cosmetic in the form that it will be offered for sale
- A sample of the label used in the containers and
- A sample of the package insert
- For controlled cosmetics a certification of observance to Good Manufacturing Practices (GMP) - This certificate must be from the country of manufacture and issued by the health authority or recognized body.

All supporting documents in languages other than English must be translated to English.

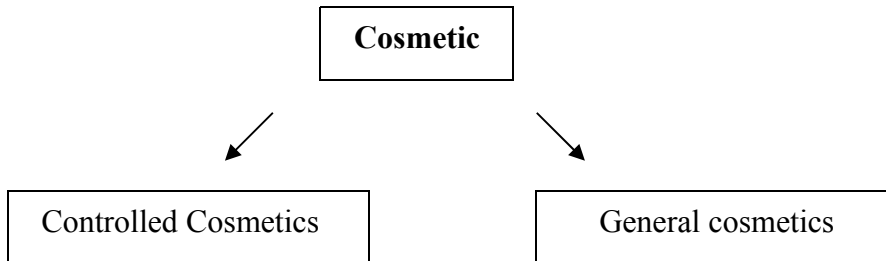
In addition the company shall

- Submit the smallest possible pack size of the product.
- Submit labels, package inserts and outer carton of each pack size if the label contents and presentations are different.

Additional details regarding the application shall be submitted if and when requested by the Licensing Authority.

CLASSIFICATION OF COSMETICS

For the purpose of registration, cosmetic products will be categorised according to their level of risk into two groups.



CONTROLLED COSMETICS

They are cosmetic products that have the potential to be absorbed through the skin or mucous membrane or contain substances that maybe harmful or are promoted for use in children. This category is subject to stringent control.

The Controlled Cosmetics are listed in Annexure 1.

GENERAL COSMETICS

All cosmetic products not listed under controlled cosmetics

COSMETIC PRODUCT CATEGORIES

Cosmetics shall be further categorised according to the intended purpose of use.

The “Cosmetic Product Categories” are listed in Annexure 2

EVALUATION PROCEEDURE OF A COSMETIC PRODUCT

COSMETIC EVALUATION SUBCOMMITTEE (CESC)

All properly submitted applications for registration as cosmetics will be reviewed by the Cosmetic Evaluation Subcommittee (CESC) appointed by the Cosmetics, Devices and Drugs Technical Advisory Committee (TAC). The CESC will meet regularly on scheduled dates once every 4 - 6 weeks and review the applications according to a established review procedure. Minutes of each meeting will be maintained. At each meeting the minutes of the previous meeting will be confirmed and sent to the TAC. The decision of the CESC will be communicated in writing to the applicant. In case of a negative decision a clearly stated reason (s) for the negative decision will be communicated to the applicant. In the case of a provisional registration any requirement and suggestions of the CESC will be communicated to the applicant.

ELEMENTS OF THE REVIEW PROCESS

Basic Criteria for a cosmetic product

A cosmetic product should fulfill at least the following three criteria

1. Active ingredient (s): The active ingredient should have low inherent toxicity (e.g. no carcinogenic properties, minimal allergenic effects) relevant for human use unless such a hazard can be appropriately addressed by labelling).
2. Intended use: Should be appropriate for classification as a cosmetic.
3. Product properties: The product should not have an unfavorable adverse event profile that needs physician's supervision during use. Claims that indicate the product is a therapeutic agent cannot be made for a product marketed as a cosmetic.

If the cosmetic meets the three basic criteria it will also need to comply with relevant statutory standards, meet labelling requirements, and compliance of manufacturing process with the Sri Lanka / WHO code of Good Manufacturing Practice (GMP).

ASSESSMENT OF QUALITY, SAFETY, STABILITY AND EFFICACY

Different kinds of evidence such as traditional use or epidemiological data and registration in reference authorities will be taken into account when evaluating for Safety, Quality, Stability and Efficacy.

GENERAL COSMETICS

A cosmetic will be assessed with reference to the following:

1. The list of prohibited / allowable ingredients / preservatives / colourants as specified in the Sri Lanka Standards (SLS 457 part 1 and 11), European Union (EEC) Cosmetics Directives, or standard reference texts and the knowledge and experience of the Cosmetic Evaluating Subcommittee (CESC)
2. "Finished Product Specification" as specified in the Sri Lanka Standards Finished Product Specification / or a Reference Authority (UK, USA, EEC, Australia, India). An analytical certificate from laboratories

acceptable to the CESC (see annexure 2) should be provided. If the product contains ingredients not included in official lists their specifications and testing methods should be included

3. Sterility: Cosmetics need not be sterile, however, they must not be contaminated with microorganisms, which may be pathogenic, and the density of non -pathogenic micro- organisms should be low. In addition, cosmetics should remain in this condition when used by consumers. The cosmetic will have to conform to the accepted microbial limits as specified by the Sri Lanka Standards Institute / Reference Authority.
4. Stability data for the cosmetic should be furnished.

CONTROLLED COSMETICS

In addition to the above a controlled cosmetic will be assessed with reference to the following:

5. Adherence to Good Manufacturing Practices (GMP)
6. Cosmetics authority strongly urges controlled cosmetic manufacturers to conduct whatever toxicological or other tests as appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, it should bear the statement.

“Warning - The safety of this product has not been determined.”

PACKAGING

Liquid oral hygiene products (e.g. mouthwashes, fresheners) and all cosmetic vaginal products (e.g. pessaries, tablets) must be packaged in tamper resistant packages when sold at retail .The package is considered tamper resistant if it has an indicator or barrier to entry which if breached or missing alerts a consumer (e.g. shrink or tape seal, sealed carton, tube or pouch aerosol container) that tampering has occurred. The tamper resistant feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper resistant feature.

ADULTERATED / MISBRANDED / COUNTERFEIT COSMETIC

A cosmetic will be considered adulterated if it contains a substance which may make the product harmful to consumers under normal conditions of use, if it contains a filthy, putrid or decomposed substance, if it container is composed of a harmful substance, or if it is manufactured or stored under unsanitary conditions, or contains a non - permitted colour. Rigorous adherence to Good Manufacturing Practices (GMP) guidelines is expected at all times of manufacture and storage.

A cosmetic will be considered misbranded if its labelling is false or misleading, if it does not bear the required labelling information, or if the container is made or filled in a deceptive manner.

A cosmetic will be considered counterfeit if it is deliberately and fraudulently mislabeled with respect to identity and /or source.

LABELLING REQUIREMENTS

The containers of all cosmetics imported, manufactured, processed or packed locally or sold or exposed for sale should have labels bearing the following information.

GENERAL COSMETICS

- The brand name, type of product / Botanical names of ingredients will not be permitted as brand names
- Product category
- The weight / volume of contents
- The date of manufacture
- If it is not stable for at least 36 months include “Best used before” / Expiry date - The date should be clearly stated and shall consist of the month and the year in that order
- The batch number or lot number assigned by the manufacturer
- The product registration number (optional)
- Country of manufacture and the name and address of the manufacturer
- The name and address of the company or person responsible for marketing the product locally.
- The function of the product unless it is clear from the presentation of the product
- Instructions on use unless it is clear from the product type or presentation
- Special precautions to be observed in its use
- Warning statements (See Annexure 4)

CONTROLLED COSMETICS

In addition to the labelling requirement stipulated above, cosmetics classified as “ controlled cosmetics” are required to bear

- An ingredient declaration.

Ingredient names used should be specified according to nomenclature in the International Cosmetic Ingredient Dictionary (INCI), British Pharmacopoeia (BP), United States Pharmacopoeia (USP), Chemical Abstracts Service (CAS) or such other approved nomenclature. The ingredient declaration must be conspicuous, so that it is easily read at the time of purchase. It may appear on any information panel of the outer container or if not packaged in an outer container on the jar, tube or bottle containing the product. The declaration may also appear on a tag or card that is firmly affixed to the container. The name of each ingredient used should be declared in descending order of predominance except that fragrances or flavour may be listed as fragrance or flavour. A cosmetic will be considered to be misbranded if its labelling is false or misleading or does not bear the required labelling information.

The source of any bovine-derived materials used, as ingredients in cosmetic products must be declared in both controlled / general cosmetics. The information should include the type of bovine-derived materials used i.e. type of tissue or organ used and the country of origin of the bovine-derived materials.

LANGUAGE AND LETTER SIZE FOR LABELS

All items should have their labeling at least in the English language, but preferably in all three languages (English, Sinhala, and Tamil). The letters of which, must not be less than 0.75mm high in the case of a small label, not less than 1.5mm high in any other case of an inch in height.

FORMAT FOR CONSUMER INFORMATION

Consumer product information when deemed necessary by the CESC will be in the following formats.

Directions on use

Warnings e.g.; Do not use this product if you are-----

Ask the doctor before use -----

Stop using this product if -----

Therapeutic claims either actual or implied are not appropriate in the labelling of cosmetics

Annexure V contains examples of claims that are cosmetic - oriented and will be acceptable the authority.

COSMETIC ADVERTISING

- ◆ No person should advertise any cosmetic / cosmetic device which is not registered with the Authority
- ◆ No person shall import into the country advertising material of any cosmetic, which is not registered with the Authority.
- ◆ No person shall make any false or exaggerated claim for any cosmetic or misuse research results or quotations from scientific literature to support such claim
- ◆ All advertising material should be sent to CESC for approval before advertising on the public media.
- ◆

REPORTING OF ADVERSE REACTIONS

The registration holder or consumer is requested to inform the DRA any adverse reaction (s) due to the registered product immediately. Reports should include details of

- The complainants name, address and contact telephone number
- Details of the reaction

ANNEXURE 1

Cosmetics will be broadly classified as

- Controlled cosmetics
- General cosmetics

CONTROLLED COSMETICS :

These include products that have the potential to be absorbed through the skin or mucous membranes and baby products.

- Products for application in the area around the eyes (except eye brow products)

Oral care products -the only benefits claimed to result from the use of the product must be consequential on improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and

(b) benefits in relation to other diseases or ailments, eg gum or other oral disease or periodontal condition, must not be claimed to result from use of the product

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- Hair dyes containing phenyldiamine, toluenediamine, their salts and derivatives
- Hair growth promoters
- Sun - tanning preparations intended to protect against sunburn – not be presented as having a sun protection factor of more than 15; and not be presented as water-resistant not have a therapeutic claim ,including any representation about skin cancer, made for it;
- Skin lightener products

Anti - Dandruff agents -The product must be presented as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp

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- Baby products
- Lip products
- Vitaminised / Hormone / Placenta containing products
- Healthcare antiseptic products
- Pediculocide shampoo
- Anti perspirants / Deodarants

- Medicated soaps
- Insect repellants

GENERAL COSMETICS :

Cosmetics which are not listed under controlled cosmetics

ANNEXURE 2

Accredited laboratories

ANNEXURE 3: LABEL WARNINGS

EXAMPLES OF WARNING STATEMENTS

- Identifying a product as being intended for use exclusively by adults are :
“Keep out of reach of children or for adult use only.

- Aerosol Products - Cosmetic aerosol products must bear the following label statement

Warning - Avoid spraying in eyes. Contents under-pressure. Do not puncture or incinerate. Do not store at temperature above 120 degree. F. Keep out of reach of children.

- ***Feminine Deodorant Sprays***

Products whose labelling states or suggests that the product is for use in the female genital area or for use all over the body must bear the following label statement.

For external use only. Spray at least 8 inches from skin. Do not apply to broken, or irritated, or itching skin.

Persistent, unusual odour or discharge may indicate conditions for which a physician should be consulted.

Discontinue use immediately if rash, irritation, or discomfort develops.

- ***Bubble Bath Products***

A foaming detergent bath product (bubble bath product) is defined as any product intended to be added to the bath for the purpose of producing foam and containing a surface active agent serving as a detergent or foaming agent. Children’s bubble bath products, and all foaming detergent bath products, not labelled as intended for use exclusively by adults, should bear adequate directions for safe use and this caution:

Use only as directed. Excessive use or prolonged exposure may cause irritation to the skin and urinary tract.

Discontinue use if rash, redness, or itching occur. Consult your physician if irritation persists. Keep out of reach of children.

- ***Hair dye Products***

A hair dye products should bear a statement_

This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should be first be made. This product must not be used for dyeing the eyelashes or eyebrows, to do so may cause blindness.

▪ ***Depilatories and Hair Straighteners -***

Should provide explicit warnings and directions for safe use.

▪ ***Products containing Oestrogenic Hormones placental Extract or Vitamins***

Products containing estrogen, estrone, estradiol, progesterone, placental extract or vitamins may be considered drugs, particularly if the label declaration is supplemented with standards implying prevention or treatment of disease or effect on the structure or any function of the human body.

The oestrogen content of an OTC product be it a drug or a drug as well as a cosmetic may not exceed 10,000 IU / ounce. Users must be directed to limit the amount of product applied daily so that no more than 20,000 IU or equivalent be used per month.

▪ ***Suntan Products***

They should have the warning statement – If itching, or rash occurs stop using and consult your doctor

▪ ***Baby powder***

Should have the warning statement “Not for use on newborn baby's naval.”

▪ **Body powder / suspension containing boric acid or sodium borate or menthol or camphor**

Should carry the warning statement “ Do not use in children under 3 years of age” and “ Do not inhale or swallow as it maybe harmful “.

▪ ***Bleaching preparations containing hydroquinone***

Hydroquinone in concentrations of 2.0% for OTC use, while 4% concentrations are allowed for professional use only.

Should carry the warning statement " avoid contact with eyes"

Test for allergic reactions before use (see PIL for test method)

Avoid sunlight on the area

Stop using if a rash or irritation occurs or if there is no improvement after 1month of continued use

▪ ***Anti dandruff preparations containing aluminium pyrithione***

Should carry the warning statement

Avoid contact with eyes

Stop using if a rash or irritation occurs.

Do not use in children under 6 years.

▪ ***Fluoride toothpastes***

Should carry the warning statement "Children under 7 years should use a very small amount (pea size) of toothpaste and should not swallow"

▪ ***Products containing aluminium acetate (0.13% - 0.5%)***

Should carry the warning statement "For external use only. Avoid contact with the eyes"

- **Products containing *Hamamelis water***

Should carry the warning statement "For external use only. Avoid contact with the eyes"

- **Egg Shampoos**

A preparation that contains less than one egg per shampoo should not be referred to as an egg shampoo and the word egg should not be used as part of the name of the preparation.

- **Topically applied cosmetic products containing alpha hydroxy acids (AHAs)**

AHAs may increase the sensitivity of skin to the sun while the products are used and for up to a week after use is stopped, and that this increased skin sensitivity to the sun may increase the possibility of sunburn. Alpha hydroxy acids are organic acids with a hydroxyl group on the carbon adjacent to the carboxylic acid group. The predominant AHAs present in cosmetic products are glycolic acid and lactic acid. Other AHAs used in cosmetic products include citric acid, α -hydroxyoctanoic acid, and α -hydroxydecanoic acid.

Labeling of a cosmetic product that contains an AHA as an ingredient and is intended for topical application to the skin or mucous membrane should bear a statement that conveys the following information.

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure while using this product and for a week afterwards.

Antibacterail products: Skin care Antibacterial skin products The product must:

(a) be presented as being active only against bacteria; and

(b) not be presented as being:

(i) active against viruses, fungi or other microbial organisms

(other than bacteria); or

(ii) for use in connection with disease, disorders or medical conditions; or

(iii) active against a named bacterium that is known to be associated with a disease, disorder or medical condition;

or

(iv) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or

(v) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or

(vi) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or

(vii) for use in connection with a procedure involving venipuncture or delivery of an injection

Anti-acne products (including spot treatments, cleansers, face scrubs and masks)

The product must be presented as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin

CHECK LIST FOR ACCEPTING A NEW COSMETIC APPLICATION

Heading	✓	✘	☐	Comments
Administrative data				
Free sales certificate				
Classification of cosmetic				
Product category of cosmetic				
Methods of preparation				
Formulation and package content				
Analytical report				
Lead, arsenic content where applicable				
List of active Ingredients				
List of colouring agents, pigments and colour additives				
Toxicity tests where applicable				
Product information leaflet				
Clinical experience where applicable				

Labelling assessment check list

Requirement	✓	✘	☐	Comment
Label written in				
English				
Sinhalese				
Tamil				
Lettering is clear, distinct and legible				
Label is firmly and securely attached to the container				
Lettering on the label is; not be less than 0.75mm high in the case of a small label, not less than 1.5mm high in any other case				
Any written or pictorial or descriptive matter on or attached to or supplied or displayed with the product <ul style="list-style-type: none"> • does not contradict or modify any statement or label required by the regulations • is not false or misleading in any way 				
Contains a description that indicates the nature of the product eg. toothpaste, shampoo				
The name and address of the manufacturer / local agent				
List of ingredients where applicable				
Weight / volume of the contents				
The batch number				
The best use before / expiry date				
Warning statement / special precautions if applicable				
Instructions on use				

✓ data available ✘ send data ☐ data not required

References

1. Subchapter G Cosmetics in Code of Federal Regulations. National Archives and Records Administration, USA. 1995; Part 700: 175 - 203
2. Cosmetics Act 1992 Ministry of Health, Thailand
3. Cosmetic Claims Guidelines. National Coordinating Committee on Therapeutic Goods, Therapeutic goods Administration. Australia
4. Cosmetic Registration Scheme, Malaysia http://www.serve.com/bpfk/html/cosmetic/registration_products_guidelines.htm

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ANNEXURE 4 COSMETIC CLAIMS GUIDELINES

ACCEPTABLE VERSUS UNACCEPTABLE LABEL CLAIMS

A claim can be a word, a sentence, a paragraph, or simply an implication. The following tables show examples of acceptable and unacceptable claims. Column A contains claims that are clearly acceptable for a cosmetic while column C contains claims that are clearly unacceptable for a cosmetic. Column b is in between and the choice of words could make it acceptable or not. These examples should be taken only as a guide and are not to be taken as the final authority.

Subject	Column A Acceptable wording for a cosmetic	Column B Maybe acceptable if modified to provide a cosmetic implication	Column C Unacceptable wording for a cosmetic (but not necessarily acceptable for a drug)
Active ingredient	<ul style="list-style-type: none"> cosmetic active ingredient 		<ul style="list-style-type: none"> medicinal (therapeutic) ingredient
Ageing, anti-wrinkle	<ul style="list-style-type: none"> cover up (hide) age spots (blemishes, dark pigmented areas) feel (look) younger (youthful) helps prevent (reduce, slow) the signs (appearance) of ageing (age lines, premature ageing) moisturize ageing skin smoothes wrinkles 	<ul style="list-style-type: none"> temporarily reduces depth of wrinkles by moisturisation anti-ageing (anti-wrinkle) 	<ul style="list-style-type: none"> any references to fading age spots (depigmentation leaching of the skin) eliminates (prevents. Stops. Reduces, slows, reverses) ageing (wrinkles, premature ageing, ageing process)
Astringent	<ul style="list-style-type: none"> refreshes * (warms, cools, tightens, tones) skin 	<ul style="list-style-type: none"> energizes (stimulates, invigorates) skin ** 	<ul style="list-style-type: none"> decongests skin removes toxins stimulates circulation
Bio, biological		<ul style="list-style-type: none"> bio (biological) 	<ul style="list-style-type: none"> action (mechanism) due to biological/physiological activity bio active (cellular) biological performance (function) growth (repair) (metabolism) (structural change)
Comedomes, acne, pimples, blackheads	<ul style="list-style-type: none"> cleaner for acne-prone skin cover (hide) comedones (acne, blemishes) removes oil 		<ul style="list-style-type: none"> prevent (stop) (heal) comedones (pimples) (acne) (blemishes)
Counter creams ***			<ul style="list-style-type: none"> any reference to treatment reduction) of cellulite (orange peel skin) enhances (smoothes) (contours)

- your silhouette
- lose inches, removes fat,
- reduces (controls) puffiness (swelling) (oedema)
- restructures skin
- slimming
- tighten (firm) sagging skin (eyelids) (chin) (muscles)

* Usually contains alcohol or equivalent
 ** Cosmetic sense of astringent by means of physical surface effect (eg. aftershave lotion)
 *** See also - Astringent, skin

Subject	Column A Acceptable wording for a cosmetic	Column B Maybe acceptable if modified to provide a cosmetic implication	Column C Unacceptable wording for a cosmetic (but not necessarily acceptable for a drug)
Dentifrice - toothpastes	<ul style="list-style-type: none"> • cleans (whitens, brightens polishes) teeth • removes stain • prevent (reduce) plaque (tartar) build-up (deposit) by brushing (other mechanical means) • helps maintain healthy teeth and gums • tooth decay - fluoride protects against, reduces cavities 		<ul style="list-style-type: none"> • any implication of effect below the gumline • references to abscess, antiseptic action, gumboil, gingivitis, inflammation of gums, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, sensitivity, stomatitis, thrush
Deodorant	<ul style="list-style-type: none"> • absorbent that helps keep you dry • anti-odorant (deodorant) • fights bad odour • kills odour-causing bacteria 	<ul style="list-style-type: none"> • helps keep you dry 	<ul style="list-style-type: none"> • antiperspirant * • controls moisture (sweat) (perspiration)
Hair	<ul style="list-style-type: none"> • removes (washes) (cleans) loose dandruff (flakes) from the hair. • Add body to (colour) (after shape of) hair • Help make hair look thicker (fuller) • Revitalise appearance (look) of hair, restore beauty (luster) (sheen) to the hair • Promotion luster 	<ul style="list-style-type: none"> • makes your hair stronger 	<ul style="list-style-type: none"> • control (eliminate) dandruff • dandruff (anti-dandruff) shampoo (formula) • alopecia • prevent (stop) (cure) hair loss, hair thinning (baldness) • replace thinning hair • restore hair cells • stimulate hair follicles (growth)

Subject	Column A Acceptable wording for a cosmetic	Column B Maybe acceptable if modified to provide a cosmetic implication	Column C Unacceptable wording for a cosmetic (but not necessarily acceptable for a drug)
Healthy	<ul style="list-style-type: none"> • healthy ** looking (healthy rowing) appearance • feels healthy 		<ul style="list-style-type: none"> • healthy (healthy tan) • promotes (restores) health
Mouthwash	<ul style="list-style-type: none"> • fight (reduce) (end) bad breath (mouth odours) • helps eliminate (kill) odour causing bacteria (bacteria that cause bad breath) 	<ul style="list-style-type: none"> • references to plaque or tartar (see under Dentifrice) 	<ul style="list-style-type: none"> • antiseptic (antiviral) germicide • kills pathogens (germs) (odour-causing germs) • antibacterial (antimicrobial)
Nails	<ul style="list-style-type: none"> • repair fingernails 	<ul style="list-style-type: none"> • reference to growth resulting from protection of fingernails (eg. by a nail hardener) 	<ul style="list-style-type: none"> • reference to growth resulting from nourishing fingernails
Nourish		<ul style="list-style-type: none"> • nurture (take care of) 	<ul style="list-style-type: none"> • nourish (in the sense of promoting growth) (skin) (hair) (fingernails) (tissue)
Perfumes (fragrances, colognes, toilet water)			<ul style="list-style-type: none"> • any implication of hormonal attraction • reference to relieving stress or improving physical well being (i.e health)
Relax	<ul style="list-style-type: none"> • relax (moisturize) skin (taut skin) 	<ul style="list-style-type: none"> • reference to relaxing the body (unless this is in the sense of bath oil a warm bath) 	<ul style="list-style-type: none"> • relax muscles • promotes skin respiration
Repair	<ul style="list-style-type: none"> • repair beauty (appearance) 		
Respiration	<ul style="list-style-type: none"> • reference to non-clogging , letting skin breath 		<ul style="list-style-type: none"> • cellular respiratory factor • promotes skin respiration
Revitalize	<ul style="list-style-type: none"> • moisturize the skin so that complexion looks radiant • revitalize the appearance (the look) of skin, hair, scalp, face 	<ul style="list-style-type: none"> • revitalize (skin) (scalp) (hair) 	<ul style="list-style-type: none"> • rejuvenate, revitalize living tissue (eg hair follicles) living cells
Skin - (Cleansers, soap)	<ul style="list-style-type: none"> • helps eliminate odour caused by bacteria • cleanse oily skin • removes top layer of dead skin • cleans all types of skin (not just oily) • cleans skin • clarify, purity 	<ul style="list-style-type: none"> • purify 	<ul style="list-style-type: none"> • antibacterial (antimicrobial) • antiseptic/disinfectant (fungicide) (germicide) (virucide) • reference to disease-causing organisms, kills pathogens • anti-blemish cream

			<ul style="list-style-type: none"> cleans cuts (wounds) helps control (treat) infection (jock itch)
Skin (Facial Peels)	<ul style="list-style-type: none"> facial scrub smooths (retextures) skin removes top layer of dead skin 	<ul style="list-style-type: none"> keratolytic 	<ul style="list-style-type: none"> remove (reduce) scars (permanent markings)
Skin - (Moisturizers)	<ul style="list-style-type: none"> moisten (hydrate) (lubricate)(soften) skin dried (chapped) by the elements long lasting protection promotes elasticity (suppleness) cools skin desensitize razor-burned skin (eg .after shave lotion) prevent (protect) skin (dry skin) (lips) chapped (dried) against the abuse of the elements (solvents)* relieves (soothes) (softens) skin (dry skin) (lips) chapped (dried) by wind (cold) (elements) soothes skin, makes skin feel fresher, smoother firms top layer of skin (temporary effect only) 	<ul style="list-style-type: none"> chapped skin feel (look) young (youthful) desensitize (makes less sensitive) reduce (prevent) irritation prevent (protect) damage (drying) relieves (soothes) itching (due to dry skin) soothing agent** 	<ul style="list-style-type: none"> reference to numbering (pain) (analgesic effects) relieves (soothes) abrasions (bites) (insect bites) (inflamed skin) (rashes)
<p>* Barrier creams, for example</p> <p>** Soothes wind-burned skin, for example</p>			

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Sun, suntan products, after-sun treatments, sun protection, tanning acceleration	<ul style="list-style-type: none"> • gives skin a bronze (suntanned) colour (appearance) (ie dyes)* • prevent (protects) against drying effects of the sun • moisturizer-type claims for after-sun moisturizing creams (e.g. soothes moisturizes) skin after tanning 	<ul style="list-style-type: none"> • reference to achieving your darkest tan with less time in the sun. • Tan enhancer (magnifier) 	<ul style="list-style-type: none"> • Helps protect (prevent) the skin against burning (harmful effects of UV rays) (sunburn) (photo ageing) • SPF number or sunscreen category description • Accelerates (speeds up) (activates) suntan • Pre-tan (tanning) accelerator • reference to allowing you to stay out in the x times longer • screens (blocks) (filters) out some of the sun's UV (UVA/UVB/UVC) (harmful rays)
Therapy, treatment	<ul style="list-style-type: none"> • care 	<ul style="list-style-type: none"> • bath (beauty) (dry skin) treatment (therapy) • treatment on surface of skin 	<ul style="list-style-type: none"> • reference to disease control (treatment) (healing) • medicated (therapeutic) • treatment for infections (burns)
Vitaminised cosmetics [NB: orals vitamin supplements are regulated as medicines, as are topical products containing vitamins (e.g. creams) if intended for a therapeutic effect].			<ul style="list-style-type: none"> • Any reference to the nutrient (therapeutic) effects of vitamins

- Dyes, some barrier creams, self tanners, sunless tanners for example. (This type of product should include a warning that it does not provide sun protection.)