



ASEAN

Consumer Information Handbook on Cosmetic Products

The Food and Drug Administration

The FDA is a regulatory agency under the Department of Health responsible for ensuring the safety, efficacy and quality of health products which include human and veterinary drugs, biological products, medical devices, food, cosmetics, and products that emit radiation.

FDA maintains and establishes science-based policies based on national and international standards as the basis for regulatory policies. It also supports innovations to deliver quality service with integrity and efficiency.

Finally, FDA is committed to advancing public health by helping the public get the accurate, science-based information they need to use health products, and bringing services closer to the people by establishing Regional Field Offices in all the regions of the country.

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Cosmetic products are part of our everyday life, whether you are young or old, male or female. It is important for consumers to make an informed decision on the types of products that best fit their needs and lifestyle.

i. WHAT ARE COSMETIC PRODUCTS?

Since ancient history, men and women have used cosmetic products to enhance their appearance. Now, cosmetic products cover a wide range of items that we use as part of our grooming (and for the ladies, “beauty”) routine every day.

A cosmetic product means any substance or preparation intended by its manufacturer to be placed in contact with the various external parts of the human body such as the skin epidermis, hair, nails, lips and external genital organs or with the teeth or the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, correcting body odors, protecting them or keeping them in good condition.

These include products that we use every day: shampoos, conditioners, shower gels, shaving creams, toothpaste, mouthwash and other products like hair dyes, depilatory products, etc. that are used on a need basis.

ii. REGULATIONS IN THE ASEAN

The ASEAN Cosmetic Directive (ACD)

The ASEAN Cosmetic Committee (ACC) has been established since 2003 to coordinate, review and monitor the implementation of the ASEAN Cosmetic Directive (ACD). They are composed of the ASEAN National Cosmetic Regulatory Authorities and the ASEAN Cosmetic Association (ACA).

The ACD was developed by the ASEAN Member States, in partnership with the ACA, to enhance cooperation amongst the ASEAN Member States in ensuring the safety and quality of cosmetic products marketed in ASEAN.

The ACD aims to eliminate technical barriers to trade of cosmetic products without compromising public health and safety to the ASEAN population through the harmonization of technical requirements. With this, consumers are able to enjoy a wider variety of cosmetic products.

Under the ACD,

The ASEAN Member States, through the National Regulatory Authorities (NRA), shall undertake all necessary measures to ensure that only cosmetic products that conform to the provisions of this Directive, its Annexes and Appendices may be placed in the market.

The company or person responsible for placing the cosmetic product in the market shall notify the authority and be responsible for the quality and claimed benefits of the cosmetic product. This Notification shall declare the company, whether a cosmetic manufacturer or a distributor or an importer, who will be responsible for the quality and claimed benefits of the cosmetic products in the market.

1. ROLE OF COSMETIC DEALERS

Under the ACD, cosmetic dealers are required to comply with the following in order to market a cosmetic product in ASEAN:

- Notify NRA of the products they intend to sell before making them available for sale;
- Ensure that the products sold are manufactured according to ASEAN Guidelines for Cosmetics Good Manufacturing Practice;
- Ensure that their products do not contain any prohibited substances which can cause health risk and that only permitted colorants, preservatives and UV filters are used;
- Ensure that restricted ingredients are used only within the allowed limits and conditions of use;
- Label their products clearly. The label must reflect key information such as the product's name, ingredients, country of manufacture and expiry date (if the product has a durability of less than 30 months) or manufacturing date;
- Keep a Product Information File (PIF) on each cosmetic product they place in the market. This record contains important information such as product's ingredients and data on product's safety as well as side-effects, if any;

2. ROLE OF THE NATIONAL REGULATORY AUTHORITIES (NRA)

NRA conducts post-market surveillance on cosmetic products available in the market to ensure compliance with the ACD.

This may include audit of Product Information File (PIF), product sampling and other compliance checks.

In addition, the list of prohibited and restricted ingredients, permitted colorants, preservatives and UV filters are also regularly reviewed at ASEAN level, taking into account the latest scientific development in the use of cosmetic ingredients. Consumers may wish to visit their respective NRA's websites for this information.



WHAT DO I NEED TO KNOW ABOUT THE USE OF COSMETIC PRODUCTS?

Although cosmetic products are generally considered to be of lower risk compared to other health products such as drugs and traditional medicines, there is no absolute guarantee on their safety and quality. As such, it is important for consumers to adopt the following practices to ensure the safe use of cosmetic products:

- Do not buy cosmetic products from unfamiliar sources, such as unknown Internet websites and be wary of products with exaggerated claims. Only purchase products from reputable sources.

- Do not be too quick to believe what you read in advertisements or labels, even if the claims are made by “scientific experts” or “backed by scientific research”. Sometimes, only partial findings from a research or study are profiled, and this information may be too brief for you to make an informed decision.
- Always read the instructions and warning information on the label/insert before using a cosmetic product. Do not use cosmetic products for other uses apart from their intended ones;
- Apply cosmetic products with clean hands or an applicator. Applicator should be thoroughly cleaned with soap and water, and dried before use;
- Use cosmetic products within their recommended Best before or expiration date printed on the product labels. Do not use cosmetic products when color or odor changes or any other unusual appearance is detected;
- Check for the ingredients that you are/might be allergic to. Try the product on a small area of skin, usually behind your ear or on the inner forearm before use. If there is no reaction after 24 hours, it should generally be safe for use;
- Do not apply cosmetic products to irritated or damaged skin;
- Do not share cosmetic products as this could expose you to someone else’s bacteria;
- Do not dilute cosmetic products with water or saliva when they dry up. The moisture will encourage bacteria growth and contaminate your cosmetic products;



THE IMPORTANCE OF READING LABELING INFORMATION

FRONT



Product content (in weight/volume)

To assist you in selecting the right product size

Brand and product name of the cosmetic product and its function

To assist you in selecting the right product according to the intended use

Batch number

An important reference when providing feedback to the manufacturer/importer/distributor or regulatory authority regarding the product

Manufacturing/expiry date of the product in clear terms (e.g. month/year)

To allow you to identify and not buy products that are left on the shelf for too long

Country of Manufacture

To inform you of the country where the product was made/produced

BACK

Instructions for use

To assist you in the proper use of the product in terms of application and frequency of use

Full Ingredient List

To keep you informed of what is contained in the product, just in case you are allergic to any particular ingredients used

Special Precautions

To guide you on the proper use or storage and any other important information to take note of. This may include information on how to handle adverse reactions relating to the use of the product

Name and Address of the Company or Person responsible for placing the product in the market:

To enable you to contact them should there be any inquiries or clarifications required on the product



With the increasing numbers of published reports and discussions on the safety concerns of cosmetic ingredients, consumers may often ponder whether the ingredients may present a health hazard.

ASEAN continually reviews the safety of these cosmetic ingredients to ensure their safe use in cosmetic products. The following are some of the cosmetic ingredients that are often the topics of discussions.

INGREDIENTS IN THE NEWS: FACT OR FALLACY?

i. PHTHALATES

Phthalates are ingredients that are used in cosmetic products to allow fragrances to last longer and as a plasticizer in nail polishes to provide resistance to chipping. The two phthalates most commonly used are diethyl phthalate (DEP) and dimethyl phthalate (DMP). There are currently three phthalates, dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diethylhexyl phthalate (DEHP) which are prohibited for use in cosmetic products in Europe and ASEAN.

Both DEP and DMP, usually used at low levels, have been assessed to be safe for use in cosmetic products, including products intended for infants and children by the European Union's (EU) scientific advisory panel, the Scientific Committee on Consumer Products (SCCP), United States (US) Cosmetic Ingredient Review Expert Panel and the US Food and Drug Administration (FDA).

ii. PARABENS

Parabens are commonly used preservatives in cosmetic products to inhibit or prevent microbial and fungal growth and extend the shelf life of the products. Commonly used parabens include methylparaben, ethylparaben and propylparaben. More than one paraben may be used in a cosmetic product, or used in combination with other types of preservatives to provide preservation against a broad range of microorganisms.

There have been studies about the effects of certain parabens disrupting natural hormones production in the body and their link to breast cancer, but the findings were inconclusive. The use of parabens within the permitted concentrations has been assessed by the EU SCCS and the US FDA to be safe for use in cosmetic products.*

iii. TALC

Talc, a naturally occurring mineral, is used in many cosmetic products, ranging from body and face powders to eye powders.

Its functions include absorbing moisture, preventing caking, making facial makeup opaque, or improving the feel of a product. Cosmetic products must be formulated with cosmetic grade talc which is free from asbestos, a known carcinogen.

Under the ACD, talc is allowed to be used in cosmetic products including baby products. Consumers should keep products containing talc away from the nose and mouth when used in children under 3 years of age.

iv. FORMALDEHYDE

Formaldehyde is a widely used chemical that also occurs naturally in many foods and even in our own metabolism. Formaldehyde is used as an ingredient in nail polishes, eyelash glues and hair gels. Some cosmetic products such as shampoos and shower gels may not be declared to contain formaldehyde. However, there is a possibility of low levels of formaldehyde being detected in them due to the presence of formaldehyde releasers such as imidazolidinyl urea, DMDM hydantoin, diazolidinyl urea and Quaternium-15.

Under the ACD, formaldehyde is allowed to be used as a preservative at its allowable limit and conditions of use.

There have been reports on the safety of hair straightening products containing formaldehyde. Formaldehyde has also been reviewed by various regulatory agencies including the EU and USA, and it has been considered safe for use at low concentrations and when used as directed.

v. PARA-PHENYLENEDIAMINE (PPD)

Para-phenylenediamine or p-phenylenediamine (PPD) is a hair colour ingredient commonly used in permanent (oxidative) hair colorants, especially in the darker shade ones.

Under the ACD, it is permitted for use as a hair dye substance in oxidative hair dye products, at its allowable limits and conditions of use.

As PPD may cause allergy on some individuals, hair dye products containing PPD are required to have a cautionary statement "Contains Phenylenediamines" and specific directions of use, including conducting a patch test before using the product. Also, people are warned not to use on eyebrows and eyelashes as it can cause blindness.

PPD is sometimes illegally found in temporary skin tattoos such as 'black henna' tattoos. The use of such product is unsafe as it can cause allergic reactions upon repeated exposure. Such product use may also lead to increase sensitivities to other products like hair dye, sun block and some types of clothing dyes.

vi. SLS AND SLES

Sodium lauryl sulphate (SLS) and sodium laureth sulphate (SLES) are surfactants (a substance like detergent, which enables a liquid to foam), which are used in many cosmetic products for its cleaning and emulsifying properties. It is used in a wide array of products, such as shampoos, shower gels or toothpaste, and sometimes found in creams and lotions.

Cosmetic grade SLS and SLES have been studied to be safe for use in rinse-off cosmetic products like shampoos and soaps by the US Cosmetic Ingredient Review (CIR) Board and the EU Scientific Committee on Consumer Safety (SCCS). SLS is present in low concentrations in cosmetics and personal care products it is not seen to cause irritation and has a long history of in-use safety.

Under the ACD, SLES is allowed to be used in cosmetic products. There is currently no evidence to show that SLES causes safety risk to consumers such as cancers as it is used at low levels and stays in contact with the skin for a very short time when used in cosmetic products.

vii. TRICLOSAN

Triclosan is commonly used in cosmetic products as a preservative to protect cosmetic products from spoilage. It is contained in a variety of consumer products such as toothpaste, mouthwash antiseptic hand-wash and body wash.

There have been reports concerning the safety of the use of Triclosan in cosmetic products. Under the ACD, triclosan is permitted for use in cosmetic products, at its allowable limit and conditions for use.

The use of Triclosan at this recommended limit has been reviewed by various regulatory agencies including the European Union, and they have considered it to be safe for use in cosmetic products as a preservative at its allowable limits and conditions of use.

As a number of cosmetic products are used daily, it is important to ensure that consumers know how to use them properly. It is important to read and follow the instructions of use on the label of cosmetic products. The information below will help you to use cosmetic products more safely, as well as to identify the potential undesired effects when using these products.

Below are some useful information and safety guidelines of common product categories:

Hair products

- Hair dye
- Hair perming
- Hair styling products

Products used on the face and body

- Products containing alpha hydroxy acids (AHA)
- Skin whitening products
- Deodorants and anti-perspirants
- Sunscreens

HAIR PRODUCTS

PRODUCT CATEGORY	HAIR DYE	HAIR PERMING	HAIR STYLING PRODUCT
WHAT IS IT?	<p>Hair dyes are products that impart colour to the hair such as covering gray hair and restoring the original hair color after they discolored. It ranges from permanent hair dyes, where the colour last a few weeks, to temporary hair dyes, where the colour last a few days.</p>	<p>A permanent wave, also known as a perm, is a chemical hair treatment that can be used to straighten or add curl and body to the hair.</p>	<p>Hairstyling products are used to change the texture or shape of the hair, or to hold it in place in a certain style.</p> <p>Examples include hair wax, hair mousse, hair gel, hair spray, etc</p>
WHAT SHOULD CONSUMERS TAKE NOTE OF?	<p>The ingredients in the hair dyes can cause allergic skin reactions in some individuals. Sometimes, sensitivity to these ingredients may be shown only after using the product a few times. As such, it is important to do a patch test before each use.</p> <p>To do the patch test, wash a small area of the skin behind your ear or on your inner forearm. Apply a small amount of the hair dye mixture of hair dye and developer and let it dry. After 24 hours, wash the area gently with soap and water. Stop using the product if there is any irritation to the skin such as redness and itching.</p> <p>consumers should strictly follow the directions for use.</p> <p>Hair dyes are not recommended to be used on children under 16 years of age.</p>	<p>Read the product label and follow the instruction strictly.</p> <p>Hair perming should preferably be performed by a professional hairdresser.</p>	<p>Do not use hair styling product if you have an inflammation or skin problem on the head.</p> <p>Avoid contact with eyes</p> <p>When using products in an aerosol container,</p> <ul style="list-style-type: none">• Avoid spraying in the eyes• Do not puncture or incinerate the aerosol can• Do not store at temperature above 50°C• Keep out of reach of children• Use only as directed. Intentional misused by deliberately concentrating and inhaling the contents can be harmful

PRODUCTS USED ON THE FACE AND BODY

PRODUCT CATEGORY	PRODUCTS CONTAINING ALPHA-HYDROXY ACIDS (AHA)	SKIN WHITENING PRODUCTS
WHAT IS IT?	<p>Alpha Hydroxy Acids (AHAs) are naturally occurring acids derived from certain plants, fruits, sugar cane, etc. The most commonly used AHAs are glycolic acid, lactic acid, citric acid and malic acid;</p> <p>Glycolic acid is perhaps the best-known of alpha-hydroxy acids (AHA). It is derived from sugar cane;</p> <p>Lactic acid is also known as milk acid;</p> <p>Citric acid is naturally found in citrus fruits like lemons, limes, oranges, grapefruits, or tangerines. You can find citric acid in certain berries too, particularly raspberries and blackberries;</p> <p>Malic Acid is derived from unripe apples.</p> <p>AHAs products act by removing dead cells from the skin's surface in order to brighten the skin.</p> <p>AHAs in various concentrations are used in chemical peels. The concentration determines its usage:</p> <ul style="list-style-type: none">• Products with concentration lower than 10% can be used by consumers;• Products with concentration between 10% and 20% should only be used by a professional like an aesthetician;• Higher concentrations of more than 20% can only be used as treatment by a qualified medical practitioner;	<p>Skin whitening or skin lightening products aim to lighten skin tone or provide an even skin complexion by lessening epidermal melanin.</p> <p>There are 2 main mechanisms for lightening skin tone and reducing pigmentation:</p> <ul style="list-style-type: none">• by reducing the concentration of existing melanin• by preventing the formation of new melanin.
WHAT SHOULD CONSUMERS TAKE NOTE OF?	<p>Limit sun exposure while using this product and for a week afterwards.</p> <p>When using a product with AHA, apply sunscreen with a high SPF.</p> <p>Wear sun protective clothing</p>	<p>Avoidance of UV ray exposure (both UVA and UVB) is recommended.</p> <p>Apply a sunscreen product, wear long-sleeve shirt and wide-brim hat and use umbrella. UV protection is recommended not only on sunny days, but for cloudy days as well.</p>

PRODUCTS USED ON THE FACE AND BODY

PRODUCT CATEGORY

DEODORANTS AND ANTI-PERSPIRANTS

WHAT IS IT?

Deodorants are applied to the body, most frequently armpits, to reduce and prevent the generation of body odor. They contain odor-masking fragrances and provide microbial control of the odor-causing bacteria. Antiperspirants, which normally contain aluminum and zirconium salts, are designed to prevent the excretion of sweat and hence provide a malodor control.

SUNSCREENS

Sunscreens work by absorbing or reflecting ultraviolet (UV) radiation in sunlight. UV radiation include UVA radiation which causes premature skin aging and skin darkening and UVB radiation which causes sunburn and skin cancer

Measurement of UVB protection

Sunburn protection is measured by the Sun Protection Factor (SPF).

The SPF indicates the time a person can be exposed to sunlight before getting sunburn with a sunscreen applied relative to the time of exposure without sunscreen.

The SPF of a sunscreen relates only to its efficacy against UVB exposure. A higher SPF means more protection against sunburn.

Measurement of UVA protection

PA measurement is a method of measuring UVA protection, similar to SPF method of measuring protection against UVB exposure. Originally developed in Japan, PA measurements have four levels;

PA+	Offer slow to medium protection against UVA rays
PA++	offers moderate protection against UVA rays
PA+++	offers high protection against UVA rays
PA++++	offers very high protection against UVA rays

WHAT SHOULD CONSUMERS TAKE NOTE OF? Do not apply on open wound.

Sunscreen should cover the surface area of the skin that is exposed to the sun before going outdoor and re-applied frequently to maintain protection especially after perspiring, swimming or toweling;

Sunscreen needs to be applied in sufficient quantity e.g. to protect the whole body of an average-sized adult, a quantity of 35 grams or approximately six filled tea spoons needs to be applied

Even with sunscreen applied, it is advisable to minimize sun exposure especially between the hours of 10.00 am and 4.00 pm. Do not stay too long in the sun, even while using a sunscreen product. Keep babies and young children out of direct sunlight.

Wear protective clothing (e.g. wide-brimmed hats, sunglasses, long-sleeved shirts and pants) outdoors.

VI

HOW SHOULD I STORE MY COSMETIC PRODUCTS?

Cosmetic products should be subjected to appropriate storage conditions to ensure maximum durability and quality of the cosmetic product. The following are some pointers for consumers to take note of when storing cosmetic products:

- Store cosmetic products away from high temperature and direct sunlight as it may affect the quality of the product.
- Keep the lid of the product tight when not in use to reduce the risk of contamination.
- Keep cosmetics out of reach of children. Some products contain ingredients which may be harmful to children when swallowed.

VII

WHAT DO I DO IN CASE I EXPERIENCE AN ADVERSE REACTION WHEN USING A COSMETIC PRODUCTS?

If you develop an adverse reaction such as allergic reaction or skin irritation, itchiness, redness or swelling, stop using the product immediately.

Wash away the cosmetic product from the applied area of your skin. Inform the company whose name and address appear on the label. Bring the suspected cosmetic product and see a doctor if condition does not go away or worsens.

You are encouraged to report the serious adverse reaction to the NRA/company by providing the details of the product used and the type of reaction occurred for further investigation and record.

VIII WHERE CAN I GO TO GET MORE INFORMATION ON COSMETIC PRODUCTS?

Consumers may contact the company marketing the product. Their contact details can be found on the product label.

You can also contact or visit the website of your local regulatory authority or the cosmetic industry association for enquiries on the regulations and safety concerns of cosmetic products.

You can also access the website of the ASEAN Cosmetic Association (ACA): www.aseancosmetics.org

FDA Email Directory

Compliance Document, Follow-ups, Verification of Registration of Products and License of Establishments concerning Center for Food Regulation and Research

cfr@fda.gov.ph

Compliance Document, Follow-ups, Verification of Registration of Products and License of Establishments concerning Center Drug Regulation and Research including veterinary medicine, vaccine, and biologicals

cdr@fda.gov.ph

Compliance Document, Follow-ups, Verification of Registration Of Products and License of Establishments concerning Center for Cosmetics Regulation and Research including household hazard/urban substances

crr@fda.gov.ph

Compliance Document, Follow-ups, Verification of Registration of products and License of Establishments concerning Center for Device Regulation, Radiation Health and Research

cdrhr@fda.gov.ph

Qualified Persons in Industry Regulatory Affairs (QPIRA) Training, Licensing Seminar and other Seminars as spearheaded by FDA

enroll.fdaacademy@gmail.com

Legal related concerns/queries/follow-ups

lssc@fda.gov.ph

Request for meetings, courtesy calls and other related matter

odg@fda.gov.ph

E-Portal Account Concerns (i.e. Requests, Change of Username, password and among others), Processes (i.e. How to Apply for FDA Certificates)

fdac@fda.gov.ph



