HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

July 2024

ADVISORY FOR SUPPLIERS

Assessing the Safety and Quality of Cosmetic Products

The information in this Guideline shall be updated or revised from time-to-time. Please refer to the latest version on our website: www.hsa.gov.sg

HSA Health Sciences Authority

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1. INTRODUCTION

The following advisory provides guidance to local suppliers of cosmetic products on assessing the safety and quality of the products you are supplying.

Responsibilities

As a supplier of cosmetic products in Singapore, you are to ensure that your products are safe, of appropriate quality, and meet all the relevant regulatory requirements under the Health Products Act and its subsidiary legislation, the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007.

You must ensure that your cosmetic product is notified with HSA before you supply the cosmetic product. You also must keep records of the supply of your cosmetic products and report serious product defects and adverse effects of the cosmetic products to HSA.

You can refer to the guidance document [Guidelines On The Control of Cosmetic Products] and other regulatory requirements available on our website at www.hsa.gov.sg/cosmetic to check if your cosmetic products comply with the relevant safety, quality and regulatory requirements.

2. GENERAL GUIDE ON ASSESSING THE SAFETY AND QUALITY OF COSMETIC PRODUCTS

Sourcing of Manufacturers, Importers and Distributors

As your cosmetic products can directly impact the safety of the users of your cosmetic products, it is important for you to work with reputable and reliable manufacturers, importers and distributors so that they will not supply you with products of dubious safety and quality.

Other than minimising the occurrence of product safety and quality issues, reputable and reliable manufacturers, importers and distributors would have in place manufacturing and traceability controls that would also facilitate timely product recalls in the event that safety and quality issues arise along the supply chain, and if necessary, to take appropriate action such as to promptly recall the product from the distribution network.

You should consider the following aspects when assessing the reliability of the companies you work with:

- Manufacturers or distributors who operate their business activities legitimately in countries where they are located;
- Ensure that the finished product manufacturers comply with the good manufacturing practice (GMP) standards such as the ASEAN Guidelines for Cosmetic Good Manufacturing Practice or other equivalent GMP guidelines. The standards would include information for quality system, personnel, equipment, sanitation, hygiene, production, quality control and documentation. You can also check that the manufacturers have proper manufacturing controls in place, as well as established processes to verify the ingredient sources and their quality;
- Manufacturers or distributors who provide test reports for every batch of their products to show the products comply with manufacturer's specifications;
- Good safety track record of the products marketed by industry counterparts of the manufacturer, importer or distributors, if applicable;
- It will be useful to visit the premises (e.g. factory, warehouse) of the manufacturer, importer or distributor to establish if there are proper systems and facilities available in handling the products and
- If necessary, consider engaging a competent consultant to assist in your assessment.

Sourcing of Products

While sourcing for cosmetic products, you should pay attention to the key aspects below:

- Check media reports and product alerts posted on the HSA website so that you do not unwittingly deal with cosmetic products that have reported safety and quality issues such as adulteration and product defects;
- Be cautious with solicitations from unknown distributors who advertise via email blasts or online platforms;
- Be wary if the pricing of the products sounds too good to be true; and
- Carefully inspect all products and packaging to look out for dubious signs such as differences in packaging from what you usually see, and unfamiliar instructions for use.

Reviewing of Cosmetic Products' Composition

You can only supply cosmetic products with products' composition that comply with the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007. In checking the full product formula, you must ensure that specific ingredients are used in compliance with their corresponding conditions, including:

- Ingredients that must not be present in cosmetic products
- Ingredients subject to restrictions and conditions
- Colouring agents allowed for use in cosmetic products
- Allowable preservatives
- Permitted UV filters

You must ensure that your products do not contain ingredients that are prohibited for use in cosmetic products and restricted ingredients are being used according to the specified conditions of use.

3. TESTING OF COSMETIC PRODUCTS

On top of the test reports that may be provided by your manufacturer or distributors, you should institute checks to confirm the product's quality as added assurance. You are encouraged to conduct your own product testing at laboratories with accredited testing methods.

The testing for the presence of prohibited and restricted ingredients in cosmetic products is important to ensure their safety and their compliance with regulatory standards as stipulated under Part I and Part II of the Third Schedule to the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations. This is to protect the safety of the users of your cosmetic products.

You may refer to the website of the Singapore Accreditation Council (SAC) for the list of local laboratories accredited to conduct testing of cosmetic products.

You are also advised to discuss with your contract laboratories and request them to highlight to you if there are anomalies observed from the testing outcome, even if they fall outside the targeted scope. For example, any unusual peaks found in the chromatogram that may potentially indicate the presence of other contaminants/adulterants should be further investigated.

The following are some examples of types of testing you can conduct on your cosmetic products to ensure that your products are safe and comply with the regulatory requirements.

(a) Heavy Metals

Heavy metals are naturally found in the environment and may be present in pigments and other raw materials used as cosmetic ingredients. Prolonged exposure to heavy metals can lead to serious and undesirable health consequences. For example, application of skin whitening creams containing mercury can cause rash, skin

discolouration and blotching while prolonged exposure to mercury can result in damage to the kidneys, digestive and nervous systems.

Heavy metals are prohibited as cosmetic ingredients and should not be intentionally added to cosmetic products. Trace amounts of heavy metals are only allowed if they are technically unavoidable in good manufacturing practice. You should ensure your cosmetic products meet the acceptable limits for heavy metals based on the ASEAN Guidelines on Limits of Contaminants for Cosmetics. The limits for heavy metals can also be found in Table 1.

Table 1: Heavy metals limits for cosmetic products

Heavy Metals	**Quantity (by weight)**
Arsenic (As)	5 parts per million
Cadmium (Cd)	5 parts per million
Lead (Pb)	20 parts per million
Mercury (Hg)	1 parts per million

(b) Undeclared Medicinal Ingredients

HSA and other overseas regulatory agencies have reported instances of cosmetic products containing undeclared medicinal ingredients that are prohibited in cosmetic products. Their presence can pose health risks to unsuspecting consumers.

Some examples of undeclared medicinal ingredients, that should be used only under medical supervision, and had been found in cosmetic products are:

- Hydroquinone;
- Steroids; and
- Tretinoin.

You should note that cosmetic products are not intended for treating any medical conditions. If your manufacturer or distributor is making such claims for the products,

be cautious that they may contain undeclared medicinal ingredients that are prohibited in cosmetic products. Apart from checking the product's composition, you are advised to send the products for testing to confirm that they do not contain undeclared medicinal ingredients.

(c) Microbial Contamination

Microbial contamination poses a significant risk to the safety and quality of cosmetic products. The presence of harmful microorganisms not only compromises the quality of the products but also poses potential health hazards to consumers, especially to the vulnerable groups, including individuals with weakened immune systems, such as the elderly, infants, pregnant women, and individuals with certain medical conditions. As such, rigorous testing for microbial contamination is essential to ensure the safety and quality of cosmetic products before they are made available on the market.

Given these risks, it is crucial for you, as the supplier, to implement stringent measures to prevent microbial contamination in your cosmetic products, especially when formulating products targeted at vulnerable groups. This includes adherence to good manufacturing practices, regular product testing, and compliance with microbial limits and standards to ensure the safety of cosmetic products for all consumers, particularly those who are more susceptible to adverse effects.

You should ensure that your cosmetic products meet the acceptable limits for microbial contaminants based on the ASEAN Guidelines on Limits of Contaminants for Cosmetics found in Table 2. The limits used are based on the current data and information and the latest scientific update in cosmetics to ensure consumer safety. The limits may change, as needed, according to the latest compendium or safety information on microbial contaminants.

Table 2: Limits of microbial contaminants for cosmetic products

	Products for children under 3 years, eye area and mucous membrane	**Other products**
Total Aerobic Mesophillic Microorganisms (Bacteria, Yeast & Moulds)	≤ 500cfu/g or cfu/ml	≤1,000cfu/g or cfu/ml
Pseudomonas aeruginosa	Absent in 0.1g or 0.1ml test sample	
Staphylococcus aureus	Absent in 0.1g or 0.1ml test sample	
Candida albicans	Absent in 0.1g or 0.1ml test sample	

(d) Other contaminants

1,4-Dioxane

1,4-Dioxane is a potential human carcinogen and is prohibited to be added into cosmetic products. Its presence in trace amounts is only allowed if it is technically unavoidable in good manufacturing practice. 1,4-Dioxane may be present in trace quantities as a byproduct from the manufacturing process of shampoo products. Your cosmetic products should not contain more than 10mg/kg or 10mg/L (10ppm) of 1,4-Dioxane based on the ASEAN Guidelines on Limits of Contaminants for Cosmetics.

(e) Testing Based on Product Categories

There are certain types of cosmetic products that may be associated with specific adulterants, non-permitted ingredients as well as containing ingredients that exceed the permissible limits. If you are dealing in these types of products, you may want to consider the following tests, such as:

(i) Toothpastes

To test for the presence of diethylene glycol, a harmful ingredient that is prohibited in cosmetic products. Diethylene glycol may be used in place of glycerol and polyethylene glycols in oral care products by unscrupulous manufacturers.

(ii) Teeth whitening products

To test the concentration of hydrogen peroxide. Hydrogen peroxide in high concentrations can corrode the teeth and may irritate to the oral mucous membranes. Only products with hydrogen peroxide of concentration up to 0.1% can be allowed for supply to consumers directly while those with concentrations more than 0.1% should be used under the supervision of a registered dentist.

(iii) Lipsticks

To test for the presence of any heavy metals and non-permitted colourants e.g. Rhodamine-B, which is a carcinogenic dye that is prohibited in cosmetics.

(iv) Skin Whitening creams

To test for the presence of adulterants e.g. hydroquinone, mercury, steroids and tretinoin. Hydroquinone and tretinoin are potent ingredients that are not suitable for use in skincare cosmetic products. The inappropriate use of hydroquinone could result in changes in skin colour and hypersensitivity reactions such as rashes, redness, tingling and burning of skin. Tretinoin could lead to redness and peeling of the skin and should only be used under medical supervision.

As the above is not an exhaustive list of ingredients to be tested, importers may seek assistance from contract laboratories on the appropriate tests to be conducted, based on the product uses and composition

4. REPORTING OF ADVERSE EFFECTS, PRODUCT DEFECTS AND PRODUCT RECALLS

As a supplier of cosmetic products, you are responsible for the safety and quality of the products you are supplying. As such, you should have adequate systems and appropriate procedures in place to receive, investigate, review and report adverse

effects and product defects to HSA, and to take appropriate action such as to promptly recall the product from the distribution network. You should also have trained personnel to manage, investigate, assess adverse effects and product defects reports and perform risk mitigation actions.

You may refer to our GUIDANCE FOR INDUSTRY - Procedures for Reporting of Adverse Effects, Product Defects and Product Recalls for Cosmetic Products for more details on how to report adverse effects, product defects and product recalls.

You must report to HSA any product defect that:

1. may cause death or may be life-threatening; or
2. may result in an any person being hospitalised or may cause persistent or significant disability or incapacity in any person.

Examples include:

a) A product adulterated with prohibited ingredient(s) that may lead to the above consequences e.g. steroids, hydroquinone, mercury, tretinoin, etc.

b) A product that does not comply with product specification that may lead to the above consequences e.g. contamination with microorganism(s) that can cause serious infections, contamination with high levels of heavy metals.

c) A product that has been manufactured using wrong ingredient(s) that may cause the above consequences.

d) A product with missing information or containing incorrect information on the product label that may lead to the above consequences.

You should maintain records of every adverse effect and product defect for at least 2 years after the date on which the product was supplied.

Where a product is considered to present a risk to the intended user and/or public health, HSA may require you to remove the product from the market by recalling the affected batch(es) or, in extreme cases, recalling all batches of the product from the

market. You may also initiate a recall of a product when a product defect is detected or has caused adverse effects or for other reasons (e.g. commercial reasons).

DISCLAIMER:

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Revision History

Version	Date of publicatio	Summary of changes*
1	July 2024	New document

*Editorial changes are not reflected

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Applied Sciences Group

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