

Information Sharing Paper on Personalised Cosmetics

Background and Objective

There is a growing trend among cosmetic brands to provide customers opportunity to personalise their cosmetic products according to their needs. This trend has grown to the point where products are being personalised according to the customer's choice at the point of sale. It is important to note that all cosmetic products would need to adhere to the regulatory, safety and quality requirement as outlined in ASEAN Cosmetic Directive.

Hence this paper is being written for the purpose of information sharing only, among AMS. It shall not constitute a guideline or reference on regulating personalised cosmetics in AMS. The management or control of personalised cosmetics shall be reserved to the National Regulatory Authority (NRA). This document is non-binding and non-obligatory.

Scope

This information paper addresses cosmetic products that are personalised at the point of sale. Trained personnel should be assigned at the point of sale to personalise and sell these products to the customer.

Definition

For the purpose of this information sharing paper, Personalised Cosmetic is defined as a cosmetic product that is tailor-made to the personal preferences of the individual customer in the form of a finished or semi-finished product. The product is personalised by the addition of other ingredients, such as colorants, fragrances and conditioning ingredients

1. Addressing regulatory, safety and quality requirements

A personalised cosmetic product needs to adhere to all regulatory, safety and quality requirements as a typical cosmetic product would be expected to. Due to the flexible nature of the formulation, it's important to consider this in the approach of notification submission requirement-particularly in the aspect of safety assessment and quality assurance.

In current operations seen in ASEAN and elsewhere, there are sets of ingredient options provided to the customer to choose from and the retailer, either in store or on-line, will fill the ingredients accordingly, pack and label before selling to the customer. Examples have been seen in make-up cosmetic products, fragrances/perfume, skin and hair care products.

2. Cosmetic Notification

It is important that the "*company or person responsible for placing the cosmetic product in the market*" (referred subsequently in this document as "responsible person") shall submit all the potential possibilities that could be sold to the customer in the particular market.

The notification should contain the information as required under the ACD. The “responsible person” is responsible for ensuring that the ingredients used comply with the ACD requirements.”

3. Preparation of Personalised Cosmetic Products

The company or person providing personalised cosmetic products should adopt hygienic practices in the preparation of a personalised cosmetic product to ensure the safety and quality of the product.

Personnel: The responsible person or the appointed agent of the responsible person needs to ensure that personnel handling the products are well trained and has the knowledge to properly prepare the products at the point of sale. It is advisable that the personnel handling the personalisation wears appropriate attire and protection to ensure proper handling of the products. For example, wearing a face mask, hair cover, disposable gloves and overgarment would minimize the contamination risk. If the personnel is unwell, he/she should refrain from handling the product.

Storage/ Preparation Area: There should be a designated area to store and prepare the product with appropriate ventilation and conditions to ensure that the materials and finished product continue to meet quality specifications. The stored material should be designated clearly and regularly inspected to ensure no expired materials. Access to these materials should also be limited to the appointed personnel only.

Cleaning/Sanitization: The preparation area must have appropriate facilities for cleaning the technician’s hands and equipment, to prevent contamination and spread of microorganisms. The equipment and environment in which the personalised product is prepared must be kept in good hygienic condition. All equipment used must be suitable, regularly maintained and calibrated to ensure that the quantities dispensed are accurate and consistent.

Record: There should be proper record-keeping to ensure that the sale of the product and the batches sold are recorded. It shall include information such as batch number, date sold, amount sold, and shelf life. The batch coding system should be robust to ensure traceability to the retailer or point of sale of the personalised cosmetics.

4. Labelling of Personalised Cosmetic Product

The labelling requirement for personalised cosmetic products is the same as for a typical cosmetic product. The label of the personalised cosmetic product has to comply with the requirements specified in the ASEAN Cosmetic Labelling Requirements. Claims on the label need to also comply with the cosmetic product definition. Relevant IT tools and label printers may be used to facilitate this.

5. Safety Assessment

The safety assessment of a personalised cosmetic product does not differ from a typical cosmetic product. However, the “responsible person” should address the safety assessment

for all possible ingredient combinations that are offered to the customer. The safety assessment may also be performed using concentration ranges.

The “responsible person” should have technical basis to support the product stability across the different variations to ensure the product delivers its benefit across the intended shelf life.

6. Post Market Surveillance

The “responsible person” shall ensure that batch records are kept for each batch of personalised cosmetics and samples are made available upon request by the National Regulatory Authority (NRA). The “responsible person” is required to report any serious adverse events or high incidences of adverse events to the NRA.

The Product Information File (PIF) should be available upon request.

7. Personalisation by third parties

It is expected that ordinarily the personalisation of the cosmetics will be managed directly by their own personnel. However, where a third party is used to manage such processes, the “responsible person” must ensure adequate training and written authorization of such third parties.

Reference:

- i) <https://www.mdpi.com/2079-9284/6/2/29/htm> The Regulation of Personalised Cosmetics in the EU by Helena Eixarch, Louis Wyness and Musa Sibanda
- ii) <https://www.mfds.go.kr/docviewer/skin/doc.html?fn=20200604013204019.pdf&rs=/docviewer/result/eng0006/71482/1/202108> Implementation of the Customized Cosmetics System by Ministry of Food and Drug Safety, Republic of Korea

Appendix 1 – A summary of types of personalised cosmetics surveyed among the ASEAN industry in September 2021

- Perfume
- Colorants (e.g. for foundation cream, for lipsticks/lip gloss with shades selected from color chart, liquid foundation)
- Key ingredient (e.g. level of salicylic acid according to the customer's skin type, booster ingredient or serum)

Other responses in the survey from industry not specific to personalised cosmetics from formulation standpoint:

- Packaging
- Repacking into smaller packaging (e.g. body lotion is dispensed into small jars or bar soap is cut into smaller weight)
- Label customization (e.g. personalised name or package label)

GLOSSARY

Finished product: A cosmetic product that may be used on its own, with or without the addition of another product or substance. The product has undergone all stages of production including packaging and its final container.

Semi-finished product: A cosmetic product that must be mixed with another cosmetic product or substance prior to application.

“Responsible person”: Cosmetic Notification Holder

NRA: National Regulatory Agency

Trained personnel: A personnel that has been trained through instruction and/or practice

Point of sale: the place at which goods are retailed

Good Manufacturing Practice - a system for ensuring that products are consistently produced and controlled according to quality standards

Retailer: A person or business that sells goods to the public in relatively small quantities for use or consumption rather than for resale.

Post Market Surveillance: The practice of monitoring the safety and quality of cosmetic products after it has been released on the market

Customer: A person that buys goods or services from a store or business

Product Information File: A cosmetic product dossier containing all the most important information about the finished product, such as, ingredients which the product is made from and updated information/documentation on product quality, safety and claimed benefit.