

ASEAN Cosmetic Directive Guidance on Product Notification Procedures

Questions on Notification procedures

1. What should I do if I intend to import or manufacture a cosmetic product for local sale?

The company or person responsible for placing the cosmetic products in the market must notify the regulatory authority responsible for cosmetics of each Member State where the product will be marketed, of the place of manufacture or of initial importation before the product is placed in the market, using the Product Notification Form prescribed by the regulatory authority. *The product can be marketed after the product notification has been sent to the regulatory authority.*

2. After filing a product notification and receiving a notification number from the regulatory authority, does it mean that the product has been approved for sale by the authority?

Acceptance of a product notification does not constitute, in any way, an agreement that the product meets all the regulatory requirements. The company or person responsible for placing the product in the market has to ensure that each consignment of the product meets the requirements of the Directive and will not cause damage to human health under normal or reasonably foreseeable conditions of use. The ASEAN Cosmetic Directive shifts from a pre-market approval system, to a post-marketing surveillance system. The Regulatory Authority will carry out a range of post-marketing monitoring and surveillance activities to ensure compliance with the Directive.

3. If my product has been notified to an ASEAN Member Country, is it exempted from notification of another ASEAN country in which I intend to market the product too?

No, *as the authority of each country where the product is going to be marketed has to be informed individually.* If you intend to market the product in 3 ASEAN Member countries, you will have to notify the regulatory authority of the 3 ASEAN Member Countries.

4. If the cosmetic product is meant solely for re-export, must notification be filed with the regulatory authority?

Cosmetic products that are imported or locally manufactured *solely* for direct re-export can be exempted from product notification requirement, as they will not impact the safety of local consumers, but the company should maintain proper records and documents. These records should be open to inspection by the regulatory authorities at any time when required. However, if you export the

products to market in an ASEAN Country, notification in that ASEAN Country is required.

5. Does each individual shade of a range of a cosmetic product or a palette of colours require a separate product notification?

No. A single notification can be made for a range of cosmetic products or a palette of colours. However, full ingredient listing (one can use “may contain” to list the colorants used in each product form the palette) and the percentage of restricted substances will have to be declared for each colour in the range or palette. Please refer to the Guidelines on filing a notification to the regulatory authority.

Please note that you will have to file a new notification for colours added to an existing range or palette that are not included in the initial notification.

6. Can a foreign company that is not registered to operate business in the country where the product will be marketed, file the product notification?

No. A company registered to operate business in the country where the product will be marketed should file a product notification.

7. ¹What are the supporting documents to be submitted with a product notification?

The following documents should be submitted with the notification:

- *Full ingredient listing (as per labeling requirements) and the percentage of restricted ingredients appearing in the annexes of the Directive;*
- *Clear & legible colour photographs or draft drawing/artwork of the product labels, package inserts, inner and outer cartons.*
- *Business Licence of the registrant or company responsible for placing the product in the market (To be submitted once if applicable).*

8. If there are any changes in the information submitted in a product notification², do I have to file a new product notification?

It will depend on the types of changes involved, as indicated below:

- a) New product notification is required for changes in:
 - Manufacturer or assembler (?)

¹ The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

² Please refer to the Template For Notification for a Cosmetic Product. The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

- Product types
 - Intended use
 - Product presentation
 - Formula (?)
 - Manufacturer (?)
- b) An amendment notification can be submitted in an amendment form as prescribed by the regulatory authority for changes involving the following particulars:
- Brand and product name
 - Company responsible for placing the product in the market
 - Person representing the local company
 - Pack sizes, packaging material, labels (?)
 - Formula (?)
 - Change of assembler (?)

Guidelines on filing a notification to the regulatory authority

Particulars of a product

9. Name of brand and product

The complete name of the product should be given, in the following sequence: brand name, line name (if applicable), product name, if a single shade is notified, the shade name/number (e.g. L'oreal Feria Color 3D Hot Ginger).

10. Product types

The illustrative list is not exhaustive and you can include other types of cosmetic products not in the list by selecting others and specifying what it is. More than one category can be selected, e.g. 'Bath or shower preparations' and 'Hair-care products' can be selected if your product is both a shower gel and hair shampoo

11. Intended use

This refers to the function or use of the product and not the directions for use e.g. to moisturize the face, hand, etc.

12. Pack size

It should be given by weight or volume, in either metric or *both* metric and imperial system.

13. Product presentation(s)

Please select only one out of the 4 choices that best fit the presentation type of the product. The following is an explanation of the presentation types:

- 'A single product' exists in a single presentation form.

- ³A *range of colours*’ is a range of cosmetic products, which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades of colour (e.g. lipsticks, eye shadows or nail polish but not composite packs of different types).
- ‘*Single palette(s) in a range*’ refers to a range of colours as defined above, which are presented in a range of single palettes.
- ‘*Combination products in a single kit*’ refer to similar and/ or different product types packed and sold in a single kit. They cannot be sold separately. (e.g. a make-up kit of eye and lip colours; a set of skin-care products sold in a single kit).

14. Particulars of the manufacturer(s)/ Assembler(s) There may be more than one manufacturer and/or assembler for one product. The full names and contact details of each of them must be submitted.

15. Particulars of company

It refers to the local company responsible for placing the cosmetic products in the market, which may be a local manufacturer, an agent appointed by a manufacturer to market the product or the company that *is responsible for bringing in the product for sale in the country*. The business registration number or its equivalent should be indicated in the notification form, if applicable.

16. Particulars of the person representing the local company

The person who represents the company to submit the product notification must possess adequate knowledge or experience in accordance with the legislation and practice of the Member Country.

Product Ingredient list

17. ⁴Full ingredient listing and nomenclature

- a) All the ingredients in the product must be specified by using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated. The following are not regarded as ingredients:
 - Impurities in the raw materials used;

³ For these presentation types, only one notification needs to be submitted.

⁴ The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

- Subsidiary technical materials used in the preparation but not present in the final product;
 - Materials used in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions.
- b) The percentage of ingredients must be declared if they are substances with restrictions for use as specified in the annexes of the ASEAN Cosmetic Directive.
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Appendix A

List of Standard References to be use for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary
2. British Pharmacopoeia
3. United States Pharmacopoeia
4. Chemical Abstract Services
5. Japanese Standard Cosmetic Ingredient
6. Japanese Cosmetic Ingredients Codex