34. Do we need to reflect the Manufacturer's name and address on the label?

A. The ASEAN Cosmetic Labeling Requirement requires the name and address of the company or person responsible for placing the product in the local market on the label. Therefore, if the manufacturer is the one responsible for placing the product on the local market, then its name and address should be reflected on the label. However, the country of manufacture should be reflected at all times.

35. I have existing inventory of old labels/packaging, What will I do with this inventory?

A. You would need to work with your regulatory authorities/cosmetic industry on the transition to the ASEAN compliant labels. It is ideal that exhaustion of old labels be worked out to avoid scrapping. Meanwhile, you would need to plan how to ensure that your product labels comply with the ASEAN Cosmetic Labeling requirements by January 2008.

F. Claims

36. How do I determine if my claim is acceptable as cosmetic?

A. If the claim is promising cosmetic benefit and not medicinal or therapeutic benefit, it is acceptable as long as it can be substantiated. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself. Refer to the ASEAN Cosmetic Claims for Guidelines for further information.

37. Is there a harmonised list of allowed/not allowed claims in ASEAN?

A. No. ASEAN does not have a harmonised list of claims. Claims/claims assessment will be subjected to national control.

G. Frequently Asked Questions in Cosmetic Product Notification

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

A. 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 only be marketed after notification has been sent to the regulatory authority and acknowledgement has been received. Member Countries shall endeavour to ensure that notifications will receive acknowledgement within three working days.

39. After filing a product notification and receiving an acknowledgement (e.g. notification number) from the regulatory authority, does it mean that the product has been approved for sale by the authority?

A. 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.

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

A. No, 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 respective 3 ASEAN Member Countries.

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

A. Cosmetic products that are imported solely for direct re-export or locally manufactured solely for export are 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 Member Country, notification in that ASEAN Member Country is required.

Country specific requirements for manufacturers or importers of cosmetic products meant solely for export or re-export must be complied with.

42. Are samples including Hotel's sample, and professionally used cosmetic exempted from notification and the requirements of ACD?

A. All product samples must be notified to the authority and comply with all the requirements of the ACD.

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

A. No. A single notification can be made for a range of cosmetic products or a palette of colours. However, if required by the regulatory authority, full ingredient listing (one can use "may contain" to list the colorants used in each product in 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.

44. Can a company that is not registered to operate as a business in the ASEAN Member Country where the product will be marketed, file the product notification?

A. No, only a company registered to operate as a business in the ASEAN Member Country where the product will be marketed can file a product notification

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

A. The following documents should be submitted with the notification:

a. Full ingredient listing (as per labeling requirements) and the percentage of restricted ingredients appearing in the annexes of the Directive, if required by regulatory authority;
b. Clear & legible colour photographs or draft drawing/artwork of the product labels, package inserts, inner and outer cartons, if required by regulatory authority;
c. Copy of the Business Licence of the registrant or company responsible for placing the product in the market, to be submitted once, if required by regulatory authority;
d. Letter of authorisation from the product owner or manufacturer, if required by regulatory authority;

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

A. It will depend on the types of changes involved, as indicated in the table below:

Types of Change	Product Notification
Brand name	New
Company change due to change of distribution rights	New
Product types	New
Product presentation (single product, palettes in a range, etc)	Amendment
Intended use	New
Product name	New
Formulation	New
Manufacturer and or assembler (name and/or address)	New
Name and/or address of company without change of distribution rights	Amendment
Person representing company	Amendment
Pack sizes, packaging materials, labels.	Amendment, but not applicable if the information need not be submitted in Product Notification Form.

H. Guidance Document on Product Notification to the Regulatory Authority

Particulars of a product

47. 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). If there are different shades, the shade name/number for each shade shall be declared.

48. 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.

49. Intended use

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

50. 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.

1) " A range of variants similar in composition for the same use but differs in colours, flavours etc" 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).

1) "Palette(s) in a range of one product type" refers to a range of colours as defined above, which may be presented in a series of palettes.

1) "Combination products in a single kit" refers 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).

51. 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.

52. Particulars of the company

It refers to the local company responsible for placing the cosmetic products in the market, which may be a local manufacturer or 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, etc. The business registration number or its equivalent should be indicated in the notification form, if applicable.

1) For these presentation types, only one notification needs to be submited

53. 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 if required by regulatory authority

54. Full 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;
- 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.

c. For a range of colours/shades or products in a single kit, complete the Product Ingredient List in the following format:

- List ingredients in the Base Formulation
- May contain' and list each colour/shade

d. For combination products in a kit, list each product and its corresponding formulation individually. You can extend the form when more space is needed.

I. A Guide Manual for the Industry on Adverse Event Reporting

55. Introduction:

Pursuant to the ASEAN Cosmetic Directive, Article 3 (1) and the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok on 7-8 June 2004 it is important to harmonise the mechanism to gather and, if necessary, take action on important safety information arising from post marketing surveillance of cosmetic products.

Thus, agreed definitions and terminology, as well as procedures, will not only ensure uniform standards in the adverse event reporting process but will also facilitate product safety information sharing among ASEAN Regulatory Authorities.

There are two issues within the broad subject of safety data management that are appropriate for harmonisation at this time:

- The development of standard definitions and terminology for key aspects of adverse event reporting, and
- The appropriate mechanism for handling adverse event reporting

This Guide shall be revised as necessary, to take into account technical progress and regulatory developments.

56. Definitions and terminologies

a. Adverse Event:

Any genuine harmful or unintended event reasonably attributable to the normal or foreseeable use of a given cosmetic product.

b. Serious Adverse Event:

A serious event is any untoward medical occurrence that:

- Results in death,
- Is life threatening (the term life threatening refers to an event in which the person was at risk of death at the time of the event;
- Requires in-patient hospitalisation, or
- Results in persistent or significant disability/incapacity

57. Who should the industry report to?

A. The company or person responsible for placing the cosmetic product in the market shall report to the regulatory authority of the ASEAN Member State where the adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc).

58. What should be reported?

A. **a. Every cases of serious Adverse Event**:

All serious adverse events should be reported. Non-serious adverse events are not required to be reported.

Whenever there is reasonable suspicion that the cosmetic product might be the cause of the reaction, reporting is necessary for all serious adverse events as defined in section 2.2. the expression “reasonable suspicion” is meant to convey in general that there are evidences to suggest a causal relationship or an association.

b. **High incidence of Adverse Event (Non-serious/severe reactions)**

There are “non-serious” adverse events that occur at a high incidence (as defined by the ratio of events to units sold) of a single “severe” reaction type that may necessitate rapid communication to the regulatory authority. However, appropriate medical and scientific judgment should be applied for each situation of non-serious, single “severe”[2] adverse reaction that has a high incidence before reporting to the regulatory authority.

2) To ensure no confusion or misunderstanding between the terms “serious” and “severe”, which are not synonymous, the following note of clarification is provided:
The term “severe” is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe reaction); the event itself, however, may be of relatively minor significance (such as skin irritation, headache). Seriousness, not severity, serves as a guide for defining regulatory reporting obligations.

59. When to report an Adverse Event?

a. Fatal or life threatening Adverse Events

Fatal or life threatening adverse event qualify for very rapid reporting to the regulatory authority, which shall be notified (e.g. by telephone, facsimile transmission, email or in writing) as soon as possible but no later than 7 calendar days after first knowledge, followed by completing the Adverse Cosmetic Event Report Form (Appendix I) within an additional 8 calendar days and providing any other information as may be requested by the regulatory authority.

b. Other serious Adverse Events

All other serious adverse events (as defined in section 2.2) that are not fatal or life threatening must be reported as soon as possible, but no later than 15 calendar days after first knowledge.

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J. Appendices Annex 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

APPENDIX 1

ASEAN Cosmetic Directive

FOR OFFICIAL USE ONLY
Date received:
Product Notification No.:

TEMPLATE FOR NOTIFICATION OF COSMETIC PRODUCT

☑ Tick where applicable

PARTICULARS OF PRODUCT

1 Name of brand & product:

1.1 Brand

1.2 Product Name

1.3 List of Variants or Shade Names

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2. Product type(s)

- ☐ Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- ☐ Face masks (with the exception of chemical peeling products)
- ☐ Tinted bases (liquids, pastes, powders)
- ☐ Make-up powders, after-bath powder, hygienic powders, etc.
- ☐ Toilet soaps, deodorant soaps, etc
- ☐ Perfumes, toilet waters and eau de Cologne
- ☐ Bath or shower preparations (salts, foams, oils. gels, etc.)
- ☐ Depilatories
- ☐ Deodorants and anti-perspirants
- ☐ Hair care products
  - hair tints and bleaches (including permanent hair dyes),
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines),
- ☐ Shaving product (creams, foams, lotions, etc.)
- ☐ Products for making-up and removing make-up from the face and the eyes
- ☐ Products intended for application to the lips
- ☐ Products for care of the teeth and the mouth
- ☐ Products for nail care and make-up
- ☐ Products for external intimate hygiene
- ☐ Sunbathing products
- ☐ Products for tanning without sun.
- ☐ Skin whitening products
- ☐ Anti-wrinkle products
- ☐ Others (please specify)

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3. Intended use

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4. Product presentation(s)

- ☐ Single product
- ☐ A range of product variants similar in composition for the same use but differs in colours, flavours etc.
- ☐ Palette(s) in a range of one product type
- ☐ Combination products in a single kit
- ☐ Others (please specify)

PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)[3]

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

5. Name of manufacturer

Address of manufacturer:

Country

Tel : Fax:

[3] *A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic product. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.*

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/immediate container which is labelled or to be labelled before the product is sold or supplied in it.

A secondary assembler is a company which is engaged only in a process of labelling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled, before the product is sold or supplied.

6. Name of assembler (Please tick accordingly. May tick more than one box):

Primary assembler□ Secondary assembler□

Address of assembler (state country):

Country

Tel:□□ Fax:

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET

7. Name of company:

Address of company:□

Tel:□□ Fax:

Business Registration Number /License to Operate Number (if applicable, submit a copy of the Business Registration Certificate):

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Name of person:□□

Tel:□□ Email:

Designation in the company:

PRODUCT INGREDIENT LIST

9. Please check the following boxes

□ □ I have examined the latest revisions of the Annexes II to VII of the ASEAN □ Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN □ Cosmetic Directive and confirmed that the product in this notification does not □ contain any prohibited substances and is in compliance with the restrictions □ and conditions stipulated in the Annexes.□

□ I undertake to respond to and cooperate fully with the regulatory authority with □ regard to any subsequent post-marketing activity initiated by the authority.

[To submit ingredient list with percentages of restricted ingredients and packaging materials as required by Member Country]

No.	Full Ingredient name (use INCI or approved nomenclature in standard references)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

*) **If product is not compliance with ACD, please provide details of non-compliance**

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices.

2. I undertake to abide by the following conditions:
   i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
   ii. Notify the Authority of fatal or life threatening serious adverse event[4] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   iii. Complete the Adverse Cosmetic Event Report Form[5] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;
   iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;
   v. Notify the Authority of any change in the particulars submitted in this notification;

3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

_____

[Name and Signature of person representing the local company]

_____ _____

[Company stamp] [Date]

[4] As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[5] Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

To:
Name & Address of the Regulatory Authority
Department
Telephone no.
Fax no.
Email address

FOR OFFICIAL USE ONLY
Date received:
Product Notification No.:

REPORT FORM FOR ADVERSE COSMETIC EVENT

I. Company Particulars

Name and address of Company		
Name & designation of person reporting		
Tel No.:	Fax No.:	Email:

II. Product Particulars

Product Name (as in product notification) Ingredient listing & pack size	(Please attach a separate list)
Product Type/Intended use	
Name of Manufacturer & country of manufacture	
Expiry or manufacturing date	
Batch No.	

III. Details of Adverse Event

Name/ Initials of person			
Identification or Passport no.			
Age		Sex	
Ethnic group / Nationality			
Date of onset of adverse event			
Description of adverse event (please use and attach a separate report if necessary) Delay between last application of the product and onset of symptoms: ___ min(s) ___hour(s)____day(s) How was the product used:			
Is the person hospitalised due to the adverse reaction?	☐ Yes	☐ No	
Did person seek medical attention?	☐ Yes	☐ No	
Outcome	☐ Recovered (Date:_____) ☐ Not yet recovered	☐ Death (Date: _____) ☐ Unknown	
Source of report	☐ Healthcare professional	☐ Consumer	☐ Others (specify)
[Signature of person making report & date of report]			

APPENDIX 3

CONTACTS: LIST OF ACC MEMBERS, ASEAN SECRETARIAT

BRUNEI DARUSSALAM
Mr. Chong Chee Kiong
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