COSMETIC NOTIFICATION

Guideline for processing notification applications

COSMETIC NOTIFICATION MANUAL



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According to the Decision on the Quality Control of Cosmetic Products No. 2580/MoH, dated November 12, 2003, the Food and Drug Department, Ministry of Health has developed this guide to facilitate individuals, legal entities or any organization that conducts business related to the production and import of cosmetic products to easily understand of the documents submission for notification and the provision of necessary documents to the Department of Food and Drug, Ministry of Health for consideration, approval or rejection the notification of cosmetic products. The details are following:

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1. What are cosmetic products?

Cosmetic products: means substances used for brushing, massaging, spraying, sprinkling, with steam or any action aimed at any part of external human body for beauty or to enhance beauty 2 which include materials used as ingredients specifically for cosmetic production or other materials that have been classified by the Ministry of Health to be cosmetic products except the jewelry.

2. Illustrative list by category of cosmetic products

There are 5 categories of cosmetic product

- Skin products
- Hair care products
- Product for care of the teeth and the mouth (Except for toothbrushes, toothpicks)
- Product for nail care
- Fragrance for external human body use

3. Conditions for business on cosmetic notification

- The person or enterprise wish to do the cosmetic registration should registered business as Import-Export company according to requirement of relevant authority such as: it is official business and having business licensing which indicate on the import export of cosmetic.
- There are apropiate facilities for storage and transport of cosmetic products to ensure product quality. it should have good warehouse, with good ventilation, security system and environement protection.

4. Requirements for cosmetic notification

Base on the risk categorization the required documents must attach while apply the notification as details below:

4.1 High risk products:

- Formulation
- Authorization Letter
- Certificate of Notification
- Certificate of Analysis
- GMP Certificate
- Labels and Batch Coding System
- Labels in Lao language or sticker
- Claim Support Summary
- Undesirable Health Effects Summary

- Safety Assessment Summary
- 4.2 Medium risk products:
 - Formulation
 - Authorization Letter
 - Certificate of Analysis
 - Labels and Batch Coding System
 - Labels or sticker in Lao language
 - Claim Support Summary
 - Undesirable Health Effects Summary
 - Safety Assessment Summary

Note: GMP certificate must be kept at the company

- 4.3 Low risk products
 - Formulation
 - Authorization Letter
 - Labels and Batch Coding System
 - Labels or sticker in Lao Language
 - Claim Support Summary

Note: These documents must be kept at the company:

- GMP Certificate
- Undesirable Health Effects Summary
- Safety Assessment Summary

5. The detail of documents

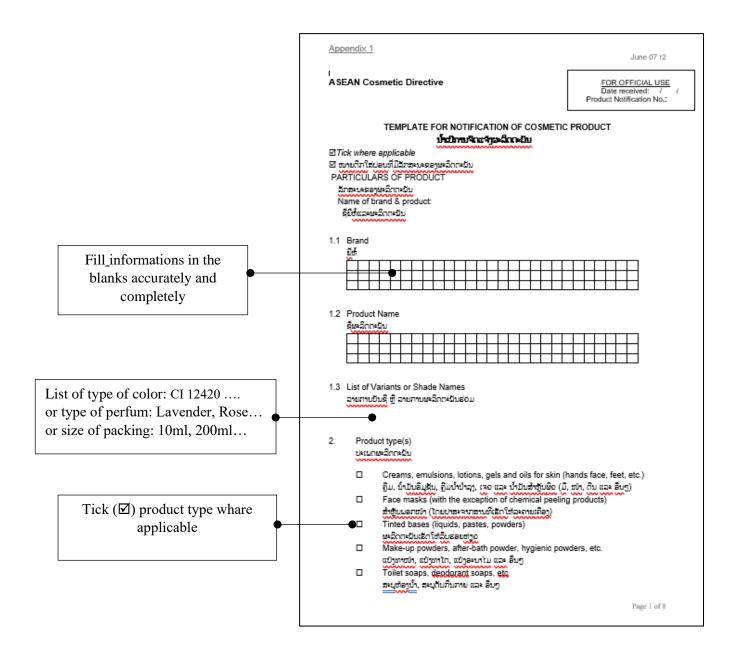
5.1 Application form

Application form can be downloaded from www.fdd.gov.la fill_informations in the blanks accurately and completely. Enter the document number, Date, Signature and Stamp before submitting.

	ສາຫາລະນະລັດ ປະຊາທິປະໄຕ ປະຊາຊົນລາວ ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ			ລອນ
	บํລິສັດ		ເລກທີ	
	ໂທລະສັບ		ນະຄອນຫຼວງວຽງຈັນ, ວໍ	วัมที:
	ມືຖື			
	E-mail:	ໜັງລືລະ	erenî	
		_		
	ຣຽນ: ທ່ານຫົວໜ້າກິມອາຫານ ແລະ ຢາ, ກະຊວງສາທາລະນະສຸກ			
	ເລື່ອງ:	ຂໍອະນຸຍາດຈິດແຈ້ງຜະລິດຕະພັນ	ແຄື່ອງສຳອາງທີ່ນຳເຂົ້າຈາກ	າຕ່າງປະເທດ.
Fulfill_informations in the blanks accurately and	ล้า ผะเจ้า		ແໜ່ງ	ມີສຳນັກງານ
completely	ດັ້ງຢູ່ຖະໜົນ	 บ้าม,	, ເມືອງ	ແຂວງ
r ,	ຖືທະບຽນວິສາຫະກິດເລກທີ	ລຶງວັນທີ		
	ມີຈຸດປະສິງຂໍຈິດແຈ້ງຜະລິດຕະພັນເຄື່ອງສຳອາງ ຈຳນວນລາຍການ ທີ່ນຳເຂົ້າມາຈາກປະເທດ			
	ດັ່ງລາຍລະອຽດລຸ່ມນີ້:			
	1			
	2			
	ດັ່ງນັ້ນ, ຈິ່ງຮຽນສະເໜີມາຍັງທ່ານຜິຈາລະນາຕາມທາງຄວນດ້ວຍ.			
				ອຳນວຍການບໍລິລັດ

5.2 The notification forms

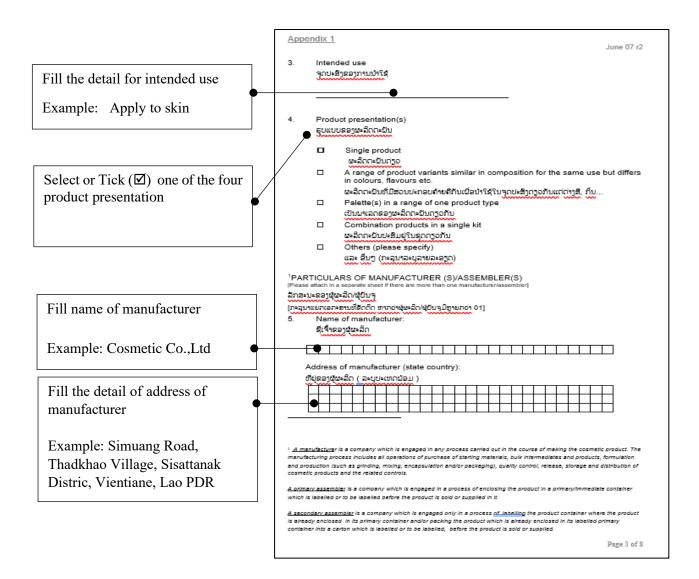
The notification form can be downloaded from www.fdd.gov.la
Using by Microsoft Word version
Fill_informations in the blanks accurately and completely (English only)



Note 1: In Section 1.3, select one of the three cases below

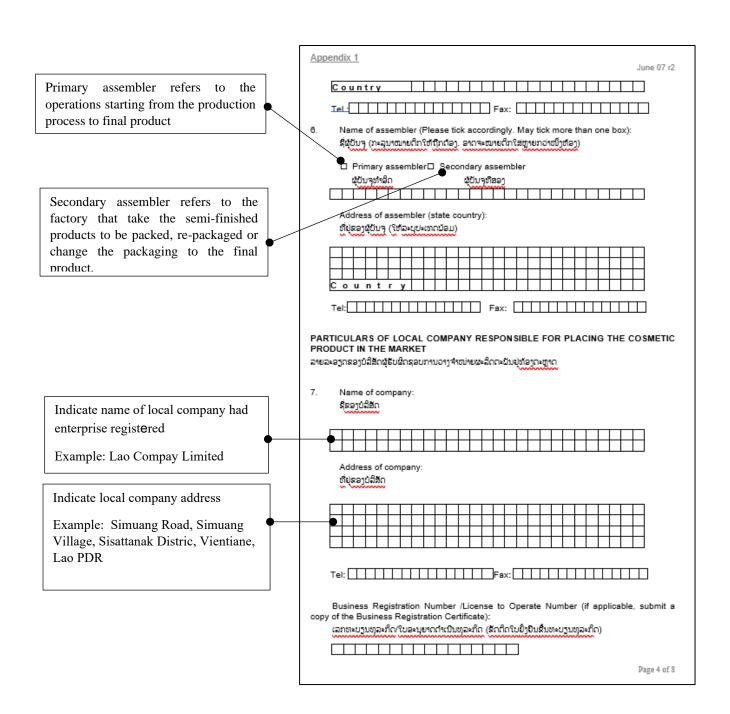
- Case 1: A range of product variants similar in composition for the same use but differs in colours, flavours etc, such as: Nail polish or lipstick must notify colour details as CI 12420, CI14700 ...
- Case 2: A range of product variants similar in composition for the same use but differs in flavours etc, such as: Parfumes, eau de tolet waters and eau de Cologne must notify flavours details as Lavender, Rose...
- Case 3: Single product must notify details of size, such as: 10ml, 20ml, 50ml, 100ml...

	Appendix 1	June 07 r2
		Depilatories ผะลึกตะมันทำจัดสิบ
		Deodorants and anti-perspirants
		กับทั้น และ ทำจัดเพื่อ
		Hair care products
		ຜະລິດຕະດັນປົກປ້ອງເສັ້ນຜົມ
		- hair tints and bleaches (including permanent hair dyes)
		ริข์ลมติม และ ปลาสิติม
		- products for waving, straightening and fixing,
		ംപ്ററംപ്വറ്റമ്പ്, ഉവരുന്നു അത്രാം വര്യം പ്രാംപ്വനംപ്വാനം
		- setting products,
		ซะมีกตะนับจักติาูนิม
		- cleansing products (lotions, powders, shampoos),
		ผะฝึกตะฝัมทำคอามสะอาก (ถิมทำข่าลุว, หขั้ງ, ยาสะฝืม)
		- conditioning products (lotions, creams, oils),
		ຜະລິດຕະຝັນເພື່ອສຸຂະພາບຜົມ (ຄູີມນ້ຳປາລຸງ, ຄູີມ, ນ້ຳມັນ)
		- hairdressing products (lotions, lacquers, brilliantines)
		ຜະລິດຕະພັນຈັດແຕ່ງຊີງຜົມ (ຄຼີມນໍ້າປ່າລຸງ, ເຄືອນເງົາ)
		Shaving product (creams, foams, lotions, etc.)
		ຜະລິດຕະມັນແຖໜວດ (ຄູີມ, ຝອງ, ຄູີມນ້ຳປຳລຸງ ແລະ ອື່ນໆ)
		Products for making-up and removing make-up from the face and the eyes
		ຜະລິດຕະມັນສຳລັບປົກປິດ ແລະ ຕົບແຕ່ງ ໜຳ ແລະ ຕາ
		Products intended for application to the lips
		<u>ສະລິດຕະໜັນ</u> ລິບສະຕິກ
		Products for care of the teeth and the mouth
		ຜະລິດຕະມັນຣັກສາແຊ້ວ ແລະ ປາກ
		Products for nail care and make-up
		ຜະລິດຕະມັນ ສຳລັບປາລຸງເລັບ ແລະ ສີທາເລັບ
		Products for external intimate hygiene (exclude personal lubricant)
		ຜະລິດຕະມັນ ສຳລັບອະນາໄມຊ່ອງຄອດ
		Sunbathing products
		ຜະລິດຕະມັນ ສຳລັບການອາບແດດ
		Products for tanning without sun.
		<u>ผะลึกกะนับปร</u> ุบสิชิอ
		Skin whitening products
For others type please tiels (M) have		๕ะลึกกะฉับ เธักใช้เชื่อสรอ
For others type please tick (☑) here		Anti-wrinkle products
Example: Sanitary		ຜະລິດຕະລັນ ລົບຮອຍຫ່ຽວ-ຕົນກາ
Example. Samary	•	Others (please specify)
		และ อื่นๆ (ทะสมาละบุลายละอรูก)
		Page 2 of 8

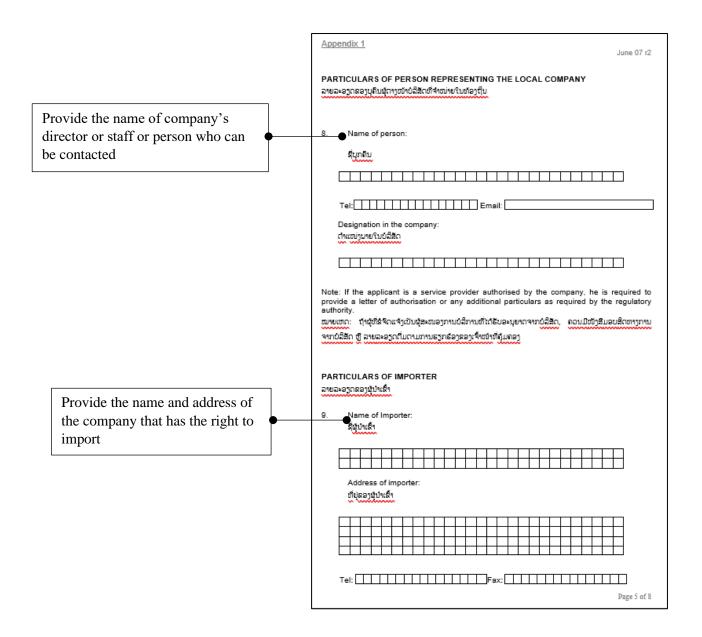


Note 2: In Section 4, select (☑) one of the four cases below

Product presentation	Example
Single product means a product with a single formula	
A range of product variants similar describes the products with the same main composition and use for the same purpose but different colours, Flavours etc (in different boxes)	
Palette(s) in a range of one product type describes the same product but with different colors or odors in the same box	0 B 0 D E F
Combination products in a single kit describe a product that has many different patterns and contain in the same box	Course name Course of the Course name Course of the Cour



Note 3: In Section 6 Please tick only one box



Note 4: In Section 9, In the case of multiple import companies, the names and addresses of all eligible import companies must be provided in full (Can be added to the form by copy & paste).

Appendix 1 June 07 r2 The applicant must understand PRODUCT INGREDIENT LIST and follow the rule at section ລາຍລະອຽດສ່ວນປະກອບຂອງຜະລິດຕະນັນ Please check the following boxes 10 and then tick **☑** two empty ກະລຸນາກວດເບິ່ງຊອງດັ່ງລຸ່ມນີ້: 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. ລ້ານະເຈົ້າໄດ້ກວດກາ, ຫົບຫວນຫຼັກສຸດຂອງຫ້າຊ້ອນຫ້າຍ, 2 ຫາ 7 ຂອງບັນຊື່ສ່ວນປະສົມເຄື່ອງສຳອາງ ອາຊຽນຕາມທີ່ໄດ້ລະບຸຢຸໃນການບັບປຸງຫຼ້າສຸດຂອງຄຸ່ມີເຄື່ອງສຳອາງອາຊຽນ ແລະ ຂໍຍິ່ງຍືນວ່າພະລິດຕະຝັນທີ່ນຳມາ ຈີດແຈ້ງນີ້ບໍ່ໄດ້ບັນຈຸສານດ້ອງຫ້າມໃດໝົດ ແລະ ສອດຄ່ອງກັບຂໍ້ໜ້າມ ແລະ ເງື່ອນໄຂທີ່ໄດ້ກຳນົດໄວ້ໃນບົດຊ້ອນ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority ຂ້ານະເຈົ້າຍິນດີປະຕິບັດ ແລະ ຮ່ວມມີກັບເຈົ້າໜ້າທີ່ຄຸ້ມຄອງລະບຽບການກ່ຽວກັບການດຳເນີນການ ຕິດຕາມພາຍຫຼັງການຈຳໜ່າຍ [To submit ingredient list with percentages of restricted ingredients as required by member country] [ໃຫ້ບອກສ່ວນປະສົມພ້ອມດ້ວຍເປີເຊັນ ຂອງສ່ວນປະກອບທີ່ຈຳກັດໃຫ້ໃຊ້ອີງຕາມແຕ່ລະປະເທດ] Full Ingredient name (use INCI or approved nomenclature in standard references) ລຳດັບ ຊື່ເຕັມຂອງສ່ວນປະກອບ (ໃຫ້ໃຊ້ INCI ຫຼື ຊື່ມາດຕະຖານທີ່ສາກິນຣັບຣຸ້) Fill all ingredients of cosmetic product with percentages required Page 6 of 8

Appendix 1 June 07 r2 DECLARATION I hereby declare on behalf of the company I represent that the product in the notification meets all the requirements of ASEAN Cosmetic Directive (ACD), its Annexes and Appendices which have been transposed into the local legislation. 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;

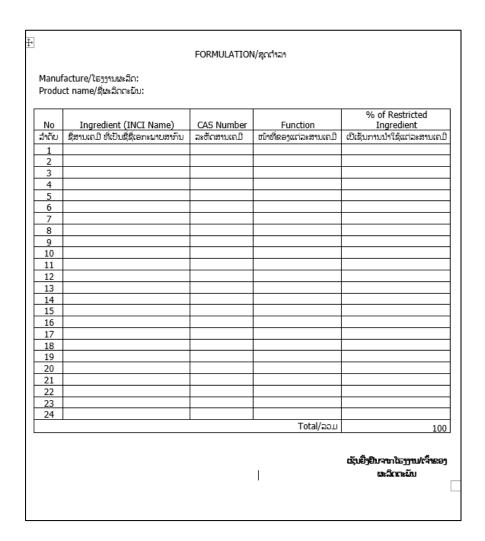
ii. Notify the Authority of fatal or life threatening serious adverse event² as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge; iii. Complete the Adverse Cosmetic Event Report Form³ within 8 calendar days 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 Cosme Report Form; v. Notify the Authority of any change in the particulars submitted in this notification: vi. Recall the product from the market, and discontinue selling or supplying the product, as directed by the Authority. 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. 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 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. Signature of person in section 8 [Name and Signature of person representing the local company] [ບຸຄົນຜູ້ຕາງໜ້າບໍລິສັດທີ່ຈຳໜ່າຍໃນຫ້ອງຖິ້ນ] Company stamp ວັນທີ ເດືອນ ປີ Date [Company stamp] ภาปะทับ 2 As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products 3 Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products Page 7 of 8 Provide the date

5.3 Formulation form

The Information on ingredients must include:

- INCI name
- Function
- Percentage of restricted ingredient
- The ingredients of cosmetics must specify the amount from more to less

Example:



5.4 The Authorization Letter.

The manufacture or Brand owner must provide an official letter to certify the right to import and distribute to the distributor in Lao PDR and/or the branch of the distributor company.

5.5 Labels and Batch Coding System

Example of labels:



Example of batch coding system

Batch Coding System ເລກລະຫັດການຜະລິດ ຊື່ຍີ່ຫໍ້/Brand name: ຊື່ຜະລິດຕະພັນ/Product name: ລະຫັດການຜະລິດ/Batch coding system: เฉกละขัด/Batch number: XX/DDMMYY = ເລກລະຫັດ/Batch number ວວດດປປ/DDMMYY= ວັນເດືອນປີຜະລິດ/Manufacturing date ວັນໝົດອາຍຸ/Expiry date: ວວດດປປປປປ/DDMMYYYY ດືວຢາງ/Example: เลกละตัด/Batch No: 01/0102016 = เลกละตัด/Batch No: 01 ວັນເດືອນປີຜະລິດ/MFD: 01 ກຸມພາ 2016 01 February 2016 ວັນໝົດອາຍຸ/Expiry date: 01022018 = ວັນໝົດອາຍຸ: 01 ກຸມພາ 2018 Expiry date: 01 February 2018 ເຊັນຢັ້ງຢືນຈາກເຈົ້າຂອງໂຮງງານ

Note 5: Content of labeling

The label of cosmetic products imported must contain the following local content:

- 1. Product name and trade name must be larger than other text;
- 2. The list of ingredients must be INCI name and match with the formula notified
- 3. Instructions for use, warnings, prohibitions.
- 4. Size of packaging;
- 5. Storage condition;
- 6. Name and address of the notification company;
- **7.** Name and address of the country of manufacture or only the country of manufacture;
- 8. Date of manufacture and date of expiry or text with similar meaning;
- 9. Batch number;
- 10. Notification numbers (Not required)
- 11. Label should be in Lao language or sticker

In the case of the size of cosmetic products is small, only items 1, 3, 7 and 8 should be in the label



The claim in the label must use content that approve by FDD and are fair to users by avoiding content that may cause harm to society, including content that refer to origin, quality, quantity, characteristics, etc.

These following texts are the content that offensive to users:

- The information is not true and over claim;
- The information is lead to misunderstanding about the important information of cosmetics, whether it is the use of references, scientific reports, statistics and acts in any way that is not true or exaggerated;
- Content on the treatment, relief and treatment of various diseases including sexual stimulation;
- Messages that are against the culture that can cause direct and indirect damage

5.6 Claim Support Summary

Refers to the active ingredients of the formula that refer to the properties of the product.

Black hair products must contain substances that can cover or dye the hair to black color



5.7 Undesirable Health Effects Summary

Means information about symptoms, effects and side effects of cosmetics including the results of remedial actions in cases where the impact is not severe

Example:

ABC COSMETICS CO., LTD				
<u>Unde:</u>	sirable Health	ı Effects Su	Date: 10/08/202 <u>mmary</u>	
Product Name		ABC Color S	hampoo-Natural Black	
ountry where Sold:		Vietnam, Chi	na, Cambodia	
Country where sold.	otal number of undesirable health effects:		10	
	ealth effects:	10		
	ealth effects:	10 2018		
Total number of undesirable h First Launch: Case Number	Date of	2018 Contact	Country	
Total number of undesirable h First Launch: Case Number 6	Date of June	2018 Contact 2019	Vietnam	
Total number of undesirable h First Launch: Case Number 6 3	Date of June Octobe	2018 Contact 2019 r 2020	Vietnam China	
Total number of undesirable h First Launch: Case Number 6	Date of June	2018 Contact 2019 r 2020	Vietnam	
Total number of undesirable h First Launch: Case Number 6 3	Date of June Octobe	2018 Contact 2019 r 2020	Vietnam China	
Total number of undesirable h First Launch: Case Number 6 3	Date of June Octobe	2018 Contact 2019 r 2020	Vietnam China Cambodia	

5.8 Safety Assessment Summary means the confirmation of safety of cosmetic products from owner or manufacturer

Example:

ABC COSMETICS CO., LTD

Date: 10/08/2021

Safety Assessment

Category: Color Shampoo

Product Name: ABC Color Shampoo-Natural Black Manufacturing Plant: ABC COSMETICS CO., LTD

This product is formulated using the ingredients suitable for use in cosmetics Directive and the formula meets the Annexes of the ASEAN Cosmetic Directive.

This product is a cosmetic according to Article 2.1 of ASEAN Cosmetic Directive. It is assessed not to cause damage to account, the product presentation, its labeling, instructions for its use and disposal as well as any other indication or information provided by the manufacturer. This assessment considers the general toxicological profile of the ingredients, their chemical structure and their level of exposure.

This assessment of human safety is carried out in accordance with ASEAN Guideline for safety evaluation of cosmetic products.

signature

Name

Position

6 Payment of fees and services

Fee: 01 Product 200,000 kip Valid 2 years.

Service: 01 Product 50,000 kip

- 7 One sample of product
- 8 Time for notification approval

New notification: 14 Working days;

Renewal: 10 Working days.

9 Risk categorization of cosmetic products

Item	HS Code	Product type	Risk categorize
1	3808.94.90.00	Hand sanitizers	High risk
2	3304.10.00.00	Products intended for application to the lips	High risk
3	3304.20.00.00	Eye make-up preparations	High risk
4	3304.99.30.00	Products for tanning without sun.	High risk
5	3304.99.30.00	Sunbathing products	High risk
6	3304.99.30.00	Skin whitening products	High risk
7	3304.99.30.00	Anti-wrinkle products	High risk
8	3306.90.00.00	Products for care of the teeth and the mouth (Tooth	High risk
		pastes, tooth powders, mouth washes, mouth sprays, solid and liquid dental preparation)	2
9	3401.11.90.00	Products for external intimate hygiene (exclude personal lubricant)	High risk
10	9619.00.12.00	Sanitary tampons of paper, paper pulp, cellulose wadding or webs of cellulose fibres	High risk
11	3304.91.00.10	After-bath powder, hygienic powders, etc.	Medium risk
12	3304.91.00.90	Products for making-up and removing make-up from the face	Medium risk
13	3304.99.20.00	Anti-acne products	Medium risk
14	3304.99.90.00	Creams, emulsions, lotions, gels and oils for skin (hands face, feet, etc.)	Medium risk
15	3304.99.90.00	Face masks	Medium risk
16	3305.10.90.00	Hair cleansing products (Lotions, powders, shampoos, liquid creams, solid creams or gels)	Medium risk
17	3305.10.90.00	Hair tonics	Medium risk
18	3305.10.90.00	Anti-hair fall/Hair loss	Medium risk
19	3305.20.00.00	Products for waving, straightening and fixing	Medium risk
20	3305.20.00.00	Hair tints and bleaches (including permanent hair dyes)	Medium risk
21	3307.20.00.00	Deodorants and anti-perspirants	Medium risk
22	3307.90.40.00	Depilatories	Medium risk
23	3401.11.40.00	Medicated soap including disinfectant soap	Medium risk
24	9619.00.11.00	Sanitary towels with an absorbent core of wadding of textile materials	Medium risk
25	3303.00.00.00	Perfumes, toilet waters and eau de Cologne	Low risk
26	3304.30.00.00	Products for hand and nail care (Nail lacquers-remover, nail creams, cuticle softeners, nail bleaches, nail whitening, etc.	Low risk
27	3305.30.00.00	Hair lacquers	Low risk
28	3305.90.00.00	Setting products	Low risk
29	3305.90.00.00	Conditioning products (lotions, creams, oils),	Low risk
30	3305.90.00.00	Hair dressing products (lotions, lacquers, brilliantines)	Low risk
31	3307.10.00.10	Shaving product (creams, foams, lotions, etc.)	Low risk
32	3307.30.00.00	Perfumed bath salts and other bath preparations	Low risk
33	3401.11.50.00	Bath or shower preparations (salts, foams, oils. gels, etc.)	Low risk
34	3401.30.00.00	Soap and preparations for washing the skin, in the form of liquid or cream and put up for retail sale, whether or not containing soap	Low risk