

ASEAN Cosmetic Directive

TEMPLATE FOR NOTIFICATION OF COSMETIC PRODUCT

ນ້ຳເບີການຈົດແຈ້ງຜະລິດຕະພັນ

Tick where applicable

ໝາຍຕົກໃສ່ບ່ອນທີ່ມີລັກສະນະຂອງຜະລິດຕະພັນ

PARTICULARS OF PRODUCT

ລັກສະນະຂອງຜະລິດຕະພັນ

Name of brand & product:

ຊື່ຍີ່ຫໍ້ແລະຜະລິດຕະພັນ

1.1 Brand

ຍີ່ຫໍ້

1.2 Product Name

ຊື່ຜະລິດຕະພັນ

1.3 List of Variants or Shade Names

ລາຍການບັນຊີ

2. Product type(s)

ປະເພດຜະລິດຕະພັນ

Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
ຄຣີມ, ນ້ຳມັນອີມູຊັນ, ໂລຊັນ, ເຈວ ແລະ ນ້ຳມັນສຳຫຼັບຜິວ(ມື, ໜ້າ, ຕີນ ແລະ ອື່ນໆ)

Face masks (with the exception of chemical peeling products)

ສຳຫຼັບພອກໜ້າ(ໂດຍປາສະຈາກສານທີ່ເຮັດໃຫ້ລະຄາຍເຄື່ອງ)

Tinted bases (liquids, pastes, powders)

ຜະລິດຕະພັນເຮັດໃຫ້ລືບຮອບທຸ່ວ

Make-up powders, after-bath powder, hygienic powders, etc.

ແປ້ງທາໜ້າ, ແປ້ງທາໂຕ, ແປ້ງອະນາໄມ ແລະ ອື່ນໆ

Toilet soaps, deodorant soaps, etc

ສະບູຫ້ອງນ້ຳ, ສະບູດັບກິນກາຍ ແລະ ອື່ນໆ.

Perfumes, toilet waters and eau de Cologne

ນ້ຳຫອມ, ນ້ຳຫອມດັບກິນທ້ອງນ້ຳ

Bath or shower preparations (salts, foams, oils, gels, etc.)

ຄຣີມອາບນ້ຳທີ່ມີ (ເກືອ, ຟອງ, ນ້ຳມັນ, ເຈວ ແລະ ອື່ນໆ)

Depilatories

ຜະລິດຕະພັນກຳຈັດຂົນ

Deodorants and anti-perspirants

ດັບກິນ ແລະ ກຳຈັດເຫືອ

Hair care products

ຜະລິດຕະພັນປົກປ້ອງເສັ້ນຜົມ

- hair tints and bleaches (including permanent hair dyes)

ສີຍ້ອມຜົມ ແລະ ຟອກສີຜົມ

- products for waving, straightening and fixing,

ຜະລິດຕະພັນດັດຜົມ, ຍືດຜົມ ແລະ ສ້ອມແຊມຜົມ.

- setting products,

ຜະລິດຕະພັນຈັດຊົງ

- cleansing products (lotions, powders, shampoos),

ຜະລິດຕະພັນທຳຄວາມສະອາດ (ໂລຊັນ, ແປ້ງ, ຢາສະຜົມ)

- conditioning products (lotions, creams, oils),

ຜະລິດຕະພັນເພື່ອສຸຂະພາບຜົມ(ໂລຊັນ, ຄຣີມ, ນ້ຳມັນ)

- hairdressing products (lotions, lacquers, brilliantines)

ຜະລິດຕະພັນຈັດແຕ່ງຊົງຜົມ(ໂລຊັນ, ເຄືອບເງົາ)

Shaving product (creams, foams, lotions, etc.)

ຜະລິດຕະພັນແຖໜວດ (ຄຣີມ, ຟອງ, ໂລຊັນ ແລະ ອື່ນໆ)

Products for making-up and removing make-up from the face and the eyes

ຜະລິດຕະພັນສຳຫຼັບປົກປັດ ແລະ ຕົບແຕ່ງ ໜ້າ ແລະ ຕາ

Products intended for application to the lips

ຜະລິດຕະພັນ ລິບສະຕິກ

Products for care of the teeth and the mouth

ຜະລິດຕະພັນ ຮັກສາແຂ້ວ ແລະ ປາກ

Products for nail care and make-up

ຜະລິດຕະພັນ ສຳຫຼັບບຳລຸງເລັບ ແລະ ສີທາເລັບ

Products for external intimate hygiene (exclude personal lubricant)

ຜະລິດຕະພັນ ສຳຫຼັບອະນາໄມຊ່ອງຄອດ

Sunbathing products

ຜະລິດຕະພັນ ສຳຫຼັບການອາບແດດ

Products for tanning without sun.

ຜະລິດຕະພັນປຸງສີຜິວໂດຍບໍ່ຕາກແດດ

Skin whitening products

ຜະລິດຕະພັນ ເຮັດໃຫ້ຜິວຂາວ

Anti-wrinkle products

ຜະລິດຕະພັນ ລົບຮອຍທຸ່ງວ, ຮອຍຕີນກາ

Others (please specify)

ແລະ ອື່ນໆ (ກະລຸນາລະບຸລາຍລະອຽດ)

3. Intended use

ຈຸດປະສົງຂອງການນຳໃຊ້

4. Product presentation(s)
ຮູບແບບຂອງຜະລິດຕະພັນ

Single product

ຜະລິດຕະພັນດຽວ

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

ຜະລິດຕະພັນທີ່ມີສ່ວນປະກອບຄ້າຍຄືກັນເພື່ອນຳໃຊ້ໃນຈຸດປະສົງດຽວກັນແຕ່ຕ່າງສີ, ກິ່ນ...

Palette(s) in a range of one product type

ເປັນພາເລດຂອງຜະລິດຕະພັນດຽວກັນ

Combination products in a single kit

ຜະລິດຕະພັນປະສົມຢູ່ໃນຊຸດດຽວກັນ

Others (please specify)

ແລະ ອື່ນໆ (ກະລຸນາລະບຸລາຍລະອຽດ)

¹PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)

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

ລັກສະນະຂອງຜູ້ຜະລິດ/ຜູ້ປັບຈຸ

[ກະລຸນາແຍກເອກະສານທີ່ຂັດຕິດ ຫາກວ່າຜູ້ຜະລິດ/ຜູ້ປັບຈຸມີຫຼາຍກວ່າ 01]

5. Name of manufacturer:

ຊື່ເຈົ້າຂອງຜູ້ຜະລິດ

Address of manufacturer (state country):

ທີ່ຢູ່ຂອງຜູ້ຜະລິດ (ລະບຸປະເທດພ້ອມ)

C o u n t r y

Tel :

Fax:

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

ຊື່ຜູ້ປັບຈຸ (ກະລຸນາໝາຍຕິກໃຫ້ຖືກຕ້ອງ. ອາດຈະໝາຍຕິກໃສ່ຫຼາຍກວ່າໜຶ່ງຫ້ອງ)

¹ *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.

Primary assembler
ຜູ້ປັບຈຸທຳອິດ

Secondary assembler
ຜູ້ປັບຈຸທິສອງ

Address of assembler (state country):
ທີ່ຢູ່ຂອງຜູ້ປັບຈຸ (ໃຫ້ລະບຸປະເທດພ້ອມ)

C o u n t r y

Tel:

Fax:

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

ລາຍລະອຽດຂອງບໍລິສັດຜູ້ຮັບຜິດຊອບການວາງຈຳໜ່າຍຜະລິດຕະພັນຢູ່ທ້ອງຕະຫຼາດ

7. Name of company:
ຊື່ຂອງບໍລິສັດ

Address of company:
ທີ່ຢູ່ຂອງບໍລິສັດ

Tel:

Fax:

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

ເລກທະບຽນທຸລະກິດ/ໃບອະນຸຍາດດຳເນີນທຸລະກິດ (ຂັດຕິດໃບຍັ້ງຢືນຂຶ້ນທະບຽນທຸລະກິດ, ຖ້າມີ)

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

ລາຍລະອຽດຂອງບຸກຄົນຜູ້ຕາງໜ້າບໍລິສັດທີ່ຈຳໜ່າຍໃນທ້ອງຖິ່ນ

8. Name of person:
ຊື່ບຸກຄົນ

Tel:

Email:

Designation in the company:
ຕຳແໜ່ງພາຍໃນບໍລິສັດ

Note: If the applicant is a service provider authorised by the company, he is required to provide a letter of authorisation or any additional particulars as required by the regulatory authority.

ໝາຍເຫດ: ຖ້າຜູ້ທີ່ຂໍຈົດແຈ້ງເປັນຜູ້ສະໜອງການບໍລິການທີ່ໄດ້ຮັບອະນຸຍາດຈາກບໍລິສັດ, ຄວນມີໜັງສືອະນຸຍາດທາງການຈາກບໍລິສັດ ຫຼື ລາຍລະອຽດຕື່ມຕາມການຮຽກຮ້ອງຂອງເຈົ້າໜ້າທີ່ຄຸ້ມຄອງ

PARTICULARS OF IMPORTER

ລາຍລະອຽດຂອງຜູ້ນຳເຂົ້າ

9. Name of Importer:
ຊື່ຜູ້ນຳເຂົ້າ

Address of importer:
ທີ່ຢູ່ຂອງຜູ້ນຳເຂົ້າ

Tel:

Fax:

PRODUCT INGREDIENT LIST

ລາຍລະອຽດສ່ວນປະກອບຂອງຜະລິດຕະພັນ

10. Please check the following boxes
ກະລຸນາກວດເບິ່ງຊ່ອງດັ່ງລຸ່ມນີ້:

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.

ຂ້າພະເຈົ້າໄດ້ກວດກາ, ທົບທວນຫຼັກສູດຂອງຫ້າຊ້ອນທ້າຍ, 2 ຫາ 7 ຂອງບັນຊີສ່ວນປະສົມເຄື່ອງສໍາອາງອາຊຽນຕາມທີ່ໄດ້ລະບຸຢູ່ໃນການປັບປຸງຫ້າສູດຂອງຄູ່ມືເຄື່ອງສໍາອາງອາຊຽນແລະຂໍຢັ້ງຢືນວ່າຜະລິດຕະພັນທີ່ນໍາມາຈົດແຈ້ງນີ້ບໍ່ໄດ້ບັນຈຸສານຕ້ອງຫ້າມໃດໜຶ່ງ ແລະ ສອດຄ່ອງກັບຂໍ້ຫ້າມ ແລະ ເງື່ອນໄຂທີ່ໄດ້ກຳນົດໄວ້ໃນບົດຊ້ອນທ້າຍຕ່າງໆ

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 as required by member country]

ຂ້າພະເຈົ້າຍິນດີປະຕິບັດ ແລະ ຮ່ວມມືກັບເຈົ້າໜ້າທີ່ຄຸ້ມຄອງລະບົບການກ່ຽວກັບການດໍາເນີນການຕິດຕາມພາຍຫຼັງການຈໍາໜ່າຍ

[ໃຫ້ບອກສ່ວນປະສົມພ້ອມດ້ວຍເປີເຊັນ ຂອງສ່ວນປະກອບທີ່ຈໍາກັດໃຫ້ໃຊ້ອີງຕາມແຕ່ລະປະເທດ]

No ລໍາດັບ	Full Ingredient name (use INCI or approved nomenclature in standard references) ຊື່ເຕັມຂອງສ່ວນປະກອບ (ໃຫ້ໃຊ້ INCI ຫຼືຊື່ມາດຕະຖານທີ່ສາກົນຮັບຮູ້)

DECLARATION

1. 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.
2. I undertake to:
 - 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 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 Cosmetic Event 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.

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.

[ຊື່ ແລະ ລາຍເຊັນຂອງບໍລິສັດຈຳໜ່າຍໃນທ້ອງຖິ່ນ]

[ກາຈຳຂອງບໍລິສັດ]

ວັນທີ ເດືອນ ປີ

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