

# COSMETIC NOTIFICATION

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GUIDELINES FOR COSMETIC INDUSTRY CLIENTS

FDA Philippines - ARISE  
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## GUIDELINES IN NOTIFYING COSMETIC PRODUCTS THROUGH THE DDF COSMETIC E-NOTIFICATION FOR INDUSTRY CLIENTS

### REGISTRATION OF E-MAIL

1. Prior notification through Cosmetics E-Notification, authorized representatives must register their e-mail addresses by submitting an authorization letter containing the details of the representative.

- 1.1. Applicants must submit this by e-mailing [cosmetic@fdd.gov.la](mailto:cosmetic@fdd.gov.la) following the prescribed format:

*(Subject)* Registration of authorized representative  
*(Body of e-mail)*  
Name of Company:  
Name of Authorized Representative:  
E-mail of authorized representative:  
*(Attachment)* Authorization.zip

- 1.2. Compress the authorization letter and attachment into a zip file named **Authorization.zip**
  - 1.3. The authorization letter must be signed by the director, owner, or general manager of the company. It may be saved either as a **.pdf, .jpg, or .png** file.

[Company Letterhead]

Date

Department of Drugs and Food  
Ministry of Health  
Kingdom of Cambodia

Subject: Authorization Letter  
Company Name

To whom it may concern:

This is to authorize (Name of authorized representative), (Designation) as this company's representative in notifying the cosmetic products we intend to place in the local market. Appended to this letter is the details of the representative and the nominated e-mail address. We undertake to bear the responsibility in ensuring that our products comply to the local regulations and the latest standards according to the ASEAN Cosmetic Directive.

Signed,

(Name and signature of the director, owner, or general manager of the company)  
[Company Stamp or Logo]

(Name and signature of the authorized representative)

- 1.4. The authorization letter must have with it appended the details of the authorized representative. The information to be provided are enumerated below. The attachment must be saved as a **.doc** or **.docx** file.

<p><b>Personal Data</b> Name Address Gender Birthdate Telephone Fax Email Cellphone</p> <p><b>Professional Background</b> Company Name Address Department/Division Date of Employment Industry Telephone Fax</p>
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## SUBMISSION OF APPLICATION

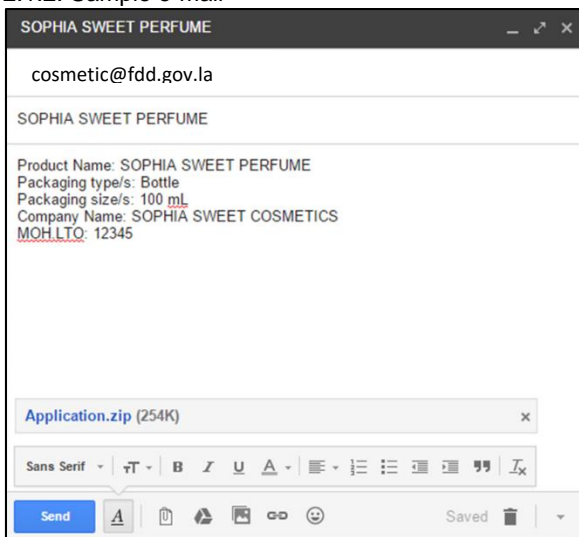
2. Applicant will submit a cosmetic notification application through e-mail

2.1. In composing the e-mail, the prescribed e-mail format must be followed:

2.1.1. Format

<p><i>(Subject)</i> Product Name <i>(Body of e-mail)</i> Product Name: Packaging Type/s: Packaging Size/s: Applicant Company: LTO/Business Registration Number: <i>(Attachment)</i> Application.zip</p>
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2.1.2. Sample e-mail



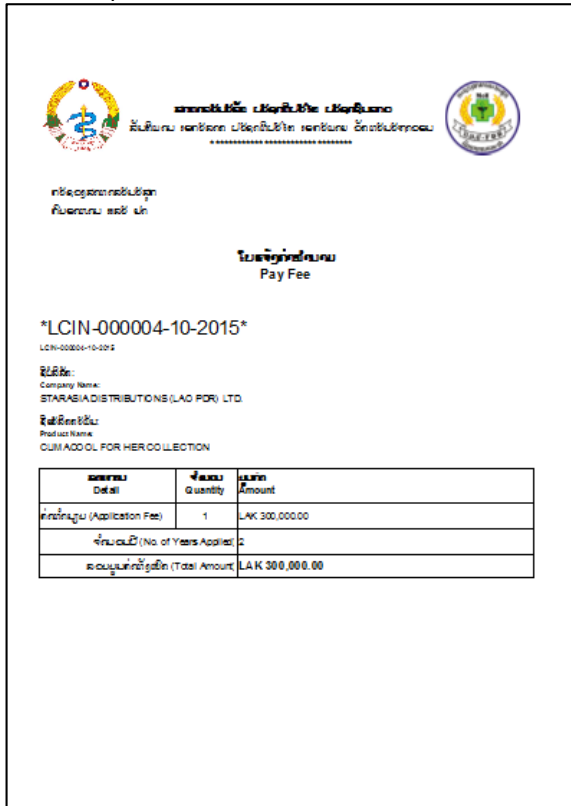
2.2. Compress forms, **ACD\_Form.pdf** and **Ingredient.csv**, into a zip file and save as Application.zip

2.3. Forms are available for download at [www.fdd.gov.la](http://www.fdd.gov.la)

**ASSESSMENT OF APPLICATION**

- 3. Two e-mails will be received from [cosmetic@fdd.gov.la](mailto:cosmetic@fdd.gov.la)
  - 3.1. First, you will receive an automatic reply to signify that your e-mail application was received by [cosmetic@fdd.gov.la](mailto:cosmetic@fdd.gov.la)
  - 3.2. Second, you will receive the assessment form which will indicate the fees needed to be paid in order to process your application. Download the assessment form and print one (1) copy.

3.2.1. Sample



- 3.3. It is highly recommended for the applicant to save [cosmetic@fdd.gov.la](mailto:cosmetic@fdd.gov.la) as a contact to avoid inadvertently receiving these messages as spam or junk.

#### PAYMENT OF APPLICATION

4. Pay the appropriate fees at the Cashier located at the Ministry of Health.

4.1. Present the assessment form to the Cashier

4.2. Pay the corresponding fees.

Type of application	Fees
New ( 2-year validity)	LAK 300,000

5. Provide the cover letter, assessment form, and copy of the proof of payment to FDD.

6. In cases where the application has deficiencies that needs clarification, FDD may contact the applicant.

7. The result of the application will be released at FDD.

**GUIDELINES IN FILLING-UP THE ASEAN COSMETIC DIRECTIVE (ACD) NOTIFICATION FORM (ACD\_FORM.PDF)**

1. Download the form from [www.fdd.gov.la](http://www.fdd.gov.la)
2. Open and edit the file using Adobe® Reader
  - 2.1. This is available free for download at [get.adobe.com/reader](http://get.adobe.com/reader)
  - 2.2. To avoid errors encountered with saving PDF files, it is recommended for the applicant to open, edit, and save ACD\_Form.pdf using Adobe® Reader only.
3. Fill the information in the fields, as applicable.

If applying for a renewal application, provide the previous notification number

Previous Notification Number if Renewal

● **ASEAN Cosmetic Directive** ●

**TEMPLATE FOR NOTIFICATION OF COSMETIC PRODUCT**  
ນຳມືການຈົດແຈ້ງຜະລິດຕະພັນ

Tick where applicable  
 ຫມາຍຕິກໂທຍເບນທີ່ມີລັກສະນະຂອງຜະລິດຕະພັນ

**PARTICULARS OF PRODUCT**  
ລັກສະນະຂອງຜະລິດຕະພັນ

Name of brand & product:  
ຊື່ຍີ່ຫໍ້ຜະລິດຕະພັນ

1.1 Brand  
ຍີ່ຫໍ້

1.2 Product Name  
ຊື່ຜະລິດຕະພັນ

1.3 List of Variants or Shade Names  
ລາຍການຍັນຊີ

2. Product type(s)  
ປະເພດຜະລິດຕະພັນ

- Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)  
ຄຣີມ, ນຳມັນສີມູຊັບ, ໂລຊັບ, ເຈວ ແລະ ນຳມັນສຳຮູ້ບຸນຍິນ ( ມື, ຜ້າ, ຕີນ ແລະ ສີນງ )
- Face masks (with the exception of chemical peeling products)  
ສຳຮູ້ບຸນຜ້າຜັງ ( ໂດຍບໍ່ລວມຈາກຜ້າຜັງທີ່ເຮັດໄດ້ລະຫນາຍເທື່ອ )
- Tinted bases (liquids, pastes, powders)  
ຜະລິດຕະພັນເຮັດໃຫ້ສີເບນ ທຸງໆ
- Make-up powders, after-bath powder, hygienic powders, etc.  
ຜົງກຸກຜັກ, ຜົງກຸກໂຕ, ຜົງກຸກບາໂມ ແລະ ສີນງ
- Toilet soaps, deodorant soaps, etc  
ສະບູຜົງກຸກຜັກ, ສະບູຜົງກຸກກາຍ ແລະ ສີນງ.
- Perfumes, toilet waters and eau de Cologne

Tick the boxes as applicable

- ນ້ຳຮອມ, ນ້ຳຮອມດັບກິນຕ້ອງນ້ຳ  
 Bath or shower preparations (salts, foams, oils, gels, etc.)  
 ຄຣີມຮາບນ້ຳຮີມີ ( ຕຣີ, ຢາງ, ນ້ຳມັນ, ເຈວ ແລະ ອື່ນໆ )
- Depilatories  
 ຜະລິດຕະພັນກຳຈັດຂົນ
- Deodorants and anti-perspirants  
 ດັບກິນ ແລະ ກຳຈັດເສື້ອ
- Hair care products  
 ຜະລິດຕະພັນປົກປ້ອງເສັ້ນຕົ້ມ  
 - hair tints and bleaches (including permanent hair dyes)  
 ສີຍ້ອມຕົ້ມ ແລະ ສີກສີຕົ້ມ  
 - products for waving, straightening and fixing,  
 ຜະລິດຕະພັນຕັດຕົ້ມ, ປິດຕົ້ມ ແລະ ສັບຂຸມຕົ້ມ.  
 - setting products,  
 ຜະລິດຕະພັນຈັດລົງ  
 - cleansing products (lotions, powders, shampoos),  
 ຜະລິດຕະພັນກຳຄວາມສະຫວາດ ( ໂລຊີນ, ພົງ, ຢາສະຕົ້ມ )  
 - conditioning products (lotions, creams, oils),  
 ຜະລິດຕະພັນເນື້ອສຸຂະພາບຕົ້ມ( ໂລຊີນ, ຄຣີມ, ນ້ຳມັນ )  
 - hairdressing products (lotions, lacquers, brilliantines)  
 ຜະລິດຕະພັນຈັດແຕງລົງຕົ້ມ( ໂລຊີນ, ເກີຍບູງົງ )
- Shaving product (creams, foams, lotions, etc.)  
 ຜະລິດຕະພັນແກ່ສວດ ( ຄຣີມ, ຢາງ, ໂລຊີນ ແລະ ອື່ນໆ )
- Products for making-up and removing make-up from the face and the eyes  
 ຜະລິດຕະພັນສຳຮູ້ບປົກປິດ ແລະ ຕົບແຕ່ງ ໜ້າ ແລະ ຕາ
- Products intended for application to the lips  
 ຜະລິດຕະພັນ ລິບສະຕິກ
- Products for care of the teeth and the mouth  
 ຜະລິດຕະພັນ ສັກສາເສັດ ແລະ ປາກ
- Products for nail care and make-up  
 ຜະລິດຕະພັນ ສຳຮູ້ບປຳລູງເລັບ ແລະ ສີຄາເລັບ
- Products for external intimate hygiene (exclude personal lubricant)  
 ຜະລິດຕະພັນ ສຳຮູ້ບສະບາໂມລູ່ອງຄອດ
- Sunbathing products  
 ຜະລິດຕະພັນ ສຳຮູ້ບການຮາບແດດ
- Products for tanning without sun.  
 ຜະລິດຕະພັນປຸງສີຕົວໂດຍບໍ່ຕາກແດດ
- Skin whitening products  
 ຜະລິດຕະພັນ ເສັດໃຫ້ເສັດຂາວ
- Anti-wrinkle products  
 ຜະລິດຕະພັນ ລິບສອຍຫຼ່ຽວ, ສອຍຕີນກາ
- Others (please specify)  
 ແລະ ອື່ນໆ ( ກະລຸນາລະບຸລາຍລະອຽດ )

When Others is ticked, specify the appropriate information as applicable

3. Intended use  
 ຈຸດປະສົງຂອງການນຳໃຊ້



When Others is ticked, specify the appropriate information as applicable

Select the country of manufacture from the provided drop down list

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  
ເປັນອາແລດຂອງຜະລິດຕະພັນດຽວກັນ
- Combination products in a single kit  
ຜະລິດຕະພັນປະສົມຢູ່ໃນສູດດຽວກັນ
- Others (please specify)  
ແລະ ອື່ນໆ ( ກະລຸນາລະບຸລາຍລະອຽດ )

**PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)**  
*(Please attach in a separate sheet if there are more than one manufacturer/ assembler)*  
ລິກາສອນຂອງຜູ້ຜະລິດ/ຜູ້ປັບປຸງ  
[ກະລຸນາແນວລາຍລະອຽດສິດສິດ ຫາກວ່າຜູ້ຜະລິດຜູ້ປັບປຸງມີຫຼາຍກວ່າ 01]

5. Name of manufacturer:  
ຊື່ຕໍາຂອງຜູ້ຜະລິດ

Address of manufacturer (state country):  
ທີ່ຢູ່ຂອງຜູ້ຜະລິດ ( ລະບຸປະເທດນັ້ນ )

Country: **AFGHANISTAN**

Tel: Fax:

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

**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/intermediate 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.

Select the country of assembly (if applicable) from the provided drop down list

Primary assembler  
ຜູ້ປັບຈຸກອິດ

Secondary assembler  
ຜູ້ປັບຈຸຕິສອງ

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

Country: **AFGHANISTAN**

Tel: Fax:

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

7. Name of company:  
ື່ນຂອງບໍລິສັດ

Address of company:  
ທີ່ຢູ່ຂອງບໍລິສັດ

Tel: Fax:

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

**PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY**  
ລາຍລະອຽດຂອງບຸກຄົນຜູ້ຕາງໜ້າບໍລິສັດທີ່ຈຳໜ່າຍໃນຕ້ອງຖິ້ມ

8. Name of person:  
ື່ນບຸກຄົນ

Tel: Email:

Indicate the appropriate e-mail in this field. The e-mail indicated here will receive all communication (e.g. assessment form and other further communication from DDF).

Designation in the company:  
ຕຳແໜ່ງນາຍໃນບໍລິສັດ

[Redacted box]

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: ຖ້າຜູ້ທີ່ຈັດແຈ້ງເປັນຜູ້ສະໜອງການບໍລິການທີ່ໄດ້ຮັບອະນຸຍາດຈາກບໍລິສັດ, ກວນມີໜ້າສົມເໝາະສົມ ທາງການຈາກບໍລິສັດ ຫຼື ລາຍລະອຽດຕື່ມຕາມການສູງກ້ອງຂອງເຈົ້າໜ້າທີ່ດຸ້ມຄອງ

**PARTICULARS OF IMPORTER**  
ລາຍລະອຽດຂອງຜູ້ນຳເຂົ້າ

9. Name of Importer:  
ຊື່ຜູ້ນຳເຂົ້າ

[Redacted box]

Address of Importer:  
ທີ່ຢູ່ຂອງຜູ້ນຳເຂົ້າ

[Redacted box]

Tel: [Redacted box] Fax: [Redacted box]

**PRODUCT INGREDIENT LIST**  
ລາຍລະອຽດສ່ວນປະກອບຂອງຜະລິດຕະພັນ

Ensure that the boxes are ticked.

10. Please check the following boxes  
ກວນກວດເບິ່ງສອງດັ່ງລຸ່ມນີ້:

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.

ຂ້າພະເຈົ້າໄດ້ຕົວຕົນ, ທີ່ບໍ່ມີການຊີ້ນຳຂອງອື່ນໆ, ທີ່ບໍ່ມີການຊີ້ນຳຂອງອື່ນໆ, 2 ຫາ 7 ຂອງບັນຊີສ່ວນປະສົມ  
ທີ່ກ່ຽວຂ້ອງຂອງສາຍພັນທີ່ໄດ້ລະບຸໃນການປະກອບສ່ວນຂອງສິນຄ້າຂອງສາຍພັນຂອງຂ້າພະເຈົ້າ  
ວ່າສະລິດຕະສົມທີ່ກ່ຽວຂ້ອງນີ້ໄດ້ມີບັນຊີສ່ວນປະສົມທີ່ກ່ຽວຂ້ອງກັບໄດ້ສົມດັບ ແລະ ສອດຄ່ອງກັບສະຖານະ  
ດ້ານໄຮສໄດ້ກຳນົດໄວ້ໃນບົດສອນຕ້ອງກຽມ

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 ສ່ວນມືກັບເຈົ້າໜ້າທີ່ດ້ານກົດໝາຍຂອງລະບົບການກຽມລັດຖະທຳມະດາເປັນ  
ການຕິດຕາມສາຍພັນການຈຳໜ່າຍ  
[ໃຫ້ບັນຊີສ່ວນປະສົມສົມດັບຕາມທີ່ຕ້ອງການຂອງສ່ວນປະສົມທີ່ກ່ຽວຂ້ອງກັບໄດ້ໃຊ້ອີງຕາມແຕ່ລະປະເທດ]

This portion of the ACD\_Form is not editable. The Ingredients are listed in a separate document (Ingredient.csv).

No ລຳດັບ	Full Ingredient name (use INCI or approved nomenclature in standard references) ຊື່ເຕັມຂອງສ່ວນປະສົມ (ໃຫ້ໃຊ້ INCI ຫຼື ຊື່ມາດຕະຖານທີ່ສາກົນອື່ນໆ)

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.
- I undertake to:
  - 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<sup>2</sup> 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<sup>3</sup> 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 ສາຍເຊັນຂອງບໍລິສັດຈຳກັດກຳມະໂນກ້ອງຕີນ]

[ຕາຈຳກັດຂອງບໍລິສັດ] ວັນທີ ເດືອນ ປີ

<sup>2</sup> As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products  
<sup>3</sup> Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

4. Save the file as **ACD\_Form.pdf**

4.1. Do not rename the file.

**GUIDELINES IN FILLING-UP THE INGREDIENT LISTING (INGREDIENT.CSV)**

1. Download the form at [www.fdd.gov.la](http://www.fdd.gov.la)
2. Open and edit using Microsoft® Excel or Notepad. The file format is called csv or comma-separated value which contains data in the column fields of Variant, Ingredient, Function, Percentage.
3. Fill-in the necessary fields, as applicable.
4. When using Microsoft® Excel to edit the ingredient list, double-check the file using Notepad. Ensure that only used separators are commas (,) and that the appropriate details are placed in the appropriate columns. Information placed in columns beyond the four (4) provided columns will not be read by the system.

Microsoft® Excel view

	A	B	C	D	E	F	G	H
1	Variant	Ingredient	Function	Percentage of Restricted Ingredient << Do not remove this Line				
2		MICA						
3		TALC						
4		MAGNESIUM STEARATE						
5		DIMETHICONE						
6		2,4-DICHLOROBENZYL ALCOHOL	PRESERVATIVE	0.1				
7		METHYLPARABEN	PRESERVATIVE	0.2				
8		ETHYLPARABEN	PRESERVATIVE	0.2				
9		METHYCHOLOROISOTHIAZOLINONE (0.000575%) AND METHYLI SOTHIAZOLINONE (0.000225%)	PRESERVATIVE	0.0008				
10	VARIANT 1	CI 77491						
11	VARIANT 1	CI 77492						
12	VARIANT 2	CI 77499						

Notepad view

```

Variant,Ingredient,Function,Percentage of Restricted Ingredient << Do not remove this Line
,MICA,,
,TALC,,
,MAGNESIUM STEARATE,,
,DIMETHICONE,,
,2;4-DICHLOROBENZYL ALCOHOL,PRESERVATIVE,0.1
,METHYLPARABEN,PRESERVATIVE,0.2
,ETHYLPARABEN,PRESERVATIVE,0.2
,METHYCHOLOROISOTHIAZOLINONE (0.000575%) AND METHYLISOTHIAZOLINONE
(0.000225%),PRESERVATIVE,0.0008
VARIANT 1,CI 77491,,
VARIANT 1,CI 77492,,
VARIANT 2,CI 77499,,
    
```

5. Save as **Ingredient.csv**. Do not rename the file.