



## ANNOUNCEMENT

DATE : 06 July 2022

TO : **ALL MANUFACTURERS, TRADERS AND DISTRIBUTORS OF COSMETIC PRODUCTS AND OTHER INTERESTED STAKEHOLDERS**

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SUBJECT : **DISSEMINATION OF THE UPDATES AND AMENDMENTS TO THE ASEAN COSMETIC DIRECTIVE (ACD) AS ADOPTED DURING THE 35<sup>TH</sup> ASEAN COSMETIC COMMITTEE (ACC) MEETING AND ITS RELATED MEETINGS**

In the interest of service, and in order to provide timely dissemination of the updates and amendments to the ASEAN Cosmetic Directive (ACD), the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hereby informs all cosmetic manufacturers, traders and distributors and other interested stakeholders, of the following information which have been adopted during the 35<sup>th</sup> ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings hosted by the ASEAN Secretariat via video conferencing and held as follows:

Date	Meeting
10-11 May 2022	35 <sup>th</sup> ASEAN Cosmetic Scientific Body (ACSB) Meeting
11-12 May 2022	18 <sup>th</sup> ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
23-24 May 2022	ASEAN Cosmetic Committee Heads of Delegations (HODs) Meeting
25 & 27 May 2022	35 <sup>th</sup> ACC Meeting

The following are the updates and amendments to the ACD. For reference, the new and modified entries as well as the given grace period are listed in **Annex A**.

- 1. Climbazole (Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. No. 326 and Annex VI - List of preservatives allowed for use in cosmetic products, Ref. No. 32)**



Referring to the proposed options provided by ASEAN Cosmetics Association (ACA), Brunei proposed that if foot care products are not extensively used in ASEAN Member States (AMS), removing this product type in the list may be considered. The product mix would then include – shampoo (2% as anti-dandruff) + hair lotion + face cream + hair conditioner (0.5%) with the Margin of Safety (MOS) = 116.

The AMS, except Myanmar, agreed to Brunei's proposal and adopted the option of the above list of products (without foot care) for the Climbazole entry in ACD Annexes VI and III (0.5% rinse-off hair conditioner) with a grace period of **18 months** – Effective **11 November 2023**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. The ACSB Secretary will inform Myanmar on the adoption and request her position.

**2. Titanium Dioxide (Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. No. 338) (EU 2021/850)**

Recalling that based on the Scientific Committee on Consumer Safety (SCCS) conclusion, the use of Titanium Dioxide in powder form containing 1% or more of particles with aerodynamic diameter  $\leq 10 \mu\text{m}$  should not be authorized for use in applications that may give rise to inhalation exposure by the end user and added to the list of restricted substances in EU Annex III for use as face products in loose powder form and in hair aerosol spray products. The use of titanium dioxide as colorant (entry 143 of EU Annex IV) and as UV filter (entry 27 of EU Annex VI) are updated to reflect the restricted use.

ACA presented the safety assessment on Titanium Dioxide and highlighted that the CMR 2 classification of the substance is mainly on the inhalation route and not on oral and dermal routes. In their review of the SCCS safety assessment, ACA proposed to adopt the EU amendment for the Titanium Dioxide entry in ACD Annex III with a grace period of **24 months**.

The AMS, except Myanmar, agreed to the ACA proposal including the grace period – Effective **11 May 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. The ACSB Secretary will inform Myanmar on the adoption and request her position.

**3. Inclusion of 4-(3-ethoxy-4-hydroxyphenyl)butan-2-one (HEPB) in Annex VI - List of preservatives allowed for use in cosmetic products, Ref. No. 60 (EU 2019/1858)**

ACA presented the SCCS safety assessment of 4-(3-ethoxy-4-hydroxyphenyl) butan-2-one (HEPB) as a preservative. With the SCCS assessment affirming the safety via MOS calculation of the substance in oral care and dermally applied products, ACA proposed to adopt the EU amendment and include HEPB as a new entry in ACD Annex VI.



It was agreed in the meeting to adopt the ACA proposal **effective immediately**. Thailand will implement within the next 6 months as she needs to go through her process of issuing local regulations. The ACSB Secretary will inform Myanmar on the adoption and request her position.

**4. Amendment of Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. Nos. 336, 337 and 330-335 and Annex VI - List of preservatives allowed for use in cosmetic products, Ref. No. 28 (EU 2019/831, EU 2020/1683)**

Consistent with the ACSB adoption of EU 2019/831 and EU 2020/1683 respectively, Indonesia updated the AMS on her decision to include the following substances in ACD Annex III – **Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide, 2-Furaldehyde**; in ACD Annex VI **Polyhexamethylenebiguanide hydrochloride** (EU 2019/831) and; in ACD Annex III, substances Ref #s 315-320 (EU 2020/1683), with a grace period of **24 months** - Effective **11 May 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

**5. Amendment of Annex II - List of substances which must not form part of the composition of cosmetic products, Ref. No. 1657 and Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. Nos. A8 (EU 2021/1099)**

- a. The AMS, except Myanmar, agreed to the ACA proposal to add the entry of **Deoxyarbutin** in ACD Annex II with a grace period of **12 months** - Effective **11 May 2023**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. It was noted that the ban is already implemented in Indonesia per her local regulation.
- b. Additionally, it was agreed in the meeting to adopt the EU Regulation and amend the current entry of **Dihydroxyacetone** in ACD Annex III, with a grace period of **18 months** - Effective **11 November 2023**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Indonesia also added to reflect “Use for dyeing eyelashes and eyebrows is not permitted” in this entry as this is the standing agreement on use of dyes in ASEAN.
- c. The ACSB Secretary will inform Myanmar on the adoption and request her position.

**6. Amendment of Annex II - List of substances which must not form part of the composition of cosmetic products, Ref. No. 573**

The AMS agreed to ACA’s proposal to remove CAS # 68171-33-5 from ACD Annex II Entry 573 as this is not included in Regulation (EC) No 1223/2009.

**7. Category 2 Material (Annex II - List of substances which must not form part of the composition of cosmetic products)**

It was agreed in the meeting to correct the letter sequencing in ACD Annex II Category Material to reflect (f) instead of the current (g) for “Mixtures of Category 2 material with Category 3 material”.

This announcement shall only serve as a **prior notification** to the cosmetic industry and shall be subsequently supplemented by an official FDA Circular. The aim of this document is to give the industry sufficient time / grace period to conduct operational activities (i.e. reformulation, testing of new formulations, phase out of products with old formulation, etc.) to ensure continued compliance with the ACD.

Should you have any inquiries and/or clarifications, you may contact us at [cchuhsrraseannotification2@fda.gov.ph](mailto:cchuhsrraseannotification2@fda.gov.ph).

For your information and guidance. Thank you very much.



Annex A  
**Updates and Amendments to the ASEAN Cosmetic Directive (ACD) Ingredient Annexes**

The updated ASEAN Cosmetic Directive (ACD) Ingredient Annexes incorporating the new and amended entries adopted during the 35th ASEAN Cosmetic Committee (ACC) Meeting and its related meetings are posted in the Food and Drug Administration (FDA) website. The tabulation below representing the new and modified entries (highlighted in yellow) of the ACD Ingredient Annexes are shown only for easy reference of the cosmetic industry.

**A. ACD Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products**

**1. ACD Annex II Ref. No. 1657 (New Entry)**

*Grace Period: 11 May 2023 (12 months)*

Substances	CAS Number	Ref. No.
4-[(tetrahydro-2H-pyran-2-yl)oxy]phenol (Deoxyarbutin, Tetrahydropyranyloxy Phenol) Except Myanmar – under review	53936-56-4	1657

**2. Revised Entries**

**ACD Annex II Ref. No. 573**

Substances	CAS Number	Ref. No.
Gases (petroleum), hydrotreated sour kerosine flash drum, if they contain > 0.1 % w/w Butadiene	68911-59-1/ 68171-33-5	573

**ACD Annex II Category 2 Material**

- (g) (f) Mixtures of Category 2 material with Category 3 material;
- (h) (g) Animal by-products other than Category 1 material or Category 3 material;

**B. ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down**

**1. ACD Annex III Ref. Nos. 338 (New Entry)**

*Grace Period: 11 May 2024 (24 months)*

Ref No ACD #  (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
338 (x)	Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter < 10 µm  Titanium Dioxide  13463-67-7/ 1317-70-0/ 1317-80-2  Except Myanmar - under review	a) face products in loose powder form  b) hair aerosol spray products  c) other products	a) 25 %; b) 1.4 % for general consumers, and 1.1% for professional use	(a) (b) Only in the pigmentary form  c) Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation';	

## 2. Revised Entries

### ACD Annex III Ref. No. 326


*Grace Period: 11 November 2023 (18 months)*

Ref No ACD #  (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
326  (310)	1-(4-Chlorophenoxy)- 1-(imidazol-1-yl)- 3,3- dimethylbutan-2-one  Climbazole  38083-17-9	a.) Rinse-off Anti-Dandruff Shampoo  b.) Rinse-off Anti-Dandruff Conditioners  For (b): Except Myanmar - under review	a.) 2.0%  b.) 0.5%	For (a) and (b): for purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	





**ACD Annex III Ref. Nos. 330-335, 336, and 337**

**Grace Period: 11 May 2024 (24 months)**

Ref No ACD #  (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
330  (315)	4-(3-aminopyrazolo[1,5-A] pyridin-2-yl)-1,1-dimethylpiperazin-1-ium chloride hydrochloride  Dimethylpiperazinium Aminopyrazolopyridine HCl  1256553- 33-9	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % (calculated as free base)  <b>Except Indonesia</b>	To be printed on the label: The mixing ratio.   Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.



Ref No ACD # (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
331 (316)	1-(3-((4-Aminophenyl) amino)propyl)- 3-methyl- 1H-imidazol-3-ium chloride hydrochloride  Methylimidazoliumpropyl p- phenylenediamine HCl  220158- 86-1	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % (calculated as free base)  <b>Except Indonesia</b>	To be printed on the label: The mixing ratio.   Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.’
332 (317)	Di-[2-[(E)-2-[4-[bis(2- hydroxyethyl)aminophenyl]vinyl] pyridin-1-ium]-ethyl]disulphide dimethanesulfonate  HC Orange No 6  1449653- 83-1	Hair dye substance in non- oxidative hair dye products	0.5 %	Methanesulfonates impurities, in particular ethyl methanesulfonate shall not be present.  <b>Except Indonesia</b>	
333 (318)	Sodium 4-[(2-hydroxy-1- naphthyl)azo]benzene sulfonate  Acid Orange 7  633-96-5	Hair dye substance in non- oxidative hair dye products	0.5 %	<b>Except Indonesia</b>	

Ref No ACD #  (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
334  (319)	Phenol, 4,4'-(4,5,6,7-tetrabromo-1,1-dioxido-3H-2,1-benzoxathiol-3-ylidene)bis [2,6-dibromo-  Tetrabromophenol Blue  4430-25-5	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative	0.2 %	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,2 % (calculated as free base)  <b>Except Indonesia</b>	To be printed on the label: The mixing ratio.   Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.’
335  (320)	<i>Indigofera tinctoria, dried and pulverised leaves of Indigofera tinctoria L</i>  <i>Indigofera tinctoria leaf Indigofera tinctoria leaf powder Indigofera tinctoria leaf extract Indigofera tinctoria extract</i>  84775- 63-3	Hair dye substance in non- oxidative hair dye products	25 %	<b>Except Indonesia</b>	

Ref No ACD # (EU #)	Substance/CAS No <sup>(19)</sup>	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
336  (311)	Diphenyl(2,4,6- trimethylbenzoyl) phosphine oxide  Trimethylbenzoyl diphenylphosphine oxide  75980- 60-8	Artificial nail systems	5.0 %	Professional use  <b>Except Indonesia</b>	For professional use only Avoid skin contact Read directions for use carefully
337  (312)	2-Furaldehyde  Furfural  98-01-1		0.001 %'	<b>Except Indonesia</b>	





C. ACD Annex VI - List of Preservatives Which Cosmetic Products May Contain

1. ACD Annex VI Ref. No. 60 (New Entry)

*Effective Immediately*

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
60	4-(3-ethoxy-4-hydroxyphenyl)butan-2-one Hydroxyethoxyphenyl Butanone CAS 569646-79-3	0.7 %	Except Myanmar – under review	

2. Revised Entries

ACD Annex VI Ref. Nos. 32

*Grace Period: 11 November 2023 (18 months)*

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one) <sup>15</sup>  Climbazole CAS 38083-17-9	Hair lotions; 0.2% Face creams; 0.2% Foot care products; 0.2% Rinse-off shampoo; 0.5% Rinse-off hair conditioner: 0.5%  For Myanmar Hair lotions; 0.2% Face creams; 0.2% Foot care products; 0.2% Rinse-off shampoo; 0.5	Except Myanmar – under review	



**ACD Annex VI Ref. Nos. 28**

***Grace Period: 11 May 2024 (24 months)***

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
28	Poly(1-hexamethylenebiguanide hydrochloride) Polyaminopropyl biguanide  CAS 32289-58-0, 27083-27-8, 28757-47-3, 133029-32-0	0.1 %	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation'  <b>Except Indonesia</b>	