



FDA CIRCULAR
No. 2022-006

12 SEP 2022

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted during the 35th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings

I. BACKGROUND

In 2005, the Department of Health (DOH) – Food and Drug Administration (FDA), then Bureau of Food and Drugs (BFAD), has adopted and implemented the Association of Southeast Asian Nations (ASEAN) Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents, including the ASEAN Cosmetic Directive (ACD), through Administrative Orders No. 2005-0015 and 2005-0025, respectively. The harmonization scheme aims to eliminate restrictions to trade of cosmetic products and enhance cooperation within the ASEAN Member States (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products.

Under the ACD, the AMS, through the National Regulatory Authorities (NRA), shall undertake all necessary measures to ensure that only cosmetic products that conform to the provisions of the ACD, its Annexes and Appendices may be placed in the market.

Amidst challenges brought about by the current COVID-19 pandemic, the ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings, through the ASEAN Secretariat, were held virtually as follows:

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

To provide the industry with timely and relevant information on standards, rules, and regulations and to establish the implementation timeline or grace period to allow sufficient time for the industry to conduct operational activities (i.e. reformulation and phase out of products with old formulation), the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), hereby, reports the highlights of the aforementioned meetings and presents the updates to the ASEAN Cosmetic Directive (ACD) as adopted in the 35th ACC Meeting.



II. OBJECTIVES

This Circular aims to provide the updates and amendments to the ACD as adopted in the 35th ACC meeting and its related meetings, including its implementation timeline or grace period to allow sufficient time for the industry to conduct relevant operational activities and ensure continued compliance with the ACD, which covers cosmetic products made available in the local market.

III. SCOPE

This Circular applies to establishments that are engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of cosmetic products.

IV. UPDATES AND AMENDMENTS TO THE ACD

A. Updates and Amendments to the ACD Ingredient Annexes

The following are the updates and amendments on cosmetic ingredients and their restrictions as indicated in the ACD Ingredient Annexes. The latest revision of the ACD Ingredient Annexes is accessible at the FDA website.

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”.

V. PENALTY CLAUSE

Any person found in violation of this Circular shall be deemed in violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

VI. SEPARABILITY CLAUSE

The provisions of this “Updates and Amendments to the ASEAN Cosmetic Directive (ACD) Ingredient Annexes” are hereby declared separable and in the event of any such provision is/are declared invalid or unenforceable, the validity or enforceability of the

remaining portions or provisions including other provisions of the ACD which are not affected by this updates/amendments, shall remain in full force and in effect.

VII. REPEALING CLAUSE

All other administrative issuances, circulars and memoranda and other regulations which are inconsistent with the remaining and valid provisions of ACD and this update/amendment are hereby withdrawn, repealed and/ or modified accordingly.

VIII. EFFECTIVITY

This Circular shall take effect after fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines, Office of the National Administrative Register.



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