



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



10 AUG 2017

FDA CIRCULAR
No. 2017-006

TO: ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive as Adopted During the 25th ASEAN Cosmetic Committee Meeting and Its Related Events

1. BACKGROUND AND RATIONALE

In 2005, the Department of Health (DOH) – Food and Drug Administration (FDA), then called Bureau of Food and Drugs (BFAD), has adopted and implemented the 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 involves the conduct of alignment meetings for the purpose of eliminating trade barriers and enhancing cooperation within the ASEAN Member States in ensuring the safety, quality and claimed benefits of cosmetic products.

On 15 to 18 November 2016, the ACC convened in Bandar Seri Begawan, Brunei Darussalam for the 25th ASEAN Cosmetic Committee (ACC), 25th ASEAN Cosmetic Scientific Body (ACSB) and 8th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings. As part of our continuous commitment to provide timely and relevant information on standards, rules, and regulations, the Food and Drug Administration – Center for Cosmetics Regulation and Research (FDA-CCRR) hereby reports the highlights of the aforementioned meetings; and, presents the updates to the ACD.

2. OBJECTIVE AND SCOPE

This Circular aims to provide the updates and amendments to the ACD as adopted in the 25th ACC and its related events; which, shall cover cosmetic products made available in the local market. This Circular shall guide 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.



3. UPDATES AND AMENDMENTS TO THE ACD

3.1. Amendments to the ACD Ingredient Annexes

The following items are updates on cosmetic ingredients, as indicated in the ACD Ingredient Annexes. For easy reference, a table of the new and modified entries and the given grace period is provided in Annex A.

3.1.1. Potassium Hydroxide as Callous Remover

3.1.1.1. The Meeting noted that 1.5% Potassium Hydroxide does not have a metabolic, immunological or pharmacological effect, and, therefore, cannot be considered a drug. Furthermore, the Meeting noted that review of Potassium Hydroxide in concentration of 1.5% or less confirmed that said levels to be cosmetic; and, that the use of Potassium Hydroxide as callous remover is consistent with the ACD Cosmetic Definition.

3.1.1.2. The Meeting, hence, agreed to add a sub-section for Potassium Hydroxide as a callous softener with a maximum authorized concentration of 1.5%.

3.1.1.3. The grace period provided for the modified entry in Annex III for Potassium Hydroxide is until 31 August 2018.

3.1.2. Zinc Oxide and Zinc Oxide (Nanoparticles or Nano)

3.1.2.1. The current entry for Zinc Oxide in ACD Annex VII Reference No. A29 is amended to include the restriction "Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation."

3.1.2.2. Zinc Oxide (Nano) is introduced as a new entry in ACD Annex VII.

3.1.2.3. Grace periods provided for the modified entry in Annex VII for Zinc Oxide and the new entry for Zinc Oxide (Nano) are until 31 August 2018.

3.1.3. Carbon Black (Nano)

3.1.3.1. The current entry for Carbon Black in ACD Annex IV Color Index (CI) No. 77266 is modified to introduce a detailed specification of the required purity of carbon black.

3.1.3.2. Carbon Black (Nano) is introduced as a new entry in ACD Annex IV.

3.1.3.3. The grace periods provided for the modified entry in Annex IV for Carbon Black and the new entry for Carbon Black (Nano) are until 31 August 2018.

3.1.4. Titanium Dioxide (Nano)

3.1.4.1. Titanium Dioxide (Nano) is introduced as a new entry in ACD Annex VII. The entry includes a detailed specification of materials that can be considered to meet the definition of Titanium Dioxide (Nano) and also restricts its usage to applications that avoid end-user's lung exposure by inhalation.

3.1.4.2. The grace period provided for the new entry for Titanium Dioxide (Nano) in ACD Annex VII is until 31 August 2018.

- 3.1.5. Ethyl Lauroyl Arginate
- 3.1.5.1. The current entry for Ethyl Lauroyl Arginate in ACD Annex VI Reference No. 58 is amended to include its use as a preservative in mouthwash with a maximum limit of 0.15% and with the restriction and warning “Not to be used for children under 10 years of age.”
- 3.1.5.2. The modified current entry for Ethyl Lauroyl Arginate in ACD Annex VI has no grace period; and, is, hence, immediately implemented.
- 3.1.6. Methylisothiazolinone
- 3.1.6.1. The use of Methylisothiazolinone as a preservative with a maximum limit of 100ppm (0.01%) under ACD Annex VI Reference No. 57 is restricted to rinse-off products only. The use of methylisothiazolinone in leave-on products is prohibited.
- 3.1.6.2. The grace period provided for the modified entry in ACD Annex VI for Methylisothiazolinone is until 31 August 2018.
- 3.1.7. Ketoconazole
- 3.1.7.1. A new entry in ACD Annex II is introduced to include ketoconazole.
- 3.1.7.2. The new entry for ketoconazole in ACD Annex II has no grace period; and, is, hence, immediately implemented.

3.2. ASEAN Joint Opinion Statement

The ACC agreed that for recurrent issues, a joint opinion statement will be issued and posted on the ASEAN website. The joint opinion statement will be drafted by the ASEAN Cosmetic Association (ACA); reviewed and approved by ACSB; and, endorsed by ACC.

3.3. Guidelines on ASEAN Sectoral Networks of Laboratories

The Meeting noted that the ASEAN Guidelines for Sectoral Reference Laboratory Network serves as a voluntary reference document for the establishment and operation of networks. This document aims for: the laboratories within the networks to be effective; to support the ASEAN Economic Community (AEC) targets; and, operate in a consistent manner as established in the ASEAN Guideline on Accreditation and Conformity Assessment and the ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures. The Guidelines appear as Annex B.

3.4. Updated List of ASEAN Cosmetic Method (ACM) Harmonised Standards

The meeting noted that the document number of the following eight (8) ACMs will be used using a three (3)-digits denomination as shown below:

ACM	Old Document Number	New Document Number
Identification of Tretinoin (Retinoic Acid) in Cosmetic Products by TLC and HPLC	ACM 01	ACM 001
Identification of Prohibited Colorants in Cosmetic Products by TLC and HPLC	ACM 02	ACM 002

ACM	Old Document Number	New Document Number
Identification and Determination of Hydroquinone in Cosmetic Products by TLC and HPLC	ACM 03	ACM 003
Identification and Determination of 2-Phenoxyethanol, Methyl, Ethyl, Propyl, and Butyl 4-Hydroxybenzoate in Cosmetic Products by HPLC	ACM 04	ACM 004
Determination of Heavy Metals (Arsenic, Cadmium, Lead and Mercury) in Cosmetic Products	ACM 05	ACM 005
Enumeration of Aerobic Mesophilic Bacteria, Yeast and Mould	ACM 06	ACM 006
Identification of Steroids in Cosmetic Products by TLC and HPLC	ACM 07	ACM 007
Evaluation of the Antimicrobial Protection of a Cosmetic Product	ACM 08	ACM 008

3.5. Updated List of Cosmetic Accredited Laboratories

The list of accredited testing laboratories in the Philippines may be found in the Department of Trade and Industry – Philippine Accreditation Bureau (DTI-PAB) website (www.pabaccreditation.dti.gov.ph/public/public_test.php) and includes the scope of their accreditation.

4. PENALTY CLAUSE

Establishments 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 who are found to be operating outside the rules and regulations of FDA shall be subjected to sanctions and penalties as prescribed by RA 9711.

5. EFFECTIVITY

This Circular shall take effect immediately.

Updates to the ACD Ingredient Annexes shall allow a grace period until 31 August 2018; except, for Ethyl Lauroyl Arginate and Ketoconazole which shall be effective immediately.


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DTN 20170104074053