Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 AUG 2017

FDA CIRCULAR
No. 2017-007

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

SUBJECT: **Updates and Amendments of the ASEAN Cosmetic Directive as Adopted During the 26th ASEAN Cosmetic Committee Meeting (ACC) and Its Related Events**

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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 1 to 5 May 2017, the ASEAN Cosmetic Committee (ACC) convened in Siem Reap, Cambodia for the 26th ACC, 26th ASEAN Cosmetic Scientific Body (ACSB) and 9th 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 Center for Cosmetics Regulation and Research (CCRR) of the FDA 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 26th 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. Updates and Amendments to the ACD Ingredient Annexes

The following items are the updates on cosmetic ingredients, as indicated in the ACD Ingredient Annexes which are updated and posted in the FDA website under the ASEAN Cosmetic Harmonization section with the exception of ACD Annex III which is still under revision. For easy reference, a table of the new and modified entries and the given grace period is provided in **Annex A**.

3.1.1. Zinc Oxide (Nanoparticles or Nano)

3.1.1.1. The current entry for Zinc Oxide (Nano) in ACD Annex VII is amended to replace the text "Uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilane-triethoxycaprylylsilane cross-polymer, or octyltriethoxysilane" with "**Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects.**"

3.1.2. Titanium Dioxide (Nanoparticles or Nano)

3.1.2.1. The current entry for Titanium Dioxide (Nano) in ACD Annex VII is amended to replace the text "Coated with silica, hydrated silica, alumina, aluminium hydroxide, aluminium stearate, stearic acid, trimethoxycaprylylsilane, glycerine, dimethicone, hydrogen dimethicone, simethicone" with "**Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects.**"

3.1.3. Diethylene Glycol Monoethyl Ether or DEGEE

3.1.3.1. A new entry in ACD Annex III is introduced to include Diethylene Glycol Monoethyl Ether or DEGEE.

3.1.3.2. The maximum authorized concentration in ready for use preparation for DEGEE is as follow:

Product Type	% Concentration
a. Oxidative Hair Dye Products	7%
b. Non-Oxidative Hair Dye Products	5%
c. Rinse-Off Products Other Than Hair Dye Products	10%
d. Other Non-Spray Cosmetic Products	2.6%
e. The following spray products: Fine Fragrances, Hair Sprays, Antiperspirants and Deodorants	2.6%

3.1.3.3. Other conditions for the use of DEGEE is that the level of ethylene glycol impurity must be less than or equal to 0.1% and that it must not be used in eye products and oral products.

3.1.3.4. Effective **1 December 2018**, only compliant cosmetic products can be placed in the market and non-compliant products must be completely withdrawn from the market.

3.1.4. Laureth-9 or Polidocanol

3.1.4.1. A new entry in ACD Annex III is introduced to include Laureth-9 or Polidocanol.

3.1.4.2. The maximum authorized concentration in ready for use preparation for Laureth-9 is as follow:

Product Type	% Concentration
a. Leave-On Products	3%
b. Rinse-Off Products	4%

3.1.4.3. Effective **1 December 2018**, only compliant cosmetic products can be placed in the market, and non-compliant products must be completely withdrawn from the market.

3.1.5. Benzophenone-3

3.1.5.1. The current entry for Benzophenone-3 in ACD Annex VII is amended to reduce the maximum authorized concentration from 10% to **6%**.

3.1.5.2. Effective **1 December 2018**, only compliant cosmetic products can be placed in the market, and non-compliant products must be completely withdrawn from the market.

3.1.6. Hair Dyes Used to Dye Eyelashes and Eyebrows

3.1.6.1. The meeting agreed that the use of hair dyes for dyeing eyelashes and eyebrows is not permitted in ASEAN. As such, Column F of the ACD Annex III is amended to include the additional warning "**Do not use to dye eyelashes or eyebrows**" in all hair dye entries and to exclude the use of dyeing eyelashes and eyebrows from the Field of Application under Column C of the same annex.

3.1.6.2. Effective **1 June 2018**, only compliant hair dye products can be placed in the market, and non-compliant products must be completely withdrawn from the market.

3.2. Grace Periods for new regulations coming into effect

3.2.1. The Meeting agreed that changes to the ACD annexes shall be categorized into those which require a grace period and those which do not. For the ACD annex changes that require Grace Periods, a case-by-case assessment of the safety concern shall be used to determine the appropriate timeframes.

3.2.2. The meeting also agreed that in setting Grace Periods, the actual dates of the deadline shall be specified (i.e. 1 December 2018 instead of eighteen (18) months) and the actions required on or before the specified date shall be made extremely clear.

3.3. Methylisothiazolinone (MI or MIT) in Rinse-Off Products

3.3.1. Following the decision to restrict the use of MIT to rinse-off cosmetic products only during the 25th ACC and its related meetings, the meeting noted an opinion from the Scientific Committee on Consumer Safety (SCCS) stating that MIT concentration of one hundred (100) parts per million (ppm) in rinse-off cosmetic products is not considered safe in terms of contact allergy and that fifteen (15) ppm is considered safe.

3.3.2. The meeting also noted that no EU regulation on MIT in rinse-off cosmetic products has been published yet, thus, the ACSB shall wait for the publication of the said regulation before taking any action to restrict the use of MIT further.

3.3.3. The meeting agreed that the cosmetic industry is encouraged to look into reformulating rinse-off cosmetic products to comply with the anticipated restriction on MIT.

3.4. ASEAN Guidelines on Limits of Contaminants for Cosmetics

The meeting agreed to adopt the latest version of the ASEAN Guidelines on Limits of Contaminants and to endorse it to ACC for publication. The final version of the ASEAN Guidelines on Limits of Contaminants appears as **Annex B**.

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

Following the revision of the ACM document numbers during the 8th ACTLC Meeting, the latest versions of the six (6) out of eight (8) ACMs are posted in the FDA website under the ASEAN Cosmetic Harmonization section.

ACM 03 (Identification and Determination of Hydroquinone in Cosmetic Products by TLC and HPLC) and ACM 04 (Identification and Determination of 2-Phenoxyethanol, Methyl, Ethyl, Propyl, and Butyl 4-Hydroxybenzoate in Cosmetic Products by HPLC), however, are still under final revision. The final versions of the aforementioned documents shall be posted together with the other ACMs as soon as they are available.

3.6. 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 and amendments to the ACD Ingredient Annexes (Section 3.1) shall allow a grace period as specified above except for the entries with no specified grace periods.

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