



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR
No. 2016-016

22 AUG 2016

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

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive as Adopted During the 24th ASEAN Cosmetic Committee Meeting and Its Related Events

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 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.

In line with the ASEAN Cosmetic Harmonization, the ASEAN Cosmetic Committee (ACC) has been established to ensure that the ACD would be implemented effectively. It is composed of representatives from each ASEAN Member State's national regulatory authority (NRA) responsible for cosmetic products as well as representatives from the ASEAN Cosmetic Industry, namely, the ASEAN Cosmetic Association (ACA). The ACC meets semi-annually to coordinate, review and monitor the implementation of the ACD as well as update the necessary technical documents. Updates and amendments that have been adopted during an ACC meeting shall be formally cascaded and disseminated to the local cosmetic industry through the issuance of a circular.

On 24 to 27 May 2016, the ACC convened in Hanoi, Vietnam during the 24th ASEAN Cosmetic Committee (ACC), 24th ASEAN Cosmetic Scientific Body (ACSB) and 7th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings. In the interest of public service, and to further our commitment of providing timely information dissemination, the Food and Drug Administration – Center for Cosmetics Regulation and Research (FDA-CCRR) hereby reports the highlights of the aforementioned meetings.

A. 24th ASEAN Cosmetic Committee (ACC) Meeting

Due to increasing safety concerns over the possible association between the use of talc-containing cosmetic products and ovarian cancer, the ACC proposed that an ASEAN Joint Opinion Statement for ingredients that are of public health concern should be developed.



In line with this proposal, a pilot task force comprised of Singapore, Philippines and Thailand was formed to conduct more research on this matter to come up with a harmonized ASEAN statement regarding the subject.

B. 24th ASEAN Cosmetic Scientific Body (ACSB) Meeting

During the ACSB meeting, clean copies of the updated ACD Annexes were presented which include:

1. Annex II- List of Substances Which Must Not Form Part of the Composition of Cosmetic Products
2. Annex IV- List of Colouring Agents Allowed for Use in Cosmetic Products
3. Annex VI- List of Preservatives Which Cosmetic Products May Contain
4. Annex VII - List of UV Filters Which Cosmetic Products May Contain

The clean copies of the ACD annexes include all the updates and amendments to the ACD Ingredient List adopted during ACC meetings. These are available for viewing and can be downloaded in the FDA website. As for the ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down, this is currently being restructured and is not yet available.

Presently, restrictions laid down in ACD Annex III for thioglycolic acid and its salts limiting its use only in cosmetic products that are intended as: (1) hair waving or straightening products, (2) depilatories, and (3) other hair care products which are removed after application. There is no indication that this ingredient is allowed to be used in eyelash-waving products. During the 24th ACSB meeting, it was decided that thioglycolic acid will not be authorized for use in eyelash-waving products, hence, ACD Annex III Ref. No. 2a will remain unchanged.

Lastly, a final format of the ASEAN Guidelines on Limits of Contaminants for Cosmetics was agreed upon. This document contains the set maximum limit for total microbial contamination (bacteria, yeast and molds), individual microbial contamination (*Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*) and heavy metals (mercury, lead, arsenic and cadmium) that may be found in cosmetic products.

C. 7th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meeting

All ASEAN Member States were requested to provide the list of accredited testing laboratories in their respective countries. For the Philippines, the list of accredited testing laboratories may be found in the Department of Trade and Industry – Philippine Accreditation Bureau (DTI-PAB) website (http://www.pabaccreditation.dti.gov.ph/public/public_test.php). The list also includes the scope of the accreditation of each testing laboratory.

The above-mentioned highlights of the 24th ACC meeting and its related events are disseminated to all concerned parties to provide pertinent information necessary in their operation as cosmetic establishments. FDA would like to reiterate that companies and/or persons responsible for placing cosmetic products in the market should be responsible for regularly checking for updates and amendments to the ACD.

This circular shall take effect fifteen (15) days following its publication in two (2) newspapers of general circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.


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