



FDA CIRCULAR
No. 2020-008

16 MAR 2020

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

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted During the 31st ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings

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 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 (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products.

On 12-15 November 2019, the FDA Philippines hosted the ASEAN Cosmetic Committee (ACC) meeting in Alabang, Muntinlupa City which includes the following meetings: 31st ACC, 31st ASEAN Cosmetic Scientific Body (ACSB) and 14th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meetings. As part of its 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 ASEAN Cosmetic Directive (ACD).

2. OBJECTIVE AND SCOPE

This Circular aims to provide the updates and amendments to the ACD as adopted in the 31st ACC meeting and its related meetings which covers 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 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 easy reference, a table of the new and modified entries as well as the given grace period is provided in Annex A.

3.1.1. Mercury-Containing Preservatives in Eye Area Cosmetic Products

(Annex VI - List of Preservatives Which Cosmetic Products May Contain, Ref.

Nos. 16 and 17 and Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products, Ref. No. 221)

3.1.1.1. The Meeting agreed to remove the entries for the Mercury-containing preservatives (**Thiomersal** and **Phenylmercuric salts**) in ACD Annex VI. In parallel, the entry for Mercury and its compounds in ACD Annex II will be revised to include the CAS #s (**54-64-8, 62-38-4, 94-43-9, 102-98-7, 1192-89-8 and 1192-89-8**) for the above mentioned Mercury-containing preservatives from Annex VI.

3.1.2. Climbazole (Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down, Ref. No. 32)

3.1.2.1. The Meeting discussed the possible interpretation of the (+) in the entry of Climbazole in Annex VI that the substance may be used other than preservative beyond its restrictions and levels as reflected in its Annex III entry. In this case, the Meeting agreed to remove the (+) for Climbazole in Annex VI, while maintaining the footnote reference.

3.2. ASEAN Cosmetic Methods (ACM)

The ACM 010 "Determination of Glycolic and Lactic Acid (AHA) by High Performance Liquid Chromatography (HPLC)" has been adopted and is available in the following websites:

FDA Website - <https://ww2.fda.gov/ph/industry-corner/downloadables/197-asean-cosmetic-harmonization>

ASEAN Trade Repository - <http://atr.asean.org/standards/result/body/13/1>

ASEAN Secretariat's website - http://asean.org/?static_post=asean-sectoral-mras

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 Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009."

5. REPEALING CLAUSE

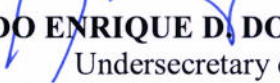
All other administrative issuances, circulars and memoranda and other regulations, which are inconsistent with the remaining and valid provisions of ACD and this update/amendment are hereby withdrawn, repealed and/ or modified accordingly.

6. 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 of 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.

7. EFFECTIVITY

This Administrative Circular shall take effect after 15 days following completion of their publication in a newspaper of general circulation and filing with the University of the Philippines, Office of the National Administrative Registrar (UP-ONAR).


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Officer-in-Charge, Director General



DTN 20191217150113

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 31st 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 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

ACD Annex II Ref. No. 221 (Revised Entry)

Substances	CAS Number	Ref. No.
Mercury and its compounds except those special cases included in Annex VI	7439-97-6	221
	54-64-8	
	62-38-4	
	94-43-9	
	102-98-7	
	1192-89-8	
	100-56-1	

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

ACD Annex VI Ref. Nos. 16 and 17 (Deleted Entry)

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
16	Entry deleted Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make up and eye make up remover only	—Contains thiomersal

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
17	Entry deleted Phenylmercuric salts (including borate)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	—Contains phenylmercuric compounds

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

ACD Annex VI Ref. No. 32 (Revised Entry)

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 (+) ¹⁵ Climbazole CAS 38083-17-9	Hair lotions; 0.2% Face creams; 0.2% Foot care products; 0.2% Rinse-off shampoo; 0.5%		