



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



17 NOV 2020

FDA CIRCULAR
No. 2020 034

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

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted during the 32nd 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 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.

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

Date	Meeting
03 September 2020	15 th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
08-09 September 2020	32 nd ASEAN Cosmetic Scientific Body (ACSB) Meeting
29 September 2020	Preliminary ASEAN Cosmetic Committee Heads of Delegations (ACC HODs) Discussion
29-30 September 2020	32 nd ACC Meeting

As part of FDA's continuous commitment to provide timely and relevant information on standards, rules, and regulations, the Center for Cosmetics Regulation and Research (CCRR), 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 32nd 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 reference, the new and modified entries as well as the given grace period is listed in Annex A.

3.1.1. *Tagetes erecta*

(ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down, Ref. No. 327)

3.1.1.1. The Meeting agreed to include *Tagetes erecta* in Annex III with the same limitations and restrictions as *Tagetes patula* and *Tagetes minuta*. Effective **08 March 2022**, only compliant products shall be made available in the market; and non-compliant products shall be withdrawn from the market.

3.1.1.2. ACD Annex III Ref. No. 327 Entry

- The maximum authorized concentration of *Tagetes erecta* is **0.01% for leave-on products** and **0.1% for rinse-off products**.
- For both, the Alpha terthienyl (terthiophen) content in the extract/oil shall be $\leq 0.35\%$.
- For leave-on products, it is not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light.
- In case of combined use, the total combined content of *Tagetes minuta* and *Tagetes patula* in ready for use preparation shall not exceed the maximum authorized concentration.

3.1.1.3. ACD Annex III Ref. Nos. 324 and 325 respectively

- Inclusion of the phrase “or *Tagetes erecta* (entry 327)” in the other limitations and requirements:
 - For (a) and (b): In case of combined use with *Tagetes patula* (entry 325) **or Tagetes erecta (entry 327)**, the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)
 - For (a) and (b): In case of combined use with *Tagetes minuta* (entry 324) **or Tagetes erecta (entry 327)**, the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)

3.1.2. Formaldehyde, Paraformaldehyde and Methylene Glycol

(Annex II - List of substances which must not form part of the composition of cosmetic products, Ref. Nos. 1577, 1578 and 1579, respectively)

3.1.2.1. The Meeting agreed to the following:

- Remove Formaldehyde, Paraformaldehyde and Methylene Glycol from Annex VI (Preservatives);
- Include Paraformaldehyde and Methylene Glycol in Annex II (Banned);
- Remove Formaldehyde from Annex III (Restricted Ingredients) and include in Annex II (Brunei, Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Singapore); Brunei Darussalam agreed to remove Formaldehyde from Annex III (restricted ingredients) and include in Annex II on the basis that there are alternatives for the use of formaldehyde in nail hardeners;
- Retain but reduce the level of Formaldehyde to 2.2% in Annex III (Lao PDR, Thailand and Vietnam) based on SCCS Opinion/Safety Assessment.

3.1.2.2. Effective **08 March 2022**, only compliant products shall be made available in the market; and non-compliant products shall be withdrawn from the market. In ASEAN, nail hardening products containing formaldehyde at 2.2% is only allowed in Lao PDR, Thailand and Vietnam.

3.1.3. Boron compounds listed in EU Annex III 1a and 1b

(Annex III - List of Preservatives Which Cosmetic Products May Contain, Ref. Nos. 1a and 1b)

3.1.3.1. The Meeting agreed to maintain the current entry for Boron compounds except for Indonesia and Singapore for further review.

3.1.4. Dibutyltin Hydrogen Borate

(Annex II - List of substances which must not form part of the composition of cosmetic products, Ref. No. 1400)

3.1.4.1. The Meeting agreed to move Dibutyltin Hydrogen Borate to Annex II. Effective **08 September 2021**, only compliant products shall be made available in the market; and non-compliant products shall be withdrawn from the market.

3.1.5. Peanut Oil Extracts & Derivatives and Hydrolyzed Wheat Protein

(Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down, Ref. No. 322 and 323, respectively)

3.1.5.1. The Meeting agreed to Indonesia's proposal to revise the current entries #322 and #323 of ACD Annex III to include the phrase 'Except Indonesia.'

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 fifteen (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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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 32nd 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 (highlighted in yellow) 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. Nos. 1400, 1577, 1578 and 1579 (New Entry)

Substances	CAS Number	Ref. No.	Grace Period
Dibutyltin hydrogen borate	75113-37-0	1400	08 September 2021
Formaldehyde (Except Lao PDR, Thailand and Vietnam)	50-00-0	1577	08 March 2022
Paraformaldehyde	30525-89-4	1578	08 March 2022
Methanediol; methylene glycol	463-57-0	1579	08 March 2022

ACD Annex III Ref. No. 1b (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
1b See also 1a	Tetraborates	(a) Bath products (b) Hair products	(a) 18% (as boric acid) (b) 8% (as boric acid)	(a) Not to be used in products for children under 3 years of age Except Indonesia and Singapore – under review.	(a) Not to be used for children under 3 years of age (b) Rinse well

ACD Annex III Ref. No. 13 (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels	Grace Period
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements		
A	B	C	D	E	F	
13	Formaldehyde CAS No 50-00-0	Nail hardening products	2.2% calculated as formaldehyde	For use as a preservative, see Annex VI, Part1, No. 5 Allowed only in Lao PDR, Thailand and Vietnam	Protects cuticles with grease or oil. Contains formaldehyde ⁽²⁾	<i>08 March 2022</i>

ACD Annex III Ref. No. 322 (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
322 (306)	Peanut oil extracts and derivatives Arachis Hypogaea Oil Arachis Hypogaea Seedcoat Extract Arachis Hypogaea Flour Arachis Hypogaea Fruit Extract Arachis Hypogaea Sprout Extract Hydrogenated Peanut Oil Peanut Acid Peanut Glycerides Peanut Oil PEG-6 Esters Peanutamide MEA Peanutamide MIPA Potassium Peanutate Sodium Peanutamphoacetate Sodium Peanutate Sulfated Peanut Oil CAS Nos 8002-03-7/8002-03-7 8002-03-7/68425-36-5 91051-35-3/91744-77-3 68440-49-3/93572-05-5 61789-56-8/61789-57-9/73138-79-1			Maximum concentration of peanut proteins: 0.5 ppm Except Indonesia	

ACD Annex III Ref. No. 323 (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
323 (307)	Hydrolyzed wheat protein CAS Nos 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5			Maximum molecular weight average of the peptides in hydrolysates: 3.5 kDa Except Indonesia	

ACD Annex III Ref. No. 324 (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
324 (308)	Tagetes minuta flower extract 91770-75-1 Tagetes minuta flower oil 91770-75-1/8016-84-0	(a) Leave-on products (b) Rinse-off products	(a) 0.01% (b) 0.1%	For (a) and (b). Alpha terthienyl (terthiophen) content in the extract/oil \leq 0.35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light. For (a) and (b): In case of combined use with Tagetes patula (entry 325) or Tagetes erecta (entry 327), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)	

ACD Annex III Ref. No. 325 (Revised Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
325 (309)	Tagetes patula flower extract 91722-29-1 Tagetes patula flower oil 91722-29-1/8016-84-0	(a) Leave-on products (b) Rinse-off products	(a) 0.01% (b) 0.1%	For (a) and (b). Alpha terthienyl (terthiophen) content in the extract/oil ≤ 0.35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light. For (a) and (b): In case of combined use with Tagetes minuta (entry 324) or Tagetes erecta (entry 327), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)	

ACD Annex III Ref. No. 327 (New Entry)

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels	Grace Period
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements		
A	B	C	D	E	F	
327 (1383 Annex II)	Tagetes erecta flower extract 90131-43-4 Tagetes erecta flower oil 90131-43-4	(a) Leave-on products (b) Rinse-off products	(a) 0.01% (b) 0.1%	For (a) and (b). Alpha terthienyl (terthiophen) content in the extract/oil ≤ 0.35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light. For (a) and (b): In case of combined use with Tagetes minuta (entry 324) or Tagetes patula (entry 325), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)		08 March 2022

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

ACD Annex VI Ref. No. 5 (Deleted Entry)

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
a	b	c	d	e	
5	Formaldehyde and paraformaldehyde(+) (7)	0.2% (except for products for oral hygiene) 0.1% (for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)		08 March 2022