



16 SEP 2019

FDA CIRCULAR
No. 2019-005

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

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted During the 30th 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 18-21 June 2019, the FDA participated in the ASEAN Cosmetic Committee (ACC) convened in Nay Pyi Taw, Myanmar for the 30th ACC, 30th ASEAN Cosmetic Scientific Body (ACSB) and 13th 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 30th 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. *Tagetes* (ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down, Ref. Nos. 324 and 325 respectively)

3.1.1.1. The Meeting agreed to adopt the part of EU Regulation 2018/978 adding the entries for *Tagetes minuta* and *Tagetes patula* in ACD Annex III. Effective **19 December 2020**, only compliant products shall be made available in the market; and non-compliant products shall be withdrawn from the market.

3.1.1.2. In ACD Annex III

- The maximum authorized concentration of *Tagetes minuta* and *Tagetes patula* 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 ≤ 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. Further review of the species *Tagetes erecta* will be presented in the next ACSB Meeting.

3.1.2. Biphenyl-2-ol and its salts (EU 2018/1847)

3.1.2.1. Except for Indonesia, the Meeting agreed to adopt the EU Regulation 2018/1847 revising the entry for Biphenyl-2-ol and its salts in ACD Annex VI - List of Preservatives Which Cosmetic Products May Contain. The entry is changed from Biphenyl-2-ol and its salts to **Biphenyl-2-ol** and from 0.2% (as phenol) to **0.2% (as phenol) in rinse-off products** and **0.15% (as phenol) in leave-on products** and to include the warning **“Avoid contact with eyes”** on the label.

3.1.2.2. Effective **18 December 2020**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Indonesia informed that she will need to further check the products impacted by this regulation to confirm agreement to the new regulation.

3.1.2.3. Furthermore, products containing salts of Biphenyl-2-ol (**MEA o-phenylphenate, potassium o-phenylphenate and sodium o-phenylphenate**) as preservatives shall not be made available in the market.

3.1.3. Phenylene Bis-Diphenyltriazine (EU 2019/680)

3.1.3.1. The Meeting agreed to adopt the EU Regulation 2019/680 and to include a new entry in ACD Annex VII - List of UV filters Which Cosmetic Products May Contain, **effective immediately**. The new entry for Phenylene Bis-Diphenyltriazine has a maximum authorized concentration of **5%** and the restriction **“not to be used in applications that may lead to exposure of the end user's lungs by inhalation.”**

3.1.3.2. Thailand informed that their implementation can proceed six (6) months from adoption to allow processing of the local regulation to include Phenylene Bis-Diphenyltriazine in their list of allowable substances for use as UV filter.

3.1.3.3. The Meeting took note of Indonesia's comment that the SCCS Final Opinion states that Phenylene Bis-Diphenyltriazine (S86) may contain impurities (N-methyl-pyrrolidone [NMP] and hydrazine) which are classified as CMR 1B. Therefore, the level of NMP and hydrazine should be kept at trace levels.

3.1.4. 2-Chloro-p-Phenylenediamine (EU 2019/681)

3.1.4.1. The Meeting agreed to adopt the EU Regulation 2019/681, adding this entry to ACD Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products, with revision. As it has been agreed upon in the 26th ACSB Meeting that all hair dyes shall not be allowed for colouring eyelashes and eyebrows, the entry shall be revised to remove reference on its use including eyebrow dye products and eyelash dye products.

3.1.4.2. The timeline is as follows: (i) for new products, effective **18 June 2020**, and (ii) for existing products, effective **18 December 2020**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

3.1.5. Climbazole (EU 2019/698)

3.1.5.1. Following the adoption of the EU Regulation 2019/698 for Climbazole during the 29th ACSB Meeting which added an entry in ACD Annex III and revised the entry in ACD Annex VI, the meeting agreed to the following timelines:

- For the revised entry in Annex VI – (i) for new products, effective **18 June 2020**, and (ii) for existing products, effective **18 June 2021**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

- For the added entry in Annex III, this is **effective immediately**. The Meeting noted that Annex III entry is already implemented in Indonesia.

3.1.6. Silver Nitrate – Removal of entry in ACD Annex III

3.1.6.1. As agreed in the 26th ACSB Meeting that the use of hair dyes for dyeing eyelashes and eyebrows shall not be permitted in ASEAN, the Meeting agreed that this shall apply to the Silver Nitrate entry. As the specific use is solely for products intended for colouring eyelashes and eyebrows, the entry will be removed from Annex III. The Meeting agreed to further review the entry for Silver Nitrate in Annex III, whether it is considered as a hair dye. ASEAN Cosmetic Association (ACA) will present the safety review of this ingredient in the next ACSB Meeting.

3.1.7. Fluoride – Revised entry in ACD Annex III

3.1.7.1. Thailand provided update of their review of the current Fluoride level following a research of The Royal College of Dental Surgeons of Thailand showing that toothpaste containing 0.15% (1500 ppm) fluoride is effective in preventing dental caries and safe for home use. Thailand will adjust the fluoride maximum concentration (calculated as Fluoride) in ref #26 - #43, #47 and #56 of Annex III from 1100 ppm (0.11%) to 1500 ppm (0.15%) calculated as Fluoride at the end of Year 2019.

3.1.8. Hair Dyes in ACD Annex III

3.1.8.1. The Meeting agreed with the proposal of Indonesia to **remove the text ‘Indonesia only: Not Permitted – under review’** from the 30 hair dyes entries in ACD Annex III.

3.1.8.2. Indonesia informed that they re-evaluated the safety of the 30 hair dyes and decided to adopt these hair dyes on the Draft of Indonesia Regulation and adding a mandatory requirement **“regularly send the report for adverse event of cosmetic containing these hair dyes to NADFC on January, April, July and October”**. Indonesia will continuously review the Adverse Event reporting period based on the data received.

3.2. 1,4-Dioxane

During the 28th ACSB Meeting, the Meeting agreed to adopt a maximum trace limit of **25 parts per million (ppm)** for 1,4-Dioxane in finished cosmetic products. Eventually, during the 29th ACSB Meeting, the Meeting noted the Scientific Committee on Consumer Safety (SCCS) recommendation that the eventual trace limit for 1,4-Dioxane is **10 ppm**.

In consideration of the time required to determine and make the validated methods available for 1,4-Dioxane for both 25 ppm and 10 ppm limits for finished products, the Meeting agreed to the following grace periods for compliance: (1) from **19 June 2020**, all products shall comply with 1,4-Dioxane at **25 ppm limit**; and (2) from **19 June**

June 2023, all products shall comply with 1,4-Dioxane at **10 ppm**. These timelines will be reflected in the ASEAN Guidelines on Limits of Contaminants for Cosmetics.

3.3. Nanometer Tooth Membrane Whitening Kit

The Meeting agreed and adopted the updated list of borderline products which included the Nanometer Tooth Whitening Kit.

3.4. ASEAN Cosmetic Methods (ACM)

Aside from the FDA website, the nine (9) ACMs and the latest versions of ACM 005 and 007 were uploaded and available for download from the following links:

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

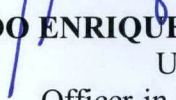
ASEAN Secretariat's website - http://asean.org/?static_post=asean-sectoral-mras

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. 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).


ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General



DTN 20190716091625

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 30th 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

1. ACD Annex II Ref. No. 1384 (New Entry)

Substances	CAS Number	Ref. No.
2-chlorobenzene-1,4-diamine (2-Chloro-p-Phenylenediamine), its sulfate and dihydrochloride salts when used as a substance in hair dye products	615-66-7 61702-44-1 (sulfate) 615-46-3 (dihydrochloride)	1384

B. ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down

1. ACD Annex III Ref. No. 324 (New 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 ≤ 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), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)	

2. ACD Annex III Ref. No. 325 (New 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 patula (entry 324), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)	

3. ACD Annex III Ref. No. 326 (New 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
326 (310)	1-(4-Chlorophenoxy)- 1-(imidazol-1-yl)-3,3- dimethylbutan-2-one Climbazole 38083-17-9	Rinse-off Anti-Dandruff Shampoos	2.0%	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

4. ACD Annex III Ref. No. 48 (Deleted 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
48	Entry Deleted Silver nitrate Silver nitrate CAS No 7761-88-8	Solely for products intended for colouring eyelashes and eyebrows	4%		<ul style="list-style-type: none"> • Contains silver nitrate • Rinse the eyes immediately if product comes into contact with them

5. ACD Annex III Ref. Nos. 26-43, 47 and 56 (Revised Entries)

Removal of the other limitations and requirements **“Thailand only 0.11% calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%”**.

6. ACD Annex III Ref. Nos. 255, 257-260, 262-263, 270, 279,282-285, 289, 290, 294, 295-298, 302-309 (Revised Entries)

Removal of the text **“Indonesia Only – Not Permitted, Under Review”**

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

1. ACD Annex VI Ref. No. 7 (Revised Entry)

From

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
7	Biphenyl-2-ol (o-phenylphenol) and its salts	0.2% expressed as phenol		

To

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
7	Biphenyl-2-ol CAS 90-43-7	Rinse-off products; 0.2% (as phenol) Leave-on products; 0.15% (as phenol)	Indonesia: Under Review	Avoid contact with eyes.

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

From

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)(+)	0.5%		

To

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)(+) Climbazole CAS 3803-17-9	Hair lotions; 0.2% Face creams; 0.2% Foot care products; 0.2% Rinse-off shampoo; 0.5%		

D. ACD Annex VII - List of UV filters Which Cosmetic Products May Contain

1. ACD Annex VI Ref. No. 30 (New 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
30	3,3'-(1,4-Phenylene) bis (5,6-diphenyl- 1,2,4-triazine) CAS 5514-22-2	5%	Not to be used in application that may lead to exposure of the end user's lungs by inhalation.'	