Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

11 FEB 2019

FDA CIRCULAR
No. 2019-002

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

SUBJECT: **Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted During the 29th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings**

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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 (AHCRS) 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 23-26 October 2018, the ASEAN Cosmetic Committee (ACC) convened in Kuala Lumpur, Malaysia for the 29th ACC, 29th ASEAN Cosmetic Scientific Body (ACSB) and 12th ASEAN Cosmetic Testing Laboratories 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 ASEAN Cosmetic Directive (ACD).

2. OBJECTIVE AND SCOPE

This Circular aims to provide the updates and amendments to the ACD as adopted in the 29th 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 are accessible at the FDA website.

For easy reference, a table of the new and modified entries is provided in **Annex A**.

3.1.1. Climbazole

Following the discussion regarding EU regulation on Climbazole and the recent SCCS opinion on its Margin of Safety (MOS) for aggregate exposure scenarios, the Meeting agreed to set new limits for Climbazole in ACD Annexes III and VI for rinse-off and leave-on cosmetic products.

For ACD Annex III, an entry for Climbazole is added with the following set limits/restrictions:

a. 2.0% maximum permitted concentration as antidandruff agent in rinse-off shampoos
b. 0.2% maximum permitted concentration in leave-on face cream, hair lotions and foot care

For ACD Annex VI, the current restriction of 0.5% maximum permitted concentration for all cosmetic products is updated as follow:

a. 0.5% maximum permitted concentration for rinse-off shampoos
b. 0.2% maximum permitted concentration for leave-on face cream, hair lotions and foot care

As to the grace period, this will be discussed during the 30th ACC meeting and its related meetings in 2019.

3.1.2. EU 2018/885

The Meeting agreed to adopt EU 2018/885 and to include a new entry in ACD Annex VII for the nano form of 2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol) or MBBT.

The new entry for MBBT (nano) have a maximum permitted concentration of 10% and the following restrictions:

a. Not to be used in applications that may lead to exposure of the end user's lungs by inhalation;
b. Only nanomaterials having the following characteristics are allowed:
    - Purity ≥98.5%, with 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1.5%;
    - Solubility <5 ng/L in water at 25°C;
    - Partition coefficient (Log Pow): 12.7 at 25°C;
    - Uncoated;

- Median particle size D50 (50% of number below this diameter): ≥120 nm of mass distribution and/or ≥60 nm of number size distribution; and

c. In case of combined use of MBBT and MBBT (nano), the total concentration shall not exceed the limit given in column g (10%).

3.1.3. Corrections in ACD Annexes II, III and VII

a. ACD Annex II Ref. Nos. 1067 (4,4'-Carbonimidoylbis[N,N-dimethylaniline]) and 1129 (Salts of 4,4'-Carbonimidoylbis[N,N-dimethylaniline]) have been combined into one (1) entry in Ref. No. 1067 and Ref. No. 1129 has been deleted.

b. ACD Annex II Ref. Nos. 1130 (1,2,3,4,5,6-Hexachlorohexanes with the exception of those specified elsewhere in this annex) and 195 (1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)) are duplicate entries listing the same substances, hence, Ref. No. 1130 has been deleted.

c. CAS No. 68127-22-0 refers to a permitted cosmetic ingredient, namely, Menthyl PCA, but has been erroneously listed under ACD Annex II Ref. No. 1117 as one of the CAS nos. referring to "trans-4-Cyclohexyl-L-proline monohydrochloride." This error has been corrected and CAS No. 68127-22-0 has been deleted from the annex entry.

d. The last revision of ACD Annex III has two (2) entries for 8(c), the 2nd of which should be 9b. Hence, the error in said annex has been corrected to reflect the following:

Old ACD Annex III version		Revised ACD sAnnex III version	
8c	Ethanol,2,2'-[(2-nitro-1,4-phenylene)diimino]bis-(9Cl) CAS No. 84041-77-0 *Placing – after entry 8a*	8c	Ethanol,2,2'-[(2-nitro-1,4-phenylene)diimino]bis-(9Cl) CAS No. 84041-77-0 *Placing – after entry 8a*
	1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene CAS No. 149330-25-6 *Placing – after entry 9a*	9b	1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene CAS No. 149330-25-6 *Placing – after entry 9a*

e. ACD Annex VII Ref. No. 22 erroneously identified 2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid as Benzophenone 5 when it is correctly identified as **Benzophenone-4**. The Meeting agreed to edit the text in ACD Annex VII Ref. No. 22 from "2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt" to "**2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-4) and its sodium salt (Benzophenone-5)**"

3.2. Thioglycolic Acid and Thiolactic Acid (ACD Annex III Ref. Nos. 2a and A9 respectively)

Current restriction on concentration in ACD Annex III for thioglycolic acid and thiolactic acid is as **% Thioglycolic acid**. The ASEAN Cosmetic Association (ACA) provided a method to calculate the % thioglycolic acid content when these ingredients are used in combination as well as to convert thiolactic acid to thioglycolic acid. This document appears as **Annex B**.

3.3. Peanut Oil and Hydrolyzed Wheat Protein (ACD Annex III Ref. Nos. 322 and 323 respectively)

Following the inclusion of the new entries for peanut oil and hydrolyzed wheat protein in ACD Annex III after the 28th ACC Meeting and its related meetings, Indonesia informed the Meeting that the implementation of the new restrictions would not proceed in her country. Instead, she would only require a warning statement on the packaging/label to highlight the presence of any of these ingredients.

The Meeting urged Indonesia to reconsider and she agreed to discuss internally and report back to the 30th ACC meeting and its related meetings in 2019.

3.4. 1,4-Dioxane

During the 28th ACC Meeting and its related meetings, the Meeting agreed to adopt a maximum trace limit of **25 parts per million (ppm)** for 1,4-Dioxane in finished cosmetic products.

The ASEAN Guidelines for Limits of Contaminants in Cosmetics has been revised to reflect this guidance limit for 1,4-Dioxane as trace impurity. However, the Meeting also noted the SCCS recommendation that the eventual trace limit for 1,4-Dioxane is 10ppm and this should be specified in the said document along with the outlined timeframe for the target trace limit. Further discussion on this matter is scheduled for the 30th ACC meeting and its related meetings in 2019.

3.5. Process for New Materials

During the 26th ACC meeting and its related meetings in 2017, it has been proposed that the ACSB should have a process for introduction of new materials into ACD Annexes III, IV, VI and VII that did not arise from any new EU regulations to help promote innovation in the ASEAN region.

After several meetings, a process has been finalized and adopted for new materials which may also be applied to ingredients for inclusion in ACD Annexes II and III. The flowchart appears as **Annex C**.

Information requirements for new material submission including step-by-step procedures, checklists and specific data requirements will be further laid down in detail.

3.6. ASEAN Cosmetic Methods (ACM)

ACM 009 Revision N°0 "Determination of Salicylic Acid (Beta Hydroxy Acid) in Cosmetic Products by High Performance Liquid Chromatography (HPLC)" is available in the following websites:

a. ASEAN Trade Repository (ATR) - http://atr.asean.org/standards/detail/316/acm-009-determination-of-salicylic-acid-beta-hydroxy-acid-in-cosmetic-products-by-high-per-formance-liquid-chromatography-hplc

b. ASEAN Secretariat's website - https://asean.org/wp-content/uploads/2012/10/ACM-009-Beta-Hydroxy-Acid-BHA_Final-Version-20171.pdf.

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

5. EFFECTIVITY

This Circular shall take effect immediately.

NELA CHARADE G. PUNO, RPh
FDA Director General

DTN 20181203092249

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 29th 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. Nos. 1067 and 1129

From

Substances	CAS Number	Ref. No.
4,4'-Carbonimidoylbis[N,N-dimethylaniline]	492-80-8	1067
Salts of 4,4'-carbonimidoylbis[N,N-dimethylaniline]	---	1129

To

Substances	CAS Number	Ref. No.
4,4'-Carbonimidoylbis[N,N-dimethylaniline] and its salts	492-80-8	1067
Moved or Deleted (See Ref. No. 1067)	---	1129

2. ACD Annex II Ref. Nos. 1130 and 195

From

Substances	CAS Number	Ref. No.
1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)	58-89-9	195
1,2,3,4,5,6-Hexachlorohexanes with the exception of those specified elsewhere in this annex	---	1130

To

Substances	CAS Number	Ref. No.
1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)	58-89-9	195
Moved or Deleted (See Ref. No. 195)	---	1130

3. ACD Annex II Ref. No. 1117

From

Substances	CAS Number	Ref. No.
trans-4-Cyclohexyl-L-proline monohydrochloride	90657-55-9/ 68127-22-0	1117

To

Substances	CAS Number	Ref. No.
trans-4-Cyclohexyl-L-proline monohydrochloride	90657-55-9	1117

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, New Entry (Climbazole)

Ref No ACD # (EU #)	Substance/CAS No	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
To be determined	Climbazole	a. Rinse off shampoos as antidandruff agent b. Leave on face cream, hair lotion and foot care	a. 2.0% b. 0.2%		

2. ACD Annex III Ref. Nos. 8(c) and 9(b)

From

Ref No ACD # (EU #)	Substance/CAS No	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
8c	Ethanol, 2,2'-[(2- nitro-1,4-phenylene)diimino]bis- (9CI) N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine CAS No. 84041-77-0	(a)Hair dye substance in oxidative hair dye products (b)Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	b. 1.5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% For (a) and (b) The direction for use "wear suitable gloves" must be included in label or leaflet text. • Do not use with nitrosating agents • Maximum nitrosamine content: 50 µg/kg(21) • Keep in nitrite-free containers	(a) To be printed on the label: The mixing ratio. ⚠ "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. (a) and (b) Do not use to dye eyelashes or eyebrows."
8c	1-Methyl-2,6-bis- (2-hydroxyethylamino)-benzene 2,6-Dihydroxyethylaminotoluene CAS No 149330-25-6	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text. • Do not use with nitrosating agents • Maximum nitrosamine content: 50 µg/kg(21) • Keep in nitrite-free containers	To be printed on the label: The mixing ratio. ⚠ "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

To

Ref No ACD # (EU #)	Substance/CAS No	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
8c	Ethanol, 2,2'-[(2- nitro-1,4-phenylene)diimino]bis- (9CI) N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine CAS No. 84041-77-0	(a)Hair dye substance in oxidative hair dye products (b)Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	b. 1.5%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% For (a) and (b) The direction for use "wear suitable gloves" must be included in label or leaflet text. • Do not use with nitrosating agents • Maximum nitrosamine content: 50 µg/kg[21] • Keep in nitrite-free containers	(a) To be printed on the label: The mixing ratio. ⚠ "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. (a) and (b) Do not use to dye eyelashes or eyebrows."
9b	1-Methyl-2,6-bis- (2-hydroxyethylamino)-benzene 2,6-Dihydroxyethylaminotoluene CAS No 149330-25-6	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text. • Do not use with nitrosating agents • Maximum nitrosamine content: 50 µg/kg[21] • Keep in nitrite-free containers	To be printed on the label: The mixing ratio. ⚠ "Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary 'black henna' tattoo in the past. Do not use to dye eyelashes or eyebrows."

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

1. ACD Annex VI Ref. No. 32 (Climbazole)

Ref No.	Substance/CAS No[19]	Maximum authorised concentration in the ready for use preparation	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) (+) a. Rinse-off shampoos b. Leave on face cream, hair lotion and foot care	a. 0.5% b. 0.2%	---	---

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

1. ACD Annex VII Ref. No. 23 and 23a (Methylene Bis-Benzotriazolyl Tetramethylbutylphenol or MBBT and its nano form)

Ref. No.	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
23	**2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol);2,2'-Methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (Methylene Bis-Benzotriazolyl Tetramethylbutylphenol/MBBT)** **CAS 103597-45-1**	10% (1)		
23a	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol);2,2'-Methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)/MBBT (nano)) CAS 103597-45-1	10% (1)	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: - Purity ≥ 98.5 %, with 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1.5 %; - Solubility < 5 ng/L in water at 25 °C; - Partition coefficient (Log Pow): 12.7 at 25 °C; - Uncoated; - Median particle size D50 (50% of number below this diameter): ≥ 120 nm of mass distribution and/or ≥ 60 nm of number size distribution.	

(1) In case of combined use of Methylene Bis-Benzotriazolyl Tetramethylbutylphenol and Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), the sum shall not exceed the limit given in column g.

2. ACD Annex VII Ref. No. 22

From

Ref. No.	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
23	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt	5% (as acid)		

To

Ref. No.	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
23	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-4) and its sodium salt (Benzophenone-5)	5% (as acid)		

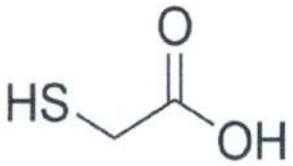
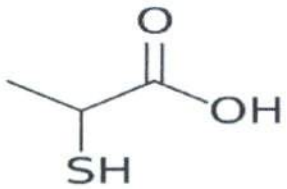
Annex B

Calculation of the Maximum Concentration of Thioglycolic Acid & Thiolactic Acid Combinations

This document was prepared as a follow-up to the 28th ACSB meeting result on clarification of the calculation maximum concentration of thioglycolic acid and thiolactic acid combinations for general use of hair waving or straightening products which must not exceed 8% calculated as thioglycolic acid.

Statement in Annex III, Refs 2a and A9:

"For general use of hair waving or straightening products the maximum concentration for combination of Thioglycolic acid and Thiolactic acid must not exceed 8% calculated as Thioglycolic Acid."

Thioglycolic acid (TGA)		**Thiolactic acid (TLA)**	
			
Chemical Formula	= $C_2H_4O_2S$	Chemical Formula	= $C_3H_6O_2S$
Molecular Weight (MW TGA)	= 92.11 g/mol	Molecular Weight (MW TLA)	= 106.14 g/mol

Calculation to convert TLA to TGA is:

$$\text{Concentration of TLA} \quad X \quad \frac{\text{MW TGA}}{\text{MW TLA}}$$

<u>Example 1 - Single Ingredient</u>

Combination of TGA and TLA in the formulation is 4% TGA and 4% TLA.

Convertion of 4% TLA to TGA = 4% x 92.11/106.14 = 3.47%

Total concentration of the combinations calculated as TGA = 4% + 3.47% = 7.47%

<u>Example 2 – Mixture Ingredient</u>

In case of both ingredients in the form of mixture ingredient, then the calculation should be break down into its composition, as follow:

Concentration of the Mixture in the formulation is 6%. Ratio TGA and TLA in the mixture is 70% : 30%.

Proportion of TGA in 6% of the mixture→ Concentration of TGA = 6% x 0.7 = 4.2%

Proportion of TLA in 6% of the mixture → Concentration of TLA = 6% x 0.3 = 1.8%

Conversion of 1.8% TLA to TGA = 1.8% x 92.11/106.14 =1.56% ~ 1.6%

Total concentration of the combinations calculated as TGA = 4.2% + 1.6% = 5.8%

The ACSB Process for Review of new cosmetic ingredients - for ACD Annexes IV, VI or VII (Positive List) -

*includes companies who are not members of the National Association/ACA

** only for the substance proposed by the NRA

For Annex II and III, when there is COI management the above ACSB work flow is also applicable.

*) [ToR of ACSB, Article 3.2] *"The ACSB may invite, upon approval by the members of the ACSB, any expert in cosmetic sector, as a resource person to provide input and facilitate technical discussions."*

(Ref) TERMS OF REFERENCE OF THE ASEAN COSMETIC SCIENTIFIC BODY (ACSB) Article 3.2 Structure of ACSB.