

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



0 9 FEB 2018

FDA ADVISORY No. 2018-034

TO:

ALL COSMETIC MANUFACTURERS, TRADERS. DISTRIBUTORS, COSMETIC SAFETY ASSESSORS,

AND FORMULATORS, RESEARCHERS, OTHER

CONCERNED PARTIES

SUBJECT: Reiteration of Grace Periods Given to the Cosmetic Industry for Ingredients Banned or Restricted During the Recent ASEAN

Cosmetic Committee (ACC) Meetings and Its Related Events

In the interest of public service and in line with the Food and Drug Administration's (FDA's) thrust to strengthen its enforcement of existing rules, regulations and standards, the Center for Cosmetics Regulation and Research (CCRR) hereby reiterates the impending end of the grace periods given to the cosmetic industry through FDA Circulars No. 2017-006 and 2017-007 for newly banned ingredients or ingredients with new restrictions adopted during the 25th and 26th ASEAN Cosmetic Committee (ACC) meetings and its related events.

FDA Circular No. 2017-006 "Updates and Amendments of the ASEAN I. Cosmetic Directive as Adopted During the 25th ASEAN Cosmetic Committee Meeting and Its Related Events

ACD Annex and Reference No.	Chemical / Substance	Maximum Authorized Concentration and/or Other Limitations and Requirements	Grace Period
Annex III Ref. No. 15d	Potassium Hydroxide	1.5% as callosity softener / remover Conditions of use and warning which must be printed on the label:	31 August 2018
Annex IV Color Index (CI) 77266	Carbon Black	Additional Restriction/Conditions of Use: Purity >97 %, with the following impurity profile: Ash content ≤ 0.15%, total sulphur ≤ 0.65%, total PAH ≤500 ppb and benzo(a)pyrene ≤ 5ppb, dibenz(a,h)anthracene ≤5 ppb, total As ≤3 ppm, total Pb ≤10 ppm, total Hg ≤ 1ppm.	31 August 2018



Carbon Black (Nano)	10%	31 August 2018
	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 >97%, with the following impurity profile: Ash content ≤0.15%, total sulphur ≤0.65%, total PAH ≤500 ppb and benzo(a)pyrene ≤5 ppb, dibenz(a,h)anthracene ≤5 ppb, total As ≤3 ppm, total Pb ≤10 ppm, and total Hg ≤1 ppm;	
2-Methyl-2H-		31 August 2018
isothiazol- 3-one Methylisothiazolinone	Allowed to be used only in rinse-off products.	
	Prohibited in leave-on products.	
Zinc Oxide	Additional Restriction/Conditions of Use: "Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation."	31 August 2018
Zinc Oxide (nano)	Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: - purity ≥96% with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water whilst other impurities are less than 1% in total. - Median diameter of the particle number size distribution D50 (50% of the number below this diameter) >30 nm and D1 (1% below this size) >20nm. - Water solubility <50 mg/l. - Coating materials can be used that have been demonstrated to be safe and not to affect the	31 August 2018
	2-Methyl-2H- isothiazol- 3-one Methylisothiazolinone Zinc Oxide	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 >97%, with the following impurity profile: Ash content ≤0.15%, total sulphur ≤0.65%, total PAH ≤500 ppb and benzo(a)pyrene ≤5 ppb, total As ≤3 ppm, total Pb ≤10 ppm, and total Hg ≤1 ppm; — Primary particle size ≥20 nm. 2-Methyl-2H-isothiazol-3-one Methylisothiazolinone Methylisothiazolinone Additional Restriction/Conditions of Use: "Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation." Zinc Oxide (nano) Dust (nano) Zinc Oxide (nano) Zinc Oxide (nano) Zinc Oxide (nano) Zinc Oxide (nano) Additional Restriction/Conditions of Use: "Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation." Zinc Oxide (nano) Zinc Oxide (nano)

Annex VII Ref. No. 27a	Titanium Dioxide (nano)	25%3	31 August 2018
	(nano)	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 ≥99%	
		- Rutile form, or rutile with up to	
		5% anatase, with crystalline	
		structure and physical appearance as	
		clusters of spherical, needle, or	
		lanceolate shapes,	
		- Median particle size based on	
		number size distribution ≥30 nm, - Aspect ratio from 1 to 4.5 and	
		volume specific surface area <460	
		m²/cm³.	
		- Coating materials can be used that	
		have been demonstrated to be safe	
		and not to affect the nanoparticle	
		properties related to the behaviour	
		and/or effects4	
		- Photocatalytic activity ≤ 10%	
		compared with corresponding non-	
		coated or non-doped reference,	
		- Nanoparticles are photostable in	
		the final formulation.	

In case of combined use of Zinc Oxide and Zinc Oxide (nano), the sum shall not exceed the maximum authorized concentration which is 25%.

II. FDA Circular No. 2017-007 "Updates and Amendments of the ASEAN Cosmetic Directive as Adopted During the 26th ASEAN Cosmetic Committee Meeting (ACC) and Its Related Events

ACD Annex and Reference No.	Chemical / Substance	Maximum Authorized Concentration and/or Other Limitations and Requirements	Grace Period
Annex III Ref. No. 312	Diethylene Glycol Monoethyl Ether (DEGEE) Ethoxydiglycol	 a. Oxidative hair dye products – 7% b. Non-oxidative hair dye products – 5% c. Rinse-off products other than hair dye products – 10% d. Other non-spray cosmetic products – 2.6% e. The following spray products: fine fragrances, hair sprays, anti-perspirants and deodorants – 2.6% 	01 December 2018

²The amendment to the original restriction on the coating material for Zinc Oxide (nano) is adopted during the 26th ACC Meeting and its related events and disseminated through FDA Circular No. 2017-007.

³ In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the maximum authorized concentration which is 25%.

⁴The amendment to the original restriction on the coating material for Titanium Dioxide (nano) is adopted during the 26th ACC Meeting and its related events and disseminated through FDA Circular No. 2017-007.

		(a) to (e) The level of ethylene glycol impurity in Ethoxydiglycol must be ≤0.1 % Not to be used in eye products and oral products.	
Annex III Ref. No. 313	Polidocanol Laureth-9	a. Leave-on products – 3.0% b. Rinse-off products – 4.0%	01 December 2018
Annex III	Hair Dye Entries	Additional conditions of use and warning which must be printed on the label: "Do not use to dye eyelashes or eyebrows"	01 June 2018
Annex VII Ref. No. 4	Oxybenzone (INN)	6% Conditions of use and warning which must be printed on the label: "Contains oxybenzone"	01 December 2018

Cosmetic establishments are strongly advised to recall their products containing the abovementioned ingredients whose use is outside the new restrictions and conditions laid down in the ASEAN Cosmetic Ingredient Annexes by the end of the grace period. Violation of the new restrictions and conditions after the grace period has ended shall subject the violator to appropriate regulatory actions.

For more information, cosmetic establishments may check the FDA website (www.fda.gov.ph) for updates and amendments to the ASEAN Cosmetic Directive (ACD), its annexes and appendices.

Dissemination of the information to all concerned is requested.

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