

Annex A

New and Modified Entries in the ASEAN Cosmetic Directive (ACD) Ingredient Annexes

The updated ACD Ingredient Annexes incorporating the new and amended entries adopted during the 25th ACC Meeting and its related events are not yet available. The tables below representing the new and modified entries are shown only for easy reference of the cosmetic industry and may be presented differently when the updated ACD Ingredient Annexes are released/issued.

A. ACD Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products

1. Ketoconazole

Substances	CAS Number	Ref. No	Grace Period
Ketoconazole	65277-42-1	To be determined (TBD)	None

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

1. Potassium Hydroxide

Ref #	Substance	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 finished cosmetic product	Other limitations and requirements		
TBD	Potassium Hydroxide	Callous Softener / Remover	1.5%	---	<ul style="list-style-type: none"> • Contains alkali. • Avoid contact with eyes • Keep out of reach of children • Read directions for use carefully 	August 31, 2018

C. ACD Annex IV - List of Colouring Agents Allowed for Use in Cosmetic Products

1. Carbon Black and Carbon Black (Nano)

Name of Common Ingredient	Colour Index (CI) Number	CAS Number	Colour	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	Grace Period
Carbon Black	CI 77266	1333-86-4, 7440-44-0	Black	---	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, total Hg ≤ 1 ppm.	August 31, 2018
Carbon Black (Nano)	CI 77266 (Nano)	1333-86-4, 7440-44-0	Black	10%	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; — Primary particle size ≥ 20 nm. '.	August 31, 2018

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

1. Ethyl Lauroyl Arginate

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
58	Ethyl Lauroyl Arginate HCl(*) Ethyl-N α -dodecanoyl- L-arginate hydrochloride CAS No. 60372-77-2 EC No. 434-630-6	(a) Mouthwash: 0.15% (b) Other Products: 0.4%	(a) Not to be used in preparations for children under 10 years of age. (b) Not to be used in lip products, oral products (other than mouthwashes) and spray products.	(a) Not to be used in preparations for children under 10 years of age.	None

(*) For other uses than preservatives, see Annex III, Ref. No. 207.

2. Methylisothiazolinone

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
57	2-Methyl-2H-isothiazol- 3-one Methylisothiazolinone CAS No. 2682-20-4 EC No. 220-239-6	0.01%	Allowed to be used only in rinse-off products. Prohibited in leave-on products.	---	August 31, 2018

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

1. Zinc Oxide and Zinc Oxide (Nano)

Reference number	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
A29	Zinc Oxide CAS No. 1314-13-2 EC No. 215-222-5	25% ^(*)	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	---	August 31, 2018
TBD	Zinc Oxide (Nano) CAS No. 1314-13-2 EC No. 215-222-5	25% ^(*)	<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> — purity \geq 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 any 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) > 20 nm; — water solubility < 50 mg/L; —uncoated or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross- polymer or octyl triethoxy silane. 	---	August 31, 2018

() In case of combined use of Zinc Oxide and Zinc Oxide (Nano), the sum shall not exceed the maximum authorized concentration.*

2. Titanium Dioxide (Nano)

Reference number	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
TBD	Titanium Dioxide (Nano) ^(*) CAS No. 13463-67-7/ 1317-70-0/ 1317-80-2	25% ^(**)	<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> — purity $\geq 99\%$; — 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; — coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone; — photocatalytic activity $\leq 10\%$ compared to corresponding non-coated or non-doped reference; — nanoparticles are photostable in the final formulation. 	---	August 31, 2018

^(*) For use as a colorant, see Annex IV.

^(**) In case of combined use of Titanium Dioxide and Titanium Dioxide (Nano), the sum shall not exceed the maximum authorized concentration.