

Annex A  
**Updates and Amendments to the ACD Ingredient Annexes**

The updated ACD Ingredient Annexes with the exception of ACD Annex III incorporating the new and amended entries adopted during the 26<sup>th</sup> ACC Meeting and its related events are posted in the FDA website under the ASEAN Cosmetic Harmonization section. The tables below especially those representing the new and modified entries of ACD Annex III are shown only for easy reference of the cosmetic industry and may be presented differently when the updated ACD Ingredient Annex is released/issued.

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

1. Diethylene Glycol Monoethyl Ether or DEGEE

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	Diethylene Glycol Monoethyl Ether (DEGEE)  Ethoxydiglycol  CAS No. 111-90-0  EC No. 203-919-7	a. Oxidative hair dye products  b. Non-oxidative hair dye products  c. Rinse-off products other than hair dye products  d. Other non-spray cosmetic products  e. The following spray products: fine fragrances, hair sprays, anti-perspirants and deodorants	a. 7%  b. 5%  c. 10%  d. 2.6%  e. 2.6%	(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.	---	1 December 2018

2. Laureth-9 or Polidocanol

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	Polidocanol Laureth-9 CAS No. 3055-99-0 EC No. 221-284-4	a. Leave-on Products b. Rinse-off Products	a. 3% b. 4%	---	---	1 December 2018

3. All hair dye entries

Conditions of use and warning which must be printed on the labels	Grace Period
Additional required warning statement: <b><u>“Do not use to dye eyelashes or eyebrows”</u></b>	1 June 2018

**B. 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
A29a	Zinc Oxide (Nano)	25% <sup>(1)</sup>	<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"> <li>— purity <math>\geq</math> 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;</li> <li>— median diameter of the particle number size distribution D50 (50% of the number below this diameter) &gt; 30 nm and D1 (1% below this size) &gt; 20 nm;</li> <li>— water solubility &lt; 50 mg/L.</li> </ul> <p>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 effects</p>	---	None

<sup>(1)</sup> In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column c.

## 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
27a	Titanium Dioxide (Nano)	25% <sup>(2)</sup>	<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"> <li>— purity <math>\geq 99\%</math>;</li> <li>— rutile form, or rutile with up to 5% anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes;</li> <li>— median particle size based on number size distribution <math>\geq 30</math> nm;</li> <li>— aspect ratio from 1 to 4.5, and volume specific surface area <math>\leq 460</math> m<sup>2</sup>/cm<sup>3</sup>;</li> <li>— 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 effects</li> <li>— photocatalytic activity <math>\leq 10\%</math> compared with corresponding non-coated or non-doped reference;</li> <li>— nanoparticles are photostable in the final formulation.</li> </ul>	---	None

<sup>(2)</sup> In case of combined use of titanium dioxide and titanium dioxide (nano), the sum shall not exceed the limit given in column c.

## 3. Benzophenone-3

Reference number	Substance	Maximum Authorized Concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label	Grace Period
4	Oxybenzone (INN)	6%	---	Contains oxybenzone <sup>(3)</sup>	1 December 2018

<sup>(3)</sup> Not required if concentration is 0.5 % or less and when it is used only for product protection purposes.