

New updates on Annexes of the ASEAN Cosmetic Directive (ACD) adopted in 24th and 25th ACSB Meetings

- 1. The following information is to update the industry on the decisions adopted by the ACSB during ACSB Meeting.**
- 2. The industry may provide your feedback on the implementation periods by 31 Jan 2017.**
- 3. The entry number may be subject to further changes.**

Summary of changes to cosmetic ingredient lists at 24th ACSB Meeting (May 2016)

Type of change	Annex of the ACD	Entry No. /Ref. No. ACD # (EU #)	Description of changes	Reference table	Implementation period
New entry	Annex II	1379	3-Benzylidene camphor is deleted from Annex VII (Ref 19) and moved to Annex II	Table 1	30 June 2016
Amendment	Annex II	419	New definition of animal materials	Table 1	-
New entry	Annex III	303 (288)	New restrictions for <u>HC Blue No 17</u> {3-[(4-amino-3-methyl-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]-N,N,N -trimethylpropan-1-aminium, methylsulfate salt	Table 2	30 Nov 2016
New entry	Annex III	304 (289)	New restrictions for <u>HC Blue No 15</u> Phosphoric acid compound with 4-[(2,6-dichlorophenyl) (4-imino-3,5-dimethyl-2,5-cyclohexadien-1-ylidene) methyl]-2,6-dimethylaniline (1:1)	Table 2	30 Nov 2016
New entry	Annex III	305 (290)	New restrictions for <u>Acid Green 25</u> Disodium 2,2'-(9,10-dioxoanthracene-1,4-diyldiimino)bis(5-methylsulphonate)	Table 2	30 Nov 2016
New entry	Annex III	306 (291)	New restrictions for <u>Acid Violet 43</u> Sodium, 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate	Table 2	30 Nov 2016
New entry	Annex III	307 (292)	New restrictions for <u>2-Methoxymethyl-p-Phenylenediamine</u> and <u>2-Methoxymethyl-p-Phenylenediamine Sulfate</u> 1,4-Benzenediamine, 2-(methoxymethyl) and 1,4-Benzenediamine, 2-(methoxymethyl)-, sulfate	Table 2	30 Nov 2016
New entry	Annex III	308 (293)	New restrictions for <u>Hydroxyanthraquinone-aminopropyl Methyl Morpholinium Methosulfate</u> 1-N-Methylmorpholiniumpropylamino-4-hydroxyanthraquinone, methyl sulfate	Table 2	30 Nov 2016
New entry	Annex III	309 (294)	New restrictions for <u>Disperse Red 17</u> Ethanol, 2,2'-[[3-methyl-4-[(E)-(4-nitrophenyl)azo]phenyl]imino]bis-	Table 2	30 Nov 2016
New entry	Annex III	310 (295)	New restrictions for <u>Acid Black 1</u> 4-Amino-5-hydroxy-3-(4-nitrophenylazo)-6-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt	Table 2	30 Nov 2016
New entry	Annex III	311 (296)	New restrictions for <u>Pigment Red 57</u> Disodium 3-hydroxy-4-[(E)-(4-methyl-2-sulfonatophenyl)diazenyl]-2-naphthoate	Table 2	30 Nov 2016

Summary of changes to cosmetic ingredient lists at 25th ACSB Meeting (Nov 2016)

Type of change	Annex of the ACD	Entry No. /Ref. No.	Description of changes	Reference table	Implementation period
New entry	Annex II	1380	To include ketoconazole in Annex II	Table 1	No grace period
Amendment	Annex III	15a	To add footnote (19)	Table 2	-
New entry	Annex III	15d	To introduce a new entry for potassium hydroxide as a callus softener into Annex III with maximum concentration of 1.5% and warning label.	Table 2	30 Nov 2017
Amendment	Annex VII	A29	To restrict usage of "Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation." into the current entry for Zinc Oxide.	Table 3	30 Nov 2017
New entry	Annex VII	A29a	To introduce a new UV filter of Zinc oxide (nano) with the material specification and to restrict usage to applications that avoid end-user's lung exposure by inhalation.	Table 3	30 Nov 2017
Amendment	Annex VII	27	To add footnote "For use as a colorant, see Annex IV, No 143."	Table 3	-
New entry	Annex VII	27a	To introduce a new entry into Annex VII for Titanium Dioxide (nano) with a detailed specification of materials and to restrict usage to applications that avoid end-user's lung exposure by inhalation. Footnotes for Ref. 27 & 27a are same.	Table 3	30 Nov 2017
Amendment	Annex IV	77266	To introduce a detailed specification into the current entry defining the required purity of Carbon Black.	Table 4	30 Nov 2017
New entry	Annex IV	77266 (nano)	To introduce a new entry for Carbon Black (nano) into Annex IV with maximum concentration of 10% and purity specification, particle size specification and a restriction to application that avoids end-user's lung exposure by inhalation.	Table 4	30 Nov 2017
Amendment	Annex VI	57	To modify the entry for Methylisothiazolinone (MIT) in Annex VI to restrict MIT for use in rinse-off products only.	Table 5	30 Nov 2017
Amendment	Annex VI	58	To modify the entry for ethyl lauroyl arginate in Annex VI to allow usage in mouthwash preparations at a maximum level of 0.15% and warning label "Not to be used for children under 10 years of age".	Table 5	No grace period

Table 1: Changes to List of Prohibited Ingredients (Annex II)

Substance	CAS Number	Ref. No
3-Benzylidene Camphor (3-Benzylidene Camphor)	15087-24-8	1379
Category 1 material and Category 2 material as defined in the ASEAN definition of animal products. (see Appendix 1)	-	419
Ketoconazole (INCI: ketoconazole)	65277-42-1	1380

APPENDIX 1

ASEAN definition of animal products category 1, 2 and 3

Ref Annex II # 419

Definitions

1. 'Animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;

2. 'Derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;

Category 1 material

Category 1 material shall comprise the following animal by-products:

(a) Entire bodies and all body parts, including hides and skins, of the following animals:

- (i) Animals suspected of being infected by a Transmissible Spongiform Encephalopathy (TSE) or in which the presence of a TSE has been officially confirmed;
- (ii) Animals killed in the context of TSE eradication measures;
- (iii) Animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;
- (iv) Animals used for experiments;
- (v) Wild animals, when suspected of being infected with diseases communicable to humans or animals;

(b) The following material:

(i) Specified risk material; Annex II Part 1 – List of substances which must not form part of the composition of cosmetic products

Version No.: 2016-06 17th November 2016 ASEAN Cosmetic Documents 65 (ii) Entire bodies or parts of dead animals containing specified risk material at the time of disposal;

(c) Animal by-products derived from animals which have been submitted to illegal treatment;

(d) Animal by-products containing residues of other substances and environmental contaminants, if such residues exceed the permitted level laid down by national legislation;

(e) Animal by-products collected during the treatment of waste water:

- (i) From establishments or plants processing Category 1 material; or
- (ii) From other establishments or plants where specified risk material is being removed;

(f) Catering waste from means of transport operating internationally;

(g) Mixtures of Category 1 material with either Category 2 material or Category 3 material or both.

Category 2 material

Category 2 material shall comprise the following animal by-products:

(a) Manure, non-mineralized guano and digestive tract content;

(b) Animal by-products collected during the treatment of waste water:

- (i) From establishments or plants processing Category 2 material; or
- (ii) From slaughterhouses other than those specifically approved;
- (c) Animal by-products containing residues of authorized substances or contaminants exceeding the permitted levels laid down by National legislation;
- (d) Products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;
- (e) Animals and parts of animals:

- (i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;
- (ii) Fetuses;
- (iii) Oocytes, embryos and semen; and
- (iv) Dead-in-shell poultry;



- (f) Mixtures of Category 2 material with Category 3 material;
- (g) Animal by-products other than Category 1 material or Category 3 material;


Category 3 material


Category 3 material shall comprise animal by-products other than those described in Category 1 or Category 2, including:


- (a) Bristles;
- (b) Feathers;
- (c) Ruminants which have been tested for TSE, with a negative result;
- (d) Blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals;
- (e) Aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals;
- (f) Animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;
- (g) The following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:
 - (i) Shells from shellfish with soft tissue or flesh;
 - (ii) The following originating from terrestrial animals:
 - Hatchery by-products,
 - Eggs,
 - Egg by-products, including egg shells,
- (h) Aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;

Table 2: Changes to List of Restricted Ingredients (Annex III)

Ref No ACD # (EU #)	Substance	Restrictions			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorized concentration in ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
303 (288)	3-[(4-amino-3-methyl-9,10-dioxo-9,10-dihydroanthracen-1-yl)amino]-N,N,N-trimethylpropan-1-aminium, methylsulfate salt HC Blue No 17 CAS No 16517-75-2	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers For (a) and (b) Indonesia : Not Accepted	(a) To be printed on the label: The mixing ratio.  Hair colorants 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: <ul style="list-style-type: none">— 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.
304 (289)	Phosphoric acid compound with 4-[(2,6-dichlorophenyl) (4-imino-3,5-dimethyl-2,5-cyclohexadien-1-ylidene) methyl]-2,6-dimethylaniline (1:1) HC Blue No 15 CAS No 74578-10-2	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance	(b) 0.2 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.2 %	(a) To be printed on the label: The mixing ratio.  Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16.

Ref No ACD # (EU #)	Substance	Restrictions			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorized concentration in ready for use preparation	Other limitations and requirements	
		in non-oxidative hair dye products		For (a) and (b) Indonesia : Not Accepted	Temporary "black henna" tattoos may increase your risk of allergy. Do not colour your hair if: <ul style="list-style-type: none"> — 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.
305 (290)	Disodium 2,2'-(9,10-dioxoanthracene-1,4-diylidimino)bis(5-methylsulphonate) Acid Green 25 CAS No 4403-90-1	Hair dye substance in non-oxidative hair dye products	0.3 %		
306 (291)	Sodium, 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate Acid Violet 43 CAS No 4430-18-6	Hair dye substance in non-oxidative hair dye products	0.5 %	Indonesia : Not Accepted	
307 (292)	1,4-Benzenediamine, 2-(methoxymethyl) 1,4-Benzenediamine, 2-(methoxymethyl)-, sulfate	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.8 % (calculated as free base)	To be printed on the label: The mixing ratio.  Hair colorants can cause severe allergic reactions. Read and follow instructions.

Ref No ACD # (EU #)	Substance	Restrictions			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorized concentration in ready for use preparation	Other limitations and requirements	
	2-Methoxymethyl-p-Phenylenediamine 2-Methoxymethyl-p-Phenylenediamine Sulfate CAS No 337906-36-2; 337906-37-3			<u>Indonesia</u> : Not Accepted	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: <ul style="list-style-type: none"> — 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.
308 (293)	1-N-Methylmorpholiniumpropylamino-4-hydroxyanthraquinone, methyl sulfate Hydroxyanthraquinone-aminopropyl Methyl Morpholinium Methosulfate CAS No 38866-20-5	Hair dye substance in non-oxidative hair dye products	0.5 %	<ul style="list-style-type: none"> — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers <u>Indonesia</u> : Not Accepted	To be printed on the label:  Hair colorants 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: <ul style="list-style-type: none"> — 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.

Ref No ACD # (EU #)	Substance	Restrictions			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorized concentration in ready for use preparation	Other limitations and requirements	
309 (294)	Ethanol, 2,2'-[[3-methyl-4-[(E)-(4-nitrophenyl)azo]phenyl]imino]bis- Disperse Red 17 CAS No 3179-89-3	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0.2 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers Indonesia : Not Accepted	(a) To be printed on the label: The mixing ratio.  Hair colorants 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.
310 (295)	4-Amino-5-hydroxy-3-(4-nitrophenylazo)-6-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt Acid Black 1 CAS No 1064-48-8	Hair dye substance in non-oxidative hair dye products	0.5 %	Indonesia : Not Accepted	
311 (296)	Disodium 3-hydroxy-4-[(E)-(4-methyl-2-sulfonatophenyl)diazenyl]-2-naphthoate Pigment Red 57	Hair dye substance in non-oxidative hair dye products	0.4 %		

Ref No ACD # (EU #)	Substance	Restrictions			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorized concentration in ready for use preparation	Other limitations and requirements	
	CAS No 5858-81-1				
15a	Potassium or sodium hydroxide ⁽¹⁹⁾ Potassium hydroxide/sodium hydroxide CAS No 1310-58-3; 1310-73-2	(a) Nail cuticle solvent (b) Hair straightener 1. General use 2. Professional use (c) pH adjuster – for depilatories (d) Other uses as pH adjuster	(a) 5% by weight ⁽⁴⁾ (b) 1. 2% by weight ⁽⁴⁾ 2. 4.5% by weight ⁽⁴⁾ (c) up to pH 12.7 (d) up to pH 11		(a) <ul style="list-style-type: none"> • Contains alkali • Avoid contact with eyes • Can cause blindness • Keep out of reach of children (b) 1. <ul style="list-style-type: none"> • Contains alkali • Avoid contact with eyes • Can cause blindness • Keep out of reach of children 2. <ul style="list-style-type: none"> • For professional use only • Avoid contact with eyes • Can cause blindness (c) <ul style="list-style-type: none"> • Keep out of reach of children • Avoid contact with eyes
15d	Potassium Hydroxide ⁽²⁰⁾ Potassium hydroxide CAS No 1310-58-3	Callosity softener/remover	1.5 % ⁽⁴⁾		<ul style="list-style-type: none"> • Contains alkali • Avoid contact with eyes • Keep out of reach of children • Read directions for use carefully

(4) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column D.

(19) For other uses of Potassium Hydroxide, see Annex III, No. 15d

(20) For other uses of Potassium Hydroxide, see Annex III, No. 15a

Table 3: Changes to List of UV filters which cosmetic products may contain (Annex VII)

Reference number	Substance	Maximum authorised concentration		Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c		d	e
A29	Zinc oxide	25 % ⁽²⁾		Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	
A29a	Zinc Oxide (nano)	25 % ⁽²⁾		<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 ≥ 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, imethoxydiphenylsilanetriethoxycaprylylsilane cross- polymer, or octyl triethoxy silane. 	
27	Titanium dioxide ⁽³⁾	25% ⁽⁴⁾			
27a	Titanium Dioxide (nano)	25 % ⁽⁴⁾		<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 ≥ 99 %, — rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, 	

				<ul style="list-style-type: none"> — median particle size based on number size distribution \geq 30 nm, — aspect ratio from 1 to 4,5, and volume specific surface area \leq 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. 	
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2. In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column c.

3. For use as a colorant, see Annex IV, CI77891.

4. In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed the limit given in column c.

Table 4: Changes to List of Colouring Agents Allowed for Use in Cosmetic Products (Annex IV)

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
77266	Black	X				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.
77266 (nano)	Black	X				<p>10% max. concentration in the finished products.</p> <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 > 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. • Primary particle size ≥ 20 nm

Table 5: Changes to List of Preservatives Allowed (Annex VI)

Reference number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
57	2-Methyl-2H-isothiazol-3-one (INCI) Methylisothiazolinone ⁽¹⁴⁾ CAS No.2682-20-4	0.01% (In Indonesia the maximum authorized concentration is 0.0015%)	Rinse-off products only	
58	Ethyl Lauroyl Arginate HCl (INCI) (+) ⁽⁶⁾ Ethyl-N α - dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2	(a) moutwashes 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 and spray products.	(a) Not to be used for children under 10 years of age