



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



14 April 2015

FDA CIRCULAR
NO. 2015-008

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD)

In the interest of service, and for the information of all, the Food and Drug Administration (FDA) hereby provides the Reports of the 21st ASEAN Cosmetic Committee (ACC), 20th and 21st ASEAN Cosmetic Scientific Body (ACSB), and 4th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings as attachments. Noting the importance of the grace periods in the industry activities, including reformulation, development, initiation of product phase-outs, among others, the FDA has consulted representatives of the different cosmetic industries via the regular regulatory update meetings. As a result, adjusted grace periods as presented below are hereby adopted:

Amendments	Agreed Grace Period
Annex II	
1374-1378	Existing products can be in the market until December 31st 2015
Annex III	
1a	Immediate effect
286	Until July 1st 2015 or earlier for products to be placed in the market and December 1st 2015 for existing products in the market.
287	
Annex IV	
CI 77510	Immediate effect
Annex VI	
12 and 12a	Local grace period/timeline will be moved to “until end of to March 2016, and for existing products in the market will be end of September 2016”
25	End of December 2015 but subject to review at the next ACSB meeting
39	Local grace period/timeline will be moved to “until Oct 1st 2015 or earlier, for products to be placed in the market and July 2016 for existing products in the market”
57	
59	Immediate effect
Annex VII	
29	Immediate effect



The FDA hereby reiterates that companies, as well as individuals who are responsible for placing cosmetic products in the market are responsible for continually checking updates and amendments to the ACD. You are also hereby directed to take note of the abovementioned grace periods.

Furthermore, previous reports of the following meetings are hereby republished in the FDA website for everyone's perusal:

ACC – 18th to 20th meetings

ACSB – 17th to 19th meetings

ACTLC – 3rd meeting

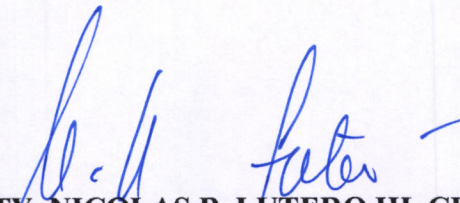
For updates and amendments, please visit the following websites:

www.fda.gov.ph

aseancosmetics.org

www.asean.org

This order shall take effect immediately.



ATTY. NICOLAS B. LUTERO III, CESO III
OIC-Director IV, Food and Drug Administration

Highlights of the Meeting

A. 21st ACSB (Manila, Philippines)

1. Amendments to the ASEAN Cosmetic Ingredient Annexes

The summary of the amendments to the ASEAN Cosmetic Ingredient Annexes are presented below:

a. Amendments to Annex II

Substances	CAS Number	Ref. No
Isopropyl 4-hydroxybenzoate (INCI: Isopropylparaben) Sodium salt or Salts of Isopropylparaben	4191-73-5	1374
Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben)	4247-02-3	1375
Sodium salt or Salts of Isobutylparaben	84930-15-4	
Phenyl 4-hydroxybenzoate (INCI: Phenylparaben)	17696-62-7	1376
Benzyl 4-hydroxybenzoate (INCI: Benzylparaben)	94-18-8	1377
Pentyl 4-hydroxybenzoate (INCI: Pentylparaben)	6521-29-5	1378

b. Amendments to Annex III

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
1a	Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex II	(a) Talc	(a) 5% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin
		(b) Products for oral hygiene	(b) 0.1% (by mass/mass as boric acid) (c) 3% (by mass/mass as boric acid)	(b) Not to be used in products for children under 3 years of age	(b) 1. Not to be swallowed 2. Not to be used in products for children under 3 years of age
		(c) Other products (excluding bath products and hair waving products)		(c) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin	(c) 1. Not to be used in products for children under 3 years of age 2. Not to be used on peeling or irritated skin

				<p>if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p> <p>As a preservative, see Annexe VI, Part 1, No 58</p>	
286*	<p>C₁₆-alkyltrimethylammonium chloride</p> <p>C₁₈-alkyltrimethylammonium chloride</p>	<p>(a) Rinse-off hair products</p> <p>(b) Leave-on hair products</p> <p>(c) Face products</p>	<p>(a) 2.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>(b) 1.0 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>(c) 0.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p>	<p>For purposes other than inhibiting the development of micro-organisms in the product. The purpose has to be apparent from the presentation of the product.</p> <p>As a preservative, see Annex VI Part 1 Ref. No. 44</p>	
287*	C ₂₂ -alkyltrimethylammonium chloride	<p>(a) Rinse-off hair products</p> <p>(b) Leave-on hair products</p> <p>(c) Face products</p>	<p>(a) 5.0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 286.</p> <p>(b) 3.0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 286.</p> <p>(c) 3.0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steartrimonium chloride set out in entry 286.</p>	<p>For purposes other than inhibiting the development of micro-organisms in the product. The purpose has to be apparent from the presentation of the product.</p> <p>As a preservative, see Annex VI Part 1 Ref. No. 44</p>	

*Post-meeting Update from the Secretary of ACSB: Reference Numbers 286 and 287 have yet to be incorporated in the Updated Ingredient Annex III, due to discrepancies found in the reference numbers used versus available reference numbers in Annex III.

The FDA noting the importance of such information being disseminated to stakeholders hereby includes the abovementioned restriction in this update. Please take note that Reference Numbers 286 and 287 may be presented differently when an updated Ingredient Annex III has been released.

c. Amendment to Annex IV

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
77510	Blue	X				Free from cyanide ion

d. Amendments to Annex VI

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
12	4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters, and their salts (INCI) 4-Hydroxybenzoic acid; CAS No. 99-96-7; Methylparaben; CAS No. 99-76-3; potassium ethylparaben; CAS No. 36457-19-9; potassium paraben; CAS No. 16782-08-4 sodium methylparaben; CAS No. 5026-62-0; sodium ethylparaben; CAS No. 35285-68-8; ethylparaben; CAS No. 120-47-8; sodium paraben; CAS No. 114-63-6; potassium methylparaben; CAS No. 26112-07-2; calcium paraben; CAS No. 69959-44-0;	0.4% (as acid) for single ester 0.8% (as acid) for mixtures of esters	Each of the ester in mixture cannot exceed 0.4% (acid)	
12a	Butyl 4-hydroxybenzoate and its salts Propyl 4-hydroxybenzoate and its salts Butylparaben; CAS No. 94-26-8; Propylparaben; CAS No. 94-13-3 sodium propylparaben; CAS No. 35285-69-9 sodium butylparaben; CAS No. 36457-20-2; potassium butylparaben; CAS No. 38566-94-8; potassium propylparaben; CAS No. 84930-16-5;	0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %	Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	For leave-on products designed for children under three years of age: "Do not use on the nappy area"
25	5-Chloro-2- (2,4-dichlorophenoxy) phenol (INCI) Triclosan (INN) (+) CAS No. 3380-34-5	(a) 0.3 % (b) 0.2 %	(a) Toothpastes Hand soaps Body soaps/Shower gels Deodorants (non-spray) Face powders and blemish concealers Nail products for cleaning the fingernails and toenails before the application of artificial nail systems (b) Mouthwashes	

39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one (INCI) Methylchloroisothiazolinone (and) Methylisothiazolinone ⁽⁹⁾ CAS No. 26172-55-4, 2682-20-4, 55965-84-9	0.0015 % (of a mixture in the ratio 3:1 of 5-chloro- 2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one)'	Rinse-off products	
57	2-Methyl-2H-isothiazol- 3-one (INCI) Methylisothiazolinone ⁽¹⁴⁾ CAS No.2682-20-4	0.01 %'		
59	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-,silver(1+) salt, monohydrate (INCI) Citric acid (and) Silver citrate	0.2 %, corresponding to 0.0024 % of silver	Not to be used in oral products and eye products"	

(9) Methylisothiazolinone is also regulated in entry 57. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product

(14) Methylisothiazolinone is also regulated in entry 39 in a mixture with Methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product

e. Amendment to Annex VII

Reference Number	Substance	Maximum authorized concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
29	1,3,5-Triazine, 2,4,6-tris [1,1'-biphenyl]-4-yl-, including as nanomaterial. [INCI Name : Tris-biphenyl triazine Tris-biphenyl triazine (nano)] CAS No. 31274-51-8	10%	Not to be used in sprays. Only nanomaterials having the following characteristics are allowed: — median primary particle size > 80 nm; — Purity ≥ 98 %; — Uncoated'	

2. Inclusion of the Strongly Recommended warning in the ASEAN Sunscreen Labeling Guideline

Strongly recommended warning:

Re-apply frequently to maintain protection, especially after sweating, swimming or toweling;

The use of sunscreens is one way to reduce the dangers from sun exposure;
Instruction for use to ensure that sufficient quantity is applied, e.g. pictogram, illustration, etc;

Over-exposure to the sun is a serious health threat;

3. Adoption of the final revision of Pilot risk assessment of botanical ingredients

The document is uploaded in the FDA website (www.fda.gov.ph) under ASEAN Cosmetic Harmonization.