



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA CIRCULAR**  
No. **2015-014**

14 DEC 2015

**TO: ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

**SUBJECT: Reiteration of Grace Periods Given to the Cosmetic Industry for Products Containing Ingredients Outside Restrictions as Adopted in the ASEAN Cosmetic Committee Meetings and its Related Events**

In line with the Food and Drug Administration's (FDA's) mandate to protect the public health, the Center for Cosmetics Regulation and Research hereby reiterates the end of the grace periods given to the cosmetic industry as cited in FDA Circulars 2015-008 and 2015-009 for the following restricted and banned ingredients:

Amendments	Substance	Restrictions / Limits	Grace Period / Deadline
<b>Annex II Part 1 – List of Substances Which Must Not Form Part of the Composition of Cosmetic Products</b>			
1374	Isopropyl 4-hydroxybenzoate (INCI: Isopropylparaben) Sodium salt or Salts of Isopropylparaben	N/A	31 December 2015
1375	Isobutyl 4-hydroxybenzoate (INCI: Isobutylparaben) Sodium salt or Salts of Isobutylparaben	N/A	
1376	Phenyl 4-hydroxybenzoate (INCI: Phenylparaben)	N/A	
1377	Benzyl 4-hydroxybenzoate (INCI: Benzylparaben)	N/A	
1378	Pentyl 4-hydroxybenzoate (INCI: Pentylparaben)	N/A	
<b>Annex III Part 1 - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down</b>			
286*	C <sub>16</sub> -alkyltrimethylammonium chloride  C <sub>18</sub> -alkyltrimethylammonium chloride	(a) Rinse-off hair products - 2.5% for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride  (b) Leave-on hair products - 1.0% for the individual concentrations	01 December 2015



		<p>or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>(c) Face products - 0.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>As a preservative, see Annex VI Part 1 Ref. No. 44</p>	
287*	C <sub>22</sub> -alkyltrimethylammonium chloride	<p>(a) Rinse-off hair products - 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) Leave-on hair products - 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) Face products - 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>As a preservative, see Annex VI Part 1 Ref. No. 44</p>	01 December 2015

<b>Annex VI - List of Preservatives Allowed For Use in Cosmetic Products</b>			
25	5-Chloro-2- (2,4-dichlorophenoxy) phenol (INCI) Triclosan (INN) (+) CAS No. 3380-34-5	0.3 % for 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  0..2% for mouthwashes	31 December 2015

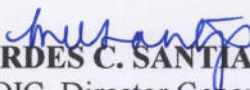
\*Post-meeting Update from the Secretary of ACSB: Reference Numbers 286 and 287 have yet to be incorporated in the Updated Ingredient Annex III, due to discrepancies found in the reference numbers used versus available reference numbers in Annex III. Please take note that Reference Numbers 286 and 287 may be presented differently when an updated Ingredient Annex III has been released.

Cosmetic companies are advised to recall their products containing the abovementioned ingredients outside the new restrictions and conditions laid down in the ASEAN Cosmetic Ingredient Annexes by the end of the grace period.

Furthermore, the FDA inspectorate is hereby instructed to collect samples of cosmetic products known to contain these ingredients from the market for laboratory analysis to verify the compliance of the cosmetic industry. Thus, all cosmetic company/ies or person/s responsible for placing cosmetic products in the market which are found to be out of specifications shall be subject to appropriate legal actions.

Moreover, company/ies or person/s responsible for placing cosmetic product/s in the market are advised to continually check for updates and amendments to the ASEAN Cosmetic Directive, its annexes and appendices and to appropriately note the cited grace periods, for proper guidance in the FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)).

For your information and strict compliance.

  
**MARIA LOURDES C. SANTIAGO, MSc, MM**  
 OIC, Director General



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 21<sup>st</sup> ASEAN Cosmetic Committee (ACC), 20<sup>th</sup> and 21<sup>st</sup> ASEAN Cosmetic Scientific Body (ACSB), and 4<sup>th</sup> 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:

<b>Amendments</b>	<b>Agreed Grace Period</b>
<b>Annex II</b>	
1374-1378	Existing products can be in the market until December 31st 2015
<b>Annex III</b>	
1a	Immediate effect
286	Until July 1st 2015 or earlier for products to be placed in the market and
287	December 1st 2015 for existing products in the market.
<b>Annex IV</b>	
CI 77510	Immediate effect
<b>Annex VI</b>	
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
57	earlier, for products to be placed in the market and July 2016 for existing products in the market"
59	Immediate effect
<b>Annex VII</b>	
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 – 18<sup>th</sup> to 20<sup>th</sup> meetings

ACSB – 17<sup>th</sup> to 19<sup>th</sup> meetings

ACTLC – 3<sup>rd</sup> meeting

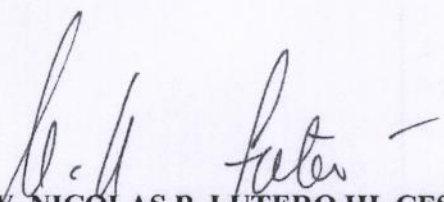
For updates and amendments, please visit the following websites:

[www.fda.gov.ph](http://www.fda.gov.ph)

[aseancosmetics.org](http://aseancosmetics.org)

[www.asean.org](http://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. 21<sup>st</sup> 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  (b) Products for oral hygiene  (c) Other products (excluding bath products and hair waving products)	(a) 5% (by mass/mass as boric acid)  (b) 0.1% (by mass/mass as boric acid)  (c) 3% (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)  (b) Not to be used in products for children under 3 years of age  (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	(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) 1. Not to be swallowed 2. Not to be used in products for children under 3 years of age  (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>C<sub>16</sub>-alkyltrimethylammonium chloride</p> <p>C<sub>18</sub>-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 <sub>22</sub> -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) pheno! (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-methylisothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one (INCI)  Methylchloroisothiazolinone (and) Methylisothiazolinone <sup>(9)</sup> 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 <sup>(14)</sup> 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](http://www.fda.gov.ph)) under ASEAN Cosmetic Harmonization.



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



09 June 2015

**FDA CIRCULAR**  
No. 2015-009

**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 22<sup>nd</sup> ASEAN Cosmetic Committee (ACC), 22<sup>nd</sup> ASEAN Cosmetic Scientific Body (ACSB), and 5<sup>th</sup> ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings as attachments. The agreed grace period of the updates and amendments of the ACD is presented in the table below:

<b>Amendments</b>	<b>Agreed Grace Period</b>
Limitations and Restrictions of Triclosan	The following grace period will apply to withdraw from the market non-compliant products: For Annex VI – until 31st December 2015 For Annex III – until 31st December 2016 or earlier
Revision of the 'field of application and/or use' and its corresponding 'maximum authorized concentration in finished products' for hydrogen peroxide (Annex III, Part 1, ref #12) in tooth-whitening products	The Meeting agreed that 12 months after adoption (June 2016), only cosmetic products which comply with these labeling requirement shall be placed in the ASEAN market.
Mouthwash labeling requirements for children under 6 years old and Mouthwash containing fluoride and alcohol	The Meeting agreed to the 12 months grace period (June 2016) for the implementation of the labeling requirement in mouthwash containing fluoride or alcohol

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.

For updates and amendments, please visit the following websites:

[www.fda.gov.ph](http://www.fda.gov.ph)  
[aseancosmetics.org](http://aseancosmetics.org)  
[www.asean.org](http://www.asean.org)

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines  
Trunk Line +63 2 857 1900 Fax +63 2 807 0751  
Website: [www.fda.gov.ph](http://www.fda.gov.ph) Email: [info@fda.gov.ph](mailto:info@fda.gov.ph)

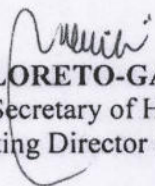


ISO 9001:2008  
Management System



www.tuv.com  
ID: 9496073206

This order shall take effect immediately.

  
JANETTE P. LORETO-GARIN, MD, MBA-H  
Secretary of Health  
Acting Director General<sup>1</sup>

DTN: 20150609152053  
<sup>1</sup> Pursuant to DPO 2015-1845

**ANNEX A**  
**HIGHLIGHTS OF THE MEETING**

**A. 22<sup>nd</sup> ACSB (Singapore)**

**1. Amendments to the ASEAN Cosmetic Ingredient Annexes**

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

- a. Limitations and Restrictions of Triclosan
  - i. The Meeting agreed with ACA recommendation to include 3 additional products (shampoo, hair conditioner and facial cleanser) under column f (part (a) of Annex VI Part 1 Ref. No. 25.
  - ii. The Meeting also agreed to remove (+) sign from Annex VI and to include Triclosan under Annex III with the same restrictions.
  - iii. Grace period  
The following grace period will apply to withdraw from the market non-compliant products:
    1. Annex VI as referred in the minutes of 21st ACSB Meeting in November 2014 ie. 31st December 2015
    2. Annex III until 31st December 2016 or earlier
- b. Revision of the 'field of application and/or use' and its corresponding 'maximum authorized concentration in finished products' for hydrogen peroxide (Annex III, Part 1, ref #12) in tooth-whitening products
  - i. The Meeting agreed to add warning "Not to be used under the age of 18" and for the percentage of Hydrogen peroxide to be declared on the label.
  - ii. Grace Period  
The Meeting agreed that 12 months after adoption (June 2016), only cosmetic products which comply with these labeling requirement shall be placed in the ASEAN market.
- c. Development of ASEAN references on non-cosmetic regulation list for the entries ref# 21, 293, 323 and 419  
The Meeting agreed with Malaysia proposal to replace for entries references as in ref # 21, 293,323 with generic statement as follows:
  - i. # 21: Sympathomimetic amines acting on the central nervous system as defined in ASEAN Member States (AMS) local law(s) or regulation(s).
  - ii. # 293: Radioactive substances, as defined in ASEAN Member States (AMS) local law(s) or regulation(s).
  - iii. # 323: Vaccines, toxins or serums as defined in ASEAN Member States (AMS) local law(s) or regulation(s).
- d. Mouthwash labeling requirements for children under 6 years old and Mouthwash containing fluoride and alcohol

- i. The Meeting agreed that Mouthwashes containing fluoride or alcohol should include a warning statement "Do not use in children below 6 years of age".
- ii. Grace period  
The Meeting agreed to the 12 months grace period (June 2016) for the implementation of the labeling requirement in mouthwash containing fluoride or alcohol.

**2. Guidance Format of the Safety Assessment Report**

The Meeting agreed to accept the Safety Assessment Report documents as a reference to be used by cosmetic safety assessors. The guidance format is uploaded at the FDA website under ASEAN Cosmetic Harmonization.

**3. Revision of the ASEAN Sunscreen Labeling Guideline**

The Meeting agreed to accept the revision of the ASEAN Sunscreen Labeling Guideline as a reference document. The guideline is uploaded at the FDA website under ASEAN Cosmetic Harmonization.

**4. Trace Limit of Cadmium**

The Meeting agreed to set a limit of 5 ppm maximum for Cadmium as trace element, recognizing 3 ppm for Thailand.

**B. 5<sup>th</sup> ACTLC (Singapore)**

**Updated List of Cosmetic Accredited Laboratories**

The Meeting noted that ACTLC has to date a total of 65 accredited laboratories which are as follows:

- Indonesia (32)
- Thailand (24)
- Philippines (5)
- Singapore (4)

The lists have been uploaded at ASEAN Secretariat Webpage at <http://www.asean.org/communities/asean-economic-community/category/other-documents-14>.