



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
Annex II Part 1 – List of Substances Which Must Not Form Part of the Composition of Cosmetic Products			
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	
Annex III Part 1 - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down			
286*	C ₁₆ -alkyltrimethylammonium chloride C ₁₈ -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 ₂₂ -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

Annex VI - List of Preservatives Allowed For Use in Cosmetic Products			
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

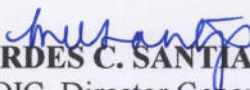
*Post-meeting Update from the Secretary of ACSB: Reference Numbers 286 and 287 have yet to be incorporated in the Updated Ingredient Annex III, due to discrepancies found in the reference numbers used versus available reference numbers in Annex III. Please take note that Reference Numbers 286 and 287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

For your information and strict compliance.


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



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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
287	December 1st 2015 for existing products in the market.
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
57	earlier, for products to be placed in the market and July 2016 for existing products in the market"
59	Immediate effect
Annex VII	
29	Immediate effect

