



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



01 JUN 2016

FDA CIRCULAR
No. 2016-005

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

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive as Adopted During the 23rd ASEAN Cosmetic Committee Meeting and Its Related Events

I. BACKGROUND

In 2005, the Department of Health (DOH) – Food and Drug Administration (FDA), then called Bureau of Food and Drugs (BFAD), has adopted and implemented the ASEAN Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents including the ASEAN Cosmetic Directive (ACD) by issuing Administrative Orders No. 2005-0015 and 2005-0025 respectively for the purpose of eliminating trade barriers and enhancing cooperation within the ASEAN Member States in ensuring the safety, quality and claimed benefits of cosmetic products.

In line with the ASEAN Cosmetic Harmonization, the ASEAN Cosmetic Committee (ACC) has been established to ensure that the ACD would be implemented effectively. It is composed of representatives from each member state's regulatory authority responsible for cosmetics as well as representatives from the ASEAN Cosmetic Industry, namely the ASEAN Cosmetic Association (ACA). The ACC meets semi-annually to coordinate, review and monitor the implementation of the ACD and review and update the technical documents as necessary. Updates and amendments that have been adopted during an ACC meeting shall be formally cascaded and disseminated to the local cosmetic industry through the issuance of a circular.


II. DETAILS


In the interest of better public service, and for the information of all concerned parties, the Food and Drug Administration – Center for Cosmetics Regulation and Research (FDA-CCRR) hereby disseminates the Reports of the 23rd ASEAN Cosmetic Committee (ACC), 23rd ASEAN Cosmetic Scientific Body (ACSB) and 6th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings.

Further, noting the importance of having ample time for the cosmetic industry to formulate, reformulate, initiate appropriate product phase outs, among others, the FDA-CCRR has consulted with representatives from different cosmetic industries via regular regulatory update meetings. Below are the adjusted grace periods for the ingredients adopted during the 23rd ACC Meeting and its related events:

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			
1379 ¹	3-Benzylidene camphor (3-Benzylidene Camphor)	N/A	31 May 2017

¹3-Benzylidene camphor (3-Benzylidene Camphor) is previously included in ACD Annex VII- List of UV Filters Which Cosmetic Products May Contain. With its inclusion in ACD Annex II, it shall be deleted from Annex VII.

Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the labels	Grace Period / Deadline
Annex III Part 1 - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down²					
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: 50µg/kg -Keep in nitrite-free containers	(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	31 May 2017

				<p>rash on your face or sensitive, irritated and damaged scalp,</p> <p>-you have ever experienced any reaction after colouring your hair,</p> <p>-you have experienced a reaction to a temporary "black henna" tattoo in the past."</p>	
<p>Phosphoric acid compound with 4-[(2,6-dichlorophenyl)(4-imino-3,5-dimethyl-2,5-cyclohexadien-1-ylidene)methyl]-2,6-dimethylaniline (1:1)</p> <p>HC Blue No 15</p> <p>CAS No. 74578-10-2</p>	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Hair dye substance in non-oxidative hair dye products</p>	(b) 0.2%	<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.2%</p>	<p>(a) To be printed on the label: The mixing ratio.</p> <p>“  Hair colorants can cause severe allergic reactions.</p> <p>Read and follow instructions.</p> <p>This product is not intended for use on persons under the age of 16.</p> <p>Temporary "black henna" tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <p>-you have a rash on your face or sensitive, irritated and</p>	31 May 2017