



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

				<p>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>Disodium 2,2'-(9,10-dioxoanthracene-1,4-diyl-diimino) bis (5-Methylsulphonate)</p> <p>Acid Green 25</p> <p>CAS No. 4403-90-1</p>	Hair dye substance in non-oxidative hair dye products	0.3%			31 May 2017
<p>Sodium, 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino] toluene-3-sulphonate</p> <p>Acid Violet 43</p> <p>CAS No. 4430-18-6</p>	Hair dye substance in non-oxidative hair dye products	0.5%			31 May 2017
<p>1,4-Benzene-diamine, 2-(methoxymethyl)</p> <p>1,4-Benzene-diamine, 2-(methoxymethyl)-, sulfate</p> <p>2-Methoxy-methyl-Phenylene-diamine p-</p>	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)	<p>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>	31 May 2017

<p>2-Methoxy-methyl- p-Phenylenediamine Sulfate</p> <p>CAS No. 337906-36-2</p> <p>CAS No. 337906-37-3</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> <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." 	
<p>1-N-Methyl-morpholinium-propylamino-4-hydroxy-anthraquinone, methyl sulfate</p> <p>Hydroxyanthraquinone-aminopropyl Methyl Morpholinium Methosulfate</p> <p>CAS No. 38866-20-5</p>	<p>Hair dye substance in non-oxidative hair dye products</p>	<p>0.5%</p>	<p>-Do not use with nitrosating agents</p> <p>-Maximum nitrosamine content: 50µg/kg</p> <p>-Keep in nitrite-free containers</p>	<p>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</p>	<p>31 May 2017</p>

				<p>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> <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.” 	
<p>Ethanol, 2,2'-[[3-methyl-4-[(E)-(4-nitrophenyl)azo] phenyl]imino] bis-</p> <p>Disperse Red 17</p> <p>CAS No. 3179-89-3</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 2.0%</p> <p>For (a) and (b):</p> <ul style="list-style-type: none"> -Do not use with nitrosating agents -Maximum nitrosamine content: 50µg/kg -Keep in nitrite-free containers 	<p>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</p>	31 May 2017

				<p>increase your risk of allergy.</p> <p>Do not colour your hair if:</p> <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." 	
<p>4-Amino-5-hydroxy-3-(4-nitrophenylazo)-6-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt</p> <p>Acid Black 1</p> <p>CAS No. 1064-48-8</p>	<p>Hair dye substance in non-oxidative hair dye products</p>	0.5%			31 May 2017
<p>Disodium 3-hydroxy-4-[(E)-(4-methyl-2-sulfonatophenyl) diazenyl]-2-naphthoate</p> <p>Pigment Red 57</p> <p>CAS No. 5858-81-1</p>	<p>Hair dye substance in non-oxidative hair dye products</p>	0.4%			31 May 2017

²The nine (9) hair dyes have yet to be incorporated in ACD Annex III. Please take note that the mentioned ingredients may be presented differently when an updated Ingredient Annex III has been released.

FDA-CCRR hereby reiterates that companies, including individuals who are responsible for placing cosmetic products in the market, are primarily responsible in continually checking updates and amendments to the ACD. They are also hereby directed to take note of the previously mentioned grace periods.

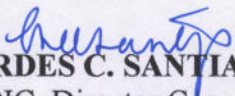
For updates and amendments, please visit the following websites:

www.fda.gov.ph

aseancosmetics.org

www.asean.org

This circular shall take effect after fifteen (15) days following its publication in two (2) newspapers of general circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.


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

ANNEX A
HIGHLIGHTS OF THE MEETING
23rd ASEAN Cosmetic Committee (ACC) Meeting and its Related Events
25-27 November 2015, Bangkok, Thailand

1. The Meeting noted that Cambodia and Lao PDR have adopted the online e-notification system for cosmetic products through EU-ARISE funding and technical assistance and training from the Philippines.

2. Amendments to the ASEAN Cosmetic Ingredient Annexes

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

a. Annex III Part 1 - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down

- i. Inclusion of nine (9) new entries of hair dyes in the ACD Annex III with a grace period of 12 months.

b. Annex II Part 1 – List of Substances Which Must Not Form Part of the Composition of Cosmetic

- i. The Meeting agreed to move 3-Benzylidene camphor (3-Benzylidene Camphor) from Annex VII (list of UV Filter) ref # 19 into Annex II ref # 1379, and to have different implementation grace period:
 - Cambodia, Lao PDR, Malaysia, Myanmar, Singapore until 30th June 2016
 - Indonesia and Philippines 6-12 months
 - Thailand and Vietnam 12 monthsand pending Brunei Darussalam input
- ii. The Meeting agreed with ASEAN Cosmetic Association (ACA) proposal on Annex II ref # 419 to replace the original text with “**Category 1 material and Category 2 material as defined in ASEAN definition of animal products Category 1, 2 and 3**”
- iii. The Meeting also agreed with Singapore’s proposal to include ASEAN definition on animal products Category 1, 2 and 3 as part of Annex II.