



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
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Website: www.bfad.gov.ph



MALAYA AT MALUSOG
NA PAMAYANAN

07 August 2008

BUREAU CIRCULAR
No. 2008- 003

SUBJECT: **Grace Period for the 2nd Updates and Amendments of the ASEAN Cosmetic Directive (ACD)**

In the interest of service, and for the information of all, the Bureau of Food and Drugs (BFAD) hereby provides the Final report of the 9th ASEAN Cosmetic Scientific Body (ACSB) and 10th ASEAN Cosmetic Committee (ACC) Meetings as attachments.

Company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any updates and amendments to the ACD for proper guidance and compliance through the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

You are hereby directed to take note of the cited grace period: as agreed during the 10th ACC Meeting.

This order shall take effect immediately after its posting at the BFAD website.


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director

Progress of the ASEAN Cosmetic Scientific Body (ACSB)

Menthol

The Meeting agreed to the following proposal from ACSB:

- a) There should be no specific restrictions for menthol in oral care or rinse-off products.
- b) The current national regulations in Indonesia and Thailand for leave-on products should remain in place until EU SCC issues an opinion and the EU Cosmetic Directive is modified to reflect this.

Camphor

The Meeting agreed that the current National regulations in Indonesia and Thailand should remain in place until EU SCC issues an opinion and the EU Cosmetic Directive is modified to reflect this.

Fluoride in Children's oral care products

- a. The Meeting agreed to add the following mandatory warning statement to column (f) for all fluoride compounds of oral hygiene products in Annex III, Part 1 entries 26-43 inclusive, 47 and 56 as follows:

'For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labeled as contra-indicated for children (e.g. "for adult use only") the following labeling is obligatory:

"Children of 6 years and younger: Use a pea sized ● amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor."

(Note that the circle is 6mm in diameter)

The Meeting also agreed on the grace period for 24 months.

- b. The Meeting agreed that the implementation of a total fluoride limit of 300 mg per single tube, should be a voluntary agreement, which is based on ISO Standard 11609. ACA will communicate to the National Industries Associations where these exist.

Product classification

Vaginal Douche Products falls outside the scope of the ACD.

Annexe II Part 1

List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
Exudation of <i>Myroxylon pereirae</i> (Royle) Klotzch (Peru Balsam: crude) when used as a fragrance ingredient'	8007-00-9	1136
Diethylene glycol	111-46-6	A1140

The meeting further agreed on grace period of 6 months.

ANNEX III – PART 1

**LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN
EXCEPT SUBJECT TO RESTRICTIONS AND CONDITIONS LAID DOWN**

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	
a	b	c	d	e	F
A6	Glycolic and lactic acid, their common salts and simple esters	<p>Skin products</p> <p>(i) For general use</p> <p>(ii) For professional use</p> <p>(iii) For use by a qualified medical practitioner</p> <p>(b) Other products</p>	<p>(a) Skin products</p> <p>(i) ≤ 10% total when calculated as the acids</p> <p>(ii) 10% - 20% total when calculated as the acids</p> <p>(iii) > 20% total when calculated as the acids</p> <p>(b) Other products None</p>	<p>(a) Skin products</p> <p>(i) Final formulation ≥ pH 3.5</p> <p>(ii) Final formulation ≥ pH 3.0 For professional use only</p> <p>(iii) Final formulation ≥ pH 3.0 for products up to 30% total when calculated as the acids.</p> <p>For use by a qualified medical practitioner only.</p> <p>(b) Other products None</p>	<p>(a) Skin products</p> <p><u>All</u> Sunburn alert: This product contains an alpha hydroxyl acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear sun protective clothing, and limit sun exposure while using this product and for a week afterwards¹³</p> <p>(ii) For professional use only</p> <p>(iii) For use by a qualified medical practitioner only</p> <p>(b) Other products None</p>
A7	Thioacids and their derivatives	products		Not for use around the eye area.	
A8	Dihydroxyacetone	ing products			This product does not contain a sunscreen and does not protect against sunburn

12	<p>Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide</p>	<p>(a) Hair-care preparations</p> <p>(b) Skin-care preparations</p> <p>(c) Nail hardening preparations</p> <p>(d) Oral hygiene products</p> <p>(e) Tooth-whitening products</p> <p>(i) For use by the consumer under the supervision of a qualified dental practitioner.</p> <p>(ii) For application by a qualified dental practitioner only</p>	<p>(a) 12% H2O2 present or released</p> <p>(b) 4% H2O2 present or released</p> <p>(c) 2% H2O2 present or released</p> <p>(d) 0.1% H2O2 present or released</p> <p>(e) Tooth-whitening products</p> <p>(i) 0.1 - 6% H2O2 present or release</p> <p>(ii) 6 - 35 % H2O2 present or released</p>	<p>(e) Tooth-whitening products</p> <p>(i) For supply only through a qualified dental practitioner. Not for direct sale to the general public</p> <p>(ii) Only to be use by a qualified dental practitioner. Not for direct sale to the general public</p>	<p>(a) (b) (c)</p> <ul style="list-style-type: none"> - Contains hydrogen peroxide. - Avoid contact with eyes. - Rinse eyes immediately if product comes into contact with them. <p>(a) Wear suitable gloves.</p> <p>(e) Tooth-whitening products</p> <p>(I) Not for direct sale to the public. For supply only through a qualified dental practitioner. Read & follow the instructions and use the product accordingly. Do not use the product within two weeks prior to, or immediately after dental restoration. Not for use by pregnant women or habitual tobacco and/or alcohol users. Stop using immediately if you experience any tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc. Store out of reach of children.</p> <p>(ii) Not for direct sale to the public. Only to be used by a qualified dental practitioner. Do not use the product within two weeks prior to, or immediately after dental restoration. Not for use on pregnant women or habitual tobacco and/or alcohol users. Stop using immediately in cases of tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc.</p>
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The Meeting agreed on the grace period of 12 months.