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/ies or person/ies 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Ref. No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exudation of Myroxylon pereirae (Royle) Klotzch (Peru Balsam; crude) when used as a fragrance ingredient</td>
<td>8007-00-9</td>
<td>1136</td>
</tr>
<tr>
<td>Diethylene glycol</td>
<td>111-46-6</td>
<td>A1140</td>
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</tbody>
</table>

The meeting further agreed on grace period of 6 months.
<table>
<thead>
<tr>
<th>Ref #</th>
<th>Substance</th>
<th>Restrictions</th>
<th>Conditions of use and warning which must be printed on the label</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Field of application and/or use</td>
<td>Maximum authorised concentration in the finished cosmetic product</td>
</tr>
<tr>
<td>a</td>
<td>Glycolic and lactic acid, their common salts and simple esters</td>
<td>(i) For general use</td>
<td>(a) Skin products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(ii) For professional use</td>
<td>(i) ≤ 10% total when calculated as the acids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(ii) For use by a qualified medical practitioner</td>
<td>(ii) 10% - 20% total when calculated as the acids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Other products</td>
<td>(iii) &gt; 20% total when calculated as the acids</td>
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<tr>
<td>a</td>
<td>Thioacids and their derivatives</td>
<td>Products</td>
<td>Not for use around the eye area.</td>
</tr>
<tr>
<td>a</td>
<td>Dihydroxyacetone</td>
<td>Tanning products</td>
<td>This product does not contain a sunscreen and does not protect against sunburn</td>
</tr>
</tbody>
</table>

10th ACC Meeting
| 12 Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide | (a) Hair-care preparations  
(b) Skin-care preparations  
(c) Nail hardening preparations  
(d) Oral hygiene products  
(e) Tooth-whitening products  
(i) For use by the consumer under the supervision of a qualified dental practitioner.  
(ii) For application by a qualified dental practitioner only | (a) 12% H₂O₂ present or released  
(b) 4% H₂O₂ present or released  
(c) 2% H₂O₂ present or released  
(d) 0.1% H₂O₂ present or released  
(e) Tooth-whitening products  
(i) 0.1 - 6% H₂O₂ present or release  
(ii) 6 - 35% H₂O₂ present or released | (a) (b) (c)  
- Contains hydrogen peroxide.  
- Avoid contact with eyes.  
- Rinse eyes immediately if product comes into contact with them.  
(a) Wear suitable gloves.  
(e) Tooth-whitening products  
(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.  
(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. |  

The Meeting agreed on the grace period of 12 months.