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Tarikh : 27 NOV 2015

SEMUA PEMEGANG NOTIFIKASI KOSMETIK

SEMUA PERSATUAN BERKENAAN

Tuan/Puan,

PEKELILING UNTUK MEMAKLUMKAN STATUS KEMASKINI BAHAN-BAHAN DALAM ANNEXES PADA *GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA*

Saya dengan hormatnya merujuk kepada perkara tersebut di atas.

2. Biro Pengawalan Farmaseutikal Kebangsaan melakukan semakan dan pindaan secara berkala pada kandungan *Guidelines for Control of Cosmetic Products in Malaysia* untuk diselaraskan dengan pindaan yang dibuat pada *ASEAN Cosmetic Directive (ACD)*.
3. Seperti mana yang telah dipersetujui di dalam mesyuarat *ASEAN Cosmetic Committee (ACC)* kali ke-22 yang telah diadakan di Singapura pada 28-29 Mei 2015 lalu, mesyuarat telah bersetuju untuk mengemaskini beberapa bahan di dalam Annexes pada ACD. Keputusan tersebut adalah selaras dengan pindaan yang dinyatakan dalam *Commission Regulation (EU) No.358/2014, No.866/2014, No.1003/2014 dan No.1004/2014* yang melibatkan Annex II, III, VI dan VII.
4. Pindaan pada **Annex II (List of Prohibited Substances)** melibatkan larangan penggunaan **lima (5) parabens sebagai bahan pengawet** iaitu isopropylparaben, isobutylparaben, phenylparaben, benzylparaben dan pentylparaben yang telah di senaraikan di dalam Annex II no. 1374-1378.
5. Terdapat kemaskini pada **Annex III (List of Restricted Substances)** dengan **kemasukan baru bahan-bahan** cetrimonium chloride dan steatrimonium chloride pada no.286 serta behentrimonium chloride pada no. 287 dengan kepekatan serta syarat-syarat yang dibenarkan bagi penggunaan bahan-bahan tersebut di dalam produk kosmetik seperti pada **Lampiran A**.
6. Kemaskini tersebut juga turut melibatkan pindaan pada kepekatan dan syarat-syarat bagi bahan-bahan yang tersenarai pada **Annex VI (List of Preservatives)** no. 12, no.12a, no. 39 dan no. 57 seperti berikut iaitu:

- i. 4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters, and their salts (no.12)
- ii. Butyl 4-hydroxybenzoate and its salts dan Propyl 4-hydroxybenzoate and its salts (no.12a)
- iii. Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one (no.39)
- iv. 2-Methyl-2H-isothiazol-3-one (no.57)

Maklumat lanjut berkenaan pindaan tersebut adalah seperti pada **Lampiran B**.

7. Merujuk kepada para 4, 5 dan 6, produk kosmetik bernetifikasi di pasaran yang mengandungi bahan-bahan tersebut dan tidak mematuhi syarat baru yang ditetapkan hanya dibenarkan dijual **sehingga 30 Jun 2016** dan **notifikasi kosmetik baru tidak lagi dibenarkan mulai 1 Januari 2016**.

8. Pindaan tersebut juga melibatkan kemaskini pada **Annex VI** no. 25 triclosan, di mana bahan tersebut hanya dibenarkan dengan kepekatan tertentu dalam beberapa kategori produk kosmetik sahaja seperti pada **Lampiran C**. **Semua produk kosmetik bernetifikasi yang mengandungi bahan tersebut perlu mematuhi syarat baru yang ditetapkan mulai 1 April 2016**.

9. Selain itu, terdapat juga kemasukan baru pada **Annex VI** no. 59 Citric acid (and) Silver citrate dan **Annex VII (List of UV Filters)** no.29 Tris-biphenyl triazine dan Tris-biphenyl triazine (nano) dengan kepekatan dan syarat-syarat tertentu seperti pada **Lampiran D** dan **tarikh kuatkuasa adalah serta-merta mulai tarikh pekeliling ini dikeluarkan**.

10. Sehubungan itu, semua pemegang notifikasi kosmetik adalah diingatkan untuk membuat perancangan yang teliti bagi mengelakkan sebarang kesulitan yang akan timbul.

11. Adalah menjadi tanggungjawab pihak Pemegang Notifikasi Kosmetik untuk mematuhi kesemua arahan dan peruntukan perundangan di Bawah Peraturan 18A Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 dan *Guidelines for Control of Cosmetic Products in Malaysia*.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

Saya yang menurut perintah,


(TAN ANN LING)

Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia.

- s.k
- i) Pengarah Kanan Perkhidmatan Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
 - ii) Pengarah Penguatkuasa Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
 - iii) Semua Timbalan Pengarah Regulatori
Biro Pengawalan Farmaseutikal Kebangsaan

nsy/za/ssar

LAMPIRAN A

Annex III no. 286 dan no.287

Ref #		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
286	<p>C16-alkyltrimethylammonium chloride</p> <p>Cetrimonium chloride⁽¹⁸⁾</p> <p>CAS No. 112-02-7</p> <p>C18-alkyltrimethylammonium chloride</p> <p>Steartrimonium chloride⁽¹⁸⁾</p> <p>CAS No. 112-03-8</p>	<p>(a) Rinse-off hair products</p> <p>(b) Leave-on hair products</p> <p>(c) Face products</p>	<p>(a) 2.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>(b) 1.0 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p> <p>(c) 0.5 % for the individual concentrations or the sum of the individual concentrations of cetrimonium chloride and steartrimonium chloride</p>	<p>For purposes other than inhibiting the development of microorganisms in the product. The purpose has to be apparent from the presentation of the product.</p>	
287	<p>C22-alkyltrimethylammonium chloride</p> <p>Behentrimonium chloride⁽¹⁸⁾</p> <p>CAS No. 17301-53-0</p>	<p>(a) Rinse-off hair products</p> <p>(b) Leave-on hair products</p>	<p>(a) 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) 3.0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steartrimonium chloride and behentrimonium</p>	<p>For purposes other than inhibiting the development of microorganisms in the product. The purpose has to be apparent from the presentation of the product</p>	

Ref #		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
		(c)Face products	chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steatrimonium chloride set out in entry 286. (c) 3,0 % for the individual concentration of behentrimonium chloride or the sum of the individual concentrations of cetrimonium chloride, steatrimonium chloride and behentrimonium chloride, while at the same time respecting the relevant maximum concentration for the sum of cetrimonium chloride and steatrimonium chloride set out in entry 286.		

Footnote:

(18) For use as a preservative, see Annex VI, entry No 44.

LAMPIRAN B

Annex VI no.12, no.12a, no.39 dan no.57

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	B	C	D	E
12	<p>4-Hydroxybenzoic acid and its Methyl- and Ethyl- esters, and their salts (INCI)</p> <p>4-Hydroxybenzoic acid; CAS No. 99-96-7;</p> <p>Methylparaben; CAS No. 99-76-3;</p> <p>potassium ethylparaben; CAS No. 36457-19-9;</p> <p>potassium paraben; CAS No. 16782-08-4</p> <p>sodium methylparaben; CAS No. 5026-62-0;</p> <p>sodium ethylparaben; CAS No. 35285-68-8;</p> <p>ethylparaben; CAS No. 120-47-8;</p> <p>sodium paraben; CAS No. 114-63-6;</p> <p>potassium methylparaben; CAS No. 26112-07-2;</p> <p>calcium paraben; CAS No. 69959-44-0;</p>	<p>0.4% (as acid) for single ester</p> <p>0.8% (as acid) for mixtures of esters</p>		
12a	<p>Butyl 4-hydroxybenzoate and its salts</p> <p>Propyl 4-hydroxybenzoate and its salts</p> <p>Butylparaben; CAS No. 94-26-8;</p> <p>Propylparaben; CAS No. 94-13-3</p> <p>sodium propylparaben; CAS No. 35285-69-9</p> <p>sodium butylparaben; CAS No. 36457-20-2;</p> <p>potassium butylparaben; CAS No. 38566-94-8;</p> <p>potassium propylparaben; CAS No. 84930-16-5;</p>	<p>0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %</p>	<p>Not to be used in leave-on products designed for application on the nappy area of children under three years of age.</p>	<p>For leave-on products designed for children under three years of age: "Do not use on the nappy area"</p>

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	B	C	D	E
39	Mixture of 5-Chloro-2-methylisothiazol 3(2H)-one and 2-Methylisothiazol 3(2H)-one Methylchloroisothiazolinone (and) Methylisothiazolinone ⁽⁹⁾ CAS No. 26172-55-4, 2682-20-4, 55965-84-9	0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2 methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one)	Rinse-off products	
57	2-Methyl-2H-isothiazol- 3-one Methylisothiazolinone ⁽¹⁴⁾ CAS No.2682-20-4	0.01%		

Footnote:

- (9) *Methylisothiazolinone is also regulated in entry 57. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product.*
- (14) *Methylisothiazolinone is also regulated in entry 39 in a mixture with Methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product*

LAMPIRAN D

Annex VI no.59

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	B	C	D	E
59	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2 hydroxy-,silver(1+) salt, monohydrate Citric acid (and) Silver citrate	0,2%, corresponding to 0,0024 % of silver	Not to be used in oral products and eye products	

Annex VII no.29

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
A	B	C	D	E
29	1,3,5-Triazine, 2,4,6-tris [1,1'biphenyl]-4-yl-, including as nanomaterial. Tris-biphenyl triazine Tris-biphenyl triazine (nano) CAS No. 31274-51-8	10%	Not to be used in sprays. Only nanomaterials having the following characteristics are allowed: — median primary particle size > 80 nm; — Purity ≥ 98 %; — Uncoated'	