



Ruj. Kami : (16) dlm.BPFK/PASCA/K/23
Tarikh : 26 JUL 2018

SEMUA PEMEGANG NOTIFIKASI KOSMETIK

SEMUA PERSATUAN BERKENAAN

Tuan/Puan,

PEKELILING BIL. 3/2018

MAKLUMAN BERKENAAN STATUS KEMASKINI BAHAN-BAHAN DALAM ANNEX PADA *GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA*

Saya dengan hormatnya merujuk kepada perkara tersebut di atas.

2. Bahagian Regulatori Farmasi Negara (NPRA) menjalankan 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. Mesyuarat *ASEAN Cosmetic Committee (ACC)* kali ke-28 yang telah diadakan di Vientiane, Lao PDR pada 1-2 Mei 2018 telah bersetuju untuk mengemaskini beberapa bahan di dalam Annex pada ACD. Keputusan tersebut adalah selaras dengan pindaan yang dinyatakan dalam *Commission Regulation (EU) No.2017/237* dan *No.2017/2228* yang melibatkan Annex III.
4. Kemaskini **Annex III** (*List of Restricted Substances*) melibatkan memasukkan bahan-bahan baharu di mana kepekatan dan syarat yang dibenarkan untuk digunakan adalah seperti pada **Lampiran A**. Produk kosmetik bernotifikasi di pasaran yang mengandungi bahan-bahan tersebut dan tidak mematuhi syarat baru yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 30 November 2019**.
5. Sehubungan itu, semua Pemegang Notifikasi Kosmetik adalah diingatkan untuk membuat perancangan yang teliti bagi mengelakkan sebarang kesulitan yang akan timbul.
6. Adalah menjadi tanggungjawab pihak Pemegang Notifikasi Kosmetik untuk mematuhi kesemua arahan dan peruntukan perundangan di bawah Peraturan 18A

Ruj. Kami : (16) dlm.BPFK/PASCA/K/23

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,



(DR. RAMLI BIN ZAINAL) RPh.1045

Pengarah
Bahagian Regulatori Farmasi Negara

WMWM/za/nsy

- s.k
- i) Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
 - ii) Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia
 - iii) Semua Timbalan Pengarah
Bahagian Regulatori Farmasi Negara


Ruj. Kami : (16)dIm.BPFK/PASCA/K/23

SENARAI EDARAN


1. Presiden
Persatuan Kosmetik, Dandanan Diri dan Haruman Malaysia,
(*The Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA)*)
95-2, Block H,
The Suites, Jaya One,
72 A, Jalan Universiti,
46200 Petaling Jaya,
Selangor

2. Presiden
*Federation of Malaysian Manufacturers Malaysian Cosmetics and Toiletries
Industry Group (FMM MCTIG)*
Wisma FMM, No. 3, Persiaran Dagang, PJU 9,
Bandar Sri Damansara,
52200 Kuala Lumpur.

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #) A	Substance/CAS No ⁽¹³⁾ B	Restrictions		Conditions of use and warning which must be printed on the labels F
		Field of application and/or use C	Maximum authorised concentration in the ready for use preparation D	
8c	Ethanol, 2,2'-[2-nitro-1,4-phenylene]diimino]bis- (9CI) N,N'-Bis(2-Hydroxyethyl)-2-Nitro-p-Phenylenediamine CAS No. 84041-77-0	(a)Hair dye substance in oxidative hair dye products (b)Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	(a) 1.5% (b) 1.5%	(a) To be printed on the label: The mixing ratio.  "Hair colourants 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 rash on your face or 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. (a) and (b) Do not use to dye eyelashes or eyebrows."
				Other limitations and requirements E


ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A 9b	B 1-Methyl-2,6-bis-(2-hydroxyethylamino)-benzene 2,6-Dihydroxyethylaminotoluene CAS No 149330-25-6	C Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	D	E After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text. • Do not use with nitrosating agents • Maximum nitrosamine content: 50 µg/kg ⁽²¹⁾ • Keep in nitrite-free containers	F To be printed on the label: The mixing ratio.  "Hair colourants 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 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. Do not use to dye eyelashes or eyebrows."


ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Other limitations and requirements	Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation		
A	B	C	D	E	F
314 (298)	Di[2-[4-[(E)-2-[4-[bis(2-hydroxyethyl)aminophenyl]vinyl]pyridin-1-ium] butanoyl]aminoethyl] di-sulfanyl dichloride HC Red No 17 CAS No 1449471-67-3	Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg ⁽²¹⁾ — Keep in nitrite-free containers The direction for use "wear suitable gloves" must be included in label or leaflet text.	Do not use to dye eyelashes or eyebrows


ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
315 (299)	Di[2-[4-(E)-2-[2,4,5-trimethoxyphenyl]vinyl]pyridin-1-ium]butanoyl]aminoethyl]disulfanyl]dichloride HC Yellow No 17 CAS No 1450801-55-4	Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants 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 rash on your face or 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. Do not use to dye eyelashes or eyebrows."

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
316 (300)	1H-Pyrazole-4,5- diamine, 1- hexyl-, sulfate (2:1) 1-Hexyl 4,5- Diamino Pyrazole Sulfate CAS No 1361000-03-4	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1% The direction for use "wear suitable gloves" must be included in label or leaflet text.	<p>To be printed on the label:</p> <p> "Hair colourants 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.</p> <p>Do not colour your hair if:</p> <ul style="list-style-type: none"> - you have a rash on your face or 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>Do not use to dye eyelashes or eyebrows."</p>


ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A 317 (301)	B 4-Hydroxy-2,5,6- triaminopyrimidine sulfate 2,5,6-Triamino- 4-Pyrimidinol CAS No 1603-02-7	C Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	D	E After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.5% The direction for use "wear suitable gloves" must be included in label or leaflet text.	F To be printed on the label:  "Hair colourants 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 rash on your face or 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. Do not use to dye eyelashes or eyebrows."


ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Other limitations and requirements	Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation		
A	B	C	D	E	F
318 (302)	302 2-[(3-Aminopyrazolo[1,5-a]pyridin-2-yl)oxy]ethanol hydrochloride Hydroxyethoxy Aminopyrazolopyridine HCl CAS No 1079221-49-0	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label: ⚠️ "Hair colourants 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 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. Do not use to dye eyelashes or eyebrows."

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation	Other limitations and requirements	
A	B	C	D	E	F
319 (303)	Phenol, 3-amino- 2,6-dimethyl 3-Amino-2,6- Dimethylphenol CAS No 6994-64-5	Hair dye substance in oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0% The direction for use "wear suitable gloves" must be included in label or leaflet text.	To be printed on the label:  "Hair colourants 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 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. Do not use to dye eyelashes or eyebrows."
320 (304)	2-Naphthalenaminiium, 8-[(4-amino-3- nitrophenyl)azo]-7-hydroxy-N,N,N- trimethyl-, chloride Basic Brown 17 CAS No 68391-32-2	Hair dye substance in non- oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	2.0%	The direction for use "wear suitable gloves" must be included in label or leaflet text.	Do not use to dye eyelashes or eyebrows

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Other limitations and requirements	Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation		
A	B	C	D	E	F
321 (305)	3-Amino-7-(dimethylamino)-2-methoxyphenoxazin-5-ium chloride Basic Blue 124 CAS No 67846-56-4	Hair dye substance in non-oxidative hair dye products Use for dyeing eyelashes and eyebrows is not permitted.	0.5%	<p>— Do not use with nitrosating agents</p> <p>— Maximum nitrosamine content: 50 µg/kg⁽²¹⁾</p> <p>— Keep in nitrite-free containers</p> <p>The direction for use "wear suitable gloves" must be included in label or leaflet text.</p>	<p>To be printed on the label:</p> <p> "Hair colourants can cause severe allergic reactions. Read and follow instructions. 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 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>Do not use to dye eyelashes or eyebrows."</p>

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Conditions of use and warning which must be printed on the labels	
		Field of application and/or use	Other limitations and requirements		
A	B	C	D	E	
322 (306)	Peanut oil extracts and derivatives Arachis Hypogaea Oil Arachis Hypogaea Seedcoat Extract Arachis Hypogaea Flour Arachis Hypogaea Fruit Extract Arachis Hypogaea Sprout Extract Hydrogenated Peanut Oil Peanut Acid Peanut Glycerides Peanut Oil PEG-6 Esters Peanutamide MEA Peanutamide MIPA Potassium Peanutate Sodium Peanutamphoacetate Sodium Peanutate Sulfated Peanut Oil CAS Nos 8002-03-7/8002-03-7/8002-03-7 8002-03-7/68425-36-5 91051-35-3/91744-77-3 68440-49-3/93572-05-5 61789-56-8/61789-57-9/73138-79-1			E Maximum concentration of peanut proteins: 0.5 ppm	F

ANNEX III-Part 1-List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Restrictions		Other limitations and requirements	Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the ready for use preparation		
A	B	C	D	E	F
323 (307)	Hydrolyzed wheat protein CAS Nos 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5			Maximum molecular weight average of the peptides in hydrolysates: 3.5 kDa	