



Rujukan : Bil (15) dlm. NPRA/PPPK/01/04

Tarikh : 16 Januari 2024

SEMUA PEMEGANG NOTIFIKASI KOSMETIK

SEMUA PERSATUAN BERKENAAN

Tuan/Puan

PEKELILING BIL 1/2024

**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) telah 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-38 yang telah diadakan di Singapura pada 22 & 23 November 2023 telah bersetuju untuk mengemaskini beberapa bahan di dalam Annex II, III, IV, VI dan VII pada ACD.

4. Pindaan pada Annex adalah seperti berikut:

4.1 **Annex II (List of Prohibited Substances)**

Kemaskini serta larangan penggunaan bahan-bahan seperti pada **Lampiran A**.

4.1.1 *Mercury and its compounds, MBM, MBO dan HPT* dikemaskini dalam Annex II seperti pada **Lampiran A**.

Produk kosmetik bernetifikasi yang mengandungi bahan-bahan tersebut tidak lagi dibenarkan berada di pasaran **mulai tarikh pekeliling ini dikeluarkan**.

- 4.1.2 *N,N-diethyl-m-toluamide / Diethyltoluamide (DEET)* dikemaskini dalam Annex II seperti pada **Lampiran A**.

Produk kosmetik bertonifikasi yang mengandungi bahan-bahan tersebut tidak lagi dibenarkan berada di pasaran **mulai tarikh pekeliling ini dikeluarkan**.

- 4.1.3 *14 bahan larangan yang dikemaskini mengikut EU Amendment of Annex II (EU 2022/1531)* seperti pada **Lampiran A**

Produk kosmetik bertonifikasi yang mengandungi bahan-bahan tersebut hanya dibenarkan berada di pasaran **sehingga 15 November 2024**.

4.2 **Annex III (List of Restricted Substances)**

Kemaskini bahan-bahan seperti pada **Lampiran B**.

- 4.2.1 *Hydrogen peroxide, Tagetes minuta flower extract/oil, Tagetes patula flower extract/oil, Tagetes erecta flower extract/oil dan Methyl-N-methylantranilate* dikemaskini dalam Annex III seperti pada **Lampiran B**.

4.3 **Annex IV (List of Coloring Agents)**

Kemaskini bahan seperti pada **Lampiran C**.

- 4.3.1 *CI 45430* dikemaskini dalam Annex VI seperti pada **Lampiran C**.

4.4 **Annex VI (List of Preservatives)**

Kemaskini seperti pada **Lampiran D**.

- 4.4.1 *Methenamine 3-chloroallylochloride (Quaternium-15)* dikeluarkan dari Annex VI.

4.5 **Annex VII (List of UV Filters)**

Kemaskini serta penambahan bahan penapis UV yang dibenarkan seperti pada **Lampiran E**.

- 4.5.1 *Benzophenone-3* dikemaskini dalam Annex VII dengan syarat-syarat yang dinyatakan. Produk kosmetik bertonifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 15 November 2026**.

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4.5.2 *Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine* dan *Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano)* dimasukkan ke dalam Annex VII dengan syarat-syarat yang dinyatakan. Bahan tersebut boleh digunakan sebagai bahan penapis UV dalam produk kosmetik bernetifikasi kuatkuasa serta-merta.

5. Sehubungan dengan itu, semua Pemegang Notifikasi Kosmetik adalah disarankan untuk membuat perancangan yang teliti bagi mengelakkan sebarang kesulitan yang akan timbul.

6. Pemegang Notifikasi Kosmetik diingatkan untuk mematuhi kesemua arahan dan peraturan perundangan di bawah Peraturan 18A Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 dan *Guidelines for Control of Cosmetic Products in Malaysia*.

Sekian, terima kasih.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,



ROSILAWATI BINTI AHMAD (RPh. 1413)

Pengarah Bahagian Regulatori Farmasi Negara

Kementerian Kesihatan Malaysia

AR/as/ec

Rujukan : Bil (15) dlm. NPRA/PPPK/01/04

- s.k
- i) Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
 - ii) Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia
 - iii) Timbalan Pengarah Pusat Penilaian Produk dan Kosmetik
Bahagian Regulatori Farmasi Negara
 - iv) Timbalan Pengarah Pusat Komplians dan Kawalan Kualiti
Bahagian Regulatori Farmasi Negara
 - v) Timbalan Pengarah Pusat Koordinasi dan Perancangan Strategik Regulatori
Bahagian Regulatori Farmasi Negara

SENARAI EDARAN

1. Presiden
Persatuan Kosmetik, Dandanan Diri dan Haruman Malaysia,
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2. Presiden
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Lampiran A

Annex II (19 entries)

Substances	CAS Number	Ref. No
N,N-diethyl-m-toluamide/Diethyltoluamide (DEET)	134-62-3, 26545-51-7	A1144
Mercury and its compounds except those special cases included in Annex VI	7439-97-6 54-64-8 62-38-4 94-43-9 102-98-7 1192-89-8 100-56-1	221
N,N'-Methylenedimorpholine; N,N'-methylenebismorpholine; [formaldehyde released from N,N'-Methylenebismorpholine]; [MBM] if the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is $\geq 0,1$ % w/w	5625-90-1	1605
Reaction products of paraformaldehyde with 2-hydroxypropylamine (3:2); [formaldehyde released from 3,3'-methylenebis[5-methyloxazolidine]; [formaldehyde released from oxazolidin]; [MBO] if the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is $\geq 0,1$ % w/w		1606
Reaction products of paraformaldehyde with 2-hydroxypropylamine (1:1)); [formaldehyde released from a,a,atrimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol]; [HPT] if the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is $\geq 0,1$ % w/w		1607
Tetrafluoroethylene	116-14-3	1681
As from 15 November 2024 for new and existing products		
6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol;[DBMC]	119-47-1	1682
As from 15 November 2024 for new and existing products		
(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone; pyriofenone	688046-61-9	1683
As from 15 November 2024 for new and existing products		
(RS)-1-{1-ethyl-4-[4-mesy-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5-yloxy}ethyl methyl carbonate; tolpyralate	1101132-67-5	1684
As from 15 November 2024 for new and existing products		
Azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridine-3(2H)-yl)methyl] O,O-dimethyl thiophosphate	35575-96-3	1685
As from 15 November 2024 for new and existing products		
3-methylpyrazole	1453-58-3	1686
As from 15 November 2024 for new and existing products		
N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide; pydiflumetofen	1228284-64-7	1687
As from 15 November 2024 for new and existing products		

N-{2-[[1,1'-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide; sedaxane As from 15 November 2024 for new and existing products	874967-67-6	1688
4-methylpentan-2-one; isobutyl methyl ketone (MIBK) As from 15 November 2024 for new and existing products	108-10-1	1689
Dimethomorph (ISO); (E,Z)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine As from 15 November 2024 for new and existing products	110488-70-5	1690
Imazamox (ISO); (RS)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid As from 15 November 2024 for new and existing products	114311-32-9	1691
Thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine As from 15 November 2024 for new and existing products	153719-23-4	1692
Triticonazole (ISO); (RS)-(E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-methyl)cyclopentanol As from 15 November 2024 for new and existing products	138182-18-0	1693
Desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenylcarbamate As from 15 November 2024 for new and existing products	13684-56-5	1694

Lampiran B

Annex III no. 12, 324, 325, 327 & 339

Ref No ACD # (EU #)	Substance/CAS No ⁽¹⁹⁾	Field of application and/or use	Restrictions		Other limitations and requirements	Conditions of use and warning which must be printed on the labels
			Maximum authorised concentration in the ready for use preparation	D		
A 12	B Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide, with the exception of the following substances in Annex II: No. 1397, 1398, 1399 CAS No 7722-84-1	C (a) Hair products (b) Skin products (c) Nail hardening products (d) Oral Hygiene products, including mouth rinse, toothpaste. (e) Tooth whitening or bleaching products (f) For general consumer use (ii) For use by the consumer under the supervision of a qualified dental practitioner (iii) For application by a qualified dental practitioner only	D (a) 12% of H ₂ O ₂ (40 volumes), present or released (b) 4% of H ₂ O ₂ , present or released (c) 2% of H ₂ O ₂ , present or released (d) 0.1 % of H ₂ O ₂ , present or released (e) (i) 0.1% H ₂ O ₂ present or released (ii) >0.1 to ≤ 6% H ₂ O ₂ present or released (iii) >6% to 35% H ₂ O ₂ present or released	E (e) (ii) For supply only through a qualified dental practitioner. Not for direct sale to the general public. (iii) Only to be used by a qualified dental practitioner. Not for direct sale to the general public.	F For (a) Wear suitable gloves For (a) (b) (c) and (e): Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them. (e) (ii) and (iii) To be printed on the label Not to be used on a person under 18 years of age. Percentage of Hydrogen Peroxide to be declared. (ii) Not for direct sale to the public. For supply only through 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>324 (308)</p>	<p>Tagetes minuta flower extract 91770-75-1 Tagetes minuta flower oil 91770-75-1/8016-84-0</p>	<p>a) Leave-on products b) Rinse-off products</p>	<p>a) 0.01% b) 0.1%</p>	<p>For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/oil \leq 0.35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light.⁽²²⁾ For (a) and (b): In case of combined use with Tagetes patula (entry 325) or Tagetes erecta (entry 327), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)</p>	
<p>325 (309)</p>	<p>Tagetes patula flower extract 91722-29-1 Tagetes patula flower oil 91722-29-1/8016-84-0</p>	<p>a) Leave-on products b) Rinse-off products</p>	<p>a) 0.01% b) 0.1%</p>	<p>For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/oil \leq 0.35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light.⁽²²⁾ For (a) and (b): In case of combined use with Tagetes minuta (entry 324) or Tagetes erecta (entry 327), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)</p>	

<p>327 (1383 Annex II)</p>	<p>Tagetes erecta flower extract 90131-43-4 Tagetes erecta flower oil 90131-43-4</p>	<p>a) Leave-on products b) Rinse-off products</p>	<p>a) 0.01% b) 0.1%</p>	<p>For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/oil ≤ 0.35 %.</p> <p>For (a): Not to be used in sunscreen products and products marketed for exposure to natural /artificial UV light. (22)</p> <p>For (a) and (b): In case of combined use with Tagetes minuta (entry 324) or Tagetes patula (entry 325), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (d)</p>	
<p>339 (323)</p>	<p>Methyl-N-methylantranilate Cas No 85-91-6</p>	<p>(a) Leave-on products (b) Rinse-off products</p>	<p>(a) 0.1 % (b) 0.2 %</p>	<p>For (a): Not to be used in sunscreen products and products marketed for exposure to natural or artificial UV light. (22)</p> <p>For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers</p>	

Annex IV CI 45430

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
45430 ⁽²⁾	Red	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 3% 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid

Lampiran D

Annex VI preamble & entry no. 31Preamble

5. All finished products containing ~~formaldehyde~~ or substances in this ANNEX and which release formaldehyde (Entries 20, 21, 27, 30, ~~34~~, 33, 46, 49, 51, 55) must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.

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
31	Methenamine 3-chloroallylochloride (INN) Entry deleted	0.2%		

Annex VII no. 4, 32 & 33

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
4	2-Hydroxy-4-methoxy-benzophenone/Oxybenzone ⁽⁶⁾ Benzophenone-3 CAS No. 131-57-7 As from 15 November 2026 for new and existing products	a) 6% b) 2.2% c) 0.5%	For a) and b) Not more than 0.5% to protect product formulation a) Face products, hand products, and lip products, excluding propellant and pump spray products. If used at 0.5 % to protect product formulation, the levels used as UV filter must not exceed 5.5%. b) Body products, including propellant and pump spray products If used at 0.5 % to protect product formulation, the levels used as UV filter must not exceed 1.7%. c) Other products	For a) and b): Contains Benzophenone-3 ⁽¹⁾
32	1,1'-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine Cas No. 919803-06-8	10% ⁽⁷⁾		

33	<p>1,1'-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone</p> <p>Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano)</p> <p>Cas No. 919803-06-8</p>	10% ⁽⁷⁾	<p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> - Purity \geq 97 % - Median particle size D50 (50 % of the number below this diameter): \geq 50 nm of number size distribution. <p>Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.</p>	
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7. In case of combined use of Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine and Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano), the sum shall not exceed 10%.