



Rujukan : Bil (10) dlm. NPRA/PPPK/01/04
Tarikh : 27 Jun 2023

SEMUA PEMEGANG NOTIFIKASI KOSMETIK

SEMUA PERSATUAN BERKENAAN

Tuan/Puan

PEKELILING BIL 2/2023

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-36 yang telah diadakan secara *virtual* pada 30 November dan 1 Disember 2022 serta Mesyuarat ACC kali ke-37 yang telah diadakan secara *virtual* pada 8 & 9 Mei 2023 telah bersetuju untuk mengemaskini beberapa bahan di dalam Annex II, III, VI dan VII pada ACD.

4. Pindaan pada Annex adalah seperti berikut:

4.1 Annex II (*List of Prohibited Substances*)

Larangan penggunaan bahan-bahan seperti pada Lampiran A.

4.1.1 19 bahan larangan yang dikemaskini mengikut EU Amendment of Annex II (EU 2019/831, EU 2019/1966 dan EU 2021/850) seperti pada Lampiran A

Produk kosmetik bernetifikasi yang mengandungi bahan-bahan tersebut hanya dibenarkan berada di pasaran **sehingga 8 Mei 2025**.

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

Kemaskini serta penambahan syarat penggunaan bahan-bahan seperti pada **Lampiran B**.

4.2.1 *Salicylic acid* dikemaskini dalam Annex III dengan syarat-syarat yang dinyatakan. Produk kosmetik bernetifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 21 November 2024**.

4.2.2 *Methyl-N-methylantranilate* dikemaskini dalam Annex III dengan syarat-syarat yang dinyatakan. Produk kosmetik bernetifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 8 Mei 2025**.

4.2.3 *Ammonium silver zinc aluminum silicate* dikemaskini dalam Annex III dengan syarat-syarat yang dinyatakan. Produk kosmetik bernetifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 8 Mei 2025**.

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

Kemaskini serta penambahan syarat penggunaan bahan seperti pada **Lampiran C**.

4.3.1 *Sodium hydroxymethylglycinate* dikemaskini dalam Annex VI dengan syarat-syarat yang dinyatakan. Produk kosmetik bernetifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 8 Mei 2025**.

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

Kemaskini serta penambahan syarat penggunaan bahan seperti pada **Lampiran D**.

4.4.1 *Octocrylene* dikemaskini dalam Annex VII dengan syarat-syarat yang dinyatakan. Produk kosmetik bernetifikasi yang tidak mematuhi syarat baharu yang ditetapkan hanya dibenarkan berada di pasaran **sehingga 8 Mei 2025**.

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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

- 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,
(*The Cosmetic, Toiletry and Fragrance Association of Malaysia (CTFA)*)
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The Suites, Jaya One,
72 A, Jalan Universiti,
46200 Petaling Jaya,
Selangor
info@ctfamalaysia.org

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.
aini@fmm.org.my

Lampiran A

Annex II (19 entries)

Substances	CAS Number	Ref. No
Cis-1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis-CTAC), quaternium-15 As from 8 May 2025 for new and existing products	51229-78-8	1386
2-Chloracetamide As from 8 May 2025 for new and existing products	79-07-2	1387
Acetaldehyde; ethanol As from 8 May 2025 for new and existing products	75-07-0	1391
N-Methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone As from 8 May 2025 for new and existing products	872-50-4	1393
Nickel diarsenide [1] Nickel arsenide [2] As from 8 May 2025 for new and existing products	12068-61-0 [1] 27016-75-7 [2]	1457
Nickel(II) trifluoroacetate [1] Nickel(II) propionate [2] Nickel bis(benzenesulfonate) [3] Nickel(II) hydrogen citrate [4] Citric acid, ammonium nickel salt [5] Citric acid, nickel salt [6] Nickel bis(2-ethylhexanoate) [7] 2-Ethylhexanoic acid, Nickel salt [8] Dimethylhexanoic acid nickel salt [9] Nickel(II) isooctanoate [10] Nickel isooctanoate [11] Nickel bis(isononanoate) [12] Nickel(II) neononanoate [13] Nickel(II) isodecanoate [14] Nickel(II) neodecanoate [15] Neodecanoic acid, nickel salt [16] Nickel(II) neoundecanoate [17] Bis(D-gluconato-O1,O2)nickel [18] Nickel 3,5-bis(tert-butyl)-4-hydroxybenzoate (1:2) [19] Nickel(II) palmitate [20] (2-Ethylhexanoato-O)(Isononanoato-O)nickel [21] (Isononanoato-O)(Isooctanoato-O)nickel [22] (Isooctanoato-O)(neodecanoato-O)nickel [23] (2-Ethylhexanoato-O)(Isodecanoato-O)nickel [24] (2-Ethylhexanoato-O)(Neodecanoato-O)nickel [25] (Isodecanoato-O)(isooctanoato-O)nickel [26] (Isodecanoato-O)(isononanoato-O)nickel [27] (Isononanoato-O)(Neodecanoato-O)nickel [28] fatty acids, C6-19-branched, nickel salts [29] fatty acids, C8-18 and C18-unsaturated, nickel salts [30] 2,7-Naphthalenedisulfonic acid, nickel(II) salt [31] As from 8 May 2025 for new and existing products	16083-14-0 [1] 3349-08-4 [2] 39819-65-3 [3] 18721-51-2 [4] 18283-82-4 [5] 22605-92-1 [6] 4454-16-4 [7] 7580-31-6 [8] 93983-68-7 [9] 29317-63-3 [10] 27637-46-3 [11] 84852-37-9 [12] 93920-10-6 [13] 85508-43-6 [14] 85508-44-7 [15] 51818-56-5 [16] 93920-09-3 [17] 71957-07-8 [18] 52625-25-9 [19] 13654-40-5 [20] 85508-45-8 [21] 85508-46-9 [22] 84852-35-7 [23] 84852-39-1 [24] 85135-77-9 [25] 85166-19-4 [26] 84852-36-8 [27] 85551-28-6 [28] 91697-41-5 [29] 84776-45-4 [30] 72319-19-8 [31]	1460

Nickel(II) sulfite [1] Nickel tellurium trioxide [2] Nickel tellurium tetraoxide [3] Molybdenum nickel hydroxide oxide phosphate [4] As from 8 May 2025 for new and existing products	7757-95-1 [1] 15851-52-2 [2] 15852-21-8 [3] 68130-36-9 [4]	1461
Nickel boride (NiB) [1] Dinickel boride [2] Trinickel boride [3] Nickel boride [4] Dinickel silicide [5] Nickel disilicide [6] Dinickel phosphide [7] Nickel boron phosphide [8] As from 8 May 2025 for new and existing products	12007-00-0 [1] 12007-01-1 [2] 12007-02-2 [3] 12619-90-8 [4] 12059-14-2 [5] 12201-89-7 [6] 12035-64-2 [7] 65229-23-4 [8]	1462
Dialuminium nickel tetraoxide [1] Nickel titanium trioxide [2] Nickel titanium oxide [3] Nickel divanadium hexaoxide [4] Cobalt dimolybdenum nickel octaoxide [5] Nickel zirkonium trioxide [6] Molybdenum nickel tetraoxide [7] Nickel tungsten tetraoxide [8] Olivine, nickel green [9] Lithium nickel dioxide [10] Molybdenum nickel oxide [11] As from 8 May 2025 for new and existing products	12004-35-2 [1] 12035-39-1 [2] 12653-76-8 [3] 52502-12-2 [4] 68016-03-5 [5] 70692-93-2 [6] 14177-55-0 [7] 14177-51-6 [8] 68515-84-4 [9] 12031-65-1 [10] 12673-58-4 [11]	1463
2-Ethylhexyl-2-ethylhexanoate As from 8 May 2025 for new and existing products	7425-14-1	1491
Quinoline As from 8 May 2025 for new and existing products	91-22-5	1527
Petroleum, coal, tar and natural gas and their derivatives generated using distillation and/or other processing methods if they contain = 0,1 % w/w benzene As from 8 May 2025 for new and existing products	85536-20-5 [1] 85536-19-2 [2] 90641-12-6 [3] 90989-38-1 [4] 91995-20-9 [5] 92062-36-7 [6] 91995-61-8 [7] 101316-63-6 [8] 93821-38-6 [9] 90641-02-4 [10] 101316-62-5 [11] 90641-03-5 [12] 65996-79-4 [13] 101794-90-5 [14] 90640-87-2 [15] 84650-03-3 [16] 65996-82-9 [17] 90641-01-3 [18] 65996-87-4 [19] 90640-99-6 [20] 68391-11-7 [21] 92062-33-4 [22] 91082-52-9 [23] 68937-63-3 [24] 92062-28-7 [25]	1539

	92062-27-6 [26]	
	91082-53-0 [27]	
	91995-31-2 [28]	
	91995-35-6 [29]	
	91995-66-3 [30]	
	122070-79-5 [31]	
	122070-80-8 [32]	
	65996-78-3 [33]	
	94114-52-0 [34]	
	94114-53-1 [35]	
	94114-54-2 [36]	
	94114-56-4 [37]	
	94114-57-5 [38]	
	90641-11-5 [39]	
	8006-61-9 [40]	
	8030-30-6 [41]	
	8032-32-4 [42]	
	64741-41-9 [43]	
	64741-42-0 [44]	
	64741-46-4 [45]	
	64742-89-8 [46]	
	68410-05-9 [47]	
	68514-15-8 [48]	
	68606-11-1 [49]	
	68783-12-0 [50]	
	68921-08-4 [51]	
	101631-20-3 [52]	
	64741-64-6 [53]	
	64741-65-7 [54]	
	64741-66-8 [55]	
	64741-70-4 [56]	
	64741-84-0 [57]	
	64741-92-0 [58]	
	68410-71-9 [59]	
	68425-35-4 [60]	
	68527-27-5 [61]	
	91995-53-8 [62]	
	92045-49-3 [63]	
	92045-55-1 [64]	
	92045-58-4 [65]	
	92045-64-2 [66]	
	101316-67-0 [67]	
	64741-54-4 [68]	
	64741-55-5 [69]	
	68476-46-0 [70]	
	68783-09-5 [71]	
	91995-50-5 [72]	
	92045-50-6 [73]	
	92045-59-5 [74]	
	92128-94-4 [75]	
	101794-97-2 [76]	
	101896-28-0 [77]	
	64741-63-5 [78]	
	64741-68-0 [79]	
	68475-79-6 [80]	
	68476-47-1 [81]	
	68478-15-9 [82]	
	68513-03-1 [83]	

	<p>68513-63-3 [84] 68514-79-4 [85] 68919-37-9 [86] 68955-35-1 [87] 85116-58-1 [88] 91995-18-5 [89] 93571-75-6 [90] 93572-29-3 [91] 93572-35-1 [92] 93572-36-2 [93] 64741-74-8 [94] 64741-83-9 [95] 67891-79-6 [96] 67891-80-9 [97] 68425-29-6 [98] 68475-70-7 [99] 68603-00-9 [100] 68603-01-0 [101] 68603-03-2 [102] 68955-29-3 [103] 92045-65-3 [104] 64742-48-9 [105] 64742-49-0 [106] 64742-73-0 [107] 68410-96-8 [108] 68410-97-9 [109] 68410-98-0 [110] 68512-78-7 [111] 85116-60-5 [112] 85116-61-6 [113] 92045-51-7 [114] 92045-52-8 [115] 92045-57-3 [116] 92045-61-9 [117] 92062-15-2 [118] 93165-55-0 [119] 93763-33-8 [120] 93763-34-9 [121] 64741-47-5 [122] 64741-48-6 [123] 64741-69-1 [124] 64741-78-2 [125] 64741-87-3 [126] 64742-15-0 [127] 64742-22-9 [128] 64742-23-0 [129] 64742-66-1 [130] 64742-83-2 [131] 64742-95-6 [132] 68131-49-7 [133] 68477-34-9 [134] 68477-50-9 [135] 68477-53-2 [136] 68477-55-4 [137] 68477-61-2 [138] 68477-89-4 [139] 68478-12-6 [140] 68478-16-0 [141]</p>	
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	<p>68513-02-0 [142] 68516-20-1 [143] 68527-21-9 [144] 68527-22-0 [145] 68527-23-1 [146] 68527-26-4 [147] 68603-08-7 [148] 68606-10-0 [149] 68783-66-4 [150] 68919-39-1 [151] 68921-09-5 [152] 85116-59-2 [153] 86290-81-5 [154] 90989-42-7 [155] 91995-38-9 [156] 91995-41-4 [157] 91995-68-5 [158] 92045-53-9 [159] 92045-60-8 [160] 92045-62-0 [161] 92045-63-1 [162] 92201-97-3 [163] 93165-19-6 [164] 94114-03-1 [165] 95009-23-7 [166] 97926-43-7 [167] 98219-46-6 [168] 98219-47-7 [169] 101316-56-7 [170] 101316-66-9 [171] 101316-76-1 [172] 101795-01-1 [173] 102110-14-5 [174] 68476-50-6 [175] 68476-55-1 [176] 90989-39-2 [177]</p>	
<p>Petroleum, coal, tar and natural gas and their derivatives generated using distillation and/or other processing methods if they contain = 0,1 % w/w 1,3-butadiene</p> <p>As from 8 May 2025 for new and existing products</p>	<p>68607-11-4 [1]; 68783-06-2 [2]; 68814-67-5 [3]; 68814-90-4 [4]; 68911-58-0 [5]; 68911-59-1 [6]; 68919-01-7 [7]; 68919-02-8 [8]; 68919-03-9 [9]; 68919-04-0 [10]; 68919-07-3 [11]; 68919-08-4 [12]; 68919-11-9 [13]; 68919-12-0 [14]; 68952-79-4 [15]; 68952-80-7 [16]; 68955-33-9 [17]; 68989-88-8 [18]; 92045-15-3 [19]; 92045-16-4 [20]; 92045-17-5 [21]; 92045-18-6 [22];</p>	<p>1542</p>

	92045-19-7 [23]; 92045-20-0 [24]; 68131-75-9 [25]; 68307-98-2 [26]; 68307-99-3 [27]; 68308-00-9 [28]; 68308-01-0 [29]; 68308-10-1 [30]; 68308-03-2 [31]; 68308-04-3 [32]; 68308-05-4 [33]; 68308-06-5 [34]; 68308-07-6 [35]; 68308-09-8 [36]; 68308-11-2 [37]; 68308-12-3 [38]; 68409-99-4 [39]; 68475-57-0 [40]; 68475-58-1 [41]; 68475-59-2 [42]; 68475-60-5 [43]; 68476-26-6 [44]; 68476-29-9 [45]; 68476-40-4 [46]; 68476-42-6 [47]; 68476-49-3 [48]; 68476-85-7 [49]; 68476-86-8 [50]; 68477-33-8 [51]; 68477-35-0 [52]; 68477-69-0 [53]; 68477-70-3 [54]; 68477-71-4 [55]; 68477-72-5 [56]; 68308-08-7 [57]	
N-Ethyl-2-pyrrolidone; 1-ethylpyrrolidin-2-one	2687-91-4	1562
As from 8 May 2025 for new and existing products		
Vinyl acetate	108-05-4	1565
As from 8 May 2025 for new and existing products		
Styrene	100-42-5	1575
As from 8 May 2025 for new and existing products		
Tetrahydro-2-furylmethanol; tetrahydrofurfuryl alcohol	97-99-4	1576
As from 8 May 2025 for new and existing products		
Imidazole	288-32-4	1589
As from 8 May 2025 for new and existing products		
Clorofene; chlorophene; 2-benzyl-4-chlorophenol	120-32-1	1602
As from 8 May 2025 for new and existing products		

Lampiran B

Annex III no. 98, 339 & 340

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
98	Benzoic acid, 2-hydroxy- Salicylic acid CAS No 69-72-7 As from 21 November 2024	(a) Rinse-off hair products (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant (c) Body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant	(a) 3.0 % (b) 2.0% (c) 0.5%	(a) (b) (c) Not to be used in preparations for children under three years of age. Not to be used in applications that may lead to exposure of the end user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product. These levels are inclusive of any use of salicylic acid. As a preservative, see Annex VI, Part 1, No 3
339 (323)	Methyl-N-methylanthranilate ⁽²²⁾ Cas No 85-91-6 As from 8 May 2025	(a) Leave-on products	(a) 0.1 %	
340 (x)	Ammonium silver zinc aluminum silicate Cas No 130328-20-0 As from 8 May 2025	(b) Rinse-off products (a) Foundation (b) Deodorant (Spray type, Non Spray type)	(b) 0.2 % (a) 1% (b) 1%	

(22) This restriction does not apply to products with secondary UV protection claims, such as moisturizing and skin lightening products as described in the preamble of ASEAN Sunscreen Labeling Guidelines

Annex VI no. 51

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
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%	Not to be used unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is < 0,1 % w/w As from 8 May 2025	

Annex VII no. 10

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
10	2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester/Octocrylene ⁽⁶⁾ Octocrylene CAS No 6197-30-4 As from 8 May 2025	a) 9 % b) 10 %	a) Propellant spray products b) Other products	