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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	15 September 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	D(2025) 109559 annex
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (Text with EEA relevance)

Delegations will find attached document D(2025) 109559 annex.

Encl.: D(2025) 109559 annex



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2025) XXX draft

ANNEX

ANNEX

to the

Commission Regulation (EU) .../...

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council
as regards the use in cosmetic products of certain substances classified as carcinogenic,
mutagenic or toxic for reproduction**

D109559/01 ANNEX

Annexes II, III, IV and V to Regulation (EC) No 1223/2009 are amended as follows:

(1) Annex II is amended as follows:

(a) entry 1397 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
‘1397	Perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt trihydrate [1];	13517-20-9 [1]	239-172-9 [1]
	Perboric acid, sodium salt, tetrahydrate [2];	37244-98-7 [2]	234-390-0 [2]
	Perboric acid (HBO(O ₂)), sodium salt, tetrahydrate [3];	10486-00-7 [3]	- [3]
	Sodium peroxoborate, hexahydrate [4];	- [4]	- [4]
	Sodium perborate [5];	15120-21-5 [5]	239-172-9 [5]
	Sodium peroxometaborate; sodium peroxoborate [6];	7632-04-4/ 10332-33-9/ 10486-00-7 [6]	231-556-4 [6]
	Perboric acid, sodium salt [7];	11138-47-9 [7]	234-390-0 [7]
	Perboric acid, sodium salt, monohydrate [8];	12040-72-1 [8]	234-390-0 [8]
	Perboric acid (HBO(O ₂)), sodium salt, monohydrate [9];	10332-33-9 [9]	- [9] ’

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(b) entries 1398 and 1399 are deleted;

(c) entry 1727 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
‘1727	Silver (nano) [1 nm < particle diameter ≤ 100 nm];	7440-22-4	231-131-3’

	Silver (massive) [particle diameter ≥ 1 mm]		
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(d) the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
[OP: please replace with the next consecutive number]	Multi-walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 μ m and a length ≥ 5 μ m and aspect ratio $> 3:1$, including Multi-Walled Carbon Nanotubes, MWC(N)T	-	-
[OP: please replace with the next consecutive number]	reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	-	-
[OP: please replace with the next consecutive number]	Acetone oxime	127-06-0	204-820-1
[OP: please replace with the next consecutive number]	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	119344-86-4	438-340-0
[OP: please replace with the next consecutive number]	2,3-epoxypropyl neodecanoate	26761-45-5	247-979-2
[OP: please replace with the next consecutive number]	Benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate	177406-68-7	-
[OP: please replace with the next consecutive number]	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	2386-87-0	219-207-4
[OP: please replace with the next consecutive number]	Sodium 3-(allyloxy)-2-hydroxypropanesulphonate	52556-42-0	258-004-5

number]			
[OP: please replace with the next consecutive number]	1,4-dichloro-2-nitrobenzene	89-61-2	201-923-3
[OP: please replace with the next consecutive number]	Fenpropidin (ISO); (<i>R,S</i>)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine	67306-00-7	-
[OP: please replace with the next consecutive number]	<i>N,N'</i> -methylenediacrylamide	110-26-9	203-750-9
[OP: please replace with the next consecutive number]	<i>tert</i> -butyl 2-ethylperoxyhexanoate	3006-82-4	221-110-7
[OP: please replace with the next consecutive number]	Trimethyl borate	121-43-7	204-468-9
[OP: please replace with the next consecutive number]	<i>S</i> -metolachlor (ISO); 2-chloro- <i>N</i> -(2-ethyl-6-methylphenyl)- <i>N</i> -[(2 <i>S</i>)-1-methoxypropan-2-yl]acetamide; (<i>R_aS_a</i>)-2-chloro- <i>N</i> -(6-ethyl- <i>o</i> -tolyl)- <i>N</i> -[(1 <i>S</i>)-2-methoxy-1-methylethyl]acetamide [contains 80-100% 2-chloro- <i>N</i> -(2-ethyl-6-methylphenyl)- <i>N</i> -[(2 <i>S</i>)-1-methoxypropan-2-yl]acetamide and 0-20% 2-chloro- <i>N</i> -(2-ethyl-6-methylphenyl)- <i>N</i> -[(2 <i>R</i>)-1-methoxypropan-2-yl]acetamide]	87392-12-9	-
[OP: please replace with the next consecutive number]	Pyraclostrobin (ISO); methyl <i>N</i> -(2-{[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxymethyl}phenyl) <i>N</i> -methoxy carbamate	175013-18-0	-'

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(2) in Annex III, the following entries are added:

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical Name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
‘[OP: please insert the next consecutive number]’	Silver (powder) [100 nm < particle diameter < 1 mm]	Silver	7440-22-4	231-131-3	(a) Toothpaste (b) Mouthwash	For (a) and (b): 0,05 %		
[OP: please insert the next consecutive number]	Hexyl 2-hydroxybenzoate	Hexyl Salicylate	6259-76-3	228-408-6	(a) Hydroalcoholic-based fragrances (except hydroalcoholic-based fragrances intended for children below 3 years of age) (b) All rinse-off products (except shower gel, hand wash, hair conditioner and shampoo intended for	(a) 2 % (b) 0,5 % (c) 0,3 % (d) 0,001 % (e) 0,001 % (f) 0,1 %	Not to be used in preparations for children under 3 years of age, with the exception of (d) “Toothpaste” and (f).’	

					<p>children below 3 years of age)</p> <p>(c) All leave-on products (except hair conditioner, body lotion, face cream, hand cream, lipstick/lip balm and fragrance products intended for children below 3 years of age)</p> <p>(d) Toothpaste</p> <p>(e) Mouthwash</p> <p>(f) Shower gel, hand wash, shampoo, hair conditioner, body, face and hand (skin) care products, lipstick/lip balm and fragrance products intended for children below 3 years of age</p>			
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(3) in Annex IV, entry 142 is replaced by the following:

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
'142	Silver (powder) [100 nm < particle diameter < 1 mm]	77820	7440-22-4	231-131-3	White	(a) Lip products (b) Eye shadow	For (a) and (b): 0,2 %'		

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(4) in Annex V, entry 7 is replaced by the following:

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'7	Biphenyl-2-ol; 2-phenylphenol; 2-	o-	90-43-7	201-993-5	(a) Rinse-off products	(a) 0,2 % (as phenol	When o-Phenylphenol	Avoid contact

	hydroxybiphenyl	Phenylphenol						
	Sodium 2-biphenylate	Sodium o-Phenylphenate	132-27-4	205-055-6	(b) Leave-on products	(b) 0,15 % (as phenol)	<p>and Sodium o-Phenylphenate are used together, the combined concentration (as phenol) shall not exceed 0,2 % in rinse-off and 0,15 % in leave-on products.</p> <p>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.</p>	with eyes'