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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 September 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	D(2026) 117774
Subject:	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, including those classified as carcinogenic, mutagenic or toxic for reproduction

Delegations will find attached document D(2026) 117774.

Encl.: D(2026) 117774



EUROPEAN
COMMISSION

Brussels, XXX
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[...] (2026) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION

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

ANNEX

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

(1) Annex II is amended as follows:

(a) entry 221 ‘Mercury and its compounds, except those special cases included in Annex V’ is replaced by ‘Mercury and its compounds’;

(b) the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
<i>‘[OP: please replace with the next consecutive number]’</i>	2-ethylhexanoic acid, monoester with propane-1,2-diol	85114-00-7	285-503-5
<i>[OP: please replace with the next consecutive number]</i>	α,α' -propylenedinitrilodi- <i>o</i> -cresol	94-91-7	202-374-2
<i>[OP: please replace with the next consecutive number]</i>	ozone	10028-15-6	233-069-2
<i>[OP: please replace with the next consecutive number]</i>	dinitrogen oxide	10024-97-2	233-032-0
<i>[OP: please replace with the next consecutive number]</i>	9-octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)- sulphooctadecanoic acid, potassium salt [3]	68609-93-8 [1]; - [2]; 67968-63-2 [3]	271-843-1 [1]; - [2]; 267-966-5 [3]
<i>[OP: please replace with the next consecutive number]</i>	2,3-epoxypropyl isopropyl ether	4016-14-2	223-672-9
<i>[OP: please replace with the next consecutive number]</i>	tetrahydrofurfuryl methacrylate	2455-24-5	219-529-5
<i>[OP: please replace with the next consecutive number]</i>	trimethyl phosphate	512-56-1	208-144-8

<i>[OP: please replace with the next consecutive number]</i>	fluoroethylene	75-02-5	200-832-6
<i>[OP: please replace with the next consecutive number]</i>	2-bromo-3,3,3-trifluoroprop-1-ene	1514-82-5	-
<i>[OP: please replace with the next consecutive number]</i>	2-phenylpropene; α -methylstyrene	98-83-9	202-705-0
<i>[OP: please replace with the next consecutive number]</i>	2,4- dihydroxybenzophenone [INCI: Benzophenone-1] (*)	131-56-6	205-029-4
<i>[OP: please replace with the next consecutive number]</i>	2,2',4,4'-tetrahydroxybenzophenone [INCI: Benzophenone-2] (*)	131-55-5	205-028-9
<i>[OP: please replace with the next consecutive number]</i>	8-[(4-aminophenyl)diazenyl]-7-hydroxy-N,N,N-trimethylnaphthalen-2-aminium chloride [INCI: Basic Brown 16] (*)	26381-41-9	247-640-9
<i>[OP: please replace with the next consecutive number]</i>	3-[(4-amino 6-bromo-5,8-dihydro-1-hydroxy-8-imino-5-oxo-2-naphtyl)amino]-N,N,N-trimethylanilinium chloride [INCI: Basic Blue 99] (*)	68123-13-7	268-544-3
<i>[OP: please replace with the next consecutive number]</i>	Prostaglandines and their analogues (*)	-	-'

‘(*) From [12 months following entry into force of this Regulation] products containing that substance shall not be placed on the Union market. From [24 months following entry into force of this Regulation] cosmetic products containing that substance shall not be made available on the Union market.’

(2) Annex III is amended as follows:

(a) entry 372 is replaced by the following:

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
'372	Hydroxyapatite (**)	Hydroxyapatite (nano)	1306-06-5/ 12167-74-7	215-145-7/ 235-330-6	(a) Toothpaste (b) Mouthwash	(a) 29,5% (b) 10%	For (a) and (b): Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: - composed of rod shaped particles of at least 87% (in particle number) have aspect ratios equal to or less	

							than 3, and the remaining 13% have aspect ratios not exceeding 9; - Hydroxyapatite (nano) particles are not coated or surface modified; - Hydroxyapatite (nano) particles with max length of 122 ± 43 nm.'	
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(b) 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 replace with the next consecuti ve number]’	2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (**)	Cannabidiol (CBD)	13956-29-1	689-176-3	(a) Leave-on products (b) Rinse-off products (c) Oral care products	0,19 % The presence of Delta- 9-tetrahydrocannabinol (THC) as an impurity must not exceed 0.00025% (2.5 ppm).	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.’	
‘[OP: please replace with the next consecuti ve number]’	Tert-butyl-4-methoxyphenol (**)	Butylated Hydroxyanisole (BHA)	25013-16-5	246-563-8	(a) Leave-on products (b) Rinse-off products	0.07%	Not to be used in oral care or in products that may lead to exposure of the end-user's lungs by inhalation.’	

‘(**) From [12 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be placed on the Union market. From [24 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be made available on the Union market.’

(3) Annex V is amended as follows:

(a) entry 12a is replaced by the following:

Reference number	Substance identification				Conditions			Wording of conditions of use and
	Chemical	Name of Common	CAS	EC number	Product type, Body	Maximum concentration in	Other	

	name/INN	Ingredients Glossary	number		parts	ready for use preparation		warnings
a	b	c	d	e	f	g	h	i
'12a	Propyl 4-hydroxybenzoate and its salts	Propylparaben sodium propylparaben potassium propylparaben	94-13-3 35285-69-9 84930-16-5	202-307-7 252-488-1 284-597-5		0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entries 12, 12a and 12b, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %	Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	For leave-on products designed for children under three years of age: 'Do not use on the nappy area.'

(b) the following entry is added:

Reference number	Substance identification				Conditions			Wording of conditions of use and
	Chemical name/INN	Name of Common	CAS number	EC number	Product type, Body parts	Maximum concentration in	Other	

		Ingredients Glossary				ready for use preparation		warnings
a	b	c	d	e	f	g	h	i
'12b	Butyl 4- hydroxybenzo ate and its salts (***)	Butylparaben sodium butylparaben potassium butylparaben	94-26-8 36457-20-2 38566-94-8	202-318-7 253-049-7 254-009-1		(a) 0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entries 12, 12a and 12b, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 % (b) For products intended for the use in children under 10 years of age - 0.14 % (as acid) in rinse-off products - 0.002 % (as acid) in leave-on products - 0.092 % (as acid) in	(b) Not to be used in any sprayable product (including mouth spray) that may lead to exposure of end-user's lungs. Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	(b) For leave-on products designed for children under three years of age: 'Do not use on the nappy area.'

						oral care products 0,8 % (as acid) for mixtures of substances mentioned in entries 12, 12a and 12b, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %		
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‘(***) From [12 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be placed on the Union market. From [24 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be made available on the Union market.’.

(4) in Annex V entries 16 and 17 are deleted (****).

‘(****) From [12 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be placed on the Union market. From [24 months following entry into force of this Regulation] cosmetic products containing these substances and not complying with the restrictions shall not be made available on the Union market.’.