



Council of the
European Union

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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 13 November 2023

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: [...] (2023) XXX draft

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 of the nanomaterials Styrene/Acrylates copolymer, Sodium Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold, Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and Colloidal Silver in cosmetics products

Delegations will find attached document [...] (2023) XXX draft.

Encl.: [...] (2023) XXX draft



Brussels, XXX
[...] (2023) XXX draft

ANNEX

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 of the nanomaterials Styrene/Acrylates copolymer, Sodium Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold, Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and Colloidal Silver in cosmetics products

D093318/01**ANNEX**

Annexes II and III are amended as follows:

(1) in Annex II, the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
X [OP: please replace with the next consecutive number]	Styrene/Acrylates copolymer (nano) [INCI]* Sodium Styrene/Acrylates copolymer (nano) [INCI]*	9010-92-8	927-710-1
X [OP: please replace with the next consecutive number]	Copper (nano) [INCI]*, Colloidal Copper (nano) [INCI]*	7440-50-8	231-159-6
X [OP: please replace with the next consecutive number]	Colloidal silver (nano) [INCI]*	7440-22-4	231-131-3
X [OP: please replace with the next consecutive number]	Gold (nano) [INCI]*, Colloidal Gold (nano) [INCI] [1]* Gold Thioethylamino Hyaluronic Acid (nano) [INCI] [2]* Acetyl heptapeptide-9 Colloidal gold (nano) [INCI] [3]*	7440-57-5 [1] 1360157-34-1 [2] - [3]	231-165-9 [1] - [2] - [3]
X [OP: please replace with the	Platinum (nano) [INCI]*, Colloidal Platinum (nano) [INCI] [1]* Acetyl tetrapeptide-17 Colloidal Platinum (nano) [INCI] [2]*	7440-06-4 [1] - [2]	231-116-1 [1] - [2]

next consecutive number]			
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* From ... [OP please insert the date = the first day of the month following 9 months after the date of entry into force of this Regulation] cosmetic products containing that substance shall not be placed on the Union market. From ... [OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] cosmetic products containing that substance shall not be made available on the Union market.’

(2) in Annex III, the following entry is 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 use preparation	Other	
a	b	c	d	e	f	g	d	h
‘x [OP: please replace with the next consecutive number]	Hydroxyapatite*	Hydroxyapatite (nano)	1306-06-5	215-145-7	(a) Toothpaste (b) Mouthwash	(a) 10 % (b) 0,465 %	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 which at least 95,8 % (in particle number) have an aspect ratio less than 3, and the remaining 4,2 % have an aspect ratio not exceeding 4,9; -the particles are not coated or surface modified	
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* From ... [OP please insert the date = the first day of the month following 9 months from the date of entry into force of this Regulation] cosmetic products containing that substance and not complying with the restrictions shall not be placed on the Union market. From ... [OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] cosmetic products containing that substance shall not be made available on the Union market.