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

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To: General Secretariat of the Council

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No. Cion doc.: [...] (2022) XXX draft - D081971 ANNEX

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Subject: ANNEX to the Commission Regulation (EU) .../... amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic products

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Delegations will find attached document [...] (2022) XXX draft - D081971 ANNEX.

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Encl.: [...] (2022) XXX draft - D081971 ANNEX



Brussels, XXX  
[...] (2022) 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 of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic products**

**D081971/01**

**ANNEX**

Regulation (EC) No 1223/2009 is amended as follows:

(1) In Annex III, the following entries are added:

Reference number	Substance identification				Restrictions			Wordings 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	h	i
'OP: please insert the next consecutive number	2,6-Di-Tert-Butyl-4-Methylphenol*	Butylated Hydroxytoluene	128-37-0	204-881-4	a) Mouthwash b) Toothpaste c) Other leave-on and rinse-off products	a) 0,001 % b) 0,1 % c) 0,8 %		
OP: please insert the next consecutive number	1H-Indene-1,3(2H)-dione, 2-(2-quinolinyl)-, sulfonated, sodium salts (CI 47005)**,**	Acid Yellow 3	8004-92-0	305-897-5	Non-oxidative hair dye products	0,5 %		

\* From ... [OP please insert the date = first day of the month following 6 months after 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 = first day of the month following 12 months after the date of entry into force of this Regulation] cosmetic products containing that substance and not complying with the restrictions shall not be made available on the Union market.

\*\* From ... [OP please insert the date = first day of the month following 6 months after the date of entry into force of this Regulation] non-oxidative hair dye products containing that substance and not complying with the restrictions shall not be placed on the Union market. From ... [OP please insert the date = first day of the month following 12 months after the date of entry into force of this Regulation] non-oxidative hair dye products containing that substance and not complying with the restrictions shall not be made available on the Union market.

\*\*\* For use as a colorant, see Annex IV, entry No. 82.’.

(2) Annex VI is amended as follows:

(a) entry 3 is replaced by the following:

Reference number	Substance identification				Conditions			Wordings 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	h	i
‘3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester/Homosalate*	Homosalate	118-56-9	204-260-8	Face products with the exception of propellant spray products	7,34 %		

\* From ... [OP please insert the date = first day of the month following 24 months after the date of entry into force of this Regulation] cosmetic products containing that substance and not complying with the conditions shall not be placed on the Union market. From ... [OP please insert the date = first day of the month following 30 months after the date of entry into force of this Regulation] cosmetic products containing that substance and not complying with the conditions shall not be made available on the Union market.’;

(b) the following entries are added:

Reference number	Substance identification				Conditions			Wordings 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	h	i
'OP: please insert the next consecutive number	1,1'-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone	Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine	919803-06-8	485-100-6		10 % *		
OP: please insert the next consecutive number	1,1'-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone	Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano)	919803-06-8	485-100-6		10 % *	Only nanomaterials having the following characteristics are allowed: - Purity $\geq$ 97 % - Median particle size D50 (50 % of the number below this diameter): $\geq$ 50 nm of number size distribution.  Not to be used in applications that may lead to exposure of the end user's lungs by	

							inhalation.	
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\* In case of combined use of Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine and Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano), the sum shall not exceed 10 %.