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

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

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Subject: ANNEX to the Commission Regulation .../... amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regard the use of Vitamin A, Alpha-Arbutin and Arbutin and certain substances with potential endocrine disrupting properties in cosmetic products

Delegations will find attached document [...] (2023) XXX draft - D 093281/1 ANNEX.

Encl.: [...] (2023) XXX draft - D 093281/1 ANNEX



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

ANNEX

ANNEX

to the

Commission Regulation .../...

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council
as regard the use of Vitamin A, Alpha-Arbutin and Arbutin and certain substances with
potential endocrine disrupting properties in cosmetic products**

D093281/01

ANNEX

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

(1) In Annex II, the following entry is 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]	3-(4'-methylbenzylidene)-camphor*; [INCI: 4-Methylbenzylidene Camphor]	36861-47-9/38102-62-4	253-242-6/-

* 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 shall not be placed on the Union market. 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 shall not be made available on the Union market'.

(2) 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

‘X [OP: please replace with the next consecutive number]	Genisteol; 4',5,7-Trihydroxyisoflavone; 5,7-dihydroxy-3-(4-hydroxyphenyl)-4-benzopyrone*	Genistein	446-72-0	207-174-9		0,007 %		
X [OP: please replace with the next consecutive number]	Daidzeol; 4',7-Dihydroxyisoflavone; 7-hydroxy-3-(4-hydroxyphenyl)-4-benzopyrone*	Daidzein	486-66-8	207-635-4		0,02 %		
X [OP: please replace with the next consecutive number]	5-Hydroxy-2-(hydroxymethyl)-4H-pyran-4-one*	Kojic Acid	501-30-4	207-922-4	Face and hand products	1 %		
X [OP: please replace with the next consecutive number]	(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexan-1-yl)nona-2,4,6,8-tetraen-1-ol**	Retinol	11103-57-4/68-26-8	234-328-2/200-683-7	(a) Body lotion	(a) 0,05 % Retinol Equivalent (RE)		For any cosmetic product containing Retinol, Retinyl Acetate or Retinyl Palmitate the following, labelling is obligatory: ‘Contains Vitamin A. Consider your daily intake before use’.
	[(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexane	Retinyl Acetate	127-47-9	204-844-2	(b) other leave-on and rinse-off products	(b) 0,3 % RE		

	n-1-yl)nona-2,4,6,8-tetraenyl] acetate**							
	[(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexan-1-yl)nona-2,4,6,8-tetraenyl] hexadecanoate**	Retinyl Palmitate	79-81-2	201-228-5				
X [OP: please replace with the next consecutive number]	4-Hydroxyphenyl-alpha-D-glucopyranoside*	Alpha-Arbutin	84380-01-8	617-561-8	(a) Face cream (b) Body lotion	(a) 2 % (b) 0,5 %	Hydroquinone levels shall remain as low as possible in formulations containing alpha-Arbutin and shall not be higher than the unavoidable trace level.	
X [OP: please replace with the next consecutive number]	4-Hydroxyphenyl-beta-D-glucopyranoside*	Arbutin	497-76-7	207-850-3	Face cream	7 %	Hydroquinone levels shall remain as low as possible in formulations containing Arbutin and shall not be higher than the unavoidable trace level.	

* From ... [OP please insert the date = first day of the month following 9 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 18 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.’

** From ... [OP please insert the date = first day of the month following 18 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 36 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.’

(3) In Annex V, entries 23 and 25 are 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
‘23	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea* **	Triclocarban	101-20-2	202-924-1	All cosmetic products, with the exception of mouthwash.	0,2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene ≤ 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene ≤ 1 ppm Not to be used in toothpaste intended for children under 6 years of age.	For toothpaste containing Triclocarban the following labelling is obligatory: ‘ <i>Not to be used for children under 6 years of age</i> ’.

25	5-Chloro-2- (2,4-dichlorophenoxy) phenol*	Triclosan	3380-34-5	222-182-2	Toothpastes; Hand soaps; Body soaps/Shower gels; Deodorants (non-spray); Face powders and blemish concealers; Nail products for cleaning the fingernails and toenails before the application of artificial nail systems;	0,3 %	Not to be used in toothpaste intended for children under 3 years of age.	For toothpaste containing Triclosan the following labelling is obligatory: ' <i>Not to be used for children under 3 years of age</i> '.
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* Cosmetic products containing that substance that do not comply with the conditions may, provided that they comply with the conditions applicable on ... [OP: please insert the date = the day before the date of entry into force of this Regulation], be placed on the Union market until ... [OP: please insert the date = the last day of the 8th month after the date of entry into force of this Regulation] and, if they have already been placed on the market before that date, continue to be made available on the Union market until ... [OP: please insert the date = the last day of the 17th month after the date of entry into force of this Regulation].

** For uses other than preservative, see Annex III, No. 100.'

(4) In Annex VI, entry 18 is deleted.