

EUROPEAN COMMISSION

> Brussels, XXX [...](2022) XXX draft

ANNEXES 1 to 2

ANNEXES

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 classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation

<u>ANNEX I</u>

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

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

	Substance identification		
Reference number	Chemical name/INN	CAS number	EC number
a	b	С	d
'[OP: please insert the next consecutive number]	Tetrafluoroethylene	116-14-3	204-126-9
[OP: please insert the next consecutive number]	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol;[DBMC]	119-47-1	204-327-1
[OP: please insert the next consecutive number]	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone; pyriofenone	688046-61-9	692-456-8
[OP: please insert the next consecutive number]	(RS)-1-{1-ethyl-4-[4-mesyl-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5- yloxy}ethyl methyl carbonate; tolpyralate	1101132-67-5	701-225-3
[OP: please insert the next	Azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)- yl)methyl] O,O-dimethyl thiophosphate	35575-96-3	252-626-0

consecutive number]			
[OP: please insert the next consecutive number]	3-methylpyrazole	1453-58-3	215-925-7
[OP: please insert the next consecutive number]	N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3- (difluoromethyl)-1-methylpyrazole-4-carboxamide; pydiflumetofen	1228284-64-7	817-852-1
[OP: please insert the next consecutive number]	N-{2-[[1,1'-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-methyl- 1H-pyrazole-4-carboxamide; sedaxane	874967-67-6	688-331-2
[OP: please insert the next consecutive number]	4-methylpentan-2-one; isobutyl methyl ketone (MIBK)	108-10-1	203-550-1
[OP: please insert the next consecutive number]	Dimethomorph (ISO); (E,Z)-4-(3-(4-chlorophenyl)-3-(3,4- dimethoxyphenyl)acryloyl)morpholine	110488-70-5	404-200-2
[OP: please insert the next consecutive number]	Imazamox (ISO); (RS)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2- yl)-5-methoxymethylnicotinic acid	114311-32-9	601-305-7
[OP: please insert the next consecutive	Thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5- methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine	153719-23-4	428-650-4

number]			
[OP: please insert the next consecutive number]	Triticonazole (ISO); (RS)-(E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1- (1H-1,2,4-triazol-1-methyl)cyclopentanol	138182-18-0	-
[OP: please insert the next consecutive number]	Desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenylcarbamate	13684-56-5	237-198-5';

(2) in Annex III, the following entry is added:

	S	Substance ident	ification		Restrictions			Wentherse
Reference number	Chemical Name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	Wording of conditions of use and warnings
a	b	с	d	е	f	g	h	i
'[OP: please insert the next consecuti ve number]	Methyl 2- hydroxybenzoate	Methyl Salicylate	119-36-8	204-317-7	 (a) Leave-on skin products (except face makeup, spray/aerosol body lotion, spray/aerosol deodorant and hydroalcoholic- based fragrances) and 	(a) 0,06 %	Not to be used in preparations for children under 6 years of age.'.	

		leave on hair products		
		(except spray/aerosol		
		products)		
		(b) Face makeup	(b) 0,05 %	
		(except lip products, eye makeup and		
		makeup remover)		
		maneup remover)		
		(c) Eye makeup and	(c) 0,002 %	
		makeup remover		
		(d) Leave-on hair	(d) 0,009 %	
		products		
		(spray/aerosol)		
		(e) Deodorant	(e) 0,003 %	
		spray/aerosol		
		(f) Body lotion	(f) 0,04 %	
		spray/aerosol		
		(a) Dince off skin	(g) 0,06 %	
		(g) Rinse-off skin products (except hand	(g) 0,00 %	
		wash) and rinse-off hair		
		products		
		(h) Hand wash	(h) 0,6 %	
		(i) Hydroalcoholic-	(i) 0,6 %	

		based fragrances		
		(j) Lip products	(j) 0,03 %	
		(k) Toothpaste	(k) 2,52 %	
		(1) Mouthwash intended for children aged 6–10 years	(1) 0,1 %	
		(m) Mouthwash intended for children above 10 years of age and adults	(m) 0,6 %	
		(n) Mouth spray	(n) 0,65 %	

ANNEX II

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

(1) in Annex II, entry 1669 is deleted;

(2) in Annex V, entry 51 is replaced by the following:

Reference number	Su	bstance identi	fication		С	onditions		Wording of conditions
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	of use and warnings
a	b	с	d	e	f	g	h	i
·51	Sodium N- (hydroxymethyl)gl ycinate	Sodium Hydroxym ethylglycin ate	70161- 44-3	274-357-8		0,5 %	Not to be used if it cannot be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the	

			market is $\geq 0,1$	
			% w/w'.	