



Council of the  
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ADD 1

ENT 61  
MI 336  
COMPET 280  
SAN 236  
ENV 378  
CHIMIE 40  
CONSOM 102  
ECO 33

#### COVER NOTE

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

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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No. Cion doc.: [...] (2022) XXX draft - D081047/1 - Annexes 1-2

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Subject: 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

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Delegations will find attached document [...] (2022) XXX draft - D081047/1 - Annexes 1-2.

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Encl.: [...] (2022) XXX draft - D081047/1 - Annexes 1-2



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**

**D081047/01**

**ANNEX I**

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

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

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
<b>a</b>	<b>b</b>	<b>c</b>	<b>d</b>
[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 consecutive number]	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
[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 number]	Thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine	153719-23-4	428-650-4
[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-phenylcarbamoxyloxyphenylcarbamate	13684-56-5	237-198-5';

(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 for use preparation	Other	
a	b	c	d	e	f	g	h	i
[OP: please insert the next consecutive 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	(a) 0,06 %	Not to be used in preparations for children	

ve number]					<p>and hydroalcoholic-based fragrances) and leave on hair products (except spray/aerosol products)</p> <p>(b) Face makeup (except lip products, eye makeup and makeup remover)</p> <p>(c) Eye makeup and makeup remover</p> <p>(d) Leave-on hair products (spray/aerosol)</p> <p>(e) Deodorant spray/aerosol</p> <p>(f) Body lotion spray/aerosol</p> <p>(g) Rinse-off skin products (except hand wash) and rinse-off hair products</p> <p>(h) Hand wash</p>	<p>(b) 0,05 %</p> <p>(c) 0,002 %</p> <p>(d) 0,009 %</p> <p>(e) 0,003 %</p> <p>(f) 0,04 %</p> <p>(g) 0,06 %</p>	<p>under 6 years of age, with the exception of (k) "Toothpaste".</p>	
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					(h) 0,6 %		
				(i) Hydroalcoholic-based fragrances	(i) 0,6 %		
				(j) Lip products	(j) 0,03 %		
				(k) Toothpaste	(k) 2,52 %		
				(l) Mouthwash intended for children aged 6–10 years	(l) 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	Substance identification				Conditions			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
'51	Sodium N-(hydroxymethyl)glycinate	Sodium Hydroxymethylglycinate	70161-44-3	274-357-8		0,5 %	Not to be used unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the	



							market is < 0,1 % w/w?	
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