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

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

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Subject: ANNEX to the Commission Regulation (EU) .../... amending Annexes II, III and V to 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

Delegations will find attached document D073715/21 ADD1.

Encl: D073715/21



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ANNEX

ANNEX

to the

Commission Regulation (EU) .../...

amending Annexes II, III and V to 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

ANNEX

Annexes II, III and V 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	Silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	409-21-2 308076-74-6	206-991-8
X	Tris(2-methoxyethoxy) vinylsilane; 6-(2-methoxyethoxy)- 6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	1067-53-4	213-934-0
X	Dioctyltin dilaurate; [1] stannane, dioctyl-, bis (coco acyloxy) derivs. [2]	3648-18-8 [1] 91648-39-4 [2]	222-883-3 [1] 293-901-5 [2]
X	Dibenzo[def,p]chrysene; dibenzo[a,l]pyrene	191-30-0	205-886-4
X	Ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1- (1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	125225-28-7 115850-69-6 115937-89-8	-
X	Bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme	143-24-8	205-594-7
X	Paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl- 2-(1H-1,2,4-triazol-1- yl)pentan-3-ol	76738-62-0	-
X	2,2-bis(bromomethyl) propane-1,3-diol	3296-90-0	221-967-7
X	2-(4-tert-butylbenzyl) propionaldehyde	80-54-6	201-289-8

X	Diisooctyl phthalate	27554-26-3	248-523-5
X	2-methoxyethyl acrylate	3121-61-7	221-499-3
X	Sodium N-(hydroxymethyl)glycinate; [formaldehyde released from sodium N-(hydroxymethyl)glycinate] if 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	70161-44-3	274-357-8
X	Pyrithione zinc; (T-4)- bis[1-(hydroxy- .kappa.O)pyridine-2(1H)- thionato- .kappa.S]zinc	13463-41-7	236-671-3
X	Flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one	61213-25-0	262-661-3
X	3-(difluoromethyl)-1- methyl-N-(3',4',5'-trifluorobiphenyl-2-yl) pyrazole-4-carboxamide; fluxapyroxad	907204-31-3	-
X	N-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]	924-42-5	213-103-2
X	5-fluoro-1,3-dimethyl-N-[2-(4- methylpentan-2-yl) phenyl]-1H-pyrazole- 4-carboxamide; 2'- [(RS)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carboxanilide; penflufen	494793-67-8	-
X	Iprovalicarb (ISO); isopropyl [(2S)-3- methyl-1- {[1-(4-methylphenyl)ethyl] amino}-1-oxobutan-2- yl]carbamate	140923-17-7	-
X	Dichlorodiocetylstannane	3542-36-7	222-583-2
X	Mesotrione (ISO); 2-[4-(methylsulfonyl)- 2-nitrobenzoyl]-1,3-cyclohexanedione	104206-82-8	-
X	Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	10004-44-1	233-000-6

X	Imiprothrin (ISO); reaction mass of [2,4- dioxo-(2-propyn-1-yl) imidazolidin-3-yl] methyl(1R)-cis-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl) imidazolidin-3-yl] methyl(1R)-trans-chrysanthemate	72963-72-5	428-790-6
X	Bis(α,α -dimethylbenzyl) peroxide	80-43-3;	201-279-3'

(2) in Annex III is amended as follows:

a) entry 24 is replaced by the following:

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
'24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate (entry 25) and zinc pyrithione	Zinc acetate, zinc chloride, zinc gluconate, zinc glutamate				1 % (as zinc)'		

	(Annex II, entry X)							
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b) entries 83 and 101 are deleted;

(3) Annex V is amended as follows:

a) entry 8 is deleted;

b) 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 hydroxymethylamino acetate	Sodium Hydroxymethylglycinate	70161-44-3	274-357-8		0,5 %	Not to be used if the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, if the mixture as placed on the market	

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