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Subject: ANNEXES to the Commission Regulation (EU) .../... amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Delegations will find attached document D062738/02-Annexes.

Encl.: D062738/02-Annexes



Brussels, **XXX**
[...] (2019) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

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

**amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the
European Parliament and of the Council on cosmetic products**

D062738/02

ANNEX I

(1) Annex II to Regulation (EC) No 1223/2009 is amended as follows:

The following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
x	Phosmet (ISO); <i>S</i> -[(1,3-dioxo-1,3-dihydro-2 <i>H</i> - isoindol-2-yl)methyl]- <i>O,O</i> -dimethyl phosphorodithioate; <i>O,O</i> -dimethyl- <i>S</i> -phthalimidomethyl phosphorodithioate	732-11-6	211-987-4
x	Potassium permanganate	7722-64-7	231-760-3
x	2-Benzyl-2-dimethylamino-4'- morpholinobutyrophenone	119313-12-1	404-360-3
x	Quinalofop- <i>p</i> -tefuryl (ISO); (+/-) tetrahydrofurfuryl (<i>R</i>)-2-[4-(6- chloroquinoxalin-2-yloxy)phenoxy]propionate	200509-41-7	414-200-4
x	Propiconazole (ISO); (2 <i>RS</i> ,4 <i>RS</i> ;2 <i>RS</i> ,4 <i>SR</i>)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3- dioxolan-2-yl]methyl}-1 <i>H</i> -1,2,4-triazole	60207-90-1	262-104-4
x	Pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7 <i>H</i> -pyrazolo[1,2- <i>d</i>][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate	243973-20-8	635-361-9
x	Tetramethrin (ISO);	7696-12-0	231-711-6

	(1,3-dioxo-1,3,4,5,6,7-hexahydro-2 <i>H</i> -isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate		
x	(1,3,4,5,6,7-Hexahydro-1,3-dioxo-2 <i>H</i> -isoindol-2-yl)methyl (1 <i>R</i> -trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	1166-46-7	214-619-0
x	Spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	148477-71-8	604-636-5
x	Reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-([2-(2-aminobutoxy)ethoxy]methyl)propoxy) but-2-ylamine	897393-42-9	447-920-2
x	1-Vinylimidazole	1072-63-5	214-012-0
x	Amisulbrom (ISO)3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)- <i>N,N</i> -dimethyl-1 <i>H</i> -1,2,4-triazole-1-sulfonamide	348635-87-0	672-776-4"

(2) Annex III to Regulation (EC) No 1223/2009 is amended as follows:

Entry 98 is replaced by the following:

"98	Benzoic acid, 2-hydroxy- (c)	Salicylic acid	69-72-7	200-712-3	(a) Rinse-off hair products (b) Other products except body lotion, eye shadow, mascara, eyeliner,	(a) 3,0 % (b) 2,0 %	Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of	Not to be used for children under 3 years of age"***
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					lipstick, roll on deodorant		the end-user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro- organisms in the product. This purpose has to be apparent from the presentation of the product.	
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(* For use as a preservative see Annex V, No 3.

** Solely for products which might be used for children under 3 years of age."

(3) Annex V to Regulation (EC) No 1223/2009 is amended as follows:

Entry 3 is replaced by the following:

	Substance Identification	Conditions	Word ing of
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Reference number								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
'3	Salicylic acid (*) and its salts	Salicylic acid	69-72-7	200-712-3		0,5 % (acid)	Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs	Not to be used for children under 3 years of age**

		Calcium salicylate, magnesium salicylate, MEA- salicylate, sodium salicylate, potassium salicylate, TEA- salicylate	824-35-1, 18917-89-0, 59866-70-5, 54-21-7, 578- 36-9, 2174-16- 5	212-525-4, 242-669-3, 261-963-2, 200-198-0, 209-421-6, 218-531-3		0,5 % (acid)	by inhalation. Not to be used in products for children under 3 years of age, except for shampoos.	Not to be used for childr en under 3 years of age ***
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* For uses other than preservative, see Annex III, No 98.

** Solely for products which might be used for children under 3 years of age

*** Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin."

ANNEX II

(1) Annex II to Regulation (EC) No 1223/2009 is corrected as follows:

(a) entry 395 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
"395	Hydroxy-8-quinoline and its sulphate bis(8-hydroxyquinolinium) sulphate, except for the uses of the sulphate provided for in entry 51 of Annex III	148-24-3	205-711-1
		134-31-6	205-137-1"

(b) entry 1396 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
"1396	Borates, tetraborates, octaborates and boric acid salts and esters, including:		
	Disodium octaborate anhydrous [1]	12008-41-2 [1]	234-541-0 [1]
	Disodium octaborate tetrahydrate [2]	12280-03-4 [2]	234-541-0 [2]
	2-Aminoethanol, monoester with boric acid [3]	10377-81-8 [3]	233-829-3 [3]
2-Hydroxypropyl ammonium dihydrogen orthoborate [4]	68003-13-4 [4]	268-109-8 [4]	

Potassium borate, boric acid potassium salt [5]	12712-38-8 [5]	603-184-6 [5]
Trioctyldodecyl borate [6]		
Zinc borate [7]	- [6]	- [6]
Sodium borate, disodium tetraborate anhydrous; boric acid, sodium salt [8]	1332-07-6 [7] 1330-43-4 [8]	215-566-6 [7] 215-540-4 [8]
Tetraboron disodium heptaoxide, hydrate [9]		
Orthoboric acid, sodium salt [10]	12267-73-1 [9]	235-541-3 [9]
Disodium tetraborate decahydrate; borax decahydrate [11]	13840-56-7 [10]	237-560-2 [10]
Disodium tetraborate pentahydrate; borax pentahydrate [12]	1303-96-4 [11]	215-540-4 [11]
	12179-04-3 [12]	215-540-4 [12]”

(c) entry 1507 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
“1507	Diaminotoluene, methyl-phenylenediamine, technical product-reaction mass of [4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine]	—	—

(d) the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
“x	Pirimicarb (ISO); 2-(dimethylamino)-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	23103-98-2	245-430-1
x	1,2-Dichloropropane; propylene dichloride	78-87-5	201-152-2
x	Phenol, dodecyl-, branched [1] Phenol, 2-dodecyl-, branched [2] Phenol, 3-dodecyl-, branched [3] Phenol, 4-dodecyl-, branched [4] Phenol, (tetrapropenyl) derivatives [5]	121158-58-5 [1] 1801269-80-6 [2] 1801269-77-1 [3] 210555-94-5 [4] 74499-35-7 [5]	310-154-3 [1] - [2] - [3] 640-104-9 [4] 616-100-8 [5]
x	Coumatetralyl (ISO); 4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl) coumarin	5836-29-3	227-424-0
x	Difenacoum (ISO); 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	56073-07-5	259-978-4
x	Brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	56073-10-0	259-980-5
x	Flocoumafen (ISO); reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin and trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-	90035-08-8	421-960-0

	trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin		
x	Acetochlor (ISO); 2- chloro- <i>N</i> -(ethoxymethyl)- <i>N</i> -(2-ethyl-6-methylphenyl)acetamide	34256-82-1	251-899-3
x	e-Glass microfibres of representative composition	-	-
x	Glass microfibres of representative composition	-	-
x	Bromadiolone (ISO); 3- [3-(4'-bromobiphenyl- 4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy- 2 <i>H</i> -chromen-2-one	28772-56-7	249-205-9
x	Difethialone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]- 4-hydroxy-2 <i>H</i> -1-benzothiopyran-2-one	104653-34-1	600-594-7
x	Perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	375-95-1 [1] 21049-39-8 [2] 4149-60-4 [3]	206-801-3 [1] - [2] - [3]
x	Dicyclohexyl phthalate	84-61-7	201-545-9
x	3,7-Dimethylocta-2,6- dienenitrile	5146-66-7	225-918-0
x	Bupirimate (ISO); 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulfamate	41483-43-6	255-391-2
x	Triflumizole (ISO); (1 <i>E</i>)- <i>N</i> -[4-chloro-2-(trifluoromethyl)phenyl]-1- (1 <i>H</i> -imidazol-1-yl)-2- propoxyethanimine	68694-11-1	604-708-8

x	<i>tert</i> -Butyl hydroperoxide	75-91-2	200-915-7”
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(2) Annex III to Regulation (EC) No 1223/2009 is corrected as follows:

(a) entry 9 is replaced by the following:

Ref No.	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
'9	Methylphenylenediamines, their N-substituted derivatives and their salts (1), with the exception of the substance listed under reference numbers 9 a and 9 b of this Annex and the substances listed under reference numbers 364,				Hair dye substance in oxidative hair dye products		(a) General use	(a) To be printed on the label: The mixing ratio. ⚠ Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy.

	413, 1144, 1310, 1313 and 1507 of Annex II						<p>(b) Professional use</p> <p>For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 5 % calculated as free base</p>	<p>Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.</p> <p>Contains phenylenediamines (toluenediamines).</p> <p>Do not use to dye eyelashes or eyebrows.’</p> <p>(b) To be printed on the label:</p> <p>The mixing ratio.</p> <p>‘For professional use only Hair colourants can cause severe</p>
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								<p>allergic reactions.</p> <p>Read and follow instructions.</p> <p>This product is not intended for use on persons under the age of 16.</p> <p>Temporary “black henna” tattoos may increase your risk of allergy.</p> <p>Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp,</p> <p>— you have ever experienced any reaction after colouring your hair,</p> <p>— you have experienced a reaction to a temporary “black henna” tattoo in the past.</p> <p>Contains phenylenediamines (toluenediamines).</p>
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