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COVER NOTE

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

date of receipt: 25 January 2021

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

No. Cion doc.: [...] (2021) XXX draft - Annex to D 071191/01

Subject: ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending and correcting Annex II and amending Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Delegations will find attached document [...] (2021) XXX draft - Annex to D 071191/01.

Encl.: [...] (2021) XXX draft - Annex to D 071191/01



Brussels, **XXX**
[...](2021) **XXX** draft

ANNEX

ANNEX

to the

**COMMISSION REGULATION (EU) .../...
of XXX**

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

D071191/01

ANNEX

Regulation (EC) No 1223/2009 is amended as follows:
(1) in Annex II the following entries are added:

Reference number	Substance identification			EC number
	Chemical name/INN	CAS number		
	a	b	c	d
'x		Cobalt	7440-48-4	231-158-0
x		Metalddehyde (ISO); 2,4,6,8-tetramethyl- 1,3,5,7-tetraoxacyclooctane	108-62-3	203-600-2
x		Methylmercuric chloride	115-09-3	204-064-2
x		Benzo[<i>rst</i>]pentaphene	189-55-9	205-877-5
x		Dibenzo[<i>b,def</i>]chrysene; dibenzo[<i>a,h</i>]pyrene	189-64-0	205-878-0
x		Ethanol, 2,2'-iminobis-, N- (C13-15-branched and linear alkyl) derivs.	97925-95-6	308-208-6
x		Cyflumetofen (ISO); 2-methoxyethyl (RS)-2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α -trifluoro- <i>o</i> -tolyl)propionate	400882-07-7	-

x	Diisohexyl phthalate	71850-09-4	276-090-2
x	halosulfuron-methyl (ISO); methyl 3-chloro-5-[[[(4,6-dimethoxypyrimidin-2-yl) carbamoyl]sulfamoyl]-1- methyl-1H-pyrazole-4- carboxylate	100784-20-1	-
x	2-methylimidazole	693-98-1	211-765-7
x	Metaflumizone (ISO); (E)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [E-isomer \geq 90 %, Z-isomer \leq 10 % relative content]; [1] (E)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2]	139968-49-3 [1] 852403-68-0 [2]	-
x	Dibutylbis(pentane-2,4- dionato-O,O')tin	22673-19-4	245-152-0';

(2) Annex III is amended as follows:
(a) entry 98 is replaced by the following:

Reference number	Substance identification			Restrictions			Wording of conditions 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
'98	Benzoic acid, 2-hydroxy-(1)	Salicylic acid	69-72-7	200-712-3	(a) Rinse-off hair products (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant (c) Body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant	(a) 3,0 % (b) 2,0 % (c) 0,5 %	(a) (b) (c) 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 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. These levels are inclusive of any use of salicylic acid.	(a) (b) (c) Not to be used for children under 3 years of age (2)

- (1) For use as a preservative, see Annex V, No 3.
 (2) Solely for products which might be used for children under 3 years of age.
 (b) 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
'x	Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 215-280-1/ 215-282-2	(a) face products in loose powder form (b) hair aerosol spray products (c) other products	(a) 25%; (b) 1.4 % for general consumers, and 1.1 % for professional use.	(a) (b) Only in the pigmentary form (c) Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation;	

(3) in Annex IV 143 is replaced by the following:

Reference number	Substance identification				Conditions				Wording of conditions and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
143	Titanium dioxide (1)	77891		236-675-5	White			<ul style="list-style-type: none"> - Purity criteria as set out in Commission Directive 95/45/E (E 171) - Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$, to be used in compliance with Annex III, No. [...] 	

‘(1) For use as a UV filter, see Annex VI, No. 27.’;
 (4) in Annex VI entry 27 is replaced by the following:

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical name/INN/XAN	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	
27	Titanium dioxide ⁽²⁾	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 215-280-1/ 215-282-2		25 % ⁽⁴⁾	Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm, to be used in compliance with Annex III, No. [...] For the product types under letter (c) of column (f) in Annex III, No [...], the maximum concentration in ready for use preparation provided in column (g) of this entry applies.		

‘(2) For use as a colorant, see Annex IV, No 143.’