Commission Implementing Directive 2012/21/EU of 2 August 2012 amending, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products (Text with EEA relevance)

COMMISSION IMPLEMENTING DIRECTIVE 2012/21/EU

of 2 August 2012

amending, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

- (1) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, subsequently replaced by the Scientific Committee on Consumer Products ('SCCP'), pursuant to Commission Decision 2004/210/EC⁽²⁾, concluded that the potential risks were of concern. The SCCP recommended that the Commission take further steps to control the use of hair dye substances.
- (2) The SCCP further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity or mutagenicity.
- (3) Following the opinions of the SCCP, the Commission agreed with Member States and stakeholders on an overall strategy to regulate substances used in hair dye products according to which the industry was required to submit files, containing updated scientific data on the safety of hair dye substances, for a risk assessment by the SCCP.
- (4) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS') pursuant to Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC⁽³⁾, assessed the safety of individual substances for which updated files had been submitted by industry.
- (5) The last step of the safety assessment strategy was to evaluate possible consumer health risk by reaction products formed by oxidative hair dye substances during the hair dyeing

- process. Based on the data yet available, the SCCS raised in its opinion of 21 September 2010 no major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the EU.
- (6) In the light of the risk assessment of the submitted safety data and the final opinions given by the SCCS on the safety of individual substances and of the reaction products, it is appropriate to include in Part 1 of Annex III to Directive 76/768/EEC 24 assessed hair dyes which are not regulated within Directive 76/768/EEC.
- (7) The substances Hydroxyethyl-2-Nitro-p-Toluidine and HC Red No 10 + HC Red No 11 were provisionally authorised for use in hair dye products until 31 December 2011 under the restrictions and conditions laid down in entries 10 and 50 in Part 2 of Annex III to Directive 76/768/EEC. Based on the final opinions given by the SCCS on their safety, Hydroxyethyl-2-Nitro-p-Toluidine and HC Red No 10 + HC Red No 11 can be considered safe in hair dye products and listed in Part 1 of Annex III to Directive 76/768/EEC.
- (8) Following the assessment by the SCCS concerning the substances 1-Naphthol and Resorcinol, listed in Part 1 of Annex III to Directive 76/768/EEC, their maximum authorised concentrations in the finished cosmetic product should be changed.
- (9) Concerning the substance HC Red No 16, the SCCS stated in its opinion of 14 December 2010 that based on the low margin of safety for the use in both oxidative and non-oxidative hair dye formulations, HC Red No 16 poses a risk to the health of the consumer. Therefore, HC Red No 16 should be listed in Annex II to Directive 76/768/EEC.
- (10) Directive 76/768/EEC should therefore be amended accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and III to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

1 Member States shall adopt and publish, by 1 March 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 September 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 2 August 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Directive 76/768/EEC is amended as follows:

(1) in Annex II, the following entry is added:

Ref. No	Chemical name	CAS No / EC No
' 1373	N-(2-Nitro-4- aminophenyl)-allylamine (HC Red No 16) and its salts	CAS No 160219-76-1'

- (2) Annex III is amended as follows:
 - (a) Part 1 is amended as follows:
 - (i) the following entries are added:

Ref. No	Substanc	Conditions			
		Field of applicati and/or use	Max. authoriso owoncentr in the finished cosmetic product	Other edimitation a tion requiren	warnings
a	b	c	d	e	f
[°] 253	2,2'-[(4- Aminophe sulphate N,N- bis(2- Hydroxye p- Phenylene Sulfate CAS No 54381-16- EC No 259-134-5	in oxidative hair dye the hair dye they believes diamine]bis(ethano	under oxidative conditions the maximum concentrat applied to hair must not exceed 2,5 % (calculated as sulphate)	number 205, column f ii(n)

				- 1 - 1 1	content: 50 µg/ kg Keep n nitrite- free containers	_
254	1,3- Benzenedi 4-chloro- 4- Chlororese CAS No 95-88-5 EC No 202-462-0	products		conditions	205, column f	i
255	gulphoto	opyrimidin i i i i i	μyC		nixing inder	number 205, column
		; ; ; ; ;	lye (ubstance a	3,4 % calculated as sulphate)		

256	p-	diamine		After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 2,0 % (calculated as sulphate)	number 205, column f i(xr)	;
257	1H- Indole-5,6 diol Dihydroxy CAS No 3131-52-0 EC No 412-130-9	vindole	Hair dye substance in oxidative hair dye products	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Affaer mixing under exidative conditions he maximum concentrat applied o hair must not exceed 0,5 %	number 205, column
		; ; ;	Hair dye substance in non- oxidative hair dye products	0,5 %	(b)	As mentioned in reference number 208, column f
258	5- Amino-4- chloro-2- methylphe hydrochlo 5- Amino-4- Chloro- o-Cresol HCl	in noxlidative		After mixing under oxidative conditions the maximum concentrate applied to hair	205, column f	;

	CAS No 110102-85	5-7		must not exceed 1,5 % (calculated as hydrochlo	
259	1H- Indol-6- ol 6- Hydroxyir CAS No 2380-86-1 EC No 417-020-4	products		After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 0,5 %	205, column f
260	1H-Indole-2,3 Dione Isatin CAS No 91-56-5 EC No 202-077-8	Hair dye -substance in non- oxidative hair dye products	1,6 %		As mentioned in reference number 208, column f
261	2- Aminopyr ol 2- Amino-3- Hydroxyp CAS No 16867-03- EC No 240-886-8	ypridihects 1		After mixing under oxidative conditions the maximum concentrat applied to hair must not exceed 1,0 %	205, column f
262	2- Methyl-1- naphthyl acetate 1- Acetoxy-2 Methylnap CAS No 5697-02-9 EC No 454-690-7	in oxidative hair dye products ohthalene		After mixing under oxidative conditions the maximum concentrat applied to hair must not	205, column f

			exceed 2,0 % (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2 Methylnapare present in a hair dye formulation the maximum concentration the head of 2-Methyl-1-Naphthol should not exceed 2,0 %.)	ohthalene on,
263	methylnap 2- Methyl-1-	oxidative hair dye products	After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 2,0 % (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2 Methylnagare present in a hair dye formulation the	205, column f i(a)

				maximum concentration the head of 2- Methyl-1- Naphthol should not exceed 2,0 %.)	l .	
264	Disodium 5,7- dinitro-8- oxido-2- naphthaler Acid Yellow 1 CAS No 846-70-8 EC No 212-690-2 CI 10316	nesulfonato	Hair dye substance in oxidative hair dye products	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Atter mixing inder oxidative conditions he maximum concentration pplied omair must not exceed	number 205, column
			Hair dye substance in non- oxidative hair dye products	0,2 %	(b)	As mentioned in reference number 208, column f
265	4- Nitro-1,2- phenylene 4-Nitro- o- Phenylene CAS No 99-56-9 EC No 202-766-3	oxidative hair dye diamlinets		After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 0,5 %	205, column f	

266	Amino-3- s nitroanilind HC Red No 7	inethanol oxidative hair dye products	1,0 %	_	DAs notentioned use witherence nitrosating agelas Marimum nitrosamine content: 50 µg/ kg Keep in nitrite- free containers
267	Yellow	sybstanino In non- oxidative hair dye products	1,5 %]-5-	_	Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in nitrite- free containers
268	2-[(2- Nitropheny HC Yellow No 2 CAS No 4926-55-0 EC No 225-555-8	(b) I	Hair Italianol Iye substance n exidative hair Iye substance n non- exidative hair lye products	(a) For (a) and (b):	After As mixing mentioned under in oxidative reference conditions number the 205, maximum column concentration applied (a) to hair must not exceed 0,75 %

		_	wise with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in nitrite- free containers
269	4-[(2- Hair dye Nitrophen Al) dustined HC in non- oxidative hair dye CAS No 54381-08-7 EC No 259-132-4	phenol	
270	2-Nitro- N1- phenyl- benzene-1, 4xidative diamine HC Red No 1 CAS No 2784-89-6 EC No 220-494-3	e	As mentioned in reference number 208, column f
271	1- Hair dye Methoxy-3substanc (β- in non- aminoethyl)xiidiative nitrobenze hair dye hydrochloride ducts HC Yellow No 9 CAS No 86419-69-4 EC No 415-480-1	e (calculated as hydrochloride)	Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in nitrite- free containers

272	1-(4'- Hair dy Aminophersylbsta) methyl-4- in non- (bis-2- oxidative hydroxyethyd)r dye aminobenzpnoduct HC Yellow No 7 CAS No 104226-21-3 EC No 146-420-6	Де /е		
273	N-(2- Hydroxyethyl)-2- nitro-4- trifluormethyl- aniline HC Yellow No 13 CAS No 10442-83-8 EC No 443-760-2 (b)	Hair dye substance in oxidative hair dye products H(di) dye substance in non-oxidative hair dye products	(a) 2,5 % For (a) and (b):	After As mixing mentioned under in oxidative reference conditions number the 205, maximum column concentration applied (a) to hair must not exceed 2,5 % Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
274	Benzenam iHaimdy 3-[(4,5- dihydro-3- in non- methyl-5- oxo-1-	ce		

Ethanol, 2,2'- [[4-[(4- aminopher Disperse Black 9 CAS No 20721-50- EC No 243-987-5 9,10- Anthracen	hair dye products 0 Hair dye	mixture inylimino ratio 1:1 of 2,2'- [4-(4-	nylazo)phe te)	nylimino]die	ethanol
		0.3 %			
1,4- bis[(2,3- dihydroxy HC Blue No 14 CAS No	in non- oxidative products		— I	nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep nitrite- free	
nitroanilin Hydroxye Nitro-p- Toluidine CAS No 100418-33 EC No	o)ethanol (sthyl-2- sthyl-2- sthyl-3-5 sthyl-3	lye substance n oxidative nair lye oroducts	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	nixing mander in exidative reconditions nutbe 20 maximum concentration applied (a o mair	entioned eference umber 05, olumn
	bis[(2,3-dihydroxy) HC Blue No 14 CAS No 99788-75-EC No 421-470-7	bis[(2,3-dihydroxy traipyd)am; HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7 2-(4-Methyl-2-nitroanilino)ethanol Hydroxyethyl-2-Nitro-p-Toluidine CAS No 100418-33-5 EC No 408-090-7 (b)	bis[(2,3- oxidative dihydroxy throipyd)æmino]- HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7 2-(4- Methyl-2- nitroanilino)ethanol Hydroxyethyl-2- Nitro-p-Toluidine CAS No 100418-33-5 EC No 408-090-7	bis[(2,3- oxidative dihydroxy haipyd)æmino]- HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7 2-(4- Methyl-2- nitroanilino)ethanol dye Hydroxyethyl-2- in oxidative hair 100418-33-5 EC No 408-090-7 (b) H(ai) 1,0 % dye	bis[(2,3- dihydroxyphrajpyd)amino]- HC Blue products No 14 CAS No 99788-75-7 EC No 421-470-7

		i 1 0	substance n non- oxidative nair dye oroducts	For (a) and (b): —	exceed 1,0 % Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
278	+ 1,4- bis- (2',3'-	propyl)am zene l propyl)am zene l	nair lye products ino-2-	(a) 2,0 % For (a) and (b): —	After As mixing mentioned under in oxidative reference conditions number the 205, maximum column concentration applied (a)' to hair must not exceed 1,0 % Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-

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(ii) the entries with reference numbers 16 and 22 are replaced by the following:

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			2.	comes into contact with them. As mentioned in reference number 205, column f (a). For professional use only Contains resorcinol. Rinse eyes immediately if product comes into contact with them. As mentioned in reference number 205, column f (a)
	H(di) lotions and shampoos	0,5 %	(b)	Contains resorcinol.'

(b) in Part 2 the entries with reference numbers 10 and 50 are deleted.

- **(1)** OJ L 262, 27.9.1976, p. 169.
- (2) OJ L 66, 4.3.2004, p. 45.
- (**3**) OJ L 241, 10.9.2008, p. 21.