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<sup>(1)</sup>, 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<sup>(2)</sup>, 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<sup>(3)</sup>, 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.
- 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.

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## 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
<b>'</b> 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	Max.	Other	of use
		of	authorise	dimitatio	
			orconcentr	a <b>tàod</b>	warnings
		and/or	in the	requiren	
		use	finished		must
			cosmetic		be
			product		printed
					on the
					label
a	b	c	d	e	f
<b>'253</b>	2,2'-[(4-	Hair dye		After	As
			]bis(ethanc	, .	mentioned
	sulphate	in		under	in
	N,N-	oxidative		oxidative	reference
	bis(2-	hair dye		conditions	
	Hydroxye	thpyb)ducts		the .	205,
	p-	1		maximum	
	Phenylene	diamine		concentrat	1(21)
	Sulfate CAS No			applied	
		7		to hair	
	54381-16- EC No	1		must not exceed	
	259-134-5			2,5 %	
	239-134-3			(calculated	1
				as	<b>,</b>
				sulphate)	
					Do
					not
					ise
					with
					nitrosating
					igents
					Maximum
				ı	nitrosamine

				— ! i	content: 50 µg/ kg Keep n itrite- iree containers	
254	1,3- Benzenedi 4-chloro- 4- Chlororesc CAS No 95-88-5 EC No 202-462-0	in oxidative o <b>hain ol</b> ye products		After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 2,5 %	205, column f	d
255	culnhata	opyrimidir	щуC	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	nixing inder oxidative conditions he naximum concentrati	number 205, column
			H(hi) dye substance in non- oxidative hair dye products	3,4 % (calculated as sulphate)		-

Commission Implementing Directive 2012/21/EU of 2 August 2012 amending, for the purpose of...

ANNEX

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256	p- phenylene sulphate Hydroxye p- Phenylene Sulfate CAS No 93841-25- EC No 298-995-1	thyybducts 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( <b>xr)</b>	:
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 ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (	Mayr nixing inder oxidative conditions he naximum concentrat applied o nair nust not exceed	205, column
			H(di) (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 Proxidative		After mixing under oxidative conditions the maximum concentrat applied to hair	number 205, column f	<b>;</b>

	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	1- Hydroxy-2 methylnap 2- Methyl-1- Naphthol CAS No 7469-77-4 EC No 231-265-2	oxidative	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 Methylnar are present in a hair dye formulation the	205, column f i(n)

				maximum concentration the head of 2- Methyl-1- Naphthol should not exceed 2,0 %.)		
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	A(ta) r nixing inder oxidative conditions he naximum concentrat applied o nair nust oxceed 1,0 %	205, column ibn
			H(hi) 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	diamine oxidative hair dye diandinats		After mixing under oxidative conditions the maximum concentrate applied to hair must not exceed 0,5 %	number 205, column f	:

Commission Implementing Directive 2012/21/EU of 2 August 2012 amending, for the purpose of...

ANNEX

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266	0 (4	TT ' 1	1.0.07		<del></del>
266	Amino-3- nitroanilind HC Red No 7	oxidative hair dye products	1,0 %	_	Das notentioned use wiellerence nitronsloteing agelets Markimum
	EC No 246-521-9	1			nitrosamine content: 50 µg/ kg
				_	Keep in nitrite- free containers
267	Yellow	kyb)stanioe	1,5 % ]-5-	_	Do not use with nitrosating agents
	CAS No 59820-43- EC No 428-840-7	8		_	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	i i 1	thanol lye substance n oxidative nair lye oroducts	(a)	After As mixing mentioned under in oxidative reference conditions number the 205, maximum column concentration applied (a) to
		(	(ai) lye substance n lon- oxidative nair lye oroducts	For (a) and (b):	hair must not exceed 0,75 %  Do not

				_	with with nitrosating agents Maximum nitrosamine content: 50 μg/ kg Keep in nitrite- free containers
269	4-[(2-	Hair dye	1,0 %		
	HC	yslydustiancelpo in non-	nenoi		
	Orange No 1	oxidative hair dye			
	CAS No 54381-08-	products			
	EC No				
270	259-132-4		1.0.0/		
270	2-Nitro- N1- phenyl- benzene-1 diamine HC Red No 1 CAS No 2784-89-6 EC No 220-494-3		1,0 %		As mentioned in reference number 208, column f
271	1- Mothovy	Hair dye	0,5 %		Do
	(β-	3substance in non-	as		not use
	aminoethy nitrobenze	lo) axindiatiov 4- enhenir dve	hydrochlo		with nitrosating
	hydrochlo				agents
	HC Yellow				Maximum nitrosamine
	No 9				content:
	CAS No 86419-69-	4			50 μg/ kg
	EC No 415-480-1				Keep in
	110 100-1				nitrite-
					free containers
	1				

Commission Implementing Directive 2012/21/EU of 2 August 2012 amending, for the purpose of...

ANNEX

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272	Aminopher methyl-4-	in non- oxidative hyd)r dye pnoducts	0,25 %		
273	N-(2- Hydroxyeth nitro-4- trifluormeth aniline HC Yellow No 13 CAS No 10442-83-8 EC No 443-760-2	(b) ]	Hair dye substance n oxidative hair dye oroducts  Hair dye oroducts  Hair dye substance n on- oxidative hair dye oroducts	(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	Benzenami 3-[(4,5- dihydro-3- methyl-5- oxo-1-	substance in non-	2,0 %		

	phenyl-1H pyrazol-4- yl)azo]- N,N,Ntrin chloride Basic Yellow 57 CAS No 68391-31- EC No 269-943-5	products nethyl-,			
275	Ethanol, 2,2'- [[4-[(4- aminopher Disperse Black 9 CAS No 20721-50- EC No 243-987-5	hair dye products	mixture enyllienino ratio 1:1 of 2,2'- [4-(4-	nylazo)phe	nylimino]diethanol
276	1,4- bis[(2,3-			— ]  ]  ]  ]  ]	Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/ kg Keep in nitrite- free containers
277	2-(4- Methyl-2- nitroanilin Hydroxye Nitro-p- Toluidine CAS No 100418-33 EC No 408-090-7	(b)	Hair dye substance n oxidative hair dye oroducts  Hair	1,0 %	After As mixing mentioned under in exidative reference conditions number the 205, maximum column concentration applied (a) to mair must not

		i 1 (	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)ami zene l propyl)ami zene l i	nair lye products ino-2-	(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 1,0 %  Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-

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		l f	ree
			ontainers

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

Field of authorizedimitations and application concentration warnings and/or use and/or use in the use warnings requirements in the finished cosmetic product warnings requirements in the use warnings requirements in the use warnings requirements in the use be printed on the label  1 - Hair dye Naphthale mulbstance in oxidative CAS No 90-15-3 EC No 201-969-4  22	Ref. No	Substance	eRestricti	ons		Conditions	
applicationeroncentrational requirements in the use finished cosmetic product series in washing series in Naphthol CAS No 201-969-4  22  1,3-benzenediofa Resorcinol CAS No 108-46-3 EC No 203-585-2 series in washing series in series in conditions and the substance in concentration applied to hair must not exceed 2,0 %  22  1,3-benzenediofa Hair dye Resorcinol CAS No 108-46-3 in concentration with the products in concentration oxidative file well maximum after concentration applied to hair use in the well maximum after concentration applied Do to not professional use in washing to exceed eyelashes 1,25 % or eyebrows. Rinse eyes immediately if			Field				
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a b c d e f '16					a <b>taod</b>	warning	S
a b c d e f  1- Hair dye Naphthale mubbstance in Naphthol CAS No 90-15-3 EC No 201-969-4  22 1,3-benzenedio (a) Resorcinol CAS No 108-46-3 EC No 203-585-2  1. general use  2. professional use    Cosmetic product   Cosmetic printed on the label			and/or		requiren	new (gich	
a b c d e f  1- Hair dye Naphthale mobbstance in Naphthale cAS No 90-15-3 EC No 201-969-4  22			use				
a b c d e f  1- Hair dye Naphthale mulbstance in Oxidative CAS No 90-15-3 EC No 201-969-4  22							
a b c d e f  1- Hair dye Naphthale mulbstance in Naphthol CAS No 90-15-3 EC No 201-969-4  22				product			
a b c d e f  1- Hair dye Naphthalersolbstance in Naphthol CAS No 90-15-3 EC No 201-969-4  22 1,3- benzenedio (A) Denzenedio (CAS No 108-46-3) EC No 203-585-2  22 2, professional use  22 1,3- benzenedio (A) Denzenedio (CAS No 108-46-3) EC No 203-585-2  23 2,3- benzenedio (A) Denzenedio (CAS No 108-46-3) EC No 203-585-2  24 2 2 3 1,3- benzenedio (A) Denzenedio (CAS No 108-46-3) EC No 203-585-2  25 3 4 1,3- benzenedio (A) Denzenedio (A) Denzenedio (CAS No 108-46-3) EC No 203-585-2  26 4 5 5 6 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0						0 00	
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Naphthol CAS No 90-15-3 EC No 201-969-4  22							d
CAS No 90-15-3 EC No 201-969-4  22  1,3- benzenedio(a) Resorcinol CAS No 108-46-3 EC No 203-585-2  1. general use    Mair dye products							
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CAS No 108-46-3 EC No 203-585-2    Substance in oxidative Rinse conditions hair the well maximum after concentration population.   Substance in oxidative Rinse conditions hair the well maximum after concentration population.   Substance in oxidative Rinse conditions hair the well maximum after concentration population.   Substance in oxidative Rinse conditions hair the well maximum after concentration in the maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration.   Substance in oxidative Rinse conditions hair the well maximum after concentration and the lateral th				dye		\ /	Contains
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EC No 203-585-2  hair dye products  1. general use  2. professional use  must not dye exceed eyelashes 1,25 % or eyebrows. Rinse eyes immediately if			j	in	(	xidative	Rinse
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dye products  1. general applied Do use to not hair use must to not dye exceed eyelashes 1,25 % or eyebrows. Rinse eyes immediately if			1			_	
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use must to not dye exceed eyelashes 1,25 % or eyebrows. Rinse eyes immediately if							
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Rinse eyes immediately if					•	1 *	
eyes immediately if							
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if							
product							-
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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(ai) lotions and shampoos	0,5 %	(b)	Contains resorcinol.'

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

- **(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.