

Commission Directive 2011/59/EU of 13 May 2011 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 DIRECTIVE 2011/59/EU  
of 13 May 2011

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/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. In its opinion of 21 September 2010 the SCCS did not raise any major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the Union.

- (6) Some hair dye substances are provisionally authorised for use in hair dye products until 31 December 2010 under the restrictions and conditions laid down in Part 2 of Annex III to Directive 76/768/EEC.
- (7) 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 provisionally authorised hair dye substances, currently listed in Part 2 of that Annex.
- (8) The safety assessment by the SCCS concerning the substances hydroxyethyl-2-nitro-p-toluidine and HC Red No 10 + HC Red No 11, listed in Part 2 of Annex III to Directive 76/768/EEC, could not be finalised before 31 December 2010. Therefore, the provisional use of the substances should be prolonged until 31 December 2011.
- (9) Concerning the substance o-aminophenol, the SCCS stated in its opinion of 22 June 2010 that based on the available data no final conclusion on the safety of that substance could be drawn. Based on that opinion o-aminophenol cannot be considered safe when used in hair dye products and should therefore 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 3 January 2012 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 3 January 2012.

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 20th day following its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 13 May 2011.

*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
'1372	2-Aminophenol (o-Aminophenol; CI 76520) and its salts	CAS No 95-55-6/67845-79-8/51-19-4 EC No 202-431-1/267-335-4'

(2) Annex III is amended as follows:

(a) Part 1 is amended as follows:

(i) the following entries are added:

Ref. No	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Max. authorised concentration in the finished cosmetic product	Other limitations and requirements	
'215	4-amino-3-nitrophenol (CAS No 610-81-1) (EC No 210-236-8)	(a)	Hair dye substance in oxidative hair dye products	(a)	As mentioned in reference number 205, column (a) for mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %
		(b)	Hair dye substance in non-oxidative hair	1,0 %	(b) As mentioned in reference number 208, column f

			dye products		
216	2,7-Naphthalenediol (CAS No 582-17-2) (EC No 209-478-7)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %
		(b)	Hair dye substance in non-oxidative hair dye products	1,0 %	
217	m-Aminophenol (CAS No 591-27-5) (EC No 209-711-2) and its salts m-Aminophenol HCl (CAS No 51-81-0) (EC No 200-125-2) m-Aminophenol sulphate (CAS No 68239-81-6) (EC No 269-475-1) sodium m-		Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,2 %
					As mentioned in reference number 205, column f (a)

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	Aminophenol (CAS No 38171-54-9)				
218	2,6-Dihydroxydimethylpyridine (CAS No 84540-47-6) (EC No 283-141-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	As mentioned in reference number 205, column f (a)
222	2-Hydroxyethyl picramic acid (CAS No 99610-72-7) (EC No 412-520-9)	(a) Hair dye substance in oxidative hair dye products		(a)	After mixing under oxidative conditions the maximum concentration applied (a) to hair must not exceed 1,5 %
		(b) Hair dye substance in non-oxidative hair dye products	2,0 %	For (a) and (b): — — —	Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
223	p-Methylaminophenol	Hair dye substance		After mixing	As mentioned

	(CAS No 150-75-4) (EC No 205-768-2) and its sulphate p-Methylaminophenol sulphate (CAS No 55-55-0/1936-57-8) (EC No 200-237-1/217-706-1)	in oxidative hair dye products		under oxidative conditions the maximum concentration applied to hair must not exceed 0,68 % (as sulphate)	in reference number 205, column f (a)  Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
225	Ethanol, 2-[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino] Hydrochloride HC Blue No 12 (CAS No 132885-85-9) (EC No 407-020-2)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products		(a) 1,5 % (as hydrochloride)  For (a) and (b):	As mentioned in reference number 205, column f (a) to hair must not exceed 0,75 % (as hydrochloride)  Do not use with

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				—	nitrosating agents Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers
227	3-Amino-2,4-dichlorophenol (CAS No 61693-42-3) (EC No 262-909-0) and its hydrochloride 3-Amino-2,4-dichlorophenol HCl (CAS No 61693-43-4)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % (as hydrochloride) As mentioned in reference number 205, maximum column concentration (a)
		(b)	Hair dye substance in non-oxidative hair dye products	1,5 % (as hydrochloride)	
230	Phenyl methyl pyrazolonein (CAS No 89-25-8) (EC No 201-891-0)		Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not As mentioned in reference number 205, maximum column f (a)

				exceed 0,25 %	
232	2-Methyl-5-hydroxyethylamine (CAS No 55302-96-0) (EC No 259-583-7)	Hair dye substance (2-amino-4-aminophenol) oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	As mentioned in reference number 205, column f (a)  Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
234	Hydroxybenzoylamine (CAS No 26021-57-8) (EC No 247-415-5)	Hair dye substance (2-amino-4-aminophenol) oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	As mentioned in reference number 205, column f (a)  Do not use with nitrosating agents Maximum nitrosamine

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				—	content: 50 µg/ kg Keep in nitrite- free containers
237	2,2'-[(4-Amino-3-nitrophenyl)imino]bisethanol (CAS No 29705-39-3) and its hydrochloride HC Red No 13 (CAS No 94158-13-1) (EC No 303-083-4)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,25 % (as hydrochloride)
		(b)	Hair dye substance in non-oxidative hair dye products	2,5 % (as hydrochloride)	
238	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3 (free base)) and its hydrochloride 2,6-Dimethoxy-3,5-pyridinediamine HCl (CAS No 56216-28-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 % (as hydrochloride)	As mentioned in reference number 205, column f (a)

	(EC No 260-062-1)				
239	HC Violet No 1 (CAS No 82576-75-8) (EC No 417-600-7)	(a) Hair dye substance in oxidative hair dye products	(a)	As mentioned in reference number 205, maximum column concentration applied (a)	
		(b) Hair dye substance in non-oxidative hair dye products	0,28 %	For (a) and (b): — — —	As mentioned in reference number 208, column f
				Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers	
241	1,5-Naphthalenediol (CAS No 83-56-7) (EC No 201-487-4)	(a) Hair dye substance in oxidative hair dye products	(a)	As mentioned in reference number 205, maximum column concentration applied (a)	
				to hair must not exceed 1,0 %	

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		(b) Hair dye substance in non-oxidative hair dye products	1,0 %		
242	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its tetrahydrochloride Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (CAS No 128729-28-2) (EC No 416-320-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,4 % (as tetrahydrochloride)	As mentioned in reference number 205, column f (a)
243	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) (EC No 220-618-6)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	As mentioned in reference number 205, column f (a)
244	2,4-Diaminophenol (CAS No 70643-19-5) and its hydrochloride and its sulphate	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied	As mentioned in reference number 205, column f (a)

	2,4-Diaminophenoxyethanol HCl (CAS No 66422-95-5) (EC No 266-357-1)			to hair must not exceed 2,0 % (as hydrochloride)	
	2,4-Diaminophenoxyethanol sulphate (CAS No 70643-20-8) (EC No 274-713-2)				
245	2-Methylresorcinol (CAS No 608-25-3) (EC No 210-155-8)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,8 %
		(b)	Hair dye substance in non-oxidative hair dye products	1,8 %	
246	4-Amino-m-cresol (CAS No 2835-99-6) (EC No 220-621-2)		Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,8 %

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				exceed 1,5 %	
248	2-Amino-4-hydroxyethylamine sulphate (CAS No 83763-47-7) (EC No 280-733-2) and its sulphate 2-Amino-4-hydroxyethylamine sulphate (CAS No 83763-48-8) (EC No 280-734-8)	Hair dye substance in oxidative hair dye products 2-Amino-4-hydroxyethylamine sulphate		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % (as sulphate)	As mentioned in reference number 205, column f (a)  Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers
249	Hydroxyethylmethylene chloride and its hydrochloride Hydroxyethylmethylene chloride HCl (CAS No 94158-14-2) (EC No 303-085-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	As mentioned in reference number 205, column f (a)  Do not use with nitrosating agents

				—	Maximum nitrosamine content: 50 µg/kg	
				—	Keep in nitrite-free containers	
250	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) (EC No 265-648-0)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,0 %	As mentioned in reference number 205, maximum column (a)
		(b)	Hair dye substance in non-oxidative hair dye products	1,85 %	For (a) and (b): Do not use with nitrosating systems	As mentioned in reference number 208, column f
				—	Maximum nitrosamine content: 50 µg/kg	
				—	Keep in nitrite-free containers	
251	4-Nitrophenylaminoethylurea (CAS No 27080-42-8) (EC No 410-700-1)	(a)	Hair dye substance in oxidative hair	(a)	After mixing under oxidative conditions the maximum	As mentioned in reference number 205, column

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			dye products		concentration applied (a) to hair must not exceed 0,25 %
		(b)	(a) Hair dye substance in non-oxidative hair dye products	0,5 %	For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers
252	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) (EC No 228-762-1)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied (a) to hair must not exceed 2,0 %
		(b)	(a) Hair dye substance in non-oxidative hair dye products	2,0 %	(b) As mentioned in reference number 208, column f'

(ii) the entry with reference number 201 is replaced by the following:

201	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) (EC No 411-440-1)	(a)	Hair dye substance in oxidative hair dye products	(a)	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 %	As mentioned in reference number 205, maximum column (a)
		(b)	Hair dye substance in non-oxidative hair dye products	3,0 %  (a) and (b): —  —  —	Do not use with nitrosating agents Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers	

(b) Part 2 is amended as follows:

- (i) the entries with reference numbers 3 to 6, 11, 12, 16, 19 to 22, 25, 27, 31 to 39, 44, 48, 49, 55 and 56 are deleted;
- (ii) in the entries with reference numbers 10 and 50, in column g, the date '31.12.2010' is replaced by '31.12.2011'.

- (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.