

DIRECTIVES

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.

⁽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.

(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	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	
a	b	c	d	e	f
'253	2,2'-[(4-Aminophenyl)imino]bis(ethanol) sulphate N,N-bis(2-Hydroxyethyl)-p-Phenylenediamine Sulfate CAS No 54381-16-7 EC No 259-134-5	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5 % (calculated as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
254	1,3-Benzenediol, 4-chloro-4-Chlororesorcinol CAS No 95-88-5 EC No 202-462-0	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5 %	As mentioned in reference number 205, column f (a)
255	2,4,5,6-Tetraaminopyrimidine sulphate Tetraaminopyrimidine Sulfate CAS No 5392-28-9 EC No 226-393-0	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 3,4 % (calculated as sulphate)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,4 % (calculated as sulphate)	(a) As mentioned in reference number 205, column f (a)

a	b	c	d	e	f
256	3-(2-Hydroxyethyl)-p-phenylenediammonium sulphate Hydroxyethyl-p-Phenylenediamine Sulfate CAS No 93841-25-9 EC No 298-995-1	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (calculated as sulphate)	As mentioned in reference number 205, column f (a)
257	1H-Indole-5,6-diol Dihydroxyindole CAS No 3131-52-0 EC No 412-130-9	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
258	5-Amino-4-chloro-2-methylphenol hydrochloride 5-Amino-4-Chloro-o-Cresol HCl CAS No 110102-85-7	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,5 % (calculated as hydrochloride)	As mentioned in reference number 205, column f (a)
259	1H-Indol-6-ol 6-Hydroxyindole CAS No 2380-86-1 EC No 417-020-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	As mentioned in reference number 205, column f (a)
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-Aminopyridin-3-ol 2-Amino-3-Hydroxypyridine CAS No 16867-03-1 EC No 240-886-8	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)

a	b	c	d	e	f
262	2-Methyl-1-naphthyl acetate 1-Acetoxy-2-Methylnaphthalene CAS No 5697-02-9 EC No 454-690-7	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2-Methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-Methyl-1-Naphthol should not exceed 2,0 %.)	As mentioned in reference number 205, column f (a)
263	1-Hydroxy-2-methylnaphthalene 2-Methyl-1-Naphthol CAS No 7469-77-4 EC No 231-265-2	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % (When both 2-Methyl-1-Naphthol and 1-Acetoxy-2-Methylnaphthalene are present in a hair dye formulation, the maximum concentration on the head of 2-Methyl-1-Naphthol should not exceed 2,0 %.)	As mentioned in reference number 205, column f (a)
264	Disodium 5,7-dinitro-8-oxido-2-naphthalenesulfonate Acid Yellow 1 CAS No 846-70-8 EC No 212-690-2 CI 10316	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 0,2 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	(a) As mentioned in reference number 205, column f (a) (b) As mentioned in reference number 208, column f
265	4-Nitro-1,2-phenylenediamine 4-Nitro-o-Phenylenediamine CAS No 99-56-9 EC No 202-766-3	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	As mentioned in reference number 205, column f (a)
266	2-(4-Amino-3-nitroanilino)ethanol HC Red No 7 CAS No 24905-87-1 EC No 246-521-9	Hair dye substance in non-oxidative hair dye products	1,0 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 208, column f

a	b	c	d	e	f
267	2-[bis(2-Hydroxyethyl)amino]-5-nitrophenol HC Yellow No 4 CAS No 59820-43-8 EC No 428-840-7	Hair dye substance in non-oxidative hair dye products	1,5 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
268	2-[(2-Nitrophenyl)amino] ethanol HC Yellow No 2 CAS No 4926-55-0 EC No 225-555-8	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,75 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
269	4-[(2-Nitrophenyl)amino]phenol HC Orange No 1 CAS No 54381-08-7 EC No 259-132-4	Hair dye substance in non-oxidative hair dye products	1,0 %		
270	2-Nitro-N1-phenyl-benzene-1,4-diamine HC Red No 1 CAS No 2784-89-6 EC No 220-494-3	Hair dye substance in non-oxidative hair dye products	1,0 %		As mentioned in reference number 208, column f
271	1-Methoxy-3-(β-aminoethyl) amino-4-nitrobenzene, hydrochloride HC Yellow No 9 CAS No 86419-69-4 EC No 415-480-1	Hair dye substance in non-oxidative hair dye products	0,5 % (calculated as hydrochloride)	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	

a	b	c	d	e	f
272	1-(4'-Aminophenylazo)-2-methyl-4-(bis-2-hydroxyethyl)aminobenzene HC Yellow No 7 CAS No 104226-21-3 EC No 146-420-6	Hair dye substance in non-oxidative hair dye products	0,25 %		
273	N-(2-Hydroxyethyl)-2-nitro-4-trifluormethyl-aniline HC Yellow No 13 CAS No 10442-83-8 EC No 443-760-2	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2,5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
274	Benzenaminium, 3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-N,N,N-trimethyl-, chloride Basic Yellow 57 CAS No 68391-31-1 EC No 269-943-5	Hair dye substance in non-oxidative hair dye products	2,0 %		
275	Ethanol, 2,2'-[[4-[(4-aminophenyl)azo]phenyl]imino]bis- Disperse Black 9 CAS No 20721-50-0 EC No 243-987-5	Hair dye substance in non-oxidative hair dye products	0,3 % (of the mixture in the ratio 1:1 of 2,2'-[4-(4-aminophenylazo)phenylimino] diethanol and lignosulfate)		
276	9,10-Anthracenedione, 1,4-bis[(2,3-dihydroxypropyl)amino]- HC Blue No 14 CAS No 99788-75-7 EC No 421-470-7	Hair dye substance in non-oxidative hair dye products	0,3 %	— Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	

a	b	c	d	e	f
277	2-(4-Methyl-2-nitroanilino)ethanol Hydroxyethyl-2-Nitro-p-Toluidine CAS No 100418-33-5 EC No 408-090-7	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 1,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
278	1-Amino-2-nitro-4-(2',3'-dihydroxypropyl)amino-5-chlorobenzene + 1,4-bis-(2',3'-dihydroxypropyl)amino-2-nitro-5-chlorobenzene HC Red No 10 + HC Red No 11 CAS No 95576-89-9 + 95576-92-4	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) 2,0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)'

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

Ref. No	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Max. authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
'16	1-Naphthalenol 1-Naphthol CAS No 90-15-3 EC No 201-969-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 %	As mentioned in reference number 205, column f (a)
22	1,3-benzenediol Resorcinol CAS No 108-46-3 EC No 203-585-2	(a) Hair dye substance in oxidative hair dye products 1. general use 2. professional use		(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,25 %	(a) 1. Contains resorcinol Rinse hair well after application.

a	b	c	d	e	f
		(b) Hair lotions and shampoos	(b) 0,5 %		<p>Do not use to dye eyelashes or eyebrows.</p> <p>Rinse eyes immediately if product comes into contact with them.</p> <p>As mentioned in reference number 205, column f (a).</p> <p>2. For professional use only</p> <p>Contains resorcinol.</p> <p>Rinse eyes immediately if product comes into contact with them.</p> <p>As mentioned in reference number 205, column f (a)</p> <p>(b) Contains resorcinol.'</p>

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