

Commission Regulation (EU) No 658/2013 of 10 July 2013 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 658/2013
of 10 July 2013

amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products⁽¹⁾, and in particular Article 31(1) thereof,

Whereas:

- (1) Regulation (EC) No 1223/2009 replacing Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽²⁾ will apply from 11 July 2013.
- (2) Annexes II and III to Directive 76/768/EEC were amended by Commission Implementing Directive 2012/21/EU⁽³⁾ after the adoption of the Regulation, by including one hair dye substance into Annex II, 26 hair dye substances into Part 1 of Annex III and by changing the maximum authorised concentrations in the finished cosmetic product for two hair dye substances in Part 1 of Annex III. Those amendments should now be reflected in Regulation (EC) No 1223/2009.
- (3) In accordance with Implementing Directive 2012/21/EU, Member States are to apply the laws, regulations and administrative provisions adopted in order to comply with that Directive from 1 September 2013. Therefore, this Regulation should apply from that date.
- (4) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 658/2013. (See end of Document for details)

Article 2

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

It shall apply from 1 September 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 July 2013.

For the Commission

The President

José Manuel BARROSO

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

ANNEX


Annexes II and III to Regulation (EC) No 1223/2009 are amended as follows:

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

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
'1373	N-(2-Nitro-4-aminophenyl)-allylamine (HC Red No 16) and its salts	160219-76-1'	

(2) Annex III is amended as follows:

(a) The following entries concerning reference numbers 198 to 200 are 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 use preparation	
'198	2,2'-[(4-Aminophenyl)sulphate]	N,N-bis(2-Hydroxyethyl)Phenylenediamine Sulfate	54381-10-9	059-134-4	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)	To be printed on the label: The mixing ratio.  Read and follow instructions. This product is not intended for use on nitrosating persons agents under the maximum nitrosamine content: 16.


Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

								<p>Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p> <p>— you have a rash on your face or sensitive, irritated and damaged scalp,</p> <p>— you have ever experienced any reaction after colouring your hair,</p> <p>— you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can</p>
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Status: Point in time view as at 31/01/2020.

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								cause severe allergic reactions.
199	1,3-Benzenechloro-	4-Chlororesorcinol	95-88-5	202-462-4	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5 %	<p>To be printed on the label: The mixing ratio.</p>  <p>Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive,</p>

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								irritated and damaged scalp, you have ever experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
200	2,4,5,6-Tetraaminopyrimidine sulphate	5392-18-2	18216-393-0	(a)	Hair dye substance in oxidative hair dye products	(a)	(a) After mixing under oxidative conditions the maximum concentration applied	To be printed on the label: Maximum concentration applied
				(b)	(b) Hair dye substances in non-oxidative hair	3,4 % (calculated as sulphate)	exceed 3,4 % (calculated as sulphate)	 Hair colorants can

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						dye products	cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring
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Status: Point in time view as at 31/01/2020.

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								—	your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past.'
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(b) The following entries concerning reference numbers 206 to 214 are added:

206	3-(2-Hydroxyethyl)-p-phenylenediamine sulphate	Hydroxyethyl-Phenylenediamine Sulfate	21841-2198-995	2198-995	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)	To be printed on the label: the mixing ratio.  Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your
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207	1H-Indole-5,6-diol	Dihydroxyindole	3,4,5,6	130-9	(a)	Hair dye substance in oxidative hair dye products	(a)	0,5 %	<p>(a) After mixing under oxidative conditions the maximum concentration applied for (a) and (b) must</p>  <p>Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p> <p>— you have a rash on your face</p>
					(b)	Hair dye substance in non-oxidative hair dye products	(b)		

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

							or sensitive, irritated and damaged scalp, you have ever experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
208	5-Amino-4-chloro-2-methylhydrochloride	5-Amino-4-chlorophenol Cresol HCl	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	To be printed on the label: The mixing ratio.  Read and follow instructions.


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							as hydrochloride	This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to
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								a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
209	1H-Indol-6-ol	6-Hydroxyindole	2380-8641	7-020	Hair dye substance in oxidative hair dye products	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 %	To be printed on the label: The mixing ratio.	 <p>Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour</p>

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

							<p>your hair if:</p> <p>— you have a rash on your face or sensitive, irritated and damaged scalp,</p> <p>— you have ever experienced any reaction after colouring your hair,</p> <p>— you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.</p>
210	1H-Indole-2,3-Dione	Isatin	91-56-5	202-07718	Hair dye substance in non-oxidative	1,6 %	 Read and


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				hair dye products		follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

								reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
211	2-Aminopyridinol	2-Amino-3-Hydroxypyridine	16867-0340-8861	240-8861	Hair dye substance in oxidative hair dye products	After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 %	To be printed on the label: The mixing ratio.	 <p>Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy.</p>


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							Do not colour your hair if:
							— you have a rash on your face or sensitive, irritated and damaged scalp,
							— you have ever experienced any reaction after colouring your hair,
							— you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
212	2-Methylnaphthyl acetate	1-Acetoxy-2-Methylnaphthalene	5697-0245	454-6901	Hair dye substance in	After mixing under oxidative	To be printed on the label:


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				oxidative hair dye products		<p>condition 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 %).</p>	<p>The mixing ratio.  Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p>	<p>— you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced</p>
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								any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
213	1-Hydroxy-2-methyl-1-naphthol	2-Methyl-1-naphthol	7469-7728	281-265	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	To be printed on the label: The mixing ratio. 	Read and follow instructions. This product is not intended for use on persons under the


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						<p>hair dye formulations the maximum concentration on the head of 2-Methyl-Naphthol should not exceed 2,0 %.)</p> <p>age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p> <ul style="list-style-type: none"> — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary 'black henna' tattoo in the past. <p>Hair</p>
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								colorants can cause severe allergic reactions.
214	Disodium 5,7-dinitro-8-oxido-2-naphthalenesulfonate CI 10316	Acid Yellow 8F	846-70-8	212-690-2				
					(a)	Hair dye substance in oxidative hair dye products	(a)	(a) After mixing under oxidative conditions the maximum concentration applied for (a) hair dye must
					(b)	Hair dye substance in non-oxidative hair dye products	0,2 %	(b) must
								 <p>Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your</p>

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)


								risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary ‘black henna’ tattoo in the past.’
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(c) The entry with reference number 240 is replaced by the following:

240	4-Nitro-1-phenylene	4-Nitro-phenylenediamine	99-56-9	202-7661	Hair dye substance in oxidative hair	After mixing under oxidative conditions the maximum	To be printed on the label: the mixing ratio.
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)


					dye products	concentr applied to hair must not exceed 0,5 %	 <p>Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p> <p>— you have a rash on your face or sensitive, irritated and damaged scalp,</p>
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								—	you have ever experienced any reaction after colouring your hair,
								—	you have experienced a reaction to a temporary 'black henna' tattoo in the past.'

(d) The entry with reference number 251 is replaced by the following:

251	2-(4-Amino-3-nitrophenyl)ethanol	HC Red No 7	24905-8246-52	24905-8246-52	Hair dye substance in non-oxidative hair dye products	1,0 %	—	 <p>nitrosating agents colorants maximum nitrosamine content: 50 µg/kg severe allergic reactions. Read and write-free instructions. Containers. This product is not intended for use on persons under the</p>
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(e) The entry with reference number 253 is replaced by the following:

253	2-[bis(2-Hydroxyethyl)amino]-5-nitrophenol	HC Yellow No 4	59820-4428-840	428-840	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
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(f) The entries with reference numbers 255 and 256 are replaced by the following:


255	2-[(2-Nitrophenyl)amino]ethanol	HC Yellow No 2	4926-5520	205-555-8	(a)	Hair dye substance in oxidative hair dye products	(a)	(After mixing be under printed oxidative conditions the label: Maximum concentration applied
					(b)	Hair dye substance in non-oxidative hair dye products	1,0 %	 <p>exceed 0,5 % Read and follow instructions. This product is not intended for use with nitrosating agents Maximum nitrosamine content: 50 µg/kg</p>

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

								cause severe allergic reactions.
256	4-[(2-Nitrophenyl)amino]phenol	HC Orange No 1	54381-0857	259-1324	Hair dye substance in non-oxidative hair dye products	1,0 %		

(g) The following entries concerning reference numbers 258 to 264 are added:

258	2-Nitro-N1-phenylbenzene-1,4-diamine	HC Red No 1	2784-8926	260-4944	Hair dye substance in non-oxidative hair dye products	1,0 %	 <p>Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: —</p>	you have a
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								<p>rash on your face or sensitive, irritated and damaged scalp, you have ever experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.</p>
259	1-Methoxy- β -aminoethyl-nitrobenzene, hydrochloride	HC Yellow No 9 amino-4-	86419-6915-480	415-480	Hair dye substances in non-oxidative hair dye products	0,5 % (calculated hydrochloride)	—	<p>Do not use with nitrosating agents Maximum nitrosamine content: 50 μg/kg</p>

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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

							—	Keep in nitrite-free containers
260	1-(4'-Aminophenyl)-4-methyl-2-(bis-2-hydroxyethyl)aminobenzene	HC No 7	104226-2463420	2463420	Hair dye substance in non-oxidative hair dye products	0,25 %		
261	N-(2-Hydroxyethyl)-4-nitro-2-trifluoromethyl-aniline	HC No 13	10442-8448-760	8448-760	(a)	Hair dye substance in oxidative hair dye products	(a)	(a) After mixing be under printed oxidative conditions the label: Maximum concentration applied
					(b)	Hair dye substance in non-oxidative hair dye products	2,5 %	(b) For (a) and (b):  exceed 2,5 % and follow instructions. This product is not intended for use with nitrosating agents on persons under 16 years of age. Maximum content: 50 µg/16 g Temporary 'black henna' henna-tattoos may increase your

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262	Benzena- 3- [(4,5- dihydro-3- methyl-5- oxo-1- phenyl-1H- pyrazol-4- yl)azo]- N,N,N-trimethyl-, chloride	Basic Yellow 57 3- 5- 1H- 4- N,N,N-trimethyl-, chloride	68391-3169-943	169-943	Fair dye substance in non- oxidative hair dye products	2,0 %		
263	Ethanol, 2,2'- [[4- [(4- aminophenyl)azo]phenyl]imino]diethanol and lignosulfate)	Disperse Black 9	20721-5040-987	040-987	Fair dye substance in non- oxidative hair dye products	0,3 % (of the mixture in the ratio 1 of 2,2'- [4-(4- aminophenylazo)phenylimino]diethanol and lignosulfate)		
264	9,10- Anthracene, 1,4- bis[(2,3- dihydroxypropyl)amino]-	HC Bledione, No 14	99788-7421-470	421-470	Fair 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

(h) The entries with reference numbers 16, 22, 221, 250 are replaced by the following:

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 use preparation	Other	
16	1- Naphthalenol	1- Naphthalenol	90-15-3	201-969	Hair dye		After mixing	To be printed


Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

					substance in oxidative hair dye products	under oxidative conditions the maximum concentr applied to hair must not exceed 2,0 %	on the label: The mixing ratio.  Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have
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								ever experienced any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
22	1,3-benzenediol	Resorcinol	108-46-2	203-585-2	(a) Hair dye substance in oxidative hair dye products	(a) 1. general use 2. professional use For 1 and 2: After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,25 %	(a) 1.	To be printed on the label: The mixing ratio.
					(b) Hair lotions and shampoos			 <p>Read and follow instructions. This product is not intended for</p>

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					dye products	1,0 %	<p>The concentration applied ratio.</p>  <p>1,0 % Read and follow instructions. Do not use with nitrosating agents on persons under the age of 16. Keep in black nitrite-free henna-free containers may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced</p>
			(b)	(b)	Hair dye substance in non-oxidative hair and dye products	1,0 %	<p>For (a) and (b):</p>

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								any reaction after colouring your hair, you have experienced a reaction to a temporary 'black henna' tattoo in the past. Hair colorants can cause severe allergic reactions.
250	1-nitro-4-(2',3'-dihydroxypropyl)chlorobenzene + 1,4-bis-(2',3'-dihydroxypropyl)nitro-5-chlorobenzene	HC Red No 10 + HC Red No 11	95576-89-9 + 95576-92-4	(a)	Hair dye substance in oxidative hair dye products	(a)	(a) After mixing under oxidative conditions the maximum concentration applied	To be printed on the label: Maximum concentration applied
				(b)	Hair dye substance in non-oxidative hair dye products	2,0 %	For (a) and (b):	 <p>exceed 10 % Hair colorants can cause severe allergic reactions. Read and follow instructions.</p>

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

											<p>Maximum propranolol is content: intended for use Keep persons undisturbed free agents 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if:</p> <p>— you have a rash on your face or sensitive, irritated and damaged scalp,</p> <p>— you have ever experienced any reaction after colouring your hair,</p> <p>— you have experienced a reaction to</p>
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Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013. (See end of Document for details)

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a temporary 'black henna' tattoo in the past.'

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 658/2013. (See end of Document for details)

- (1) OJ L 342, 22.12.2009, p. 59.
- (2) OJ L 262, 27.9.1976, p. 169.
- (3) OJ L 208, 3.8.2012, p. 8.

Status:

Point in time view as at 31/01/2020.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 658/2013.