



Scientific Committee on Consumer Safety

SCCS

## **Memorandum on hair dye Chemical Sensitisation**

The SCCS adopted this memorandum at its 18<sup>th</sup> Plenary meeting  
of 26 February 2013

### About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat. They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

### SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

### Scientific Committee members

Jürgen Angerer, Ulrike Bernauer, Claire Chambers, Qasim Chaudhry, Gisela Degen, Elsa Nielsen, Thomas Platzek, Suresh Chandra Rastogi, Vera Rogiers, Christophe Rousselle, Tore Sanner, Jan van Benthem, Jacqueline van Engelen, Maria Pilar Vinardell, Rosemary Waring, Ian R. White

### Contact

European Commission  
Health & Consumers  
Directorate D: Health Systems and Products  
Unit D3 - Risk Assessment  
Office: B232 B-1049 Brussels  
[Sanco-SCCS-Secretariat@ec.europa.eu](mailto:Sanco-SCCS-Secretariat@ec.europa.eu)

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Dr. C. Rousselle  
Prof. T. Sanner  
Dr. J. van Benthem  
Prof. M.P. Vinardell  
Dr. I.R. White (rapporteur)

### External experts

Dr. Mona-Lise Binderup National Food Institute, Denmark

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A “Memorandum on hair dye substances and their sensitising properties” adopted during the 10<sup>th</sup> Plenary of the SCCP on 19 December 2006, summarised the evaluation on the 48 hair dye substances that had been assessed by the SCCP at that time. 27 of the dyes were noted to fulfil the EU criteria for classification as skin sensitizers (R43). Additionally, 10 of the 27 classifiable hair dye substances were categorised as extreme sensitizers, 13 as strong and 4 as moderate sensitizers.

The SCCP stated that hair dye substances which fulfil the criteria for classification as R43 may not be safe for consumers and that this is particularly so for hair dye substances categorised as extreme and strong sensitizers.

It was necessary to write the Memorandum as the assessment of the safety of hair dyes has been in terms of general toxicology rather than sensitization potential. Hence, “hair dye chemical X is safe for use at Y% in hair dyes intended for the consumer apart from its potential to cause skin sensitization”.

The response to the above Memorandum by the European Commission (29 March 07) was:

1. The Commission services will now extend their assessment in order to minimise possible risks of allergic reactions caused by hair dyes.
2. Epidemiological studies are necessary to examine the extent of skin allergies to hair dyes in the EU’s population.
3. Threshold values for sensitizers of high concern need to be determined to take appropriate measure on a possible decrease of exposure.

An updated review of the sensitizing potency of the hair dye chemicals now evaluated by the SCCS, the former SCCP and SCCNFP, is below (which should be considered as indicative, as evaluations are ongoing). The SCCS confirms the views expressed in the earlier Memorandum, that hair dye substances which fulfil the criteria for classification as R43 (now Skin Sens 1 H317 according to CLP) may not be safe for consumers and that this is particularly so for hair dye substances categorised as extreme and strong sensitizers.

Extreme	13
Strong	23
Moderate	20
Insufficient testing + Possibly sensitising	24 + 5
Not classifiable	29

Table 1. Hair dye substances assessed by the SCCS and the former SCCP and SCCNFP concerning their skin sensitising property, based on submissions by industry. Results from studies performed by OECD guideline methods (LLNA, GPMT and Buehler test). Typically, results from one study per method are displayed. The substances fulfilling the criteria for

classification as skin sensitiser (R43, Skin Sens 1 H317 according to CLP) were categorised according to their sensitising potency (Memorandum on hair dye substances and their skin sensitising properties, SCCP 2006; Memorandum on classification and categorisation of skin sensitisers and grading of test reactions, SCCP 2005). If data from more than one method is given, the data used for categorisation is in bold letters

COLIPA n°	INCI name (CAS n°) <i>Common name in italic</i>	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	References
A5	Toluene-2,5-diamine (95-70-5)	Extreme	0.31	<b>GPMT 0.1/100</b> (modified method)	SCCS/1390/10
A7	p-Phenylenediamine (106-50-3)	Extreme	0.06		SCCS/1443/11
A8	2-Chloro-p-phenylenediamine (615-66-7)	Moderate ?	?	?	4 Oct 1991
A9	N-Phenyl-p-phenylenediamine (101-54-2; 2198-59-6, hydrochloride; 4698-29-7, sulfate)	Extreme	0.02	-	SCCP/0991/06
A11	Resorcinol (108-46-3)	Strong	1.4	-	SCCS/1270/09
A12	4-Chlororesorcinol (95-88-5)	Moderate	5.8	-	SCCS/1224/09
A15	m-Aminophenol (591-27-5; 51-81-0, hydrochloride; 68239-81-6, sulfate; 38171-54-9, sodium salt)	Strong	0.24	-	SCCP/0978/06
A16	p-Aminophenol (123-30-8, free base) (51-78-5, HCl)	Results indicate sens potential	-	Non-guideline tests indicating strong sens potency	SCCS/1409/11
A17	1-Naphthol (90-15-3)	Strong	<b>1.3</b>	Non-guideline tests, not conclusive	SCCP/1123/07
A18	1,5-Naphthalenediol (83-56-7)	Moderate	3.4	-	SCCS/1365/10
A19	2,7-Naphthalenediol (582-17-2)	Moderate	2.8	-	SCCS/1366/10

<b>COLIPA n°</b>	<b>INCI name (CAS n°)</b> <i>Common name in italic</i>	<b>Sensitising potency category, based on results from LLNA or guinea pig assays</b>	<b>LLNA EC3 value (%)</b>	<b>Guinea pig assay</b>  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	<b>References</b>
A22	p-Methylaminophenol (150-75-4)	Moderate	2.2	-	SCCP/0963/05
A25	Hydroxybenzomorpholine (26021-57-8)	Not classifiable	-	GPMT 1/0	SCCP/0965/05
A27	4-Amino-2-hydroxytoluene (2835-95-2)	Strong	0.44	-	SCCP/1001/06
A31	2-Methyl-5-hydroxyethylaminophenol (55302-96-0)	Not classifiable	no value	-	SCCP/0957/05
A33	1,2,4-Trihydroxybenzene (533-73-3)	Extreme	0.08	-	SCCP/0962/05
A39	Phenyl methyl pyrazolone (89-25-8)	Strong	≤1	-	SCCP/1033/06
A42	2,4-Diaminophenoxyethanol HCl (66422-95-5)	Moderate	<b>3.2</b>	Buehler 100/10	SCCS/1367/10
A43	3-amino-2,4-dichlorophenol (61693-42-3; 61693-43-4, hydrochloride)	Moderate	16.8	-	SCCP/1205/08
A44	2-Methylresorcinol (608-25-3)	Moderate	50	-	SCCP/1206/08
A50	N,N-bis(2-Hydroxyethyl)-p-phenylenediamine sulfate (54381-16-7, sulfate)	Strong	<0.25 *; 1.04	-	SCCP0983/06
A53	Tetraaminopyrimidine (5392-28-9, sulfate)	Insufficient testing	No value. Should have been tested at higher conc. or in other vehicle		SCCP/1118/07
A74	4-Amino-m-cresol (2835-99-6)	Strong	1.45	-	SCCP/0895/05
A75	6-Amino-m-cresol (2835-98-5)	Strong	1.55	-	SCCS/1400/11

COLIPA n°	INCI name (CAS n°) <i>Common name in italic</i>	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	References
A79	1,3-Bis-(2,4-diamino-phenoxy)- propane HCl (81892-72-0, free base; 74918-21-1, HCl)	Moderate	14.7	-	SCCP/1098/07
A80	Hydroxyethyl-p-phenylenediamine sulphate (93841-25-9)	Strong	0.57	-	SCCS/1310/10
A84	2-Amino-4- hydroxyethylaminoanisole (83763- 47-7)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1250/09
A98	Hydroxyethyl-3,4- methylenedioxyaniline HCl (94158- 14-2)	Strong	< 0.5 *	-	SCCS/1269/09
A99	2,6-Dihydroxy-3,4-dimethyl- pyridine (84540-47-6)	Results indicate sens potential	≤25 *; no value.	-	SCCP/1034/06
A101	2,6-Dimethoxy-3,5-pyridinediamine HCl (85679-78-3, free base; 56216- 28-5, hydrochloride)	Strong	<b>1.25</b>	GPMT 1/15	SCCP/0908/05
A111	Dihydroxyindole (3131-52-0)	Extreme	<b>0.17</b>	GPMT 0.1/0	SCCP/0952/05
A117	5-Amino-4-chloro-o-cresol HCl (110102-85-7)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCP/1120/07
A121	Hydroxypropyl bis (N- hydroxyethyl-p-phenylenediamine) HCl (128729-30-6, free base; 128729-28-2, hydrochloride)	Strong	-	GPMT 1/90	SCCS/1244/09

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A128	6-Hydroxyindole (2380-86-1)	Extreme	<0.2 *; <b>0.2</b>	GPMT 0.5/40  Buehler 5/30	SCCP/0947/05
A129	Isatin (91-56-5)	Extreme	<1 *; 2.5	<b>GPMT 0.1/100;</b>  Buehler 25/0 **	SCCP/0876/05
A130	6-Methoxy-2-methylamino-3-aminopyridine HCl (83732-72-3, 2HCl; 90817-34-8, HCl)	Strong	5.6	<b>GPMT 1/90</b>	SCCP/1121/07
A132	2-Amino-3-hydroxypyridine (16867-03-1)	Not classifiable	no value	-	SCCP/1126/07
A136	2,6-Diaminopyridine (141-86-6)	Strong	0.25	-	SCCS/1450/11
A138	2,6-Dihydroxyethylaminotoluene (149330-25-6)	Not classifiable	no value	-	SCCS/1425/11
A143	2,5,6-Triamino-4-pyrimidinol sulfate (1603-02-7)	Insufficient testing	-	GPMT Inappropriate testing	SCCP/1122/07
A147	Dihydroxyindoline HBr (29539-03-5)	Moderate	-	<b>GPMT 10/55;</b>  Buehler 40/0	SCCNFP/0669/03
A153	1-Acetoxy-2-methoxynaphthalene (5697-02-9)	See A156			
A154	1-Hydroxyethyl-4,5-diamino pyrazole sulfate (155601-30-2)	Strong	No value. Should have been tested at higher conc.	<b>GPMT 1/100</b>  Buehler: 40/0	SCCS/1449/11



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A155	2,2'-Methylenebis 4-aminophenol (63969-46-0; 27311-52-0, HCl)	Not classifiable	-	GPMT inadequate. Too low conc. used  <b>Buehler 50/5</b>	SCCP/1142/07
A156	2-Methyl-1-naphthol (7469-77-4)	Strong	<b>1.28</b>	Buehler 5/20	SCCP/1163/08
A157	<i>Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) (223398-02-5)</i>	Not classifiable	no value	-	SCCS/1435/11
A158	2-Amino-5-ethylphenol HCl (149861-22-3)	Moderate	6.6	-	SCCS/1442/11
A159	2,3- diaminodihydropyrazolopyrazolone dimethosulfonate (857035-95-1)	Submission I to be evaluated			
B1	Acid Yellow 1 (846-70-8)	Moderate	No value. Should have been tested at higher conc.	<b>GPMT 5/100</b>	SCCP/1160/08
B5	Disperse Red 17 (3179-89-3)	Insufficient testing	-	GPMT Results equivocal **	SCCP/1161/08
B7	Basic Brown 17 (68391-32-2, HCl)	Extreme	No value. Should have been tested at higher conc.	GPMT 0.1/70	SCCS/1448/11  SCCP/0683/03

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B24	4-Nitro-o-phenylenediamine (99-56-9)	Extreme	≤0.05	-	SCCP/0980/06
B28	Picramic acid ( 96-91-3)	Moderate	6.7	-	SCCS/1227/10
B31	HC Red n° 13 (94158-13-1)	Moderate	<b>8.2</b>	GPMT inadequate. Too low conc. used	SCCS/1368/10
B34	N,N'-bis(Hydroxyethyl)-2-nitro-p-phenylenediamine (84041-77-0)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1463/12
B36	HC Red n° 7 (24905-87-1)	Strong	1.2	-	SCCS/1229/09
B37	HC Blue n° 2 (33229-34-4)	Results indicate sens potential	≤5; no value	-	SCCP/1035/06
B38	HC Yellow n° 4 (52551-67-4 / 59820-43-8)	Not classifiable	No value. Should have been tested at higher conc.	GPMT Inadequate Too low conc. used  <b>Buehler 75/0</b>	SCCS/1230/09
B41	HC Yellow n° 2 (4926-55-0)	Insufficient testing	No value. Should have been tested at higher conc.	GPMT Inadequate	SCCS/1309/10

COLIPA n°	INCI name (CAS n°) <i>Common name in italic</i>	Sensitising potency category, based on results from LLNA or guinea pig assays	LLNA EC3 value (%)	Guinea pig assay  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	References
B47	HC Orange n° 1 (54381-08-7)	Not classifiable	No value. Should have been tested at higher conc.	<b>GPMT 0.1/0</b>	SCCP/1164/08
B48	HC Red n° 1 (2784-89-6)	Extreme	<2 *	<b>GPMT 0.1/100</b>	SCCP/0981/06
B50	HC Red n° 3 (2871-01-4)	Extreme	2 *	<b>GPMT 0.1/100</b>  Buehler 3/0	SCCS/1293/10
B51	4-Amino-3-nitrophenol (610-81-1)	Extreme	0.2	-	SCCP/1207/08
B52	2-Hydroxyethylamino-5-nitro- anisole (66095-81-6)	Not classifiable	no value	-	SCCS/1243/09
B54	3-Nitro-p-hydroxyethylaminophenol (65235-31-6)	Extreme	0.07	-	SCCP/1036/06
B58	3-Methylamino-4-nitrophenoxy ethanol (59820-63-2)	Not classifiable	no value	-	SCCP/1089/07
B60	2-Nitro-5-glyceryl-methylaniline (80062-31-3)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCP/1162/08
B66	HC Violet n° 1 (82576-75-8)	Strong	<b>0.9</b>	GPMT 25/0 **	SCCP/1025/06
B67	HC Orange n° 2 ( 85765-48-6)	Strong	<b>1.10</b>	GPMT 1/40	SCCP/1103/07

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B69	HC Yellow n° 9 (86419-69-4; 141973-33-3)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1301/10
B70	4-Nitrophenyl aminoethylurea (27080-42-8)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1369/10
B71	HC Red n° 10 + HC Red n° 11 (95576-89-9 + 95576-92-4)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1406/11
B72	2-Hydroxyethyl picramic acid (99610-72-7)	Results indicate sens potential	No value. Should have been tested at higher conc. Results indicate sens.	-	SCCP/1208/08
B73	HC Blue n° 12 (104516-93-0, free base; 132885-85-9)	Moderate	5.0	-	SCCP/1209/08

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B75	Hydroxyethyl-2-nitro-p-toluidine (100418-33-5)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1387/10
B77	HC Blue n° 11 (23920-15-2)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCP/1079/07
B80	HC Yellow n° 7 (104226-21-3)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1292/10
B81	HC Yellow n° 10 (109023-83-8)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCP/1080/O7
B87	4-Amino-2-nitrodiphenylamine-2'- carboxylic acid (117907-43-4)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1302/10

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B89	2-Chloro-6-ethylamino-4-nitrophenol (131657-78-8)	Moderate	2.79	-	SCCP/1090/07
B98	HC Violet n° 2 (104226-19-9)	Moderate	5.9	-	SCCP/1082/07
B99	2-Amino-6-chloro-4-nitrophenol (6358-09-4)	Strong	0.68	-	SCCP/0948/05
B100	4-Hydroxypropylamino-3-nitrophenol (92952-81-3)	Not classifiable	No value	-	SCCP/1082/07
B102	HC Yellow n° 13 (10442-83-8)	Not classifiable	-	GPMT 10/0	SCCS/1322/10
B111	2,6-Diamino-3-((pyridin-3-yl)azo)pyridine (28365-08-4)	Not classifiable	-	<b>GPMT 0.001/11;</b>  Buehler 25/0	SCCS/1338/10
B113	Basic Orange 69 (226940-14-3)	Results indicate sens potential	-	GPMT Results indicative of sens. Additional conc. should have been used	SCCP/1116/07
B115	Basic Violet 2 (3248-91-7)	Insufficient testing	-	GPMT and Buehler Inconclusive **	SCCS/1340/11
B116	Basic Red 51 (77061-58-6)	Not classifiable	-	GPMT 5/0	SCCS/1436/11
B117	Basic Yellow 87 (68259-00-7)	Not classifiable	-	GPMT 1/0	SCCS/1333/10
B118	Basic Orange 31 (97404-02-9)	Moderate	<b>3.12</b>	GPMT 5/0 – test not considered adequate	SCCS/1447/11

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C8	Basic Red 76 (68391-30-0)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1385/10
C9	Basic Brown 16 (26381-41-9)	Moderate	12.2	-	SCCP/1165/08
C10	Basic Yellow 57 (68391-31-1)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1231/09
C15	Acid Orange 7 (633-96-5)	Not classifiable	No value. Should have been tested at higher conc.	<b>GPMT 25/0</b>	SCCS/1382/10
C22	Acid Red 33 (3567-66-6)	Not classifiable	-	GPMT 10/0	SCCP/1102/07
C29	Acid Yellow 23 (1934-21-0)	Not classifiable	-	GPMT 5/0	SCCNFP/0786/04
C40	Acid Blue 9 (3844-45-9)	Not classifiable	no value	-	SCCNFP/0787/04

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C53	Acid Red 92 (18472-87-2)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1428/11
C54	Acid Yellow 3 (8004-92-0)	Insufficient testing	-	Test by non- guideline method	SCCNFP/0789/04
C63	Acid Violet 43 (4430-18-6)	Not classifiable	no value	-	SCCP/0964/05
C64	Disperse Violet 1 (128-95-0)	Moderate	3.75	-	SCCS/1232/09
C67	Acid Blue 62 (4368-56-3)	Not classifiable	no value	-	SCCP/0878/05
C106	Disperse Black 9 (12222-69-4) (20721-50-0)	Insufficient testing	-	GPMT 0.1/0 - Inadequate description	SCCS/1233/09
C117	Hydroxyanthroquinone aminopropyl methyl morpholinium methosulphate (38866-20-5)	Strong	-	<b>GPMT 0.875/90</b>  Buehler 8.65/47	SCCP/0875/05
C146	Lawsone (83-72-7)	Strong	-	GPMT 1/65 **	SCCNFP/0798/04
C169	Lawsonia inermis (syn. Henna) (84988-66-9; 83-72-7)	Not classifiable	-	Buehler 50/0 **	SCCP/0943/05
C170	Indigofera tinctoria (84775-63-3)	Extreme	-	<b>GPMT 0.1/100,</b> 0.25/80  Buehler 20/0 **	SCCS/1439/11



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C172	HC Blue n° 14 (99788-75-7)	Not classifiable	No value. Should have been tested at higher conc.	<b>GPMT 2.5/0</b>	SCCS/1383/10
C174	Curry Red (25956-17-6)	Not classifiable	no value	-	SCCNFP/0791/04
C175	Acid Red 18 (2611-82-7)	Not classifiable	no value	-	SCCNFP/0792/04
C177	Acid Red 52 (3520-42-1)	Not classifiable	-	GPMT 5/0	SCCP/1115/07
C178	Acid Green 25 (4403-90-1)	Insufficient testing	-	GPMT 5/0 too low conc. **	SCCP/0879/05
C179	Disperse Blue 337 (67674-26-4 + 67701-36-4 + 4471-41-4)	Insufficient testing	No value. Should have been tested at higher conc.	Buehler 10/0 **	SCCS/1399/11
C181	Pigment Red 57 (5858-81-1)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS1411/11

<b>COLIPA n°</b>	<b>INCI name (CAS n°)</b> <i>Common name in italic</i>	<b>Sensitising potency category, based on results from LLNA or guinea pig assays</b>	<b>LLNA EC3 value (%)</b>	<b>Guinea pig assay</b>  GPMT: i.d. induction conc (%)/incidence of sens (%)  Buehler test: topical induction conc (%)/incidence of sens (%)	<b>References</b>
C182	HC Blue 15 (74578-10-2)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1440/11
C183	Tetrabromophenol Blue (4430-25-5)	Insufficient testing	No value. Should have been tested at higher conc.	-	SCCS/1426/11

\*The lowest test concentration was too high and EC3 value could not be calculated; or EC3 value was not calculated in the reference

\*\* Staining of the skin might have interfered with reading of test reaction