

List of hair dye substances proposed for a ban (regulation in the EU)

1. Subject

The Commission is considering banning the use of certain hair dye substances in cosmetic products by amending Council Directive 76/768/EEC of 27 July 1976 (“Cosmetics Directive”).

These substances are proposed to be included in the “List of substances which must not form part of the composition of cosmetic products” under Annex II of the Cosmetics Directive. The relevant Commission directive is expected to be adopted by the end of 2006.

A full listing of the substances proposed to be banned is contained in an appendix to this note.

2. Background

In view of safety concerns expressed in relation to the use of some hair dyes, the Commission agreed in April 2003 together with Member States and the stakeholders, on an overall detailed strategy to regulate hair dye substances within the framework of the Cosmetics Directive. The strategy was published as an “*Information note on the use of ingredients in permanent and non-permanent hair dye formulations (dye precursors and direct dyes)*” on the following web site of the Commission:

<http://europa.eu.int/comm/enterprise/cosmetics/doc/hairdyestrategyinternet.pdf>

The overall objective of this strategy is to regulate the use of hair dye substances on the basis of scientific evaluation of safety data according to the most recent safety requirements of the Scientific Committee on Consumer Products (SCCP). The main element of the strategy is a tiered, modulated approach requiring industry to submit, by certain deadlines, safety files on hair dye substances to be assessed by the SCCP.

Substances used in hair dye products for which no files were submitted for an appropriate risk assessment by the SCCP before the cut-off date of 30 September 2003 (as agreed in the above mentioned strategy) will be considered for a ban, on the highest priority basis.

Concerning the listed hair dye substances proposed for a ban, as no updated safety files were submitted for a risk assessment by the SCCP, there is no evidence that these substances can be considered safe for human health when used in cosmetic products.

APPENDIX:**Proposed list of hair dye substances to be banned**

	Hair dye substance	CAS No.
1	1-Methyl-2,4,5-trihydroxybenzene	1124-09-0
2	2,6-Dihydroxy-4-methyl-pyridine	4664-16-8
3	5-Hydroxy-1,4-benzodioxane	10288-36-5
4	3,4-Methylenedioxyphenol	533-31-3
5	3,4-Methylenedioxyaniline	14268-66-7
6	Hydroxypyridinone	822-89-9
7	3-Nitro-4-aminophenoxyethanol	50982-74-6
8	4-Nitroguaiacol	3251-56-7
9	Acid Black 131	12219-01-1
10	Phloroglucinol	108-73-6
11	1,2,4-Benzenetriacetate	613-03-6
12	HC Blue No. 5	68478-64-8
13	HC Blue No. 4	158571-57-4
14	Sodium sulfanilate	515-74-2
15	Acid Brown 13	6373-79-1
16	Basic Red 46	12221-69-1
17	Disperse Brown 1	23355-64-8
18	Basic Blue 41	12270-13-2
19	Pigment Yellow 73	13515-40-7
20	Pigment Yellow 12	6358-85-6
21	Direct Yellow 12	2870-32-8
22	Solvent Black 3	4197-25-5

23	Direct Black 51	3442-21-5
24	Direct Red 81	2610-11-9
25	Direct Violet 48	37279-54-2
26	Direct Red 23	3441-14-3
27	Direct Red 80	2610-10-8
28	Basic Violet 4	2390-59-2
29	Basic Yellow 28	54060-92-3
30	Basic Yellow 11	4208-80-4
31	Solvent Black 5	11099-03-9
32	Basic Blue 3	33203-82-6
33	Basic Blue 6	966-62-1
34	Solvent Yellow 44	2478-20-8
35	Basic Blue 47	67905-56-0
36	Laccaic Acid / CI Natural Red 25	6219-66-5 / 60687-93-6
37	Acid Orange 3	6373-74-6
38	Disperse Orange 3	730-40-5
39	4-Nitro-m-phenylenediamine	5131-58-8
40	Disperse Violet 4	1220-94-6
41	N-Methyl-3-nitro-p-phenylenediamine	2973-21-9
42	HC Yellow No. 5	56932-44-6
43	HC Yellow No. 3	56932-45-7
44	2-Nitro-N-hydroxyethyl-p-anisidine	57524-53-5
45	N,N'-Dimethyl-N-Hydroxyethyl-3-nitro-p-phenylenediamine	10228-03-2
46	HC Blue No. 6	93633-79-5
47	N-Ethyl-3-Nitro PABA	2788-74-1

48	Basic Red 118	71134-97-9
49	Basic Red 22	12221-52-2
50	Basic Orange 2	532-82-1
51	Basic Orange 1	4438-16-8
52	Acid Red 35	6441-93-6
53	Basic Brown 4	4482-25-1
54	HC Brown No. 2	83803-99-0
55	HC Brown No. 1	83803-98-9
56	Basic Green 1	633-03-4
57	Disperse Blue 3	2475-46-9
58	Disperse Red 11	2872-48-2
59	Disperse Blue 7	3179-90-6
60	HC Blue No 8	22366-99-0
61	HC Yellow No. 8	66612-11-1
62	HC Red No. 9	56330-88-2
63	Basic Blue 9	61-73-4
64	4,6-Bis(2-Hydroxyethoxy)-m-Phenylenediamine HCl	94082-85-6
65	5-Amino-2,6-Dimethoxy-3-Hydroxypyridine	104333-03-1
66	4,4-Diaminodiphenylamine	537-65-5
67	N,N-Diethyltoluene-2,5-Diamine	2051-79-8
68	N,N-Diethyl-p-phenylenediamine sulfate	6065-27-6; 6283-63-2
69	N,N-Dimethyl-p-phenylenediamine sulfate	99-98-9; 6219-73-4
70	Toluene-3,4-Diamine	207-826-2
71	2,4-Diamino-5-methylphenoxyethanol	141614-05-3; 113715-27-8
72	6-Amino-o-cresol	17672-22-9

73	Hydroxyethylamino-methyl-p-aminophenol	110952-46-0
74	2-Amino-3-nitrophenol	603-85-0
75	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine	506-10-28-1
76	2-Nitro-p-phenylenediamine	5307-14-2
77	Basic Blue 26	2580-56-5
78	Basic Violet 14	632-99-5
79	Hydroxyethyl-2,6-dinitro-p-anisidine	122252-11-3
80	6-Nitro-2,5-pyridinediamine	69825-83-8
81	Basic Red 2	477-73-6
82	Acid Black 52	3618-58-4
83	HC Yellow no 6	104333-00-8
84	HC Yellow no 12	59320-13-7
85	HC Blue no 10	102767-27-1; 173994-75-7
86	HC Blue no 9	114087-42-2
87	Ponceau SX	4548-53-2
88	Basic Blue 7	2390-60-5