

THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS  
INTENDED FOR CONSUMERS

OPINION

CONCERNING

HAIR DYES WITHOUT FILE SUBMITTED

adopted by the SCCNFP on 23 April 2004  
by means of the written procedure

## 1. Terms of Reference

### 1.1 Context of the question

Commission services together with Member States agreed on a detailed programme of an overall strategy to regulate hair dyes within the framework of the Cosmetics Directive 76/768/EEC. The strategy was published as “Information note on the use of ingredients in permanent and non-permanent hair dye formulations (dye precursors and direct dyes) on <http://pharmacos.eudra.org/F3/cosmetic/doc/HairDyeStrategyInternet.pdf>.”

This new strategy has been decided following two opinions of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP). In its opinion of June 2001 on the Use of Permanent Hair Dyes and Bladder Cancer Risk, doc. n° SCCNFP/484/01, the SCCNFP concluded that “*the potential risk for the development of bladder cancer in past users of permanent hair dyes is of concern*”.

The SCCNFP recommended that “*the European Commission provides resources for the urgent review of the information, further epidemiological studies are performed to evaluate the possible association between bladder cancer and the use of permanent hair dyes in the EU and the European Commission takes further steps to control the use of hair dye chemicals since the potential risks of using this category of substances give cause for concern*”.

In its opinion of 17 December 2002 on Assessment Strategies for Hair Dyes, doc. n° SCCNFP/0553/02, the SCCNFP recommended an overall safety assessment strategy for hair dyes including the requirements for testing hair dye cosmetic ingredients for their potential genotoxicity/mutagenicity. This safety assessment strategy is not restricted to the risk assessment of permanent hair dyes.

Therefore, Commission services together with Member States agreed to apply their regulatory strategy to all hair dyes used. The main element of the strategy is a tiered, modulated approach requiring industry to submit by certain deadlines files on hair dyes to be evaluated by the SCCNFP. Thus the overall objective of this strategy is to regulate the use of these substances on the basis of scientific evaluation of files according to the most recent requirements of the SCCNFP. Substances for which no file has been submitted for risk assessment by the SCCNFP will be treated on the highest priority basis whereas substances for which information is available will be regulated progressively.

In the first step the strategy foresees to ban all substances for which there is no file submitted for evaluation. By September 2003 no file was submitted for the permanent and non-permanent hair dyes listed in the Annex to this request.

### 1.2. Mandate to the SCCNFP (doc. n° ENTR 000977 of 5 February 2004)

The SCCNFP is requested to answer the following questions:

- \* Does the SCCNFP consider that the use of the ingredients that are part of the Annex to this mandate and for which no file was submitted can be justified for the use as ingredients in hair dye formulations?

- \* Or does the SCCNFP have any other source that justifies the use of the above mentioned ingredients listed in the Annex to this request as ingredients in hair dye formulations?

### 1.3 Statement on the toxicological evaluation

The SCCNFP is the scientific advisory body to the European Commission in matters of consumer protection with respect to cosmetics and non-food products intended for consumers. The Commission's general policy regarding research on animals supports the development of alternative methods to replace or to reduce animal testing when possible. In this context, the SCCNFP has a specific working group on alternatives to animal testing which, in co-operation with other Commission services such as ECVAM (European Centre for Validation of Alternative Methods), evaluates these methods.

The extent to which these validated methods are applicable to cosmetic products and its ingredients is a matter of the SCCNFP.

SCCNFP opinions include evaluations of experiments using laboratory animals; such tests are conducted in accordance with all legal provisions and preferably under chemical law regulations. Only in cases where no alternative method is available will such tests be evaluated and the resulting data accepted, in order to meet the fundamental requirements of the protection of consumer health.

## 2. Review

This list of substances without file submission for evaluation of their use in hair dyes contains both organic and inorganic colorants that may be employed in direct dyeing or oxidative products.

For those substances which are not present in Annexes III and IV of the Cosmetics Directive, and for which SCCNFP has not been provided with a toxicological dossier for safety evaluation, no risk assessment can be undertaken.

Some of the substances may already be listed in the Cosmetics Directive (Annex III and IV). If existing toxicological dossiers for these substances meet current requirements for safety evaluation, then they may be considered safe as hair dyeing agents.

## 3. Opinion

The SCCNFP is of the opinion that the use of the substances listed in the Addendum to this document cannot be considered safe for hair dyeing purposes, unless they are regarded as such on the basis of an adequate safety dossier.

## Addendum

<b>INCI Names</b>	<b>COLIPA N°</b>
6-METHOXY-2,3-PYRIDINEDIAMINE HCl	A 134
1,2,4-BENZENETRIACETATE	
2,3-NAPHTHALENEDIOL	A 051
2,4-DIAMINODIPHENYLAMINE	
2,6- BIS(2-HYDROXYETHOXY)-3,5-PyridineDIAMINE HCl	A 104
2,6-DIAMINOPYRIDINE	A 136
2-METHOXYMETHYL-p-AMINOPHENOL HCl	A 119
2-NITRO-N-HYDROXYETHYL-p-ANISIDINE	B 044
3-NITRO-4-AMINOPHENOXYETHANOL	
4, 4 DIAMINO DIPHENYLAMINE	A 085
4,5-DIAMINO-1-METHYLPYRAZOLE HCl	A 120
4,5-DIAMINO-1-((4-CHLOROPHENYL)METHYL)-1H-PYRAZOLE-SULFATE	A 150
4,6-BIS(2-HYDROXYETHOXY)-m-PHENYLENEDIAMINE HCl	A 110
4-CHLORO-2-AMINOPHENOL	
4-HYDROXYINDOLE	A 106
4-METHOXYTOLUENE-2,5-DIAMINE HCl	
4-NITROGUAIACOL	
4-NITRO-m-PHENYLENEDIAMINE	B 011
5-AMINO-2,6-DIMETHOXY-3-HYDROXYPYRIDINE	A 109
5-AMINO-4-FLUORO-2-METHYLPHENOL SULFATE	A 149
ACACIA CATECHU	
ACID BLACK 131	
ACID BLACK 2	C 058
ACID BLUE 1	C 038
ACID BLUE 3	C 039
ACID BLUE 74	
ACID BROWN 13	
ACID GREEN 1	
ACID GREEN 50	
ACID ORANGE 24	C 030
ACID ORANGE 3	B 003
ACID ORANGE 6	
ACID RED 14	C 013
ACID RED 27	C 019
ACID RED 51	
ACID RED 73	
ACID RED 87	
ACID RED 95	
ACID VIOLET 9	C 051
ACID YELLOW 73 SODIUM SALT	C 052
ALKANNA TINCTORIA	
BASIC BLUE 3	
BASIC BLUE 41	

BASIC BLUE 47	
BASIC BLUE 6	
BASIC BLUE 9	C 151
BASIC BROWN 4	C 031
BASIC GREEN 1	C 037
BASIC GREEN 4	
BASIC ORANGE 1	C005
BASIC ORANGE 2	C 004
BASIC RED 118	B 112
BASIC RED 2	C 055
BASIC RED 22	C 003
BASIC RED 46	
BASIC VIOLET 4	
BASIC YELLOW 11	
BASIC YELLOW 28	
BRILLIANT BLACK 1	C 034
CASSIA ANGUSTIFOLIA	
CHROMIUM HYDROXIDE GREEN	C 166
CHROMIUM OXIDE GREENS	C 165
CURCUMA LONGA	
DIRECT BLACK 51	
DIRECT BLUE 86	
DIRECT RED 23	
DIRECT RED 80	
DIRECT RED 81	
DIRECT VIOLET 48	
DIRECT YELLOW 12	
DISPERSE BLUE 1	B 022
DISPERSE BLUE 3	C 065
DISPERSE BLUE 7	C 069
DISPERSE BROWN 1	
DISPERSE ORANGE 3	B 004
DISPERSE RED 11	C 066
DISPERSE RED 15	C 061
DISPERSE VIOLET 4	B 020
FAST GREEN FCF	C 176
FOOD BLACK 2	C 033
FRANGULA ALNUS	
FRAVINUS EXCELSIOR	
HC BLUE NO. 4	
HC BLUE NO. 5	
HC BLUE NO. 6	B 079
HC BLUE NO. 8	C 118
HC BROWN NO. 1	C 036
HC BROWN NO. 2	C 035
HC RED NO. 9	C 135
HC YELLOW NO. 5	B 035
HC YELLOW NO. 8	C 133

HYDROXYPYRIDINONE	
ISOLEUCINE	
IRON OXIDE	
JUGLANS REGIA	
LACCAIC ACID	
LACTOFLAVIN	
N,N DIETHYL m-AMINOPHENOL	A 072
N,N-DIETHYLTOLUENE-2,5-DIAMINE	
N,N-DIMETHYL 2,6-PYRIDINEDIAMINE HCl	
N,N'-DIMETHYL-N-HYDROXYETHYL-3-NITRO-p-PHENYLENDIAMINE	B 053
N-CYCLOPENTYL-m-AMINOPHENOL	A 140
N-ETHYL-3-NITRO PABA	B 083
NITROPHENOL	
N-METHOXYETHYL PARAPHENYLENE DIAMINE HCl	A 040
N-METHYL-3-NITRO-p-PHENYLENEDIAMINE	B 033
N-N DIETHYL P-PHENYLENEDIAMINESULFATE	A 035
N-N DIMETHYL PARAPHENYLENE DIAMINE	A 041
PHLOROGLUCINOL	
PIGMENT BLUE 15	C 072
PIGMENT GREEN 7	
PIGMENT RED 112	
PIGMENT RED 172 ALUMINUM LAKE	
PIGMENT RED 4	
PIGMENT RED 48	
PIGMENT RED 5	
PIGMENT RED 63:1	
PIGMENT RED 64:1	
PIGMENT RED 83	
PIGMENT RED 90:1 ALUMINUM LAKE	
PIGMENT VIOLET 19	
PIGMENT VIOLET 23	
PIGMENT YELLOW 12	
PIGMENT YELLOW 13	
PIGMENT YELLOW 73	
SODIUM SULFANILATE	
SOLVENT BLACK 3	
SOLVENT BLACK 5	
SOLVENT GREEN 3	
SOLVENT GREEN 7	C 167
SOLVENT ORANGE 1	
SOLVENT RED 1	C 160
SOLVENT RED 23	
SOLVENT RED 3	
SOLVENT RED 43	
SOLVENT RED 72	
SOLVENT RED 73	

SOLVENT VIOLET 13	C 062
SOLVENT YELLOW 29	
SOLVENT YELLOW 33	
SOLVENT YELLOW 44	
SUNSET YELLOW	C 018
TOLUENE-3,4-DIAMINE	
ULTRAMARINES	C 164
VAT RED 1	