



**EUROPEAN COMMISSION**  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment  
**C7 - Risk assessment**

## **SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS**

### **SCCP**

### **Opinion**

### **concerning**

### **Request for Confirmation of the SCCNFP Opinion 0474/01 on Chemical Ingredients in Cosmetic Products Classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to Council Directive 67/548/EEC**

Adopted by the SCCP  
during the 4<sup>th</sup> plenary of 21 June 2005

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## BACKGROUND

In its opinion of September 2001 on "Chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemicals directive 67/548/EEC" SCCNFP/0474/01, final, the SCCNFP considered that:

*“The presence of carcinogens, mutagens, or substances toxic to reproduction in cosmetic products is of concern to the health of the consumer. Substances classified according to Council Directive 67/548/EEC as carcinogens category 1 or 2 (except substances only carcinogenic by inhalation), mutagens category 1 and 2, or toxic to reproduction category 1 or 2 and substances with similar potentials, must not be intentionally added to cosmetic products.*

*Substances classified according to Council Directive 67/548/EEC as carcinogens category 3, mutagens category 3, or toxic to reproduction category 3 and substances with similar potentials, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.*

*If a carcinogen, mutagen, or a substance toxic to reproduction is present in a cosmetic product from its presence in a natural ingredient, as an impurity, or because it is formed during the manufacture, it must be demonstrated that the product does not pose a threat to the health of the consumer.”*

Based on this opinion, the Council and the European Parliament adopted on the 27<sup>th</sup> February 2003 the Directive 2003/15/EC<sup>1</sup> that introduced in the Directive 76/768/EEC a new provision namely Article 4b.

Article 4b of the Council Directive 76/768/EEC relating to cosmetic products stipulates that *“the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.”*

In order to implement that provision, the Commission, in accordance with Article 8, paragraph 2, of the Directive 76/768/EEC, has consulted the SCCNFP.

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<sup>1</sup> OJ L 66, 11.03.2003, p. 26. See recital (12).

(12) *“The SCCNFP stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances 1 as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.”*

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On 25 May 2004, the SCCNFP confirmed its opinion of 25 September 2001 (SCCNFP/0825/004).

Since this submission the Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>2</sup> has been amended by Commission Directive 2004/73/EC of 29 April 2004<sup>3</sup>. It classified and so added in its Annex I certain substances as CMR category 1, 2 and 3.

Article 4b of the Cosmetics Directive, prohibits the use in cosmetic products of substances CMR category 1, 2 and 3 classified in the Annex I of the Council Directive 67/548/EEC. Some of these newly classified substances are already regulated in Annex II of Directive 76/768/EEC and so are not mentioned in Annexes of this mandate.

The current request refers to:

- all substances newly classified as CMR category 1 and 2 and not yet covered by the Annex II of the Cosmetics Directive (76/768/EEC) (annex 1)
- all substances newly classified as CMR category 3 and not yet covered by an Annex of the Cosmetics Directive (76/768/EEC) (annex 2)
- phenol, substance newly classified as CMR category 3, listed in Annex III but without scientific opinion (annex 3).
- N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate, substance newly classified as CMR category 3. Borates in general are listed in Annex III. This substance is a borate too, but without scientific opinion (annex 3).
- *m*-phenylenediamine, substance classified as CMR substance 3, listed in Annex III, with a negative opinion (SCCNFP/0635/03) and no further commitment from Industry (May 05) (annex 3).

Currently mandates on substances, newly classified as CMR category 3 are in the process of being submitted for risk assessment to the SCCP:

- Bishydroxyethyl biscetyl malonamide CAS 149591-38-8
- Toluene CAS 108-88-3

The current request will not affect:

- Musk xylene, substance newly classified as CMR category 3, listed in Annex III/96 as a positive opinion exists (SCCNFP/0817/04).

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<sup>2</sup> OJ L 196, 16.08.1967, p. 0001

<sup>3</sup> OJ L 152, 30.04.2004.

## **1. TERMS OF REFERENCE**

In relation to the substances annexed, the SCCP is asked whether there are new elements that would lead it to amend its opinions on CMR substances of 25 September 2001, and if so, to revise it accordingly.

Annexed: Annex 1, 2 and 3.

## **2. OPINION**

The SCCP is of the opinion that there are no new elements that would lead it to amend its opinion on CMR substances of 25 September 2001 (doc. n° SCCNFP/0474/01).

## **3. CONCLUSION**

See point 3. Opinion

## **4. MINORITY OPINION**

Not applicable

## **5. REFERENCES**

Not applicable

## **6. ACKNOWLEDGEMENTS**

Not applicable

**Annex 1: list of substances newly classified as CMR 1 and 2 (Commission Directive 2004/73/EC) (29<sup>th</sup> ATP) and not yet covered by the Annex II of the Cosmetics Directive (76/768/EEC)**

Chemical name	EC	CAS No
isobutyl nitrite	208-819-7	542-56-3
isoprene (stabilized)	201-143-3	78-79-5
2-methyl-1,3-butadiene		
1-bromopropane	203-445-0	106-94-5
n-propyl bromide		
chloroprene (stabilized)	204-818-0	126-99-8
2-chlorobuta-1,3-diene		
1,2,3-trichloropropane	202-486-1	96-18-4
1,2-dimethoxyethane	203-794-9	110-71-4
ethylene glycol dimethyl ether (EGDME)		
dinocap (ISO)	254-408-0	39300-45-3
diaminotoluene, technical product - mixture of [4-methyl- <i>m</i> -phenylene diamine] and [2-methyl- <i>m</i> -phenylene diamine]	246-910-3	25376-45-8
methyl-phenylenediamine		
$\alpha,\alpha,\alpha,4$ -tetrachlorotoluene	226-009-1	5216-25-1
<i>p</i> -chlorobenzotrichloride		
diphenylether; octabromo derivate	251-087-9	32536-52-0
1,2-bis(2-methoxyethoxy)ethane	203-977-3	112-49-2
TEGDME		
Triethylene glycol dimethyl ether		
triglyme		
tetrahydrothiopyran-3-carboxaldehyde	407-330-8	61571-06-0
4,4'-bis(dimethylamino)benzophenone	202-027-5	90-94-8
Michler's ketone		
oxiranemethanol, 4-methylbenzene-sulfonate, (S)-	417-210-7	70987-78-9
1,2-benzenedicarboxylic acid, dipentylester, branched and linear [1]	284-032-2 [1]	84777-06-0 [1]
n-pentyl-isopentylphthalate [2]	- [2]	- [2]
di-n-pentyl phthalate [3]	205-017-9 [3]	131-18-0 [3]
diisopentylphthalate [4]	210-088-4 [4]	605-50-5 [4]
BBP	201-622-7	85-68-7
benzyl butyl phthalate		
1,2-benzenedicarboxylic acid di-C7-11-branched and linear alkylesters	271-084-6	68515-42-4
A mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate	402-660-9	-
trisodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-oxido-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate		
(methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diyl)))-1,1'-dipyridinium dichloride	401-500-5	-
dihydrochloride		
2-[2-hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]fluoren-9-one	420-580-2	-
azafenidin	-	68049-83-2
2,4,5-trimethylaniline [1]	205-282-0 [1]	137-17-7 [1]
2,4,5-trimethylaniline hydrochloride [2]	- [2]	21436-97-5 [2]

## Opinion on substances classified as carcinogenic, mutagenic or toxic for reproduction

Chemical name	EC	CAS No
4,4'-thiodianiline and its salts	205-370-9	139-65-1
4,4'-oxydianiline and its salts <i>p</i> -aminophenyl ether	202-977-0	101-80-4
<i>N,N,N',N'</i> -tetramethyl-4,4'-methylendianiline	202-959-2	101-61-1
C.I. Basic Violet 3 with $\geq 0.1$ % of Michler's ketone (EC no. 202-027-5)	208-953-6	548-62-9
6-methoxy- <i>m</i> -toluidine <i>p</i> -cresidine	204-419-1	120-71-8
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2
A mixture of: 1,3,5-tris(3-aminomethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione a mixture of oligomers of 3,5-bis(3-aminomethylphenyl)-1-poly[3,5-bis(3-aminomethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione	421-550-1	-
2-nitrotoluene	201-853-3	88-72-2

**Annex 2: list of substances newly classified as CMR 3 (Commission Directive 2004/73/EC) (29<sup>th</sup> ATP) and not yet covered by an Annex of the Cosmetics Directive (76/768/EEC)**

Chemical name	EC	CAS No
tributyl phosphate	204-800-2	126-73-8
naphthalene	202-049-5	91-20-3
nonylphenol [1]	246-672-0 [1]	25154-52-3 [1]
4-nonylphenol, branched [2]	284-325-5 [2]	84852-15-3 [2]
1,1,2-trichloroethane	201-166-9	79-00-5
Pentachloroethane	200-925-1	76-01-7
1,1-dichloroethylene	200-864-0	75-35-4
vinylidene chloride		
3-chloropropene	203-457-6	107-05-1
allyl chloride		
1,4-dichlorobenzene	203-400-5	106-46-7
<i>p</i> -dichlorobenzene		
bis(2-chloroethyl) ether	203-870-1	111-44-4
bisphenol A	201-245-8	80-05-7
4,4'-isopropylidenediphenol		
1,3,5-trioxan	203-812-5	110-88-3
trioxymethylene		
propargite (ISO)	219-006-1	2312-35-8
2-(4- <i>tert</i> -butylphenoxy) cyclohexyl		
prop-2-ynyl sulphite		
1-chloro-4-nitrobenzene	202-809-6	100-00-5
molinate (ISO)	218-661-0	2212-67-1
<i>S</i> -ethyl		
1-perhydroazepinecarbothioate		
<i>S</i> -ethyl perhydroazepine-1-carbothioate		
fenpropimorph	266-719-9	67564-91-4
<i>cis</i> -4-[3-( <i>p</i> - <i>tert</i> -butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine		
Epoxiconazole	406-850-2	133855-98-8
(2 <i>RS</i> ,3 <i>SR</i> )-3-(2-chlorophenyl)-2-(4-fluorophenyl)-[(1 <i>H</i> -1,2,4-triazol-1-yl)methyl]oxirane		
methyl isocyanate	210-866-3	624-83-9
Fuels, diesel	269-822-7	68334-30-5
Gasoil - unspecified		
H <sub>2</sub> N		
O,O'-(ethenylmethylsilylene)	421-870-1	-
di[(4-methylpentan-2-one)oxime]		
A 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chroman-1-yl)resorcinol-4-yl-tris(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chroman-1-yl)resorcinolbis(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)	414-770-4	140698-96-0
A mixture of: reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxo-naphthalenesulfonate (1:2) Reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3)	417-980-4	-



Chemical name	EC	CAS No
malachite green hydrochloride [1]	209-322-8 [1]	569-64-2 [1]
malachite green oxalate [2]	219-441-7 [2]	18015-76-4 [2]
1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3
5-(3-butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino)propyl]-3-hydroxycyclohex-2-en-1-one	414-790-3	138164-12-2
trans-4-phenyl-L-proline	416-020-1	96314-26-0
bromoxynil heptanoate (ISO) 2,6-dibromo-4-cyanophenyl heptanoate	260-300-4	56634-95-8
A mixture of: 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo]benzoic acid and 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl)azo]benzoic acid	418-230-9	163879-69-4
2-{4-(2-ammoniopropylamino)-6-[4-hydroxy-3-(5-methyl-2-methoxy-4-sulfamoylphenylazo)-2-sulfonatophenyl]-1,3,5-triazin-2-ylamino}-2-aminopropyl formate	424-260-3	-
5-nitro- <i>o</i> -toluidine [1]	202-765-8 [1]	99-55-8 [1]
5-nitro- <i>o</i> -toluidine hydrochloride [2]	256-960-8 [2]	51085-52-0 [2]
1-(1-naphthylmethyl)quinolinium chloride	406-220-7	65322-65-8
(R)-5-bromo-3-(1-methyl-2-pyrrolidinyl methyl)-1H-indole	422-390-5	143322-57-0
pymetrozine (ISO) ( <i>E</i> )-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2 <i>H</i> )-one	-	123312-89-0
oxadiargyl (ISO) 3-[2,4-dichloro-5-(2-propynyloxy)phenyl]-5-(1,1-dimethylethyl)-1,3,4-oxadiazol-2(3 <i>H</i> )-one 5- <i>tert</i> -butyl-3-[2,4-dichloro-5-(prop-2-ynyloxy)phenyl]-1,3,4-oxadiazol-2(3 <i>H</i> )-one	254-637-6	39807-15-3
chlorotoluron 3-(3-chloro- <i>p</i> -tolyl)-1,1-dimethylurea	239-592-2	15545-48-9
N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl]acetamide	416-860-9	-
1,3-Bis(vinylsulfonylacetamido)-propane	428-350-3	93629-90-4
N,N'-dihexadecyl-N,N'-bis(2-hydroxyethyl)propanediamide	422-560-9	149591-38-8
4-ethoxyaniline <i>p</i> -phenetidine	205-855-5	156-43-4

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**Annex 3: list of substances classified as CMR 3 (Commission Directive 2004/73/EC and already covered by Annex III of the Cosmetics Directive (76/768/EEC))**

<b>Chemical name</b>	<b>EC</b>	<b>CAS No</b>	<b>Exist reg</b>
phenol carbolic acid monohydroxybenzene phenylalcohol	203-632-7	108-95-2	III/19
N,N-dimethylanilinium tetrakis (pentafluorophenyl)borate	422-050-6	118612-00-3	III/1
<i>m</i> -phenylenediamine	108-45-2	203-584-7	III/8