



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 3rd plenary of 15 March 2005

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1. BACKGROUND

In its opinion of September 2001 on "Chemical ingredient in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemical directive 67/548/EEC" SCCNFP/0474/01, final, the SCCNFP¹ 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 27th February 2003 the Directive 2003/15/EC² that introduce 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 stipulate 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.”*

¹ Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers

² 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 2 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.”*

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.

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 substances³ has been amended by Commission Directive 2004/73/EC of 29 April 2004⁴. It classified and so add in its Annex I certain substances as CMR category 1, 2 and 3.

Article 4 b 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 new 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 2).

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

- Bis(2-hydroxyethyl) malonamide CAS 149591-38-8
- Toluene CAS 108-88-3

2. 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.

³ OJ L 196, 16.08.1967, p. 0001

⁴ OJ L 152, 30.04.2004.

3. 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).

4. CONCLUSION

See point 3. Opinion

5. MINORITY OPINION

Not applicable

6. REFERENCES

Not applicable

7. ACKNOWLEDGEMENTS

Not applicable

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

	Chemical Name	Note	CAS N°	Classification
	Linuron (ISO) 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea	E	330-55-2	Repr.Cat.2: R61 Repr.Cat.3: R62 Carc.Cat.3: R40
	Isobutyl nitrite	E	542-56-3	Carc.Cat.2: R45 Muta.Cat.3: R68
	Dimethyl sulfate	E	77-78-1	Carc.Cat.2: R45
	Chromium (VI) trioxide	E	1333-82-0	Carc.Cat.1: R45 Muta.Cat.2: R46 Repr.Cat.3: R62
	Potassium dichromate	E	7778-50-8	Carc.Cat.2: R45 Muta.Cat.2: R46 Repr.Cat.2: R60-61
	Ammonium dichromate	E	7789-09-5	Carc.Cat.2: R45 Muta.Cat.2: R46 Repr.Cat.2: R60-61
	Sodium dichromate anhydrate	E	10588-01-9	Carc.Cat.2: R45 Muta.Cat.2: R46 Repr.Cat.2: R60-61
	Sodium dichromate, dihydrate	E	7789-12-0	Carc.Cat.2: R45 Muta.Cat.2: R46 Repr.Cat.2: R60-61
	Cobalt sulphate	E	10124-43-3	Carc.Cat.2: R49
	Isoprene (stabilized) 2-methyl-1,3-butadiene	D	78-79-5	Carc.Cat.2: R45 Muta.Cat.3: R68
	4-nonylphenol, branched		84852-15-3 [2]	Repr.Cat.3: R63
	1-bromopropane		106-94-5	Repr.Cat.2: R60 Repr.Cat.3: R63
	2-chlorobuta-1,3-diene	DE	126-99-8	Carc.Cat.2: R45
	1,2,3-trichloropropane	D	96-18-4	Carc.Cat.2: R45 Repr.Cat.2: R60
	1,2-dimethoxyethane EGDME		110-71-4	Repr.Cat.2: R60 Repr.Cat.2: R61
	2,3-epoxypropan-1-ol glycidol	E	556-52-5	Carc.Cat.2: R45 Muta.Cat.3: R68 Repr.Cat.2: R60
	Phenyl glycidyl ether	E	122-60-1	Carc.Cat.2: R45 Muta.Cat.3: R68
	Dinocap (ISO)	E	39300-45-3	Repr.Cat.2: R61
	2-methoxyaniline <i>o</i> -anisidine	E	90-04-0	Carc.Cat.2: R45 Muta.Cat.3: R68
	4,4'-diaminodiphenylmethane methylenedianiline	E	101-77-9	Carc.Cat.2: R45 Muta.Cat.3: R68
	Diaminotoluene, technical product – mixture of [2] and [3] methyl-phenylenediamine [1] 4-methyl- <i>m</i> -phenylene diamine [2] 2-methyl- <i>m</i> -phenylene diamine [3]	E	25376-45-8 [1] 95-80-7 [2] 823-40-5 [3]	Carc.Cat.2: R45
	2-methylaziridine propyleneimine	E	75-55-8	Carc.Cat.2: R45
	Carbendazim (ISO) methyl benzimidazol- 2-ylcarbamate		10605-21-7	Muta.Cat.2: R46 Repr.Cat.2: R60-61
	Benomyl (ISO) methyl 1- (butylcarbamoyl)benzimidazol-2-		17804-35-2	Muta.Cat.2: R46 Repr.Cat.2: R60-61

	Chemical Name	Note	CAS N°	Classification
	ylcarbamate			
	Creosote oil, acenaphthene fraction, acenaphthene-free Wash Oil Redistillate	H	90640-85-0	Carc.Cat.2: R45
	Residues (coal tars), creosote oil distn. Wash Oil Redistillate	H	92061-93-3	Carc.Cat.2: R45
	Creosote oil, acenaphthene fraction Wash Oil	H	90640-84-9	Carc.Cat.2: R45
	Cresosote oil	H	61789-28-4	Carc.Cat.2: R45
	Creosote oil, high-boiling distillate	H	70321-79-8	Carc.Cat.2: R45
	Creosote oil	H	8001-58-9	Carc.Cat.2: R45
	Extract residue (coal), creosote oil acid Wash Oil Extract Residue	H	122384-77-4	Carc.Cat.2: R45
	Creosote oil, low-boiling distillate	H	70321-80-1	Carc.Cat.2: R45
	$\alpha,\alpha,\alpha,4$ -tetrachlorotoluene <i>p</i> -chlorobenzotrichloride	E	5216-25-1	Carc.Cat.2: R45 Repr.Cat.3: R62
	Diphenylether; octabromo derivate		32536-52-0	Repr.Cat.2: R61 Repr.Cat.3: R62
	1,2-bis(2-methoxyethoxy)ethane TEGDME		112-49-2	Repr.Cat.2: R61 Repr.Cat.3: R62
	Tetrahydrothiopyran-3-carboxaldehyde		61571-06-0	Repr.Cat.2: R61
	4,4'-bis(dimethylamino)benzophenone Michler's ketone		90-94-8	Carc.Cat.2: R45 Muta.Cat.3: R68
	Oxiranemethanol		70987-78-9	Carc.Cat.2: R45 Muta.Cat.3: R68
	1,2-benzenedicarboxylic acid, dipentylester, branched and linear [1] n-pentyl-isopentylphthalate [2] di-n-pentyl phthalate [3] diisopentylphthalate [4]		84777-06-0 [1]-[2] 131-18-0 [3] 605-50-5 [4]	Repr.Cat.2: R60-61
	Benzyl butyl phthalate BBP		85-68-7	Repr.Cat.2: R61 Repr.Cat.3: R62
	1,2-benzenedicarboxylic acid di-C ₇₋₁₁ -branched and linear alkylesters		68515-42-4	Repr.Cat.2: R61 Repr.Cat.3: R62
	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		-	Repr.Cat.2: R61
	2-[2-hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)carbamoyl-1-naphthylazo]fluoren-9-one		-	Repr.Cat.2: R61
	azafenidin		68049-83-2	Repr.Cat.2: R61 Repr.Cat.3: R62
	2,4,5-trimethylaniline [1] 2,4,5-trimethylaniline hydrochloride [2]	E	137-17-7[1] 21436-97-5[2]	Carc.Cat.2: R45
	4,4'-thiodianiline and its salts	E	139-65-1	Carc.Cat.2: R45
	4,4'-oxydianiline and its salts	E	101-80-4	Carc.Cat.2: R45 Carc.Cat.2: R46
	2,4-diaminoanisole 4-methoxy-m-phenylenediamine [1] 2,4-diaminoanisole sulphate [2]		615-05-4[1] 39156-41-7[2]	Carc.Cat.2: R45 Muta.Cat.3: R68
	<i>N,N,N',N'</i> -tetramethyl-4,4'-methylenedianiline		101-61-1	Carc.Cat.2: R45

	Chemical Name	Note	CAS N°	Classification
	C.I. Basic Violet 3 with $\geq 0.1\%$ of Michler's ketone (EC no. 202-027-5)	E	548-62-9	Carc.Cat.2: R45
	6-methoxy-m-toluidine p-cresidine	E	120-71-8	Carc.Cat.2: R45
	A mixture of: 1,3,5-tris(3-aminoethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione a mixture of oligomers of 3,5-bis(3-aminoethylphenyl)-1-poly[3,5-bis(3-aminoethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione		-	Carc.Cat.2: R45 Repr.Cat.2: R61
	2-nitrotoluene	E	88-72-2	Carc.Cat.2: R45 Muta.Cat.2: R46 Repr.Cat.3: R62

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

	Chemical Name	Note	CAS N°	Classification
	Isoproturon 3-(4-isopropylphenyl)-1,1-dimethylurea		34123-59-6	Carc.Cat.3: R40
	Tributyl phosphate		126-73-8	Carc.Cat.3: R40
	UVCB condensation product of: tetrakis(hydroxymethyl)phosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine		166242-53-1	Carc.Cat.3: R40
	n-hexane		110-54-3	Repr.Cat.3: R62
	Nonylphenol		25154-52-3 [1]	Repr.Cat.3: R62
	tetrachloromethane		56-23-5	Carc.Cat.3: R40
	1,2-trichloroethane		79-00-5	Carc.Cat.3: R40
	1,1-dichloroethylene	D	75-35-4	Carc.Cat.3: R40
	3-chloropropene	D	107-05-1	Carc.Cat.3: R40 Muta.Cat.3: R68
	1,4-dichlorobenzene		106-46-7	Carc.Cat.3: R40
	Bis(2-chloroethyl) ether		111-44-4	Carc.Cat.3: R40
	4,4-isopropylidenediphenol, Bisphenol A		80-05-7	Repr.Cat.3: R62
	1,3,5-trioxan		110-88-3	Repr.Cat.3: R63
	Propargite (ISO) 2-(4-tert-butylphenoxy)cyclohexyl prop- 2-ynyl sulphite		2312-35-8	Carc.Cat.3: R40
	Bromoxynil (ISO) and its salts 3,5- dibromo-4-hydroxybenzonitrile bromoxynil phenol		1689-84-5	Repr.Cat.3: R63
	Ioxynil (ISO) and its salts 4-hydroxy-3,5- diiodobenzonitrile		1689-83-4	Repr.Cat.3: R63
	Chlorothalonil (ISO) tetrachloroisophthalonitrile		1897-45-6	Carc.Cat.3: R40
	Bromoxynil octanoate (ISO) 2,6-dibromo-4-cyanophenyl octanoate		1689-99-2	Repr.Cat.3: R63
	Ioxynil octanoate (ISO) 4-cyano-2,6-diiodophenyl octanoate		3861-47-0	Repr.Cat.3: R63
	1-chloro-4-nitrobenzene		100-00-5	Carc.Cat.3: R40 Muta.Cat.3: R68
	Amitrole (ISO) 1,2,4-triazole-3-ylamine		61-82-5	Repr.Cat.3: R63
	Molinate (ISO) S-ethyl 1- perhydroazepinecarbothioate S-ethyl perhydroazepine-1-carbothioate		2212-67-1	Carc.Cat.3: R40 Repr.Cat.3: R62
	Fenpropimorph cis-4-[3-(p-ert- butylphenyl)-2-methylpropyl]-2,6- dimethylmorpholine		67564-91-4	Repr.Cat.3: R63
	Epoxiconazole (2RS,3SR)-3-(2- chlorophenyl)-2-(4-fluorophenyl)-[(1H- 1,2,4-triazol-1-yl)methyl]oxirane		133855-98-8	Carc.Cat.3: R40 Repr.Cat.3: R62 Repr.Cat.3: R63
	Methyl isocyanate		624-83-9	Repr.Cat.3: R63
	m-tolylidene diisocyanate		26471-62-5 [3]	Carc.Cat.3: R40
	Alachlor (ISO) 2-chloro-2',6'-diethyl-N- (methoxymethyl)acetanilide		15972-60-8	Carc.Cat.3: R40
	N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate		118612-00-3	Carc.Cat.3: R40
	O,O'-(ethenylmethylsilylene)di[(4-		-	Repr.Cat.3: R62

	Chemical Name	Note	CAS N°	Classification
	methylpentan-2-one)oxime]			
	A 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinol-4-yl-tris(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinolbis(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)		140698-96-0	Carc.Cat.3: R40
	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-oxo-naphthalenesulfonate (1:3)		-	Carc.Cat.3: R40
	Malachite green hydrochloride [1] Malachite green oxalate [2]		569-64-2[1] 18015-76-4[2]	Repr.Cat.3: R63
	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol		107534-96-3	Repr.Cat.3: R63
	5-(3-butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino)propyl]-3-hydroxycyclohex-2-en-1-one		138164-12-2	Repr.Cat.3: R62-63
	Trans-4-phenyl-L-proline		96314-26-0	Repr.Cat.3: R62
	Bromonil heptanoate (ISO) 2,6-dibromo-4-cyanophenyl heptanoate		56634-95-8	Repr.Cat.3: R63
	A mixture of: 5-[(4[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo] benzoic acid 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-3-[(3-phosphophenyl)azo]benzoic acid		163879-69-4	Repr.Cat.3: R62
	C.I. Basic Violet 3 4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride		548-62-9	Carc.Cat.3: R40
	5-nitro-o-toluidine [1] 5-nitro-o-toluidine hydrochloride [2]		99-55-8 [1] 51085-52-0 [2]	Carc.Cat.3: R40
	1-(1-naphthylmethyl)quinolinium chloride		65322-65-8	Carc.Cat.3: R40 Muta.Cat.3: R68
	(R)-5-bromo-3-(1-methyl-2-pyrrolidinylmethyl)-1H-indole		143322-57-0	Repr.Cat.3: R62
	Pymetrozine (ISO) (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	Carc.Cat.3: R40
	Oxadiargyl (ISO) 3-[2,4-dichloro-5-(2-propynyloxy)phenyl]-5-(1,1-dimethylethyl)-1,3,4-oxadiazol-2(3H)-one 5-tert-butyl-3-[2,4-dichloro-5-(prop-2-ynyloxy)phenyl]-1,3,4-oxadiazol-2(3H)-one		39807-15-3	Repr.Cat.3: R63
	Chlorotoluron 3-(3-chloro-p-tolyl)-1,1-dimethylurea		15545-48-9	Carc.Cat.3: R40 Repr.Cat.3: R63

	Chemical Name	Note	CAS N°	Classification
	N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl]acetamide		-	Repr.Cat.3: R62
	1,3-bis(vinylsulfonylacetamido)propane		93629-90-4	Muta.Cat.3: R68
	p-phenetidine		156-43-4	Muta.Cat.3: R68

Specific case of phenol

	Chemical Name	Note	CAS N°	Classification
III 19	Phenol		108-95-2	Muta.Cat.3: R68