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

CONCERNING

ACID YELLOW 3

COLIPA n° C54

Adopted by the SCCNFP during the 28th plenary meeting
of 25 May 2004

1. Terms of Reference

1.1 Context of the question

The adaptation to technical progress of the Annexes to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

1.2 Request to the SCCNFP

The SCCNFP is requested to answer the following questions :

* Is Acid Yellow 3 safe for use as a hair dye ingredient?

* Does the SCCNFP propose any restrictions or conditions for its use in cosmetic products?

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. Toxicological Evaluation and Characterisation

2.1. General

Acid Yellow 3 is listed as CI 10316 and CI 47005 in Annex IV, part 1 – list of colouring agents allowed for use in cosmetic products – to Directive 76/768/EEC on cosmetic products.
Acid Yellow 3 is a colorant allowed in Europe for food (Directive 94/36/EC, Annex 1, E104 quinoline yellow). It is approved for use in drugs and cosmetics in the USA.

2.1.1. Primary name

Acid Yellow 3 (INCI)

2.1.2. Chemical names

Mixture of the disodium salts of the mono- and disulfonic acids of 2-(2-quinolyl)-1H-indene-1,3(2H)-dione

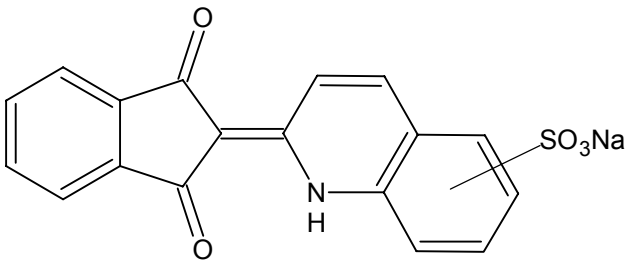
2.1.3. Trade names and abbreviations

COLIPA n°	:	C 54
Trade name	:	D&C Yellow Nº 10
Other names	:	Quinoline Yellow, E104, Food Yellow 13

2.1.4. CAS / EINECS / Colour INDEX number

CAS	:	/
EINECS	:	/
Colour index	:	CI 10316; CI 47005

2.1.5. Structural formula



2.1.6. Empirical formula

Emp. Formula	:	$C_{18}H_{10}NNaO_5S$ (principal compound)
Mol weight	:	375.3 g/mol (monosulfonic)
		477.0 g/mol (disulfonic)

2.1.7. Purity, composition and substance codes

All analytical data are related to batches 0679AB, DCOYM/1 and AK6423

Purity

Titre as determined by HPLC	:	89.26% (290 and 418 nm) (qualitative)
Monosulphonated	:	85-93.7%
Disulphonated	:	3.6-13.8%
Unsulphonated	:	< 1.0%
NaCl	:	0.1-1.6%
Na_2SO_4	:	0.1-3.5%
Water insoluble matter	:	0.2%
Heavy metals	:	< 24 ppm

Reagents and intermediate reaction products

Sulfonated 2-methyl quinoline	:	0.05%
2-(2-quinolyl)-1H-indene-1,3-(2H)-dione:		< 4 ppm

2.1.8. Physical properties

Appearance	:	Yellow powder
Melting point	:	>150ºC (decomposition)
Boiling point	:	/
Density	:	/
Rel. vap. dens.	:	/
Vapour Press.	:	/
Log P_{ow}	:	0.7

2.1.9. Solubility

20% soluble in water, 5% soluble in saline, 2.5% soluble in DMSO, 2% in standard formulation.

General comments on analytical and physico-chemical characterisation

* The identity of the substance is not clear.
* Two additional peaks are detected by HPLC.
* Details on stability are not provided.
* Information on batches is only given for some studies. The majority is reported as an overview of published literature.

2.2. Function and uses

Acid Yellow 3 is used in non-oxidative hair dye formulation at a maximum concentration of 0.5%. It is intended for once monthly use with typical application of 100 ml.

TOXICOLOGICAL CHARACTERISATION

The toxicological data were established between 1960 and 1980. They were evaluated in detail by FDA (ref.1), JECFA (Joint Expert Committee of FAO and WHO, latest update. ref. 2) and the EU (ref. 3). The acceptable daily intake (ADI) was set at 0-10 mg/kg bw/day.

For use in cosmetics, the compound was evaluated by the German DFG (Farbstoffkommission der Deutschen Forschungsgemeinschaft, ref. 4). A toxicity profile including a summary of toxicological data was compiled by BIBRA in 1990 (ref. 5).

2.3. Toxicity

2.3.1. Acute oral toxicity

LD50 (rat) > 2 g/kg bw
LD50 (dog) > 1 g/kg bw
LD50 (rat) > 2 g/kg bw
LD50 (rat) > 5 g/kg bw

The data in the dossier were taken from the literature or unpublished reports. No study details are available.

Ref.: 6, 7, 8

2.3.2. Acute dermal toxicity

No data

2.3.3. Acute inhalation toxicity

No data

2.3.4. Repeated dose oral toxicity

See point 2.3.10.

2.3.5 Repeated dose dermal toxicity

No data

2.3.6. Repeated dose inhalation toxicity

No data

2.3.7. Subchronic oral toxicity

See point 2.3.10.

2.3.8. Sub-chronic dermal toxicity

No data

2.3.9. Sub-chronic inhalation toxicity

No data

2.3.10. Chronic toxicity

Summary of toxicological studies

At present, no studies on acute, subacute, subchronic, chronic, reproductive and developmental toxicity and carcinogenicity are available to the SCCNFP for evaluation. From the documents supplied by the applicant, it can be derived that many of such studies were performed between 1960 and 1980. The studies are summarized in the table.

The Scientific Committee on Food (SCF) established an ADI value of 0-10 mg/kg bw/day, based on a NOEL of 1000 mg/kg bw/day in a long term mouse study (ref. 3). The same study (table, study n° 11) was evaluated by JECFA and the same ADI value was estimated (ref. 2). FDA derived an acceptable daily intake of 10 mg/kg bw/day, based on a NOAEL of 1000 mg/kg bw/day, corresponding to 2% in the diet. This was based on 2 chronic toxicity and carcinogenicity feeding studies in rats and mice (table, studies n° 8 and 9, ref. 1). These studies were additionally evaluated by BIBRA and the DFG. Based on body and organ weight changes, BIBRA and DFG deduced a NOAEL of 250 mg/kg bw/day, corresponding to 0.5% in the diet.

Furthermore, it has to be mentioned that the evaluation of a reproductive toxicity study by BIBRA (study 12 in the table) concluded that an increase in postnatal mortality and a decrease in postnatal weight gain occurred at and above 0.5%. From these findings, a NOAEL of 50 mg/kg bw/day could be deduced.

Table : overview of toxicological studies

No.	study type / Species / No.	Application route / time / doses	Source / evaluation	Parameters / effects	NOEL
1	Subacute / cat / number unknown	Po / 7 d / 100 mg/kg bw	Oettel et al. 1965 / DFG + BIBRA	Red blood cells / no effect	/
2	Subchronic / rat / 5m + 5 f	diet / 90 d / 0, 0.25, 0.5, 1.0, 2.0, 5.0 %	Hansen et al. 1960 / DFG + BIBRA	Body weight, food consumption, haematology, organ weight / No adverse effects	2500 mg/kg bw/d
3	Subchronic / dog / number unknown	diet / 90 d / 3 %	Hazleton 1962 / DFG	Parameters not given/ Body weight reduction	/
4	Subchronic / rat / 20 m + 20 f	diet / 90 d / 3 %	Hazleton 1965 / BIBRA	Body weight, clinical signs, haematology, urinalysis, pathology / no effect	1500 mg/kg bw/d
5	Chronic / rat / 10 m + 10 f	Sc / 7 m / 50 mg/kg bw/d	Oettel et al. 1965 / BIBRA	Parameters not given / no effects	> 50 mg/kg bw/d

6	Chronic / mouse / 60 m + 60 f	diet / 23-24 m max. dose 5 %	Biodynamics 1980 / BIBRA	Parameters not given / no effects	> 7500 mg/kg bw/d
7	Chronic / dog / 3 m + 3 f	diet / 2 y / 0.03, 0.2 %	Hazleton 1967 / BIBRA	Parameters not given / no effects	> 70 mg/kg bw/d
8	Chronic toxicity / carcinogenicity / rat / 70 m + 70 f	diet / 30 m, exposure start in utero / 0.03, 0.1, 0.5, 2.0, 5.0 %	Biodynamics 1980 & 1981 / DFG + BIBRA + FDA	Body weight, clinical signs, ophthalmoscopy, organ weight, pathology / reduction of body and several organ weights without tissue damage at 2 and 5 %, no carcinogenicity	FDA: 1000 mg/kg bw/d BIBRA, DFG: 250 mg/kg bw/d
9	Chronic toxicity, carcinogenicity / mouse/60 m + 60 f	diet / 30 m / 0.03, 0.1, 0.5, 2.0, 5.0 %	Biodynamics 1980 & 1981 / DFG + BIBRA + FDA	Body weight, clinical signs, ophthalmoscopy, organ weight, pathology / no carcinogenic effects	/
10	Chronic toxicity, carcinogenicity, exposure start in utero / mouse / 50 m + 50 f	diet / 21-23 m, exposure start in utero / 0, 0.1, 0.3, 1.0, 3 %	IFREB 1981 / DFG + BIBRA	Body weight, mortality, pathology / reduction white blood cells count high dose, no carcinogenic effects	300-1000 mg/kg bw/d
11	Chronic toxicity, carcinogenicity, Reprotox / mouse / 65 m + 65 f	diet / 9 w prior to mating until (Fo) and 21-23 months (F1) / 0, 0.1, 0.3, 1.0%	IFREB 1981 (Coquet et al.) / BIBRA + JECFA	a) Fertility parameters / no effects b) mortality, body weight, haematology, pathology / no effects	1000-1500 mg/kg bw/d
12	Reprotox / rat / 60 m + 60 f	diet / exposure start 2 m prior to mating until end of lactation / 0, 0.5, 5.0, 15.0, 50 mg/kg bw	Biodynamics 1980 & 1981 / DFG + BIBRA	Mortality (adult, postnatal), fertility, weight gain / postnatal mortality increase and postnatal weight gain decreased at and above 0.5 %	50 mg/kg bw/d
13	3 generations exposure start 2 weeks prior to mating / rat / 10 m + 20 f	Diet / 3 generations / 0, 0.5, 5.0, 15.0, 50 mg/kg bw	Smith 1973 (Biodynamics 1973) / DFG + BIBRA	Mortality, body weight; food consumption, mating, fertility, pathology / no adult toxicity, no Reprotoxicity	> 50 mg/kg bw/d
14	Teratogenicity / rat / 20 per dose	Po / 6-15 day of gestation / max. dose 150 mg/kg bw	Biodynamics 1972 / BIBRA	Parameters not given / no effect	> 150 mg/kg bw/d
15	Teratogenicity rabbit / 15	Po / 6-18 day of gestation / max. dose 150 mg/kg bw	Biodynamics 1972 / BIBRA	Parameters not given / no effect	> 150 mg/kg bw/d

2.4. Irritation & corrosivity

2.4.1. Irritation (skin)

From the information supplied on two references without detailed information available on study design and quality, it was reported that Acid Yellow 3 is slightly irritant to the skin.

Ref.: 8, 9

2.4.2. Irritation (mucous membranes)

From the information supplied on a reference without detailed information available on study design and quality, it was reported that Acid Yellow 3 is slightly irritant to the mucous membranes.

Ref.: 8

2.5. Sensitisation

Buhler Method

Guideline	:	/
Species/strain	:	Hartley albino guinea pigs
Group size	:	15
Test substance	:	Acid Yellow 3 in water
Batch No.	:	Substance K7059 (purity unknown)
Concentrations	:	Topical induction: Test material (40 %) for 24 h
		Challenge: 1.0, 3.0 and 10 %
GLP	:	/

Topical induction was by application of test substance (40%) for 24 hours occluded patch in the nuchal area once weekly for three consecutive weeks. Test and vehicle control groups were rinsed off concurrently. An interval of two weeks was allowed after induction and then the animals were challenged by 1.0, 3.0 and 10% of the test substance under occlusive patch for 24 hours. Cutaneous reactions were evaluated at 24 hours.

Results
After challenge no skin reactions were observed. Therefore, based on the results obtained, the test substance was judged as non-sensitizer.

Ref.: 9

Guinea Pig Maximization Test

Guideline	:	/
Species/strain	:	Hartley guinea pig
Group size	:	20 animals per test material and 20 as control
Test substance	:	Two different purified samples of Acid Yellow 3 (92.8 and 97.8 %) in water. The samples were purified by precipitation of the dye from aqueous solution with ethyl alcohol.

Concentrations	:	intradermal induction:	0.1 ml Freund's Complete Adjuvant 0.1 ml test substance (5%)
		induction of irritation:	10 % sodium lauryl sulphate (0.5 ml)
		topical induction:	0.5 ml 5% test substance for 48 hours, occluded
		challenge:	0.5 ml 5% test substance, open batch test
GLP	:	/	

Induction commenced with intradermal injection of Freund's Complete Adjuvant and the test substance. Eight days later, 0.5 ml of 10 % sodium lauryl sulphate was applied to the injection site to induce a local irritation and the next day the induction process was completed with a single topical application of 0.5 ml of the test substance under occlusive path for 48 hours. After an interval of 2 weeks, the animals were challenged by a single 0.5 ml topical application of the test substance (5%) under open patch test. The cutaneous reactions were evaluated at 24 and 48 hours after removal of the challenge patches.

Results
After challenge, no skin reactions were observed and the test substance was classified as non-sensitizer.

Ref.: 10

Human maximization testing

Humans (15) were exposed to five skin applications (on upper right arm using Duhring chamber) of Acid Yellow 3 in water. The test substance was purified in order to get a quinonaphthalone content below 0.01 ppm. These skin applications were on sites pretreated with an irritant (Sodium lauryl sulphate). After 10 days rest period, the forearm human skin was challenged by a 5% solution of the test substance applied in Finn Chambers for 48 hours. The challenge site was evaluated at 48 and 72 hours using a conventional 5-point grading scale.

Results
Acid Yellow 3 failed to sensitize any of the 15 subjects. From the paper it is concluded that the dye is not a significant contact allergen.

Ref.: 11

2.6. Reproductive Toxicity / Teratogenicity

See point 2.3.10

2.7. Toxicokinetics (incl. Percutaneous Absorption)

Percutaneous Absorption *in vitro*

Guideline	:	/
Tissue	:	Porcine ear skin obtained by dissection
Method	:	Flow-through Franz diffusion cells
Test substance	:	Acid Yellow 3: 5mg/ml of test substance in saline or 0.5% of test substance in a conventional formulation. Both samples adjusted to pH 3.0
Batch No	:	0 679 AB (Lot Nº: AK 0828), purity 90%.
Dose levels	:	Saline sample : 1ml (5 mg/cm² of the test substance)

		Formulation : 1.2 grams (about 6 mg/cm² of the test substance)
Receptor fluid	:	Saline (adjusted to pH 3.0). The dye is soluble up to 5%.
Replicate cells	:	6 cells
Analyt. method	:	HPLC (Detection at 430 nm) Detection limit: 150 ng / ml
GLP	:	in compliance

The skin penetration of Acid Yellow 3 was evaluated in a glass flow-through diffusion cell system using porcine ear skin previously dissected (thickness about 400µm). The integrity of the skin was checked by conductivity without any indication of substantial loss of skin barrier properties. The solubility of the dye in the receptor fluid was higher than 150 ng/ml.
The test substance in saline or in a conventional formulation was applied on the skin surface (exposure area: 1cm²) for 30 min and covered with Parafilm. Then, the skin surface excess was removed with a shampoo solution and water. Following the washing procedure, the donor chamber was filled with 1ml of saline (pH 3.0). The collecting vials of the acceptor chambers were changed after 0.5, 1, 2, 4, 6, 8, and 24 hours. After skin extraction, the dye content was quantified by HPLC.

Results
The mean recovery of the test substance was 99.2% in the first and 85.3% in the second experiment. Under the present experimental conditions, no measurable penetration through the skin occurred at any time point within the time frame of both experiments. The amount of penetrated test substance found in the receptor fluid plus that found in the skin extracts are considered as absorbed. Since the stratum corneum was not separated from the epidermal and dermal compartments, the amount found in the skin extract is added to those in the receptor solution. The maximal possible calculated flux of the test substance across the skin barrier was in both cases (saline and formulation) 5.4µg/cm² (0.11% of the applied dose). The amounts of the dye in the skin extracts were 2.86µg/cm² for the saline solution and 12.90µg/cm² for the formulation.
Together with the skin extracts, the global percutaneous absorption results in 8.3 µg/cm² (0.17% of the applied dose) for the saline solution and 18.3 µg/cm² (0.37% of the applied dose) for the formulation. As a consequence, a final value of 18.3 µg/cm² is reported for the percutaneous absorption of Acid Yellow 3.

Comment
The pH of the receptor fluid (3.0) is not appropriate, therefore the test is not acceptable.

Ref.: 12

2.8. Mutagenicity/Genotoxicity

2.8.1 Mutagenicity/Genotoxicity *in vitro*

Bacterial Reverse Mutation Assay

Guideline	:	OECD 471 (July 1997)
Species/strain	:	*S. typhimurium* TA 98, TA 100, TA 1535, TA 1537; *E. coli* WP2 uvr A
Test substance	:	Acid Yellow 3 (CI 47005)
Batch number	:	0679AB
Lot no.	:	AK0828
Purity	:	certified total colour content 90%

Concentrations	:	33-5000 µg/plates (6 doses)
Replicate	:	Triplicate plates; 2 independent experiments
Positive controls	:	according to guidelines
Metabolic act.	:	phenobarbital +ß- Naphthoflavone induced rat liver homogenate (S9)
GLP	:	in compliance

Results
Toxicity study: In a preliminary experiment with 8 doses, no toxicity was observed, although some toxicity was observed in the first experiment at the high doses.
Mutagenicity study: there was no increase in the number of revertants in all strains and in the two experiments in all conditions.
The positive controls gave the expected results.

Conclusion
In the condition of the assay, Acid Yellow 3 is non-mutagenic in the bacterial reverse mutation assay.

Ref.: 13

***In vitro* Mammalian Cell Gene Mutation Test**

Guideline	:	OECD 476 (July 1997)
Species/strain	:	Mouse Lymphoma L5178Y (Thymidine kinase locus)
Test substance	:	Acid Yellow 3 (CI 47005)
Batch number	:	0679AB
Lot number	:	AK0828
Purity	:	cert. total colour content 90%
Concentrations	:	118-3800 µg/ml (with and without S9)
Replicates	:	2 cultures/experiment. 2nd experiment without S9
Treatment time	:	1st : 4 hours; 2nd : 24 hours
Metabolic activ.	:	Phenobarbital + ß- Naphthoflavone induced rat liver homogenate (S9
Positive controls	:	MMS (-S9); 3-MC (+S9)
GLP	:	in compliance

Results
Toxicity study: No toxicity was observed until the dose of 3800 µg/ml.

Mutagenicity study
MMS in the 1st experiment: 1 culture did not show a mutagenic effect for the production of large mutant colonies (gene mutations); the number of small mutant colonies was increased compared to the negative control: in the 24 hours treatment the increase of the number of small and large mutant colonies induced by MMS was significantly higher than the number of the control.
3–MC induced small and large mutant colonies.

The test item did not induce a significant increase of the number of mutant colonies (small and large) in the presence and in the absence of a metabolic activation system in the replicated cultures.
Acid Yellow 3 is non-mutagenic/clastogenic in the mouse lymphoma assay.

Ref.: 14

2.8.2 Mutagenicity/Genotoxicity *in vivo*

Mammalian Erythrocyte Micronucleus Test

Guideline	:	OECD 474 (July 1997)
Species/strain	:	NMRI mice
Test substance	:	Acid Yellow 3
Batch number	:	DCOYM/1
Lot number	:	AK 3596 (22402)
Purity	:	cert. total colour content 87%
Dose levels	:	500, 1000, 2000 mg/kg 5 males+5 females/group
Treatment	:	Oral; 24 hours for all doses; 48 hours for the max. dose (2000 mg/kg)
Positive control	:	CPA 40 mg/kg (24 hours)
GLP	:	in compliance

Results
Toxicity study: In a preliminary experiment 4 animals (2males and 2 females) were treated with 2000 mg/kg and observed for 48 hours. All the animals did not express toxic reactions.

Mutagenicity study:
CPA induced 1.38 % of MN compared with the percentage of 0.075 of the animals treated with the vehicle (deionised water).
Acid Yellow 3 did not induce MN in a frequency higher than the vehicle-treated animals.
There was no sign of toxicity induced by the test item in the bone marrow cells, which could indicate the presence of the test item in the target cells.
The study is inadequate for the evaluation.

Ref.: 15

2.9. Carcinogenicity

See 2.3.10

2.10. Special investigations

No data

2.11. Safety evaluation

Not applicable

2.12. Conclusions

The identity of the substance is unclear.

Assuming a systemic exposure of 0.213 mg/kg bw/day by the use of Acid Yellow 3 in hair dye formulations, only a small portion (2.1 %) of the ADI of 10 mg/kg would be used. Even when assuming a lower NOAEL of 250 or 50 mg/kg bw/day of Acid Yellow 3, MOS would be 1174 or

235 respectively. It is recommended that a re-evaluation of the ADI for this food colour should be performed.

Acid Yellow 3 has been tested in a bacterial reverse mutation assay and in a mammalian cell gene mutation assay *in vitro*: the test item is considered non mutagenic and non clastogenic in mammalian and bacterial cells.
Acid Yellow 3 has been tested *in vivo* in mice for the induction of micronuclei in the bone marrow cells; there is no demonstration that the substance has reached the target cells. The study is considered inadequate.

According to the knowledge of the SCCNFP, no data on carcinogenicity has been published following the evaluation made by FDA, JECFA and the SCF, which would change these evaluations.

2.13. References

1. Fed. Reg. 48: 39217-39220 (1983)
2. WHO Food Additives Series n° 19, p. 86-90 (1984)
3. Report of the Scientific Committee for Food (14th series) on colouring matters authorised for use in foodstuffs intended for human consumption, opinion expressed on 7 July 1983
4. Kosmetische Färbemittel. Farbstoffkommission der Deutschen Forschungsgemeinschaft, VCH, 3. ed, 1991
5. BIBRA Toxicology profile of quinoline Yellow (1990)
6. Hazelton Laboratories Inc. 1962*, Lu & Lavallé 1964; cited in Bibra Tox. Profile 1990; report not published
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8. Sandoz, unpublished data; cited in DFG-Kosmetischen Färbemittel, VCH-Verlagsgesellschaft mbH, Weinheim, 1991
9. Lamson S.A.; Kong B.; De Salva S.J.; Contact dermatitis 8, 200-203, 1982
10. Sato Y., Kutsuna H., Kobayashi T., Mitsui T.; Contact Dermatitis 1984, 10: 30-38
11. Kita S., Kobayashi T., Kutsuna H., Kligman M., Contact Dermatitis 1984, 11: 210-213
12. Wollny H.E., Skin permeability in vitro absorption through porcine ear skin with D&C Yellow 10 (C.I. 47005); RCC Project No. 636303; Test Report, Rossdorf, May 17, 2000
13. Wollny H.E.; Salmonella typhimurium and Escherichia coli reverse mutation assay with D&C Yellow 10 (C.I. 47005), RCC-CCR Project 636301, Rossdorf/Germany, 16.7.1999
14. Wollny H.E., Cell mutation assay at the thymidine kinase locus ($TK^{+/-}$) in mouse lymphoma L5178Y cells with D&C Yellow 10 (C.I. 47005), RCC-CCR Project 636302, Rossdorf/Germany, April 04, 2000
15. Honarvar N., Micronucleus assay in bone marrow cells of the mouse with D&C Yellow 10, RCC-CCR Test report, No. 741301, Rossdorf/Germany, 2003

3. Opinion of the SCCNFP

There are important data gaps in the safety dossier submitted. The identity of the substance is not clear. Additionally, the original data for many of the studies were not available and the SCCNFP has depended on assessments made by others.

This substance is a food colorant and the amount absorbed through the skin would be very small compared to the potential oral exposure.

Assuming that the risk evaluation undertaken for the dietary use of this colouring agent has been based upon sound analysis of appropriate studies, then its use as a hair dye ingredient is deemed acceptable.

It is, however, recommended that a re-evaluation of the ADI for this food colour should be performed.

4. Other considerations

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5. Minority opinions

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