

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: HC Yellow No. 13 (CAS 10442-83-8) submission III (B102)

1. Background

Submission I for HC Yellow No. 13 with the chemical name 4-(2'-Hydroxyethyl)-amino-3-nitrotrifluoromethylbenzene has been submitted in October 1993 by COLIPA¹ .²

Submission II for HC Yellow No. 13 has been submitted in April 2002 by COLIPA².

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) adopted at its 24th plenary meeting on 24-25 June 2003 an opinion (SCCNFP/0689/03, final) with the conclusion that:

*“HC Yellow n° 13 consists for more than 99 % of N-(2-hydroxyethyl)-2-nitro-4-trifluoromethyl-aniline. However, relevant physico-chemical parameters are not given. Purity of the test material in several studies is not reported. The dye is a secondary alkanolamine, and thus, it is prone to nitrosation. No data is provided on the nitrosamine content of the dye and in hair dye formulations. The data provided on stability are insufficient. HC Yellow n° 13 was found to be of low acute oral and dermal toxicity in rats. No signs of eye or skin irritation were observed. The sensitisation test results were negative. In a 90-day oral toxicity study in rats, 30 mg/kg bw was the NOAEL. In a rat teratogenicity study, no structural abnormalities were observed in the foetuses, however, there were slight indications of developmental retardations following administration of 30 and 90 mg/kg/bw/day during the critical days of organogenesis. 10 mg/kg bw was the level without developmental anomalies. Skin penetration (rat in vivo study, using ¹⁴C-labelled a.i.) indicated a maximum penetration of 2.5 µg/cm² for oxidative hair dyes (max. in-use concentration 2.5%) , and of 9.69 µg/cm² for colour setting lotions (max. in-use concentration of 5%). HC Yellow n° 13 was tested in procaryotic cells for gene mutation in several tester strains of *S. typhimurium*. The test is unsuitable for genotoxicity evaluation. A second Bacterial Reverse Mutation Test was provided and was acceptable for evaluation. Based on the reversion rate, it is concluded that HC Yellow n° 13 dissolved in DMSO is negative in any *S. typhimurium* tester strains in the absence or the presence of S9 mix. The earlier in vitro mammalian chromosomal aberration test is negative. However, the test is unsuitable for genotoxicity evaluation. A more recent suitable in vitro mammalian chromosomal aberration test has been provided in submission II with HC Yellow n° 13 in DMSO. It is positive for clastogenicity. HC Yellow n° 13 gave negative results in the mammalian erythrocyte micronucleus test. However, the study did not demonstrate that bone marrow was reached by the test agent.”*

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

² According to records of COLIPA.

Submission III for HC Yellow No. 13 was submitted by COLIPA in July 2005. According to this submission the substance is used as:

a) a non-reactive hair colouring agent (“direct dye”) in non-oxidative hair dye formulations at a maximum on-head concentration of 2.5%. It is common practice to apply 35 to 50 g of the product over a period of 30 minutes followed by rinse off with water and shampoo. The application may be repeated at weekly intervals.

b) a non-reactive hair colouring agent (“direct dye”) in oxidative hair dye formulations at a maximum on-head concentration of 2.5%. The colouring component and a developer (hydrogen peroxide) are mixed in ratios between 1:1 to 1:3. It is common practice to apply up to 100 g of the finished mixed product for a period of 30 to 45 minutes followed by rinse off with water and shampoo. The application may be repeated at monthly intervals

Submission III presents updated scientific data on the above mentioned substance in line with the second step of the strategy for the evaluation of hair dyes (<http://europa.eu.int/comm/enterprise/cosmetics/doc/hairdyestrategyinternet.pdf>) within the framework of the Cosmetics Directive 76/768/EEC.

2. Terms of reference

- 1. Does the Scientific Committee on Consumer Products (SCCP) consider HC Yellow No. 13 safe for use as a non-oxidative hair dye with an on-head concentration of maximum 2.5% taken into account the scientific data provided?*
- 2. Does the SCCP consider HC Yellow No. 13 safe for use in oxidative hair dye products with an on-head concentration of maximum 2.5% taken into account the scientific data provided*
- 3. Does the SCCP recommend any further restrictions with regard to the use of HC Yellow No. 13 in any non-oxidative or oxidative hair dye formulations?*

3. Deadline

December 2006.