

## SCIENTIFIC COMMITTEE ON CONSUMER PRODUCT (SCCP)

**Request for a scientific opinion: Hair dye Basic Red 76 (CAS 68391-30-0) submission III (C008)**

### 1. Background

Submission I for Basic Red 76 with the chemical name [7-Hydroxy-8-[(2-methoxyphenyl)azo]-2-naphthyl]-trimethylammonium chloride was submitted in August 1992 by COLIPA<sup>1</sup>.

Submission II for Basic Red 76 was submitted in July 2001 by COLIPA.

The Scientific Committee on Consumer Products and Non Food Products intended for Consumers (SCCNFP) adopted its opinion SCCNFP/0661/03 at the 23<sup>rd</sup> plenary meeting of 18<sup>th</sup> March 2003 with the conclusion, that

*“Commercial grade dye of different batches has been used for various tests, but purity (>98%) of the dye has been described only in one case. The impurities in the dye should be described. The test substance is an azo-dye, therefore, free aromatic amine (2-methoxy aniline) content in the dye (in all batches) are required for the evaluation of carcinogenic potential of the dye. The dye formulation contains 16% sugar and 14.5% inorganic salts. A complete description of the sugar and salts is required. Following physical properties are also required: density and Log P<sub>ow</sub>. The sensitisation data in the dossier used a concentration too low for intradermal induction. The studies on percutaneous absorption are inadequate. The test concentrations were well below the expected use concentration. Basic Red 76 has been tested for the induction of gene mutation in bacterial cells (positive results) and in the mammalian cells, in vitro (negative results), and for chromosome aberration in mammalian cells in vitro (negative results). The in vitro UDS study was inadequate. The in vivo micronucleus test gave negative results; no firm evidence that the bone marrow was reached by the test agent was noted. No conclusion can be drawn”.*

According to current submission III Basic Red 76 is used as a direct dye for hair colouring products. The final concentration on the scalp is proposed up to 2.0%.

### 2. Terms of reference

1. *Does SCCP consider Basic Red 76 safe for use as an ingredient in both oxidative hair dyes and non-oxidative hair dye formulations with a concentration on the scalp of maximum 2.0% taken into account the scientific data provided?*
2. *And/or does the SCCP have any other concerns with regard to the use of Basic Red 76 in both oxidative hair dyes and non-oxidative hair dye formulations?*

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<sup>1</sup> COLIPA - European Cosmetics Toiletry and Perfumery Association