

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: HC Red No. 7 (CAS 24905-87-1) submission III (B036)

1. Background

Submission I for HC Red No 7 with the chemical name 1-Amino-2-nitro-4-(β -hydroxyethyl)-aminobenzene has been submitted in July 1997 by COLIPA^{1,2}.

Submission II for this substance has been submitted in January 1988 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 the opinion (SCCNFP/0678/03, final) with the conclusion that:

“The SCCNFP is of the opinion that the information submitted is inadequate to assess the safe use of the substance. Before further consideration, the following information is required:

quantitative data on solubility in e.g. water and ethanol; determination of the purity of all batches used in the toxicity studies; determination of the impurities in these batches and their related health hazards; experimental data on the stability of the test substance;

analytical data on the nitrosamine content in more than one sample as well as in hair dye formulations;

the effects on the spleen in the sub-chronic toxicity study have to be re-evaluated

data on genotoxicity/mutagenicity following the relevant SCCNFP opinions and in accordance with the Notes of Guidance.”

Submission III for HC Red No. 7 was submitted by COLIPA in July 2005. According to this submission HC Red No. 7 is used in semi-permanent hair dye formulations at a maximum concentration of 1.0%.

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 Red No. 7 safe for use as a non-oxidative hair dye with a concentration of maximum 1.0 % taken into account the scientific data provided?*

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

² According to records of COLIPA.

2. *Does the SCCP recommend any further restrictions with regard to the use of HC Red No. 7 in any non-oxidative hair dye formulations?*

3. Deadline

December 2006.