SCIENTIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: Acid Orange 7 (4-[(2-hydroxy-1-

naphthalenyl)azo] benzenesulfonic acid, sodium salt (CAS 633-96-5), Submission II (C015)

1. Background

Submission I for this substance was submitted in September 2003 by COLIPA¹.

The Scientific Committee on Cosmetic and Non-Food Products (SCCNFP) adopted on 23 April 2004 its opinion (SCCNFP/0785/04) on Acid Orange 7. In the conclusions in was said:

- data are missing about the content of the substance in the batch testing material, and the stability of the substance was not reported.
- before assessment of the substance a percutaneous absorption study is needed in accordance with the SCCNFP Notes of Guidance.

Acid Orange 7 is identical with CI 15510 also used as a colouring agent "allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover."

Submission II of Acid Orange 7 was submitted by COLIPA in July 2005. According to this submission acid orange 7 is a non-reactive dye, used as direct hair colouring agent up to an on-head concentration of 0.5% in non-oxidative as well as in oxidative hair dye formulations. For non-oxidative dye formulations it is common practice to apply 35-50 mL of undiluted formulations, while for oxidative colouring formulations 100 mL are applied after mixing with hydrogen peroxide. The application time for both formulations covers a period of 30 minutes followed by washing off with water and shampoo. It is assumed that application may be repeated at weekly intervals for non-oxidative and monthly intervals for oxidative dyes.

Submission II 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 Acid Orange 7 safe for use in non-oxidative hair dye formulations with a concentration on-head of 0.5 % taken into account the scientific data provided?

2. Does the SCCP consider Acid Orange 7 safe for use in oxidative hair dye formulations with a concentration on-head of 0.5% taken into account the scientific data provided?

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

3. Does the SCCP recommend any restrictions with regard to the use of Acid Orange 7 in oxidative or non-oxidative hair dye formulations (e.g. max conc. in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning?)

3. Deadline

December 2006.