

## SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

**Request for a scientific opinion: Acid Green 25 (CAS 4403-90-1). Submission II (C178)**

### 1. Background

Submission I for Acid Green 25, with the chemical name: 1,4-Di-((2-sulpho-4-methylphenyl)amino)-9,10 anthracenedione disodium salt, was submitted in September 2003 by COLIPA<sup>1</sup>. Acid Green 25 is identical with CI 61570 also used as a colouring agent allowed in all cosmetic products.

The SCCP adopted at its 4<sup>th</sup> plenary meeting of 21 June 2005 an opinion (SCCP/0879/05) with the conclusion, “*that the information submitted is insufficient to assess the safe use of the substance. Before any further consideration, the following information is required:*

- *complete information on the >10% impurity;*
- *Data on exposure from other cosmetic products;*
- *a percutaneous absorption study according to the Notes of Guidance;*
- *Data on teratogenicity;*
- *An additional in vitro test specifically detecting chromosomal aberrations (preferably an in vitro micronucleus test which detects clastogenic and aneugenic effects) should be performed.”*

According to the current submission II, submitted by COLIPA in July 2005, Acid Green 25 is proposed to be used as a non-reactive hair colouring agent (“direct dye”) in semi-permanent hair dye formulations at a maximum on-head concentration of 0.3%. 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.

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 Green 25 safe for use in non-oxidative hair dye formulations with a concentration of maximum 0.3 % in the finished product taking into account the scientific data provided?*
2. *Does the SCCP recommend any restrictions with regard to the use Acid Green 25 in hair dye formulations ?*

### 3. Deadline

December 2006.

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