

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCT (SCCP)

**Request for a scientific opinion: Hair dye Basic Violet 2 (CAS 3248-91-7)
submission II (B115)**

1. Background

Submission I for Basic Violet 2 with the chemical name 4-((4-Amino-3-methylphenyl)(4-imino-3-methyl-2,5-cyclohexadien-1-ylidene)methyl)-2-methylphenylamine monohydrochloride has been submitted in September 2003 by COLIPA¹ according to COLIPA.

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers adopted 23 April 2004 an opinion (SCCNFP/0784/04) 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 any further consideration, the following information is required:

- * *complete physico-chemical characterisation of the test substances used;*
- * *sub-chronic toxicity study providing a NOAEL;*
- * *percutaneous absorption study in accordance with the SCCNFP Notes of Guidance;*

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

Basic Violet 2 is identical with CI 42520 also used as a colouring agent allowed for use in cosmetic products intended to come into contact only briefly with the skin.

Submission II of Basic Violet 2 was submitted by COLIPA in July 2005. According to this submission Basic Violet 2 is proposed to be used as a non-reactive hair colouring agents (“direct” dye) in oxidative and semi-permanent hair dye formulations at a maximum concentration of 0.25 and 0.5% in the finished cosmetic product, respectively.

It is common practice to apply 35 mL of the formulation over a period of 30 minutes followed by washing off with water and shampoo. The application may be repeated at weekly intervals.

And additional submission III was submitted in May 2008 applying for use of a higher concentration of this substance in oxidative hair dyes. The concentration applied for increase from 0.25% up to 1.0% on the scalp.

2. Terms of reference

1. *Does SCCP consider Basic Violet 2 safe for use as an oxidative hair dye with a maximum concentration up to 1.0 % on the scalp taken into account the scientific data provided?*

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

2. *Does SCCP consider Basic Violet 2 safe for use as a non-oxidative hair dye with a maximum concentration of 0.5 % in the finished cosmetic product taken into account the scientific data provided?*
3. *And/or does the SCCP have any further scientific concerns with regard to the use of Basic Violet 2 in hair dye formulations?*