



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on hair dye 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) (CAS 533-73-3). Submission VI

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

Submission I on 1,2,4-trihydroxybenzene (1,2,4-THB) was submitted by COLIPA1 in August 1981. On 4 November 1991, the SCC deferred the assessment of that substance due to inadequate data.

Submission II was made by COLIPA in September 1994, and Submission III in August 2001.

Submission IV in 2003 provided additional updated scientific data on the above substance which is in line with the second step of the strategy on the evaluation of hair dyes.

Submission V was made to the SCCS in 2011.

In December 2012 the SCCS adopted an opinion on 1,2,4-trihydroxybenzene (SCCS/1452/11)2, with the following conclusion:

'The SCCS 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:

- *Proper characterisation and quantification of 1,2,4-Trihydroxybenzene as well as identification and quantification of impurities in all test batches.*
- *Characterisation of the oxidation reaction product(s) of 1,2,4-trihydroxybenzene to which the consumer is exposed, because of the reported instability of 1,2,4-trihydroxybenzene in aqueous systems. In the case of relevant exposure to the reaction products, further toxicity data might be required.*
- *In vivo testing would be required to explore the potential to induce gene mutations; such tests are no longer permitted.*

1,2,4-Trihydroxybenzene was found to be an extreme skin sensitiser.'

Submission VI on the hair dye 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) (CAS 533-73-3) was transmitted by Combe in October 2017.

According to the applicant the current submission constitutes industry's response to the request for further information in last SCCS opinion (SCCS/1452/11). In particular, the current submission is intended to support the use of 1,2,4-THB as an auto-oxidative dye in permanent hair dye formulations (not requiring the action of peroxide) at a maximum level of 2.5%, and in gradual hair colouring shampoos at a maximum level of 0.7%.

2. Terms of reference

- (1) *In light of the data provided, does the SCCS consider 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) safe for use as an auto-oxidative hair dye in permanent hair dye formulations, not requiring the action of peroxide, with a concentration on-head of maximum of 2.5%?*
- (2) *In light of the data provided, does the SCCS consider 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) safe for use as an auto-oxidative hair dye in hair colour shampoo formulations, not requiring the action of peroxide, with a concentration on-head of maximum of 0.7%?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) in cosmetic products?*

3. Deadline: June 2018

4. Supporting documents:

- *Submission VI to the Scientific Committee on Consumer Products 1,2,4-trihydroxybenzene (1,2,4-THB) (A33) by Combe- October 2017.*
- *Folder Reference.zip*

The SCCS approved this mandate by written procedure on 22 December 2017.