

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Submission IV on hair dye N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (Colipa No B34) CAS No 84041-77-0, EC No 281-856-4.

1. Background

The hair dye N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine (B34) CAS No 84041-77-0, EC No 281-856-4 is intended to be used as hair dye in cosmetic hair coloring products with or without the addition of an oxidizing agent (e.g. hydrogen peroxide). The final on-head concentration of B34 is up to a maximum of 1.0 % or 1.5 % respectively in presence or absence of hydrogen peroxide.

Submission I and II on hair dye N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine (B34) were transmitted by COLIPA¹ in May 1994 and May 2005 respectively.

The latest safety evaluation on hair dye N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine (B34) was adopted by Scientific Committee on Consumer Safety (SCCS) in September 2012 in reply to Submission III of December 2010. The SCCS concluded that:

"a conclusion on the gene mutation potential of N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine cannot be drawn without further testing.

On the basis of the submitted data, the SCCS considers N,N'-bis(2-hydroxyethylamino)-2-nitro-p-phenylenediamine not safe for use as an oxidative hair dye with a concentration on head of maximum 1.0 % and as a non-oxidative hair dye with a concentration up to 1.5 %." (SCCS/1463/12)

In December 2014, Cosmetics Europe has submitted additional data on mutagenicity in order to review the issues raised by the SCCS in the opinion of September 2012.

2. Terms of reference

- (1) *In light of the new data provided, does the SCCS consider N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine (B34) safe when used as an oxidative hair dye with a concentration on-head of maximum 1.0 % and as a non-oxidative hair dye with a concentration up to 1.5 %?*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine (B34) in other cosmetic products?*

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

3. Deadline:

4. Supporting documents:

1. Colipa B 034 N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylamine Submission IV. Cosmetics Europe. December 2014
2. Folder "References"