



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 Tetrabromophenol Blue, 4,4'-(4,5,6,7-tetrabromo-1,1-dioxido-3H-2,1-benzoxathiol-3-yliden)bis-2,6-dibromophenol (CAS 4430-25-5) (C183). Submission IV

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

1. Background

The hair dye Tetrabromophenol Blue (C183), with the chemical name 4,4'-(4,5,6,7-tetrabromo-1,1-dioxido-3H-2,1-benzoxathiol-3-yliden)bis-2,6-dibromophenol (CAS 4430-25-5) is intended to be used as a hair dye in oxidative and non-oxidative hair colouring products with a final on-head concentration up to 0.2%.

A series of submissions from the industry on this substance have been evaluated by scientific committees as follows:

- Submission I by COLIPA, received in September 2003, was evaluated by the Scientific Committee on Consumer and Non-Food Products in the opinion SCCNFP/0794/04 adopted in May 2004.
- Submission II by COLIPA, updating submission I, received in July 2005, was reviewed by the Scientific Committee on Consumer Safety (SCCS) in the opinion SCCS/1426/11 adopted in June 2012.
- Submission III by Cosmetics Europe (former COLIPA), received in July 2013, was evaluated by the SCCS in the opinion SCCS/1573/16 adopted in March 2017.

This latest evaluation by the SCCS has the following conclusions:

" The margin of safety calculated in this Opinion relates to the previously supplied batch quality of the material. However, because of the large discrepancies noted between the specifications provided for the representative market quality batch intended for commercial use and that used in toxicological testing, SCCS cannot conclude on the safety of Tetrabromophenol Blue (C183).

The test material is not composed of a single substance, but of different homologues. Analysis of different batches has shown a large variation in the homologue mixture composition of the test material intended for commercial use. The safety assessment of Tetrabromophenol Blue (C183)

will require a clear well-defined set of specifications for the composition of the substance intended for use in cosmetic products. This will also require toxicological data on a representative batch, and/or a scientifically valid justification for showing toxicological similarities amongst the homologues." (SCCS/1573/16)

With the current submission IV, received in July 2018 from Cosmetics Europe, the applicant provides additional data to address the above concerns of the SCCS and to support the safe use of Tetrabromophenol Blue at an on-head concentration of up to 0.2% both in oxidative and non-oxidative hair dye formulations.

2. Terms of reference

In light of the new data provided, does the SCCS consider Tetrabromophenol Blue (C183) safe when used as a hair dye in oxidative and non-oxidative hair colouring products with a final on-head concentration of up to 0.2%?

3. Deadline: February 2019

4. Supporting documents:

1. Submission IV to the Scientific Committee on Consumer Products: Hair Dye Tetrabromophenol Blue COLIPA No 183. Cosmetics Europe. Received in July 2018
2. Folder References.zip

The SCCS approved this mandate during Plenary meeting on 24-25 October 2018.