Request for a scientific opinion: Submission III 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 (C183) (CAS 4430-25-5)

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 hair dye in oxidative and non-oxidative hair colouring products with a final on-head concentration up to 0.2%.

Submission I and II on hair dye Tetrabromophenol Blue (C183) were transmitted by COLIPA1 in September 2003 and July 2005 respectively.

The latest safety evaluation on hair dye Tetrabromophenol Blue (C183) was adopted by Scientific Committee on Consumer Safety (SCCS) in June 2012 with the following conclusions:

"Based on the data provided, the SCCS is of the opinion that the use of Tetrabromophenol Blue with a maximum on-head concentration of 0.2% in non-oxidative hair dye formulations does pose a risk to the health of the consumer due to the low Margin of Safety. Tetrabromophenol Blue is a mixture octa-, hepta- and hexa-bromo phenolsulfonphthaleins, and does not contain any Tetrabromo-homologue, therefore the INCI name is misleading. The criteria for meeting the specifications of other batches, similar to the present mixture should be defined.

No acceptable dermal absorption study under oxidative conditions was provided. An assessment of the use of Tetrabromophenol Blue in oxidative hair dye formulations cannot be performed without an adequate dermal absorption study and stability data in an oxidative environment." (SCCS/1426/11)

In July 2013, Cosmetics Europe (former COLIPA) submitted additional data to address the issues raised by the SCCS in the opinion of June 2012.

2. Terms of reference

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

(2) Does the SCCS have any further scientific concerns with regard to the use of Tetrabromophenol Blue (C183) in other cosmetic products?

1 COLIPA - European Cosmetics Toiletry and Perfumery Association
3. **Deadline:** June 2016

4. **Supporting documents:**

   1. Comments submitted under the Public Consultation to the SCCS Opinion on Tetrabromophenol Blue, Colipa n° C183 (SCCS/1479/11). Cosmetics Europe. August 2012

   2. Supplementary submission Tetrabromophenol Blue – C183 (Royal Blue). Cosmetics Europe. July 2013

   3. Folder "Scientific Package Submission III"