



## EUROPEAN COMMISSION

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

Dir F: Ecosystems I: Chemicals, food, Retail

Unit F2: Bioeconomy, Chemicals & Cosmetics

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on the hair dye ‘Sodium Brothymol Blue (C186)’ (CAS No. 34722-90-2, EC No. 252-169-7)

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

#### 1. Background

The ingredient with the INCI name ‘Sodium Brothymol Blue’ and chemical name ‘Sodium  $\alpha$ -(3-bromo-5-isopropyl-4-oxo-2-methyl-2,5-cyclohexadienylidene)-2-(3-bromo-4-hydroxy-5-isopropyl-2-methylphenyl)toluenesulphonate’ (CAS No. 34722-90-2, EC No. 252-169-7) is a weak acid in solution and thus exists in ionized and non-ionized forms that result in the appearance of different colours. Sodium Brothymol Blue is intended to be used as a hair dye in non-oxidative hair colouring products with a final on-head concentration up to 0.5%.

In order to demonstrate the safety of Sodium Brothymol Blue, this dossier submission is established on a battery of non-animal methods and approaches, including *in silico* and *in vitro* methods, assessing inter alia irritation, skin sensitization, genetic toxicity and percutaneous absorption, while following Good Laboratory Practice and OECD guidelines. In particular, notwithstanding the absence of data on repeated dose or reproductive/developmental toxicity, the submitters have used the Toxicological Threshold of Concern (TTC) approach to support the safe use of this ingredient based on the very low consumer exposure estimate.

#### 2. Terms of reference

- (1) *In light of the data provided, does the SCCS consider Sodium Brothymol Blue, safe when used in non-oxidative hair colouring products up to a maximum on-head concentration of 0.5 %?*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of Sodium Brothymol Blue in cosmetic products?*

#### 3. Deadline

9 months.

#### **4. Supporting documents**

Submission I to the Scientific Committee on Consumer Products '*Sodium Bromothymol Blue – Safety dossier revised version*' by Cosmetics Europe February 2022.

The SCCS approved this mandate during the plenary meeting on 16 March 2022.