



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 advice on the ‘HC Red 18 (B124 or FPK 245)’ (CAS No. 1444596-49-9, EC No. -)

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

1. Background

The ingredient with the INCI name ‘HC Red 18’ and chemical name ‘2-chloro-4-{{(E)-[3-(methylthio)-1,2,4-thiadiazol-5-yl]diazonyl}}phenol’ (CAS No. 1444596-49-9, EC No. -) may be used as an ingredient in oxidative hair dye formulations.

In 2015, the Commission services received a dossier from industry to support the safe use of ‘HC Red 18’ in cosmetic products. In its corresponding opinion (SCCS/1569/15)¹, the SCCS concluded that ‘...the use of HC Red No. 18 (B124) as an ingredient at 1.5 % in oxidative hair dye formulations is safe’. In addition, the SCCS stated that ‘Neither the purity of HC Red No. 18 nor its impurities are quantified adequately. Data on purity and impurities of HC Red No. 18 (B124) should be provided, together with purity specifications of the substance intended for use in cosmetic products’.

With the current submission (i.e., submission II), received in February 2024, the applicant requests to assess the safety of ‘HC Red 18’ in view of the newly provided information on its purity, when used as an ingredient at 1.5 % in oxidative hair dye formulations and at 0.5 % in non-oxidative hair dye formulations.

2. Terms of reference

- (1) *In light of the data provided, does the SCCS consider HC Red 18 safe, when used as an ingredient at 1.5 % in oxidative hair dye and at 0.5 % in non-oxidative hair dye formulations?*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of HC Red 18 in cosmetic products?*

¹ https://health.ec.europa.eu/publications/revision-opinion-hc-red-no-18-b124_en

3. Deadline

7 + 5 = 12 months.

4. Supporting documents

HC Red 18 (B124 or FPK 245) dossier

- The SCCS approved this mandate during plenary meeting on 27 March 2024.**
- An extension of 5 months was agreed by the mandating DG early June 2024 due to the delay asked by the Applicant to respond to clarification request from the SCCS.**