SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific advice on the hair dye 'HC Yellow 16 (B123)' (CAS No. 1184721-10-5, 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 Yellow 16' and chemical name '2-chloro-4-[(1E)-(1-methyl-1H-pyrazol-5-yl)diazenyl]-phenol' (CAS No. 1184721-10-5, EC No. -) may be used as an ingredient in oxidative and non-oxidative hair dye formulations.

In 2015, the Commission services received a dossier from industry to support the safe use of 'HC Yellow 16' in cosmetic products. In its corresponding opinion (SCCS/1568/15)¹, the SCCS concluded that '...the use of HC Yellow No. 16 (B123) as an ingredient at 1 % in oxidative hair dye formulations and at 1.5 % in non-oxidative hair dye formulations is safe'. In addition, the SCCS stated that 'The purity of HC Yellow No. 16 and impurities in it are not adequately quantified. Data on purity and impurities of HC Yellow No. 16 (B123) 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 Yellow 16' in view of the newly provided information on its purity, when used as an ingredient at 1 % in oxidative hair dye formulations and at 1.5 % in non-oxidative hair dye formulations.

2. Terms of reference

(1) In light of the data provided, does the SCCS consider HC Yellow 16 safe, when used as an ingredient at 1 % in oxidative hair dye and at 1.5 % in non-oxidative hair dye formulations?

(2) Does the SCCS have any further scientific concerns with regard to the use of HC Yellow 16 in cosmetic products?

¹ https://ec.europa.eu/health/scientific committees/consumer safety/docs/sccs o 192.pdf

3. Deadline	2		
7 months.			
4. Support	ing documents		
HC Yellow	6 (B123) dossier		

→ The SCCS approved this mandate during plenary meeting on 27 March 2024.