## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Toluene-2,5-diamine (CAS No 95-70-5 and EC No 202-442-1) (A5)

## 1. Background

Submission I for Toluene-2,5-diamine was submitted in December 1979 by COLIPA<sup>1</sup> according to COLIPA.

The Scientific Committee on Cosmetology (SCC) has expressed its opinion at the meeting the 2<sup>nd</sup> September 1980 with the conclusion, that it is acceptable for use in cosmetic products.

The 2<sup>nd</sup> scientific opinion (SCCP/1084/07) was adopted 2 October 2007 with the following conclusion:

"The SCCP is of the opinion that the use of toluene-2,5-diamine cannot be considered safe based on the available data. This conclusion may be re-evaluated if human toxicokinetic data were to become available in which dosages used more closely approximate the intended use of the substance.

Toluene-2,5-diamine is an extremely potent skin sensitiser.

Clarification must be given on the myocyte degeneration in the dose range finding study of the 90 day study.

Toluene-2,5-diamine sulfate itself has no mutagenic potential in vivo.

However, studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance"

The substance and its salts is currently regulated in entry 9a of Annex III to the Cosmetics Directive on the list of substances, which cosmetic products must not contain except subject to restrictions and conditions laid down.

The current submission III is answer to the above opinion from 2007.

## 2. Terms of reference

1. Does SCCS consider Toluene-2,5-diamine and its sulfate salt safe for use as an oxidative hair dyes with a concentration on-head of maximum 4.0 % (calculated as free base) taken into account the scientific data provided?

2. And/or does the SCCS have any scientific concern with regard to the use of Toluene-2,5-diamine and its sulfate salt in oxidative hair dye formulations?

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<sup>&</sup>lt;sup>1</sup> COLIPA – The European Cosmetics Association