

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: **Soytrimonium chloride (CAS No 61790-41-8; EC No 263-134-0)**

1. Background

Soyatrimethylammonium chloride (CAS No 61790-41-8; EC No 263-134-0) with the INCI-name Soytrimonium chloride is a mixture of C16 and C18, saturated and unsaturated alkyl trimethylammonium chlorides.

According to Colipa¹, Soytrimonium chloride falls under the definition of Alkyl (C16, C18, and C22) trimethyl ammonium chloride.

Many alkyl trimethylammonium compounds are currently listed in Annex VI, entry 44 and covered by "*Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (*)*" of the Cosmetics Directive (76/768/EEC) as preservatives. The asterix (*) indicates that these substances are allowed for other uses than preservation.

The first scientific opinion (SCCP/917/05) on Alkyl (C16, C18, C22) trimethylammonium chloride for other uses than as a preservative was adopted on 17 April 2006, a second on 21 March 2007.

The 3rd scientific opinion (SCCP/1246/09) on Alkyl (C16, C18, C22) trimethylammonium chloride for other uses than as a preservative was adopted on 8 December 2009 with the conclusion:

"As far as systemic and local toxicity are concerned, the chemical analogy between the three compounds seems to permit a read-across approach for cetrimonium chloride, steartrimonium chloride and behentrimonium chloride.

The calculation of the Margin of Safety leads to a value of 192.

Apart from the fact that quaternary ammonium derivative formulations have the potential to be irritative, especially when combinations of the concerned compounds are used, the SCCS is of the opinion that the use of cetrimonium chloride, steartrimonium chloride and behentrimonium chloride does not pose a risk to the health of the consumer under the following concentration limits:

Cetrimonium chloride (C16), steartrimonium chloride (C18):

Rinse-off hair care products up to 2.5%

Leave-on hair care products up to 1.0%

Leave-on facial cream products:

sum of cetrimonium chloride and steartrimonium chloride up to 0.5%

Behentrimonium chloride (C22):

Rinse-off hair care products up to 5.0%

Leave on hair care and facial cream products up to 3.0%"

¹ Colipa: The European Cosmetics Association

The current submission concerns the use of soytrimonium chloride in hair dyes products for purposes other than as a preservative.

2. Terms of reference

1. *Does SCCS consider Soytrimonium chloride safe when used in oxidative and non-oxidative hair colourants products in a concentration on-head up to maximum 3.0% for purposes other than as a preservative?*
2. *And/or does the SCCS have any further scientific concern with regard to the use of Soytrimonium chloride in cosmetic products?*