

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCT (SCCP)

Request for a scientific opinion: **Request for a scientific opinion on the preservative Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ration of 3:1 (CAS 55965-84-9) submission X (P56)**

1. Background

Submission I for the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 was submitted in January 1983 by COLIPA¹.

Submission II –VII was delivered in the year 1984.

The Scientific Committee on Cosmetology expressed on the 1st July 1986 an opinion concerning certain preservatives. The preservative mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate was evaluated amongst the preservatives “*whose use in cosmetic products can be maintained for the time being, but concerning which the Committee would like to obtain additional data*”.

Submission VIII was submitted in September 2001 and Submission IX was submitted in May 2002. These two submissions were mainly concerned obtaining permission to use other stabilisers than magnesium chloride and magnesium nitrate mentioned in the current regulation.

The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) adopted its opinion (SCCNFP/0670/03) at the 24th plenary meeting of 24-25th June 2003 with the conclusion, that “*the replacement of magnesium chloride and magnesium nitrate by copper sulphate or any other authorised cosmetic ingredient as a stabiliser system in the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one does not alter the toxicological profile of this mixture.*”

The term “*authorised*” raised some problems in implementing the opinion and the SCCP was asked for a clarification, which was given in the opinion (SCCP/0849/04) adopted at the 2nd plenary meeting the 7th December 2004.

Meanwhile, the Commission was requested by the Member states to ask Industry for a complete new dossier more in line with modern standards.

The current submission X, submitted in April 2006 is a full and updated dossier for the preservative mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1.

The preservative is currently regulated as a preservative in the cosmetic directive (76/768/EEC) in annex VI, part 1, entry 39 with the maximum authorized concentration 0.0015% (15 ppm) of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

2. Terms of reference

- *Does the SCCP consider, with the scientific data provided that the preservative mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 is safe for the consumers, when used as a preservative up to a maximum authorised concentration of 0.0015 % in rinse-off cosmetic products?*