

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion Request for a scientific opinion on the current regulated preservative Methenamine 3-chloroallylochloride EC No 223-805-0 (CAS No 4080-31-3) P63

1. Background

Quaternium-15 (INCI name) with the chemical name Methenamine 3-chloroallylochloride and EC No 223-805-0 and CAS No 4080-31-3 is currently regulated as a preservative in Annex VI, entry 31 of the Cosmetic Directive in a concentration up to 0.2%.

Submissions I and II were provided by Colipa¹ in 1983 and 1984, respective to support the continued use of this up to then provisionally allowed preservative.

An opinion was expressed by the Scientific Committee on Cosmetology in 1986 with the statement that "*a short-term oral study with dose-levels sufficiently high to induce a systemic effect, information on dermal absorption through human skin, and a chromosomal aberration test is needed to evaluate this substance. Information is also requested on the purity of the substance and on the presence of the trans-isomer.*

However, the Committee sees no objections to maintaining the use of this substance as preservative in cosmetic products".

From the above opinion it could be inferred that the Quaternium-15 is a mixture of isomers, where the *cis*-form is the dominant form and where the *trans*-form is the minor component present as an impurity.

Recently, the *cis*-form has been classified as a CMR substance with the classification toxic to reproduction, category 3. This classification only concerns the *cis*-isomer:

Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (EC No 426-020-3; CAS No 51229-78-8) referred to as *cis*-CTAC,

Whereas the current entry in the Cosmetics Directive refers to:

Methenamine 3-chloroallylochloride (EC No 223-805-0; CAS No 4080-31-3), which designates the mixture of *cis/trans*-CTAC.

A new dossier was submitted to support a continuation of the use of Methenamine 3-chloroallylochloride as a preservative. The current submission only covers the *cis*-isomer, which, according to the information provide by the applicant, is also the one, which has been traditionally sold for cosmetic preservation. Consequently, should the SCCS establish the safety of this ingredients at the intended use concentration, it is

¹ Colipa – European Cosmetics Association

planned to change the entry for the Methenamine 3-chloroallylochloride to cover only the cis-form with the name : *Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride* (EC No 426-020-3; CAS No 51229-78-8).

2. Terms of Reference

- *Based on the scientific data provided, does the SCCS consider that Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is safe for the consumers, when used as a preservative in a concentration up to 0.2% in cosmetic products?*
- *Does the SCCS have any scientific concerns for the continued use or any modification in the specifications for the substance?*