



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Opinion on

Cetylpyridinium chloride

COLIPA N° P97

Adopted by the SCCP
during the 7th plenary meeting of 28 March 2006

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1. BACKGROUND

COLIPA has submitted a dossier for the safety evaluation of cetylpyridinium chloride.

Based on the toxicological profile and the risk assessment on the cosmetic use of the above preservative presented in Submission I, industry proposes to include this substance in Annex VI to the Cosmetics Directive 76/768/EEC.

2. TERMS OF REFERENCE

1. *Is the SCCP of the opinion that the information submitted is sufficient to allow an adequate risk assessment of cetylpyridinium chloride to be carried out?*
2. *If yes, is cetylpyridinium chloride safe when used as a preservative:*
 - a) *in mouthwashes cosmetic products up to the maximum authorised concentration of 0.1 %?*
 - b) *in all other oral hygiene cosmetic products up to the maximum authorised concentration of 1.0 %?*
 - c) *in skin lotions and creams up to the maximum authorised concentration of 0.2 %?*
 - d) *in anti-prespirant deodorants up to the maximum authorised concentration of 2.0 %?*
3. *Does the SCCP recommend any further restrictions on the conditions of use and a maximum authorised concentration for cetylpyridinium chloride when used as a preservative in cosmetic products?*

3. OPINION

3.1. Chemical and Physical Specifications

Cetylpyridinium chloride (INCI name)

3.2. Function and uses

Request for inclusion in Annex VI – List of Preservatives which Cosmetic Products may contain - to Council Directive 76/768/EEC on cosmetic products.

Request for use in:

- a) 0.1% (in mouthwashes)
- b) 1.0% (in all other oral hygiene products)
- c) 0.2% (in skin lotions & creams)
- d) 2.0% (in anti-perspirant deodorants)

3.3. Toxicological Evaluation

The Scientific Committee on Consumer Products wishes to call attention that it considers that a dossier of this quality should not be submitted for evaluation:

- This dossier does not conform to the ‘agreed’ standard format eg numbered references. The presentation of many of these references either as paper copies or pdf-files are of poor quality, (including incomplete pages, hand written notes), that makes reading very difficult.
- Many studies did not conform to current accepted standards or guidelines.
- A bias in the interpretation of the same data was noted. (to ensure that effects would put P97 in the best light).
- Many of the studies were performed on formulations instead of on the substance itself.

As a consequence, the quality of the dossier was such that an adequate assessment of the safety of Cetylpyridinium chloride (P97) was not possible.

A new dossier should be submitted in which data is provided to all relevant toxicological endpoints and conforming to currently accepted standards.

4. CONCLUSION

The dossier is another example of an inadequate and poor submission provided by industry. Due to the many shortcomings mentioned above, it is impossible for the SCCP to assess whether Cetylpyridinium chloride is safe for use in cosmetic products for the requested function and uses.

In view of the poor quality of the toxicological data presented in the current dossier, the SCCP requires a new dossier to be submitted in which data is provided to all relevant toxicological end-points and conforming to currently accepted standards.

5. MINORITY OPINION

Not applicable

6. REFERENCES

Not applicable

7. ACKNOWLEDGEMENTS

Members of the working group are acknowledged for their valuable contribution to this opinion. The members of the working group are:

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