

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP)

Request for a scientific opinion: Request for a scientific opinion on the preservative Triclosan (CAS 3380-34-5) Submission III and IV (P32)

1. Background

Triclosan (CAS 3380-34-5) with the chemical name 5-chloro-2-(2,4-dichlorophenoxy)phenol or 2,4,4'-trichloro-2'-hydroxy-diphenyl ether has a long history of use as a preservative in cosmetic products. It is currently regulated in Annex VI, entry 25 with a maximum concentration of 0.3%.

An opinion on Triclosan (SCCP/1040/06) was adopted by the SCCP at the 9th plenary meeting of 10 October 2006 with the following conclusions to the request:

1. *"On the basis of the available data, the SCCP is of the opinion that there is presently no evidence of clinical resistance and cross-resistance occurring from the use of triclosan in cosmetic products. Information is required on consumer exposure to triclosan from all sources, including cosmetic products.*
2. *For a toxicological assessment of the safe use of triclosan, the SCCP requires a dossier to be submitted in which data is provided to all relevant exposure and toxicological end-points and conforming to currently accepted standards. This should be regarded as a matter of urgency because triclosan has been identified in human milk of some European populations."*

The dossier provided by Industry consists of an update on the bacterial resistance issue (submission III) and of a toxicological dossier for Triclosan (submission IV).

Furthermore the Norwegian authority on cosmetics has earlier this year submitted a report "Risk assessment on the use of triclosan in cosmetics; Development of antimicrobial resistance in bacteria – II".

2. Terms of reference

1. *Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe for the consumer at the current concentration limit of maximum 0.3% taking into account the provided toxicological data?
(Answered in SCCP opinion SCCP/1192/08)*
2. *Does SCCP consider a continued use of Triclosan as a preservative in cosmetic products as safe taking into account the new provided documentation of resistance development by certain micro-organisms and cross-resistance?*