

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Updated request for a scientific opinion: Triclosan (CAS 3380-34-5) (EINECS 222-182-2) Supplement I (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 been included in the annexes of the Cosmetic Directive since 1986. It is currently regulated as a preservative in Annex VI, entry 25 with a maximum concentration of 0.3%.

A dossier containing both toxicological data and information on the aspect of microbial resistance was submitted in 2007 by COLIPA.

In the resulting opinion (SCCP/1192/08) adopted on 21 January 2009, addressing the toxicological properties of Triclosan, the SCCP concluded:

"Taking into account the provided toxicological data, the SCCP considers that the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.

However, its use at a maximum concentration of 0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks ("common-use products" as defined by the applicant) are considered safe. Any additional use of triclosan in face powders and blemish concealers at this concentration is also considered safe but the use of Triclosan in other leave-on products (e.g. body lotions) and in mouthwashes is not considered safe for the consumer due to the resulting high exposures.

Importantly, before a final conclusion on the safety of triclosan in cosmetic products can be reached, the potential development of resistance to triclosan and cross-resistance by certain micro-organisms must be assessed. This aspect is not covered in this document and will be discussed in a separate opinion.

Inhalation exposure to triclosan from spray products (e.g. deodorants) was not assessed."

Meanwhile, a preliminary opinion (SCCS/1251/09) on triclosan and antimicrobial resistance was adopted at the SCCS plenary meeting 23 March 2010 with the opinion:

"At present, several distinct hazards have been identified: (i) the effect of triclosan on the triggering/regulation of resistance genes in bacteria (ii) the existence of mechanisms which can promote resistance and cross-resistance to biocides and antibiotics in bacteria, (iii) high concentrations of triclosan have been measured in certain environmental compartments, (iv) the presence of resistance genes in soil bacteria, and, (v) bacterial biofilms are widespread in the environment and are able to survive exposure to adverse environmental factors. The first two of these hazards have been identified in vitro. However, the six in situ studies and the one meta-analysis quoted in this document have failed to demonstrate an increase in antibiotic resistance following triclosan use. While these results are at first sight reassuring, these in situ data are not sufficient to draw a conclusion on whether the continuous use of triclosan is involved in the development of resistance. Thus, additional in situ information is needed to provide an answer on the level of risk. This opinion concerns the safety of triclosan in terms of microbiology, i.e. generation of bacterial resistance harmful for human health. Based on the available scientific information, it is not possible to quantify the risk of development of antimicrobial resistance induced by triclosan applications, including its use in cosmetics. However, there are environmental concentrations in a number of

geographically distinct areas high enough to suggest that triggering of bacterial resistance could also occur in the environment. The applications of triclosan which contribute to those high environmental concentrations cannot be properly identified nor quantified at present. This should be taken into account when considering the current and future uses of triclosan in all applications so as to ensure that the demonstrable benefits for human health in certain applications are not compromised.

The current supplementary submission contains the applicant's response to the opinion of January 2009 with the toxicological endpoints and provides arguments for an alternative interpretation of the available safety data on triclosan.

On the same issue a new exposure scenario was submitted by Colipa on e.g. mouthwashes, based on their new exposure study forwarded to the Commission services in September 2009. Colipa applies for an additional use of triclosan in mouthwash products at a maximum concentration up to 0.15%

Furthermore, another applicant claims that the concentration in mouthwash product should be up to 0.2%. And finally, an applicant has asked for authorisation of an additional use of triclosan in nail cosmetics at a concentration up to 0.3%.

2. Terms of reference

1. *In the light of this supplementary submission and the preliminary opinion on antimicrobial resistance, does the SCCS consider it necessary to revise the toxicological evaluation made by the SCCP in its opinion SCCP/1192/08? If the answer to question 1 is yes, does the SCCS consider a continued use of Triclosan as a preservative in all cosmetic products as safe for the consumers at the current concentration limit of maximum 0.3%*
2. *Taking into account the safe use of Triclosan at a maximum concentration of 0.3% in toothpaste, hand soaps, body soap/shower gels and deodorant sticks ("common use products"), does the SCCS consider an additional use of Triclosan in mouthwashes as safe for the consumer at a concentration limit of maximum 0.15%, alternative 0.2% taking into account the provided exposure data and the preliminary opinion on antimicrobial resistance?*
3. *Taking into account the safe use of Triclosan at a maximum concentration of 0.3% in toothpaste, hand soaps, body soap/shower gels and deodorant sticks ("common use products"), does the SCCS consider an additional use of Triclosan in nail products as safe for the consumer at a concentration limit of maximum 0.3% taking into account the provided exposure data and the preliminary opinion on antimicrobial resistance?*