



Risk assessment on the use of triclosan in cosmetics

Prepared by the Scientific Committee in cooperation with the Panel on Biological Hazards and the Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics

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SUMMARY

Triclosan is a widely used biocide. It is included in many contemporary consumer- and professional health-care products, particularly oral and dermal products, but also in household items including plastics, textiles and food packaging materials.

Concerns have been raised regarding the widespread use of triclosan; both as regards the potential for selection of resistant bacterial strains that may confer cross-resistance to other antimicrobial agents and as regards the potential harm to the environment. Triclosan is classified as “very toxic to aquatic organisms” and “may cause long-term adverse effects to the environment” by the European Commission.

In March 2004, the Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety to prepare an updated risk assessment of the use of triclosan in cosmetics, regarding development of resistance in pathogenic bacteria. The authority also asked for a comprehensive toxicological examination of the chemical with indication of the margin of safety as regards use in cosmetic products.

In response, three assessments were initiated; one to address the risk for development of antimicrobial resistance in bacteria, one to address the toxicological aspects, and one to address ecotoxicological matters.

From these three assessments, general conclusions have been drawn by the Scientific Committee based on the conclusions from the Panel on Biological Hazards and the Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics.

The conclusions are:

Widespread use of triclosan, including use in cosmetic products, selects for development of triclosan resistance. Since this may contribute to the development and spread of concomitant resistance to clinically important antimicrobial agents, such use represents a public health risk. Therefore, the use of triclosan should be restricted.

The current regulation of use of triclosan in cosmetic products is from a toxicological point of view a matter of concern and it is recommended that human exposure to triclosan should be reduced. Moreover, triclosan is classified as an agent that may cause adverse environmental effects and hence the use should be restricted also from an ecotoxicological standpoint.

BACKGROUND

Triclosan has been widely used since its introduction 40 years ago. However, in more recent years the use of triclosan as a preservative, antiseptic and disinfectant in the USA and Europe has risen significantly.

In Europe concerns have been raised regarding the widespread and increasing use of triclosan, in view of the potential for selection of resistant bacterial strains that may confer cross-resistance to clinically relevant antimicrobial agents. The former Norwegian Food Control Authority (SNT) therefore asked scientific experts at the Norwegian Institute of Public Health to perform a risk assessment on the use of triclosan in cosmetics (4th September 2000). The conclusion of this assessment was as follows:

“...care must be taken to contribute as little as possible to the selection of resistant bacteria.....with this in mind, particularly in light of recent indications of its association with the development of antibiotic resistance in bacteria, we recommend against the use of triclosan in cosmetics and other products in general use, in which disinfectant action is neither useful nor desirable.”

In 2002, the former Scientific Steering Committee (SSC) of the EU appointed a working group of experts with the mandate to draft a scientific report that could be used as input for the preparation of a scientific opinion of the SSC regarding the safety of triclosan, especially related to the risk for resistance development in certain microorganisms. The SSC concluded that:

“There is no convincing evidence that triclosan poses a risk to humans or to the environment by inducing or transmitting antibacterial resistance under current conditions of use.”

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) of the EU evaluated the opinion of the SSC and concluded that:

“1: Under current conditions of use of triclosan as a preservative in cosmetic products, it is safe taking into account the risk of resistance by certain micro-organisms.

2: There is no need for setting a new concentration limit for the use of triclosan in cosmetic products.”

The experts at the Norwegian Institute of Public Health evaluated the assessment of the SSC and SCCNFP, and concluded that their own recommendations of September 2000 remain valid (8th November 2002). The Norwegian Food Control Authority, in a letter to the European Commission, DG Enterprise (Biotechnology, competitiveness in pharmaceuticals, cosmetics), called for a re-evaluation of the permission to use triclosan in cosmetic products (20th December 2002). The recommendations from the Norwegian experts were also stressed at a meeting in the Working Party on Cosmetics in the European Commission. The call for re-evaluation was answered in March 2003, where the European Commission asked the Norwegian Food Control Authority for an assessment based on new data and after consideration of the SCCNFPs opinion on triclosan.

Triclosan is approved for use in cosmetic products in Norway and the European Union. In the EU, Triclosan is also approved for use in food contact material made of plastic. In that context the EU Scientific Committee on Food (SCF) did a toxicological evaluation of triclosan in 2000 which is considered in the toxicological part of this risk assessment. Because of the extensive use of triclosan in cosmetics there is a need to review and update the toxicological information and to assess the margin of safety in the use of triclosan in cosmetics.

Furthermore, triclosan is classified as “very toxic to aquatic organisms” and “may cause long-term adverse effects to the environment” by the European Commission.

TERMS OF REFERENCE

Based on the opinion from Norwegian experts, as well as the reports from SSC and SCCNFP, regarding the use of triclosan and the possibility for development of antimicrobial resistance in bacteria, it was concluded that an updated risk assessment was necessary. In March 2004, the Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety:

“to prepare an updated risk assessment for the use of triclosan in cosmetics, regarding development of resistance in pathogenic bacteria¹. The authority also asks for a comprehensive toxicological examination of the chemical with indication of the margin of safety as regards the usage in cosmetic products²”

Because of the broad use of triclosan and the subsequent possibility for the chemical to be spread out in the environment, the Committee found it relevant to also include a summary of an evaluation of the environmental effects of triclosan that the Norwegian Institute for Water Research has prepared previously for the Norwegian Pollution Control Authority.

ASSESSMENT

Three assessments have been prepared and are attached. The conclusions from each of these assessments are as follows:

I: Development of antimicrobial resistance in bacteria

Bacterial isolates with reduced susceptibility to triclosan have been produced in laboratory experiments by repeated exposure of bacteria to sub-lethal doses of triclosan.

A number of studies have verified the occurrence of acquired triclosan resistance among dermal, intestinal and environmental bacterial species, including some of clinical relevance. However, studies involving clinical isolates have been relatively limited. A number of different mechanisms for the development of acquired triclosan resistance have been demonstrated.

The possibility that acquired triclosan resistance may contribute to reduced susceptibility to clinically important antimicrobial agents, due to either cross-resistance or co-resistance mechanisms, is a matter of major concern. Experimental data have confirmed the potential for such a link.

The Panel on Biological Hazards refers to the report [“Development of antimicrobial resistance in bacteria”](#)

II: Toxicity of triclosan in cosmetic products

Based on reviews of the extensive toxicological data-base for triclosan the Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics identified a No Observed Adverse Effect Level (NOAEL) of 25 mg/kg/day. The Panel used

¹ Mattilsynet (ber) med dette brev om at VKM utarbeider en oppdatert risikovurdering når det gjelder bruk av triclosan i kosmetikk og kroppspfleieprodukter. Dette gjelder risiko for resistensutvikling i patogene bakterier.

² Vi ønsker samtidig en utfyllende toksikologisk gjennomgang av stoffet med angivelse av sikkerhetsmargin for kosmetikkbruk

the SCCNFP notes of guidance to calculate the global estimate of exposure of preservatives based on extensive use scenarios including levels permitted for use in cosmetic products. The exposure of triclosan from other sources, which is considered to be very small, was not taken into account. The estimated safety margin in relation to permitted levels was found to be less than 100 and therefore the Panel found the current regulation of triclosan content in cosmetic products to be a matter of concern. Based on the relative contributions from different sources of cosmetic products the Panel gave the following recommendations:

- The content of triclosan in mouthwash should be as low as possible
- The maximal level of triclosan in rinse-off products and toothpaste should be reduced
- The current maximal level in eye products and non rinse-off products do not represent a toxicological problem

The Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics refers to the report "[Toxicity of triclosan in cosmetic products](#)"

III: Environmental effects of triclosan

Triclosan has a log octanol/water partition coefficient of 4.76 which indicates a potential for bioaccumulation. Bioaccumulation in fish has been documented in several studies.

The possibility that today's use of triclosan could cause adverse environmental effects on some sensitive algae species can not be excluded.

The Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics refers to the report "[Environmental effects of triclosan](#)"

GENERAL CONCLUSIONS

Widespread use of triclosan, including in cosmetic products, selects for development of triclosan resistance. Since this may contribute to the development and spread of concomitant resistance to clinically important antimicrobial agents, such use represents a public health risk. Therefore, the use of triclosan should be restricted.

The current regulation of use of triclosan in cosmetic products is from a toxicological point of view a matter of concern and it is recommended that human exposure to triclosan should be reduced. Moreover, triclosan is classified as an agent that may cause adverse environmental effects and hence the use should be restricted also from an ecotoxicological standpoint.

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