



SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Triclosan in Cosmetic Products.

1. Introduction

- 1.1 Triclosan (5-Chloro-2-(2,4-dichlorophenoxy)phenol, CAS No. 3380-34-5: Figure 1) is currently included on the list of substances permitted for use up to a concentration of either 0.3% or 0.2% as a preservative within Annex V (Entry 25) of the Cosmetic Products Regulation.

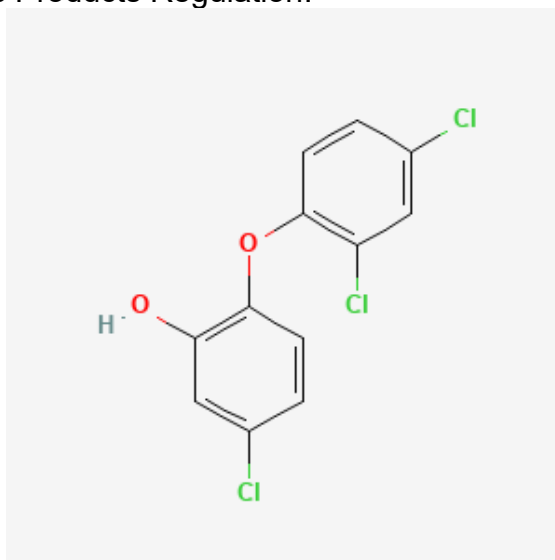


Figure 1: The chemical structure of triclosan (Source: PubChem)

- 1.2 Triclosan is classified as causing serious eye and skin irritation under the GB Classification, Labelling and Packaging (CLP) Regulation.
- 1.3 Triclosan is, however, suspected of having endocrine disrupting properties, and was included in a call for data by OPSS in 2023 for cosmetic ingredients with suspected endocrine disrupting properties. No data were received from industry to support the use of triclosan.
- 1.4 Current permitted uses and concentrations for triclosan are presented in Table 1 below.



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Table 1: Current regulatory status of triclosan under the Cosmetic Products Regulation UK No 1223/2009 (as amended).

Substance	Annex	Maximum Concentration (%)	Notes
Triclosan	V/25		Preservative Function
		i) 0.3	i) Toothpastes, hand soaps, body soaps/ shower gels, deodorants (non-spray), face powders and blemish concealers, nail products for cleaning the fingernails and toenails before the application of artificial nail systems.
		ii) 0.2	ii) Mouth washes.



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2. Background

- 2.1 Triclosan is a polychlorinated aromatic ether compound which has been used extensively over several decades as an antimicrobial agent.
- 2.2 Triclosan is widely used as an antiseptic, preservative, and disinfectant in medical settings, cosmetics, household cleaning products, plastic materials, toys and paints. Triclosan is also widely applied to the surfaces of medical devices, plastic materials, textiles, and kitchen utensils in which it acts as a bactericide ([Iacopetta, 2021](#); [SCCS, 2022](#)).

3 Potential Endocrine Disrupting Properties

- 3.1 *In vitro* evidence suggests that triclosan exhibits a degree of estrogenic and anti-androgenic activity ([Plosnik et al, 2015](#); [Kenda et al, 2020](#)).
- 3.2 Several standardised guideline studies produced consistent negative results regarding the endocrine effects of triclosan *in vivo* showing no dose response relationship ([Montagnini et al, 2018](#); [Pernoncini et al, 2018](#)).
- 3.3 There is limited and inconsistent evidence of endocrine effects regarding thyroid effects and birth outcomes from human studies on triclosan.

4 Previous Expert Group Opinions on Triclosan

- 4.1 Triclosan was initially listed as an allowed preservative up to a concentration of 0.3% in Annex VI of the EU Cosmetics Directive 76/768/EEC. Triclosan was designated the symbol (+) which allowed higher concentrations to be used than those laid down in the Annex for other specific purposes apparent from the presentation of the products.
- 4.2 In 2002, the SCCNFP assessed triclosan and concluded that there was no need to set a new concentration limit for use of triclosan in cosmetic products ([SCCNFP, 2002](#)).
- 4.3 The SCCP were mandated to re-evaluate the safety of triclosan in cosmetic products in 2006 and concluded that a toxicological dossier should be submitted as a matter of urgency owing to the identification of triclosan in human milk of some European populations ([SCCP, 2006](#)).
- 4.4 A dossier was received and, in 2008, the SCCP published their opinion on triclosan concluding that the current maximum concentration of 0.3% in all cosmetic products was not safe for the consumer because of the magnitude of the aggregate exposure. The SCCP considered the use of triclosan up to 0.3% to be safe for use in toothpastes, hand soaps, body soaps/shower gels, deodorant sticks, face powders and blemish concealers. Triclosan was not considered safe for use in leave-on products, such as body lotions, and in mouthwashes owing to high exposure ([SCCP, 2009](#)). A further opinion on antimicrobial resistance was subsequently published by the then SCCS ([SCCS, 2010](#)) which recommended further studies.



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- 4.5 An addendum to the SCCP opinion on triclosan (SCCP/1192/08) was subsequently published by the SCCS in 2011 which considered the safe level of 0.3% in light of the SCCS opinion on triclosan antimicrobial resistance (SCCS/1251/09) and also the safe use of triclosan in mouthwashes up to a maximum concentration of 0.15% or 0.2% and the safe use of triclosan in nail products up to 0.3% ([SCCS, 2011](#)). The SCCS concluded, in light of the Notes of Guidance revision (7th edition), that the conclusions of the SCCP should be upheld and that use of triclosan up to 0.3% was not considered safe for all cosmetic products. The SCCS agreed that use of triclosan up to 0.3% was safe for use in toothpastes, hand soaps, body soaps/shower gels, deodorant sticks, face powders and blemish concealers. Again, triclosan was not considered safe for use in leave-on products, such as body lotions, owing to high exposure. The SCCS further concluded that use of triclosan as a preservative in mouthwashes was considered safe at a concentration limit of up to 0.2%, and that consumer exposure from an additional use of triclosan in nail products at a concentration of 0.3% was considered negligible (safe) under the provisions of the intended use (in products for the cleaning of finger and toenails) and frequency (every 3 to 4 weeks or every 2 weeks as worst-case) ([SCCS, 2011](#)).
- 4.6 In their 2022 opinion, the SCCS identified a new NOAEL of 8mg/kg bw/day based on a number of reproductive studies in Wistar rats including two 2 generation reproduction study (OECD 416 and 426), a Hershberger Assay (OECD 441) and a uterotrophic assay ([EPA's OPPTS 890.1600 guideline](#)) which showed some effects below the previous NOAEL of 12 mg.kg bw/day (Montagnini *et al*, 2018; Montagnini *et al*, 2021; and Pernoncini *et al*, 2018). The SCCS concluded that triclosan continued to be considered safe when used as a preservative at a maximum concentration of 0.2% in mouth washes and 0.3% in toothpaste, hand soaps, body soaps/ shower gels, deodorants (non-spray), face powders and blemish concealers, nail products for cleaning the fingernails and toenails before the application of artificial nail systems, when used individually or in combination by adults. Triclosan was not considered safe up to a level of 0.3% when used in body lotion when used individually or in combination in adults or children ([SCCS, 2022](#)). The SCCS looked at children's exposures in particular for a range of age groups (Infants 0.5-1 year; toddlers 1-3 years; children 3-10 years; younger adolescents 10-14 years, and older adolescents 14-18 years) and concluded that triclosan was not considered safe for use in mouthwashes in children and adolescents at 0.2% or in toothpastes at 0.3% when used in combination with other products.

5 Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

- 5.1 At their July 2022 meeting, the SAG-CS discussed a paper which focussed on risks posed to health by triclosan when used in cosmetic products.



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- 5.2 Members discussed analytical methods for detection and quantification of triclosan. Triclosan is poorly soluble in water and readily soluble in alkaline solutions and many organic solvents. At least one HPLC method exists in the literature for triclosan with reasonable performance characteristics and satisfactory LOD and LOQ values of 15 µg/g and 50 µg/g, respectively, in cosmetic products ([Liu & Wu, 2012](#)).
- 5.3 Overall, members were satisfied with the quantity and quality of the toxicological data provided.
- 5.4 Members were satisfied with the available genotoxicity data. Members noted that the *in vitro* tests presented had been comprehensively covered with almost all studies presenting a negative response. Members acknowledged that results from *in vivo* studies were also wide ranging. Members noted that *in vivo* studies using non-standard methods presented some positive results whereas OECD Guideline compliant studies reported negative results. More weighting was applied to the guideline compliant studies. Overall, members considered that triclosan did not exhibit a genotoxic effect based upon a weight of evidence assessment.
- 5.5 Carcinogenicity studies were largely negative, other than one dose-dependent liver effect, which may be a secondary effect and could be due to a liver-thyroid effect or from higher-than-expected dose levels used. Overall, members concluded that this effect was likely to be rodent specific and considered triclosan to be non-carcinogenic. This view is supported by a review by Dinwiddie et al, 2014.
- 5.6 The metabolism of triclosan was deemed to be predominantly via conjugation with sulphotransferase and glucuronyltransferase enzymes. A paper was cited which described metabolism of triclosan and its ability to compete with the estrogenic sulfonation pathway, hence presenting a potential for endocrine activity ([James, 2010](#)). The effect was dose-dependent with an IC₅₀ value for inhibition of estrone sulfonation being 0.60 ± 0.06 nM. Members further discussed the potential production of dioxin related photoproducts from triclosan although no evidence was presented to relate this to use in cosmetic products (Wu et al, 2019). Due to their relative hydrophilicity, glucuronide conjugates are excreted in the urine with a half-life of 2 hours and the ortho-hydroxy sulphate conjugates likely through the bile with a half-life of 20h (SCCP, 2009).
- 5.7 Members noted that in studies conducted in rats (Long Evans, Sprague Dawley and Wistar) at doses ranging from 9-300 mg/kg bw/day there were decreases in thyroxine levels reported and that the likely mode of action was an increase in thyroxine clearance. They considered that the rat was likely to be a more sensitive model for chemically induced changes in thyroid hormones compared with humans and noted that there are significant differences in thyroid physiology between rats and humans ([Lewandowski et al, 2004](#)). This end point was therefore not used in the risk assessment.



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- 5.8 Members noted that *in vitro* evidence was available on endocrine activity and some *in vivo* evidence was available with respect to endocrine related effects, with a Point of Departure (PoD) identified as a NOAEL of 12 mg/kg bw/day (Ciba-Geigy FAT 80'023, 1986 Cited in [SCCP opinion 1192/08](#)). The NOAEL from this study related to haemotoxicity rather than endocrine endpoints. Additionally, there were no observed effects at 8 mg/kg bw/day with respect to uterine weight and oestrous cycle in a rat two-generation study. Further, there were no observed effects in the Hershberger assay ([OECD Test Guideline 441](#)) or reproductive toxicity assays in rats ([OECD Test guideline 416](#)). Changes in thyroid hormones and length of oestrous cycle were observed at 1 mg/kg bw/day in mice. There was considered to be no bioaccumulation potential and the observed effects were considered to be related to metabolism. A dose-response relationship could be related to the binding of endocrine hormones.
- 5.9 Five clinical studies showed no overt toxicity in humans. Members concluded that the studies presented no clear or conclusive positive endocrine disrupting effect (Barnes and Mentadent, 1991; Colgate-Palmolive Co. 1994; Fishman 1994; Lücker 1990; Safford 1991; all cited in SCCP 2009).
- 5.10 Members discussed potential interactions of triclosan with tetrabromobisphenol-A through inhibition of conjugating enzymes for bisphenol-A metabolism. There is competition among chemicals and endogenous steroids for conjugating enzymes ([Pollock, 2017](#)).
- 5.11 Overall, members agreed that there was evidence to suggest that triclosan was endocrine active in some *in vitro* assays, but there was insufficient information available to determine if it is an endocrine disruptor according to the WHO definition¹. Any effects that could potentially be attributed to an Endocrine Disrupting Chemical (EDC) in the toxicity data package were only observed at doses above 12 mg/kg bw/day.
- 5.12 Members agreed that triclosan was safe for use in toothpastes, hand soaps, body soaps/shower gels, deodorants (non-spray), face powders and blemish concealers, and nail products for cleaning the fingernails and toenails before the application of artificial nail systems, up to a maximum concentration of 0.3%; and for mouthwashes up to a maximum concentration of 0.2%.
- 5.13 Members highlighted that lower levels of triclosan were advised in body lotion by other advisory bodies; with the SCCS advising a maximum concentration of 0.03%. This is due to aggregate exposures causing the Margin of Safety (MoS)

¹ An **Endocrine disruptor** is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations. A **potential endocrine disruptor** is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub) populations. ([IPCS, 2002](#))



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to fall to 78, well below the acceptable MoS of 100. This product type was not considered by the SAG-CS on this occasion, pending further information and refinement by industry of exposures from this product category.

- 5.14 Following a call for data in 2023, which did not yield any additional information from industry, the SAG-CS reviewed the available literature published since the SCCS opinion and the previous review at their meeting in September 2024. The majority of this data related to the environmental effects of triclosan which falls outside of the remit of OPSS and the SAG-CS. Two additional papers by Chrz et al 2024 and Querido et al, 2022 explored the genotoxicity, mutagenicity and endocrine activity of triclosan. Members concluded that these papers did not change the original conclusions from the group. Other new studies considered included Baur et al, 2022; Baur et al, 2023; Chen et al, 2023a; Chen et al, 2023b and Zhang et al, 2022, but again these did not have a significant impact on the conclusions.
- 5.15 Table 2 below provides the key data required to calculate the SED and margin of safety (MoS) for triclosan.



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Table 2: Key data used in the calculation of the SED and MoS for adults and the results of these calculations for triclosan.

	Preservative function in currently permitted dermally applied products ²	Oral exposure (toothpaste)	Oral exposure (mouthwash)	Aggregate without mouthwash	Aggregate with mouthwash	Reference
Dermal absorption value (%)	8%	-	-	8%	8%	SCCP 2009
Use level in product (%)	0.3	0.3	0.2	-	-	
Bodyweight (kg)	70	70	70	70	70	SAG-CS Guidance
Oral absorption value (%)	-	100	100	-	-	SCCS Notes of Guidance
SED (mg/kg bw/day)	0.0081	0.0065	0.065	0.015	0.080	
POD systemic (mg/kg bw/day)	8	8	8	8	8	Montagnini et al, 2018, Montagnini et al ,2021, Pernoncini et al ,2018 Cited in SCCS opinion 1643/22
MoS	983	1234	123	547	100	

² In hand soaps, body soaps, shower gels, deodorants (non-spray), face powders and blemish concealers, nail products for cleaning the fingernails and toenails before the application of artificial nail systems only.



6 Conclusions

Members noted that no response was received from industry following the OPSS call for data on triclosan. Conclusions were based on the evidence that was publicly available.

Members noted that a reasonable analytical method for detection of triclosan was available.

Genotoxicity data for triclosan were adequate and did not indicate a risk for genotoxicity.

The Committee agreed that there is in silico and in vitro evidence to suggest that triclosan may have endocrine activity, but the overall data package available to the OPSS did not show triclosan to be an endocrine disruptor in vivo.

Based on a NOAEL of 8 mg/kg bw/day from haemotoxicological observations in an OECD Guideline 453 compliant 2-year carcinogenicity study, the SAG-CS concluded that triclosan was safe for preservative use at 0.2% in mouthwashes and 0.3% in toothpastes, hand soaps, body soaps/shower gels, deodorants (non-spray), face powders and blemish concealers and nail products for cleaning finger and toenails before the application of artificial nail systems.

The Committee were of the opinion that a full risk assessment in children and adolescents should be conducted when adequate data and an appropriate methodology become available.

Members noted that any potential environmental impacts of triclosan fall outside of the remit of OPSS.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

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* Studies carried out using animals but not commissioned to support the safety assessment of cosmetics.