



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

Final Opinion on Triclocarban in Cosmetic Products.

1. Introduction

1.1 Triclocarban (1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea, CAS No. 101-20-2), Figure 1, is currently included on the list of substances restricted for use in cosmetic products up to a concentration of 1.5% in rinse off products within Annex III (Entry 100) of the Cosmetic Products Regulation UK No 1223/2009 (as amended)¹. Additionally, triclocarban is permitted for use up to a concentration of 0.2% as a preservative within Annex V (Entry 23) of the UK Cosmetic Products Regulation.

1.2 Triclocarban has not yet been evaluated and does not have any human health related harmonised classifications under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended)².

1.3 Triclocarban is 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.

1.4 No data were received from industry to support the use of triclocarban in cosmetic products.

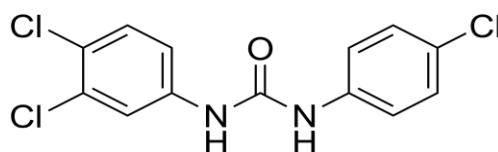


Figure 1: Structure of Triclocarban (Source: PubMed)

¹ The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by [SI 696/2019 Product Safety and Metrology \(EU Exit\) Regulations](#). The full consolidated UK text will be available in due course

² The GB CLP Regulation No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. The full consolidated UK text will be available in due course.



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1.5 Current permitted uses for triclocarban are laid out in Table 1 below.

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

Substance	Annex	Maximum Concentration (%)	Notes
Triclocarban	III/100	1.5	Rinse-off products only. Purity Criteria: 3, 3', 4, 4'-Tetrachloroazobenzene < 1 ppm; 3, 3', 4, 4'-Tetrachloroazoxybenzene < 1 ppm. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.
Triclocarban	V/23	0.2	Preservative Function Purity Criteria: 3, 3', 4, 4'-Tetrachloroazobenzene < 1 ppm; 3, 3', 4, 4'-Tetrachloroazoxybenzene < 1 ppm.



2 Background

- 2.1 Triclocarban is a polychlorinated diphenyl urea compound which has been used extensively over several decades as an antimicrobial agent.
- 2.2 Triclocarban is used in a wide variety of personal care products, including soaps, body lotions, deodorants, detergents, medical disinfectants, aftershave soaps, hand sanitizers, toothpaste, handwash and mouthwash, body washes, cleansing lotions, baby teethingers, and wipes ([Iacopetta et al., 2021](#); [SCCS, 2022](#)).

3 Potential Endocrine Disrupting Properties

- 3.1 *In silico* investigations have indicated moderate binding of the androgen and oestrogen receptor, alongside weak binding of the thyroid receptor, for triclocarban ([Plošnik et al., 2015](#); [Kenda et al., 2020](#)).
- 3.2 *In vitro* evidence suggests that triclocarban exhibits moderate estrogenic and androgenic activity ([Ahn et al., 2008](#); [Yueh et al., 2012](#); [Tarnow et al., 2013](#); [Kolšek et al., 2014](#); [Kenda et al., 2020](#)). Additionally, evidence suggests that triclocarban has a weak affinity for the thyroid receptor ([Kenda et al., 2020](#)).
- 3.3 *In vivo* evidence suggests no treatment related effects of triclocarban were seen during pregnancy in a non-guideline study in Sprague-Dawley rats but reduced offspring survival was observed during lactation following maternal dietary exposure in both dose groups (0.2% and 0.5% w/w triclocarban-supplemented diet). All pups nursed by control dams survived, regardless of their *in utero* exposure ([Kennedy et al. 2015](#)). Triclocarban has also been reported to induce hepatic steatosis, which may be through an endocrine mechanism, although the exact mode of action is unclear ([ANSES, 2020](#)). An OECD 421 study in Wistar rats administered 0, 0.3, 1.5 or 3.0 mg/kg bw/day triclocarban by gavage from gestational day 0 to lactational day 21, showed statistically significant decreases in progesterone levels in the 3.0 mg/kg bw/day group and oestradiol in the 0.3 and 3.0 mg/kg bw/day groups but not in the 1.5 mg/kg bw/day group. An increase in preimplantation loss was observed in the top dose female offspring. No other effects were observed (Costa 2020a). In the male offspring, increased testosterone levels were observed and decreased interstitial volume of testis were observed in the top dose group compared to controls at post-natal day (PND) 21. At PND 40, a decrease in seminiferous tubules was observed in the top dose group. At PND 90, 4/8 male offspring were considered sexually competent. No differences between test and control animals at PND 120 were observed (Costa, 2020b). The NOAEL derived from this study was 1.5 mg/kg bw/day in both sexes (Costa, 2020a; Costa, 2020b).



3.4 The available human studies do not provide robust evidence for endocrine disruptive effects resulting from triclocarban exposure ([Aker et al., 2019](#) [Aker et al., 2018](#) [Geer et al., 2017](#) [Smarr et al., 2017](#) [Wei et al., 2017](#)).

4. Previous Expert Group Opinions on Triclocarban

4.1 Triclocarban was initially listed as a permitted preservative up to a concentration of 0.2% in Annex V of the EU Cosmetics Directive 76/768/EEC. Triclocarban 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 1999, the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) adopted an opinion concerning restrictions on materials listed in Annex VI of the EU Cosmetics Directive 76/768/EEC in which they concluded that triclocarban, when incorporated into cosmetic formulations for non-preservative functions, should be subjected to the same restrictions in usage levels and warnings as when used for a preservative function. This effectively limited the maximum use concentration of triclocarban to 0.2% ([SCCNFP, 1999](#)).

4.3 Following a submission from industry, the Scientific Committee on Consumer Products (SCCP) in 2004 assessed the safety of triclocarban for uses other than a preservative and concluded that use of triclocarban up to a maximum concentration of 1.5% for non-preservative purposes in rinse-off hand and body care products does not pose a direct risk to the health of the consumer ([SCCP, 2004](#)).

4.4 In their 2022 opinion, the Scientific Committee on Consumer Safety (SCCS) used a NOAEL of 25 mg/kg bw/day in their safety assessment. This was also identified in the SCCP (2004) opinion and was derived from a 2-year chronic feeding study in Sprague Dawley rats (Monsanto, 1981). The SCCS concluded that the use of triclocarban as a preservative in dermally applied cosmetic products is safe up to a maximum concentration of 0.2%. This is for both children (aged 0.5-18 years) and adults when used individually or in combination. The use of triclocarban is also safe up to a maximum concentration of 1.5% in rinse-off products, when used individually, or in combination, for both children (aged 0.5-18 years) and adults.

4.5 The SCCS concluded that triclocarban was not considered safe for use in mouthwashes in adults, children or adolescents at 0.2% or in toothpastes for children below 6 years old at 0.2%.



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 the safety of triclocarban when used in cosmetic products.
- 5.2 Members discussed analytical methods for detection and quantification of triclocarban. Triclocarban is soluble in methanol and in acetone. At least one high-performance liquid chromatographic (HPLC) method exists in the literature for triclocarban with reasonable performance characteristics including a relatively low limit of detection (LOD) and limit of quantification (LOQ) values. For triclocarban the LOD and LOQ are 5 µg/g and 17 µg/g, respectively, in cosmetic products ([Liu, 2012](#)).¹
- 5.3 Members further discussed analysis of known impurities in triclocarban, such as 3, 3', 4, 4'-tetrachloroazobenzene and 3, 3', 4, 4'-tetrachloroazoxybenzene. Members concluded that some limited methods were available, predominantly using gas chromatography-mass spectrometry (GC-MS) methods. Further impurities were discussed, including 4,4'-dichloro-carbanilide.
- 5.4 Members wished to note that any impurities stated above must be kept within the currently tolerated limits of less than 1 ppm (1 mg kg⁻¹) for 3, 3', 4, 4'-tetrachloroazobenzene and 3, 3', 4, 4'-tetrachloroazoxybenzene.
- 5.5 The available dermal absorption data were of good quality and suitable for derivation of a systemic exposure dose (SED). The most suitable absorption figure in human skin was found to be 6.0 ± 2.0% which makes a maximal value of 8% (Wester et al, 1985 as cited in [SCCP/0851/04](#)) and this figure was used in the calculation of the SED.
- 5.6 The primary route of metabolism of triclocarban is via conjugation with either N- or N'-glucuronide or sulphate, possibly preceded by hydroxylation. 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). although this figure does not take into account first pass metabolism ([Hiles and Birch, 1978](#)). In a study by [Waidyanatha et al., 2020](#), human and mouse hepatocytes were found to clear triclocarban at twice the rate of rat hepatocytes, whilst also showing that 29% of the oral dose given to rats was identified in the bile. Drawing from these studies but bearing in mind that the members had not seen the original data, the SAG-CS concluded that the oral bioavailability of 27% as used by the SCCS was considered conservative but appropriate given the lack of more accurate data and therefore an oral bioavailability value of 27% has been used in this assessment.



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- 5.7 Genotoxicity data for triclocarban were considered adequate. Each *in vitro* test was concluded to be negative and each complied with relevant test guidelines. Owing to the negative *in vitro* tests, no *in vivo* tests were reported.
- 5.8 Two 24-month carcinogenicity studies were also recorded as being negative but one was only available as an abstract and the other was not provided to the SAG-CS, who only had access to the publicly available summaries from [SCCP](#) and [Health Canada](#). One study appeared to be test guideline compliant and was undertaken in Sprague Dawley rats (80/sex/group) who were provided with triclocarban in their feed at 0, 25, 75 and 250 mg/kg bw/day (Monsanto 1981). The other study was not available in adequate details to be able to form an opinion on its usefulness. No evidence of carcinogenicity was suggested by these summaries and neither SCCP nor Health Canada concluded a carcinogenic risk in relation to triclocarban.
- 5.9 Members discussed the difference between endocrine activity and endocrine disruptive effects, taking note of the World Health Organisation (WHO) definitions for these, which state that “*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*”.
- 5.10 Members agreed that there is *in silico* and *in vitro* evidence that triclocarban shows endocrine activity ([Ahn et al., 2008](#); [Yueh et al., 2012](#); [Tarnow et al., 2013](#); [Kolšek et al., 2014](#); [Kenda et al., 2020](#), [Kenda et al., 2020](#)). There is limited evidence *in vivo* regarding its endocrine activity.
- 5.11 Members stated that the most appropriate point of departure (POD) for use in the risk assessment is based upon reproductive effects observed in a 2-year chronic feeding study in rats which gave a NOAEL of 25 mg/kg bw/day (Monsanto, 1981). The SAG-CS have had to rely on secondary summaries of this study as they do not have access to the original literature.
- 5.12 Given the PoD was identified as 25mg/kg bw/day and the oral bioavailability was derived to be 27%, the SAG-CS concluded the PoD_{sys} to be 25mg/kg bw/day x 27% = 6.75 mg/kg bw/day.
- 5.13 There is no clear mechanistic link between the endocrine activity seen *in silico*, *in vitro* and *in vivo*, and the observable reproductive effects in rats. There are no endocrine-relevant effects reported in humans at relevant exposure levels ([Geer et al., 2017](#); [Smarr et al., 2017](#); [Wei et al., 2017](#), [Aker et al., 2018](#); [Aker et al., 2019](#)).
- 5.14 Members noted that the consideration of environmental effects is outside the remit of the group.



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- 5.15 In September 2024, the SAG-CS reviewed additional literature on triclocarban, published since their assessment in 2022. This followed a call for data for triclocarban issued by OPSS in 2023, which received no responses from industry bodies wishing to defend its use in cosmetic products in GB.
- 5.16 Members discussed the new post-2022 literature available for triclocarban, with a particular focus on a paper by [Chrząszcz et al., 2024](#) which explored the genotoxicity, mutagenicity and endocrine activity of triclocarban using a battery of *in vitro* methodologies. Members concluded that the new literature did not add anything significant to the discussion, and thus, did not change the original conclusions of the group.
- 5.17 The SAG-CS note that the SCCS undertook a safety assessment on children and adolescents in 2022. Since 2022, a more detailed methodology for children has been developed by the SCCS which the SAG-CS are in the process of reviewing. As the SAG-CS have not finalised their views on this methodology, they were unable to conclude on the safety of triclocarban for children and adolescents and therefore conclusions for these age groups have not been specifically drawn in this opinion.
- 5.18 Table 2 in appendix 1 provides the key data required to calculate the SED and margin of safety (MoS) for triclocarban.
- 5.19 Calculations for the adjusted NOAEL (Table 2) are presented in appendix 1 to this opinion

6. Conclusions

Members noted that a reasonable analytical method for detection of triclocarban was available subject to matrix specific validation.

Genotoxicity data for triclocarban did not indicate a risk for genotoxicity.

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

The SAG-CS concluded that a NOAEL of 25 mg/kg bw/day from a 2-year carcinogenicity study as summarised in the SCCP opinion on triclocarban, where observations in the reproductive organs of rats were observed in doses exceeding the NOAEL, provided the most suitable PoD for triclocarban.

*The SAG-CS noted that the dermal absorption value of 8% was derived from an *in vitro* study using human skin and the oral absorption value of 27% derived from an ADME study in humans. Given these figures, the PoD_{sys} was calculated to be 6.75 mg/kg bw/day.*



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Based on these values and calculated exposures the SAG-CS concluded that triclocarban was safe at 1.5% in rinse-off products for use by adults and for preservative use at 0.2% in all cosmetics (excluding mouthwash for all age groups and children's toothpaste).

Following review of the limited available data and the SCCS conclusions after consultation with industry, the SAG-CS agreed with the SCCS that the use of triclocarban in mouthwashes for children, adolescents and adults at 0.2% and in toothpastes for children below 6 years old at 0.2% could cause the aggregate exposure to triclocarban to exceed acceptable margins of safety.

Members were of the opinion that a full risk assessment in children and adolescents should be conducted when adequate data and appropriate methodology becomes available.

Members noted that any potential environmental impacts of triclocarban fall outside of the remit of OPSS and SAG-CS.

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

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Abbreviations

CLP	Classification, Labelling and Packaging
GC-MS	Gas Chromatography-Mass Spectrometry
HPLC	High-Performance Liquid Chromatography
LOD	Limit of Detection
LOQ	Limit of Quantification
MoS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
OPSS	Office for Product Safety & Standards
PoD	Point of Departure
SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers
SCCP	Scientific Committee on Consumer Products
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose



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Appendix 1

Table 2- Calculation of SED and MoS for triclocarban using adjusted PoD of 6.75 mg/kg bw/day (considering oral bioavailability to be 27%)

Product category	Individual products	Relative daily exposure (mg/kg bw/day)	Triclocarban concentration (%)	Dermal absorption (%)	SED (mg/kg bw/day)	MoS
Rinse off skin and hair cleansing products	Shower gel	2.79	1.5	9.8	0.00410	1646
	Hand wash soap	3.33	1.5	9.8	0.00490	1379
	Shampoo	1.51	1.5	9.8	0.00222	3041
	Hair conditioner	0.67	1.5	9.8	0.00098	6853
Leave on skin and hair cleansing products	Body lotion	123.2	0.2	9.8	0.02415	280
	Face cream	24.14	0.2	9.8	0.00473	1427
	Hand cream	32.1	0.2	9.8	0.00629	1073
	Deodorant (non-spray)	22.08	0.2	9.8	0.00433	1560
	Hair styling products	5.74	0.2	9.8	0.00113	6000
Make-up products	Liquid foundation	7.9	0.2	9.8	0.00155	4359
	Make-up remover	8.33	0.2	9.8	0.00163	4134
	Eyeshadow	0.33	0.2	9.8	0.00006	104360
	Mascara	0.42	0.2	9.8	0.00008	81997
	Eyeliner	0.08	0.2	9.8	0.00002	430485
	Lipstick/lip salve	0.9	0.2	100	0.00180	3750
Oral care products	Toothpaste	2.16	0.2	100	0.00432	1563
	Mouthwash	32.54	0.2	100	0.06508	104
				Aggregate	0.12737	53