



Environment and  
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# **Canadian Environmental Protection Act, 1999**

## **Federal Environmental Quality Guidelines**

### ***Triclocarban***

**Environment and Climate Change Canada**

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## Introduction

Federal Environmental Quality Guidelines (FEQGs) provide thresholds of acceptable quality of the ambient environment. They are based solely on the toxicological effects or hazard of specific substances or groups of substances. FEQGs serve three functions: first, they can be an aid to prevent pollution by providing targets for acceptable environmental quality; second, they can assist in evaluating the significance of concentrations of chemical substances currently found in the environment (monitoring of water, sediment and biological tissue); and third, they can serve as performance measures of the success of risk management activities. The use of FEQGs is voluntary unless prescribed in permits or other regulatory tools. Thus FEQGs, which apply to the ambient environment, are not effluent limits or "never-to-be-exceeded" values, but may be used to derive effluent limits. The development of FEQGs is the responsibility of the Minister of the Environment under the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999). The intent is to develop FEQGs as an adjunct to the risk assessment/risk management of priority chemicals identified in the Chemicals Management Plan (CMP) or other federal initiatives.

Where data permit, FEQGs are derived following Canadian Council of Ministers of the Environment (CCME) protocols. FEQGs are developed where there is a federal need for a guideline (e.g., to support federal risk management or monitoring activities), but where the CCME guidelines for the substance have not yet been developed or are not reasonably expected to be updated in the near future. For more information, please visit the Federal Environmental Quality Guidelines (FEQG) page.

This factsheet describes the FEQGs for water and sediment to protect aquatic life from adverse effects of triclocarban (Table 1). There are no existing FEQGs or CCME guidelines for triclocarban. The aquatic and sediment toxicity data in this factsheet are current to March 2020 and March 2021, respectively. No FEQGs have been developed for the soil or biological tissue compartments at this time. While a soil guideline is desirable given triclocarban's environmental fate, a literature review current to March 2021 indicated there is inadequate soil toxicity data on which to base a guideline value. Given triclocarban's documented bioaccumulation in gastropods and invertebrates, a biological tissue guideline would also be desirable. However, a biological tissue guideline could not be pursued due to lack of toxicity data that measured tissue burdens.

Table 1. Federal environmental quality guidelines for triclocarban.

Water (µg/L)	Sediment <sup>a</sup> (mg/kg dry weight)
0.15	0.09

<sup>a</sup>Normalized to 1% organic carbon (OC). Monitoring data should be normalized to 1% OC to assess whether the guideline value is exceeded.

## Substance Identity

Triclocarban (C<sub>13</sub>H<sub>9</sub>Cl<sub>3</sub>N<sub>2</sub>O; CAS Registry Number 101-20-2; Urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)-) is a chlorinated aromatic compound with urea as the functional group between the diphenyl rings (Figure 1). There are no known natural sources of triclocarban and its presence in the environment is exclusively due to anthropogenic activity. In Canada, triclocarban was identified as a priority for assessment as it met the categorization criteria of CEPA. Environment and Climate Change Canada (ECCC) and Health Canada (2023) completed a final screening assessment for triclocarban. Based on its current exposure profile in Canada, triclocarban did not meet any criteria set out in section 64 of CEPA (ECCC, HC 2023). However, triclocarban's ecological hazard characterization determined it to have a high hazard based on its inherent toxicity in aquatic organisms and high potential for bioaccumulation in aquatic invertebrates (ECCC, HC 2023).

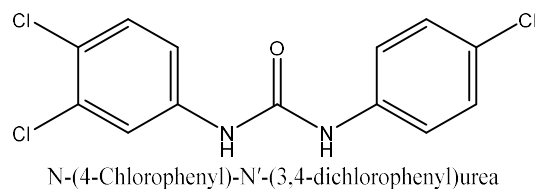


Figure 1. Structure of triclocarban

### Sources and Uses

Triclocarban is an antimicrobial compound, commonly used in cosmetics, personal care products and pharmaceuticals (PPCPs). The most common use is in personal care products, mainly in bar soaps, deodorants, cleansing lotions, wipes, shampoos, creams, mouthwash and toothpaste (Chu and Metcalfe 2007; Rochester et al. 2017; Yang et al. 2020). Reported concentrations of triclocarban in bar soaps and facial cleansers used in Canada range from 0.1% to 3% (internal data, Consumer and Hazardous Products Safety Directorate, Health Canada, dated January 7, 2019; unreferenced). Triclocarban was reported to be imported into Canada in the amounts of 10 000-100 000 kg in 2008 reducing to 1000-10 000 kg by 2015, for use as an active ingredient in natural health products and as an antibacterial agent in soaps and to prevent body odour (Canada 2009, 2017). Based on notifications submitted under the *Cosmetic Regulations* to Health Canada from December 2015 to December 2018, triclocarban is used in Canada in seven cosmetic products including in bar soaps and facial cleansers (ECCC, HC 2023).

Triclocarban is restricted in cosmetics in Europe to less than 1.5% in rinse-off products when used for purposes other than as a preservative (European Commission 2018a) and is restricted to no more than 0.2% in cosmetics when used as a preservative (European Commission 2018b). In Europe, it is also used in a variety of other product categories including coatings and paints, air care products, fillers, putties, plasters, modelling clay, finger paints, inks and toners, and washing and cleaning products (Ministère de la Transition Écologique et Solidaire 2018). Triclocarban was not identified in these or other products available to consumers in Canada, other than those described above. The US FDA has published a final rule stating that triclocarban (and 18 other active ingredients) is not generally recognized as safe or effective (GRAS/GRAE) in consumer antiseptic washes (hand and body) based on a lack of data to support safety and efficacy in this context (US FDA 2016). Products containing these ingredients are considered new drugs requiring US FDA approval for the purposes of marketing.

### Fate, Behaviour and Partitioning

Environmental releases of triclocarban include “down-the-drain” disposal from industrial processing or manufacturing of triclocarban-containing products and consumer use of these products. Removal rates of triclocarban at wastewater treatment plants (WWTSs) vary across treatment systems with activated sludge systems demonstrating more efficient removal of triclocarban (i.e.,  $\geq 88\%$ ) compared to plants with trickling filters where more variable removal rates were measured (i.e., 65-93%) (TCC Consortium 2002; Heidler et al. 2006). However, most of the triclocarban removed from WWTS influents partitions to biosolids during the wastewater treatment process due to strong sorption to particulate matter (Gledhill 1975; Heidler et al. 2006). While an earlier study suggested triclocarban undergoes significant degradation via activated sludge (Gledhill 1975), in a more recent study only 21% of triclocarban was transformed while 76% sorbed to sewage sludge at a WWTS with an anaerobic digestion time of 19 days (Heidler et al. 2006). Thus, most of the triclocarban entering WWTSs is anticipated to be released to land by municipal sludge (biosolids). Ogunyoku and Young (2014) studied the degradation of triclocarban in typical sludge processing systems by comparing initial sludge triclocarban concentrations (corrected for volatile solids reduction) to finished biosolids concentrations. They measured a 15-68% removal rate for various digester systems with half-lives ranging from 8-46 days for triclocarban.

Triclocarban removal rates were determined in winter and summer for six Canadian WWTSs employing either aerated lagoon, facultative lagoon, chemically-assisted primary, secondary activated sludge (n=2) or advanced treatment

systems. With the exception of one low removal rate observed in winter for one secondary treatment plant, the facultative lagoon, secondary and advanced treatment systems had  $\geq 70\%$  removal efficiency of triclocarban, irrespective of season. In contrast, the aerated lagoon and primary treatment systems showed less efficient removal with primary treatment achieving 57% removal in summer and the aerated lagoon recording 4% and 33% removal in summer and winter, respectively (Guerra et al. 2014). In addition, a WWTS comprised of a constructed wetland located in Whitehorse, Yukon achieved an 87% removal rate for triclocarban (Yacura 2017). In the United States, an activated sludge WWTS in the Greater Baltimore region employing tertiary treatment achieved  $\geq 97\%$  removal rate of triclocarban (Halden and Paull 2005; Heidler et al. 2006).

In soil, triclocarban appears to be stable, relatively immobile and its degradation is impeded when introduced to soil via biosolids. In a laboratory study held under aerobic conditions, a half-life of 108 days was recorded for triclocarban in a loam soil (Ying et al. 2007). Under the same study conditions, triclocarban underwent  $< 2\%$  degradation in 42 days in a sandy loam soil and  $< 4\%$  degradation in 7.5 months in fine sand and silty clay loam soils amended with  $^{14}\text{C}$ -triclocarban-spiked biosolids (Al-Rajab et al. 2009; Snyder et al. 2010a). Triclocarban concentrations were much lower at depth ( $> 30\text{ cm}$ ) compared to surface soils in a field receiving biosolids application for 33 consecutive years, suggesting limited mobility through the soil profile (Xia et al. 2010). Further, a laboratory study with fine, sandy loam spiked with triclocarban or biosolids confirmed triclocarban's limited mobility and that biosolids-amended soils impeded triclocarban degradation (Kwon and Xia 2012). There is some evidence that triclocarban undergoes reductive dechlorination and hydrolysis in soil producing breakdown products carbanilide and 3,4-dichloroaniline (3,4-DCA), respectively. However, both transformation pathways are speculated to be minor since carbanilide and 3,4-DCA each represented  $\leq 0.7\%$  of triclocarban transformed on a molar basis (Kwon and Xia 2012).

With respect to fate in other media, the presence of dichloro-, monochloro- and unsubstituted carbanilide in estuarine sediment cores sampled near WWTPs in Chesapeake Bay, Maryland and Jamaica Bay, New York provided evidence that triclocarban undergoes reductive dechlorination in deep sediments (Miller et al. 2008).

Although triclocarban WWTP effluent concentrations are usually in the ng/L range due to high removal rates, given its documented high hazard in aquatic organisms, there is a desire to track triclocarban in receiving water bodies to ensure their environmental levels and risk remain low. While triclocarban is stable to hydrolysis (Audu and Heyn 1988; Craig et al. 1989), it is susceptible to photolysis. Moreover, triclocarban's photolysis products produced in the presence of dissolved organic matter (DOM) are more toxic to *Daphnia magna* (96h  $\text{LC}_{50}$  of  $0.032 \pm 0.015\text{ }\mu\text{M}$ ) than the photolysis products produced in the absence of DOM (96h  $\text{LC}_{50}$  of  $2.67 \pm 0.6\text{ }\mu\text{M}$ ) (Albanese et al. 2017). In triclocarban-photolyzed DOM solutions, based on the metabolites identified, 4-chloroaniline appears to exert the majority of the toxicity with 3,4-DCA, chlorophenyl isocyanate, and 3,4-dichlorophenyl isocyanate exerting toxicity to a lesser extent (Albanese et al. 2017).

Triclocarban has limited water solubility with measured values ranging from 0.045 - 11 mg/L (Roman et al. 1957; TCC Consortium 2002; Snyder et al. 2010b; REACH 2019) and a high sorption potential, having a very high  $\log K_{oc}$  of 4.8 (Table 5). Given its  $\text{pK}_a$  of 12.7 (PubChem 2021) triclocarban is not expected to ionize in most natural water bodies. Having a low predicted Henry's law constant ( $4.6 \times 10^{-6}\text{ Pa}\cdot\text{m}^3/\text{mol}$ ) (PubChem 2021) along with a low, predicted vapour pressure ( $4.8 \times 10^{-7}\text{ Pa}$  at  $25\text{ }^\circ\text{C}$ ) indicates that triclocarban is unlikely to volatilize from surface water (PubChem 2021). Triclocarban is expected to persist in the environment, with predicted half-lives of 60 days in water, 120 days in soil and 540 days in sediment (Halden and Paull 2005) and measured half-lives of 108 days in soil and greater than 225 days in biosolids-amended soil (Ying et al. 2007; Snyder et al. 2010a).

Triclocarban is a hydrophobic compound with a moderate measured  $\log K_{ow}$  of 3.5-3.6 (Snyder et al. 2010b; REACH 2019) and demonstrated bioaccumulation in algae, snail, mussel, fish and blackworm (*Lumbriculus variegatus*). Triclocarban from fresh water and biosolids was reported to accumulate in algae, snails, fish and earthworms, due to its high lipophilicity. Log bioaccumulation factors (BAFs) ranging between 3.2-4.4 were reported for algae (*Cladophora spp.*), snail (*Helisoma trivolvis*) and unionid mussel (*Lasmigona costata*) (Coogan et al. 2007; Coogan and La Point 2008; de Solla et al. 2016). Schebb et al. (2011) also report a log BCF for fish (*Oryzias latipes*) of  $2.86 \pm 0.05$ . Higgins et al. (2009) demonstrated triclocarban bioaccumulates in blackworm with lipid-normalized, directly measured and steady-state biota sediment accumulation factors (BSAFs) of  $1.6 \pm 0.6$  and  $2.2 \pm 0.2$ , respectively. In an agricultural field that received biosolids application for seven consecutive years, triclocarban was present

throughout the terrestrial food web (Sherburne et al. 2016). Specifically, at the treatment site, triclocarban concentrations were five times higher in eggs of European starling (*Sturnus vulgaris*) compared to the reference (biosolids-free) site, and was detected in earthworms (*Lumbricus*) and liver of deer mice (*Peromyscus maniculatus*) whilst absent in these species at the reference site. While triclocarban concentrations were 3 and 4 times higher in deer mice liver and starling eggs (secondary consumers), respectively, compared to earthworm (primary consumer), there was an insufficient sample size to draw any conclusions regarding biomagnification in this food chain. Taking into consideration its toxicity and fate lines of evidence, triclocarban is considered persistent, bioaccumulative and inherently toxic while its biomagnification potential is uncertain.

### Measured Concentrations in the Environment

The main source of release of triclocarban to aquatic ecosystems is effluents from WWTPs. Detected influent, effluent and biosolids concentrations measured at six Canadian WWTPs with varying treatment systems ranged from 14.2 – 271 ng/L, 3.6 – 32.9 ng/L and 1200-8900 ng/g dry weight, respectively (Guerra et al. 2014). Available measured Canadian surface water data indicate that triclocarban concentrations are below the reported detection limit of 0.006 µg/L (Garcia-Ac et al. 2009; Ahmadi et al. 2017). In Canada, 120 samples had detectable concentrations of triclocarban in sediment, with concentrations ranging from 1-500 µg/kg dw and a median concentration of 16 µg/kg dw (ECCC 2019).

### Mode of Action

To date, the mode of action of triclocarban remains largely unknown, with only a few aspects having been elucidated, such as its *in vitro* (Morisseau et al. 1999) and *in vivo* (Liu et al. 2011) inhibition of the soluble epoxide hydrolase (sEH), an enzyme that metabolizes harmful epoxides into diols through its mediation of inflammation (Morisseau et al. 1999). Triclocarban has been suggested to have non-specific deleterious effects through its inhibition of fatty acid uptake, synthesis and oxidation (Xie et al. 2018) and its interruption of interstitial protein function (European Commission - Health & Consumer Protection Directorate-General 2005). Despite its narcotic-like effects, triclocarban is also an endocrine disruptor and exhibits targeted effects like the enhancement of hormonal activity through its suggested behaviour as a cofactor (Ahn et al. 2008; Chen et al. 2008; Cao et al. 2020). Some evidence suggests that triclocarban binds non-competitively to endocrine receptors, such as the androgen receptor (Chen et al. 2008), a key transcription factor of reproductive development, while other evidence suggests that triclocarban exhibits estrogenic effects through competitive binding with estrogen-related receptor gamma (ERRγ), an important regulator of energy metabolics and tumour development (Cao et al. 2020). Additionally, triclocarban can enhance endogenous hormone activity through increased transcription, as seen by the 45% increase of testosterone-induced transcriptional activity by coupled triclocarban and testosterone exposure *in vitro* (Chen et al. 2008), and the increased gene expression of estradiol-dependent induction of luciferase when estradiol and triclocarban were incubated together *in vitro* (Ahn et al. 2008). Among other endocrine disrupting effects, triclocarban has been shown to induce vitellogenin expression in fish (Zenobio et al. 2014; Wang et al. 2016), although fathead minnows appear to be largely unaffected (Ankley et al. 2010; Schultz et al. 2012; Villeneuve et al. 2017). Additional adverse effects of triclocarban include genotoxicity (Gao et al. 2015; Xu et al. 2015), thyroid toxicity (Hinther et al. 2011; Wu et al. 2016; Dong et al. 2018) and cytotoxicity (Morita et al. 2012; Kanbara et al. 2013).

### Federal Water Quality Guideline Derivation

Federal Water Quality Guidelines (FWQGs) are preferably developed using the CCME (2007) protocol and are intended to protect all forms of aquatic life for indefinite exposure periods. Moreover, within the protocol, Type A guidelines are preferred since they are derived from a species sensitivity distribution (SSD) which is considered a more statistically robust approach for guideline development compared to deterministic (i.e., Type B) approaches. The minimum requirements for a freshwater Type A guideline include long-term, freshwater data for three fish (including one salmonid and one non-salmonid), three invertebrates (including one planktonic crustacean) and one plant or algal species.

A literature review current to March 2020 identified 18 studies with acceptable short-term and/or long-term, freshwater aquatic data for triclocarban in ten and seven species, respectively. Each toxicity study underwent a comprehensive review; a summary of all the studies evaluated, including their quality rating, is organized in an Excel sheet, which can be made available upon request. The existing long-term, freshwater toxicity database for triclocarban contains two fish (*Pimephales promelas*, *Danio rerio*), four invertebrates (*Potamopyrgus antipodarum*, *Daphnia magna*, *Ceriodaphnia dubia*, *Caenorhabditis elegans*) and one algal species (*Pseudokirchneriella subcapitata*) (Table 2). Unfortunately, triclocarban's long-term minimum dataset (CCME 2007) is lacking a salmonid species. Given this limitation, an alternative approach was applied to develop a Type A guideline for triclocarban. The long-term dataset was augmented with data estimated from short-term endpoint data, which included the necessary salmonid, and extrapolated to long-term, non-lethal, low effect levels using acute-to-chronic ratios (ACRs) of 20 and 30 for fish and invertebrates, respectively. The aquatic toxicity data set used to develop the FWQG for triclocarban is shown in Table 2. The first seven rows represent the long-term data set (n=7). The *C. elegans* endpoint is classified as chronic but was corrected from median effect to low effect by using an assessment factor (AF) of 10. The remaining seven short-term studies, including the requisite salmonid study, were extrapolated from short-term, median, lethal effect to long-term, non-lethal, low level effect using an ACR of 20 and 30 for fish and invertebrates, respectively (see Tables 3 and 4 for details).

Table 2. Long-term aquatic toxicity data used for developing the federal water quality guideline for triclocarban.

Species	Group	Endpoint	Concentration (µg/L)	Final (Extrapolated) Concentration (ug/L)	Reference
<i>Potamopyrgus antipodarum</i>	Invertebrate (snail)	28-d MATC (reproduction)	0.15	0.15	Geiss et al. 2016
<i>Daphnia magna</i>	Invertebrate (amphipod)	21-d NOEC (reproduction)	0.25	0.25	EG&G Bionomics 1978a
<i>Ceriodaphnia dubia</i>	Invertebrate (amphipod)	8-d NOEC (reproduction)	1.9	1.9	Tamura et al. 2013a
<i>Pimephales promelas</i>	Fish	22-d NOEC (reproduction)	1.0	1.0	Villeneuve et al. 2017
<i>Pseudokirchneriella subcapitata</i>	Plant (green algae)	3-d NOEC (growth inhibition)	5.7	5.7	Tamura et al. 2013a
<i>Caenorhabditis elegans</i>	Invertebrate (nematode)	96-h EC50 (reproduction)	119	12	Vingskes and Spann 2018
<i>Danio rerio</i>	Fish	9-d NOEC (survival and reproduction)	24	24	Tamura et al. 2013a
<i>Gammarus fasciatus</i>	Invertebrate (amphipod)	96-h LC50 (mortality)	13	0.4	Springborn Life Sciences, Inc. 1987
<i>Chironomus plumosus</i>	Invertebrate (insect)	48-h EC50 (immobilization)	97	3.2	Fan et al. 2019
<i>Lepomis macrochirus</i>	Fish	96-h LC50 (mortality)	70 <sup>a</sup>	3.5	EG&G Bionomics 1976; EG&G Bionomics 1978b-g; Monsanto Co. 1978
<i>Oryzias latipes</i>	Fish	96-h LC50 (mortality)	85	4.3	Tamura et al. 2013a
<i>Oncorhynchus mykiss</i>	Fish	96-h LC50 (mortality)	120	6.0	EG&G Bionomics 1976

Species	Group	Endpoint	Concentration (µg/L)	Final (Extrapolated) Concentration (ug/L)	Reference
<i>Ictalurus punctatus</i>	Fish	96-h LC50 (mortality)	140	7.0	Springborn Life Sciences, Inc. 1988b
<i>Limnodrilus hoffmeisteri</i>	Invertebrate (annelid)	96-h LC50 (mortality)	10622	354	Fan et al. 2019

<sup>a</sup> Geometric mean (n=8)

Triclocarban's ACRs were calculated using existing short-term and long-term aquatic toxicity databases for freshwater and marine species, including native and non-native species. Individual ACRs were calculated for each species for which paired short-term and long-term data were available, and average ACRs were determined by taking the geometric mean of the species-specific ACRs for fish and invertebrates each (Table 3 and Table 4).

Table 3. Acute-to-chronic ratios of fish for triclocarban.

Species	Acute Endpoint	Acute Conc. (ug/L)	Acute Reference	Chronic Endpoint	Chronic Conc. (ug/L)	Chronic Reference	Species ACR
<i>Gobiocypris rarus</i>	96-h LC50 (mortality)	110.3	Fan et al. 2019	28-d NOEC (survival)	41.24	Fan et al. 2019	3
<i>Oryzias latipes sinensis</i>	96-h LC50 (mortality)	1189	Fan et al. 2019	28-d LC10 (survival)	32.73	Fan et al. 2019	36
<i>Pimephales promelas</i>	96-h LC50 (mortality)	92	Springborn Life Sciences, Inc. 1988c	21-d NOEC (growth) 22-d NOEC (reproduction)	1.6 <sup>a</sup> 1 <sup>a</sup>	Schultz et al. 2012 Villeneuve et al. 2017	73
						Geomean of fish ACRs	~20

<sup>a</sup> Geometric mean of two values, 1.3, used to compute *P. promelas* ACR

Table 4. Acute-to-chronic ratios of invertebrates for triclocarban.

Species	Acute Endpoint	Acute Conc. (µg/L)	Acute Reference	Chronic Endpoint	Chronic Conc. (µg/L)	Chronic Reference	Species ACR
<i>Ceriodaphnia dubia</i>	48-h EC50 (immobility)	3.1	Springborn Life Sciences, Inc. 1988a	8-d NOEC (reproduction)	1.9	Tamura et al. 2013a	2
<i>Paratanytarsus parthenogenetica</i>	48-h LC50 (mortality)	96	Monsanto Co. 1980	21-d MATC (emergence)	2.0	Monsanto Co. 1980	49
<i>Daphnia magna</i>	48-h LC50 (mortality)	13	EG&G Bionomics 1978a	21-d NOEC (reproduction)	0.25	EG&G Bionomics 1978a	52
<i>Mysidopsis bahia</i>	96-h LC50 (mortality)	15	EG&G Bionomics 1980	28-d MATC (survival)	0.08	EG&G Bionomics 1980	177
						Geomean of invertebrate ACRs	~30

The 96-h endpoint for *C. elegans* was considered long-term, given the relatively short life span (i.e., 12-18 days) of this species (Kenyon 1997). However, since this endpoint represents a median effect, it was extrapolated to a low

effect using a smaller AF of 10 according to Okonski et al. (2021). The AF is a combination of three factors, endpoint standardization ( $F_{ES}$ ), species variation ( $F_{SV}$ ) and mode of action ( $F_{MOA}$ ) as follows:

$$AF = F_{ES} \times F_{SV} \times F_{MOA} \quad \text{Eq. 1}$$

Endpoint standardization refers to the factor applied to extrapolate a toxicity value to a long-term, sub-lethal, low- or no-effect value. Therefore, there are three possible extrapolations to consider when determining this factor (i.e., short to long-term, lethal to sub-lethal, median to low- or no-effect extrapolations). If two or less extrapolations are required, the  $F_{ES}$  is 5; if all three extrapolations are required, the  $F_{ES}$  is 10. Since the *C. elegans* study only requires one extrapolation (i.e., median to low), the  $F_{ES}$  is 5. The  $F_{SV}$  accounts for the uncertainty in the toxicity database with respect to the number and diversity of species represented. This factor can range from 1 to 50. A chemical with a robust toxicity dataset (i.e., seven or more species across three taxonomic groups) is assigned the lowest factor (x1) whilst a chemical with a weak toxicity dataset (i.e., represented by only one species) receives the highest  $F_{SV}$ . Both marine and freshwater species, as well as short-term and long-term exposure studies are considered when determining the  $F_{SV}$ . The  $F_{SV}$  for triclocarban is 1 as there are 18 species across three taxonomic groups represented in triclocarban's toxicity database. Lastly, the  $F_{MOA}$  refers to the mode of action (MoA) of a chemical. Substances with a non-narcotic MoA action are assigned a  $F_{MOA}$  of 2. Since triclocarban's lines of evidence suggest it is an endocrine disrupter and exhibits more specifically-acting MoAs beyond its narcotic action, it is classified as a non-narcotic and its  $F_{MOA}$  is 2. Therefore, as per equation 1, the AF to extrapolate *C. elegans* to a long-term effect is as follows:

$$AF = 5 \times 1 \times 2 = 10$$



A model averaged species sensitivity distribution (SSD) was fit to the long-term and extrapolated short-term toxicity data (Figure 1 and Table 2) using the web application, ssdtools (version 0.3.3) (Dalgarno 2018). This web application fits toxicity data to multiple cumulative distribution functions (e.g. log-normal, log-logistic, gamma) and constructs an average SSD and HC<sub>5</sub> estimate based on the relative goodness of fit of each respective model. More information on this approach can be obtained from CCME (2019). In the case of triclocarban, the toxicity data fits the log-normal and log-logistic model relatively equally with a poor fit to the gamma distribution. The log-logistic is weighted the greatest, followed closely by the log-normal, and the 5th percentile of the model averaged SSD plot is 0.15 µg/L.

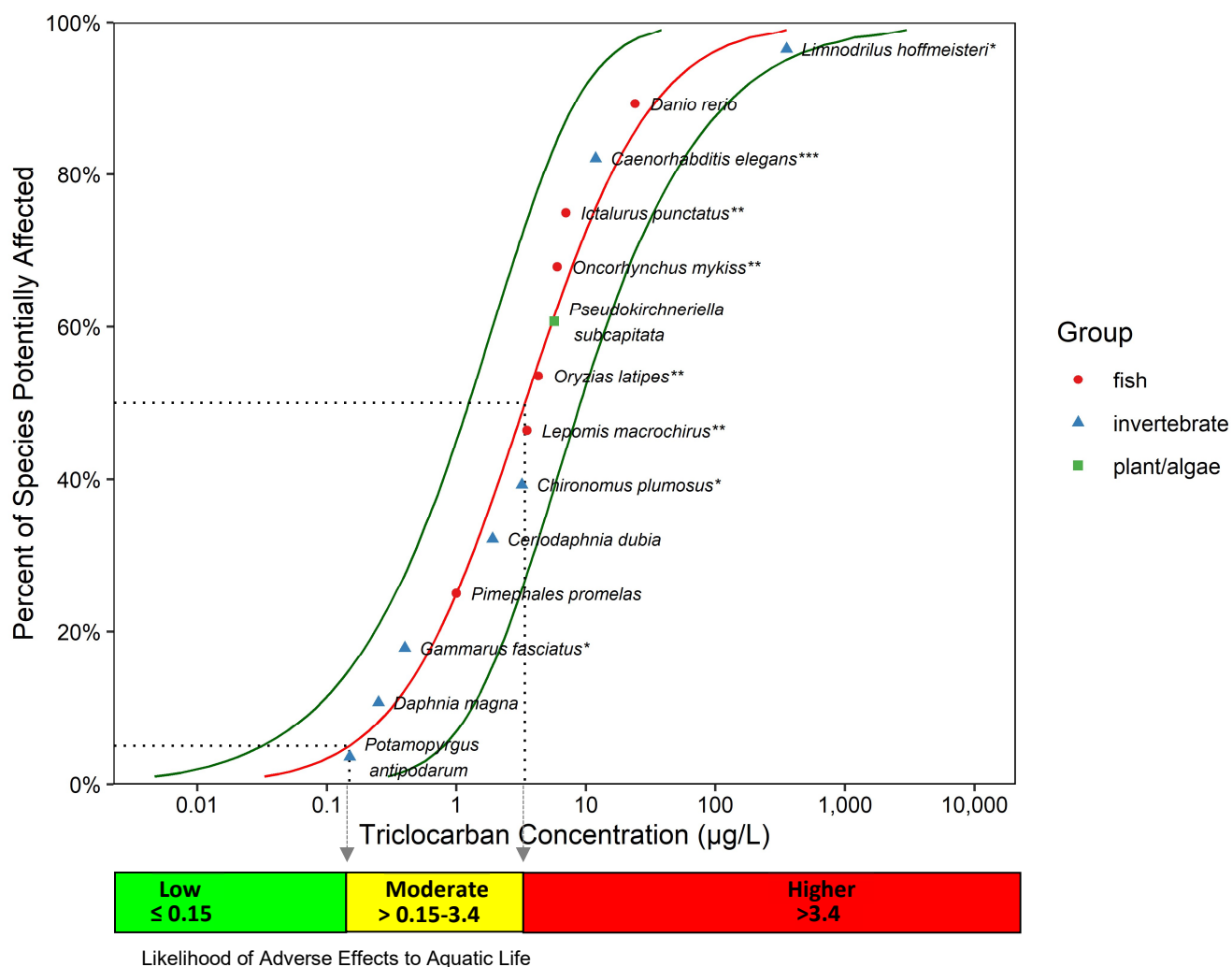


Figure 2. Species sensitivity distribution (SSD) for the long-term toxicity of triclocarban and relative likelihood of adverse effects of triclocarban to freshwater species. \* Endpoints for these species were extrapolated from short-term to long-term low effect concentration using an ACR of 30 (Table 3). \*\* Endpoints for these species were extrapolated from short-term to long-term low effect concentration using an ACR of 20 (Table 4). \*\*\*The endpoint for *C. elegans* was extrapolated from a median to a low effect concentration using an AF=10 as per Okonski et al. (2021). See text for more context for AF selection.

The 5th percentile calculated from the SSD (0.15 µg/L), is the FWQG for protection of freshwater organisms (Figure 2). The guideline represents the concentration at or below which there would be negligible, if any, adverse effects on aquatic life. In addition to this guideline, two other concentration ranges are provided for use in risk management. At concentrations between > 5th percentile and the 50th percentile of the SSD (i.e., >0.15 to 3.4 µg/L) there is a moderate likelihood of adverse effects to aquatic life. Concentrations greater than the 50th percentile (> 3.4 µg/L) have a higher likelihood of being associated with adverse effects.

### Federal Sediment Quality Guideline Derivation

The Federal Sediment Quality Guideline (FSeQG Table 1) is intended to protect sediment-dwelling biota. The FSeQG applies to indefinite exposure periods to sediments, and specifies the concentration of triclocarban found in bulk sediment (dry weight) not expected to result in adverse effects. The guideline may not be appropriate to evaluate the impacts of triclocarban in aquatic macrophytes growing in sediment as there are no published toxicity data for these species.

Sediment quality guidelines can be developed according to two approaches (CCME 1995): 1) the National Standards and Trends Program (NSTP) or 2) Spiked-Sediment Toxicity Test. Since there were insufficient sediment data for the former, the NSTP approach was not considered further. For spiked sediment toxicity tests, low effect endpoints are the preferred endpoint type for guideline derivation following CCME protocol (1995). Specifically, four studies (two of which must be partial or full life-cycle) are required on two or more sediment-dwelling North American invertebrate species (including one arthropod and one crustacean).

Reliable freshwater sediment toxicity data for triclocarban are scarce. The literature search current to March 2021 identified four studies of varying quality that evaluated the sediment toxicity of triclocarban in three species (Table 5). EG&G Bionomics (1979) measured a decrease in larval length for *Paratanytarsus parthenogenetica* at the lowest dose tested in the study and determined an unbounded NOEL of <0.12 mg/kg dw for growth. While this endpoint is the lowest concentration in triclocarban's sediment toxicity data set, unusual observations in the treatment groups suggests there may have been some issues with the study's design thereby confounding its results. A 28-d spiked sediment test using a natural sediment (0.92% OC) measured a NOEL and LOEL of 2.8 and 5.9 mg/kg dw, respectively, for reproduction (i.e., reduced number of eggs/mass) in *P. parthenogenetica* (Monsanto Co. 1980). Tamura et al. (2013b) conducted a 28-d spiked sediment toxicity test with artificial sediment (2% OC) on *Chironomus yoshimatsui* following OECD test guideline 218 and measured a NOEL and LOEL of 2.5 and 5.0 mg/kg dw, respectively, for reduced emergence of adult midges. Lastly, Higgins et al. (2009) studied the bioaccumulation of triclocarban in sediments to *Lumbriculus variegatus*. To determine a safe level of exposure for the bioaccumulation study, they conducted a preliminary 10-d short-term toxicity test that recorded no mortality of *L. variegatus* from triclocarban sediment concentrations up to 100 mg/kg dw. There were no additional details in the latter study to evaluate its quality.

Table 5. Endpoints for organisms exposed to triclocarban through sediment.

Species	% OC <sup>a</sup>	Endpoint	Concentration (mg/kg dw)	OC-adjusted concentration (mg/kg dw) <sup>b</sup>	Reference
<i>P. parthenogenetica</i>	0.92 <sup>c</sup>	10-d NOEC (growth)	<0.16	<0.17	EG & G Bionomics 1979
<i>P. parthenogenetica</i>	0.92	28-d LOEC (reproduction)	5.9	6.4	Monsanto Co. 1980
<i>C. yoshimatsui</i>	2	20-d LOEC (emergence)	5.0	2.5	Tamura et al. 2013b
<i>L. variegatus</i>	3.3	10-d LC50 (mortality)	>100	>30	Higgins et al. 2009

<sup>a</sup> Organic carbon

<sup>b</sup> Concentration normalized to a 1% organic carbon sediment

<sup>c</sup> OC% not stated in study. OC% assumed to be the same as Monsanto Co. (1980) since the same sediment (Missouri River Bottom soil) was used in the two studies.

Given the paucity of data, there were an insufficient number of studies to meet the minimum data requirements to develop sediment quality guidelines based on the Spiked-Sediment Toxicity Test Approach in the CCME protocol (CCME 1995). Therefore, the approach used was to calculate a value to protect organisms exposed to sediment pore water based on the concentration in the water column which should be protective of all aquatic organisms (i.e., the FWQG of 0.15 µg/L) and to convert that pore water value to a concentration in bulk sediment using the equilibrium partitioning method (Di Toro et al. 1991).

Table 6. Soil-adsorption coefficient (K<sub>OC</sub>) for triclocarban.

K <sub>OC</sub> (L/kg-dw)	Log K <sub>OC</sub>	Reference
3060	3.5	European Chemicals Agency 2021
54800	4.7	TCC Consortium 2002
111200	5.0	TCC Consortium 2002
48900	4.7	Wu et al. 2009
64000	4.8	Wu et al. 2009
58700	4.8	Wu et al. 2009
71700	4.9	Wu et al. 2009
Median = 58700	Median = 4.8	

Using the median K<sub>oc</sub> for triclocarban of 58700 L/kg (Table 6) and normalizing the value to 1% OC in sediment (FSeQG = 0.01 x 58700 L/kg-dw x 0.00015 mg/L), the resulting FSeQG is 0.09 mg/kg dw.

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## **List of acronyms and abbreviations**

AF – Assessment Factor

BAF - Bioaccumulation Factor

BCF - Bioconcentration Factor

BSAF – Biota-Sediment/Soil Accumulation Factor

CCME – Canadian Council of Ministers of the Environment

CEPA – Canadian Environmental Protection Act

CMP – Chemicals Management Plan

DOM – Dissolved Organic Matter

EC – Effect Concentration

FEQG – Federal Environmental Quality Guidelines

F<sub>ES</sub> – Endpoint Standardization Factor

F<sub>MOA</sub> – Mode of Action Factor

F<sub>SV</sub> – Species Variation Factor

FWQG – Federal Water Quality Guideline

FSeQG – Federal Sediment Quality Guideline

GRAS/GRAE – Generally regarded as safe/Generally regarded as effective

K<sub>OC</sub> – Soil adsorption coefficient, K<sub>d</sub>, normalized to soil organic carbon

K<sub>OW</sub> – Octanol-Water Partition Coefficient

LC – Lethal Concentration

LOEC/L – Lowest Observed Effect Concentration/Level

MATC – Maximum acceptable toxicant concentration

NSTP – National Standards and Trends Program

NOEC/L – No Observed Effect Concentration/Level

OC – Organic Carbon

Pa – Pascal

pK<sub>a</sub> – negative logarithm of acid dissociation constant, K<sub>a</sub>

SSD – Species Sensitivity Distribution

USEPA – United States Environmental Protection Agency

US FDA – United States Food and Drug Administration

WWTP – Wastewater Treatment Plant