Canadian Environmental Protection Act, 1999

Federal Environmental Quality Guidelines

Siloxane D4

(Octamethylcyclotetrasiloxane)

Environment and Climate Change Canada

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Introduction

Federal Environmental Quality Guidelines (FEQGs) describe 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, soil, and biological tissue); and third, they can serve as performance measures of the effectiveness 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 or 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 (FEQGs) page.

This factsheet describes the FEQGs for water, sediment, aquatic biota tissue and wildlife diet to protect aquatic life and mammalian consumers of aquatic life from adverse effects of octamethylcyclotetrasiloxane (D4) (Table 1). It is largely based on the data found in the screening assessment published under Canada's Chemicals Management Plan (Environment Canada, Health Canada (EC, HC) 2008)) as well as additional data and information identified up to January 2018.

Table 1. Federal Environmental Quality Guidelines for D4.

Water (µg/L)	Aquatic Biota Tissue [a] (µg/g lipid weight)	Sediment [b] (mg/kg dry weight)	Mammalian Wildlife Diet (mg/kg food wet weight)
0.20	210 (0.72 µmol/g lipid weight)	0.03	1.9

[a] The biota tissue guideline expressed in µg/g lipid weight or µmol/g lipid weight can be applied to D4. Given the shared narcotic mode action of cyclic volatile methyl-siloxanes (cVMS), the guideline expressed in µmol/g lipid weight can be applied to the sum of cVMS concentrations measured in tissue.
[b] Normalized to 1% organic carbon (OC). Monitoring data should be normalized to 1% OC to assess whether the guideline value is exceeded.

Substance Identity

Octamethylcyclotetrasiloxane or D4 (CAS RN 556-67-2) is an industrial chemical that belongs to a group of cyclic volatile methyl-siloxanes (cVMS) with relatively low molecular weight (<600 g/mol) and high vapour pressure. These cVMS are volatile, low-viscosity silicone fluids consisting of $[-Si(CH_3)_2O-]_x$ structure units in a cyclic configuration (EC, HC 2008). D4 has four $[-Si(CH_3)_2O-]$ structure units, while other well-known siloxanes such as decamethylcyclopentasiloxane (D5, CAS RN 541-02-6) and dodecamethylcyclohexasiloxane (D6, CAS RN 540-97-6) have five and six $[-Si(CH_3)_2O-]$ structure units, respectively. With the exception of the biota tissue guideline (expressed in µmol/g lipid weight) which can be applied to the sum of cVMS (see footnote 1 of Table 1), this factsheet and the associated FEQGs apply only to D4. Environment and Climate Change Canada (ECCC) and Health Canada (HC) (2008) have assessed the potential ecological and human health effects of D4 under the Chemicals Management Plan. Based on the screening assessment for D4, this substance has been determined to be persistent in air and sediment but not in water or soil as per the persistence criteria in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act* (CEPA) (Canada 2000). Further, based on both its empirical bioconcentration factor (BCF) and modelled bioaccumulation factor (BAF) being greater than 5000 L/kg, D4 may have high potential to accumulate in aquatic organisms (EC, HC 2008); however, due to conflicting

evidence between various empirical and predicted bioaccumulation metrics (i.e., bioconcentration, bioaccumulation and biomagnification) for fish and invertebrates, the screening assessment (completed in 2008) was unable to conclude that D4 meets the criterion for bioaccumulation (BCF or BAF ≥ 5000) as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000). Nonetheless, D4's bioaccumulative potential remains somewhat uncertain as the research on the bioaccumulation of cVMS continues to evolve. The screening assessment concluded that D4 meets the criteria under paragraph 64(*a*) of CEPA, as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it was concluded that D4 does not meet the criteria under paragraph 64(*b*) of CEPA, as it is not entering the environment or under conditions that constitute or may constitute a danger to the environment on which life depends.

Sources and Uses

The principal sources of D4 to the environment include industrial processes where it is reacted to form silicone polymers; from blending, formulation and packaging operations; as well as from use and disposal of consumer products such as personal care products (EC, HC 2008). D5, D6 and other cVMS may also be sources of D4 observed in the Canadian environment, as D4 is an impurity in these substances (ECHA 2019).

Data indicated that in 2006 D4 was not manufactured by any company in Canada in a quantity above the reporting threshold of 100 kg, but between 1 000 000 and 10 000 000 kg were imported into Canada as an essentially pure substance, in mixtures with other cVMS, as a residual in silicone polymers, and in finished consumer products (EC 2007).

The most common use of high-purity D4 in Canada is as a raw material in the manufacture of silicone polymers and copolymers, which contain trace amounts of unreacted D4. Silicone polymers can be grouped as fluids, gums and resins. Silicone polymers in fluid form are used in personal care products; pharmaceuticals; processing aids such as defoamers; surfactants and mould release agents; lubricants; polishes and coatings; sealants; mechanical, heat transfer and dielectric fluids; and reprography. Biomedical uses of silicone polymers in gel and fluid forms include medical devices; blood handling equipment; as a blood defoaming agent; as protective barriers and lubricants; and for surface treatment of wound dressings (Will et al. 2007 as cited in EC, HC 2008). Silicone polymers in gum form are used to produce elastomers (for sealants and adhesives); molded silicone rubber; coatings and encapsulation. Silicone polymers in resin form are primarily used in speciality coatings and in the production of silicone-modified polymers (EC, HC 2008).

The use of silicone formulants containing D4 in certain pesticide products is regulated in Canada under the *Pest Control Products Act* (Canada 2002).

Cyclomethicone is a mixture of low molecular weight volatile cyclic siloxanes, the principal ingredients of which are D4, D5 and D6, in varying proportions. In Canada, the most common uses of the mixtures of low molecular weight volatile cyclic siloxanes, which may contain a high percentage of D4 or of D5, are in the preparation of personal care products, including hair and skin care products and antiperspirants (EC 2007; EC, HC 2008).

Fate, Behaviour and Partitioning in the Environment

Based on physical-chemical properties and use patterns, the principal receiving environments of D4 are expected to be air, wastewater and agricultural soil (EC, HC 2008). The majority of D4 is volatilized into the air as a result of the use of consumer products such as skin creams, sun creams or polishes and residues in silicone polymers. Releases to wastewater occur from on-site formulation of personal care products and from diffuse sources associated with the use of personal care products (EC, HC 2008). The application of D4-containing pesticides and the disposal of sewage sludge on agricultural land and in landfills will result in the release of D4 to environmental media (EC, HC 2008).

In air, D4 is persistent, with calculated atmospheric half-lives of more than 5 days. Additionally, it has the potential to be transported over long distances in the atmosphere; however, it has a low potential to be

deposited in water or soil in remote regions (EC, HC 2008). The half-life, as well as vapour pressure (140 Pa) (Flaningam 1986) and Henry's Law Constant (1 220 000 $Pa \cdot m^3/mol$) (EC, HC 2008) of D4 indicate that all of the mass fraction released to air will remain there until degraded by hydroxyl radicals (EC, HC 2008). The log K_{aw} (air-water partition coefficient) is 2.69 at 25°C (Xu and Kropscott 2007).

In water, hydrolysis half-lives under Canadian water conditions (pH 6-9, temperature 5-25°C) are estimated to range from hours to 45 days, indicating that D4 is not persistent in water. Hydrolysis is the major degradation process for D4 in water. Dimethylsilanediol is the final hydrolysis product and is expected to biodegrade slowly. When released to water, D4 is expected to adsorb to suspended solids, such as sewage sludge and sediments, based on its moderate log K_{oc} value of 4.22 (Miller 2007). Fugacity modelling suggests that when released to water, approximately 10% will partition to air, 40% to sediment and 50% will remain in the aqueous phase (New EQC 2011). Given that the log K_{oc} for D4 is in the moderate to high sorption range and its entry into aquatic environments is expected to be primarily from wastewater treatment plants (WWTPs), when released to water a significant amount of D4 is expected to be already sorbed to suspended particles and will sink to bottom sediments, thereby providing a continuous source to water from bed sediments. D4 is sparingly soluble in water (solubility limit of 56.2 µg/L) (Varaprath et al. 1996). Additional experimental solubility values that are summarized in the assessment are specific to fresh water (74 µg/L) and salt water (33 µg/L) (Hobson and Silberhorn 1995). D4 is lipophilic (log K_{ow} value of 6.49) (Kozerski and Shawl 2007), and highly volatile (vapour pressure of 140 Pa). A steady-state BCF of 12 400 L/kg has been experimentally derived for fathead minnow (Fackler et al. 1995). There has since been debate regarding whether D4 reached steady-state in this study; results from this study were re-evaluated by Smit et al. (2012) resulting in a revised kinetic BCF for fathead minnow of 14 900 L/kg, suggesting a high accumulation potential in aquatic biota from water.

In sediment, half-lives range from 49 to 588 days, indicating that D4 may be persistent in sediment. Calculated biota sediment accumulation factors (BSAFs) values ranging from 0.7 to 2.1 in *Chironomus tentans* suggests a low level of bioaccumulation in sediment macroinvertebrates (Kent et al. 1995; EC, HC 2008). D4 is not persistent in soil. When released to soil only a small percentage is expected to remain in soil due to partitioning to air as well as clay-catalyzed hydrolysis (EC, HC 2008).

Measured Concentrations

There are no known natural sources of D4. Measured concentrations of D4 in Canada were available for various media including wastewater, sediment, soil and biota.

Water from nine sewage treatment plants in urban centres of southwestern Ontario sampled in the fall and winter of 2005 had D4 concentrations ranging from <2 to 24 µg/L in influents and from <2 to 2.92 µg/L in effluents. Seasonal variation was observed in the influents with higher concentrations in the winter compared to the fall (EC, HC 2008). Eleven WWTPs from southern Ontario and southern Quebec sampled in 2010 had D4 concentration ranges of 0.282 to 6.69 µg/L, <0.009 to 0.045 µg/L and <0.009-0.023 µg/L in influent, effluent and receiving waters, respectively (Wang et al. 2013). Mean removal efficiency of D4 was 98% (Wang et al. 2013). At a municipal WWTP discharging to Lake Ontario, concentrations of D4 were 0.166-1.13 µg/L in the influent and <0.009-0.026 µg/L in the final effluent, measured in the winter of 2011 (Wang et al. 2015).

Surface sediment sampled from the Toronto Harbour in Lake Ontario in 2006 had D4 concentrations of 0.29 mg/kg dry weight (dw), while surface sediment from the Kingston Basin of the lake was below the analytical detection limit of 0.006 mg/kg dw (Powell and Kozerski 2007). Surface and core sediment sampled from a remote lake in 2007 (Lake Opeongo in Algonquin Provincial Park, ON) did not contain D4, with a detection limit of <0.001 mg/kg wet weight (ww) (Powell 2010). D4 was also not detected in zooplankton sampled from this site (Powell 2008). Surface sediments sampled in 2010 from 11 locations adjacent to WWTP discharge sites in southern ON and southern QC had D4 concentrations ranging from <0.003 to 0.049 mg/kg dw (Wang et al. 2013). Additional, unpublished data from ECCC monitoring reported D4 concentrations in surface sediment from various locations in Atlantic (n=20, sampled 2011-2015), Ontario (n=206, sampled 2011-2016), Pacific (n=10, sampled 2009-2011) and Quebec (n=169, sampled 2010-2015) regions ranging from <0.0002 to 0.0044 mg/kg dw, <0.0002 to 0.22 mg/kg dw, <0.0002 to 0.061 mg/kg dw and <0.0002 to 0.026 mg/kg dw, respectively (ECCC unpublished). D4 concentrations in suspended sediment from Ontario

(n=25, Detroit River and Hamilton Harbor sampled 2012) and Quebec (n=34, Montreal sampled in 2012) regions ranged from <0.0005 to 0.063 mg/kg dw and <0.0006 to 0.097 mg/kg dw, respectively (ECCC unpublished). At a wastewater treatment plant in Montreal, QC, suspended and bottom sediment concentrations of D4 measured within the WWTP's plume were 0.058 mg/kg dw and 0.0067 mg/kg dw, respectively, compared to 0.001 and 0.0005 mg/kg dw outside its plume (ECCC unpublished). Surface sediments collected at 5 different locations in Lake Ontario from 2011 to 2016 ranged from 0.0038 to 0.012 mg/kg dw for Hamilton Harbour and were below the detection limit (<0.002 mg/kg dw) at inner lake locations (CES 2018).

Concentrations in agricultural soil from farms in Ontario where biosolids from WWTPs were applied ranged from <0.008 to 0.017 mg/kg dw (Wang et al. 2013).

Invertebrates collected in bulk near a Montreal, QC wastewater treatment plant had D4 concentrations of 22.8 ng/g ww within the WWTP's plume and 9.0 ng/g ww outside its plume (ECCC unpublished). Mysid shrimp collected in 2011-2016 from Lake Ontario had a mean D4 concentration of 1.42 ng/g ww (20.1 ng/g lipid weight (lw)) (CES 2018).

Fish collected in 2009-2010 from 16 water bodies in Canada were analyzed for D4 concentrations in whole body homogenates. The water bodies included lakes, rivers and reservoirs that ranged from remote locations to areas with intense agriculture and industrial activities. D4 was detected in all samples of fish, and concentrations were highest in the Laurentian Great Lakes. Lake trout collected near Niagara on the Lake consistently had the highest reported concentrations of D4 ranging from 2.5 to 28 ng/g ww (McGoldrick et al. 2014a). Aquatic biota at various trophic levels were collected from Lake Erie and analyzed for concentrations of cVMS and evidence of biomagnification. Concentrations of D4 were below detection (<2 ng/g) in composite plankton, 7.0 ng/g ww in burrowing mayfly *Hexagenia* (McGoldrick et al. 2014b) and ranged from 9 to 13 ng/g ww in fish. The occurrence of biomagnification was unclear (McGoldrick et al. 2014b). Mean D4 concentrations measured between 2008-2012 in lake trout of Lake Ontario, Lake Huron, Lake Superior as well as walleye in Lake Erie ranged from 2.3 to 14 ng/g ww (McGoldrick et al. 2016). Fish species sampled inside the plume of a Montreal, QC wastewater treatment plant had D4 concentrations of 2.8, 10.9, 7.3 and 33.2 ng/g ww for round goby, yellow perch, northern pike and walleye, respectively (ECCC unpublished). The same fish species had D4 concentrations of 2.0, 1.8, 1.2 and 4.0 ng/g ww when sampled outside the WWTP's plume (ECCC unpublished). Mean D4 concentrations in goby, lake trout, alewife and rainbow trout measured in Lake Ontario from 2011 to 2016 ranged from 0.677 to 8.16 ng/g ww (20.3 to 43.7 ng/g lw) (CES 2018). Mean D4 concentrations in small goby (<10 cm total length), goby, lake trout, alewife and rainbow smelt were 0.677, 1.12, 8.16, 1.91 and 1.10 ng/g ww, respectively (27.5, 33.5, 43.7, 24.3 and 20.3 ng/g lw, respectively) (CES 2018).

D4 was measured in bird eggs from locations across Canada. Median concentrations in eggs of various gull species from sites across British Columbia, Nunavut, Ontario, Quebec, Alberta, Northwest Territories, Manitoba, New Brunswick and Newfoundland ranged from 1.11 to 5.85 ng/g ww. Median concentrations in European Starling eggs ranged from below detection to 5.16 ng/g ww for sites of various land use including landfill, urban industrial and 40-km distance from major urban centers across British Columbia, Alberta, Ontario, Quebec and Nova Scotia (Lu et al. 2017). In Herring gull eggs sampled at a Montreal, QC wastewater treatment plant, D4 concentrations were 4.1 ng/g ww inside the WWTP's plume, compared to 4.2 ng/g ww outside its plume (ECCC unpublished).

D4 was measured in the blood of turtles, cormorants and seals, all representing high trophic level piscivores. Mean concentrations in the blood of turtles sampled from Hamilton Harbour, ON and Toronto Harbour, ON (considered by the study as contaminated sites) were 0.122 and 0.091 ng/g ww, respectively, compared to 0.077 ng/g ww at a reference site. Mean concentrations in the blood of cormorants from Toronto Harbour and Hamilton Harbour were 0.051 and 0.085 ng/g ww, respectively, no different from 0.083 ng/g ww at a reference site. Mean concentrations in the blood of Northwest Atlantic harbour seals (*Phoca vitulina concolor*) were 0.314 ng/g ww in the St. Lawrence Estuary (considered by the study as a contaminated site) compared to 0.186 ng/g ww at a reference site in the northern Gulf of St. Lawrence (Wang et al. 2017).

Mode of Action

The mode of toxic action of D4 is via nonspecific, nonpolar narcosis, whereby the chemical accumulates in tissue to a critical (toxic) body burden and exerts its effect through non-specific interference with cell membranes (Hobson and Silberhorn 1995; Fairbrother and Woodburn 2016; Redman et al. 2012). This is supported by the following: (i) observations of toxicity in fish and daphnids only after sustained exposures, (ii) the temporal pattern of mortality being consistent with uptake kinetics and time to achieve maximum body burden and (iii) the observation of other toxic symptoms such as darkened coloration and loss of equilibrium (Hobson and Silberhorn 1995; Fackler et al. 1995; Sousa et al. 1995). While some jurisdictions consider or suspect D4 to be an endocrine-disrupting chemical (EDC) in mammals (Hass et al. 2017), there is a lack of consensus on D4's EDC potential in this regard (Borgert et al. 2018; Franzen et al. 2017). To date, there are no definitive tests confirming endocrine disrupting activity of D4 in aquatic organisms.

Federal Water Quality Guideline Derivation

Federal Water Quality Guidelines (FWQGs) are benchmarks for aquatic ecosystems that are intended to protect all forms of aquatic life (vertebrates, invertebrates and plants/algae) from direct adverse effects for indefinite exposure periods via the water column. FWQGs are preferably developed according to CCME (2007) protocols using no- to low-effect endpoint data from chronic aquatic toxicity studies. A literature review current to January 2018 did not identify any new aquatic studies published since the Government of Canada's screening assessment of D4 (EC, HC 2008). Therefore, the toxicity data available for guideline derivation was limited to the studies documented in Table 10a of the D4 screening assessment (EC, HC 2008) reproduced in Table 2 for ease of reference.

Table 2: Empirical aquatic toxicity data for D4 (EC, HC 2008).

Test organism	Type of test	Duration	Endpoint	Value (mg/L)	Reference
Rainbow trout *Oncorhynchus mykiss*	Acute	14-d	LC_{50}	0.010	Sousa et al. 1995
Rainbow trout *Oncorhynchus mykiss*	Acute	14-d	NOEC	0.0044	Sousa et al. 1995
Rainbow trout embryos *Oncorhynchus mykiss*	Chronic	93-d	NOEC	0.0044	Sousa et al. 1995
Shrimp *Mysidopsis bahia*	Acute	96-h	LC_{50}	> 0.0091	Sousa et al. 1995
Sheepshead minnow *Cyprinodon variegatus*	Acute	14-d	NOEC	0.063	Sousa et al. 1995
Sheepshead minnow *Cyprinodon variegatus*	Acute	14-d	LC_{50}	> 0.063	Sousa et al. 1995
Water flea *Daphnia magna*	Acute	48-h	NOEC	0.015	Sousa et al. 1995
Water flea *Daphnia magna*	Chronic	21-d	NOEC	0.008	Sousa et al. 1995
Water flea *Daphnia magna*	Chronic	21-d	LOEC	0.015	Sousa et al. 1995
Midge *Chironomus tentans*	Chronic	14-d	NOEC	≥ 0.015	Kent et al. 1994
Freshwater algae *Selenastrum capricornutum*	Acute	96-hr	EC_{50}	Invalid	Springborn Laboratories 1990

Each toxicity study underwent a comprehensive review; a summary of all the studies evaluated, including their quality rating, can be made available upon request to ec.rqe-eqg.ec@canada.ca. The existing aquatic database for D4 was inadequate to develop a Type A or B guideline according to CCME protocol (2007). Specifically, it was not even possible to develop a Type B2 guideline which has the least onerous data requirements, since Type B guidelines are based on chronic, low effect endpoints. The minimum data requirements for a Type B guideline are chronic, low effect endpoints in two fish species (including one salmonid) and two aquatic or semi-aquatic invertebrate species (including one planktonic crustacean). In the case of D4, there was only one such chronic, low effect endpoint available (i.e., 21-d *D. magna* LOEC) for Type B guideline development[1].

Given the need to develop a FWQG to support risk management of this substance, the predicted no effect concentration (PNEC) derived in the assessment of D4 was adopted as the FWQG. As described in the D4 screening assessment, the PNEC was based on a 14-day rainbow trout LC_{50} of 10 µg/L (Sousa et al. 1995) to which an assessment factor (AF) of 50 was applied, yielding a PNEC of 0.2 µg/L (EC, HC 2008). The FWQG applies to freshwater systems. The AF of 50 was chosen to extrapolate the rainbow trout LC_{50} to a long-term, multi-species, no-effect level. The AF is a combination of three factors, endpoint standardization (F_{ES}), species variation (F_{SV}) and mode of action (F_{MOA}) as follows:

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

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. In the case of D4, since the rainbow trout study required all three extrapolations, the F_{ES} is 10. 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 whilst chemicals 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 acute and chronic exposure studies are considered when determining the F_{SV}. The F_{SV} for D4 is 5 as there are five species across two taxonomic groups represented in D4's toxicity database. Lastly, the F_{MOA} refers to the mode of action of a chemical. Substances with a narcotic mode of action are assigned a F_{MOA} of 1. Given D4 is considered a narcotic, its F_{MOA} is 1. Therefore, as per equation 1, the AF for D4 is as follows:

$$AF = 10 \times 5 \times 1 = 50$$

The target lipid model (TLM) (McGrath et al. 2018), described in detail in the Biota Tissue Guideline Derivation section below, provides a supporting line of evidence for the FWQG as it predicts a water quality guideline of 0.3 µg/L for D4, based on its log K_{OW} of 6.49.

Federal Aquatic Biota Tissue Guideline Derivation

Typically, Federal fish tissue guidelines are developed for aquatic ecosystems to protect fish from direct adverse effects of bioaccumulated contaminants and provide a supplementary benchmark to water quality guidelines to assess potential adverse effects. Preferably, fish tissue guidelines are derived from studies that relate fish tissue concentrations to adverse effects. However, there are no supporting studies of this nature to derive a fish tissue guideline for D4. Alternatively, fish tissue guidelines have been developed using an equilibrium partitioning approach to estimate the whole body concentration from the FWQG and the degree to which fish accumulate the substance. However, there are no available field- or experimentally-derived BAFs for D4. While some guideline developers may substitute a BCF for a BAF when applying the equilibrium partitioning approach, Arnot and Gobas (2006) advise against this practice. The measurement

[1] As noted in Table 2, there were 3 chronic toxicity studies available for D4: 93-d rainbow trout early life stage test, 21-d *Daphnia magna* life cycle test and 14-d test with the midge *Chironomus tentans*. There were no effects noted at the highest dose tested for both the rainbow trout (4.4 µg/L) and midge (15 µg/L) tests and therefore, LOECs are not available for these studies.

uncertainty and natural variability associated with BCF studies leads to underestimates of the true BCF and, therefore, BAF (Arnot and Gobas 2006). Therefore, even though an empirical BCF is available for D4, it was not used to develop a fish tissue guideline using an equilibrium partitioning approach.
However, since the mode of action of D4 is narcosis (Hobson and Silberhorn 1995) and the use of the TLM was validated for D4 (Redman et al. 2012), the TLM can be used to estimate a chronic, critical target lipid body burden (CTLBB) [i.e., (C^*_L (5%)] for D4 in biota tissue.

The TLM is a quantitative structure-activity relationship (QSAR) developed for nonpolar narcotics based on the premise of critical body burden theory (McCarty et al. 1991, 1992; Di Toro et al. 2000; McGrath et al. 2018). The model predicts no-effect concentrations in water based on a chemical's K_{OW}. Since the TLM was developed for hydrocarbons, its training set does not include silicone-containing substances. However, based on limited toxicity data, Redman et al. (2012) validated the application of the TLM to cVMS by demonstrating that the measured acute toxicities of D4 and D5 are consistent with TLM predictions. In addition, the median acute to chronic ratio (ACR) used in the TLM (i.e., 5.2, range 1.0->95.2) is more conservative than the median ACR (i.e., 2.5, range 1.4-6.1) for cVMS calculated by Redman et al. (2012), affording some additional conservatism to TLM predictions for D4. The following TLM equation derives long term, no-effect concentrations in water (i.e., chronic HC_5 values[2]) for Type I narcotic chemicals (with log K_{OW} <6.5) (McGrath et al. 2018):

$$Chronic\ Log(HC_5) = E[m]log(K_{OW}) + \mathrm{E}[\log(\mathrm{C}_\mathrm{L}^*)] + \Delta c - \mathrm{E}[\log(\mathrm{ACR})] \qquad \text{Eq. 2}$$

$$- \mathrm{K_Z}\sqrt{\mathrm{V[m]}\log(K_{OW})^2 + V[\log(C_L^*)] + V[\log(ACR)] + 2\log(K_{OW})\,[Cov(m,\log(C_L^*)]}$$

Where, the universal narcosis slope is E[m] = -0.940 with a variance of V[m]=0.000225, the log mean value of 79 critical target lipid body burdens (CTLBBs) is E[log(C^*_L)]=1.85 with a variance of V[log(C^*_L)]=0.135, log mean acute to chronic ratio (ACR) is E[log(ACR)]=0.718 with a variance of V[log(ACR)]=0.149, the covariance between slope and log CTLBB Cov(m,log(C^*_L))= -0.0079, and the 95% confidence sample size-dependent extrapolation factor k_Z=2.396 (McGrath et al 2018).

By solving for HC_5 when Log K_{OW} and Δ_c are both zero, the equation yields a universal chronic CTLBB or, C^*_L (5%), of 0.72 µmol/g lipid weight.[3] This occurs because when the Log K_{OW}=0, the concentration found in water (i.e., HC_5) is equal to the concentration in the target lipid [i.e., C^*_L (5%)].

A Federal Aquatic Biota Tissue Guideline (FBTG) for D4 is derived by multiplying C^*_L (5%) by its respective molecular weight:

FBTG = C^*_L (5%) x molecular weight D4 Eq. 3

= 0.72 µmol/g lw x 296 g/mol

= 213 µg/g lw

Since the TLM includes toxicity data from 79 marine and freshwater species across various taxonomic groups (e.g., fish, invertebrates, algae, higher plants) and C^*_L (5%) is expressed on a lipid basis, the FBTG can be applied to lipid-adjusted tissue concentrations of D4 in freshwater and marine biota. While the FBTG is presented for D4, given the shared narcotic mode of action of cVMS, the FBTG expressed in µmol/g lw (i.e., 0.72 µmol/g lw) can also be compared to the sum of cVMS concentrations in a tissue sample. An important limitation regarding the TLM is that it does not consider chemical metabolism. However, studies examining bioconcentration and/or metabolism of D4 in fathead minnow or rainbow trout (Fackler et al. 1995;

[2] HC_5 represents a water concentration below which adverse effects are unlikely from repeated, chronic exposure.
[3] The TLM was revised resulting in improvements to the model which reduced the chronic C^*_L (5%) from 2.6 µmol/g lw to 0.72 µmol/g lw (McGrath et al. 2018).

Domoradzki et al. 2017) and biomagnification in rainbow trout (Drottar 2007; Compton 2019) suggest metabolism of D4 in fish is very limited.

Sediment Toxicity

Toxicity data for the development of a Federal Sediment Quality Guideline (FSeQG) for D4 were obtained from the screening assessment (EC, HC 2008). An updated literature search to January 2018 was completed and some new data were identified. All data were screened for quality and completeness following guidance from CCME protocol (1995) for derivation of sediment quality guidelines. Each toxicity study underwent a comprehensive review; a summary of all the studies evaluated, including their quality rating, can be made available upon request to ec.rqe-eqg.ec@canada.ca. Acceptable toxicity data from four studies were available for three invertebrate species, including midges (*Chironomus tentans* and *C. riparius*) and the black worm *Lumbriculus variegatus* (Kent et al. 1994; Krueger et al. 2008, 2009; Picard 2009). Preferred endpoints as per CCME protocol (1995) are presented in Table 3.

Kent et al. (1994) examined the effect of organic carbon (OC) ranging from 0.27 to 4.1% OC on sediment toxicity of D4 to *C. tentans*. In the low OC exposure (LOC= 0.27% OC), no effects on survival were seen at the highest concentration tested (130 mg/kg dw), and the 14-d LOEC value for biomass was 130 mg/kg dw. In the medium (MOC= 2.3% OC) and high OC (HOC= 4.1% OC) exposures, no effects on growth were observed, and the 14-d LOEC values for survival were 250 and 170 mg/kg dw, respectively. The authors concluded that OC did not affect D4 toxicity. However, given the variable percent recoveries (i.e., 16%, 35% and 26% for LOC, MOC and HOC studies, respectively) and differences in exposure systems (i.e., closed for LOC and MOC and open for HOC), measured concentrations varied considerably across the three studies for each nominal concentration, making it difficult to conclude on the influence of OC on D4 sediment toxicity in *C. tentans*. In spite of the foregoing, OC content appeared to influence the toxicodynamics of D4. When measured concentrations were held approximately constant (i.e., 17, 18 and 19 mg/kg dw, respectively, for LOC, MOC and HOC), tissue concentrations decreased with increasing OC content. Measured tissue concentrations at this exposure level were 30, 22 and 13 mg/kg for the LOC, MOC and HOC studies, respectively (Kent et al. 1994).

For *C. riparius*, 28-d LOEC values of 131 mg/kg dw for emergence and 355 mg/kg dw for time to emergence were reported by Krueger et al. (2008) at 4% OC. For *L. variegatus*, 28-d LOEC values of >38 mg/kg dw for biomass and 0.73 mg/kg dw for survival and reproduction were reported by Krueger et al. (2009) at 2.4% OC. Picard (2009) reported a 28-d LOEC of 19 mg/kg dw for *L. variegatus* at 2.2% OC for effects on survival.

Table 3. Endpoints for organisms exposed to D4 through sediment.

Species	% OC[a]	Endpoint	Concentration (mg/kg dw)	OC-adjusted concentration (mg/kg dw)[b]	Reference
Chironomus tentans	0.27	14-d LOEC (biomass wet weight)	130	481	Kent et al. (1994)
C. tentans	4.1	14-d LOEC (survival)	170	41	Kent et al. (1994)
C. riparius	4	28-d LOEC (emergence)	131[c]	33	Krueger et al. (2008)
C. riparius	4	28-d LOEC (time to emergence)	355	89	Krueger et al. (2008)
Lumbriculus variegatus	2.4	28-d LOEC (biomass dry weight)	>38	>16	Krueger et al. (2009)
L. variegatus	2.4	28-d LOEC (survival and reproduction)	0.73	0.3	Krueger et al. (2009)
L. variegatus	2.2	28-d LOEC (survival)	19	8.6	Picard (2009)

[a] Organic carbon

[b] Concentration adjusted to a 1% organic carbon sediment.
[c] A 28-d LC_{50} of 114 mg/kg dw was also reported in this study, indicating the LOEC does not represent a low effect. Specifically, at 131 mg/kg dw, there was 55% mortality in treated organisms.

Federal Sediment Quality Guideline Derivation

The Federal Sediment Quality Guideline (FSeQG) is intended to protect sediment-dwelling biota (Table 1). The FSeQG applies to indefinite exposure periods to sediments, and specifies the concentration of D4 found in bulk sediment (dry weight) not expected to result in adverse effects. The guideline may not be appropriate to evaluate the impacts of D4 in aquatic plants growing in sediment as there are no published toxicity data for these species. The FSeQG applies to freshwater sediments.

For spiked sediment toxicity tests, low effect endpoints are the preferred endpoint type for guideline derivation following CCME protocol (1995). A PNEC for sediment was not previously developed in the risk assessment (EC, HC 2008). Data were available for three species of invertebrates including *Chironomus tentans*, *C. riparius* and *Lumbriculus variegatus*. While it's more conventional to represent only the lowest endpoint for each species, given its limited sediment toxicity data, all acceptable, low effect endpoint data are provided in Table 3 to convey the variability in D4 sediment toxicity due to intraspecies variation and endpoint selection.

The most sensitive LOEC of 0.73 mg/kg dw for survival of *L. variegatus* (2.4% OC) was adjusted to 1.0% OC (0.3 mg/kg dw) and a safety factor of 10 was applied to yield a sediment quality guideline of 0.03 mg/kg dw. A safety factor (SF) of 10 was chosen for lab to field extrapolation and because of limitations in the dataset (a crustacean species was not represented) (CCME 1995). According to the sediment protocol for the spiked sediment toxicity testing approach (assuming the minimum data requirements are met), if using a chronic study for guideline derivation, a SF of 5 is recommended and accounts for intraspecies variation, variation due to endpoint selection, extrapolation from median lethal to NOEC and lab-field extrapolations (CCME 1998). However, since one of the required studies was missing (i.e., crustacean) to meet the minimum data requirements for guideline development, the SF was increased to 10 to account for missing data. Typically, FSeQGs are normalized to 1% OC to provide a conservative benchmark for which to compare monitoring data. Therefore, before making comparisons to the FSeQG, monitoring data should be normalized to 1% OC to assess whether the guideline value is exceeded.

As an additional line of evidence to support D4's FSeQG, if equilibrium partitioning (DiToro et al. 1991) is applied to the FWQG to derive the FSeQG, a very similar value is obtained as follows:

$$FSeQG = FWQG\ (mg/L) \times K_{OC}\ (L/kg) \times \%\ OC \qquad \text{Eq. 4}$$

$$= 0.0002\ mg/L \times 10^{4.22}\ L/kg \times 0.01$$

$$= 0.03\ mg/kg\ dw$$

The log K_{OC} of 4.22 (i.e., K_{OC} of 16596) for D4 was used in Eq. 4.

Federal Wildlife Dietary Guideline

The Federal Wildlife Dietary Guideline (FWiDG) is intended to protect non-human mammalian consumers of aquatic biota. This is a benchmark concentration of a substance in aquatic biota (whole body, wet-weight) that may be consumed by terrestrial and semi-aquatic wildlife. The FWiDG for mammals may not be appropriate to extrapolate the impacts of D4 to other terrestrial consumers (e.g., birds or reptiles). Oral toxicity data for avian species were not available and hence no avian dietary wildlife guideline can be derived.

Toxicity data for the development of FWiDGs for D4 were obtained from the screening assessment (EC, HC 2008). An updated literature search to January 2018 was completed and no new data were identified. All data were screened for quality and completeness following guidance from CCME protocol (1998) for derivation of tissue residue guidelines. Each toxicity study underwent a comprehensive review; a summary of all the studies evaluated, including their quality rating, can be made available upon request to ec.rqe-

eqg.ec@canada.ca. Acceptable mammalian oral toxicity endpoints for D4 were available from four gavage studies on two species; three studies with rats and one with New Zealand white rabbit (Table 4).

Table 4. Oral toxicity endpoints for mammals exposed to D4.

Species	Administration	Endpoint	Dose (mg/kg bw[a]•d)	Reference
Rat (S-D)[b]	Oral gavage	14-day LOAEL / NOAEL (body weight decrease)	1600 / 400	Dow Corning (1990)[c]
Rabbit (NZ white)[d]	Oral gavage	14-day LOAEL (body weight decrease, food consumption decrease)	500 (lowest test concentration)	Dow Corning (1992)
Rat (S-D, F344)[b,e]	Oral gavage	4-day LOAEL / NOAEL (body weight decrease)	1000 / 500	McKim et al. (2001)
Rat (S-D)[b]	Oral gavage	8-day LOAEL / NOAEL (fetal body weight decrease)	100 / 20	Falany and Li (2005)

[a] bw = body weight
[b] S-D = Sprague Dawley rat
[c] The assessment of D4 (EC, HC 2008) also noted an increase in liver weights at 100 and 25 mg/kg bw in male and female rats, respectively. However, given the uncertainty of whether increases in liver weights due to D4 treatment was adaptive or adverse, this effect was considered collectively with effects seen in other organ systems at similar doses when establishing the critical effect level for D4 from repeated-oral exposure.
[d] NZ = New Zealand white rabbit
[e] F344 = Fischer 344 rat

EC, HC (2008) identified 100 mg/kg body weight (bw)•d as the critical effect level for repeated-dose oral exposure in the human health assessment. The tolerable daily intake (TDI) used in derivation of the FWiDG for D4 is the same as that given in the screening assessment and is based on the lowest observed adverse effect level (LOAEL) of 100 mg/kg bw•d and no observed adverse effect level (NOAEL) of 20 mg/kg bw•d for decreased fetal body weight (Falany and Li 2005) as it represents the most sensitive ecologically relevant effect endpoint in the acceptable dataset. The TDI for non-human mammals was calculated as the geometric mean of the LOAEL and NOAEL, with an uncertainty factor (UF) of 100 applied to account for interspecies differences (UF=10) and subchronic to chronic effects (UF=10) (CCME 1998). The TDI was then adjusted by the largest food intake:body weight ratio (FI:BW) of mammalian aquatic consumers, that of American mink (0.24 kg prey/kg body weight of predator/day) (CCME 1998). The resulting FWiDG is 1.86 mg/kg food wet weight (FWiDG = tolerable daily intake/FI:BW). In summary, the TDI and FWiDG were calculated as follows:

TDI = geomean (LOAEL, NOAEL) mg/kg bw•d ÷ UF Eq. 5
= geomean (100, 20) mg/kg bw•d ÷100
= 0.447 mg/kg bw•d

FWiDG = TDI ÷ FI:BW ratio (American mink) Eq. 6
= 0.447 mg/kg bw•d ÷ 0.24 food ww/bw•d
= 1.86 mg/kg food ww

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List of Acronyms and Abbreviations

ACR – acute to chronic ratio
AF – assessment factor
BAF – bioaccumulation factor: the ratio of the concentration of a chemical compound in an organism relative to the concentration in the exposure medium, based on uptake from the surrounding medium and food
BCF – bioconcentration Factor: the ratio of the concentration of a chemical compound in an organism relative to the concentration of the compound in the exposure medium (e.g. soil or water)
BSAF – biota sediment accumulation factor
CAS RN – Chemical Abstracts Service Registry Number
CCME – Canadian Council of Ministers of the Environment
CEPA – Canadian Environmental Protection Act
CMP – Chemicals Management Plan
CTLBB – critical target lipid body burden
cVMS – cyclic volatile methyl-siloxanes
ECHA – European Chemical Agency
EDC – endocrine disrupting chemical
FBTG – federal aquatic biota tissue guideline
FEQG – federal environmental quality guideline
FI:BW – food intake to body weight ratio
FSeQG – federal sediment quality guideline
FWQG – federal water quality guideline
FWiDG – federal wildlife dietary guideline
LC – lethal concentration
Log K_{OC} – organic carbon-water partition coefficient
Log K_{aw} – air-water partition coefficient
Log K_{OW} – octanol-water partition coefficient
LOAEL – lowest observed adverse effect level
LOEC – lowest observed effect concentration
NOAEL – no observed adverse effect level
OC – organic carbon
PNEC – predicted no effect concentration
SF – safety factor
TDI – tolerable daily intake
TLM – target lipid model
UF – uncertainty factor
WWTP – waste water treatment plant