Substance Profile for The Challenge
Octamethylcyclotetrasiloxane (D4)
CAS No. 556-67-2

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) required the Minister of Health and Minister of the Environment to categorize the approximately 23,000 substances on the Domestic Substances List (DSL). Categorization involved identifying those substances on the DSL that are a) considered to be persistent (P) and/or bioaccumulative (B), based on criteria set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000), and "inherently toxic" (iT) to humans or other organisms, or b) that present, to individuals in Canada, the greatest potential for exposure (GPE).

Further to this activity, the Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that meet the categorization criteria. A screening assessment involves a scientific evaluation of available information for a substance to determine whether the substance meets the criteria set out in section 64 of CEPA 1999. Based on the results of a screening assessment, the Ministers can propose taking no further action with respect to the substance, adding the substance to the Priority Substances List (PSL) for further assessment or recommending the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999 and, where applicable, the implementation of virtual elimination of releases to the environment. Substances found to meet the criteria under section 64 are subject to risk management measures.

A number of substances have been identified by the Ministers as high priorities for action based on the information obtained through the categorization process. This includes substances:

- that were found to meet all of the ecological categorization criteria, including persistence, bioaccumulation potential and inherent toxicity to aquatic organisms (PBiT), and that are known to be in commerce, or of commercial interest, in Canada, and/or
- that were found either to meet the categorization criteria for GPE or to present an intermediate potential for exposure (IPE), and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity.

Based on a consideration of the ecological and/or human health concerns associated with these substances, and the requirement under section 76.1 of CEPA 1999 for the Ministers to apply a weight of evidence approach and the precautionary principle when conducting and interpreting the results of an assessment, sufficient data are currently available to conclude whether these substances meet the criteria under section 64 of CEPA 1999.

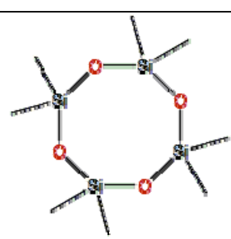
As such, the Ministers have issued a Challenge to industry and other interested stakeholders through publication in Canada Gazette Part I December 9, 2006 to submit, within the timelines stated in the Challenge section of this document, specific information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

The substance octamethylcyclotetrasiloxane (D4) was identified as a high priority for action as it was found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada, and it was determined to have a high potential for exposure to individuals in Canada (IPE) and is considered to present a high hazard to human health. The technical human health and ecological information that formed the basis for concern associated with this substance is contained in Appendices I and II, respectively.

Substance Identity

For the purposes of this document, octamethylcyclotetrasiloxane will be referred to as D4, an abbreviated name derived from the General Electric's siloxane notation (Hurd 1946).

D4 belongs to a group of cyclic volatile methyl-siloxanes (VMS) with relatively low molecular weight (< 600) and high vapour pressure. These cyclic VMS are volatile, low-viscosity silicone fluids consisting of three to six -$(CH_3)_2SiO$- structure units in a cyclic configuration. D4 consists of four of the -$(CH_3)_2SiO$- structure units as shown in the chemical structure below.

CAS Registry Number	556-67-2
Inventory names	Cyclotetrasiloxane, octamethyl-; Octamethylcyclotetrasiloxane (English, French); Octamethylcyclotetrasiloxan (German); octametilciclotetrasiloxano (Spanish)
Other names	Abil K 4; Cyclic dimethylsiloxane tetramer; D4; Dabco DC 5258; DC 344; DC 5258; Dow Corning 244; Dow Corning 344; KF 994; LS 8620; Mirasil CM 4; NSC 345674; NUC Silicone VS 7207; Octamethylcyclotetrasiloxanes; SF 1173; SH 244; SH 344; Silbione 70045V2; Silbione V 2; TSF 404; Tetracyclomethicone; UC 7207; Union Carbide 7207; Volasil 244; VS 7207; Y 7175
Chemical group	Discrete organics
Chemical sub-group	Cyclic Volatile Methyl Siloxanes (VMS)
Chemical formula	C8H24O4Si4
Chemical structure	
SMILES	C[Si]1(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O1
Molecular mass	296.62 g/mol

It should be noted that D4 is also contained under another CAS No. 69430-24-6 (dimethylcyclosiloxane, or cyclomethicone). Dimethylcyclosiloxane is a compound made up of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) (Danish EPA 2004). The relative proportions of the two substances are not known.

Based on information submitted in response to a legal Notice published in 2006 under section 71 of CEPA 1999 (Environment Canada 2006a), D4 was not manufactured in Canada in 2005 in a quantity meeting the 100 kg reporting thresholds. In total, thirty-five companies reported import of this substance into Canada in 2005, with nineteen companies in the 100-1,000 kg range, twelve companies in the 1,001 – 100,000 kg range and four companies reporting in the >100,000 kg range.

D4 is used in a variety of industry activities such as construction; textiles; leather and hide tanning and finishing; chemical manufacture; the manufacture of pharmaceuticals, cleaning compounds and toiletries; and the paint, coating and adhesive industry (Environment Canada 2006a). It is also an ingredient in pesticide formulations (PMRA 2005). Additional and more detailed descriptions of industry activity codes are provided in Appendix II. In other countries, D4 is used in personal care preparations such as lipstick, creams, lotions, hair care products and anti-perspirants which are applied to the skin, as well as in paints, laquers, colourants, waxes, shoe polish and other consumer products (HSDB 2006, KEMI 2005). It may also be found in, or may be used in the manufacture of, a wide variety of products, including: silicone fluids, elastomers and resins (HSDB 2006) detergents and cleaning agents; pharmaceuticals; fuel additives; and printing inks (SPIN 2007).

THE CHALLENGE

Respecting direction under section 76.1 of CEPA 1999, and in the absence of additional relevant information as a result of this Challenge, the Ministers are predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic under section 64 of CEPA 1999. As such, the Ministers are prepared to then recommend to the Governor in Council that this substance be added to the List of Toxic Substances in Schedule 1 of CEPA 1999, with the intent of initiating the development of risk management measures taking into account socio-economic considerations.

If it is determined that the substance meets the virtual elimination criteria in subsection 77(4) of CEPA 1999, then subsequent risk management activities will be based on the objective of eliminating the release of any measurable quantity of the substance to the environment. In the absence of further information on existing management practices for a substance, actions would be proposed based on the assumption of worst-case practices. The management actions being considered for such substances at this time include prohibition through regulations, of the manufacture, use, sale, offer for sale and import of this substance, except for those activities controlled under the *Pest Control Products Act* and/or the *Food and Drugs Act.*

Exceptionally, should no information be identified to indicate that this substance is in commerce in Canada, the Ministers will conclude, based on a screening assessment, that this substance does not satisfy the definition of toxic under section 64 of CEPA 1999. However, given the properties of this substance, there is concern that new activities for the substance that have not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore it would be recommended that this substance be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of this substance in quantities greater than 100 kg/year is notified, and that ecological and human health risk assessments are conducted as specified in section 83 of the Act prior to the substance being introduced into Canada.

Section 71 Notice

Under the Challenge, information deemed necessary for improved decision making may be gathered by the Minister of Environment using section 71 of CEPA 1999. This information may be used for the purpose of assessing whether a substance is toxic or is capable of becoming toxic as defined under section 64 of CEPA 1999, or for the purpose of assessing whether to control, or the manner in which to control a substance.

The information mandated through the notices may relate to, among other things; quantity of the substance imported, manufactured, used, or released, concentrations, suppliers, customers, as well as types of uses of the substance.

Copies of the section 71 notice and guidance on how to comply with it are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca), or from the contact provided below.

Opportunity to Submit Additional Information to Inform Screening Assessment

The Ministers of Health and Environment are inviting the submission of additional information for consideration during screening assessment of this substance. Data of the types described in the following paragraphs are considered most relevant, although other submitted information will be considered.

Data on the persistence, bioaccumulation, and potential for toxicity of the substance to organisms in different environmental media – Through the categorization exercise, available experimental data were collected up to December 2005. Where acceptable experimental data were not available, Quantitative Structure Activity Relationships (QSARs) or read across data were used to fill the data gaps. Since experimental data are preferred, interested parties have an opportunity to provide new or additional relevant experimental study information on the persistence, bioaccumulation, and potential for toxicity of this substance to organisms in different environmental media (air, water, sediment, soil). Efforts should focus on providing data for the endpoints for which quality experimental data does not already exist, as demonstrated by the information summarized in Appendix II of this document. As submitted data will be evaluated for completeness and robustness, it is recommended that stakeholders follow the guidance for test protocols and alternative approaches for test data, as described in Section 8 of the "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers".[1]

Data on the toxicity of the substance to human health - Through the categorization exercise, the high health priorities for action were those substances identified by various agencies as representing a high health hazard on the basis of potential to induce cancer, and/or adversely affect reproduction and development, two critical determinants of the health of Canadians of all ages. The hazard classifications used were those developed by national or international agencies in which large numbers of substances have been classified for endpoint-specific hazard based on original review and critical evaluation of data, assessments of weight of evidence and extensive peer review. Interested parties have an opportunity to provide new or additional relevant experimental study information on the toxicity of the substance to human health which could inform the screening assessment.

Responses to this part of the challenge for this substance should be received at the address provided below by November 13, 2007.

[1] "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers (version 2005)", Government of Canada, Available from http://www.ec.gc.ca/substances/nsb/eng/cp_guidance_e.shtml

Opportunity to Submit Additional Information on Current Uses and Existing Control Measures to Inform the Risk Management Approach for this Substance

The Ministers of Health and Environment are inviting the submission of additional information that is deemed beneficial by interested stakeholders, relating to the extent and nature of the management/stewardship of substances listed under the Challenge.

Organizations that may be interested in submitting additional information in response to this invitation include those that manufacture, import, export or use this substance whether alone, in a mixture or in a product, including manufactured items.

Additional information is being invited in the following areas:

- Import, manufacture and use quantities
- Substance and product use details
- Releases to the environment and spill management
- Current and potential risk management and product stewardship actions
- Existing legislative or regulatory programs controlling/managing the substance
- Information to support the development of a regulatory impact assessment.

A questionnaire is available which provides a detailed template as an example for the submission of this information. Guidance on how to respond to the challenge questionnaire is also available. Interested stakeholders are invited to provide available additional information, recognizing that not all questions in the questionnaire may be relevant to a particular substance, use, or industrial sector.

Copies of the questionnaire and associated guidance are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca), or from the contact provided below.

Responses to this part of the challenge for this substance should be received at the address provided below by November 13, 2007.

Request for Documents and Submission of Information

Documents and instructions may be requested from the following contact. Information in response to the above Challenge must be submitted to this address:

DSL Surveys Coordinator
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530/819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: DSL.surveyco@ec.gc.ca

Appendix I
Human Health Information
to Support The Challenge for
Octamethylcyclotetrasiloxane (D4)
CAS No. 556-67-2

Introduction

Under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), Health Canada undertook to categorize all substances on the Domestic Substances List (DSL) to identify those representing the greatest potential for human exposure (GPE) and those among a subset of substances considered persistent (P) and/or bioaccumulative (B) that are also considered to be "inherently toxic" to humans.

In order to efficiently identify substances that represent the highest priorities for screening assessment from a human health perspective, Health Canada developed and applied a Simple Exposure Tool (SimET) to the DSL to identify those substances that meet the criteria for GPE, Intermediate Potential for Exposure (IPE) or Low Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

Octamethylcyclotetrasiloxane (D4) (CAS No. 556-67-2) is considered to meet the criteria for IPE under SimET and for high hazard under SimHaz. This document summarizes the currently available information used to support the inclusion of this substance in the Challenge.

Exposure Information from Health Related Components of DSL Categorization

SimET was developed and used to identify substances on the DSL considered to represent GPE. This approach was based on three lines of evidence: 1) the quantity in commerce in Canada, 2) the number of companies involved in commercial activities in Canada (i.e., number of notifiers), and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an Intermediate (IPE) or Lowest Potential for Exposure (LPE), based on criteria for quantity and nature of use (Health Canada 2003).

Results of the Application of SimET

D4 has been determined to be IPE based on a consideration of the DSL nomination information listed below.

Nomination Information for DSL 1984-86

Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 1,110,000 kg.

Number of Notifiers

The number of notifiers in the calendar years 1984-86 was fewer than four.

Use Codes and Description

The following DSL use codes have been identified for the substance:

21- Formulation component
60- Cosmetics
76- Organic chemicals, industrial
86- Plastics

Potential Uses in Canada

Potential uses in Canada are provided in Appendix II.

Hazard Information from Health Related Components of DSL Categorization

Simple Hazard Tool (SimHaz)

SimHaz is a tool that has been used to identify, among all of the approximately 23 000 substances on the DSL, those considered to present either high or low hazard to human health based on formalized weight of evidence criteria and/or peer review/consensus of experts. This tool has been developed through extensive compilation of hazard classifications of Health Canada and other agencies and consideration of their robustness based on availability of transparent documentation of both process and criteria (Health Canada 2005).

Results of the Application of SimHaz

D4 is considered to be a potentially high hazard substance based on its classification for reproductive toxicity by the European Commission (EC).

The European Commission has classified D4 as Category 3 for reproductive toxicity (Substance which causes concern for human fertility) (European Chemicals Bureau 2004).

Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL that are considered to be human health priorities for further consideration. It is recognized that they do not include a number of elements normally considered in a human health risk assessment such as a comprehensive characterization of exposure and hazard, a comparison of exposure metrics to hazard metrics and a detailed analysis of uncertainties; however, as a result of the combination of the severe hazard properties of these substances and their high potential for exposure to humans, evaluation of the need for preventative and protective actions is required.

References

European Chemicals Bureau. 2004. Summary Record: Meeting of the Technical Committee C & L on the Classification and Labelling of Dangerous Substances. Riga, 12-14 May 2004. ECBI/147/04 –Rev3.
http://ecb.jrc.it/classlab/SummaryRecord/14704r3_sr_TC_C&L_HEALTH_0504.doc
http://ecb.jrc.it/ESIS/

Health Canada. 2003. Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for Human Exposure.
http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs- sesc/pdf/contaminants/existsub/greatest_potential_human_exposure.pdf

Health Canada. 2005. Proposed Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999.
http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/framework-int-cadre_e.pdf

Appendix II
Ecological Information
to Support The Challenge for
Octamethylcyclotetrasiloxane (D4)
CAS No. 556-67-2

The information in this document will form the basis of a screening assessment under section 74 of CEPA, 1999. Data relevant to an ecological screening assessment were identified in original literature, review documents, commercial and government databases prior to December 2005. Properties and characteristics may also have been estimated using Quantitative Structure Activity Relationship (QSAR) models. In addition, an industry survey was conducted for the year 2005 through a Canada Gazette Notice issued pursuant to section 71 of CEPA 1999 (Environment Canada 2006b). This Notice requested data on the Canadian manufacture and import of the substance.

Physical and chemical properties

Table 1 contains experimental and modelled physical-chemical properties of D4 which are relevant to its environmental fate.

Table 1. Physical and chemical properties for D4

Property	Type	Value	Temperature ºC	Reference
log K_{ow} (Octanol-water partition coefficient)	Experimental	5.1		TSCATS 2006
log K_{ow} (Octanol-water partition coefficient)	Modelled	5.09		Kowwin v.1.67
Boiling point ºC	Experimental	175.80		SRC PHYSPROP Database 2003
Boiling point ºC	Modelled	159.41		MPBPWIN v1.41
Melting point ºC	Experimental	17.50		SRC PHYSPROP Database 2003
Melting point ºC	Modelled	1.78		MPBPWIN v1.41
Vapour Pressure (Pa)	Experimental	140.0 (1.05 mm Hg)	25	Flaningam 1986
Vapour Pressure (Pa)	Modelled	157.3 (1.18 mm Hg)	25	MPBPWIN v1.41
Henry's Law Constant (Pa·m^3/mol)	Experimental	11855.1 (0.117 atm-m^3/mol)	25	ChemIDPlus Basic Information
Henry's Law Constant (Pa·m^3/mol)	Experimental	42556.7 (0.42 atm-m^3/mol)	Not provided	Silicones Health Councils 1989, as cited in HSDB 2006
Henry's Law	Modelled	9119.3	25	HenryWin v3.10

Table 1. Physical and chemical properties for D4

Property	Type	Value	Temperature °C	Reference
Constant (Pa·m^3/mol)		(0.09 atm-m^3/mol)		
log K_{oc} (Organic carbon-water partition coefficient)	Modelled	4.25		PCKOCWIN v1.66
Water solubility (mg/L)	Experimental	0.005	15-25	Dow Corning, 1987 as cited in HSDB 2006
Water solubility (mg/L)	Modelled	0.05	25	WSKOWWIN v1.41

Manufacture, Importation, and Uses

Manufacture and Importation

In Canada, no manufacture of D4 was reported in response to a CEPA section 71 survey notice for the 2005 calendar year in a quantity meeting the 100kg reporting threshold (Environment Canada 2006a). There were thirty-five companies reported import of D4 into Canada in 2005 (Environment Canada 2006a), with nineteen companies in the 100-1,000 kg/year range, twelve companies in the 1,001 – 100,000 kg/yr range and four companies reporting in the >100,000 kg/year range (See Appendix I for the quantity of D4 reported in commerce in Canada during the calendar year 1986). D4 is also a constituent of CAS No. 69430-24-6 (dimethylcyclosiloxane); however, dimethylcyclosiloxane was not surveyed under CEPA section 71 by Environment Canada in 2006 (Environment Canada 2006b). In Canada, the quantity of dimethylcyclosiloxane reported in commerce during the calendar year 1986 was 2,220,197 kg/year.

Elsewhere, D4 has been identified as a High Production Volume (HPV) chemical by the Organisation for Economic Co-operation and Development (OECD), the European Chemicals Bureau (ECB), the US Environmental Protection Agency (EPA), and the International Congress & Convention Association (ICCA). According to information from the US EPA, the import/production of D4 was in the range of 22,500 – 45,000 tonnes in all reporting years from 1986 to 2002.

In Europe, four companies have been identified as producers/importers of D4: Bayer AG and Wacker-Chemie GmBH of Germany, Rhone-Poulenc Chimie of France and Dow Corning Europe of Belgium (ECB 2006). In Nordic countries, the SPIN database indicated that the total registered consumption of D4 and dimethylcyclosiloxane (CAS No. 69430-24-6) during 2000 to 2004 was less than 120 and 85 tons per year, respectively (SPIN 2007). D4 has been classified as a Persistent, Bioaccumulative, and Toxic (PBT) or very Persistent, very Bioaccumulative (vPvB) chemical and is a phase-out substance in the priority database (PRIO) of the Swedish Chemicals Inspectorate and is reported not to be used in any new chemical applications in Sweden (Norden 2005). Denmark is planning to introduce substitution for D4 by the Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries (Danish EPA 2004).

Uses

In response to a CEPA section 71 survey notice for the 2005 calendar year, companies importing D4 identified their business activity as (Environment Canada 2006a):

Mining and Construction

- Mining of Oil and Gas Extraction
- Construction of Residential and Nonresidential Buildings
- Heavy and Civil Engineering Construction (such as highways, streets and bridges)
- Foundations, Structures and Building Exterior Contractors (i.e., glazing and roofing work)
- Building Equipment Contractors (such as electrical contractors)

Manufacturing

- Other Foods (which could include perishable prepared foods like salads, fresh pizza/pasta)
- Textile Mills
  - Fiber, Yarn and Thread Mills
  - Textile and Fabric Finishing
  - Fabric Coating Mills (except carpets and rugs)
  - Leather and Hide Tanning and Finishing
- Pulp, Paper and Paperboard Mills
- Converted Paper Products (such as paper bag, and coated and treated paper)
- Petroleum and Coal Products
- Basic Chemicals
- Other Basic Organic Chemicals
- Pharmaceuticals and Medicines
- Paint, Coating and Adhesives
- Soap, Cleaning Compound and Toilet Preparation (i.e., cosmetic preparations)
- Other Chemical Product and Preparation (except basic chemicals; resins, synthetic rubber, cellulosic and noncellulosic fibers and filaments; pesticides, fertilizers, and other agricultural chemicals; pharmaceuticals and medicines; paints, coatings, and adhesives; soaps and cleaning compounds; and toilet preparations)
- Plastics and Rubber Products
  - Plastics Packaging Materials
  - Unlaminated Film and Sheet
  - Urethane and Other Foam Product (except polystyrene)
  - Rubber Products (except tires, hoses, and belting)
- Fabricated Metal Product
- Forging and Stamping, Machine Shops
- Turned Product
- Screw, Nut and Bolt
- Computer and Peripheral Equipment
- Semiconductor and Other Electronic Component

- Electrical Equipment,
- Appliance (i.e., household appliances)
- Component Manufacturing
- Transportation Equipment
    - Motor Vehicle Parts
    - Aerospace Products and Parts
    - Medical Equipment and Supplies

Wholesale Trade and Distribution
- Chemical (except agricultural) and Allied Products
- Personal and Household Goods (includes pharmaceuticals, toiletries, cosmetics and sundries)
- Wholesale Agents and Brokers

Retail Trade
- Motor Vehicle and Parts Dealers (includes automotive parts, accessories and tire stores)
- Health and Personal Care Stores
- Shoe Stores (except hosiery and specialty footwear, such as golf shoes, bowling shoes and spiked shoes)
- General Warehousing and Storage

The above industrial activities identified through the CEPA section 71 Notice are based on the North American Industry Classification System (NAICS) codes. These codes define the company's sectors and business lines, but do not describe the use of the substance or product within the company. This differs from the DSL Nomination Functional Use Codes utilized during categorization and listed in Appendix I. Use Codes indicate specific applications or uses for the substance or products containing the substance. NAICS has currently defined over 3000 NAICS codes. The Functional Use Codes were defined for the purposes of the DSL Nomination.

The number of industrial activities identified as using D4 in 2005 is considerably greater than the number of DSL Use Codes for this substance identified in 1986. A NAICS defines the activities of a company rather then a substance, so the broad number of activities identified may only be distantly relevant to the substance. As well, there were an increased number of notifiers importing or manufacturing the substance as well as an increase in the amount of this substance being manufactured or imported into Canada.

The following use patterns for D4 have been identified worldwide (SPIN 2007, unless otherwise specified):

- Raw materials, intermediates, or by-products in productions of silicone fluids, elastomers, and resins (HSDB 2006).
- Raw materials for production of cosmetics, or intermediates for cosmetics and hygienic articles
- Paint, lacquers and varnishes

- Tanning and dressing of leather; manufacture of luggage, handbags, saddlery, harness and footwear.
- Surface treatment and polishing agents for motor vehicles and other plastic materials
- Inert ingredient in pesticide formulation (USEPA 2004).
- Impregnation materials in pesticides, paints, textile industry etc.
- Adhesives, binding agents.
- Anti-set-off and anti-adhesive agents.
- Cleaning/washing agents, softeners, surfactants, detergents.
- Construction materials, fillers or sealing compounds.
- Fuel additives.
- Pharmaceuticals.
- Process regulators.
- Reprographic agents.
- Printing inks, Serigraphy inks - Publishing, printing and reproduction of recorded media.
- Lubricants and additives.
- Viscosity adjustors

Similar uses are expected in Canada based on the use/activity codes reported by industry during the section 71 survey (as listed previously), and those reported to the DSL during the calendar year 1986 in Canada (see Appendix I). D4 is also used as an inert ingredient in pesticide formulations in Canada (PMRA 2005).

According to the Swedish Chemical Agency (KEMI 2005), more than 85% of D4 is used as a raw material in the manufacture of polydimethylsiloxanes (PDMS), which are polymers of varying molecular weight. PDMS are used in hundreds of applications including caulking and sealants, castable elastomers, lubricants, water repellants, anti-foaming agents, as well as biomedical applications such as tubing for fluids and implants. PDMS are used extensively in food and beverage preparation as anti-foaming and anti-clotting agents and they are used in pharmaceutical preparations (KEMI 2005). D4 may be present in PDMS materials either as an intended addition or as a residual from polymerisation. While no information on the use of D4 in the manufacture of PDMS in Canada is available, it is assumed that, similar to Sweden, D4 may be used in large quantities for this purpose.

Since D4 belongs to a group of substances used in various industry applications and in consumer products such as personal care, detergents, and fuel additives, etc., it may be released to the environment in a dispersive manner.

Releases, Fate, and Presence in the Environment

Releases

D4 is not naturally produced in the environment. Measured data concerning the environmental releases of this substance from uses in Canada were not collected as part of the s. 71 survey. Its disperse use pattern suggests possible release to air, sewage treatment plants (STPs) and landfills. D4 may enter the environment through evaporation due to its high volatility. When released to STPs, its high log K_{ow} and K_{oc} values indicate partitioning of the compound to the active sludge that may then be applied to agricultural soil as fertilizer or landfilled. Disposal of consumer and industrial products containing D4 can also lead to the release of D4 to landfills. Agricultural, landfill, and STP releases may lead to groundwater, soil and sediment exposure.

Fate

D4 is expected to partition into air based on its high vapour pressure and Henry's law constant. The high log K_{ow} and log K_{oc} values indicate that this substance will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicates that if this substance is released equally to the three major environmental compartments (air, water, and soil), it will partition into all compartments including air, water, soil, and sediments, with the latter two compartments being predominant (Table 2).

Table 2. Results of the Level III fugacity modelling for D4 (EPIWIN v3.12)

Receiving media	% in Air	% in Water	% in Soil	% in Sediment
Air (100%)	97.60	0.02	2.28	0.07
Water (100%)	4.49	24.90	0.11	70.50
Soil (100%)	2.93	0.01	97.00	0.02
Air, water, soil (33.3% each)	6.80	9.78	55.70	27.70

If D4 is released solely to air, a vapour pressure of 140 Pa and Henry's Law constant around 11855.1 Pa·m^3/mole indicates it will remain mainly in air. Only a very small amount of D4 will partition into other environmental compartments (< 3 %, Table 2).

If released to water, D4 is expected to adsorb to suspended solids and sediment based upon its high log K_{oc} value. Although volatilization from water surfaces is also expected based upon the Henry's Law constant of this compound, its high adsorptivity to sediment may reduce the potential for volatilization. Thus, if water is a receiving medium, D4 is expected to remain mainly in water and partition into sediments and, to some extent in air, as illustrated by the results of the Level III fugacity modelling (Table 2).

If released to soil, D4 is expected to rapidly volatilize from dry and moist soil to the air based on its vapour pressure. The high log K_{oc} value of D4 also indicates that this substance will adsorb to and be relatively immobile in soil, thus reducing its potential for volatilization. Thus, if released to soil, D4 will remain mainly in soil and, to some extent air, which can be illustrated by the results of the Level III fugacity modelling (Table 2).

Presence in the Environment

Once released into the environment, D4 appears to be relatively persistent in the environment. No monitoring data relating to the presence of the substance in Canadian environmental media (air, water, soil, sediment) have yet been identified.

Elsewhere, an environmental monitoring program of volatile methylated siloxanes initiated by Nordic countries found that D4 was present in all sampled media except soil in the environment. It was suggested that this substance was distributed in the Nordic environment mainly in urban areas and near or within STPs through its dispersive uses (Norden 2005). D4 was also detected in aquatic organisms in Nordic countries and Germany. The Swedish National Screening Programme in 2004 indicated that D4 was present in STP sludge and in air, but was not found in surface water, sediments or any fish muscles (Kaj et al. 2005). In the US, D4 was only detected in one of 21 sampled sediments (Ann Arbor Technical Services 1985, as cited in Chandra et al. 1997). D4 was also detected in STP influents (HydroQual Inc. 1993, as cited in Hobson et al. 1997).

In Air

D4 was found in Nordic air samples during 2003 - 2005. The concentration of D4 in air ranged from 0.08 - 4 μg/cm^3 in urban areas, landfills, STPs and other sampling sites. D4 was generally the predominant cyclosiloxane detected in air other than in STPs, where typically the concentration of D5 was significantly greater relative to other siloxanes (Norden 2005). The concentration of D4 in air at four landfill or STP locations in Germany ranged from 2.87 - 8.84 mg/m^3 (Schweigkopfler and Niessner 1999). It has also been detected as a volatile emission from landfills in Singapore (Koe and Ng 1987).

Sweden conducted indoor air measurements in 400 households in children's bedroom. D4 was detected in 73 homes at concentrations of 0.6 – 51.2 μg/m^3 (personal communication, Norbert Schmidbauer, Norweigian Institute for Air Research, 2005, as cited in Kaj et al. 2005). D4 was also detected in indoor air in northern Italy (10 – 13 μg/m^3, De Bortoli et al. 1986) and the United States (0.4 – 37 μg/m^3 in office buildings, VOC data base 1990, as cited in USEPA 1992). In a qualitative study, six of eight air samples in the United States contained D4 (Wallace et al. 1984). Indoors, emissions from new carpeting can contribute to D4 in the air (Hodgson et al. 1992 and Pleil and Whiton 1990, as cited in USEPA 1992). Outside of an office building in New Jersey, concentrations of D4 from three samples ranged from 6.6-22.6 μg/m^3 (VOC data base 1990, as cited in USEPA 1992).

In Water

D4 was not detected in the Nordic water samples collected at background or urban sites (detection limit < 0.1 μg/L), but was detected in some samples from landfills and incoming water to STPs, although at concentrations below 5 μg/L (Norden 2005). The concentration of D4 in percolate water near a Swedish landfill was 1-2 μg/L (Schweigkopfler and Niessner 1999).

In the US, a sampling program sponsored by the Silicones Environmental, Health and Safety Council (SEHSC) monitored D4 concentrations in STP influents and effluents at various locations (HydroQual Inc. 1993, as cited in Hobson et al. 1997). The mean D4 influent concentrations from five STPs ranged from 0.64 – 7.09 µg/L, and the mean effluent concentrations ranged from 0.06 – 0.41 µg/L. D4 was also detected in 1 of 3 water samples collected from Lake Pontchartrain, LA, at ~ 0.03 µg/L (McFall et al. 1985) and qualitatively detected in drinking water systems (Wallace et al. 1984).

In Singapore, D4 was found in both the influent and the post-aerated waste water at a sewage treatment facility (Koe and Tan 1990).

In Soil

D4 was not detected (detection limit < 10 ng/g dry weight) in soil samples taken from two landfills from the Faroe Islands (Norden 2005).

In Sediments

Concentrations of D4 were all < 85 ng/g dw in sediments collected from the Nordic environment (Norden 2005). In the US, D4 was found above the detection limit (185 µg/kg) in one of 21 sediments from 6 locations sampled during the late seventies (Pellenbarg 1979).

In STPs

D4 was found in some but not all of the sludge samples from the Nordic and Swedish screening programmes. Concentrations of D4 were ~100 – 1000 ng/g dw in the Nordic study (Norden 2005) and ~ 390 ng/g dw in Sweden (Kaj et al. 2005).

In Aquatic Organisms

D4 was detected in the livers of fish and marine mammals in Nordic countries. The concentration in both freshwater and marine fish, from sampling sites in urban areas and near STPs, was generally in the range of < 5 – 13 ng/g ww, except for one sample of cod liver (9 livers pooled) collected at a location near a city centre in Norway that had a higher concentration of D4 (70 ng/g ww). The concentrations varied with species, gender, and age. Among marine mammals monitored in Nordic countries, D4 was only detected in seal blubber in Denmark at the level of 12 ng/g ww (Norden 2005). D4 was also detected in fish samples in Germany at concentrations ranging from 0.1– 1.0 mg/kg (SEHSC 2005a).

As concentrations of D4 in Nordic waters were <5 µg/L, except for STP influents, the detection of D4 in biota indicates that D4 has the potential to bioaccumulate (Norden 2005).

Rationale for P, B and iT status

Environmental Persistence

Once released in the environment, D4 appears to be relatively persistent in air, water, soil and sediments. The Level III Fugacity model indicates D4 will partition to air, where it is expected to be oxidized by the gas-phase reaction with photochemically produced hydroxyl radicals. The empirical half-life for D4 in the gas-phase hydroxyl radical reaction is in the range of 10.6 – 16 days (Atkinson 1989, 1991) (Table 3a). The reaction with hydroxyl radicals was found to be accelerated in the presence of water (Abe et al. 1981). D4 is not expected to react, or react appreciably, with other photo oxidative species in the atmosphere, such as O_3 and NO_3, nor is it likely to degrade via direct photolysis (Atkinson 1991). Therefore, it is expected that reactions with hydroxyl radicals will be the most important fate process in the atmosphere for this substance. The model AOPWIN (v1.91) (Table 3b) also provides evidence supporting the persistence potential of this substance with a predicted atmospheric oxidation half-life of ~ 9 days. Thus, the data demonstrate that this substance is persistent in air (half-life > 2 days).

Table 3a. Empirical persistence data for D4

Medium	Fate Process	Degradation Value	Degradation Endpoint	Reference
Air	OH reaction	10.58	half-life (days)	Atkinson, 1989
Air	OH reaction	16	half-life (days)	Atkinson, 1991
Water/sediments	Biodegradation	No biodegradation	% degradation	Silicones Health Council, 1991 as cited in HSDB 2006

Table 3b. Modelled persistence data for D4

Medium	Fate Process	Degradation Value	Degradation Endpoint	Model
Air	atm-oxidation	8.94	half-life (days)	AOPWIN v1.91
Water/soil	Biodegradation	37.5	half-life (days)	BIOWIN v4.02, Ultimate survey
Water/soil	Biodegradation	0	probability	BIOWIN v4.02, MITI Linear Probability
Water/soil	Biodegradation	0.0028	probability	BIOWIN v4.02, MITI Non-linear Probability

Experimental data demonstrated no biodegradation of D4 in an aerobic water/sediment system (Silicones Health Council 1991, as cited in HSDB 2006). No empirical data on the biodegradation of D4 in soil were found, therefore, a weight-of-evidence approach (ESD 2006a) was applied by reading across data from a similar chemical and using the models shown in Table 3b. D4 is structurally similar to, and a close analogue of, hexamethylcyclotrisiloxane (D3, CAS No. 541-05-9) and it is expected that D4 will exhibit similar biodegradation potential as D3. Experimental data show no biodegradation of D3 over 28 days in a ready-biodegradation test (SEHSC 2005b), suggesting that it is persistent in water, sediment and soil. These data are further supported by two models in Table 3b which indicate the probability of biodegradation of D4 occurring in water or soils is effectively zero. Thus, the weight-of-evidence indicates that D4 will be persistent in water, sediment and soil.

The long-range transport potential (LRTP) of D4 from its point of release to air is estimated to be high according to the model prediction presented in Table 4. The TaPL3 model was used to estimate Characteristic Travel Distance (CTD), defined as the maximum distance traveled by 63% of a substance; or in other words, the distance that 37% of the substance may travel beyond. Beyer et al. (2000) have proposed CTD's of >2,000 km as representing high LRTP, 700-2,000 km as moderate, and <700 km as low. Based on the result shown in Table 4, D4 is judged to behave like a persistent organic pollutant (POP) and have the potential to travel to the Arctic.

Table 4. Model Predicted Characteristic Travel Distance (CTD) for D4

Characteristic Travel Distance	Model (Reference)
2219 Km	TaPL3 (CEMC 2003)

The empirical data (Table 3a) demonstrate that D4 meets the persistence criteria for air half-life > 2 days), while empirical, modelled and read-across data, following a weight-of-evidence approach, demonstrate that D4 meets the persistence criteria for soils, sediments and water (half-lives in soil and water ≥ 182 days; in sediments ≥365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

Potential for bioaccumulation

The empirical and modelled log K_{ow} values for D4 (Table 1) suggest that this substance has the potential to bioaccumulate in the environment.

Empirical data indicates that D4 has the ability to bioconcentrate in aquatic organisms. A bioconcentration study for D4 was conducted on fathead minnows (*Pimephales promelas*) in a flow-through system. The uptake of radio-labelled [^{14}C] D4 in fish tissue was investigated at a concentration of 0.5 µg/L (nominal) over a 28-day period and depuration over a 14-day period. Steady-state was reached and the mean BCF_{ss} was reported to be 12 400 L/kg (Fackler et al. 1995) (Table 5a). Fish tissue analysis also indicated that the depuration half-life for radio-labelled D4 was 7 – 12 days and that an average of 45% of accumulated D4 still remained in fish after 14 days of depuration. The metabolic potential of D4 was also investigated during this BCF study. In each tissue type, the entire extracted radioactivity (> 95 %) was identified as D4, indicating that metabolism of D4 is negligible.

The Modified GOBAS BAF middle trophic level model (Arnot and Gobas 2003) produced a BAF of 23,988 L/kg wet weight, indicating that this substance has the potential to bioconcentrate and biomagnify in the environment. The GOBAS BCF middle trophic level model (Arnot and Gobas 2003) and OASIS model (OASIS 2005) (Table 5b) also provide a weight-of-evidence to support the bioconcentration potential of this substance. The BCFWIN model (Table 5b) appears to underestimate the BCF for D4, as it is much lower than the value obtained experimentally for *Pimephales promelas* (Table 5a). While the modelled bioaccumulation values do not take into account the metabolic potential of the substance, this was found to be negligible in the experimental BCF study (Fackler et al. 1995).

Table 5a. Empirical bioaccumulation data for D4

Test Organism	Endpoint	Value wet wt	Reference
Pimephales promelas	BCF	12,400 L/kg	Fackler et al. 1995

Table 5b. Modelled bioaccumulation data for D4

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	23,988 L/kg	Gobas BAF T2MTL (Arnot and Gobas 2003)
Fish	BCF	5,888 L/kg	Gobas BCF T2LTL (Arnot and Gobas 2003)
Fish	BCF	19,953 L/kg	OASIS 2005
Fish	BCF	1,698 L/kg	BCFWIN v2.15

Therefore, the weight of evidence indicates that D4 meets the bioaccumulation criteria (BCF, BAF ≥ 5,000) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

Ecological Effects

In the Aquatic Compartment

There is experimental and modelled evidence that the substance causes harm to aquatic organisms at relatively low concentrations (e.g., LC50 < 1 mg/L) (Tables 6a and 6b). The empirical ecotoxicity values (Table 6a) indicate D4 is very toxic to aquatic organisms, with extremely high short- and long-term toxicity near or within its solubility limit (0.005 mg/L, Table 1). For rainbow trout, the lowest concentration causing 50 % mortality (LC50) in an acute test is 0.01 mg/L, with a No Observed Effect Concentration (NOEC) of 0.0044 mg/L. Affected fish exhibited darkened pigmentation, loss of equilibrium, and lethargic behaviour before they died, consistent with a narcosis mechanism of toxicity. No effects were also observed in a chronic, early-life stage study at the highest concentration tested (0.0044 mg/L) (Sousa et al. 1995). The chronic NOEC for the water flea, *Daphnia magna*, an important species of zooplankton in ecosystems, ranged from 0.004 mg/L for reproduction to 0.008 mg/L for survival (Sousa et al. 1995). Table 6b provides the results of model predictions considered to be reliable. The modelled ecotoxicity values agree well with the experimental values predicting acute/chronic toxicities in the range of 0.07 mg/L – 0.271 mg/L to aquatic organisms.

Table 6a. Empirical data for aquatic toxicity

Test Organism	Type of Test	Endpoint	Value (mg/L)	Reference
Rainbow trout *Oncorhynchus mykiss*	Acute	LC50	0.010	Sousa et al. 1995
Rainbow trout *Oncorhynchus mykiss*	Acute	NOEC	0.0044	Sousa et al. 1995
Shrimp	Acute	NOEC	≥0.01	Sousa et al. 1995
Crustaceans	Acute	EC50	≥500	ECB 2000
Daphnia	Acute	NOEC	0.015	Sousa et al. 1995
Daphnia	Chronic	NOEC	0.004-0.008	Sousa et al. 1995
Daphnia	Acute	EC50	25.2	ECB 2000
Midge	Chronic	NOEC	≥ 0.015	ECOTOX 2007
Algae	Acute	EC50	≥2000	ECB 2000

Table 6b. Modeled data for aquatic toxicity

Organism	Endpoint	Duration	Concentration (mg/L)	Reference
Daphnia	EC50	16 d	0.072	ECOSAR v.0.99g
Green Algae	EC50	96 h	0.271	ECOSAR v.0.99g

The European Union classifies D4 as R62 “possible risk of impaired fertility” and as R53 “may cause long-term adverse effects in the aquatic environment” (KEMI 2004, as cited in Kaj et al. 2005).

The experimental and modelled data indicate that the substance is highly hazardous to aquatic organisms (i.e. acute LC/EC50<1.0 mg/L and chronic NOEC < 0.1 mg/L).

In Other Media

The toxicity of D4 in sediments was evaluated using midges in a series of 14 day exposures in three different sediments and in water only (Kent et al. 1994). Tests were conducted with sediments of low- (LOC), medium- (MOC), and high- (HOC) organic carbon contents ranging from 0.27 % - 4.1 %. Significant adverse effects or mortality were observed at 250 and 170 mg/kg for the MOC and HOC sediments, respectively, and growth effects were observed at 130 mg/kg for the LOC sediments. The NOECs for mortality were 130 (the highest concentration tested), 120, and 54 mg/kg for the LOC, MOC, and HOC sediments, respectively.

Potential to Cause Ecological Harm

Evidence that a substance is highly persistent and bioaccumulative as defined in the *Persistence and Bioaccumulation Regulations* of CEPA 1999 (Government of Canada 2000) together with evidence of commercial activity provides a significant indication of its potential to be entering the environment under conditions that may have harmful long term ecological effects (ESD 2006b). Substances that are persistent remain in the environment for a long time, increasing the potential magnitude and duration of exposure.

Substances that have long half-lives in mobile media (air and water) and partition into these media in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially for top predators. Evidence that a substance is both highly persistent and bioaccumulative, when taken together with other information (such as evidence of toxicity at relatively low concentrations, and evidence of uses and releases) may therefore be sufficient to indicate that the substance has the potential to cause ecological harm.

The volume of D4 imported into Canada in 2005 (Environment Canada 2006a) is very high, in the order of more than 1000 tonnes. Its large importation volumes and dispersive use, especially its wide application in household products, along with its volatile nature indicates potential for releases into the Canadian environment. Once released in the environment, because of its resistance to degradation, D4 will remain in air, water, sediment and soil for a long time, and may be transported long distances. As it persists in the environment, it will likely bioaccumulate and may be biomagnified in trophic food chains. It has also been demonstrated to have very high toxicity. This information suggests that D4 has the potential to cause ecological harm in Canada.

Uncertainties

The confidence in the conclusion that D4 is P, B, and iT is high because the conclusions are based on empirical data.

A source of uncertainty is the lack of information or data on environmental concentrations of D4 in Canada. The most recent monitoring data in the United States are from the 1980's. The environmental monitoring data from the Swedish National Screening Programme and Nordic countries indicate that the concentrations of D4 in surface water, sediments, and soil did not reach the levels that have been estimated to cause significant adverse effects to aquatic and soil-dwelling organisms in laboratory settings or models. However, the use volumes in Sweden and Nordic countries are relatively small compared to that in Canada and the United States.

Another uncertainty arises because D4 is also one of the components in CAS No. 69430-24-6 (dimethylcyclosiloxane), which had an imported quantity of more than 2220 tonnes in commerce in Canada during the calendar year 1986. The total quantity of D4 being released into the Canadian environment should therefore be considered higher than that from CAS No. 556-67-2 alone. However, the amount of D4 released that is associated with use of dimethylcyclosiloxane cannot be estimated as the proportion of D4 in dimethylcyclosiloxane is not known.

Regarding the toxicity of D4 in sediments, empirical data are available but the quality of the study has yet to be evaluated. No empirical effects data are available for soil, which is another important medium of exposure based on the predicted partitioning behaviour of this substance.

The experimental or predicted concentrations, associated with inherent toxicity for aquatic organisms, may have an additional source of uncertainty in some situations, e.g. where these concentrations exceed the solubility of the chemical in water (either experimental or predicted). Given that concentrations for both the toxicity and water solubility often vary considerably (up to several orders of magnitude), it is acknowledged that these uncertainties exist.

There is also uncertainty associated with basing the overall conclusion that D4 may be causing ecological harm solely on information relating to its persistence, bioaccumulation, relative toxicity and use pattern. Typically quantitative risk estimates (i.e., risk quotients or probabilistic analyses) are important lines of evidence when evaluating a substance's potential to cause environmental harm. However, when risks for persistent and bioaccumulative substances such as this cyclosiloxane are estimated using such quantitative methods, they are highly uncertain and are likely to be underestimated (ESD 2006b). Given that long term risks associated with persistent and bioaccumulative substances cannot at present be reliably predicted, quantitative risk estimates have limited relevance. Furthermore, since accumulations of such substances may be widespread and are difficult to reverse, a conservative response to uncertainty (that avoids underestimation of risks) is justified.

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