

**Summary of Public Comments Received on the Government of Canada’s Draft Screening Assessment Report and Risk Management Scope on Siloxanes - Octamethylcyclotetrasiloxane (D4) CAS No. 556-67-2, Decamethylcyclopentasiloxane (D5) CAS No. 541-02-6, Dodecamethylcyclohexasiloxane (D6) CAS No. 540-97-6**

Formal comments made during the 60-day public comment period that took place from May 17, 2008 to July 16, 2008 on the draft screening assessment report and risk management scope on siloxanes, a substance included in Batch 2 of the substances to be addressed as part of the Chemicals Management Plan Challenge under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), were provided by Bluestar, Silicones, Canadian Consumer Products Specialty Association (CCSPA), The Canadian Cosmetic, Toiletry and Fragrance Association, Canadian Environmental Law Association (CELA)/Chemical Sensitivity Manitoba (CSM), Canadian Society for Chemistry (CSC), Colgate-Palmolive, Dow Chemical Canada Inc., Dow Corning, GreenEarth Cleaning, Johnson & Johnson Inc., Men’s Warehouse, Mentor Corporation, Procter & Gamble, Reach for Unbleached Foundation & Crofton Airshed Citizens Group, Silicones Environmental, Health and Safety Council (SEHSC) of North America, Siltech, U.K. Environment Agency, Science Department. Other comments may have been made outside of the formal 60-day public comment period. The table below provides an overview of comments received.

A summary of comments and responses is included below, organized by topic:

- Human Exposure
- Risk to the Environment
- Effects on Human Health
- Validity of Evidence
- Consumer Use
- Environmental Impacts
- Transboundary Risks
- Persistence and Bioaccumulation
- Monitoring and Research
- Risk Management

TOPIC	COMMENT	RESPONSE
Validity of Evidence	The screening assessment of the D4, D5, D6 did not take into account additional data that is available on and needed to identify pivotal values for modelling the assessments.	The assessments for D4, D5, D6 have been revised based on the new data. The environmental fate models have been updated in the final assessment reports to reflect new accepted data. A table for environmental fate model input parameters is attached as “Annex 5” at the end of each screening assessment report.
	Additional physical-chemical data was provided to be used in models. Please provide justification if they were not used in the final assessment.	The available critical values have been identified in the Section on “physical and chemical properties” and in Annex 5 at the end of each assessment report. Empirical data was preferred over modelled data. When more than one empirical data point was available, the rationale for choosing the critical value was discussed in this section of the assessment.
	There are additional studies that have been done on environmental impacts of the 3 siloxanes. These studies suggest that siloxanes pose no risk to	The Government of Canada acknowledges and thanks the submitter’s effort in conducting studies on the health and environmental impacts of these cyclic siloxanes and other silicon-based substances. Information and comments received under The Challenge and public comment period have been considered in drafting

	the environment and human health when used in accordance with accepted health and safety principles.	the final screening assessment reports.
	<p>There is uncertainty in the findings of persistence for D4, D5 and D6. Further testing and field studies are underway and will be available in the next year or two. Screening assessments should be based on the complete science. The Government is urged to consider deferring a final decision on these siloxanes until these new data are available. The European Union has set aside any decisions until these new data/studies are available, studies that have been specifically designed by the regulatory authorities to address these regulatory uncertainties concerning D4/D5's bioaccumulative status.</p> <p>The Government of Canada should wait for the field monitoring data as agreed by the European Union.</p>	<p>The Government of Canada is appreciative of the data that were provided during the Chemicals Management Plan challenge phase. The data were reviewed and considered.</p> <p>The United Kingdom (in support of the European Union) has identified that D4 may meet the persistence and bioaccumulative screening criteria and that D5 may meet the very persistent and very bioaccumulative screening criteria based on the laboratory data. However, uncertainties have been recognised in terms of laboratory and monitoring field data. The EU decision regarding the risk management has been delayed 18 months until further monitoring is completed. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:139:0008:0009:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:139:0008:0009:EN:PDF</a></p> <p>The final assessment recognises the uncertainties associated with the persistence and bioaccumulation potentials of these substances. It does not conclude on whether D4 and D5 meet the bioaccumulation criterion under regulation due to the conflicting evidence on the laboratory and modelled bioaccumulation data. The Government of Canada recognises that ongoing research being conducted can be used to support a determination as to whether these cyclic siloxanes meet the bioaccumulation regulation.</p>
	D4, D5, and D6 should not be considered as meeting persistence and bioaccumulative regulations and are not inherently toxic.	The final assessment reports have been modified to reflect the change in the persistence and bioaccumulative profiles of D4, D5, and D6 based on comments and additional information received during the public comment period.
	An issue was raised that certain releases of the cyclic siloxanes were not addressed in the Draft Screening Assessments. Data on detections of cyclic siloxanes would support claims that these are substances of emerging concern in the Great Lakes Basin.	Siloxanes in residual sludges that have been transported to incinerators, landfills, or agricultural soils have been considered as potential sources in the assessment reports. Where incinerated, the siloxanes will be chemically transformed. Studies have identified the releases of D4 and D5 from landfills as bio gas. Siloxanes in residue sludge applied to agriculture soil will either be degraded in soil under dry soil conditions, or volatilise into air. These siloxanes in air will eventually be degraded by hydroxyl radicals in the atmospheric compartment.

		In addition, monitoring at landfill sites is part of the program being considered under the CMP.
	The international classifications used to determine human health priorities (under categorization) should not be used to determine the assessment priority for D5 and D6.	The Draft Screening Assessments of D5 and D6 focuses on information relevant to the evaluation of risks to human health and ecological risks. As stated in the D5 and D6 Screening Assessments, “Although the categorization exercise did not determine [D5] [D6] to be a priority for assessment with respect to risks to human health, it was recommended that a human health assessment be conducted due to its structure and use pattern similarity to D4, also known as octamethylcyclotetrasiloxane, a high priority for assessment for both human health and ecological risks under CEPA 1999, and its increased use as an alternative to D4.”
Releases to the Environment	Issues were raised on the contribution of cVMSiloxane releases from transient degradation of PDMSiloxane under realistic environmental conditions. Studies cited in the draft assessment reports relate to conditions outside those where PDMSiloxane products are normally used. Research shows that formation of cyclic siloxanes from thermal breakdown of PDMSiloxanes may occur in some situations, but it is not possible to quantify this potential source of release and the emissions are likely to be small compared with other sources of emission.	The assessment reports were modified to indicate that this source of environmental release is expected to be small relative to other sources under realistic environmental conditions.
	Release values may be overestimated because a significant portion of the Canadian population has STP treatment.	Different types of removal of siloxanes from municipal sewage treatment plants in Canada have been considered in the exposure characterization under the section “Characterization of Ecological Risk.”
Consumer Use	Additional information on D5 use and release in the dry cleaning industry	The Government of Canada appreciates the information on the use, recycling, release, and waste disposal operations of D5 in the dry cleaning industry. The

	were provided. It is concluded that the contribution of D5 release to air from dry cleaning operations is small. The dry cleaning industry would value further discussion to minimise risk from industrial releases.	government will continue to work with this industry on D5 applications in their dry cleaning, for consideration during risk management.
	D4 is present in cyclomethicone and dimethicone (PDMS), and that the absence of release data on these compounds in the screening assessment could potentially result in risk management proposals that are less restrictive and less protective to human health and the environment.  Approximate figures for the presence of D4, D5, and D6 in cosmetics in Canada were provided as part of the public comments.	Information from the CEPA section 71 survey indicated some companies did report cyclomethicone under individual cyclic siloxanes. This data gap has been discussed in the “Sources of Releases” and “Uncertainties” sections of the final assessments.  We invite the stakeholder to indicate the source of the information so that it can be further considered during risk management.
	There is concern that the 90% release of cyclic siloxanes from cosmetics into the atmosphere, and up to 3% residue in PDMSiloxane indicated in the draft assessment reports had underestimated the cumulative amount of the substances’ use and release during our life time.	The 90% estimation was applied to all quantities reported by industry as used in the cosmetics in year 2006 in Canada under the CEPA section 71 survey (2007). The 3% residue of D4, D5, and D6 contained in the final PDMSiloxane products were considered in the draft assessments in the Mass Flow Tool based on the total quantity of D4 used as polymerisation raw material in Canada in year 2006 under S.71 survey (2007). Note that each Draft assessment for D4, D5, and D6 states that the cumulative exposures of the other cyclosiloxanes in polydimethylsiloxanes (PDMS) is not considered in the individual assessments, but notes that D4, D5 and D6 are being assessed simultaneously.
	One commenter provided information to show that potential diffusion from silicone breast implants is infinitesimal.	The commenter’s information had already been considered during preparation of the draft screening assessment. Note that the screening assessment specifies that silicone fluid/gel mixtures are used for implants and silicone elastomers are used in a large number of biomedical applications, including implants.
Human Exposure	If a more detailed exposure assessment of D4, D5, and D6, is	For each of D4, D5, and D5, the probabilistic exposure assessment submitted by industry was further reviewed and its validity was considered.

	<p>conducted, then it should be a probabilistic exposure assessment. However, it was recognized that the screening assessment states that a critical review of a probabilistic analysis is beyond the scope of a screening assessment.</p>	
	<p>The final assessment should include estimates of exposure of workers to this substance.</p>	<p>Exposure of the general population to chemicals through environmental media (e.g., food, ambient air, soil, consumer products) is taken into account in the screening assessment (and risk management). However, estimates of occupational exposures are largely a provincial mandate and therefore beyond the scope of assessments under CEPA 1999. Hazard information obtained from occupational settings, if it is available, is considered under the “Health Effects” section of the screening assessment. For these screening assessments, no individual epidemiological studies were identified for each of D4, D5 or D6.</p>
	<p>D4, D5, and D6 may pose a threat to northern communities due to studies showing bioaccumulation in fish livers and other marine life.</p>	<p>The low Arctic contamination potential was concluded under the Ecological part of the final screening assessment. Arctic communities are considered to be part of the general population and thus are addressed under the section “Characterization of Risk to Human Health.” of the screening assessment report.</p>
	<p>The screening assessment should include consideration of impacts of exposure to vulnerable populations, such as children.</p>	<p>Vulnerable populations are addressed in the screening assessment in the discussion of margins of exposure (e.g. critical effect levels were based on the lowest effect levels determined for different durations of exposure; margin of exposure based on chronic effects, as documented, accounts for potential exposure to children.</p>
	<p>The government should show its calculations of the oral dose computed for the personal care product scenarios, where the reciprocals of the oral absorption factor were utilized.</p>	<p>Corrections were made by changing the oral absorption factor from 52% to 100% and then re-calculating the total systemic dose for the personal care product scenario to allow comparison with a critical effect level that was based on 100% oral absorption. The text will be changed to “equivalent systemic dose...”</p>
	<p>If a more refined assessment is conducted, then a more thorough analysis of the physiologically based pharmacokinetic modelling of</p>	<p>Only experimental data on absorption were used in the assessment at this time, but should analysis of physiologically based pharmacokinetic modelling be necessary in the future, the government will consider it.</p>

	inhalation and dermal absorption data should be conducted.	
Effects on Human Health	There are assessments of siloxanes being undertaken by another agency and any discrepancy in approaches between these assessments and the draft screening assessment lies with the interpretation of the effects seen in the liver. The draft screening assessment stated that it is uncertain whether liver weight increases were adaptive or adverse, whereas the assessment by the other agency considered that the liver weight increases were potentially adverse.	It is uncertain whether the liver weight increases are adaptive or adverse. Therefore, the critical effect level was based on increased liver weight together with other effects in the liver and other organ systems.
	If a more refined assessment is conducted of D4 and D5, then a more thorough analysis of the mode of action should be conducted for determining the relevance of the dopamine agonist argument for the high-dose effects observed in the 2-year rat inhalation study for D4, D5.	As stated in the draft screening assessment, “Although Silicones Environmental, Health and Safety Council argued that the endometrial adenomas and hyperplasia are not relevant to humans, this position has not been supported to date by international reviews due to lack of a thorough mode-of-action analysis...”
	If a more refined assessment is conducted of D4, then a more thorough analysis of the mode of action should be conducted for determining the relevance of the suppression of luteinizing hormone release in rats.	As stated in the draft screening assessment, “The reproductive toxicity of D4 was associated with inhibition of luteinizing hormone release in rats, and the relevance to humans of this mechanism is an area of uncertainty as differing opinions have been expressed by SCCP (2005), SEHSC (2007d) and the European Commission (2006, 2007).”
Environmental Impacts	There is disagreement with the draft screening assessment conclusion that D6 has the potential to cause long-	The final assessment report has been modified to reflect that D6 does not cause long-term harm to aquatic organisms below its water solubility limit in the laboratory test.

	term harm to sensitive aquatic organisms and meeting bioaccumulation criteria.	D6 has been concluded as not meeting the bioaccumulation criterion based on available information, but it may have some potential to bioaccumulation in biota, though its potential is lower than D4 and D5 due to reduced bioavailability.
	The Government of Canada should reject results of the Springborn 1991 biodegradation study for D4 and as read across for D5 and D6 due to inadequate experimental design.	The uncertainties of the Springborn (1991) study have been considered in the screening assessments. A preliminary D4 water/sediment study has been received and reviewed in the final assessment reports.
	Uncertainties were recognised in the hydrolysis study for D4 and D5, especially under pH7. However, the second order reaction rate constants for the hydronium ion (acid) catalysed reaction and the hydroxide ion (base) catalysed reaction extracted from acid and base conditions can be used for calculating the hydrolysis rate constants for D4 and D5.	The hydrolysis studies for D4 and D5 have been reviewed and updated rate constants for hydronium and hydroxide are used in calculating the hydrolysis half-lives for D4 and D5 in the final screening assessments.
	How are environmental conditions considered in reaching the persistence conclusion for D5 in water, when many realistic environmental conditions yield half life values of less than 182 days.	When evaluating environmental persistence, the Government of Canada considers the range of conditions typically found in the Canadian environment. In the case of water, that means a pH range of 6-9 and a temperature range of 5-25 °C. When results vary depending on the conditions assumed, the Government of Canada makes a decision based on conditions representing a "reasonable worst case" scenario.
	The overall persistence of D4, D5, and D6 in soil is a concern. Studies have shown cVMSiloxane can be degraded under dry soil conditions, but not in soil with 100% relative humidity. Under realistic environmental conditions, sewage sludge containing cVMSiloxane may be applied during crop growing	Since hydrolysis occurs relatively quickly and most soils in Canada are expected to be affected by some dry periods hydrolytic degradation is expected. Or these cVMS are expected to evaporate rapidly from moisture soil into air where they will eventually be degraded by hydroxyl radicals.

	season with extensive watering. Degradation of cVMSiloxane may not occur under these conditions.	
Transboundary Risks	The values cited in draft assessments can not be reproduced. D4, D5 and D6 behave as persistent organic pollutants and should be managed accordingly.	<p>The values have been revised in the final assessments to reflect new critical values and the criteria for identifying substances with long range transport plan using the OECD Tool have been revised. The input parameters were chosen based on the highest quality data available reflecting the most recent information on persistence and partition coefficients. The values have been listed as appendix 5 at the end of each assessment report.</p> <p>It is concluded that D4, D5, and D6 have the potential to be transported over long distances in the atmosphere. However, the modeled transfer efficiencies for these siloxanes are low which suggests they lack the potential to be deposited in water or soil in remote regions. The new information on the monitoring results of Lake Opeongo also supported the low atmospheric deposition potential for the cyclic siloxanes. It is expected that air-borne cyclic siloxanes will be eventually degraded by hydroxyl radicals in air. It is therefore considered D4, D5 and D6 do not behave as POP-like substances.</p>
	Contrary to the Government of Canada's conclusions, D4, D5, and D6 do not have potential for long range transport (LRT).	Long range transport models have been updated to reflect new available critical values and thresholds. The updated common technical documents indicated these substances have potential for long range transport.
Persistence and Bioaccumulation	<p>The higher kinetic Biomagnification factor (BMF) compared to the steady-state BMF in the fish dietary study may be due to the fact that no growth dilution was factored in the steady-state BMF.</p> <p>Steady-state corrected BMF values for D4 and D5 were submitted to the Government of Canada for consideration.</p>	<p>Growth dilution has been factored into the steady state Biomagnification factor (BMF) when fish naturally adjust food intake with growth. This is a good point though. The importance of considering growth dilution was illustrated in the supplement submission we received, in which modified fish growth rate was shown to influence the model output significantly.</p> <p>The corrected BMF values were considered in the final assessment.</p>

	<p>A more appropriate set of kinetic Biomagnification factor (BMF) values for D4 and D5 were submitted.</p> <p>Uptake of highly lipophilic chemicals from water (via gills) is considered to be small relative to dietary uptake (via gut) for most fish species at naturally-occurring food/water chemical concentration ratios, and the importance of dietary uptake of lipophilic chemicals increases with increasing log Kow. Bioconcentration is not a significant contributing factor in natural aquatic systems for D4, D5, and D6; and all field-determined BAF values are less than the regulatory 'B' criteria of 5000 L/kg. The bioaccumulation of chemicals into fish via the diet may be examined in a feeding study.</p>	<p>The final assessments have been modified to incorporate the refined Biomagnification factor (BMF) data. The growth rate corrected kinetic BMF values were added in the final screening assessment.</p> <p>Available laboratory and field bioconcentration factor (BCF) data show that uptake from water in various organisms still occurs at higher log Kow ranges (5-8) (see Arnot and Gobas 2006). When field BAF/BMF data are inconclusive, laboratory BCF and modeled Bioaccumulation factor (BAF) can be used to demonstrate a substance's bioaccumulative potential. The preliminary field data are considered to be inconclusive at this time and the dietary feeding study has been considered in the weight of evidence for D4, D5 and D6. As well, D6 is considered to have some bioaccumulation potential in biota, but is not expected to be high given its lower bioavailability than D4 and D5. It is concluded that that D4 and D5 have bioaccumulation potential in biota, but considering the conflicting evidence from laboratory studies and predictive models, it is not possible to conclude whether D4 and D5 meet the criterion for bioaccumulation. It is also concluded that D6 does not meet the Canadian criteria for bioaccumulation.</p>
	<p>The empirical BCF value for D6 was not adequately considered in the draft assessment report. D6 should be considered not meeting the bioaccumulation criterion.</p>	<p>The final assessment report has been modified to reflect that the empirical BCF does not meet the bioaccumulation criteria. However, the modeled BAF value derived from the BCF study gave a value of above 5000. It is therefore concluded that D6 has some bioaccumulation potential in biota, but its potential is likely to be lower than D4 and D5. It is also concluded that based on lack of high bioconcentration potential as well as read-across evidence for low bioaccumulation via dietary exposures in fish, D6 does not meet the bioaccumulation criterion.</p>
<p>Risk Management</p>	<p>Environment Canada should work with stakeholders while developing the risk management instruments in order to gather more information on the feasibility of reducing D4, D5 and</p>	<p>The Government of Canada will consult with stakeholders in various sectors involved during the development of the risk management instrument(s).</p>

	D6 in products, reducing residual D4, D5 and D6 in silicone polymers, as well as to allow industry to provide Environment Canada with feedback concerning their industry's use of these siloxanes.	
	From the data presented in the draft risk assessment, estimated exposures do not exceed the identified critical threshold values and no risks were specifically identified for action in the risk management scope document. Risk management should be taken within the context of the risk. Since no risk was identified, there should not be any action.	The characterizations of ecological risks are proposed in the draft screening assessment reports. The final screening assessment reports will conclude on ecological risks related to the siloxanes. The risk management approach will be based on the findings of the final screening assessments, which includes a section on addressing the identified risks and will provide a more specific approach to risk management.
	The restriction of D4, D5 and D6 and silicone polymers containing these siloxanes is a concern as well as the potential major negative impact on Canada's economy and Canadians' lifestyle.	The risk management process will consider each sector and will take action appropriate to the sector. The development of risk management actions will take into account socioeconomic and other considerations.
Monitoring and Research	Insufficient information provided on some of the monitoring data from sewage treatment plants.	The original data referenced in the assessment report are available upon request.
	The limit of detection (LOD) of the analytical method should be reported along with the Norwegian biota concentrations reported.	The Norwegian biota concentrations data are above the LOD for D4. Data below LOD were identified as < d.l. (below detection limit) in the assessment reports. The LOD values and the sampling sites/matrix have been added in the assessment reports.
	A conclusion of "CEPA-toxic", at this juncture, is premature and not entirely reflective of the available evidence. Also cVMSiloxane should undergo	Risk quotients have been estimated based on realistic worst-case exposure scenarios for aquatic organisms in the final assessment reports. These further support the conclusions of "CEPA-toxic" for D4 and D5. D6 has been concluded not to be "CEPA-toxic" based on combined weight of evidences from its physical-

	further “risk assessment” under the Chemical Management Plan.	chemical properties, relatively low bioavailability according to its bioaccumulation potential, and low expected ecotoxicity from read-across and laboratory test data.
	<p>D4, D5 and D6 should be added to existing ambient air monitoring programs. Sampling locations should be chosen to reflect where the current concentrations are expected to be elevated and where the impacts of the approach can be measured. Measurements should also include background concentrations. Emission reporting was not recommended, but if siloxanes were to be added to the National Pollutant Release Inventory (NPRI), a reporting threshold of 10 tonnes manufactured, processed or otherwise used (MPO) was recommend.</p>	<p>The Government of Canada is considering the addition of D4, D5 and D6 to its ambient air monitoring program. Consideration will be given to selection of appropriate sampling locations, both in urban areas and areas removed from point or area sources.</p>