# Silanol Terminated Polydimethylsiloxane (Silanol Terminated PDMS) (CAS #70131-67-8) Viscosity 50 to 120 cs (Low Viscosity) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment

**Prepared for:**

**Washington State Department of Ecology**

**Prepared by:**

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**October 14, 2014**


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# GreenScreen® Executive Summary for Silanol Terminated Polydimethylsiloxane (PDMS), Viscosity 50 to 120 cs (CAS #70131-67-8)

Silanol Terminated PDMS (50 to 120 cs) is a chemical that functions to caulk joints in construction, to improve insulation, to provide anti-shock, damp-proof, and anticorrosion properties for electronic components, to mold and demold rubber products, as a smooth and isolating agent for leathers, and as a basic material for the manufacture of room temperature vulcanizeable (RTV) silicones used in fabric finishing and daily-use chemical industry.

Silanol terminated PDMS (50 to 120 cs) was assigned a GreenScreen® Benchmark Score of 2 ("Use but Search for Safer Substitutes") as it has very High Persistence (P) and Moderate (M) Group II Human Toxicity (Moderate Eye Irritation, or IrE, and Skin Irritation, or IrS). This corresponds to GreenScreen® benchmark classification 2c (High P and Moderate T (Ecotoxicity or Group I, II, or II* Human)) in CPA 2011. Data gaps (DG) exist for Endocrine Activity (E) and Respiratory Sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), silanol terminated PDMS (50 to 120 cs) meets requirements for a GreenScreen® Benchmark Score of 2 despite the hazard data gaps. In a worst-case scenario, if silanol terminated PDMS (50 to 120 cs) were assigned a High score for the data gap E, it would be categorized as a Benchmark 1 Chemical. If it were assigned a High score for the data gap SnR*, it would still be categorized as a Benchmark 2 Chemical.

**GreenScreen® Benchmark Score for Relevant Route of Exposure:**
All exposure routes (oral, dermal and inhalation) were evaluated together, as a standard approach for GreenScreen® evaluations, so the GreenScreen® Benchmark Score of 2 ("Use but Search for Safer Substitutes") is applicable for all routes of exposure.

**GreenScreen® Hazard Ratings for Silanol Terminated PDMS (50 to 120 cs)**

| Group I Human | | | | | Group II and II* Human | | | | | | | | | Ecotox | | Fate | | Physical | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| C | M | R | D | E | AT | ST | | N | | SnS* | SnR* | IrS | IrE | AA | CA | P | B | Rx | F |
| | | | | | | single | repeated* | single | repeated* | | | | | | | | | | |
| L | L | L | L | DG | L | L | L | L | L | L | DG | M | M | L | L | vH | vL | L | L |

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated (modeled) values, authoritative B lists, screening lists, weak analogues, and lower confidence. Hazard levels in **BOLD** font are used with good quality data, authoritative A lists, or strong analogues. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Please see Appendix A for a glossary of hazard acronyms.

# GreenScreen® Assessment for Silanol Terminated Polydimethylsiloxane (PDMS), Viscosity 50 to 120 cs (CAS #70131-67-8)

**Method Version: GreenScreen® Version 1.2[1]**
**Assessment Type[2]: Certified**

**Chemical Name**: Silanol Terminated Polydimethylsiloxane (PDMS), viscosity 50 to 120 cs[3] (low viscosity)

**CAS Number:** 70131-67-8

**GreenScreen® Assessment Prepared By:**
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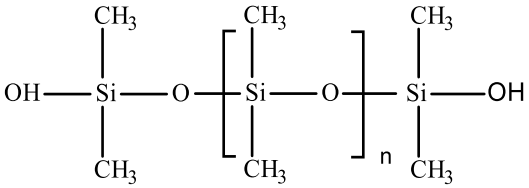
Date: October 14, 2014

**Confirm application of the *de minimus* rule[4]:** GreenScreen® Guidance states that catalysts, monomers, and processing aids must be reported, even if present at less than 0.01% and they must be reviewed if present at or equal to 0.01%. For this specific GreenScreen®, ToxServices has been informed that residual cyclomethicones, specifically D4 (cyclotetrasiloxane, CAS# 556-67-2) and D5 (cyclopentasiloxane, CAS# 541-02-6) are present at <0.1% and <0.15%. These residuals have been assessed using the List Translator and the results are discussed in this report.

**Chemical Structure(s):**



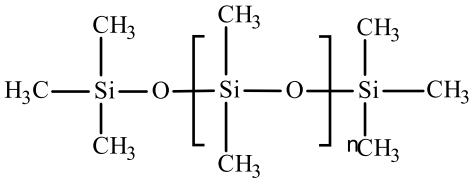

**Silanol Terminated Polydimethylsiloxane (PDMS),（50 - 120 cs, n approximately 40 – 70) (ECETOC 2011)**

**Also called:**
Hydroxy-terminated dimethyl siloxanes and silicones; Poly(oxy(dimethylsilyene), alpha-hydro, omega-hydroxy-; Polydimethylsiloxane, hydroxyl end-blocked; Silanol-terminated di-Me siloxanes; alpha-Hydro-omega-hydroxypoly(dimethylsiloxane); Siloxanes and silicones di-Me, hydroxyl-

[1] Use GreenScreen® Assessment Procedure (Guidance) V1.2
[2] GreenScreen® reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen® Practitioner), "CERTIFIED" (by Licensed GreenScreen® Profiler or equivalent) or "CERTIFIED WITH VERIFICATION" (Certified or Authorized assessment that has passed GreenScreen® Verification Program)
[3] cs: Centistoke, unit for viscosity
[4] Every chemical in a material or formulation should be assessed if it is:
1. intentionally added and/or
2. present at greater than or equal to 100 ppm

terminated 42% in dimethyl hydrolyzate; Siloxanes and silicones, di-Me, hydroxyl-terminated (ChemIDplus 2013)

**Chemical Structure(s) of Chemical Surrogates Used in the GreenScreen®:**
Limited health effects or environmental data are available on silanol terminated PDMS (50 to 120 cs). Therefore, data on the class of (linear) PDMS chemicals (CAS #63148-62-9/9016-00-6/9006-65-9, also known as dimethicones) are used to fill the data gaps. For these PDMS chemicals, the molecular weights determine their viscosities, and the number of repeating units (n) governs the molecular weights (ECETOC 2011). PDMS chemicals are high molecular weight silica polymers with viscosities ranging from 10 to > 100,000 cs, which correspond to the molecular weight of approximately 1,125 – 74,000, or $n \geq 13$. The relationship of viscosity and average number of repeating units is summarized in Table 1 below (ECETOC 2011). When ample data are available on PDMS of different viscosities for a certain hazard endpoint, only data on surrogates with viscosities closest to or smaller than 50 – 120 cs are described.



**CAS #63148-62-9/9016-00-6/9006-65-9(n≥13)**
**(Chemical Surrogate)**

**Table 1: Relationship Between Viscosity and Degree of Polymerization for Linear PDMS (CAS #63148-62-9)**

| Viscosity (cs) at 25°C | Average Number of Repeating Units |
|---|---|
| 10 | 15 |
| 50 | 40 |
| 100 | 70 |
| 1,000 | 200 |
| 10,000 | 500 |
| 100,000 | 1,000 |

**Identify Applications/Functional Uses:** (Shanghai Polymer Commodities 2013)

1. To caulk joints in construction
2. To improve insulation, anti-shock, damp-proof and anticorrosion for electronic components
3. In molding and demolding for rubber products
4. As smooth agents and isolating agents for leathers
5. A basic material for the manufacture of room temperature vulcanizeable (RTV) silicones used in fabric finishing and daily-use chemical industry

**GreenScreen® Summary Rating for Silanol Terminated PDMS (50 to 120 cs)[5]:** Silanol terminated PDMS (50 to 120 cs) was assigned a GreenScreen® Benchmark Score of 2 2 ("Use but Search for Safer Substitutes") as it has very High Persistence (P) and Moderate (M) Group II Human

[5] For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.

Toxicity (Moderate Eye Irritation, or IrE, and Skin Irritation, or IrS). This corresponds to GreenScreen® benchmark classification 2c (High P and Moderate T (Ecotoxicity or Group I, II, or II* Human)) in CPA 2011, 2012a. Data gaps (DG) exist for Endocrine Activity (E) and Respiratory Sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), silanol terminated PDMS (50 to 120 cs) meets requirements for a GreenScreen® Benchmark Score of 2 despite the hazard data gaps. In a worst-case scenario, if silanol terminated PDMS (50 to 120 cs) were assigned a High score for the data gap E, it would be categorized as a Benchmark 1 Chemical. If it were assigned a High score for the data gap SnR*, it would still be categorized as a Benchmark 2 Chemical.

**Figure 1: GreenScreen® Hazard Ratings for Silanol Terminated PDMS (50 to 120 cs)**

| Group I Human | | | | | Group II and II* Human | | | | | | | | | Ecotox | | Fate | | Physical | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| C | M | R | D | E | AT | ST | | N | | SnS* | SnR* | IrS | IrE | AA | CA | P | B | Rx | F |
| | | | | | | single | repeated* | single | repeated* | | | | | | | | | | |
| L | L | L | L | DG | L | L | L | L | L | L | DG | M | M | L | L | vH | vL | L | L |

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated (modeled) values, authoritative B lists, screening lists, weak analogues, and lower confidence. Hazard levels in **BOLD** font are used with good quality data, authoritative A lists, or strong analogues. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Please see Appendix A for a glossary of hazard acronyms.

Silanol terminated PDMS may contain the cyclomethicone residuals, D4 and D5 (cyclotetrasiloxane, CAS #556-67-2; and cyclopentasiloxane, CAS #541-02-6, respectively), which were evaluated using the List Translator. Both D4 and D5 are possible Benchmark 1 chemicals, and their presence should be considered when comparing the GreenScreen® Benchmark Score for Silanol Terminated PDMS with the GreenScreen® Benchmark Scores of alternative chemicals. Should the client choose to have this GreenScreen® Verified, a full evaluation of the residuals may be required.

**Transformation Products and Ratings:**

**Identify feasible and relevant fate and transformation products** (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**[6]

Silanol terminated PMDS (50 to 120 cs) are expected to be insoluble in water. They are therefore not expected to undergo hydrolysis. Neither are they expected to volatize, due to their low vapor pressure. The polymer is temperature and chemical resistant (for details, refer to the physiochemical properties section). PDMS are stable at 150ºC, but they can be oxidized at 250ºC (Bingham et al. 2001). Almost all PDMS are expected to be removed during sewage treatment. When released into the environment, PMDS will strongly sorb to particulate matter in water and soil, where they are immobilized. Abiotic break down will occur slowly to produce dimethylsilanediol (CAS #1066-42-8), a water soluble compound which can ultimately biodegrade to carbon dioxide, water and inorganic silicate, as demonstrated in the laboratory (ECETOC 2011). Based on the molecular formula of silanol terminated PMDS, possible combustion products are CO, $CO_2$ and silicon dioxide. All three chemicals (i.e., CO, $CO_2$ and silicon dioxide) are naturally occurring, ambient substances

[6] A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

that are not relevant with respect to the GreenScreen score for silanol terminated PMDS (50 to 120 cs).

**Table 2: Feasible and Relevant Transformation Products of Silanol Terminated PDMS (50 to 120 cs (CAS #70131-67-8)**

| Functional Use | Life Cycle Stage | Transformation Pathway | Transformation Products | CAS # | Feasible and Relevant? | List Translator Results[7,8] |
|---|---|---|---|---|---|---|
| Non-known | Intermediate | Abiotic Degradation | Dimethylsilanediol | 1066-42-8 | | **Possible Benchmark 2** |

A Pharos search of dimethylsilanediol revealed that this chemical is on the German FEA list of Substances Hazardous to Waters (VwVwS) as a Class 1 substance (Low Hazard to Waters).

**Residuals of the Polymerization Process for Silanol Terminated PDMS**

Silanol terminated PDMS (50 to 120 cs) contains residual levels of the cyclomethicones cyclotetrasiloxane (D4) (CAS #556-67-2) and cyclopentasiloxane (D5) (CAS #541-02-6). D4 may be present in silanol terminated PDMS at concentrations <0.1% and D5 may be present at concentrations <0.15%. A discussion of the hazards associated with these chemicals is presented below and in Appendices D-F.

**Table 3: Potential Residuals from Polymerization Process for Silanol Terminated PDMS (50 to 120 cs) (CAS #70131-67-8)**

| Functional Use | Polymerization Component | Chemical Name | CAS # | List Translator Results[5,6] |
|---|---|---|---|---|
| Non-known | Residual monomer | Cyclotetrasiloxane (D4) | 556-67-2 | **Possible Benchmark 1** |
| Non-known | Residual monomer | Cyclopentasiloxane (D5) | 541-02-6 | **Possible Benchmark 1** |

The List Translator results for the residual chemicals D4 and D5 were obtained on Pharos and can be found in Appendix D and E, respectively, and are summarized as follows;

Cyclotetrasiloxane (D4) is listed as:

- a very high hazard as a PBT chemical by Oregon Department of Environmental Quality,
- a high hazard as a PBT chemical toward aquatic organisms and humans by Environment Canada – Domestic Substances List,
- a medium hazard as a PBT chemical by the ESIS-PBT system (EU PBT),
- a high hazard of reproductive toxicity as it is associated with EU Risk phrase R62 – possible risk of impaired fertility,
- GHS Hazard Phrase H362f – suspected of damaging fertility,
- a high endocrine hazard as a Category 1 (*in vivo* evidence of endocrine disruption activity) chemical in the EC priority Endocrine Disrupters list (EU ED), and as a potential endocrine disrupter in the TEDX database,

[7] The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to screen for GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2013) is an online list-searching tool that is used to screen chemicals against the lists in the List Translator electronically.
[8] The way you conduct assessments for transformation products depends on the Benchmark Score of the parent chemical (See Guidance).

- a medium hazard for acute mammalian toxicity via the dermal and oral routes of exposure as in the New Zealand HSNO/GHS database with the 6.1D classifications,
- a 6.1E (inhalation) classification in the New Zealand HSNO/GHS database, indicating that it is potentially acutely toxic via the inhalation pathway,
- a medium hazard for chronic aquatic toxicity as it is associated with the EU Risk Phrase R53 – may cause long-term adverse effects in the aquatic environment, and GHS Hazard Phrase H413 – may cause long-lasting harmful effects to aquatic life, D4 also has
- a medium flammability hazard as it is listed in New Zeeland HSNO/GHS as a 3.1D flammable liquid, and,
- a substance hazardous to waters (VwVwS: Class 3 Severe Hazard to Waters) by the German FEA.

Based on these classifications, cyclotetrasiloxane (D4) is classified as a possible Benchmark 1 chemical.

Cyclopentasiloxane (D5) is listed as:

- a very high hazard as a PBT chemical by Oregon Department of Environmental Quality,
- a high hazard as a PBT chemical toward aquatic organisms by Environment Canada – Domestic Substances List,
- a medium hazard as a PBT chemical by the ESIS-PBT system (EU PBT),
- a medium flammability hazard as it is listed in New Zeeland HSNO/GHS as a 3.1D flammable liquid.

Based on these classifications, cyclopentasiloxane (D5) is classified as a possible Benchmark 1 chemical.

A brief review of the human health and environmental hazards for D4 and D5 is presented in Appendix F. Repeat dose, carcinogenicity, and reproductive toxicity have been observed in laboratory animals following exposure to D4 or D5. However, the EU Scientific Committee on Consumer Safety (SCCS) concluded that cyclomethicones, including D4 and D5, do not pose a risk for human health under the current practices of use (SCCS 2010), and the Cosmetic Ingredient Review (CIR) Expert Panel determined that cyclomethicones are safe for use in cosmetic and personal care products at concentrations up to 89% of the formulated product (CIR 2012). The presence of these residuals should be considered when doing an alternatives assessment involving PDMS.

**Introduction**

The most common liquid silicones are PDMS. These polymers have extremely low glass transition temperatures (i.e., the temperature at which the reversible transition occurs from a hard and relatively brittle state into a molten or rubber-like state for amorphous materials), resistance to high temperature, oxidation, vapor permeability, and hydrophobicity (Xiameter 2009). The silanol groups of the silanol-terminated PDMS polymers render the PDMS susceptible to condensation under both acid and base conditions (Stealth 316 2002). The condensation of silanol groups form siloxane bonds which are used to cross-link siloxanes in commercial applications and to take full advantage of the unique properties of PDMS polymers (Xiameter 2009). A typical reaction system consists of a silanol terminated PDMS, a cross-linker and a catalyst. Upon cure, lightly cross-linked silicone films are produced which are capable of dissipating normal and shearing stresses at high temperatures (as in release coating applications). In addition, tough and flexible silicone elastomers that are

temperature resistant can be produced this way. In general, the higher the molecular weight of the silanol terminated PDMS, the higher strength of the elastomers produced (Xiameter 2009). Low viscosity silanol fluids, such as the silanol terminated PMDS with a viscosity of 50 to 120 cs, are mainly used as filler treatments and structure control additives in silicone rubber compounding (Power Chemical 2008).

ToxServices assessed silanol terminated PDMS (50 to 120 cs) against GreenScreen® Version 1.2 (CPA 2013) following procedures outlined in ToxServices' SOP 1.37 (GreenScreen® Hazard Assessment) (ToxServices 2013).

**GreenScreen® List Translator Screening Results**

The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to identify GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2013) is an online list-searching tool that is used to screen chemicals against the List Translator electronically. The output indicates benchmark or possible benchmark scores for each human health and environmental endpoint. The output for silanol terminated PMDS (50 to 120 cs) can be found in Appendix C and a summary of the results can be found below:

Silanol terminated PMDS is listed as having a medium hazard for the following endpoints:

- Eye Irritation – GHS New Zealand – Category 6.4A, irritating to the eye (equivalent to GHS Category 2 eye irritant).

Silanol terminated PMDS is listed has having a low hazard for the following endpoints:

- Restricted list - German FEA in Substance hazardous to waters (VwVwS): Class 1 Low Hazard to Waters

**PhysioChemical Properties of Silanol Terminated PDMS (50 to 120 cs)**

Limited data are available on silanol terminated PDMS (50 to 120 cs). PDMS polymers with more than 15 repeating units and a viscosity of 10 to 1,000 cs are a family of large, linear polymers with molecular weights over 1,000 and essentially no water solubility or volatility (Dow Corning 1999). Silanol terminated PDMS (50 to 120 cs) are low viscosity, colorless, clear liquids. Based on its structural similarity to the general PDMS polymers, this polymer is expected to have a high molecular weight (>1,000), low volatility and low water solubility. Since the surrogate PDMS polymers with viscosities ranging from 50 to 100 cs have an average number of 40 to 70 repeating units, silanol terminated PDMS (50 to 120 cs) are expected to have a similar n range. Their densities are similar to water at room temperature.

| Table 4: Physical and Chemical Properties of Silanol Terminated PDMS (50 to 120 cs) (CAS #70131-67-8) | | |
|---|---|---|
| **Property** | **Value** | **Reference** |
| Molecular formula | $HO[-Si(CH_3)_2O-]nOH$ | GuideChem 2013 |
| SMILES Notation | N/A | |
| Molecular weight | 1,250 – 5,970[9] | Kuo 1999 |
| Physical state | Liquid | Sigma-Aldrich 2012 |
| Appearance | Colorless clear dense liquid | Shanghai Polymet Commodities 2013 |
| Melting point | < -60°C | GuideChem 2013 |
| Vapor pressure | 0[10] | Dow Corning 1999 |
| Water solubility | Insoluble[11] | Dow Corning 1999 |
| Dissociation constant | N/A | |
| Density/specific gravity | 0.97 g/mL at 25°C | Sigma Aldrich 2012 |
| Partition coefficient | N/A | |

**Hazard Classification Summary Section:**

**Group I Human Health Effects (Group I Human)**

**Carcinogenicity (C) Score (H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for carcinogenicity based on negative findings in rodents. GreenScreen® criteria classify chemicals as a Low hazard for carcinogenicity when adequate negative data are available, the chemical does not have structural alerts for carcinogenicity, and it is not classified under GHS (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ECETOC 2011
  - *Oral: PDMS (10 cs)* – In a combined chronic toxicity and carcinogenicity study, PDMS was given to Fischer 344 rats (90/sex/dose) in the diet at doses of 0, 100, 300 or 1,000 mg/kg/day for 24 months. Ten animals/sex/group were killed at 12 months and 20 animals/sex/group were treated for 12 months followed by a 12-month recovery period. Clinical observations, body weight and food consumption were recorded during the study. Ophthalmoscopy and necropsies were performed on all animals, and select organ and tissue weights and microscopic examinations were obtained from all animals. Survival was not affected by the treatment, nor was the occurrence of palpable masses. No treatment related changes were observed on body weight, food consumption, clinical pathology parameters, ophthalmic findings, organ weights and macroscopic and microscopic findings. Slightly increased (statistical significance not reported) incidences of ocular opacities were found in the 300 mg/kg/day females and the 1,000 mg/kg/day males and females, which were most probably the result of local irritation from

[9] Estimated according to Kuo (1999): Molecular weights of trimethylsiloxy terminated PDMS are 1,250 (viscosity=10 cs) and 5,970 (viscosity=100 cs). Molecular weights of silanol terminated PDMS is expected to be similar to trimethylsiloxy terminated PDMS, as the terminal groups are different by one functional group (i.e., –OH vs $–CH_3$).

[10] PDMS with viscosity of 10 cs and above and MW of 1,000 and above, have essentially no volatility. Therefore the volatility of silanol terminated PDMS is expected to be the same.

[11] PDMS with viscosity of 10 cs and above and MW of 1,000 and above are insoluble in water. Therefore the solubility of silanol terminated PDMS is expected to be very low as well.

contacting PDMS-containing food. Increased (statistical significance not reported) incidences of eye opacity were found in the chronic recovery group without dose-response in males, which may be treatment-related. The eye opacity correlated with the microscopic findings of keratitis and with the incidental microscopic findings of corneal dystrophy, but these effects were not considered directly related to the ingestion of PDMS. No indication of carcinogenicity was observed for PDMS.

- *Oral: KS66 (a mixture containing 92% PDMS and 8% silica)* – Fischer 344 rats (50/sex/dose) received KS66 in the diet at doses of 0, 1.25% or 5% (average intakes were 0, 444.9, and 1893.9 mg/kg/day in females and 0, 530.1 and 2,233.9 mg/kg/day for males) for 104 weeks. Parameters examined included general health, signs of toxicity, body weight and food intake. At necropsy, hematological measurements were performed, including red blood cell/white blood cell counts, hemoglobin concentration, hematocrit values and platelet counts. Blood smears were checked for leukemia. Gross pathology was done and organ weights were measured for the brain, liver, kidneys, spleen, heart, adrenals and testes/ovaries. Full histopathology was performed on the control and highest dose groups. No changes were observed on physical appearance and behavior of the rats. No treatment-related effects were seen on survival, food consumption and hematology. Some rats in the low dose group died or became moribund and therefore were killed during the study. Body weight increase was found in all dosed females and in low dose males (statistical significance not reported). Relative liver weights in males receiving the high dose were significantly decreased (statistical significance not specified). Significant (statistical significance not reported) increase in the incidence of thyroid C-cell adenomas was observed in high dose females, but the authors considered this change spontaneous based on historical data. The incidence of prostate carcinomas was significantly decreased in the high dose males (statistical significance not reported). No differences in the incidence of other neoplastic and non-neoplastic lesions were found between the treated and control animals. It was concluded that KS66 is not carcinogenic in Fischer 344 rats of either sex.

- HSDB 2011
  - *Oral: Silicone antifoam agent (94% PDMS and 6% finely divided silica)* – Male and female Carshalton bred mice (number not reported) received the test material in the diet at doses of 9.25 and 2.5% (up to 3,750 mg/kg/day, ECETOC 2011) for 76 weeks from weaning. No increase in malignant or benign tumor and no treatment-related toxic effects were found.

**Mutagenicity/Genotoxicity (M) Score (H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for mutagenicity/genotoxicity based on negative *in vitro* and *in vivo* test results on PDMS. GreenScreen® criteria classify chemicals as a Low hazard for mutagenicity/genotoxicity when adequate negative data are available for both chromosomal aberrations and gene mutations, the chemical does not have structural alerts, and they are not GHS-classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ECETOC 2011
  - *In vitro: PDMS (60,000 cs)* – Negative in Bacterial Reverse Mutation Assays using *S. typhimurium* tester strains TA98, TA100, TA1535 and TA1537, and *E. coli* strains WP2 uvrA and WP2 uvrA (pKM 101) with and without metabolic activation at concentrations

of up to 5,000 µg/plate.
    - *In vitro: PDMS (350 cs)* – Negative for mutagenicity in a plate incorporation assay (Ames test) using *S. typhimurium* tester strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation at concentrations up to 100 µl/plate.
    - *In vitro: PDMS (50 cs)* – Negative for mutagenicity in Ames tests using *S. typhimurium* tester strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation at concentrations of up to 500 µl/plate.
    - *In vitro: PDMS (0.65, 100 and 1,000 cs)* – Negative for mutagenicity in Ames tests using *S. typhimurium* tester strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation (concentrations not reported).
- Isquith et al. 1988a,b
    - *In vitro: 12 organosilicon compounds representing potential intermediates in the synthesis and degradation of PDMS (identity not reported in the abstract)* – In a battery of assays, including Ames bacterial mutation assay in *S. typhimurium*, mitotic gene conversion in *S. cerevisiae* D4 and DNA repair in *E. coli pol* $A^{+/-}$ , forward gene mutation, sister-chromatic exchange, DNA alkaline elution and chromosome aberration potential in mouse lymphoma L5178Y cells with and without metabolic activation, none of the 12 organosilicon compounds were mutagenic. However, 6 demonstrated potential clastogenic activity.
    - *In vivo: 6 organosilicon compounds with clastogenic activity tested in vitro as above (identity not reported in the abstract)* – In rat bone marrow cytogenetic assays and rat dominant lethal tests, none of the 6 compounds showed *in vivo* clastogenic activities. It was concluded that organosilicon compounds involved in the synthesis and degradation of PDMS were not genotoxic in these *in vivo* clastogenicity tests.
- Gene-Tox 1992
    - *In vivo: PDMS DC 360* – Negative for chromosome effects in a dominant lethal test in mammalian germ cells in male rodents (species not specified). No further details were provided.
- Based on the weight of evidence, silanol terminated PDMS (50 – 120 cs) is not likely to be genotoxic, as PDMS were not mutagenic *in vitro*, and not clastogenic *in vivo.*

**Reproductive Toxicity (R) Score (H, M, or L): L**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for reproductive toxicity based on negative findings in male rodents. GreenScreen® criteria classify chemicals as a Low hazard for reproductive toxicity when adequate negative data are available, the chemicals don't have any structural alerts and are not classified under GHS (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* Not on any screening lists.
- ECETOC 2011
    - *Oral: PDMS (350 cs)* – Male Sprague-Dawley rats (10/dose) received PDMS at the concentrations of 0 (water) or 1,000 mg/kg/day for 5 days/week for 4 weeks. Body weights, food consumption and clinical observations were monitored throughout the study. At sacrifice, the weights of testes, epididymides and prostate were recorded. No adverse effects were seen on any of the parameters measured. As a result, no treatment related effects were observed on male reproductive organs. The NOAEL was established at over 1,000 mg/kg/day.
    - *Dermal: PDMS (350 cs)* – Five male albino rabbits received PDMS at 3,000 mg/kg/day

on the shaved backs for 5 days /week for 4 weeks (the equivalent dose for a 7-day week is 2,143 mg/kg/day). Following each dosing, the animals were immobilized in restrainers for 6 – 7 hours, before the test material was gently swabbed from them. Control animals received water or "white's A&D ointment" without hexachlorophene. Body weight was monitored during the study and semen samples were collected weekly. At necropsy, testes and epididymides were removed, weighed and examined microscopically. Semen samples were evaluated for volume, viscosity and color, sperm number, motility and morphology. No effects were seen on any of the measured parameters and the NOAEL was considered to >2,143 mg/kg/day.

- Based on the weight of evidence, silanol terminated PDMS (50 – 120 cs) is not likely to be toxic to reproduction.

**Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): L**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for developmental toxicity based on negative findings in rabbits. GreenScreen® criteria classify chemicals as a Low hazard for developmental toxicity when adequate negative data are available, the chemicals don't have structural alerts and are not GHS-classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ECETOC 2011
  - *Oral: PDMS (10 or 350 cs)* – Pregnant New Zealand White rabbits (23/dose) were treated with PDMS at dose levels of 0, 33, 300 or 1,000 mg/kg/day by gavage from days 6 – 19 after mating. None of the reproductive parameters (not specified in the summary) was significantly affected. No significant changes in the incidence of abnormalities in the offspring (not specified in the summary) were observed. The NOAEL was established at 1,000 mg/kg/day.
- Based on the weight of evidence, silanol terminated PDMS (50 – 120 cs) is not likely to be a developmental toxicant.

**Endocrine Activity (E) Score (H, M, or L):** DG
Silanol terminated PDMS (50 to 120 cs) was assigned a score of DG for endocrine disruption based on lack of data identified for silanol terminated PDMS or for its surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- No data were identified for silanol terminated PDMS or for its surrogates.

**Group II and II* Human Health Effects (Group II and II* Human)**

***Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.***

**Acute Mammalian Toxicity (AT) Group II Score (vH, H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for acute toxicity based on LD/$C_{50}$ values of > 2,000 mg/kg (dermal), 8.75 mg/L (inhalation) and 15,4000 mg/kg (oral). GreenScreen® criteria classify chemicals as a Low hazard for acute toxicity when they have LD/$C_{50}$ values of over 2,000 mg/kg (oral and dermal) and 5 mg/L (inhalation of dust/mist/fumes) (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ChemIDplus 2013
  - Dermal $LD_{50}$ > 2,000 mg/kg in rabbits
  - Inhalation $LC_{50}$ > 8,750 mg/$m^3$ in rats
  - Oral $LD_{50}$ > 15,400 mg/kg in rats

**Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)**

***Group II Score (single dose)* (vH, H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for systemic toxicity (single dose) based on no GHS classification from animal studies. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (single dose) when adequate negative data are available, the chemicals have no structural alerts, and not GHS-classifiable (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ECETOC 2011
  - *Oral: PDMS (1,000 cs)* – Wistar rats (5/sex) received 4,800 mg/kg PDMS orally after fasting for 16 hours. After dosing, a 14-day observation period followed. No deaths and no signs of reaction to treatment were seen. All animals achieved anticipated body weight gains, and necropsy revealed no treatment-related macroscopic lesions. $LD_{50}$ was established at >4,800 mg/kg/day.
  - *Oral: PDMS (100 cs)* – No signs of toxicity were observed in Wistar rats receiving a single dose of 4,800 mg/kg PDMS by gavage.
  - *Oral: PDMS (140 cs)* – Rats (strain not specified) (2/group) were given single oral doses of PDMS at 9.6, 14.3 or 19 g/kg. No signs of toxicity were observed. In addition, no signs of toxicity were observed when 9.6 g/kg PDMS was given orally to 1 dog, 1 cat and 1 rabbit.
  - *Dermal: PDMS (350cs)* – Sprague-Dawley rats (5/sex) received PDMS on the skin at 2,008 mg/kg according to OECD Test Guideline 402. No mortality or behavioral abnormality was noted during the test period (up to 14 days post dosing). No erythema or edema was observed. Body weight was not affected by the treatment and no noticeable macroscopic abnormality was noted during necropsy. The $LD_0$ was established at >2,008 mg/kg.
  - *Inhalation: PDMS (100,000 cs)* – Wistar rats (5/sex/dose) were exposed nose-only to

25% PDMS dissolved in petroleum ether for 4 hours. Exposure concentrations were 0, 4,315 or 11,582 mg/m$^3$(equivalent to 0, 4.315 or 11.582 mg/L, respectively). A 14-day observation period followed the exposure. Clinical symptoms and mortality were comparable between treated and control animals. No clinical effects were seen. No substance related organ changes were found at necropsy.

- *Inhalation: PDMS (100,000 cs)* – Wistar rats (5/sex/group) received PDMS dissolved in dichloromethane via aerosol inhalation accordance with OECD Test Guideline 403. Exposure concentrations were 0, 153.5, 322.0, 334.6 or 694.8 mg/m$^3$. The top dose was the highest technically achievable concentration. A 14-day observation period followed the exposure. No clinical signs, changes in reflexes, body weight changes and mortality were seen. No organ changes were identified at necropsy.
  The weight of evidence indicate that no adverse effects were observed with PDMS at doses tested up to 19,000 mg/kg (oral), 2,008 mg/kg (dermal) and 11.582 mg/L (inhalation).

***Group II* Score (repeated dose)*** **(H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for systemic toxicity (repeated dose) based on no expected toxic effects at the dose of 100 mg/kg/day by the oral exposure and at the dose of 1,000 mg/kg/day by dermal exposure. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (repeated dose) when oral effect levels are greater than 100 mg/kg/day and/or dermal effect levels are greater than 200 mg/kg/day (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- ECETOC 2011
  - *Oral: PDMS (10 and 350 cs)* – CDF-(F344)-CrlBr rats (10/sex/group) received PDMS at concentrations of 1 – 10% (equivalent to 1,065 – 10,650 mg/kg/day[12]) in the diet for 28-days. Clinical signs, body weight, food consumption and pathology parameters were monitored during the study. Ophthalmoscopy and necropsies were done on all animals. A dose-related increase of matting for the fur of both sexes at 5% and 10% (10 cs) or 10% (350 cs) was observed. Increased incidences of corneal opacities and inflammation (microscopically confirmed) were observed in all treated groups. The area involved in the ocular changes increased dose-dependently. Ocular findings were considered the result of direct contact of fur and eyes with the test material contained in the food at high concentrations. A treatment-related compensatory increase in food intake was seen at 5% and 10% (10 cs) or 5 – 10% (350 cs), although no changes in body weight were observed. No changes in hematology and urinalysis parameters were seen. Mean triglycerides and low and very low density lipoprotein levels were statistically significantly decreased in the 2.5 and 5% group males and in the 10% males and females. However, this was not considered an adverse effect. No additional alterations were seen at necropsy and organ weights were not changed. The NOAEL was established at 10% in the diet (i.e. 10, 650 mg/kg/day). The ocular findings are considered a result of direct contact with the test material and are not systemic effects.
  - *Oral*: *PDMS (35, 350 and 1,000 cs)* – In a 90-day feeding study, Sprague-Dawley rats (10/sex/group) received PDMS of three viscosities at doses of 1, 5, or 10% in the diet

[12] Food factor for Fisher 344 rats in subchronic studies are 0.1 and 0.113 kg/kg/day for males and females, respectively (U.S. EPA 1988). The mean food factor for males and females is (0.1 + 0.113)/2 = 0.1065 kg/kg/day = 106.5 g/kg/day. 1% in the diet is therefore 1% x 106.5 g/kg/day = 1.065 g/kg/day = 1,065 mg/kg/day.

(equivalent to 920, 4,600 and 9,200 mg/kg/day[13]). Body weights and food consumption were monitored during the study. At necropsy, organs were examined for gross and microscopic alterations. No systemic toxicity was observed during the study or at pathologic examinations. Anal leakage of the test substance was detected mainly in the high dose groups dosed with the more viscous material. Compensatory increase of food consumption was recorded at the mid and high dose levels with all three viscosities of PDMS. Non-dose-related, but treatment-related changes of slight chronic corneal inflammation and neovascularization were present in the eyes, which were attributed to direct ocular contact with PDMS in the food. ToxServices established a NOAEL of 9,200 mg/kg/day for this study.

- *Oral*: *PDMS (35, 350, or 1,000 cs)* – In a subchronic oral toxicity study, male rats (100/group, strain not specified) received PDMS in the diet at 10% (equivalent to 9,600 mg/kg/day[14]) for 90 days. Clinical signs, mortality, body weight, food consumption, hematology, gross necropsy and histopathology of major organs were examined. No treatment-related behavioral changes were seen in any group. A compensatory increase in food consumption was seen in all treated groups. No biologically relevant differences were found in hematology, necropsy, and histopathology. The NOAEL was established at 10% (9,400 mg/kg/day).
- *Oral*: *PDMS (10 cs)* – In a 13-week study, Fischer 344 rats (15/sex/group) received PDMS in the diet at 1 – 5% (equivalent to 1,065 – 5,325 mg/kg/day[9]). Clinical signs, body weight, food consumption and clinical pathology parameters were monitored during the study. Ophthalmoscopy and necropsies were performed on all animals. Selected organs were weighed and examined microscopically. Treatment-related clinical changes included a dose-related increase of matting of the fur in the 2,5 and 5% groups of both sexes, and an increased incidence of corneal opacity (crystals) and inflammation with vascularization (microscopically confirmed) in both sexes of animals treated with 2.5 and 5% PDMS. Both effects were considered the results of direct contact of fur and eyes with the test material in food at high concentrations. A presumably compensatory increase in food uptake was recorded at 1, 2.5 and 5% without changes in body weights. Hematology and urinalysis did not reveal any adverse effects. Cholesterol and high density lipoprotein levels and phospholipids levels decreased in all treated males. However, this was not regarded as an adverse effect. No additional alterations were found at necropsy. The NOAEL for systemic toxicity was established at 5% (5,325 mg/kg/day) for this study. The ocular findings are considered a result of direct contact with the test material in food and are not systemic effects.
- *Oral: PDMS (350 cs)* – In a 13-week study, Fisher 344 rats (15/sex/group) received PDMS in the diet at concentrations of 0.5 – 5% (equivalent to 533 – 5,325 mg/kg/day[9]). Two additional groups received PDMS at 0, 500 or 2,500 mg/kg/day via gavage to determine the potential of PDMS to induce corneal opacity through different routes of exposure. Clinical signs, body weight, food consumption and clinical pathology parameters were monitored during the study. Ophthalmoscopy and necropsies were performed on all animals. Selected organs were weighed and examined microscopically. One male and 2 females of the high does gavage group died during week one. Treatment-related clinical signs were yellow matting at the base of the tail in the 2,500

[13] Food factor for Sprague-Dawley rats in subchronic studies are 0.086 and 0.098 kg/kg/day for males and females, respectively (U.S. EPA 1988). The mean food factor for males and females is (0.086 + 0.098)/2 = 0.092 kg/kg/day = 92 g/kg/day. 1% in the diet is therefore 1% x 92 g/kg/day = 0.92 g/kg/day = 920 mg/kg/day.

[14] Average food factor for rats in subchronic studies is 0.096 kg/kg/day (U.S. EPA 1988). 10% in the diet is therefore 10% x 96 g/kg/day = 9.6 g/kg/day = 9,600 mg/kg/day.

mg/kg/day group rats during the second half of the study. Corneal opacities and inflammation (microscopically confirmed) were observed in all animals of all groups (including control) after 3 weeks of treatment. A dose-dependent increase of its intensity was observed (No explanation was provided regarding the significance and the relevance of this effect). A presumably compensatory increase in food consumption was recorded at 5% in the diet. Hematology, urinalysis and clinical chemistry parameters were unaffected. No additional alterations were found at necropsy. The NOAEL of systemic toxicity was established at 5% in the diet (5,325 mg/kg/day).

- *Oral: PDMS (10cs)* – In a combined chronic toxicity and carcinogenicity study in Fischer 344 rats as described in Carcinogenicity section above, slightly increased (statistical significance not reported) incidences of ocular opacities were found in the 300 mg/kg/day females and the 1,000 mg/kg/day males and females, which were most probably the result of local irritation. Increased (statistical significance not reported) incidences of eye opacity were found in the chronic recovery group without dose-response in males, which may be treatment-related. The eye opacity correlated with the microscopic findings of keratitis and with the incidental microscopic findings of corneal dystrophy. The NOAEL for systemic toxicity was established at 1,000 mg/kg/day, which is the highest dose tested. The ocular findings are considered a result of direct contact with the test material and are not systemic effects. This result is supported by an earlier dietary study in male and female Carshalton bred mice that received up to 3,750 mg/kg/day PDMS for 76 weeks.
- *Oral: KS66 (a mixture containing 92% PDMS and 8% silica)* – In a chronic toxicity study described previously in Carcinogenicity section, Fischer 344 rats (50/sex/dose) received KS66 in the diet at doses of 0, 1.25% or 5% (average intakes were 0, 444.9, and 1893.9 mg/kg/day in females and 0, 530.1 and 2,233.9 mg/kg/day for males) for 104 weeks. No treatment related systemic toxicity was observed. Ophthalmologic examination was not performed in the study. ToxServices established a NOAEL of 2,233.9 mg/kg/day for this study.
- *Oral: PDMS* – Six healthy human volunteers received PDMS at 1% or 2% (equivalent to 290 and 580 mg/kg/day[15]) of the daily diet (duration not reported). Evaluation of tolerance included assessment of observed or reported changes in bowel habits, stool appearance and consistency and anal leakage. Blood samples, urine and feces were collected to assess the absorption of selected nutrients. Clinical laboratory parameters and body weights were also monitored and fecal microflora was examined. No significant signs of adverse effects were seen. No further details were presented.
- *Oral: PDMS* – Seven healthy male volunteers received PDMS at ascending doses (2%, 3%, 4% and 5% in the diet by weight, equivalent to up to 1,450 mg/kg/day[12]) for 5 consecutive 3-day periods. Evaluation of tolerance included assessment of observed or reported changes in bowel habits, stool appearance and consistency and anal leakage. Blood samples were collected to assess vitamin K absorption by prothrombin time and partial thromboplastin time evaluations. All subjects experienced flatulence during the study. No other significant discomfort was reported. Some minor changes in biological parameters were reported (not specified). An increase in percentage neutrophil count over pre-study values was accompanied by a decrease in percentage lymphocyte count with a slight decrease in total white blood cell count. A slight weight loss was observed for 3 subjects. The clinical significance of these findings is not known.

[15] Mean total food intake for adult is 29 g/kg/day (U.S. EPA 2011). Therefore, 1% in the diet = 1% x 29 g/kg/day = 0.29 g/kg/day = 290 mg/kg/day.

  - *Dermal***:** *PDMS (350 cs)* – New Zealand White rabbits (10/sex/group) received dermal applications of PDMS at doses of 0, 100, 300 or 1,000 mg/kg/day for 4 weeks. The test substance was removed after 6 hours of exposure each day. Before each dose, the application site was examined for signs of irritation. Animals were observed daily for signs of toxicity. Body weights and food consumption were monitored during the study. Blood samples were collected for hematology and blood chemistry evaluations on day 29 for males and day 30 for females. Macroscopic evaluation was performed at the end of the study. Selected organs were weighed and processed for microscopic examination. No treatment-related deaths or adverse signs were found. No changes on body weight, body weight gain, food consumption, hematology, blood chemistry and macroscopic and histopathologic findings were seen. The NOAEL for this study was therefore established at 1,000 mg/kg/day.
- HSDB 2011
  - *Inhalation: Mercapto-functional poly(dimethylsiloxane) silicone oil* – A vapor was generated by passage of air through the heated oil. Rats (strain, sex or number not reported) were exposed to 0.15 or 0.45 mg/L such oil vapors for 90 days. No significant effects were observed regarding pathology, clinical examinations and hematology. No further details about this study were provided.
- Oral and dermal pharmacokinetic studies on PDMS (10 and 350 cs) indicate that this inert polymer has essentially no potential for absorption (ECETOC 2011). The above oral studies conducted in animals consistently found ocular opacity at doses as low as 300 mg/kg/day in a chronic dietary study (no such effects were observed at 100 mg/kg/day) and microscopic changes and keratitis. Although the study authors attributed the effect to direct eye contact with food, a 90-day oral study revealed that ocular effects were found in animals exposed to PDMS via gavage and diet in a dose dependent manner (it should be noted that this effect was also found in control animals). No explanation was provided for the ocular results in controls or in treated animals dosed by gavage. Human oral studies revealed that PDMS at doses up to 2% (580 mg/kg/day) did not cause any adverse effects. At higher doses, however, flatulence and some changes in hematology were found, with unknown clinical significance. The weight of evidence suggests that no adverse systemic effects are expected to happen with silanol terminated PDMS (50 – 120 cs) at the oral dose of 100 mg/kg/day and greater. Dermal studies in rabbits did not find any adverse effects at doses of up to 1,000 mg/kg/day. Inhalation exposure to PDMS did not induce any adverse effects at doses tested up to 0.45 mg/L.

**Neurotoxicity (N)**

***Group II Score (single dose)* (vH, H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for neurotoxicity (single dose) based on negative findings in animals on PDMS. GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (single dose) when adequate negative data are available, chemicals have no structural alerts, and are not GHS-classifiable (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- ECETOC 2011
  - None of the single dose acute toxicity studies described under Systemic Toxicity Single Dose section reported any adverse neurological effects. It was not clear, however, if neurological endpoints were examined in all the studies. Those that specified some

neurological examinations are described again below:

- *Dermal: PDMS (350cs)* – Sprague-Dawley rats (5/sex) received PDMS on the skin at 2,008 mg/kg according to OECD Test Guideline 402. No behavioral abnormalities were noted during the test period (up to 14 days post dosing). .
- *Inhalation: PDMS (100,000 cs)* – Wistar rats (5/sex/group) received PDMS dissolved in dichloromethane via aerosol inhalation accordance with OECD Test Guideline 403. Exposure concentrations were 0, 153.5, 322.0, 334.6 and 694.8 mg/m$^3$. The top dose was the highest technically achievable concentration. A 14-day observation period followed the exposure. No changes in reflexes were observed with treatment.

- Based on the weight of evidence and the non-absorption of PDMS, no neurotoxicity is expected to happen as the result of silanol terminated PDMS (50 – 120 cs) exposure at oral dose of 2,008 mg/kg and inhalation dose of 0.695 mg/L (highest technically achievable concentration). These data indicate that silanol terminated PDMS (50 – 120 cs) is not classifiable under GHS.

***Group II* Score (repeated dose)* (H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for neurotoxicity (repeated dose) based on negative findings in animals studies at oral doses of up to 9,600 mg/kg/day on PDMS. GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (repeated dose) when adequate negative data are available, the chemicals have no structural alerts, and they are not GHS-classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- ECETOC 2011
  - None of the repeat dose toxicity studies described under Systemic Toxicity Repeated Dose section reported any adverse neurological effects. It was not clear, however, if neurological endpoints were examined in all the studies. Those that specified some neurological examinations are described again below:
  - *Oral*: *PDMS (35, 350 or 1,000 cs)* – In a subchronic oral toxicity study, male rats (100/group, strain not specified) received PDMS in the diet at 10% (equivalent to 9,600 mg/kg/day[16]) for 90 days. No treatment-related behavioral changes were seen in any group.
  - *Oral: KS66 (a mixture containing 92% PDMS and 8% silica)* – Fischer 344 rats (50/sex/dose) received KS66 in the diet at doses of 0, 1.25% or 5% (average intakes were 0, 444.9, and 1893.9 mg/kg/day in females and 0, 530.1 and 2,233.9 mg/kg/day for males) for 104 weeks. No changes were observed on the behavior of the rats.

**Skin Sensitization (SnS) Group II* Score (H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for skin sensitization based on negative results in animals and humans on PDMS. GreenScreen® criteria classify chemicals as a Low hazard for skin sensitization when adequate negative data are available, the chemicals have no structural alerts, and are not GHS-classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* Not on any screening lists.

[16] Average food factor for rats in subchronic studies is 0.096 kg/kg/day (U.S. EPA 1988). 10% in the diet is therefore 10% x 96 g/kg/day = 9.6 g/kg/day = 9,600 mg/kg/day.

- ECETOC 2011
    - The sensitization potential for PDMS of different viscosities (10 to 60,000 cs) was tested in multiple studies in mice, guinea pigs and 83 human subjects, and no evidence of cutaneous allergenic potential was displayed.
    - *PDMS (12,500 cs):* In a repeated insult patch test in humans, PDMS was used as a solvent control to dissolve a not specified substance at 5% (v/v). The study population consisted of 115 subjects between 18 and 70 years old. Aliquots of 0.2 ml study material and PDMS were applied under semi-occlusive conditions. The induction phase included 9 consecutive applications. The challenge phase was initiated during the 6$^{th}$ week of the study. Under the conditions of this study, no evidence of sensitization was found.

**Respiratory Sensitization (SnR) Group II* Score (H, M, or L):** DG
Silanol terminated PDMS (50 to 120 cs) was assigned a score of DG for respiratory sensitization based on lack of data.

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* Not on any screening lists.
- No data were identified.

**Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M, or L): M**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of M for skin irritation/corrosivity based on minimal/mild irritation in animals and humans on PDMS. GreenScreen® criteria classify chemicals as a Moderate hazard for skin irritation/corrosivity when they are mild skin irritants according to GHS classification criteria (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* Not on any screening lists.
- ECETOC 2011
    - PDMS with viscosities ranging from 20 to 100,000 cs are non-irritating to the skin in multiple tests under semi-occlusive conditions. Multiple sources support that PDMS fluids are non-irritating in classic Draize irritation tests. PDMSs are used as non-irritating reference compounds in the validation process of *in vitro* skin irritation assays. Other non-standard tests are described below:
    - *Hydroxy-terminated PDMS (60,000 cs)*: In an acute dermal toxicity limit test in rabbits, erythema was found at the site of application when applied for 24 hours under occlusive conditions. This irritation effect was fully reversible.
    - *PDMS (10 and 350 cs):* In a 28-day dermal toxicity study, the test compounds were not irritating when applied daily for 6 hours under semi-occlusion.
    - *PDMS (140 cs):* Repeated treatment to the ear of a rabbit (dose not specified) over 60 working days did not produce signs of toxicity.
    - *PDMS (unspecified viscosity):* Skin irritation was observed after 24 hours of contact under occlusion in rabbits.
    - *PDMS (unspecified viscosity):* No skin irritation was seen after 24-hour contact on the forearm in 54 male volunteers.
    - *PDMS (350 cs):* In a simple patch test using Finn chambers, healthy volunteers (25/sex, 18 – 37 years old) received 20 µl test compound on the back for 24 hours. No skin reaction was observed. The authors concluded that the local tolerance of the compound was good.

  - ECETOC concluded that PDMS fluids can be generally considered non-irritant to human skin under normal conditions of use. Only under extreme conditions (i.e. 24 hours under occlusion) can they cause reversible skin irritation.
- CIR 2012
  - Most dermal irritation studies in rabbits classified dimethicone (i.e., PDMS) as a minimal irritant.
- Based on the weight of evidence, PDMS compounds are considered mild dermal irritants. Therefore, silanol terminated PDMS (50 – 120 cs) is expected to be a mild dermal irritant (Category 3), according to GHS classification criteria.

**Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M, or L): M**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of M for eye irritation/corrosivity based on mild to moderate ocular irritation potential of PDMS which classify it to GHS Category 2B, and GHS categorization of 2 by New Zealand. Since the GHS New Zealand classification is based on transient conjunctival irritation that lasted 24-48 hours, the classification of Category 2B for ocular irritation is appropriate since the irritation resolved within 7 days after exposure (UN 2013). GreenScreen® criteria classify chemicals as a Moderate hazard for eye irritation/corrosivity when they are classified as GHS Category 2B (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* GHS-New Zealand – Category 6.4A (equivalent to GHS Category 2A/2B) for serious eye damage/eye irritation (differentiation between 2A and 2B was not made), due to:
    - Transient conjunctival irritation both in rabbits and humans for 24-48 hours after contact.
- CIR 2012
  - Most ocular irritation studies using rabbits classified dimethicone (i.e. PDMS) as a mild to minimal irritant, with a conjunctival reaction as the most frequently observed adverse effect.
- HSDB 2011
  - Lower viscosity PDMS oils cause slight transient sensation of irritation when applied to rabbit or human eyes, but no injury of the cornea. However, they delay healing of experimental corneal erosions.
- ECETOC 2011
  - *PDMSs* are used as non-irritating reference compounds in the validation process of *in vitro* eye irritation assays.
  - In 12 *in vivo* ocular irritation tests in rabbits (Draize tests), PDMS with viscosities ranging from 20 to 100,000 cs tested mostly negative for eye irritation. Minimal conjunctiva redness and chemosis were observed in some studies. Only in one study, PDMS (500 cs) induced mild epithelial edema. Other supporting evidence is described below:
  - *PDMS (viscosity not specified):* Slight and transient redness of conjunctiva was seen 1 hour after instillation of 0.1 ml test compound. This redness persisted for a longer time as viscosity increases. No further information was available.
  - *PDMS of varying viscosities* are mildly and transiently irritating to the eyes. No further information was provided.
  - *PDMS (100 cs):* Five samples with diverging acidities were tested in mice, guinea pigs and rabbits by instillation of a drop of the test substance onto the eyes once daily for 10

days. Only the two samples with high acidity values (acidity not specified) caused eye irritation.
    - ECETOC concluded that PDMS fluids can be considered mildly irritating to non-irritating to the human eye. Contact with low viscosity liquid may cause transitory conjunctival redness, probably due to the physical effect of the silicone causing disruption of the tear film and hence producing a "dry eye" effect. Atypical contact over a prolonged period may cause more marked irritation.
    - Several oral studies conducted in animals as discussed under repeated dose toxicity section consistently found ocular opacity at doses as low as 300 mg/kg/day in a chronic dietary study (no such effects were observed at 100 mg/kg/day) Microscopic ocular changes and keratitis were also observed. Although the study authors attributed the effect to direct eye contact with food, a 90-day oral study revealed that ocular effects were found in animals exposed to PDMS via gavage and diet in a dose dependent manner (it should be noted that this effect was also found in control animals). No explanation was provided for the ocular results in controls or in treated animals dosed by gavage.
- Based on the weight of evidence, lower viscosity PDMS compounds are mildly to moderately irritating to the eyes, which classifies them to GHS Category 2A (irritating). Silanol terminated PDMS (50 – 120 cs) is expected to have similar eye irritation potentials.

**Ecotoxicity (Ecotox)**

**Acute Aquatic Toxicity (AA) Score (vH, H, M, or L): L**

Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for acute aquatic toxicity based on low solubility and acute aquatic toxicity of PDMS. GreenScreen® criteria classify chemicals as a Low hazard for acute aquatic toxicity when sufficient data are available and the chemicals are not GHS classified, or the acute L/$EC_{50}$ values are greater than 100 mg/L (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* DSL – Silanol terminated PDMS is not "inherently toxic to aquatic organisms".
- ECETOC 2011
    - *Fish:* Early studies conducted with PDMS concentrations far in excess of their low water solubility (<1 ng/L) demonstrated that PDMS has very low acute toxicity to fish. Nominal $LD_{50}$ values were generally greater than 1,000 mg/L.
    - *Daphnia:* PDMS fluids have been tested in daphnia at concentrations above water solubility. Physical entrapment of daphnia may be observed when excess undissolved PDMS form a surface film. Therefore, these early studies are not relevant to the assessment of aquatic toxicity for PDMS.
    - *Daphnia: PDMS (50, 350 and 1,000 cs)* – Using a water soluble fraction and water accommodated fraction techniques, PDMS fluids were tested at concentrations of 50 – 100 ng/L. No mortalities were observed after 48 hours. According to ECETOC, as most of the water extractable silicon was lost probably due to evaporation from the test system, water accommodated fractions and water soluble fractions, these tests cannot be used to determine an accurate $LC_{50}$ or NOEC value.
    - *Marine copepod: PDMS (10 cs)* – 48 h $LC_{50}$ (immobilization) > 88,865 mg/L (the concentration refers to PDMS-water mix from which the water accommodated fraction was derived, rather than the final solution)

  - *Marine algae: PDMS (10 cs)* – $EC_{50}$ (growth and biomass) > 100,000 mg/L (nominal) in the diatom alga *Skeletonema costatum*. A slight effect on biomass was seen at 33,900 mg/L.
- Based on the weight of evidence, no adverse effects or even mortality were seen in aquatic organisms exposed to PDMS at concentrations far exceeding its water solubility. Therefore, the acute aquatic toxicity of silanol terminated PDMS (50 – 120 cs) is expected to be low.

**Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L): L**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for chronic aquatic toxicity based on low water solubility and chronic aquatic toxicity of PDMS. GreenScreen® criteria classify chemicals as a Low hazard for chronic aquatic toxicity when effect levels are higher than 10 mg/L (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* DSL – Silanol terminated PDMS is not "inherently toxic to aquatic organisms".
- ECETOC 2011
  - *Fish: PDMS (50 cs)* – In a fish early life-stage test, sheepshead minnow (*Cyprinodon variegatus*) embryos and larvae were exposed to PDMS emulsion for 33 days. Adverse effects on hatchability were observed at 212 mg/L. However, the emulsion control without PDMS also induced significant mortality and reduction in larval weight and length compared to the blank, and therefore emulsion components at least partially contributed to the adverse effects seen.
  - *Fish: PDMS (350 cs)* - In a 28-day feeding study, rainbow trout (*Oncorhynchus mykiss,* 10 in total) received PDMS at an estimated dose of 10,000 mg/kg/day. Fish were allowed a 14-day recovery after exposure. No mortality or changes in behavior or growth were observed. No abnormalities were found upon histopathologic examination of skin, muscle, liver, bile, adrenal, stomach and gut.
  - *Daphnia: PDMS (350 cs)* – As most PDMS in water is absorbed to particulate matter, aquatic organisms are most likely exposed to PDMS through sediment. In a 21-day life-cycle study, sediments with a medium (2 – 4%) organic carbon content were treated with 572 ± 23 mg/kg (measured) radiolabelled PDMS. Daphnids (60/group) were exposed to PDMS in flow-through test chambers for 21 days. The number of immobilized parental daphnids, cumulative number of offspring produced per adult female, and growth of offspring were evaluated. No adverse effects were observed in the study, and no radioactivity was detected in the overlying water during the study.
- Based on the weight of evidence, no adverse effects or even mortality were seen in aquatic organisms exposed to PDMS at concentrations exceeding water solubility. Therefore, the chronic aquatic toxicity of silanol terminated PDMS (50 – 120 cs) is expected to be low.

**<u>Environmental Fate (Fate)</u>**

**Persistence (P) Score (vH, H, M, L, or vL): vH**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of vH for persistence based on measured biodegradation half-life of over 70 days in water and over 876 – 1443 days in soil. GreenScreen® criteria classify chemicals as a very High hazard for persistence when biodegradation half-lives are greater than 60 days in water and over 180 days in soil (CPA 2012a).

- Authoritative and Screening Lists

  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* DSL – Silanol terminated PDMS is not persistent.
- HSDB 2011
  - *PDMS (300 cs):* No biodegradation was seen for $C^{14}$-labelled PDMS exposed to activate sludge for 70 days.
  - *PDMS (viscosity not specified):* Less than 10% biodegradation was observed when PDMS were incubated with activated sludge under aerobic and anaerobic conditions for approximately 2 months.
  - *PDMS (viscosity not specified):* In a 4-year field study, biodegradation half-life ranged from 876 days (in the top 10 cm of soil) to 1443 days, and over 50% loss was observed in the 0 – 2 cm layer over a 6-month growing season. The data suggest that biodegradation is not an important environmental fate process for PDMS.
  - *PDMS (204 cs):* $C^{14}$-labelled PDMS was added to moist soil and allowed to dry in order to generate silanols; fresh soil was then added and incubated for 4 months. Volatilization, oxidation, covalent binding with the soil, microbial mediated mineralization were responsible for the generation of small quantities of $C^{14}O_2$.
- PDMS compounds have measured biodegradation half-life of greater than 70 days in water, and greater than 180 days in soil.

**Bioaccumulation (B) Score (vH, H, M, L, or vL): vL**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of vL for bioaccumulation based on measured BCF of less than 100 and no bioaccumulation potential in aquatic, sediment and soil organisms for PDMS. GreenScreen® criteria classify chemicals as a very Low hazard for bioaccumulation when BCF values are less than 100 (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not on any authoritative lists.
  - *Screening:* DSL – Silanol terminated PDMS is not bioaccumulative.
- HSDB 2011
  - *PDMS (MW 1,200 – 56,000):* Bioconcentration of PDMS fluids were measured in silver carp. Following a 72-hour incubation period, fish had mean BCF values of 2.9, 7.1, 386 and 1,250 for molecular weights of 1,200, 6,000, 25,000 and 56,000, respectively. As silanol terminated PDMS (50 – 120 cs) is most likely to have a molecular weight between 1,000 and 6,000 as discussed in the beginning of this document, the most likely BCF for silanol terminated PDMS (50 – 120 cs) is between 2.9 and 7.1
  - *PDMS (viscosity not specified):* Phytoplankton (*Tetraselmis sp.*) exposed to PDMS for 9 days and then fed to mollusks (*Mytilis edulis*) for 12 days showed no evidence of bioconcentration.
  - *PDMS (viscosity not specified):* Phytoplankton and crustacean (*Artemia salina*) were exposed to PDMS for 8 days before fed to gold fish (*Carassius auratus*) for 15 days. No bioconcentration was observed.
  - *PDMS (viscosity not specified):* Annelids (*Nereis diversicolor*) were exposed to PDMS for 8 days before fed to fish (*Scorpaena porcus*) or crabs (*Carcinus maenas*) for 15 days. A BCF of less than 1 was observed.
- ECETOC 2011
  - PDMS fluids with viscosities > 10 cs are expected to have log $K_{ow}$ values greater than 10. Measuring log $K_{ow}$ is difficult due to extremely low water solubility (< 1 ng/L). Using reverse phase HPLC, PDMS with up to 14 repeating ($Si[CH_3]_2$) units were measured. Log $K_{ow}$ increased with molecular weight and PDMS with 14 repeating siloxy units had a

log $K_{ow}$ of 12.5. The number of repeating units in PDMS of viscosity > 10 cs is greater than 14 and therefore log $K_{ow}$ of linear PDMS (viscosity > 10 cs) is expected to be greater than 14.
    - *Linear PDMS with 2 – 7 repeating siloxy groups:* No detectable uptake (detection limit 0.3 mg/kg) was seen in rainbow trout after 56 days exposure to water containing 24 µg/L colloidal dispersion.
    - *PDMS (5cs, with an average of 12 siloxy repeating units):* Dietary exposure of gold fish for 67 days and guppy (*Poecilia reticulata*) for 20 days resulted in the detection of lower molecular weight PDMS in some fish tissue samples but no PDMS molecules more than 12 siloxy units (MW > 1,050) were found. Linear siloxanes with MW > 1,050 showed no bioconcentration or bioaccumulation in fish.
    - *PDMS (200 and 350 cs):* In two benthic macro-invertebrates, the midge larva of *Chironomus tentans* and the sediment worm *Lumbriculus variegatus*, no or limited bioaccumulation was found when they were exposed to up to 560 mg/kg (dry weight) PDMS in the sediment.
    - *PDMS (350 cs):* In an uptake-depuration study, no bioaccumulation potential was found in earthworms (*Eisenia foetida*) at nominal soil concentrations of 100 or 1,000 mg/kg after a 28-day exposure phase followed by a 14-day depuration period.
- Although silanol terminated PDMS (50 – 120 cs) is likely to have very high log $K_{ow}$ values probably due to very low water solubility, measured data in aquatic, soil and sediment organisms on PDMS revealed that it is unlikely to have any bioaccumulation potential.

**Physical Hazards (Physical)**

**Reactivity (Rx) Score (vH, H, M, or L): L**
Silanol terminated PDMS (50 – 120 cs) was assigned a score of L for reactivity based on non-explosiveness and absence of other information on reactivity. GreenScreen® criteria classify chemicals as a Low hazard for reactivity when there are negative data on as few as one relevant sub-category (e.g. explosivity) as long as there are no data stating otherwise (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* Not on any screening lists.
- ICSC 2001
    - PDMS liquid is not explosive
- CHRIS 1999
    - PMDS is not reactive with water or common materials
    - PMDS is stable during transport
- Sigma-Aldrich 2012
    - NFPA rating for Reactivity Hazard = 0

**Flammability (F) Score (vH, H, M, or L): L**
Silanol terminated PDMS (50 to 120 cs) was assigned a score of L for flammability based on that it is not a flammable liquid. GreenScreen® criteria classify chemicals as a Low hazard for flammability when negative data are available in as few as one relevant sub-category (e.g. flammable liquid) (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not on any authoritative lists.
    - *Screening:* Not on any screening lists.

- ICSC 2001
    - PDMS liquids are combustible.
- Sigma-Aldrich 2012
    - HMIS classification of Flammability = 0
    - NFPA rating for Fire = 0

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## APPENDIX A: Hazard Benchmark Acronyms
**(in alphabetical order)**

**(AA) Acute Aquatic Toxicity**

**(AT) Acute Mammalian Toxicity**

**(B) Bioaccumulation**

**(C) Carcinogenicity**

**(CA) Chronic Aquatic Toxicity**

**(D) Developmental Toxicity**

**(E) Endocrine Activity**

**(F) Flammability**

**(IrE) Eye Irritation/Corrosivity**

**(IrS) Skin Irritation/Corrosivity**

**(M) Mutagenicity and Genotoxicity**

**(N) Neurotoxicity**

**(P) Persistence**

**(R) Reproductive Toxicity**

**(Rx) Reactivity**

**(SnS) Sensitization- Skin**

**(SnR) Sensitization- Respiratory**

**(ST) Systemic/Organ Toxicity**

# APPENDIX B: Results of Automated GreenScreen® Score Calculation for Silanol Terminated PDMS (50 to 120 cs) (CAS #70131-67-8)

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

## GreenScreen® Score Inspector

**Table 1: Hazard Table**

| | | | Group I Human | | | | | Group II and II* Human | | | | | | | | | Ecotox | | Fate | | Physical | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Carcinogenicity | Mutagenicity/Genotoxicity | Reproductive Toxicity | Developmental Toxicity | Endocrine Activity | Acute Toxicity | Systemic Toxicity | | Neurotoxicity | | Skin Sensitization* | Respiratory Sensitization* | Skin Irritation | Eye Irritation | Acute Aquatic Toxicity | Chronic Aquatic Toxicity | Persistence | Bioaccumulation | Reactivity | Flammability |
| **Table 2: Chemical Details** | | | | | | | | | S | R * | S | R * | * | * | | | | | | | | |
| Inorganic Chemical? | Chemical Name | CAS# | C | M | R | D | E | AT | STs | STr | Ns | Nr | SNS* | SNR* | IrS | IrE | AA | CA | P | B | Rx | F |
| No | Silanol terminated PDMS | 70131-67-8 | L | L | L | L | DG | L | L | L | L | L | L | DG | M | M | L | L | vH | vL | L | L |

**Table 3a: Hazard Summary Table**

| Benchmark | a | b | c | d | e | f | g |
|---|---|---|---|---|---|---|---|
| 1 | No | No | No | No | No | | |
| 2 | No | No | Yes | No | No | No | No |
| 3 | STOP | | | | | | |
| 4 | STOP | | | | | | |

**Table 4**

| Chemical Name | Preliminary GreenScreen® Benchmark Score |
|---|---|
| Silanol terminated PDMS | 2 |

**Note:** Chemical has not undergone a data gap assessment. Not a Final GreenScreen™ Score

**Table 6**

| Chemical Name | Final GreenScreen® Benchmark Score |
|---|---|
| Silanol terminated PDMS | 2 |

After Data gap Assessment
**Note:** No Data gap Assessment Done if Preliminary GS Benchmark Score is 1.

**Table 5: Data Gap Assessment Table**

| Datagap Criteria | a | b | c | d | e | f | g | h | i | j | bm4 | End Result |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | | | |
| 2 | Yes | Yes | Yes | Yes | Yes | | | | | | | 2 |
| 3 | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | |

## APPENDIX C: Pharos Output for Silanol Terminated PDMS (50 to 120 cs) (CAS #70131-67-8)

### Siloxanes and Silicones, di-Me, hydroxy-terminated

**CAS RN: 70131-67-8**

**Synonyms: Polydimethylsiloxane, hydroxy end-block**

**Direct Chemical and Compound Hazard Quickscreen** — Detailed Hazard Listings

High Hazard of...

TERRESTRIAL — New Zealand HSNO/GHS (GHS-New Zealand): 9.4A - Very ecotoxic to terrestrial invertebrates - Not evaluated by GreenScreen

Medium Hazard of...

EYE IRRITATION — New Zealand HSNO/GHS (GHS-New Zealand): 6.4A - Irritating to the eye - GreenScreen Benchmark Unspecified

Low Hazard of...

RESTRICTED LIST — German FEA - Substances Hazardous to Waters (VwVwS): Class 1 Low Hazard to Waters - GreenScreen Benchmark Unspecified - occupational hazard only

This chemical is NOT present on the hazard lists scanned for the following health and ecotoxicity endpoints...

| | | | | |
|---|---|---|---|---|
| PBT | CANCER | DEVELOPMENTAL | REPRODUCTIVE | ENDOCRINE |
| GENE MUTATION | RESPIRATORY | NEUROTOXICITY | MAMMALIAN | SKIN IRRITATION |
| SKIN SENSITIZE | ORGAN TOXICANT | ACUTE AQUATIC | CHRON AQUATIC | FLAMMABLE |
| REACTIVE | GLOBAL WARMING | OZONE DEPLETION | | |

**Lifecycle Hazard Quickscreen** — Full Lifecycle Map

Research Status: Preliminary literature review drafted

The Pharos team has undertaken a preliminary literature review of some of the processes involved in the manufacture of this substance and identified the following chemicals. This list of chemicals is not exhaustive of all chemicals that may be involved in the production or life cycle of this substance.

May contain residual manufacturing chemicals that have a hazard of...

Comes from additional manufacturing chemicals that have a hazard of...

MAMMALIAN — Silicon, elemental [7440-21-3] - Integral Feedstock

FLAMMABLE — Silicon, elemental [7440-21-3] - Integral Feedstock

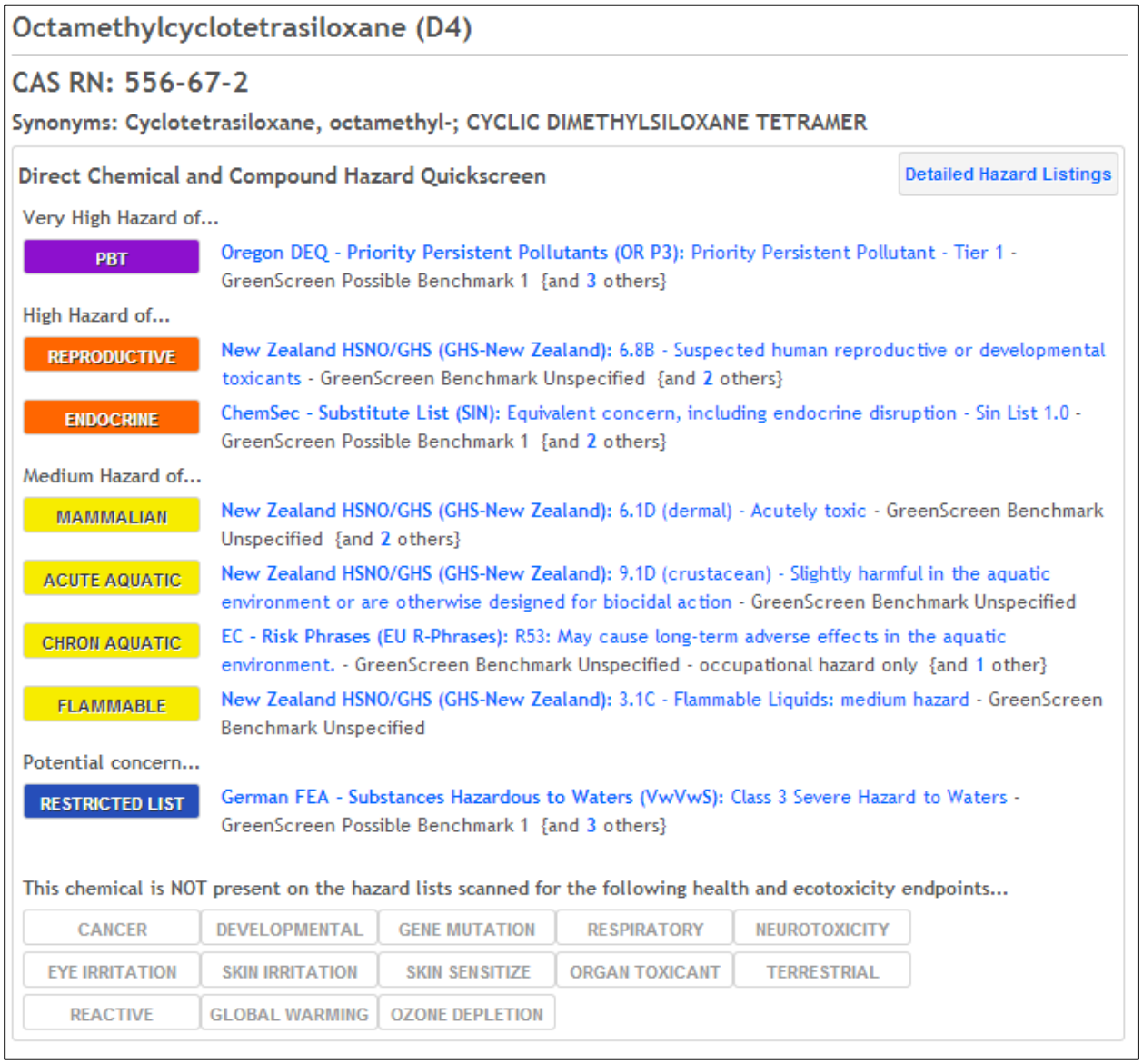
Description:

Mainly used in sealants, padding materials, paint and laquer. (Danish study)

VOC designation: VOC (Boiling point: 182 degrees Celsius)

More Information: http://webnet.oecd.org/CCRWEB/ChemicalDetails.aspx?ChemicalID=9f168816-1bd0-4eb7-9755-f853f13401e4

## APPENDIX D: Pharos Output for Cyclotetrasiloxane (D4) (CAS #556-67-2)



Octamethylcyclotetrasiloxane (D4)

CAS RN: 556-67-2

Synonyms: Cyclotetrasiloxane, octamethyl-; CYCLIC DIMETHYLSILOXANE TETRAMER

Direct Chemical and Compound Hazard Quickscreen — Detailed Hazard Listings

Very High Hazard of...

PBT — Oregon DEQ - Priority Persistent Pollutants (OR P3): Priority Persistent Pollutant - Tier 1 - GreenScreen Possible Benchmark 1 {and 3 others}

High Hazard of...

REPRODUCTIVE — New Zealand HSNO/GHS (GHS-New Zealand): 6.8B - Suspected human reproductive or developmental toxicants - GreenScreen Benchmark Unspecified {and 2 others}

ENDOCRINE — ChemSec - Substitute List (SIN): Equivalent concern, including endocrine disruption - Sin List 1.0 - GreenScreen Possible Benchmark 1 {and 2 others}

Medium Hazard of...

MAMMALIAN — New Zealand HSNO/GHS (GHS-New Zealand): 6.1D (dermal) - Acutely toxic - GreenScreen Benchmark Unspecified {and 2 others}

ACUTE AQUATIC — New Zealand HSNO/GHS (GHS-New Zealand): 9.1D (crustacean) - Slightly harmful in the aquatic environment or are otherwise designed for biocidal action - GreenScreen Benchmark Unspecified

CHRON AQUATIC — EC - Risk Phrases (EU R-Phrases): R53: May cause long-term adverse effects in the aquatic environment. - GreenScreen Benchmark Unspecified - occupational hazard only {and 1 other}

FLAMMABLE — New Zealand HSNO/GHS (GHS-New Zealand): 3.1C - Flammable Liquids: medium hazard - GreenScreen Benchmark Unspecified

Potential concern...

RESTRICTED LIST — German FEA - Substances Hazardous to Waters (VwVwS): Class 3 Severe Hazard to Waters - GreenScreen Possible Benchmark 1 {and 3 others}

This chemical is NOT present on the hazard lists scanned for the following health and ecotoxicity endpoints...

| | | | | |
|---|---|---|---|---|
| CANCER | DEVELOPMENTAL | GENE MUTATION | RESPIRATORY | NEUROTOXICITY |
| EYE IRRITATION | SKIN IRRITATION | SKIN SENSITIZE | ORGAN TOXICANT | TERRESTRIAL |
| REACTIVE | GLOBAL WARMING | OZONE DEPLETION | | |

## Lifecycle Hazard Quickscreen

Full Lifecycle Map

Research Status: Preliminary literature review drafted
The Pharos team has undertaken a preliminary literature review of some of the processes involved in the manufacture of this substance and identified the following chemicals. This list of chemicals is not exhaustive of all chemicals that may be involved in the production or life cycle of this substance.

May contain residual manufacturing chemicals that have a hazard of...

Comes from additional manufacturing chemicals that have a hazard of...

| | |
|---|---|
| RESPIRATORY | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| MAMMALIAN | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| EYE IRRITATION | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| SKIN IRRITATION | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| ORGAN TOXICANT | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| ACUTE AQUATIC | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| TERRESTRIAL | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| FLAMMABLE | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| REACTIVE | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| RESTRICTED LIST | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |

Description:

Octamethylcyclotetrasiloxane has widespread use in a variety of applications including fermentation processes, instant coffee production, paper coatings and sizing, diet soft drinks, waste yeast tanks, food washing solutions, adhesives, textiles, deasphalting, boiler treatments, detergents, cleaning solutions, surfactants, cosmetic products, and polishes. [USEPA/OTS; Tech Sup Doc Octamethylcyclotetrasiloxane (1985)]

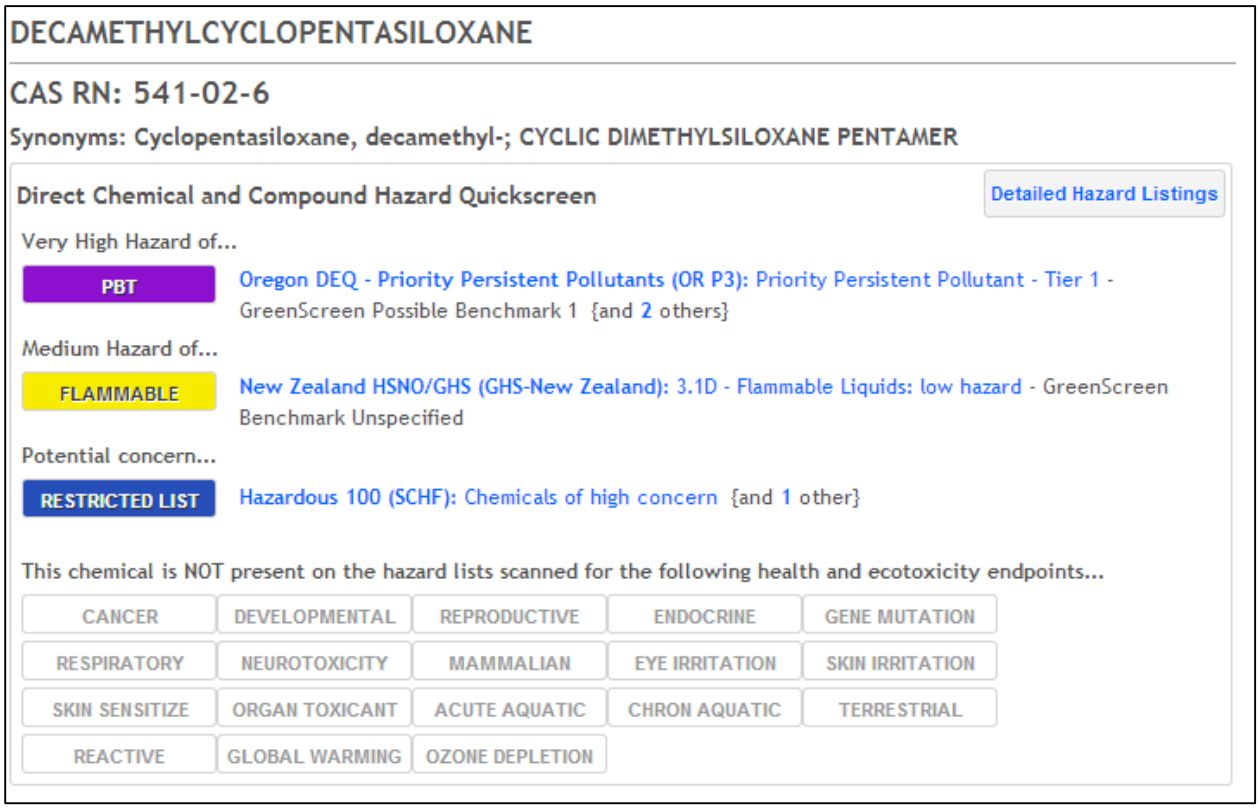
"D4 is an intermediate in the manufacture of polydimethylsiloxanes, which are used in industrial and consumer (personal care and household products) applications including fermentation processes, instant coffee production, paper coatings and sizing, diet soft drinks, waste yeast tanks, food washing solutions, adhesives, textiles, de-asphalting, boiler treatments, detergents, cleaning solutions, surfactants, cosmetic products, and polishes. In combination with D5, D4 is used in the cosmetics and toiletries industry under the trade name cyclomethicone. Annual U.S. import/production volume of D4 was between 100 and 500 million pounds in 2002 (U.S. EPA 2002). D4 has been detected in wastewater streams (Mueller et al. 1995). Human exposures can occur when personal care products, cosmetics and other consumer products containing this substance are used, and potentially could also occur through environmental exposures (HSDB). Horii and Kannan (2008) used measurements of D4 in consumer products to estimate the daily exposure rate for women in the United Sates (ages 19-65) to D4 from the use of personal-care products as approximately 1 milligram (mg)/day." (California study)

"...D4 is on Annex I to the Substance Directive (67/548/EEC) with a health classification as toxic to reproduction in category 3. The German justification for classification of D4 with regard to carcinogenic, mutagenic and reprotoxic effects is included in the reference list. D4 is on the list of potential PBT and vPvB (very persistent and very bioaccumulative) substances selected on the basis of screening criteria in the EU (DEPA 2003)."

VOC designation: VOC (Boiling point: 175 degrees Celsius)

More Information: http://oehha.ca.gov/multimedia/biomon/pdf/1208cyclosiloxanes.pdf

## APPENDIX E: Pharos Output for Cyclopentasiloxane (D5) (CAS #541-02-6)



DECAMETHYLCYCLOPENTASILOXANE

CAS RN: 541-02-6

Synonyms: Cyclopentasiloxane, decamethyl-; CYCLIC DIMETHYLSILOXANE PENTAMER

Direct Chemical and Compound Hazard Quickscreen

Detailed Hazard Listings

Very High Hazard of...

PBT — Oregon DEQ - Priority Persistent Pollutants (OR P3): Priority Persistent Pollutant - Tier 1 - GreenScreen Possible Benchmark 1 {and 2 others}

Medium Hazard of...

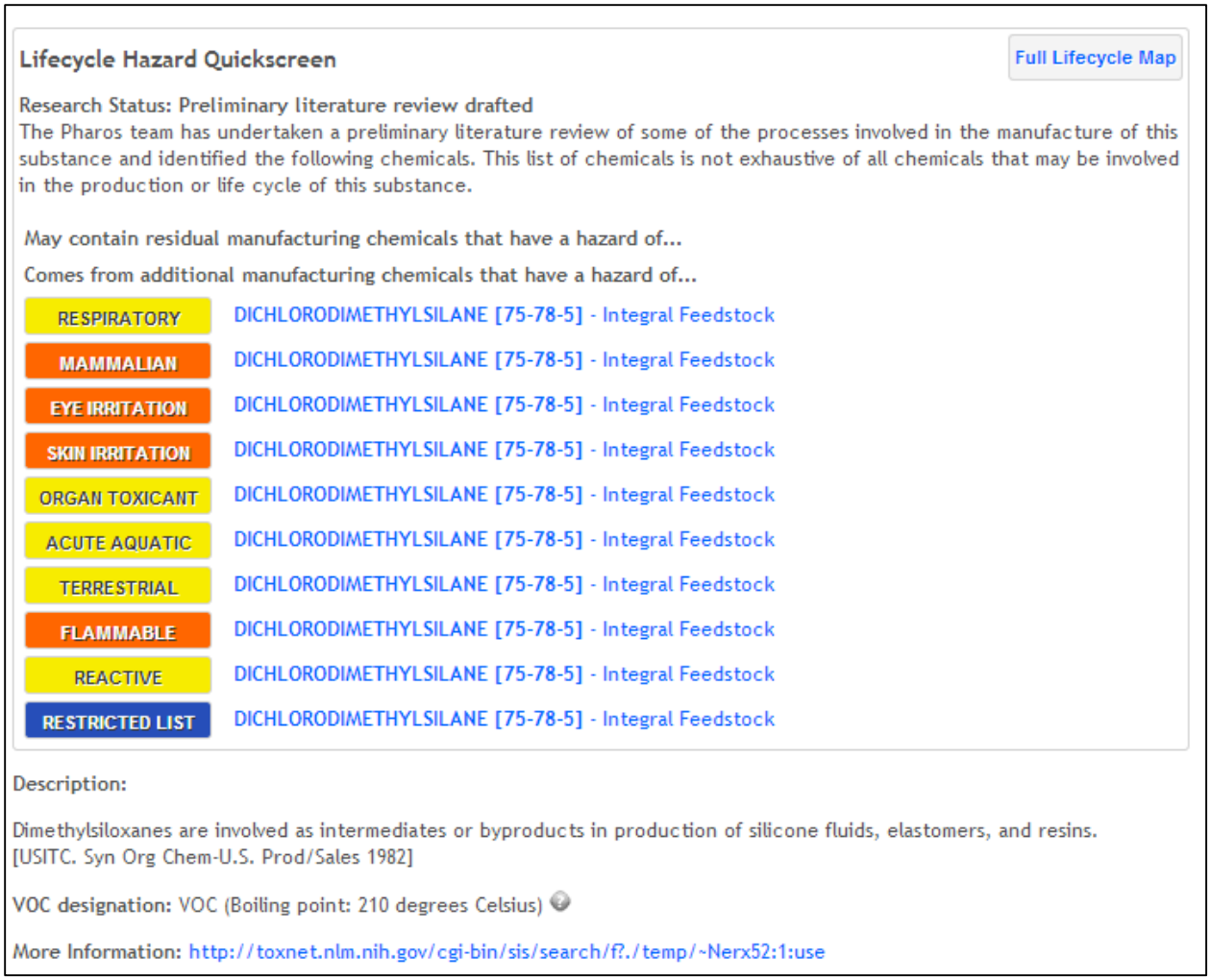
FLAMMABLE — New Zealand HSNO/GHS (GHS-New Zealand): 3.1D - Flammable Liquids: low hazard - GreenScreen Benchmark Unspecified

Potential concern...

RESTRICTED LIST — Hazardous 100 (SCHF): Chemicals of high concern {and 1 other}

This chemical is NOT present on the hazard lists scanned for the following health and ecotoxicity endpoints...

| | | | | |
|---|---|---|---|---|
| CANCER | DEVELOPMENTAL | REPRODUCTIVE | ENDOCRINE | GENE MUTATION |
| RESPIRATORY | NEUROTOXICITY | MAMMALIAN | EYE IRRITATION | SKIN IRRITATION |
| SKIN SENSITIZE | ORGAN TOXICANT | ACUTE AQUATIC | CHRON AQUATIC | TERRESTRIAL |
| REACTIVE | GLOBAL WARMING | OZONE DEPLETION | | |



## Lifecycle Hazard Quickscreen

Full Lifecycle Map

Research Status: Preliminary literature review drafted
The Pharos team has undertaken a preliminary literature review of some of the processes involved in the manufacture of this substance and identified the following chemicals. This list of chemicals is not exhaustive of all chemicals that may be involved in the production or life cycle of this substance.

May contain residual manufacturing chemicals that have a hazard of...

Comes from additional manufacturing chemicals that have a hazard of...

| | |
|---|---|
| RESPIRATORY | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| MAMMALIAN | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| EYE IRRITATION | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| SKIN IRRITATION | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| ORGAN TOXICANT | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| ACUTE AQUATIC | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| TERRESTRIAL | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| FLAMMABLE | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| REACTIVE | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |
| RESTRICTED LIST | DICHLORODIMETHYLSILANE [75-78-5] - Integral Feedstock |

Description:

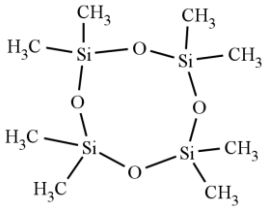
Dimethylsiloxanes are involved as intermediates or byproducts in production of silicone fluids, elastomers, and resins. [USITC. Syn Org Chem-U.S. Prod/Sales 1982]

VOC designation: VOC (Boiling point: 210 degrees Celsius)

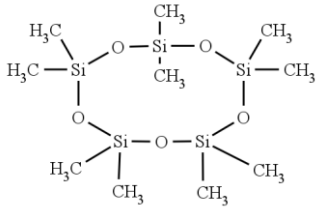
More Information: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~Nerx52:1:use

## APPENDIX F: Health Hazards of Cyclotetrasiloxane (D4) (CAS #556-67-2) and Cyclopentasiloxane (D5) (CAS #541-02-6)

Cyclotetrasiloxane (D4) and cyclopentasiloxane (D5) belong to the cyclomethicone and cyclic dimethyl siloxane chemical families. They are characterized by the $-Si(CH_3)_2-O-$ repeating unit, with D4 containing 4 of these repeating units closed in a circle, and D5 containing 5 (CES 2013). Their chemical structures are presented below:



**Cyclotetrasiloxane (D4)**
**(CAS #556-67-2)**



**Cyclopentasiloxane (D5)**
**(CAS #541-02-6)**

### Human Health Hazards

As mentioned in the GreenScreen® List Translator Screening Results section, D4 is associated with EU Risk Phrase R62 – possible risk of impaired fertility, and GHS Hazard Phrase H362f – suspected of damaging fertility (EC 2013). No EU Risk Phrases or GHS Hazard Phrases relating to human health hazards were identified for D5.

The health effects of cyclomethicones have been evaluated by the European Union Scientific Committee on Consumer Safety (SCCS) ( SCCS 2010), the European Union Scientific Committee on Consumer Products (SCCP) (SCCP 2005), the Canadian Ministries for Environment and Health (2008a,b), the California Office of Environmental Health Hazard Assessment (OEHHA) (2007, 2008), and the Cosmetic Ingredient Review (CIR 2009). The EU Scientific Committee on Consumer Safety (SCCS) reviewed available toxicity data on cyclotetrasiloxane (D4) and cyclopentasiloxane (D5) as part of their review of cyclomethicones in cosmetic products. In its review, SCCS noted that many of the studies would be considered unacceptable by current standards for toxicity testing.

The potential carcinogenicity of D4 was investigated in a long-term (2 year) inhalation study in male and female Fischer 344 rats (Plotzke et al. 2005). Inhalation exposure to D4 was associated with an increased incidence of mononuclear cell leukemia (MNCL) in male rats and benign uterine (endometrial) adenomas and hyperplasia in female rats at the highest concentration of D4 tested . Long-term exposure to D5 was also associated with increases in tumors. In a long-term (2 year) inhalation study in male and female Fischer 344 rats (Dow Corning 2003, 2005a,b), female rats exposed to D5 exhibited an increase in malignant tumors of the uterine endometrium (specifically, uterine adenocarcinoma).

The EU Scientific Committee on Consumer Products (SCCP) concluded that uterine neoplasms observed in female rats exposed to D4 via inhalation were related to a mode of action that is not relevant for humans due to the large degree of differences in endocrine regulation systems between rats and humans (SCCP 2005). However, both the SCCS (2010) and OEHHA (2007) noted that there are insufficient data to determine the relevance of the endometrial tumors reported in the cancer studies of D4 and D5.

Health effects data on cyclomethicone and cyclomethicone mixtures, including those containing D4 and D5, indicate that reproductive toxicity, hepatotoxicity, and carcinogenicity are critical health effects endpoints for this class of chemicals. Although adverse effects, particularly adverse effects on fertility, were seen with both D4 and D5, the EU SCCS concluded that cyclomethicone does not pose a risk for human health under the current practices of use (SCCS 2010). Cyclomethicones have been found by the CIR Expert Panel to be safe for use in cosmetics at up to 89% (CIR 2012).

**Environmental Hazards**
As mentioned in the GreenScreen® List Translator Screening Results section, D4 is associated with EU Risk Phrase R53 – may cause long-term adverse effects in the aquatic environment, and GHS Hazard Phrase H413 – may cause long lasting harmful effects to aquatic life (EC 2013). No EU risk phrases or GHS Hazard Phrases relating to environmental hazards were identified for D5.

Environment Canada assessed D4 and D5 in 2008, and concluded that cyclomethicones pose a hazard to the environment (Health Canada 2008a,b). In February 2012, the Canadian Environment Minister endorsed the findings of an independent scientific panel, known as the Board of Review (2012), which concluded that D5 does not pose a significant hazard to the environment based on a lack of evidence of toxicity to aquatic biota up to the limit of solubility in any environmental matrix and a lack of biomagnification. However, the Board of Review did not assess the environmental hazards of D4.

Wang et al. (2012) reviewed the fate and behavior of D4 and D5 in the environment. Wang et al. found that there was no evidence of trophic biomagnification of D4 or D5 in aquatic food web, while some aquatic organisms demonstrated a high degree of bioconcentration and bioaccumulation. Concentrations of cyclomethicones in water, sediment, and soil were all below their no-observed-effect-concentrations, suggesting that these compounds are unlikely to be environmentally hazardous.

**Overall Hazard Evaluation of Cyclotetrasiloxane and Cyclopentasiloxane**
Cyclomethicones used in personal care products are primarily cyclotetrasiloxane (D4) and cyclopentasiloxane (D5). In terms of potential adverse human health effects, exposure to high concentrations of D4 or D5 is associated with increased tumors in animals, although their relevance to humans is uncertain. D4 has been classified as an EU Category 3 reproductive toxicant (EU Risk Phrase R62: possible risk of impaired fertility). In addition to the potential carcinogenicity and reproductive toxicity of specific cyclomethicones, the liver, kidney, and thymus have been identified as target organs of toxicity in rodent studies. D4 is associated with EU Risk Phrase R53 – may cause long-term adverse effects in the aquatic environment, and GHS Hazard Phrase H413 – may cause long lasting harmful effects to aquatic life (EC 2013). D5 appears to pose a low risk to the environment; however, it is likely to persist in the environment, and appears to have the potential to bioaccumulate.

**Sources to Check for GreenScreen® Hazard Assessment**

Note: For a GreenScreen® Hazard Assessment, data queries should be initially limited to the following references. If data gaps exist after these references have been checked, additional references may be utilized.

*U.S. EPA High Production Volume Information System (HPVIS):*
*http://www.epa.gov/hpvis/index.html*

*UNEP OECD Screening Information Datasets (SIDS):*
*http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html*

*OECD Existing Chemicals Database: http://webnet.oecd.org/hpv/ui/SponsoredChemicals.aspx*

*European Chemical Substances Information System IUCLID Chemical Data Sheets:*
*http://esis.jrc.ec.europa.eu/index.php?PGM=dat*

*National Toxicology Program: http://ntp.niehs.nih.gov/*

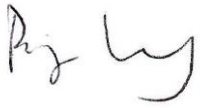
*International Agency for the Research on Cancer:*
*http://monographs.iarc.fr/ENG/Classification/index.php*

*Human and Environmental Risk Assessment (HERA) on ingredients of household cleaning products: http://www.heraproject.com/RiskAssessment.cfm*

*European Chemicals Agency (ECHA) REACH Dossiers: http://echa.europa.eu/*

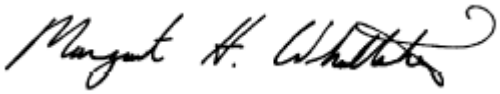
**Licensed GreenScreen® Profilers**

**Silanol Terminated PDMS GreenScreen® Evaluation Prepared by:**



Bingxuan Wang, Ph.D.
Toxicologist
ToxServices LLC

**Silanol Terminated PDMS GreenScreen® Evaluation QC'd by:**



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Managing Director and Chief Toxicologist
ToxServices LLC