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GS-144

# SILOXANES AND SILICONES, DI-ME, HYDROXY-TERMINATED

**(CAS #70131-67-8)**

**GREENSCREEN® FOR SAFER CHEMICALS (GREENSCREEN®)**

**ASSESSMENT**

**Version 1.5a**

**Prepared by:**

**ToxServices LLC**

**Assessment Date: October 23, 2026**

**Expiration Date: October 23, 2031**

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**GreenScreen® Polymer Substance Assessment**

**Polymer Substance Name:** Siloxanes and silicones, di-me, hydroxy-terminated (CAS #70131-67-8)[1]

**Trade Name:** Generic

**Manufacturer:** Not applicable

**Method Version: GreenScreen® for Safer Chemicals v1.5a**

**Assessment Details:**

| | |
|---|---|
| **Assessment Type[2]:** | Certified |
| **Current Assessment v1.5a Prepared By:** | Deb Remeikas, B.S., M.A.<br>Toxicologist<br>ToxServices LLC |
| **Current Quality Control v1.5a Performed By:** | Bingxuan Wang, Ph.D., D.A.B.T.<br>Senior Toxicologist<br>ToxServices LLC |
| **Assessment v1.5a Prepared For:** | Washington Department of Ecology |
| **Date Assessment 1.5a Completed:** | October 23, 2026 |
| **Assessment Expiration Date:** | October 23, 2031 |
| **Assessor Type:** (Licensed GreenScreen® Profiler or equivalent, Authorized GreenScreen® Practitioner or Unaccredited) | Licensed GreenScreen® Profiler |

[1] Siloxanes and silicones, di-Me, hydroxy-terminated is an inorganic polymer (EC 2012) and therefore is assessed as a polymer substance per GreenScreen® Chemical Hazard Assessment Guidance v1.5a.

[2] **Assessment Type**: GreenScreen® reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen® Practitioner), or "CERTIFIED" (by Licensed GreenScreen Profiler or equivalent);-**Assessment Prepared By**: Licensed GreenScreen® Profilers must provide name of organization; Authorized GreenScreen® Practitioners must provide their name;
**Assessment Prepared For**: Optional for Licensed GreenScreen® Profilers, mandatory for Authorized Practitioners; **Date Assessment Completed**: Assessments by Licensed GreenScreen® Profilers require quality control tracked via internal documentation;
**Assessment Expiration Date**: Assessments expire five years from the date of completion starting from January 1, 2019. An assessment expires three years from the date of completion if completed before January 1, 2019 (CPA 2023).

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# GREENSCREEN BENCHMARK™ SUMMARY FOR SILOXANES AND SILICONES, DI-ME, HYDROXY-TERMINATED (CAS #70131-67-8)

**Method Version: GreenScreen® Version 1.5a**
**Assessment Type: Certified**
**Assessor Type: Licensed GreenScreen® Profiler**
**See Appendix A for an overview of endpoint-specific hazard acronyms.**
**Databases Appendix B were searched for relevant chemical, human health, environmental, and physical hazard data (Note: Klimisch 3 or 4 rated studies are not included in the CHA).**
**See Appendix C for Artificial Intelligence (A.I.)-based search output (Google AI or ChatGPT).**

Siloxanes and silicones, di-Me, hydroxy-terminated functions as a chemical intermediate, industrial anti-seizing and structure-control agent, as well as an antifoaming and moisturizing agent in cosmetics. Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a **GreenScreen Benchmark™ Score of 2** ("Use but Search for Safer Substitutes") based on the following hazard score combination:

- Benchmark 2c
    - Very High Persistence-P + Moderate (Group II Human)-Eye irritation (IrE)

A data gap (DG) exists for endocrine activity-E. As outlined in Annex 5 (GreenScreen Benchmark™ Data Requirement), siloxanes and silicones, di-Me, hydroxy-terminated meets the requirements for a GreenScreen Benchmark™ Score of 2 despite the hazard data gap. In a worst-case scenario, if siloxanes and silicones, di-Me, hydroxy-terminated were assigned a High score for the data gap E, it would be categorized as a Benchmark 1 Chemical.

Common residual monomers reported in the literature for silicone oils in general include hexamethylcyclotrisiloxane (D3), octamethylcyclotetrasiloxane (D4), and decamethylcyclopentasiloxane (D5). These residuals are GreenScreen Benchmark™ 1 chemicals. However, levels of these residuals are not reported for the specific polymer under assessment.

This GreenScreen® assessment evaluates a generic siloxanes and silicones, di-Me, hydroxy-terminated polymer with a molecular weight > 1,000 and residual monomers < 100 ppm. Therefore, residual monomer hazards do not affect the final benchmark score in a Chemical of High Concern (CoHC) analysis. There are no known environmental transformation products that could affect the final benchmark score. The GreenScreen® Polymer Hazard Summary Table is presented in Table 1, below.

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**Table 1. GreenScreen® Polymer Hazard Summary Table**[3]

| GreenScreen® Polymer Hazard Summary Table for Siloxanes and Silicones, di-Me, Hydroxy-Terminated | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Group I Human | | | | | Group II and II* Human | | | | | | | | | Ecotox | | Fate | | Physical | | Climate Impact | | |
| | % By Weight | Carcinogenicity | Genotoxicity/Mutagenicity | 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 | Ozone Depletion Potential | Global Warming Potential | GreenScreen Benchmark™ |
| | | | | | | | | single | repeat* | single | repeat* | * | * | | | | | | | | | | | |
| **Polymer Substance** | 100 | **L** | **L** | **L** | **L** | DG | **L** | **L** | **L** | *L* | *L* | **L** | *L* | **L** | *M* | **L** | *L* | **vH** | **vL** | *L* | **L** | NA | NA | 2 |

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated 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 Group II Human Health endpoints 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. Group II* Human Health endpoints are indicated by an * after the name of the hazard endpoint or after "repeat" for repeated exposure sub-endpoints. The "Not Applicable (NA)" hazard level is reserved for the Climate Impact endpoints (ODP, GWP) and is assigned to non-volatile compounds or for substances that are not gases or vapors under normal conditions.

[3] For Systemic Toxicity and Neurotoxicity, repeated exposure data are preferred. Lack of single exposure data is not a Data Gap when repeated exposure data are available. In that case, lack of single exposure data is shown as a shaded cell instead of DG.

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## POLYMER PROPERTIES AND CONSTITUENTS

Siloxanes and silicones, di-me, hydroxy-terminated is an α,ω-dihydroxydimethyl-polysiloxane, a polymer consisting of repeating units of dimethylsiloxane terminated with hydroxyl groups produced via condensation. An increase the molecular weight occurs when produced in the presence of acid or alkaline catalysis, releasing water and also allowing ethoxylation to occur. It is also known as dimethiconol, belonging to the chemical class of linear polydimethylsiloxane (PDMS) chemicals, also known as dimethicone, and associated with the CAS #s 70131-67-8, 31692-79-2 (CIR 2017), and 63148-60-7 (Pharos 2026, ECHA CHEM 2026).

Siloxanes and silicones, di-me, hydroxy-terminated functions as a chemical intermediate, anti-seizing agent, and structure-control agent used in various industries (i.e., textile, polymer, silicone (room temperature vulcanizing (RTV)-rubber), and daily-use chemical industries) (Sunoit 2026, UCT 2013), and an antifoaming, skin conditioning (emollient), and moisturizing agent in cosmetic formulations (EC 2026).

Siloxanes and silicones, di-me, hydroxy-terminated is a liquid that is insoluble in water. The polymer reviewed in this GreenScreen® assessment is a generic polymer with a molecular weight > 1,000 Da and residual monomer concentrations < 100 ppm. A search of various products registered under the name dimethiconol and/or CAS #70131-67-8 / 31692-79-2 indicates that it is available in various viscosities ranging from 15 – 1,000,000 cSt corresponding to molecular weights 400 – 310,000, the majority of which are > 1,000 Da (CIR 2017, Cymit Quimica 2026).

The Cosmetic Ingredient Review (CIR) Expert Panel evaluated the safety of siloxanes and silicones, di-me, hydroxy-terminated (aka dimethiconol) and its esters as a group due to their common function in cosmetic formulations (CIR 2003, 2010, 2017). As the present report is for the generic polymer, ToxServices evaluated the following tradename materials as the target polymer which were identified by CIR (2017) and PubChem (2026) with data and containing > 80% siloxanes and silicones, di-Me, hydroxy-terminated (CAS #70131-67-8):

- *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*: contains ≤ 2% dimethylcyclosiloxanes (CAS #69430-24-6)) (Wacker Chemie GmbH 2024, CIR 2017).
- *Siloxanes and silicones, di-Me, hydroxy terminated in uncured DC 5392 (96% purity, CAS #70131-67-8)* (Dow Corning 1994a; CIR 2017).
- *Dow Corning Q4-2797 (4-2797 INT and PA fluid) (≥ 95% purity, CAS #70131-67-8)*: contains < 5% cyclic polysiloxanes as predominantly D4 (CAS #556-67-2) and D5 (CAS #541-02-6)) (Dow Corning 1994b; CIR 2017).
- *Dow Corning X7-9192 (≥ 95% purity, CAS #70131-67-8)*: contains < 5% cyclic polysiloxanes as predominantly D4 (CAS #556-67-2) and D5 (CAS #541-02-6)) (CIR 2017).
- *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8)* (Dow Corning 1998, CIR 2017).
- *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*: a mixture consisting of 80% CAS #70131-67-8 and 20% 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysiloyl propyl (P82-450)) (Union Carbide Corporation 1992; CIR 2017).
- *Silicone L-9000/1000 (1,000 cSt, CAS #70131-67-8)* (Union Carbide Corporation 1994; PubChem, CAS #70131-67-8, 2026).

Additional tradenames with data were identified by CIR (2017) and/or reported in TSCA submissions; however, the test substances contained low concentrations of the target polymer, and therefore only data for higher concentrated/pure target polymer substances are summarized.

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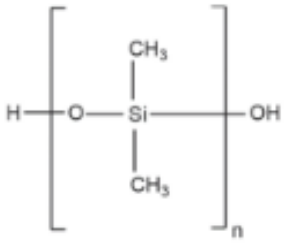
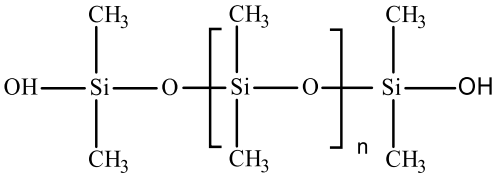
**Table 2. Structural Properties for the Polymer Substance**

| Property | Description | Reference |
|---|---|---|
| Molecular Formula | $HO[-Si(CH_3)_2O-]_nOH$; Variable | ECETOC 2011; CIR 2017 |
| General polymer class | Inorganic – Primary backbone consists of silicon | ECETOC 2011, CIR 2017 |
| Structure (include whether monomers are blocked and the pattern) |   | ECETOC 2011; CIR 2017 |
| Number average molecular weight (Mn) | >1,000 | |
| Weighted-average molecular weight (Mw) | >1,000 | |
| Physical state | Liquid | Dow 2026 |
| Percent Amine Nitrogen (%A-N) [4] | Not applicable | |
| Reactive Functional Group (with their respective charge), and Functional Group Equivalent Weight | Silicon Hydroxyl groups (SiOH) | CIR 2017 |
| | Not available | |
| Overall Charge | Neutral | Expert judgment |
| Solubility (mg/L water @ 25ºC) | Insoluble | CIR 2017 |
| Swellability (Insoluble/non-water absorbing ("non-swellable"), or Water absorbing ("swellable")) | Insoluble/non-water absorbing | ECETOC 2011, CIR 2017 |
| Particle Size Distribution (microns) | Not applicable (liquid) | |
| Other key characteristics (e.g., surface chemistry) | Not available | |

[4] The percent of amine nitrogen (or other cationic atom) can be used in the cationic nitrogen polymer Structural Activity Relationships (SARs) for estimation of aquatic toxicity.

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**Table 3. Inventory of Polymer Substance Constituents**

| Constituent | Chemical Name | CASRN | Weight Percent (Wt %) in Polymer Substance | Additional Information (synonyms, etc.) |
|---|---|---|---|---|
| **1) Polymer Substance:** | | | | |
| a) Polymer species > 0 ppm (0%) | Siloxanes and silicones, di-Me, hydroxy-terminated | 70131-67-8 | 100 | Not available |
| b) Residual Monomer(s) ≥ 100 ppm (0.01%) | None | N/A | N/A | N/A |
| c) Oligomer(s) with a molecular weight (MW) below 500 Dalton | None | N/A | N/A | N/A |
| d) Oligomer(s) with a molecular weight (MW) below 1000 Dalton | None | N/A | N/A | N/A |
| e) Stabilizer(s) ≥ 100 ppm 0.01%) | None | N/A | N/A | N/A |
| f) Substance Impurities ≥ 100 ppm (0.01%): | | | | |
| i) Catalyst | None | N/A | N/A | N/A |
| ii) Other | None | N/A | N/A | N/A |

No qualifying constituents[5] are assumed to be present in siloxanes and silicones, di-me, hydroxy-terminated as all impurities including residual monomers are assumed to be below the GreenScreen® Guidance specified cutoff level of 1,000 ppm (0.1%) as described in Annex 8 (CPA 2026). Additionally, as no oligomers are assumed to be present, the hazards of the oligomers do not need to be considered separately in the assessment.

## SIMILAR POLYMER SUBSTANCES

*Note: The term "similar polymer substance" in the GreenScreen® guidance v1.5a is used for applying GHS bridging principles. "Similar polymer substance" is defined as a polymer similar to the original polymer but with residual or unreacted monomers and other impurities equal to or greater than the concentration of the same monomer or impurity in the original polymer (CPA 2026).*

Similar polymers are not applicable because the polymer reviewed in this GreenScreen® assessment is a generic polymer, and all polymers associated with the CAS number 70131-67-8 are considered the target polymer.

## CHEMICAL SURROGATES

Due to limited available health effects and environmental data on the target generic polymer, methyl-terminated linear PDMS (CAS #63148-62-9/9016-00-6/9006-65-9) are used as surrogates. Methyl-

[5] According to GreenScreen® Guidance v1.5a (Annex 8), qualifying constituents are defined as any impurities such as catalyst or additive or residual monomers present in the polymer substance at ≥ 1,000 ppm (0.1%) (CPA 2026).

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terminated linear PDMS is a structurally similar polymer sharing the same polysiloxane backbone and principal repeating unit –$Si(CH_3)_2$–O–, but differs from the target polymer in that it is methyl-terminated instead of hydroxy-terminated.

PDMS are the most common liquid silicones. 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 (Utrera-Barros et al. 2025). The target polymer, siloxanes and silicones, di-Me, hydroxy-terminated, of various grades (i.e., silanol-terminated PDMS), are used to produce methyl-terminated PDMS. The silanol groups of the hydroxy-terminated PDMS polymers render the PDMS susceptible to condensation under both acid and base conditions (Stealth 316 Undated). The condensation of silanol groups forms siloxane bonds which are used to cross-link siloxanes in commercial applications and to take full advantage of the unique properties of PDMS polymers (Utrera-Barros et al. 2025). A typical reaction system consists of a hydroxy-terminated PDMS, a crosslinker 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.

Cyclic and linear PDMS have been evaluated by numerous agencies including the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1979 and re-evaluated in 2011 (JECFA 2026), the United States Environmental Protection Agency (U.S. EPA) , the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) in 2004 and re-evaluated in 2011 (ECETOC 2011), the European Food Safety Authority (EFSA) in 2004 and re-evaluated in 2020 (EFSA 2020), the Danish Technical University (DTU) National Food Institute in 2005 and 2014 (Danish EPA 2005, 2014), Health Canada (HC 2023), and CIR (2003, 2010, 2022).

For linear PDMS chemicals, the molecular weights determine their viscosities, and the number of repeating units (n) governs the molecular weights (ECETOC 2011). Similar to the target polymer, 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 4 below (ECETOC 2011).

Although the target polymer also belongs to the broad chemical class of PDMS, ToxServices uses the term PDMS hereafter in this GreenScreen® assessment to refer to methyl-terminated linear PDMS.

**Table 4. Relationship Between Viscosity and Degree of Polymerization for Linear PDMS (CAS #63148-62-9/9016-00-6/9006-65-9)**

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

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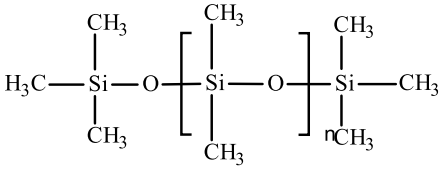
**Surrogate Structure:**



Surrogate: Methyl-terminated PDMS (CAS #63148-62-9/9016-00-6/9006-65-9)
(when n > 10, MW > 1,125) (ECETOC 2011)

## ENVIRONMENTAL TRANSFORMATION PRODUCTS

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

Siloxanes and silicones, di-me, hydroxy-terminated 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 in general, including the target chemical, 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, PDMS will strongly adsorb to particulate matter in water and soil, where they are immobilized. Abiotic breakdown 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). Dimethylsilanediol is an LT-UNK chemical and listed on the German FEA list of Substances Hazardous to Waters (VwVwS) as a Class 1 substance (Low Hazard to Waters). Based on the molecular formula of siloxanes and silicones, di-me, hydroxy-terminated, 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 that are not relevant with respect to the GreenScreen® score for siloxanes and silicones, di-me, hydroxy-terminated.

As no feasible and relevant environmental transformation products are identified with LT-1 scores, the benchmark score of the parent compound is not modified by transformation products.

[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.

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| Table 5. Feasible and Relevant Transformation Products of Siloxanes and Silicones, di-Me, Hydroxy-Terminated (CAS #70131-67-8) | | | | | | |
|---|---|---|---|---|---|---|
| **Life Cycle Stage** | **Transformation Pathway** | **Environmental Transformation Products** | **CAS #** | **Feasible (Yes or No)** | **Relevant (Yes or No)** | **GreenScreen® List Translator Score or GreenScreen® Benchmark™ Score[7,8]** |
| Intermediate | Abiotic Degradation / Hydrolysis (Acid) | Dimethylsilanediol | 1066-42-8 | Yes | No | LT-UNK |

## POTENTIAL CHEMICALS OF HIGH CONCERN

The GreenScreen® Polymer Criteria (CPA 2026) require a Chemicals of High Concern (CoHC) analysis when the following conditions are met: any of the Group I human Health endpoints are assessed using Polymer Criteria Step 2c procedure (i.e., based on data on qualifying constituents or components), the final score for that endpoint is Moderate, Low or DG, and the residual monomer/catalyst of concern is present at 100 ppm or above.

No potential Chemicals of High Concern (CoHC) were identified as any residual monomer or catalyst are present in the polymer at <100 ppm (0.01%).

## SPECIAL CASE IMPURITIES

**Table 6. Special Case Impurities < 100 ppm in the Polymer Substance**

| Chemical Name | CASRN | (ppm) | GreenScreen® List Translator score | Function | Reason for Inclusion |
|---|---|---|---|---|---|
| Hexamethylcyclotrisiloxane (D3) | 541-05-9 | < 100 | BM-1 | Residual monomer | Monomers < 100 ppm are considered special case impurities |
| Octamethylcyclotetrasiloxane (D4) | 556-67-2 | < 100 | BM-1 | Residual monomer | |
| Decamethylcyclopentasiloxane (D5) | 541-02-6 | < 100 | BM-1 | Residual monomer | |

The List Translator results were obtained from Pharos (2026) and can be found in Appendix G for the residual chemicals D3, D4, and D5, which were identified by CIR (2017) as potential impurities of the target chemical. However, the EU Scientific Committee on Consumer Safety (SCCS) concluded that cyclomethicones, including D4 and D5, are of low concern for human health under the current practices of use (SCCS 2010, 2016). Furthermore, the Cosmetic Ingredient Review (CIR) Expert Panel determined that D4 and D5 are safe for use in cosmetic and personal care products at concentrations up to 89% of formulated products, and there are no reported use of D3 in these products (CIR 2011). The presence of these residuals should be considered when doing an alternatives assessment involving PDMS.

[7] The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to screen for GreenScreen Benchmark™ 1 chemicals (CPA 2026). Pharos (Pharos 2026) is an online list-searching tool that is used to screen chemicals against the lists in the List Translator electronically.
[8] A GreenScreen® assessment of a transformation product depends on the Benchmark score of the parent chemical (see GreenScreen® Guidance).

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## TOXICOKINETICS

No toxicokinetic data were identified for siloxanes and silicones, di-Me, hydroxy-terminated. As a high molecular weight polymer, it is not expected to be significantly bioavailable (CIR 2017).

Similarly, surrogate PDMS is not expected to be significantly bioavailable as a high molecular weight polymer. Oral toxicokinetic studies in rats exposed to 10 – 1,000 cSt viscosity PDMS at doses up to 2,500 mg/kg resulted in trace amounts of test substance in tissues, with 93.6% of the test substance almost completely recovered in the feces without detectable degradation or metabolic products (ECETOC 2011).

- *In vivo: Oral*: *Surrogate: PDMS (35 or 1,000 cSt)*: Male Sprague-Dawley rats (number not specified) were administered oral doses of PDMS (35 or 1,000 cSt viscosity) at 250 or 2,500 mg/kg/day (0.5% or 5.0%, respectively) in the feed for 13 days followed by a single oral dose of $^{14}$C-radiolabeled PDMS on day 14. All of the animals were sacrificed 48 hours after receiving the radiolabeled dose. The bulk of the dose was identified in the gastro-intestinal tract or feces, and only trace amounts of radioactivity were identified in other tissues. No shifts in mass or metabolites were observed when the samples were analyzed via chromatography.
- *In vivo: Oral*: *Surrogate: PDMS (10 or 350 cSt)*: Male and female Fischer 344 rats (number not specified) were administered single oral doses of $^{14}$C-radiolabeled PDMS (10 or 350 cSt) at 1,000 mg/kg via gavage. Groups of animals were sacrificed after 12, 24, 48, and 97 hours. Excreta were collected over the observation period, up to 96 hours. No significant levels of radioactivity were measured outside of the gastrointestinal tract. Approximately 93.6% of the administered dose was recovered and 99.6-99.8% of the recovered dose was identified in the feces. No detectable degradation or metabolic products were identified.

## HAZARD CLASSIFICATION SUMMARY

***Note: Step 2 for classifying human health and ecotoxicity hazards of polymer consists of four separate sub steps. These are 2a: Use test data for polymer, 2b: Apply bridging principles for similar polymer, 2c: Apply hazard criteria for qualifying constituents or components and 2d: Apply expert judgment. See GreenScreen® Guidance v1.5a, Figure 3 for more details.***

### GROUP I HUMAN HEALTH EFFECTS (GROUP I HUMAN)

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

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for carcinogenicity based on a negative chronic study in dogs as an implant, its expected lack of bioavailability, lack of structural alerts, and negative results in chronic studies in rats and mice exposed to surrogate PDMS by the oral route. GreenScreen® criteria classify polymers as a Low hazard for carcinogenicity when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score was high as it is based on a study on the target chemical via more conservative routes of exposure, and on studies on strong surrogates.

- **Polymer Substance (2a):**
  - Dow Corning 1994a, CIR 2017
    - *Siloxanes and silicones, di-Me, hydroxy terminated in uncured DC 5392 (96% purity, CAS #70131-67-8)*: In chronic implantation studies, pure-bred Beagle dogs (n=38, approx. 5-7 months old) received surgically placed intramuscular, intraperitoneal, and subdermal implants composed of uncured tradename

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siloxanes and silicones, di-Me, hydroxy terminated for 3, 9, 24, or 36 months. There were no treatment-related histopathology or gross pathology findings and no evidence of tumorigenesis.

- *Note: Although these exposure routes are representative of exposures related to medical device implants instead of the standard routes (i.e., oral, dermal, or inhalation) assessed in GreenScreen®, they result in higher exposure levels and more systemic exposure. Therefore, a lack of findings in these studies supports expected lack of carcinogenic effects by oral, dermal, and inhalation routes.*

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - No qualifying constituents are identified for siloxanes and silicones, di-Me, hydroxy-terminated.
- **Professional Judgment (2d):**
  - CIR 2017, U.S. EPA 2013
    - Siloxanes and silicones, di-Me, hydroxy-terminated is unlikely to be significantly bioavailable because it will not be metabolized or absorbed due to its high MW (> 1,000) and insolubility. Therefore, no carcinogenicity is expected.
  - OECD 2026
    - The representative structure for the target polymer (SMILES: C[Si](C)(O)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O), contains no structural alerts for carcinogenicity (Appendix I).
  - ECETOC 2011, EFSA 2020, CIR 2022
    - *Oral: Surrogate: PDMS (1,500 cSt, Tradename: DC Antifoam A)*: In a pre-GLP, pre-guideline 2-year study published in 1950, male and female Wistar rats (25/sex/group) were fed a diet containing 0.3% of a PDMS-containing compound (Tradename: DC Antifoam A, 93% PDMS, 1,500 cSt, and 7% silica treated with polydimethylsiloxane (CAS# 67762-90-7)), reported by EFSA to be equivalent to 139 mg/kg/day assuming 93% PDMS. Hematological examinations were performed periodically in a group of 10 female rats (treated and control) during the course of the study, and at study termination, hematology, clinical chemistry, organ weights, and histopathology of major organs were performed. The average final body weight of treated male rats was increased compared to controls. No adverse effects were reported
    - *Oral: Surrogate: PDMS (10 cSt, Tradename: DC 200 fluid)*: In a combined chronic/carcinogenicity study conducted according to OECD Guideline 453, male and female Fischer rats (90/sex/group) received 0, 100, 300, and 1,000 mg/kg/day PDMS (10 cSt; MW 1,125; identified as DC 200 fluid) in their feed for 12 and 24 months. An interim sacrifice of 10 animals/sex/group occurred after 12 months of treatment. An additional 20 animals/sex/group were treated for 12 months, and then maintained for another 12 months without treatment. Corneal opacity incidence was increased slightly in males in the high dose group and in females in the mid and high dose groups during the first and second years of the study. An increased incidence of bilateral keratitis (inflammatory cells, including mononuclear cells and neutrophils) was observed in all dose groups when compared to controls, as well as inflammation of the nasolacrimal duct. Study authors suggest that the corneal and nasolacrimal effects are due to local irritation

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as a result of draining of the test chemical from the eye. There was also a statistically significant increase in the incidence of pancreatic islet cell adenomas in high dose males; however, the incidence was within the historical control range for Fischer 344 rats in the National Toxicology Program (NTP) historical database, therefore it was not considered to be treatment related by the EFSA Expert Panel. The expert panel established a NOAEL of 1,000 mg/kg/day, the highest dose tested.

- *Oral: Surrogate: PDMS (310 cSt, Tradename: KS66)*: In a GLP-compliant 26-month carcinogenicity study performed according to the Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives of the Japanese Ministry of Health and Welfare and published in 2005, F344 rats were administered PDMS (tradename K266, 310 cSt with 8% silica) in the feed for 104 weeks at 0, 1.25, and 5% (reported by EFSA to be equivalent to 0, 530, and 2,234 mg/kg/day in males, and 0, 445, and 1,849 mg/kg/day in females). Animals were evaluated for clinical signs of toxicity, mortality, food consumption, body weight and weight gain, hematology, organ weight changes, gross pathology, histopathology, and ophthalmology. There was a significant increase in final body weights in females at both doses along with decreases in relative organ weights in the kidneys, brain, and heart, and decreases in relative liver and adrenal weights at the lowest dose. Decreased liver weight was also measured in high dose males. The EFSA Panel considered the decreases of relative organ weights to be not toxicologically relevant. There were no toxicologically relevant treatment-related effects or increased incidences for any non-neoplastic or neoplastic lesions. The EFSA Panel assigned the NOAEL at 1,894 and 2,234 mg/kg/day in females and males, respectively, equivalent to 1,742 and 2,055 mg/kg/day based on 92% PDMS.

- CIR 2003, ECETOC 2011, HSDB 2017a,b, EFSA 2020
  - *Oral: Surrogate: PDMS (Tradename: Silicone antifoam agent)*: In a 76-week study in male and female outbred mice (number not reported) were provided a feed containing 0.25% or 2.5% of a compound containing 91% PDMS (Tradename: Silicone antifoam agent (94% PDMS and 6% finely divided silica)), reported by EFSA to be equivalent to 520 and 5,200 mg/kg/day, respectively); no treatment-related adverse effects were observed.

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

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for mutagenicity/genotoxicity based on its expected lack of bioavailability and negative results for mutagenicity and clastogenicity in *in vitro* assays performed with the target polymer. GreenScreen® criteria classify polymers as a Low hazard for mutagenicity when adequate data are available and negative for both mutagenicity and clastogenicity, and they are not GHS classified (CPA 2026, Annex 7). The confidence in the score is high due to high quality measured data on the target polymer.

- **Polymer Substance (2a):**
  - JECDB 2018a
    - *In vitro*: Negative results for mutagenicity were obtained in a GLP-compliant bacterial reverse mutation test. *Salmonella typhimurium* test strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* $WP_2$ *uvrA* were exposed to siloxanes and silicones, di-Me, hydroxy-terminated (purity assumed to be 100%)

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in acetone at concentrations up to 5,000 µg/plate with and without metabolic activation in dose-finding, main, and confirmatory experiments. The metabolic activation system was rat liver S9 mix produced from phenobarbital and 5,6-benzoflavone induced male Sprague-Dawley rats. Precipitation was observed at the highest concentration, 5,000 µg/plate with and without metabolic activation. Cytotoxicity was observed at ≥ 313 µg/plate in tester strains TA100 and TA 1535 without metabolic activation, and in the presence of metabolic activation at ≥ 625 µg/plate in tester strains $WP_2$ *uvrA* and TA1537, ≥ 1,250 µg/plate in tester strain TA98, and at 5,000 µg/plate in the remaining tester strains. There were no increases in the frequency of revertants observed in any strain at any dose level with or without metabolic activation. Vehicle, untreated negative, and positive (i.e., 9-aminoacridine, 2-aminoanthracene, sodium azide, and 2-(2-furyl-3-(5-nitro-2-furyl)acrylamide (AF-2)) controls were reported as valid.

- JECDB 2018b
  - *In vitro*: Negative results for clastogenicity were obtained in a GLP-compliant mammalian cell chromosome aberration test. Chinese hamster lung (CHL)/IU cells were exposed to the siloxanes and silicones, di-Me, hydroxy-terminated (purity assumed to be 100%) in DMSO at concentrations up to 2,000 µg/mL in the presence and absence of metabolic activation with short-term exposure and in the absence of metabolic activation with 24-hour continuous treatment. The metabolic activation system was rat liver S9 mix produced from phenobarbital and 5,6-benzoflavone induced male Sprague-Dawley rats. No precipitation was observed. At 1,000 µg/mL, growth was 50% inhibited in the presence of metabolic activation. Cell proliferation tests were repeated 5 times due to the rapid cytotoxicity observed in the absence of metabolic activation with short-term and continuous exposures in which 50% inhibition was observed at 500 µg/mL. There were no increases in chromosome damage or damage to the cell division apparatus at any dose level with or without metabolic activation. Vehicle and positive controls (i.e., cyclophosphamide and mitomycin C) controls were reported as valid
  - Dow Corning 1994b; CIR 2017*In vitro*: *Dow Corning Q4-2797 (4-2797 INT and PA fluid) (≥ 95% purity, CAS #70131-67-8)*: Negative results for mutagenicity were obtained in a GLP-compliant bacterial reverse mutation test conducted according to 46 FR (Federal Register, Volume 46) / OECD Guideline 471 (1981). *S. typhimurium* test strains TA97, TA98, TA100, and TA1535, and *E. coli* $WP_2$ were exposed to the test substance (identified as TX-85-0130-65) in DMSO at concentrations up to 5,000 µg/plate with and without metabolic activation. The metabolic activation system was rat liver S9 mix produced from Aroclor 1254 induced male Sprague-Dawley rats. No precipitation or cytotoxicity were observed, but tested up to current guideline concentration. There were no increases in the frequency of revertants observed in any strain at any dose level with or without metabolic activation. Vehicle and positive (i.e., sodium azide, 4-nitroquinoline-N-oxide, daunomycin, N-methyl-N-nitro-N-nitrosoguanidine, 2-aminoanthracene, and 2-aminofluorene)) controls were reported as valid
- .CIR 2017
  - *In vitro: Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8)*: Negative results for mutagenicity were obtained in a bacterial reverse mutation test (guideline and GLP-unspecified). *S. typhimurium* test strains TA98, TA100, and TA1535, and TA 1537, and *E. coli* WP2*uvrA* and

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WP2*uvr*A (pKM101) were exposed to the test substance (≥ 95% purity, vehicle not reported) at concentrations up to 5,000 µg/plate with and without metabolic activation. There were no increases in the frequency of revertants observed in any strain at any dose level with or without metabolic activation. Vehicle and positive (i.e., sodium azide, 2-nitrofluorene, 9-aminoacridine, methyl methanesulfonate, and 2-aminoanthracene) controls were reported as valid. No further details were provided.

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no mutagenicity is expected.

**Reproductive Toxicity (R) Score (H, M, or L): L**

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for reproductive toxicity based on its expected lack of bioavailability and a lack of reproductive effects in a three-generation oral toxicity study in rats. GreenScreen® criteria classify polymers as a Low hazard for reproductive toxicity when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score is high as it is based on high quality, measured data on a strong surrogate polymer.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - CIR 2017, U.S. EPA 2013
    - Siloxanes and silicones, di-Me, hydroxy-terminated is unlikely to be significantly bioavailable because it will not be metabolized or absorbed due to its high MW (> 1,000) and insolubility. Therefore, no reproductive toxicity is expected.
  - ECETOC 2011
    - *Oral:* *Surrogate: PDMS (350 cSt)*: Male Sprague-Dawley rats (10/dose) received PDMS at the doses 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:* *Surrogate: PDMS (350 cSt)*: Five male albino rabbits received PDMS at 3,000 mg/kg/day on the shaved backs for 5 days /week for 4 weeks (ToxServices calculated an equivalent dose for a 7-day week of 2,143 mg/kg/day). Following each dosing, the animals were immobilized in restrainers

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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.

- EFSA 2020
  - *Oral: Surrogate: PDMS:* A three-generation reproductive toxicity study was performed in weanling rats (GLP compliance, study guideline, and strain not specified) and reported in 1959. Rats were administered 0, 0.01, or 0.1% test substance (Tradename: DC Antifoam A, purity unspecified) in the feed at 0, 4.5, or 45 mg/kg/day beginning at 16 weeks pre-mating for parental animals (F0). F1 and F2 animals were each mated at 15 weeks of age. Animals were evaluated based on body weight changes, reproductive performance, number of litters, pups per litter, and pup survival on post-natal day (PND) 21. The number of litters born in each group and the number of pups in each litter were recorded. Litters were culled to 8 pups each. Surviving F0 animals were sacrificed at 2 years, F1 animals at 28 weeks, and F2 animals at 23 weeks and were assessed for hematological, histology of main organs, and body and organ weight changes, including the ovaries, uterus, and testes. There were significant differences in body weights in treated F1 and F2 animals compared to controls but there was no dose-related trend and authors determined the effects were not toxicologically significant. Survival in F0 animals was slightly higher at the highest dose compared to controls, and was slightly lower in F1 animals at the highest dose compared to controls. Due to lack of corresponding effects and the modest differences, study authors considered the effects not toxicologically relevant. No other significant differences were reported. The EFSA Panel noted the reporting of the study was limited, and the highest tested dose was only 45 mg/kg/day.

**Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): L**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for developmental toxicity based on its expected lack of bioavailability and a lack of developmental effects in studies performed with the surrogate PDMS, including oral prenatal developmental toxicity studies in rats and rabbits and a three-generation oral toxicity study in rats. GreenScreen® criteria classify polymers as a Low hazard for reproductive toxicity when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score is high as it is based on high quality, measured data on strong surrogate polymers.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - CIR 2017, U.S. EPA 2013

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        - Siloxanes and silicones, di-Me, hydroxy-terminated is unlikely to be significantly bioavailable because it will not be metabolized or absorbed due to its high MW (> 1,000) and insolubility. Therefore, no developmental toxicity is expected.
    - ECETOC 2011
        - *Oral: Surrogate: PDMS*: 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 (i.e., gestation days (GD) 6-19). 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. A NOAEL of 1,000 mg/kg/day was identified.
    - CIR 2003, EFSA 2020
        - *Oral: Surrogate: PDMS*: In a developmental toxicity study in rabbits (strain not specified) administered 200 mg/kg PDMS to the shaved skin on the back or 20, 200, or 1,000 mg/kg PDMS by subcutaneous injection on GD 6-18, no treatment-related abnormalities were observed.
            - *ToxServices identified a NOAEL of 1,000 mg/kg/day, the highest dose tested. Note: Although subdermal exposure is not a standard route (i.e., oral, dermal, or inhalation) assessed in GreenScreen®, it may result in more systemic exposure and therefore was included as part of the weight of evidence.*
    - EFSA 2020
        - *Oral: Surrogate: PDMS (7 cSt)*: A prenatal developmental toxicity study (GLP-compliance and guidance not specified) was conducted in female rats (strain and number of animals/group) administered oral doses of PDMS (Tradename: DC 700 vapor booster pump fluid, purity unspecified) by gavage at 0, 300, and 1,000 mg/kg/day from GD 6 to 15. Dams were sacrificed on GD 20 and the uterus, ovaries, and fetuses were examined. In addition, the numbers of implantation sites and live and dead pups were recorded, and pups were examined for gross and skeletal abnormalities. There were no treatment related effects reported. Details about study are limited. *ToxServices identified a NOAEL of 1,000 mg/kg/day, which was the highest dose tested.*
        - *Oral: Surrogate: PDMS*: In the previously described three-generation reproductive toxicity study performed in weanling rats (GLP compliance, study guideline, and strain not specified), rats were administered 0, 0.01, or 0.1% test substance (Tradename: DC Antifoam A, purity unspecified) in the feed at 0, 4.5, or 45 mg/kg/day beginning at 16 weeks pre-mating for parental animals (F0). F1 and F2 animals were each mated at 15 weeks of age. Animals were evaluated based on body weight changes, reproductive performance, number of litters, pups per litter, and pup survival on PND 21. The number of litters born in each group and the number of pups in each litter were recorded. Litters were culled to 8 pups each. Surviving F0 animals were sacrificed at 2 years, F1 animals at 28 weeks, and F2 animals at 23 weeks and were assessed for hematological, histology of main organs, and body and organ weight changes, including the ovaries, uterus, and testes. There were significant differences in body weights in treated F1 and F2 animals compared to controls but there was no dose-related trend and authors determined the effects were not toxicologically significant. Survival in F0 animals was slightly higher at the highest dose compared to controls, and was

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slightly lower in F1 animals at the highest dose compared to controls. Due to lack of corresponding effects and the modest differences, study authors considered the effects not toxicologically relevant. No other significant differences were reported. The EFSA Panel noted the reporting of the study was limited, and the highest tested dose was only 45 mg/kg/day.

**Endocrine Activity (E) Score (H, M, or L):** DG
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Data Gap for endocrine activity due to lack of sufficient data. Although it is expected to have no significant bioavailability, GreenScreen® criteria classify polymers as a Low hazard for endocrine activity when adequate negative data are available for all critical endocrine pathways (CPA 2026, Annex 7).

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no endocrine activity is expected.

**GROUP II AND II* HUMAN HEALTH EFFECTS (GROUP II AND II* HUMAN)**
*Note: Group II and Group II* endpoints are distinguished in the v1.5a Benchmark system (the asterisk indicates repeated exposure). For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints. See GreenScreen® Guidance v1.5a, Annex 2 for more details.*

**Acute Mammalian Toxicity (AT) Score (vH, H, M, or L): L**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for acute toxicity based on oral and dermal $LD_{50}$ values of > 2,000 mg/kg and inhalation $LC_{50}$ values of > 5 mg/L (inhalation of dust/mist/fumes). GreenScreen® criteria classify polymers as a Low hazard for acute toxicity when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). The confidence in the score is high based on high quality measured data on the target polymer.

- **Polymer Substance (2a):**
  - *Siloxanes and silicones, di-Me hydroxy-terminated, MW = 4200 (CAS #70131-67-8)*:
    - PubChem, CAS #70131-67-8, 2026; ThermoFisher Scientific 2025, RTECS 1999a
      - *Oral:* $LD_{50}$ (rats, sex and strain unspecified) > 15,400 mg/kg (non-guideline, GLP-status unspecified).
      - *Dermal:* $LD_{50}$ (rabbits, sex and strain unspecified) > 2,000 mg/kg (non-guideline, GLP-status unspecified).
      - *Inhalation:* $LC_{50}$ (rats, sex and strain unspecified) > 8,750 mg/m$^3$ (ToxServices calculated an equivalent dose of 8.75 mg/L)[9] (non-

[9] 8,750 mg/m$^3$ * 1 m$^3$/1,000 L = 8.75 mg/L

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guideline, GLP-status unspecified).
- *Note:* These results are listed in the PubChem (2026) record for the target polymer (CAS #70131-67-8). The associated TSCA submission report, identified as OTS0509158, is not available via NTIS to confirm the composition of this substance because the same TSCA report and associated acute toxicity data is reported in the RTECS (1999b) record as "siloxanes and silicones, di-Me, hydroxy-terminated 42% in dimethyl hydrolysate". Additionally, a safety data sheet for ≤ 100% target polymer as product name "polydimethylsiloxane, hydroxy-terminated, MW 4200". Therefore, due to the uncertainty of the composition of the test substance, this data did not weigh heavily in the weight of evidence, because more reliable data associated with target polymers is available with composition information.

- *Silicone L-9000/1000 (1,000 cSt, CAS #70131-67-8)*:
  - PubChem, CAS #70131-67-8, 2026; RTECS 1999b; Union Carbide Corporation 1994; Sigma-Aldrich 2024
    - *Oral:* $LD_{50}$ (male Wistar rats) > 64 mL/kg (ToxServices calculated an equivalent dose of 62,400 mg/kg)[10] (non-guideline, GLP-unspecified).
    - *Dermal:* $LD_{50}$ (male albino rabbits) > 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg)[11] (non-guideline, GLP-unspecified).
  - Union Carbide Corporation 1994
    - *Inhalation:* 8-hour whole-body vapor $LC_{50}$ (male Wistar rats) > substantially saturated vapor (non-guideline, GLP-unspecified).
- *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*:
  - Union Carbide Corporation 1992; CIR 2017
    - *Oral:* $LD_{50}$ (male and female Hilltop-Wistar albino rats) > 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg)[13] (non-guideline, GLP-unspecified).
    - *Dermal:* $LD_{50}$ (male and female New Zealand white rabbits) > 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg)[13] (non-guideline, GLP-unspecified).
    - *Inhalation:* 6-hour whole-body vapor $LC_{50}$ (male and female Hilltop-Wistar albino rats) > substantially saturated vapor (non-guideline, GLP-unspecified
- *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8)*:
  - Dow Corning 1998, CIR 2017
    - *Oral:* $LD_{50}$ (male and female Sprague-Dawley [Crl:CD(CD)Br] rats) > 2,000 mg/kg (GLP-compliant, OECD Guideline 401).
  - CIR 2017
    - *Dermal:* $LD_{50}$ (male and female New Zealand white rabbits) > 2,000 mg/kg (guideline- and GLP-unspecified).
- *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*:
  - CIR 2017
    - *Oral:* $LD_{50}$ (male and female Sprague-Dawley [Crl:CD(CD)Br] rats)

[10] 64 mL/kg * 0.975 g/cm$^3$ * (1 cm$^3$/1 mL) * (1,000 mg/g) = 62,400 mg/kg
[11] 16 mL/kg * 0.975 g/cm$^3$ * (1 cm$^3$/1 mL) * (1,000 mg/g) = 15,600 mg/kg

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> 2,000 mg/kg (guideline- and GLP-unspecified).
- *Dermal:* $LD_{50}$ (male and female New Zealand white rabbits) > 2,000 mg/kg (guideline- and GLP-unspecified).

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - CIR 2017, U.S. EPA 2013
    - Siloxanes and silicones, di-Me, hydroxy-terminated is unlikely to be significantly bioavailable because it will not be metabolized or absorbed due to its high MW (> 1,000) and insolubility. Therefore, no acute toxicity is expected.

**Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-single) Score (H, M, or L): L**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for single dose systemic toxicity/organ effects based on its expected lack of bioavailability and lack of systemic toxicity at doses up to 2,000 mg/kg, the cut-off for classification, in acute oral and dermal toxicity studies. Furthermore, a lack of systemic toxicity was observed in rats exposed whole-body to significantly saturated vapors for 6-8 hours. GreenScreen® criteria classify polymers as a Low hazard for single dose systemic toxicity/organ effects when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score was high based on high quality data, including guideline studies for the target polymer.

- **Polymer Substance (2a):**
  - *Silicone L-9000/1000 (1,000 cSt, CAS #70131-67-8)*:
    - Union Carbide Corporation 1994
      - *Oral:* In an acute oral toxicity study (non-guideline, GLP-specified), male Wistar rats (3-5/dose) were administered a single oral dose of 4, 16, or 64 mL/kg test substance (ToxServices calculated equivalent doses of 3,900, 7,800, and 15,600 mg/kg, respectively, based on a density of 0.975 $g/cm^3$). There were no deaths, and no treatment related effects on weight development. Clinical signs of wet fur were reported at 16 mL/kg, and gross pathology revealed mottled livers with acini prominent and slightly pink stomachs and injected intestines. No further details were provided.
      - *Dermal:* In an acute dermal toxicity study (non-guideline, GLP-unspecified), six male albino rabbits were administered topical applications of 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg)[12] test substance. There were no deaths, and no treatment related effects on clinical signs, weight development. Gross pathology revealed pale kidneys. No further details were provided.
      - *Inhalation:* In an acute inhalation toxicity study (non-guideline, GLP-unspecified), six male Wistar rats were exposed to whole body inhalation of substantially saturated vapor for 8 hours. The exposure atmosphere was not analytically examined and the "substantially saturated vapor" was prepared by spreading 50 grams of the test chemical over a 200 $cm^2$ area on a shallow tray that was placed in a sealed chamber for a minimum of 16 hrs. The air was then introduced to rats in a cage designed to minimize vapor loss. There were no deaths, and no treatment related effects on clinical signs, weight development or gross pathology.

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- *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*:
  - Union Carbide Corporation 1992, CIR 2017
    - *Oral:* In an acute oral toxicity study (non-guideline, GLP-specified), male and female Hilltop-Wistar albino rats (5/sex/dose) were administered a single oral dose of 16 mL/kg (ToxServices calculated an equivalent dose of equivalent to 15,600 mg/kg) test substance. There were no deaths, and no treatment related effects on clinical signs or weight development. Gross pathology revealed red, pink or dark red mottled lungs.
    - *Dermal:* In an acute dermal toxicity study (non-guideline, GLP-unspecified), male and female New Zealand white rabbits (4/sex/dose) were administered a single topical application of 16 mL/kg (ToxServices calculated an equivalent dose of equivalent to 15,600 mg/kg) test substance. There were 1/4 and 0/4 deaths reported for males and females, respectively. Prior to death, the one male exhibited clinical signs of prostration and necropsy revealed red lungs, livers, and trachea. For the survivors, there were no treatment related effects on clinical signs, signs of skin irritation, body weight development, or gross pathology of survivors. No further details were provided.
    - *Inhalation:* In an acute inhalation toxicity study (non-guideline, GLP-unspecified), male and female Hilltop-Wistar albino rats (5/sex/dose) were exposed to whole body substantially saturated vapor for 6 hours. The exposure atmosphere was not analytically examined and the "substantially saturated vapor" was prepared by spreading 50 grams of the test chemical over a 200 $cm^2$ area on a shallow tray that was placed in a sealed chamber for a minimum of 16 hrs. The air was then introduced to rats in a cage designed to minimize vapor loss. There were no deaths, and no treatment related effects on clinical signs, weight development and gross pathology. No further details were provided.
- *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8)*
  - Dow Corning 1998, CIR 2017
    - *Oral:* In a GLP-compliant acute oral toxicity study conducted according to OECD Guideline 401, male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single oral dose of 2,000 mg/kg test substance and observed for 14 days. There were no deaths, and no treatment related effects on clinical signs, weight development, or gross pathology.
  - CIR 2017
    - *Dermal:* In an acute dermal toxicity study (guideline- and GLP-unspecified), male and female New Zealand white rabbits (5/sex/dose) were administered a single topical application of 2,000 mg/kg test substance for 24 hours. There were no deaths, and no treatment related effects on clinical signs or gross pathology. Erythema was observed at application sites and resolved by day 7.
- *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*:
  - CIR 2017

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- *Oral:* In an acute oral toxicity study (guideline- and GLP-unspecified), male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single oral dose of 2,000 mg/kg test substance and observed for 14 days. There were no deaths, and no treatment related effects on clinical signs or gross pathology.
- *Dermal:* In an acute dermal toxicity study (guideline- and GLP-unspecified), male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single topical application of 2,000 mg/kg) test substance. There were no deaths, and no treatment related effects on clinical signs or gross pathology.

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no systemic toxicity is expected after single exposure.

**Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-repeat) (Group II*) Score (H, M, or L): L**

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for repeated dose systemic toxicity/organ effects based on its expected lack of bioavailability and oral NOAELs ≥ 860 mg/kg/day in subchronic toxicity studies in rats with the surrogate PDMS, which is greater than the GHS guidance value for classification (100 mg/kg/day in a 90-day study). GreenScreen® criteria classify polymers as a Low hazard for repeated dose systemic toxicity/organ effects when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score is high as it is based on high quality, measured data on strong surrogates.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - CIR 2017, U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no systemic toxicity is expected after repeated exposure.
  - EFSA 2020
    - *Oral: Surrogate: PDMS (35 cSt)*: In a GLP-compliant repeated dose toxicity study, CD-1 mice (15/sex/dose) received 0, 5, and 10% test substance in the feed (reported by EFSA to be equivalent to 0, 10,000, and 20,000 mg/kg/day) for 90 days. Mortality, daily clinical signs of toxicity, appearance, behavioral changes, body weight, and food consumption were recorded. At sacrifice, major organs (not specified) were collected, weighed, and evaluated for histopathology. In the 10% treatment group, minimal to moderate anal leakage of fluid and oily fur were

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observed. A significant increase in food consumption was observed in both treatment groups. There were no other treatment-related findings of significance.

- *ToxServices identified a NOAEL of 20,000 mg/kg/day PDMS (35 cSt), which was the highest dose tested.*

- *Oral:* *Surrogate: PDMS (35 or 1,000 cSt)*: In another repeated dose toxicity study (GLP compliance and guideline not specified), CD-1 mice (6/sex/dose) received 1, 5, and 10% test substance in the feed (reported by EFSA to be equivalent to 0, 2,000, 10,000 and 20,000 mg/kg/day) for 28 days. Slight to severe anal leakage was noted in the 5 and 10% treatment groups of the 35 cSt PDMS. A statistically significant increase in food consumption was observed in the mid and high dose groups. There were no other significant treatment-related findings.
  - *ToxServices identified a NOAEL of 20,000 mg/kg/day PDMS (35 or 1,000 cSt), which was the highest dose tested.*
- *Oral:* *Surrogate: PDMS (10 cSt)*: In a 28-day gavage study (OECD Guideline 407) in Fischer 344 rats (10/sex/dose) received 0, 10,000, 25,000, 50,000, and 100,000 mg/kg PDMS (10 cSt, Tradename: DC 200 fluid) in the feed (reported by EFSA to be equivalent to 0, 978, 2,545, 5,244, and 11,228 mg/kg/day for males and 0, 1,043, 2,706, 5,623, and 12,058 mg/kg bw/day for females, respectively). Corneal opacities (as corneal crystals) were observed in all animals with the highest incidences in the 25,000, 50,000, and 100,000 mg/kg/day treatment groups. Hyperplasia, hemorrhage, granulomatous inflammation, and suppurative inflammation of the corneal stroma were observed in the two highest treatment groups. The authors suggest that the effects on the cornea are due to direct contact with the test material in feed and in the feces. An increase in mean food consumption was observed in the 50,000 and 100,000 mg/kg/day treatment groups. In males at 25,000 and 50,000 mg/kg/day and in both sexes at 100,000 mg/kg/day, mean triglycerides and low density and very low density lipoprotein cholesterol levels were significantly decreased. Mean relative kidney weights were significantly increased in males in the 50,000 and 100,000 mg/kg/day treatment groups and relative brain weights were significantly decreased in females in the 25,000 and 50,000 mg/kg/day treatment groups.
  - *ToxServices identified a NOAEL of 10,000 mg/kg/day PDMS (10 cSt, Tradename: DC 200 fluid) based on decreased relative brain weight in treated animals at 25,000 mg/kg/day.*
- *Oral:* *Surrogate: PDMS (350 cSt)*: In another 28-day gavage study (OECD Guideline 407) in Fischer 344 rats (10/sex/dose) received 0, 10,000, 25,000, 50,000, and 100,000 mg/kg/day PDMS (350 cSt, Tradename: DC 200 fluid) in the feed (reported by EFSA to be equivalent to 0, 950, 2,428, 4,986, and 10,615 mg/kg/day for males and 0, 1,013, 2,562, 5,286, and 11,325 mg/kg/day for females, respectively). Corneal opacities (as corneal crystals) were observed in all animals with the highest incidences in the 25,000, 50,000, and 100,000 mg/kg/day treatment groups in addition to keratitis with corneal vascularization observed in all treatment groups with the highest incidence of 14 (compared to 0 for controls) in the 100,000 mg/kg/day group. Hyperplasia and granulomatous inflammation of the corneal stroma were observed in a dose dependent manner, with the highest incidences occurring at the highest dose. The authors suggest that the effects on the cornea are due to direct contact with the test material in

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feed and in the feces. An increase in mean food consumption was observed in males at 25,000 mg/kg/day and in both male and female 50,000 and 100,000 mg/kg/day treatment groups.

- *ToxServices identified a NOAEL of 10,000 mg/kg/day PDMS (350 cSt, Tradename: DC 200 fluid) based on decreased relative brain weight in treated animals at 25,000 mg/kg/day.*

- CIR 2003, ECETOC 2011, EFSA 2020
  - *Oral: Surrogate: PDMS (35, 350, and 1,000 cSt)*: In a GLP-compliant repeated dose toxicity study conducted according to OECD Guideline 408, Sprague-Dawley rats (20/sex/dose) received 1, 5, and 10% PDMS (35, 350, and 1,000 cSt; identified as DC 6370 fluid) (reported by EFSA to be equivalent to 0, 900, 4,500, and 9,000 mg/kg/day) in the feed for 90 days. Slight to moderate anal leakage was noted in the 10% group. There was significantly higher food consumption in the 5 and 10% groups. Corneal opacities, neovascularization, and chronic inflammation of the cornea were observed in treated animals. Study authors suggest that the corneal effects may be related to direct ocular irritation from exposure to the test chemical in the feed. One undifferentiated lymphoma was reported in a male 1% group. A follow-up GLP-compliant repeated dose study was conducted to further examine the significance of the lymphoma finding. Male Sprague-Dawley rats (100 animals/group) received 10% PDMS (35, 350, and 1,000 cSt) (reported by EFSA to be equivalent to 9,000 mg/kg/day) for 90 days. Mean food consumption was higher in the treated animals. There were no additional significant findings and there was no increase in the number of lymphomas in treated animals.
  - *Oral: Surrogate: PDMS (10 cSt)*: In a GLP-compliant repeated dose toxicity study conducted according to OECD Guideline 408, Fischer 344 rats (15/sex/dose) received 0, 5,000, 10,000, 25,000, and 50,000 mg/kg/day PDMS (10 cSt, tradename: DC 200 fluid) in the feed (reported by EFSA to be equivalent to 0, 351, 2,545, 5,244, and 11,228 mg/kg/day for males and 0, 1,043, 2,706, 5,623, and 12,058 mg/kg/day for females, respectively) for 90 days. An increased matting of fur was observed at 25,000 and 50,000 ppm in males and females. Direct contact of the material with fur and eyes resulted in corneal opacity and inflammation with vascularization. No treatment-related effects were observed on body weight, hematology parameters, urinalysis parameters, organ weights, gross pathology, or histopathology. High density lipoprotein, cholesterol, and phospholipid levels decreased in all treated males, but the ECETOC authors did not consider them to be adverse effects. The study authors identified a NOAEL of 50,000 ppm (reported by EFSA to be equivalent to 11,228 and 12,058 mg/kg/day for males and females, respectively), the highest dose tested.
- CIR 2003, EFSA 2020
  - *Oral: Surrogate: PDMS (50, 350, 1,000, 10,000, and 60,000 cSt)*: In a 90-day oral toxicity study, male and female Sprague-Dawley rats (10/sex) were administered a feed containing 1% PDMS, (Tradename: DC 200 fluid) at 5 different viscosities (50, 350, 1,000, 10,000, and 60,000 cSt), reported by EFSA to be equivalent doses of 183, 192, 190, 190, and 180 mg/kg/day for males, and 180, 180, 182, 175, and 177 mg/kg/day for females, respectively. There were no effects on food consumption, weight gain, hematological parameters, organ

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weights, and microscopic parameters.
- *ToxServices identified a NOAEL of 1% PDMS, the only dose tested, and reported by EFSA to be equivalent doses with ranges of180-192 and 175-182 mg/kg/day in males and females, respectively, for all viscosities).*

▪ *Oral: Surrogate: PDMS :* In a 90-day study in dogs (3/sex/group, strain not reported) fed 120, 380, or 1,200 mg/kg/day test substance (Tradename: DC Medical Antifoam 351, containing 95% PDMS). No significant adverse effects were reported on body weight gain, blood chemistry, hematology, urinalysis, organ weights, and histopathology and gross pathology.
- *ToxServices identified a NOAEL of 1,200 mg/kg/day, the highest dose tested.*

o ECETOC 2011, EFSA 2020, CIR 2022

▪ *Dermal***:** *Surrogate: PDMS (350 cSt)*: New Zealand White rabbits (10/sex/group) were dermally administered PDMS via occlusive patches at 0, 100, 300 or 1,000 mg/kg/day for 28 days. The test substance was removed after 6 hours of exposure each day. There were no deaths or other significant findings and authors assigned the NOAEL at 1,000 mg/kg/day.

**Neurotoxicity (N-single) Score (H, M, or L):** *L*

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for single dose neurotoxicity based on its expected lack of bioavailability and the lack of neurotoxic effects seen following single oral and dermal exposures at doses up to 2,000 mg/kg. Furthermore, a lack of neurotoxicity was observed in rats exposed whole-body to significantly saturated vapors for 6-8 hours. GreenScreen® criteria classify polymers as a Low hazard for single dose neurotoxicity when adequate data are available and they are not GHS classified for single dose systemic toxicity due to neurotoxicity (CPA 2026, Annex 7). Confidence in the score was low due to limited neurotoxicity examination in acute toxicity studies for the target polymer and expert judgement.

- **Polymer Substance (2a):**
  - *Silicone L-9000/1000 (1,000 cSt, CAS #70131-67-8)*:
    - Union Carbide Corporation 1994
      - *Oral:* In the previously described acute oral toxicity study (non-guideline, GLP-specified), male Wistar rats (3-5/dose) were administered a single oral dose of 4, 16, or 64 mL/kg test substance (ToxServices calculated equivalent doses of 3,900, 7,800, and 15,600 mg/kg based on a density of 0.975 g/cm$^3$). There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology. No further details were provided.
      - *Dermal:* In the previously described acute dermal toxicity study (non-guideline, GLP-unspecified), six male albino rabbits were administered topical applications of 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg)[12] test substance. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology. No further details were provided.
      - *Inhalation:* In the previously described acute inhalation toxicity study (non-guideline, GLP-unspecified), six male Wistar rats were exposed to whole body inhalation of substantially saturated vapor for 8 hours. There

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were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology. No further details were provided.

- *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*:
  - Union Carbide Corporation 1992, CIR 2017
    - *Oral:* In an acute oral toxicity study (non-guideline, GLP-specified), male and female Hilltop-Wistar albino rats (5/sex/dose) were administered a single oral dose of 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg) test substance. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology.
    - *Dermal:* In the previously described acute dermal toxicity study (non-guideline, GLP-unspecified), male and female New Zealand white rabbits (4/sex/dose) were administered a single topical application of 16 mL/kg (ToxServices calculated an equivalent dose of 15,600 mg/kg) test substance. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology.
    - *Inhalation:* In an acute inhalation toxicity study (non-guideline, GLP-unspecified), male and female Hilltop-Wistar albino rats (5/sex/dose) were exposed to whole body substantially saturated vapor for 6 hours. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology. No further details were provided.
- *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8))*:
  - Dow Corning 1998, CIR 2017
    - *Oral:* In the previously described GLP-compliant acute oral toxicity study conducted according to OECD Guideline 401, male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single oral dose of 2,000 mg/kg test substance and observed for 14 days. There were no treatment related effects on clinical signs of neurotoxicity or gross pathology.
  - CIR 2017
    - *Dermal:* In the previously described acute dermal toxicity study (guideline- and GLP-unspecified), male and female New Zealand white rabbits (5/sex/dose) were administered a single topical application of 2,000 mg/kg test substance for 24 hours. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology.
- *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*:
  - CIR 2017
    - *Oral:* In the previously described oral toxicity study (guideline- and GLP-unspecified), male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single oral dose of 2,000 mg/kg test substance and observed for 14 days. There were no treatment related effects reported on clinical signs of neurotoxicity or gross pathology.
    - *Dermal:* In the previously described acute dermal toxicity study (guideline- and GLP-unspecified), male and female Sprague-Dawley [Crl:CD(CD)Br] rats (5/sex/dose) were administered a single topical application of 2,000 mg/kg) test substance. There were no treatment

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related effects reported on clinical signs of neurotoxicity or gross pathology.

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no neurotoxicity is expected following single exposure.

**Neurotoxicity (N-repeated) (Group II*) Score (H, M, or L):** *L*

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for repeated dose neurotoxicity based on its expected lack of bioavailability and the lack of neurotoxicity observed at doses ≥ 1,849 mg/kg/day, which exceed the GHS guidance value for classification (100 mg/kg/day in a 90-day oral study) in oral subchronic and chronic studies with surrogate PDMS. GreenScreen® criteria classify polymers as a Low hazard for repeated dose neurotoxicity when adequate data are available and they are not GHS classified for repeated dose systemic toxicity based on neurotoxicity (CPA 2026, Annex 7). Confidence in the score is low as there were no formal neurobehavioral examinations such as those conducted in a functional observation battery.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to cell membranes, and hence not likely to be significantly bioavailable. Therefore, no neurotoxicity is expected after repeated exposure.
  - None of the repeated dose acute toxicity studies described under Systemic Toxicity Repeated Dose section reported any adverse neurological effects. However, it does not appear that any of those studies specifically evaluated neurotoxicity within a functional observation battery. Those that specified some neurological examinations are described again below:
  - CIR 2003, ECETOC 2011, EFSA 2020
    - *Oral: Surrogate: PDMS (35, 350, and 1,000 cSt)*: In the previously described GLP-compliant repeated dose toxicity study conducted according to OECD Guideline 408, Sprague-Dawley rats (20/sex/dose) received 1, 5, and 10% PDMS (35, 350, and 1,000 cSt; identified as DC 6370 fluid) (reported by EFSA to be equivalent to 0, 900, 4,500, and 9,000 mg/kg/day) in the feed for 90 days. A follow-up GLP-compliant repeated dose study was conducted in which male Sprague-Dawley rats (100 animals/group) received 10% PDMS (35, 350, and 1,000 cSt) (reported by EFSA to be equivalent to 9,000 mg/kg/day) for 90 days. No treatment-related behavioral changes were seen in any group.

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- ECETOC 2011, EFSA 2020, CIR 2022
  - *Oral: Surrogate: PDMS (310 cSt)*: In the previously described GLP-compliant 26-month carcinogenicity study performed according to the Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives of the Japanese Ministry of Health and Welfare and published in 2005, F344 rats were administered the test substance (Tradename K266, 310 cSt with 8% silica) in the feed for 104 weeks at 0, 1.25, and 5% (reported by EFSA to be equivalent to 0, 530, and 2,234 mg/kg/day in males, and 0, 445, and 1,849 mg/kg/day in females). No changes were observed on the behavior of the rats.

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

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for skin sensitization based on its expected lack of bioavailability and lack of sensitization seen in a human repeat insult patch test (HRIPT) and guinea pig maximization tests (GPMTs). GreenScreen® criteria classify polymers as a Low hazard for skin sensitization when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). The confidence in the score is high due to high quality measured data on the target polymer.

- **Polymer Substance (2a):**
  - CIR 2017
    - In an HRIPT, 104 volunteers were administered 9 topical induction applications of a body lotion containing 1.125% siloxanes and silicones, di-Me, hydroxy-terminated (0.2 g per 1 $in^2$ patch) to the upper back for 24 hours under semiocclusion and at the end of a 2-week non-treatment period received a 24-hour challenge patch. There were no positive sensitization reactions reported with induction or challenge.
  - CIR 2017
    - *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*: In a GPMT, 20 Dunkin-Hartley albino guinea pigs (2/groups) received a 0.1 mL intradermal induction injection of 10 or 20% test substance and an induction topical application of 0.5 mL neat test substance to an 8 $cm^2$ test patch under occlusion for 48 hours followed by challenge topical application of neat test substance to a 4$cm^2$ test patch under occlusion for 24 hours. No positive reactions were observed, and the study authors concluded the test substance did not induce sensitization.
    - *Dow Corning X7-9192 (≥ 95% purity, CAS #70131-67-8)*: In a GPMT, male and female guinea pigs (strain unspecified, 5/sex) were administered a 0.1 mL intradermal induction injection of the test substance, followed 7 days later with a topical application under occlusion for 48 hours and challenged 21 days later with a topical application under occlusion for 24 hours. The study authors concluded the test substance did not induce sensitization.
    - *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8))*: In a GPMT, male Hartley guinea pigs (20/test, 10/control) were administered 0.1 mL induction intradermal injections of neat test substance followed by a topical application of test substance under semiocclusion for 48 hours, and challenged 2 weeks later with 0.3 mL intradermal injection of neat test substance. No positive reactions were observed, and the study authors concluded the test substance was not sensitizing to the skin.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.

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- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The high MW (> 1,000) and insolubility make it impermeable to the skin to elicit immune responses. Therefore, no skin sensitization is expected.

**Respiratory Sensitization (SnR) (Group II*) Score (H, M, or L):** *L*
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for respiratory sensitization based on extrapolation from skin sensitization data according to ECHA's recommended strategy on evaluation of respiratory sensitization. GreenScreen® criteria classify polymers as a Low hazard for respiratory sensitization when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). Confidence in the score was low due to this evaluation not including non-immunologic mechanisms of respiratory sensitization and lack of specific data for respiratory sensitization.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - OECD 2026
    - The representative structure for the target polymer, (SMILES: C[Si](C)(O)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O), does not contain any structural alerts for respiratory sensitization (Appendix I).
- Based on the weight of evidence and guidance from ECHA regarding assessment of respiratory sensitization potential, a score of Low was assigned. The guidance from ECHA states that the mechanisms leading to respiratory sensitization are essentially similar to those leading to skin sensitization (ECHA 2017). ECHA recommended that if a chemical is not a dermal sensitizer based on high quality data, it is unlikely to be a respiratory sensitizer. ECHA also noted that this rationale does not cover respiratory hypersensitivity caused by non-immunological mechanisms, for which human experience is the main evidence of activity (ECHA 2017). As siloxanes and silicones, di-Me, hydroxy-terminated is not a skin sensitizer, a literature search did not find any human evidence of respiratory sensitization, and the representative structure of siloxanes and silicones, di-Me, hydroxy-terminated does not contain any structural alerts for respiratory sensitization, it is not expected to be a respiratory sensitizer.

**Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M, or L): L**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for skin irritation/corrosivity based on a lack of irritation seen in an HRIPT and in guinea pigs and rabbits. GreenScreen® criteria classify polymers as a Low hazard for skin irritation/corrosivity when adequate data are available and they are not GHS classified (CPA 2026, Annex 7). The confidence in the score is high based on reliable, measured data on the target polymers.

- **Polymer Substance (2a):**
  - CCID 2026
    - In a local cutaneous tolerance test, no erythema or edema were reported in six rabbits (sex and strain unspecified) administered siloxanes and silicones, di-Me,

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hydroxy-terminated (Tradename: Rhodorsil Oil 70047 V 100) to intact and abraded skin for 24 and 72 hours.

- CIR 2017
  - In the previously described HRIPT, 104 volunteers were administered nine topical induction applications of a body lotion containing 1.125% siloxanes and silicones, di-Me, hydroxy-terminated (0.2 g per 1 $in^2$ patch) to the upper back for 24 hours under semiocclusion and at the end of a 2-week non-treatment period received a 24-hour challenge patch. There were no positive irritations reactions reported with induction or challenge.
  - *Polymer FD 80 (≥ 98% purity, CAS #70131-67-8)*: In three preliminary GPMT irritation studies, guinea pigs (4/study) received intradermal injections and topical applications of 10%, 50%, and 100% test substance in which weak to moderate and moderate irritation was observed with 10% and 50% intradermal injections, respectively, and weak to no irritation was observed with topical application neat and 50% concentrations.
  - *Dow Corning X7-9192 (≥ 95% purity, CAS #70131-67-8)*: In a primary irritation test, 4 guinea pigs (sex and strain unspecified) received a topical application of 0.1 mL of 25-100% test substance in water under occlusion and observed for 72 hours. No irritation was observed.
- Union Carbide Corporation 1992, CIR 2017
  - *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*: Six New Zealand white rabbits (3/sex) received a 0.5 mL topical dose of neat test substance to the clipped, intact skin under occlusion for 4 hours. No irritation was evident.
- Dow Corning 1998, CIR 2017
  - *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8))*: Three female New Zealand white rabbits received a 0.5 mL topical application of neat test substance to the clipped, intact skin under semi-occlusion for 4 hours. No irritation was evident.
- Union Carbide Corporation 1994, PubChem, CAS #70131-67-8, 2026
  - *Silicone L-9000/1000 (1,000 cSt, CAS #70131-67-8)*: Five male albino rabbits received a 0.01 mL topical dose of 0.01%, 0.1%, 1%, 10% and 100% test substance in solvent to the clipped, intact skin under occlusion for 24 hours. No irritation was evident.

- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - Not applicable.

**Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M, or L):** *M*

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Moderate for eye irritation/corrosivity based on moderate irritation of the eye, which resolved within 7 days, in at least 2 of 3 rabbits in an acute ocular irritation study with a high purity target polymer. GreenScreen® criteria classify polymers as a Moderate hazard for eye irritation/corrosivity when they are classified to GHS Category 2B (CPA 2026, Annex 7). The confidence in the score is low due to lack of data on eye response scores reported, precluding GHS classification in a definitive quantitative manner.

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- **Polymer Substance (2a):**
  - CCID 2026
    - Transient conjunctival irritation was reported in rabbits and man up to 72 hours after contact with test substance (Tradename: Rhodorsil Oil 70047 V 100). *ToxServices notes that the purity of this tradename is unknown.*
      - *Based on the results of this study, GHS New Zealand has classified the target polymer as a GHS Category 2 eye irritant [H319: Causes serious eye injury].*
  - Dow Corning 1998, CIR 2017
    - *Dow Corning 60,000 cSt, no co-solvent in corn oil (20% w/v; ≥ 95% purity, CAS #70131-67-8))*: Three female New Zealand White rabbits received a single instillation of 0.1 mL undiluted test substance into the right eye. Conjunctival erythema, chemosis, and discharge were observed in all rabbits; however, all irritation resolved within 72 hours. No individual animal measurements were provided, and no lesions of the cornea or iris were reported.
      - *Based on the results of this study in which moderate irritation was reported in all three animals with full reversal within 7 days of observation , ToxServices classified the target polymer as a GHS Category 2B eye irritant.*
  - Union Carbide Corporation 1992, CIR 2017
    - *Silicon Fluid 45-71 (80% purity, CAS #70131-67-8)*: Six New Zealand White rabbits (3/sex) received single installations to the eyes of 0.005 - 0.5 mL neat test substance without washing. Moderate, persistent corneal and conjunctival injury was reported in all animals from 0.005 - 0.1 mL and moderate iritis was evident in 3/6 animals from 0.1 mL. Although iritis was fully resolved within 7 days for all animals, vascularization of the cornea persisted through 14 days for 2 animals (2/6 = 0.32) and persisted through 21 days for one animal 1/6 = 0.16).
      - *Based on the results of this study in which moderate irritative effects (iritis) were reversible within 7 days, ToxServices classified the target chemical as a GHS Category 2B eye irritant. Although cornea vascularization persisted for up to 21 days, this particular effect is not considered in the GHS classification criteria.*
  - Union Carbide Corporation 1994, PubChem, CAS #70131-67-8, 2026
    - *Silicone L-9000/1000 (1,000 cSt , CAS #70131-67-8)*: Five male albino rabbits received a single installation to the eyes of up to 0.5 mL neat test substance without washing, no irritation was evident.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - Not applicable.

**ECOTOXICITY (ECOTOX)**

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

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for acute aquatic toxicity based on low solubility and lack of acute toxicity for surrogate PDMS.

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GreenScreen® criteria classify polymers as a Low hazard for acute aquatic toxicity when acute aquatic toxicity values are > 100 mg/L or when there are no effects at saturation (CPA 2026, Annex 7). Confidence in the score was high due to high quality measured data on a strong surrogate for all three trophic levels.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - Insoluble polymers are not expected to be toxic unless in the form of fine particles which may lead to occlusion of respiratory organs such as gills. In general, acute toxicity values are > 100 mg/L.
  - *Surrogate: PDMS:*
    - Nendza 2007
      - Soluble fractions of PDMS have low toxicity to aquatic and benthic organisms.
    - ECETOC 2011
      - In water saturated with PDMS, no acute toxic effects were observed in fish.
      - The toxic effects observed for PDMS at high concentrations were demonstrated to be due to the emulsifier using the in formulations.
      - *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 $LC_{50}$ 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:* Using a water soluble fraction and water accommodated fraction techniques, PDMS fluids (50, 350, and 1,000 cSt) 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:* 48 h $LC_{50}$ (immobilization) > 88,865 mg/L (the concentration refers to PDMS (10 cSt)-water mix from which the water accommodated fraction was derived, rather than the final solution).

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- *Marine algae:* $EC_{50}$ (growth and biomass, 10 cSt) > 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 were seen in aquatic organisms exposed to surrogate PDMS at concentrations far exceeding its water solubility. Therefore, the acute aquatic toxicity of siloxanes and silicones, di-Me, hydroxy-terminated is expected to be low.

**Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L):** *L*

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for chronic aquatic toxicity based on low toxicity for surrogate PDMS. GreenScreen® criteria classify polymers as a Low hazard for chronic aquatic toxicity when chronic aquatic toxicity values are > 10 mg/L (CPA 2026, Annex 7). Confidence in the score was low due to lack of measured data for the algae trophic level.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - Insoluble polymers are not expected to be toxic unless in the form of fine particles which may lead to occlusion of respiratory organs such as gills. In general, chronic toxicity values are > 10 mg/L.
  - Nendza 2007
    - *Surrogate: PDMS:* Soluble fractions of PDMS have low toxicity to aquatic and benthic organisms.
  - ECETOC 2011
    - *Fish: Surrogate: PDMS (50 cSt)*: 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: Surrogate: PDMS (350 cSt)*: 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: Surrogate: PDMS (350 cSt)*: 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) radiolabeled 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

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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 were seen in aquatic organisms exposed to surrogate PDMS at concentrations exceeding water solubility. Therefore, the chronic aquatic toxicity of siloxanes and silicones, di-Me, hydroxy-terminated is expected to be low.

**ENVIRONMENTAL FATE (FATE)**

**Persistence (P) Score (vH, H, M, L, or vL): vH**

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Very High for persistence based on expert judgment that the majority of polymers are not biodegradable supported by measured data on surrogate PDMS with a measured biodegradation half-life of over 70 days in water and over 876 – 1,443 days in soil. GreenScreen® criteria classify chemicals/polymer substance as a Very High hazard for persistence when they have half-lives of > 180 days in soil or sediment, > 60 days in water, and/or > 5 days in air (CPA 2026, Annex 7). Confidence in the score is high due to high quality measured data on a strong surrogate.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - The vast majority of polymers are essentially non-biodegradable.
    - Due to the large size and insolubility of most polymers, they are typically of low concern for bioconcentration.
  - ECETOC 2011
    - *Surrogate: PDMS:* PDMS compounds have measured biodegradation half-lives of greater than 70 days in water, and greater than 180 days in soil.
    - *Surrogate: PDMS:* PDMS break down slowly via abiotic processes when in contact with soil.
  - HSDB 2011
    - *Surrogate: PDMS (300 cSt)*: No biodegradation was seen for $C^{14}$-labelled PDMS exposed to activate sludge for 70 days.
    - *Surrogate: 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.
    - *Surrogate: 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 1,443 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.
    - *Surrogate: PDMS (204 cSt)*: $C^{14}$-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 $C^{14}O_2$.

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**Bioaccumulation (B) Score (vH, H, M, L, or vL): vL**

Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of was assigned a hazard classification level of Very Low for bioaccumulation based on its large molecular size and water insolubility indicating that it is unlikely to be bioaccumulative supported by a lack of bioaccumulation reported in marine organisms exposed to surrogate PDMS. GreenScreen® criteria classify chemicals/polymer substances as a Very Low hazard for bioaccumulation when the BCF/BAF is < 100 (CPA 2026, Annex 7). Confidence in the score is high due to high quality measured data on a strong surrogate polymer and expert judgement.

- **Polymer Substance (2a):**
  - No measured data were identified for the polymer substance.
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - U.S. EPA 2013
    - Due to the large size and insolubility of most polymers, they are typically of low concern for bioconcentration. Siloxanes and silicones, di-Me, hydroxy-terminated is insoluble in water with MW of > 1,000. Therefore, it is not expected to be bioaccumulative.
  - HSDB 2017a,b
    - *Surrogate: 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.
    - *Surrogate: 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.
    - *Surrogate: PDMS (viscosity not specified)*: Phytoplankton and crustacean (*Artemia salina*) were exposed to PDMS for 8 days before fed to goldfish (*Carassius auratus*) for 15 days. No bioconcentration was observed.
    - *Surrogate: 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
    - *Surrogate: PDMS (viscosity > 10 cSt)*: PDMS fluids with viscosities > 10 cSt 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.
    - *Surrogate: 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.
    - *Surrogate: PDMS (5 cSt, with an average of 12 siloxy repeating units)*: Dietary exposure of goldfish for 67 days and guppy (*Poecilia reticulata*) for 20 days

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resulted in the detection of lower molecular weight PDMS in some fish tissue samples but no PDMS molecules containing more than 12 siloxy units (MW > 1,050) were found. Linear siloxanes with MW > 1,050 showed no bioconcentration or bioaccumulation in fish.
    - *Surrogate: PDMS (200 and 350 cSt)*: 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.
    - *Surrogate: PDMS (350 cSt)*: 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 siloxanes and silicones, di-Me, hydroxy-terminated 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 surrogate PDMS polymers revealed that siloxanes and silicones, di-Me, hydroxy-terminated is unlikely to have any bioaccumulation potential.

**PHYSICAL HAZARDS (PHYSICAL)**

**Reactivity (Rx) Score (vH, H, M, or L):** *L*
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for reactivity based on ToxServices not classifying it as a reactive substance under GHS criteria due to lack of structural alerts for oxidizing and explosive endpoints. GreenScreen® criteria classify chemicals/polymers as a Low hazard for reactivity when they are not classified per GHS for any of the reactivity sub-endpoints and when they are not present on authoritative or screening lists (CPA 2026, Annex 7). Confidence in the score was low due to the lack of measured data.

- **Polymer Substance (2a):**
    - Dow 2026
        - Not explosive per product SDS for Tradename: Xiameter™ PMX-0156 Silanol fluid, section 9 (no additional details).
        - Not classified as a reactivity hazard and stable under normal conditions per product SDS for Tradename: Xiameter™ PMX-0156 Silanol fluid, section 9 (no additional details).
    - Dow 2026, ThermoFisher 2025, NFPA Undated
        - NFPA instability rating of 0, "Materials that do not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand".
- **Similar Polymer Substance (2b):**
    - No relevant information is available.
- **Qualifying Constituents (2c):**
    - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
    - UN 2025
        - ToxServices used screening procedures for explosivity to estimate the reactivity property of the target polymer. These procedures are listed in GHS (UN 2025).
            - Based on its representative chemical structure, siloxanes and silicones, di-Me, hydroxy-terminated is not considered explosive or self-reactive based

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on lack of functional groups associated with explosive or self-reactive properties (Appendix J).
- Siloxanes and silicones, di-Me, hydroxy-terminated is not considered to have oxidizing properties as it does not contain any structural groups known to be correlated with a tendency to react exothermally with combustible material.

**Flammability (F) Score (vH, H, M, or L): L**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a hazard classification level of Low for flammability based on not being classified as a flammable liquid per GHS (flash point > 93ºC). GreenScreen® criteria classify chemicals/polymers as a Low hazard for flammability when they are not classified per GHS for flammability and when they are not present on authoritative or screening lists (CPA 2026, Annex 7). Confidence in the score is high based on measured data on the target chemical.

- **Polymer Substance (2a):**
  - Dow 2026
    - Siloxanes and silicones, di-Me, hydroxy-terminated (CAS #70131-67-8, Tradename: Xiameter™ PMX-0156 Silanol fluid) has a reported flashpoint > 120°C in a Pensky-Martens closed cup test, section 9 per product SDS (no additional details).
  - ThermoFisher 2025
    - Siloxanes and silicones, di-Me, hydroxy-terminated (CAS #70131-67-8, Tradename: Xiameter™ PMX-0156 Silanol fluid) as a reported flashpoint > 110°C, section 9 per product SDS (no additional details).
  - Dow 2026, ThermoFisher 2025, NFPA Undated
    - NFPA flammability rating of 1, "Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur".
- **Similar Polymer Substance (2b):**
  - No relevant information is available.
- **Qualifying Constituents (2c):**
  - Not applicable. There are no qualifying constituents for this endpoint.
- **Professional Judgment (2d):**
  - Not applicable

**CLIMATE IMPACT**

**Ozone Depletion Potential (ODP) Score (H, M, L, or NA): N/A**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a score of Not Applicable for ozone depletion potential based on not being a gas or vapor.

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

**Global Warming Potential (GWP) Score (H, M, L, or NA): N/A**
Siloxanes and silicones, di-Me, hydroxy-terminated was assigned a score of Not Applicable for global warming potential based on not being a gas or vapor.

- No data were identified.

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## APPENDIX A: HAZARD BENCHMARK ACRONYMS (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**

**(GWP) Global Warming Potential**

**(IrE) Eye Irritation/Corrosivity**

**(IrS) Skin Irritation/Corrosivity**

**(M) Mutagenicity and Genotoxicity**

**(N) Neurotoxicity**

**(ODP) Ozone Depletion Potential**

**(P) Persistence**

**(R) Reproductive Toxicity**

**(Rx) Reactivity**

**(SnS) Sensitization- Skin**

**(SnR) Sensitization- Respiratory**

**(ST) Systemic/Organ Toxicity**

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## APPENDIX B: DATA SOURCES SEARCHED

| Table 7. Sources Searched for Relevant Chemical, Health Effects, and Ecotoxicity Data | | |
|---|---|---|
| **Mandatory Sources to Search** | **Website** | **Notes** |
| PubChem | https://pubchem.ncbi.nlm.nih.gov/ | Searched September 1, 2026:<br>CAS #70131-67-8:<br>https://pubchem.ncbi.nlm.nih.gov/substance/135316257<br>PDMS, hydroxyl-terminated:<br>https://pubchem.ncbi.nlm.nih.gov/substance/?source=chemidplus&sourceid=0070131678 |
| eChemPortal | https://www.echemportal.org/echemportal/ | Searched September 1, 2026:<br>CAS #70131-67-8:<br>https://www.echemportal.org/echemportal/substance-search?query_term=70131-67-8<br>CAS #31692-79-2:<br>https://www.echemportal.org/echemportal/substance-search?query_term=31692-79-2 |
| ECHA/ECHACHEM | https://echa.europa.eu/information-on-chemicals | Searched September 1, 2026: No lead or inactive dossiers available: PDMS, CAS #70131-67-8, #31692-79-2 |
| ECHA's Substance Evaluation Portal | https://chem.echa.europa.eu/activity-lists/substanceEvaluation | Searched September 1, 2026:<br>No listings available |
| CIR | https://cir-reports.cir-safety.org/ | Searched September 1, 2026: CIR 2017:<br>https://journals.sagepub.com/doi/epub/10.1177/1091581817739429 |
| Pharos | https://pharos.habitablefuture.org/ | Searched September 1, 2026, Appendix F:<br>CAS #70131-67-8:<br>https://pharos.habitablefuture.org/chemicals/2022631<br>CAS #63148-60-7:<br>https://pharos.habitablefuture.org/chemicals/2085877<br>Searched September 5, 2026: Impurities D3, D4, and D5: Appendix G |
| Google | www.google.com | Searched September 1, 2026 by chemical name, CAS# AND toxicity:<br>EFSA (2020): Re-eval PDMS:<br>https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6107<br>HC Canada (2023): Siloxanes:<br>https://publications.gc.ca/collections/collection_2023/eccc/En84-342-2023-eng.pdf |
| EPA ChemView | https://chemview.epa.gov/chemview/ | Searched September 1, 2026:<br>https://chemview.epa.gov/chemview/?tf=0&ch=80122&chLabels=70131-67-8&su=2-5-6-7-37574985-56071369&as=3-10-9-8-58916628&ac=1-15-16- |

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| | | |
|---|---|---|
| | | 6378999&ma=4-11-1981377&st=1_23389071-1_23389070-4_16848473-4_16848474-4_49007566&modal=chemDetail&modalId=80122&modalSrc=2-5-6-7-37574985-56071369-3-10-9-8-58916628-1-15-16-6378999-4-11-1981377 |
| NTIS National Technical Reports Library (NTRL) | https://ntrl.ntis.gov/NTRL/ | Searched September 1&7, 2026 – Study OTS numbers reported in CIR 2017 were accessed via NTIS. |
| RIFM's Fragrance Material Safety Assessment Database | https://fragrancematerialsafetyresource.elsevier.com/ | Searched September 1, 2026 – no records |
| OECD Toolbox | Use Version 4.8.2 (or more recent version if requested by senior staff) https://qsartoolbox.org/download/ | Data found from other sources – search not necessary (September 1, 2026) |
| RTECS | https://www.ccohs.ca/ccinfoweb | Searched September 1, 2026 – https://ccinfoweb2.ccohs.ca/rtecs/records/VW3157812.html https://ccinfoweb2.ccohs.ca/rtecs/records/VW3168750.html |
| GESTIS Substance Database | https://gestis-database.dguv.de/ | Data found from other sources – search not necessary (September 1, 2026) |

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## APPENDIX C: ARTIFICIAL INTELLIGENCE (A.I.)-BASED SOURCES ACCESSED TO IDENTIFY USE AND CHEMICAL DESCRIPTIVE INFORMATION ON SILOXANES AND SILICONES, DI-ME, HYDROXY-TERMINATED (CAS #70131-67-8)

**CAS RN: 70131-67-8**
**Primary identity:** *Siloxanes and silicones, di-Me, hydroxy-terminated*
**Other names:** Hydroxy-terminated polydimethylsiloxane; silanol-terminated PDMS; dimethylpolysiloxane; dimethyl silicones and siloxanes, hydroxy terminated.
ECHA identifies CAS 70131-67-8 under the regulatory substance name "Siloxanes and Silicones, di-Me, hydroxy-terminated" and gives EC/List No. 613-154-4. It is REACH registered.
**Structurally, it can be represented approximately as:**
$HO–[Si(CH_3)_2–O]_n–Si(CH_3)_2–OH$
The important distinction from ordinary trimethylsiloxy-terminated PDMS (CAS 63148-62-9) is the presence of terminal Si–OH groups rather than $Si–CH_3$ end groups.
Because *n* varies, there is no single molecular weight for CAS 70131-67-8. Commercial materials span different viscosity and molecular-weight grades.

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**U.S. regulatory status**
**TSCA**
CAS 70131-67-8 is reported as listed on the U.S. TSCA Inventory. Multiple commercial SDSs identify the substance as TSCA-listed, and the historical EPA/ITC record specifically identifies CAS 70131-67-8 as dimethyl silicones and siloxanes, hydroxy terminated.
An important historical point is that EPA's Interagency Testing Committee evaluated the siloxane polymers as a group. The 39th ITC report states that toxicity of CAS 70131-67-8 was expected to be predictable from testing of dimethyl silicones and siloxanes, CAS 63148-62-9, because the latter was considered to have lower molecular weight, lower cross-linking ability, and greater bioavailability potential.
That is particularly relevant to a read-across assessment.
Other inventories
Available regulatory/SDS records indicate listing or exemption on several international inventories, including:

- U.S. TSCA
- EU/EEA REACH
- New Zealand NZIoC
- China IECSC
- Korea KECL
- Philippines PICCS
- Vietnam chemical inventory

The ECHA database confirms REACH registration.

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**EU REACH / CLP status**
ECHA identifies the substance as REACH registered and reports C&L Inventory notifications. However, it is important not to interpret the existence of C&L notifications as an EU harmonized classification.
I do not find evidence that CAS 70131-67-8 has a specific EU CLH harmonized classification comparable to substances such as D4, D5 or D6.
This distinction matters because individual suppliers may classify their particular grade differently. For example, a Sigma-Aldrich SDS for hydroxy-terminated PDMS does not identify the substance as PBT/vPvB at ≥0.1%.

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**GHS classification — important variability**
This is probably the most important regulatory caveat.
Classification reported for the neat substance
Some SDSs classify hydroxy-terminated PDMS as not hazardous under GHS.
For example, a Chemlyte SDS identifies CAS 70131-67-8 as a 100% substance and states:
GHS classification: Not a hazardous substance or mixture.
Other sources report Eye Irrit. 2 / H319. New Zealand's EPA Chemical Classification and Information Database currently identifies:
Eye Irrit. 2 — H319: Causes serious eye irritation.
And some commercial suppliers report substantially more severe classifications. For example, ChemScene's 90–120 cSt product is listed as:

- GHS07
- GHS08
- GHS09
- H302 — Harmful if swallowed
- H350 — May cause cancer
- H410 — Very toxic to aquatic life with long-lasting effects

I would not use H350/H410 as the intrinsic classification of CAS 70131-67-8 without further investigation.
That classification is an outlier relative to the other SDS/regulatory information I found.
It is especially important because silicone products can contain residual low-molecular-weight cyclic siloxanes, such as D4, D5 and D6. Those substances have very different toxicological and regulatory profiles from the high-MW polymer.
For example, a Dow silicone encapsulant SDS identifies hydroxy-terminated PDMS as the primary substance but separately identifies residual D4 at 0.15–0.21% and gives D4 its own classifications.
Therefore, a supplier's classification of a particular commercial grade cannot automatically be assigned to the CAS substance as a whole.

**Overall toxicological assessment**
**My weight-of-evidence assessment would be:**

| Endpoint | Assessment |
|---|---|
| Acute oral toxicity | Low |
| Acute dermal toxicity | Low |
| Skin irritation | Low/limited |
| Eye irritation | Potential hazard — H319 supported |
| Skin sensitization | No convincing evidence |
| Genotoxicity | No evidence; OECD 476 negative |
| Carcinogenicity | No convincing evidence for polymer itself |
| Reproductive toxicity | No convincing evidence |
| Repeated-dose systemic toxicity | Expected low; direct data limited |
| Bioavailability | Expected very low for high-MW polymer |
| Aquatic toxicity | Difficult to characterize from water-solubility testing; intrinsic polymer toxicity expected to be limited by bioavailability |

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| Endpoint | Assessment |
|---|---|
| PBT/vPvB | Not demonstrated for polymer itself |
| Concern from impurities | Potentially significant, particularly D4/D5/D6 |

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**Regulatory bottom line**

**There is also a particularly strong regulatory read-across precedent:** EPA's historical ITC assessment explicitly concluded that toxicity of CAS 70131-67-8 could be predicted from CAS 63148-62-9, because the latter was considered to have greater bioavailability potential.

One caution about the CAS number

There is some database inconsistency in the naming/identity associated with 70131-67-8. ECHA identifies it as *siloxanes and silicones, di-Me, hydroxy-terminated*, while some commercial databases simply call it "polydimethylsiloxane."

For a regulatory submission, I would therefore use the CAS + substance definition + molecular-weight/viscosity range, rather than relying on the CAS name alone.

If your ultimate purpose is a read-across justification, CAS 63148-62-9 is actually a very interesting comparator for 70131-67-8. EPA specifically selected that relationship historically. I can next build a formal OECD-style read-across justification comparing 70131-67-8 vs. 63148-62-9, including structural similarity, molecular weight, water solubility, absorption, hydrolysis/degradation, acute toxicity, repeated-dose toxicity, genotoxicity, reproductive toxicity, and environmental endpoints.

---

The central conclusion is favorable: 63148-62-9 is a scientifically defensible source substance for qualitative read-across to 70131-67-8, particularly for systemic toxicity endpoints. Importantly, there is also unusually strong historical regulatory support for this exact analogue relationship: EPA's 39th ITC report explicitly stated that toxicity of 70131-67-8 was likely to be predicted from testing of 63148-62-9 because the latter was a lower-MW polymer with greater bioavailability potential.

**Target substance:** CAS 70131-67-8, *Siloxanes and silicones, di-Me, hydroxy-terminated*
**Source substance:** CAS 63148-62-9, *Polydimethylsiloxane (PDMS)*
**The proposed read-across is based on:**

1. Very high structural similarity — both substances consist predominantly of repeating dimethylsiloxane units, –[Si($CH_3$)$_2$–O]–.
2. The same dominant chemical functionality — the siloxane backbone and methyl substitution pattern are identical.
3. Similar physicochemical behavior — both are high-MW, hydrophobic, low-water-solubility silicone polymers.
4. Limited systemic bioavailability — the polymers are poorly absorbed, with the majority of orally administered material expected to be eliminated in feces.
5. A conservative direction of read-across — 63148-62-9 generally has equal or greater potential for systemic availability than the higher-MW/hydroxy-terminated target.
6. A common toxicological mode of action dominated by physical/biokinetic properties rather than a reactive molecular pharmacophore.
7. Substantial existing toxicological data for 63148-62-9, including repeated-dose, reproductive/developmental and genotoxicity information.
8. Direct regulatory precedent — EPA specifically identified 63148-62-9 as an appropriate source for predicting toxicity of 70131-67-8.

Under the OECD grouping/read-across framework, this is best characterized as a qualitative analogue read-across based on structural similarity, physicochemical similarity, and a common toxicokinetic profile, with the source substance representing a conservative analogue for systemic toxicity. The

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current OECD grouping guidance specifically recognizes qualitative read-across where the presence or absence of a property in the target can be inferred from the analogue.

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**Substance identity**

| Parameter | Target | Source |
|---|---|---|
| CAS RN | 70131-67-8 | 63148-62-9 |
| Substance name | Siloxanes and silicones, di-Me, hydroxy-terminated | Polydimethylsiloxane |
| Polymer | Yes | Yes |
| Principal repeat unit | –Si(CH₃)₂–O– | –Si(CH₃)₂–O– |
| Terminal groups | Silanol, Si–OH | Typically trimethylsiloxy/variable polymer termini |
| Backbone | Polysiloxane | Polysiloxane |
| Molecular weight | Variable/distribution | Variable/distribution |
| Physical state | Silicone fluid/polymer | Silicone fluid/polymer |
| Water solubility | Very low | Very low |
| Expected systemic absorption | Very low | Very low |

ECHA identifies 70131-67-8 as “Siloxanes and Silicones, di-Me, hydroxy-terminated”, while CAS 63148-62-9 is identified as polydimethylsiloxane. Both are REACH-registered substances.

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**Structural similarity**

The common structural element is exceptionally strong.

The target can be represented schematically as:

$HO–[–Si(CH_3)_2–O–]_n–Si(CH_3)_2–OH$

whereas conventional PDMS can be represented approximately as:

$R–[–Si(CH_3)_2–O–]_n–R'$

where R/R′ are silicone end groups.

Thus, essentially the entire polymer backbone of the target is present in the source.

The principal structural difference is the terminal functionality.

Target

The target has terminal silanol groups (Si–OH).

Source

The source encompasses PDMS polymers having different terminal groups, including predominantly nonpolar silicone termini.

This difference is important but is not expected to create a fundamentally different toxicological profile because the overwhelming majority of the molecular structure—and therefore the physicochemical behavior—is the same.

**Structural similarity conclusion**

**High.**

The difference in terminal groups should be considered a potential uncertainty, but not a fundamental barrier to read-across.

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**4. Molecular-weight considerations**

**Molecular weight is actually one of the strongest arguments supporting the proposed read-across.**

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EPA's historical assessment explicitly characterized 63148-62-9 as a siloxane polymer having:

- lower molecular weight
- lower cross-linking ability
- greater bioavailability potential

than 70131-67-8 and related polymers. EPA consequently concluded that toxicity of 70131-67-8 was likely to be predictable from testing of 63148-62-9.
This produces a favorable source-to-target direction:
63148-62-9 → 70131-67-8
rather than the reverse.
If systemic toxicity is driven by absorption and subsequent interaction with biological targets, a source substance with greater potential for absorption is generally conservative for predicting the hazard of a less bioavailable target.

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**Toxicokinetic basis**
**This is the critical mechanistic element of the read-across.**
Available information indicates that PDMS is characterized by:

- very low water solubility;
- high hydrophobicity;
- high molecular weight;
- limited gastrointestinal absorption;
- predominant fecal elimination.

A regulatory review of 63148-62-9 reports that metabolism studies commonly found that dimethyl silicones and siloxanes were excreted almost exclusively in feces.
Consequently, systemic toxicity is expected to be limited by bioavailability.
The target's terminal silanol groups may modestly alter surface properties, but they do not convert the molecule into a small, readily absorbed compound. The substance remains a high-MW polysiloxane.
**Toxicokinetic conclusion**
The two substances are expected to have qualitatively similar toxicokinetics, with the target expected to have no greater systemic bioavailability than the source.
This supports conservative read-across.

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**Impurity consideration**
Commercial silicone polymers can contain residual low-MW siloxanes.
For example, historical information on materials containing 70131-67-8 documents products in which the polymer was accompanied by substantial amounts of cyclic siloxanes, including D4 and D5.
Those impurities must not be treated as intrinsic properties of the polymer.
This distinction is particularly important because:
70131-67-8 ≠ D4 ≠ D5 ≠ D6
and these substances have materially different toxicological and environmental profiles.
Therefore, the read-across should be based on well-characterized polymeric test material, preferably with quantified D4/D5/D6 and low-MW oligomer concentrations.

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**Key differences and uncertainty analysis**

| Difference | Potential significance | Effect on read-across |
|---|---|---|
| Hydroxy vs. non-hydroxy termini | Could alter surface properties | Low–moderate uncertainty |

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| Difference | Potential significance | Effect on read-across |
|---|---|---|
| Molecular-weight distribution | Controls bioavailability/physical behavior | Important, but source is conservative if lower MW |
| Viscosity | Proxy for MW | Should be documented |
| Residual cyclic siloxanes | Could drive hazard | Important |
| Residual monomers/oligomers | Potentially biologically active | Should be quantified |
| Local irritation | May depend on grade/formulation | Prefer direct data |
| Systemic toxicity | Primarily limited by bioavailability | Strong read-across |
| Genotoxicity | No reactive structural alert | Strong read-across |
| Reproductive toxicity | Requires systemic exposure | Strong read-across |
| Carcinogenicity | No demonstrated mechanism | Strong/moderately strong |

**Overall analogue suitability**

| Criterion | Assessment |
|---|---|
| Chemical identity | Very high similarity |
| Structural similarity | Very high |
| Functional similarity | High |
| Physicochemical similarity | High |
| Toxicokinetic similarity | High |
| Existing source data | High |
| Mechanistic similarity | High |
| Direction of read-across | Conservative |
| Impurity uncertainty | Moderate |
| Endpoint-specific local effects | Moderate uncertainty |
| Overall systemic-toxicity read-across confidence | High |

**Formal read-across hypothesis**

For inclusion in a dossier, I would phrase the central hypothesis approximately as follows:
The target substance, CAS 70131-67-8 (siloxanes and silicones, di-Me, hydroxy-terminated), and the source substance, CAS 63148-62-9 (polydimethylsiloxane), share the same principal dimethylsiloxane polymer backbone and therefore possess closely related structural and physicochemical properties. The principal difference is the nature of the terminal groups. Both substances are high-molecular-weight, hydrophobic polysiloxanes with very low expected systemic bioavailability. Available toxicokinetic information indicates limited gastrointestinal absorption and predominant fecal elimination of dimethylsiloxane polymers. The source substance, 63148-62-9, has a substantially more extensive toxicological database and, importantly, has historically been characterized as having lower molecular weight and greater bioavailability potential than 70131-67-8. Therefore, use of 63148-62-9 as the source substance provides a conservative basis for predicting the systemic toxicological properties of 70131-67-8.

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That last point is unusually strong because EPA made essentially this same analogue determination explicitly: it stated that toxicity of 70131-67-8 was likely to be predicted from testing of 63148-62-9 and specifically cited the lower molecular weight and greater bioavailability of the source substance.

**Endpoint-by-endpoint read-across conclusion**

| Endpoint | Proposed prediction for 70131-67-8 from 63148-62-9 | Confidence |
|---|---|---|
| Acute oral toxicity | Low toxicity | High |
| Acute dermal toxicity | Low toxicity | High |
| Acute inhalation toxicity | Low systemic toxicity | Moderate-high |
| Skin irritation | Low/limited | Moderate |
| Eye irritation | Use target-specific data | Low for read-across |
| Skin sensitization | No classification expected | Moderate |
| Genotoxicity | Negative | High |
| Carcinogenicity | No classification expected | Moderate-high |
| Repeated-dose toxicity | Low systemic toxicity | High |
| Reproductive/developmental toxicity | No adverse effect expected | Moderate-high |
| Aquatic toxicity | Low bioavailability-driven hazard | Moderate |
| PBT/vPvB | Not expected for polymer | Moderate |

**OECD/ECHA acceptability**

Under the OECD grouping framework, the justification is strongest when the analogue hypothesis is supported simultaneously by structural similarity, physicochemical similarity, toxicokinetic similarity and consistent experimental toxicity. The OECD's current guidance specifically emphasizes establishing the scientific basis for the read-across and addressing uncertainty rather than relying simply on structural resemblance.

ECHA similarly requires the registrant to demonstrate that the target and source substances are likely to have similar toxicological properties and specifically calls for detailed information on the identity and composition of both substances.

For this pair, the strongest regulatory argument is therefore not simply "they are both PDMS." It is: same siloxane backbone → similar physicochemical behavior → similarly limited bioavailability → same general toxicological profile → source has greater bioavailability → source data are conservative for target.

That is a much more defensible OECD-style read-across argument.

**Overall conclusion**

I would consider CAS 63148-62-9 an appropriate and scientifically strong source substance for qualitative read-across to CAS 70131-67-8 for systemic human-health endpoints.

The relationship is strengthened considerably by the fact that EPA historically evaluated this exact source/target pair and concluded that toxicity of 70131-67-8 could be predicted from 63148-62-9.

**The main limitations are:**

1. different terminal groups;
2. potential differences in molecular-weight distribution;

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3. limited direct target-specific chronic toxicity data; and
4. potential residual D4/D5/D6 or other low-MW siloxanes in commercial grades.

Accordingly, I would use the read-across with high confidence for acute systemic toxicity, repeated-dose systemic toxicity and genotoxicity, somewhat lower confidence for reproductive/developmental and carcinogenicity endpoints, and would not use it as the primary basis for eye irritation when target-specific information is available.

**Particularly important regulatory precedent**

The strongest single piece of evidence supporting the approach is EPA's statement:
"Toxicity of siloxane polymers bearing CAS numbers ... 70131–67–8 is likely to be predicted from testing of dimethyl silicones and siloxanes bearing CAS number 63148–62–9."
EPA's rationale was that 63148-62-9 is the lower-MW, lower-cross-linking, more bioavailable material.

**That is almost exactly the conservative source-to-target argument that an OECD/ECHA read-across justification should make.**

**Bottom line:** I would characterize the proposed analogue as "strongly supported" for systemic toxicity, with moderate residual uncertainty associated primarily with terminal-group chemistry, molecular-weight distribution, and low-MW siloxane impurities.
For a submission, the next useful step would be to convert this into a REACH Annex XI/OECD read-across dossier format, with a data matrix for each endpoint (OECD TG, species, route, dose, duration, NOAEL/LOAEL, reliability/Klimisch, and source citation) and an explicit uncertainty assessment and conclusion for each endpoint.

---

**A useful representation is:**
$HO–[–Si(CH_3)_2–O–]_n–Si(CH_3)_2–OH$
So its classification is:

| | |
|---|---|
| **Polymer characteristic** | CAS 70131-67-8 |
| **Polymer family** | Polysiloxane / silicone |
| **Backbone** | Polydimethylsiloxane (PDMS) |
| **Architecture** | Predominantly linear |
| **Repeat unit** | $–[Si(CH_3)_2–O]–$ |
| **End groups** | Silanol (Si–OH) at both ends |
| **Functional polymer?** | Yes — reactive terminal OH groups |
| **Cross-linked?** | No, not inherently |
| **Cyclic?** | No — not a cyclic siloxane |
| **Branched?** | Not as the defining structure |
| **Thermoset?** | No; the neat material is a linear silicone fluid/polymer |
| **Molecular weight** | Variable, depending on chain length/grade |

ECHA identifies CAS 70131-67-8 as "Siloxanes and Silicones, di-Me, hydroxy-terminated" and also uses the name dimethylpolysiloxane.
Commercial products confirm that this CAS covers different molecular-weight/viscosity grades. For example, Thermo Fisher lists a hydroxy-terminated PDMS grade with MW ~4,196 and viscosity 80–130 cSt, while Sigma-Aldrich sells a ~750 cSt grade under the same CAS.
The important distinction from other silicone polymers
The silanol termini are the defining feature. They make the polymer reactive toward other silanes/silicones and enable condensation/cross-linking reactions. A manufacturer describes CAS

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70131-67-8 specifically as a hydroxy-terminated PDMS whose terminal hydroxyl groups provide its reactivity.

**One important regulatory nuance**

Although I would call it a linear polymer, CAS 70131-67-8 is a generic CAS substance definition, not necessarily one single molecular species or one narrowly defined molecular-weight grade. The database record includes products ranging from relatively low-MW material to very high-viscosity grades.

Also, commercial materials may contain residual cyclic siloxanes. A safety assessment found several commercial materials containing ≥95% CAS 70131-67-8 with the balance consisting primarily of D4/D5 cyclics.

That distinction is very important for the toxicological read-across we discussed: the intrinsic toxicology of the linear silanol-terminated PDMS polymer should be separated from the toxicology of residual low-MW cyclic siloxanes.

**In short:** CAS 70131-67-8 = linear, α,ω-dihydroxy (silanol-terminated) PDMS. It is a functional linear polysiloxane, not a cyclic, branched, or cross-linked silicone polymer.

---

**Which of these types of polymers: Thermoplastic/Thermosetting/Inorganic is CAS# 70131-67-8?**

CAS 70131-67-8 is best classified as an *inorganic polymer* among the three choices you gave: Thermoplastic / Thermosetting / Inorganic.

The reason is that its polymer backbone is a siloxane (Si–O–Si) backbone, rather than a carbon-chain backbone. ECHA identifies 70131-67-8 as *siloxanes and silicones, di-Me, hydroxy-terminated* / dimethylpolysiloxane.

**Classification**

| Polymer type | CAS 70131-67-8? | Why |
|---|---|---|
| **Thermoplastic** | ❌ No | It is not a conventional carbon-chain thermoplastic that softens/melts and can be remolded repeatedly. |
| **Thermosetting** | ❌ No, as supplied | The unreacted material is a linear, hydroxy-terminated silicone polymer. It can become cross-linked through reactions of its silanol groups, but the CAS substance itself is not inherently a thermoset. |
| **Inorganic polymer** | ✅ Yes | Its primary polymer backbone is Si–O–Si, with silicon and oxygen forming the polymer chain. |

**Why "inorganic" is the appropriate choice**

**The structure is approximately:**

$HO–[Si(CH_3)_2–O]_n–Si(CH_3)_2–OH$

**The repeating backbone is:**

–Si–O–Si–O–Si–O–

rather than the carbon backbone characteristic of organic polymers.

The methyl groups (–$CH_3$) are organic substituents attached to the inorganic siloxane backbone. Consequently, silicone polymers are often described more precisely as organosilicon polymers or semi-inorganic polymers, but if your classification system gives you only the three choices you listed, “Inorganic” is the appropriate selection.

One additional point: the Canadian government's polymer assessment also explicitly lists CAS 70131-67-8 as *Siloxanes and Silicones, di-Me, hydroxy-terminated*, distinguishing it from conventional organic polymers.

So, for a form/database asking you to select one category: → INORGANIC POLYMER.

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## APPENDIX D: CHANGE IN BENCHMARK SCORE

Table 8 provides a summary of changes to ToxServices' GreenScreen® Benchmark™ for siloxanes and silicones, di-Me, hydroxy-terminated. The GreenScreen® Benchmark Score for siloxanes and silicones, di-Me, hydroxy-terminated has not changed over time. ToxServices performed the original GreenScreen® assessment in 2014 under version 1.2 criteria and ToxServices assigned a Benchmark 2 (BM-2) score. The BM-2 score was maintained with a version 1.5a update in 2026 following a weight of evidence evaluation of this chemical's 2026 dataset.

**Table 8. Change in ToxServices' GreenScreen® Benchmark™ for Siloxanes and Silicones, di-Me, Hydroxy-Terminated (CAS #70131-67-8)**

| Date | GreenScreen® Benchmark™ | GreenScreen® Version | Comment |
|---|---|---|---|
| October 14, 2014 | BM-2 | v. 1.2 | Original GreenScreen® assessment. |
| October 23, 2026 | BM-2 | v. 1.5a | No change in BM score. The GreenScreen® assessment was updated with a v.1.5a template. |

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## APPENDIX E: RESULTS OF AUTOMATED GREENSCREEN® SCORE CALCULATION FOR SILOXANES AND SILICONES, DI-ME, HYDROXY-TERMINATED (CAS #70131-67-8)[12]

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** | **Siloxanes and silicones, di-Me, hydroxy-terminated** | **70131-67-8** | **L** | **L** | **L** | **L** | DG | **L** | **L** | **L** | *L* | *L* | **L** | *L* | **L** | *M* | **L** | *L* | **vH** | **vL** | *L* | **L** |

**Table 3: 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 |
|---|---|
| Siloxanes and silicones, di-Me, hydroxy- | 2 |

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

**Table 6**

| Chemical Name | Final GreenScreen® Benchmark Score |
|---|---|
| Siloxanes and silicones, di-Me, hydroxy- | 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 | | | | | | | | | | | | |

[12] Climate impact endpoints do not affect version 1.5a Benchmark scores and are not included in the GreenScreen® Score Inspector. Future versions of the Inspector will be updated to incorporate climate impact endpoints when they impact a chemical's Benchmark score.

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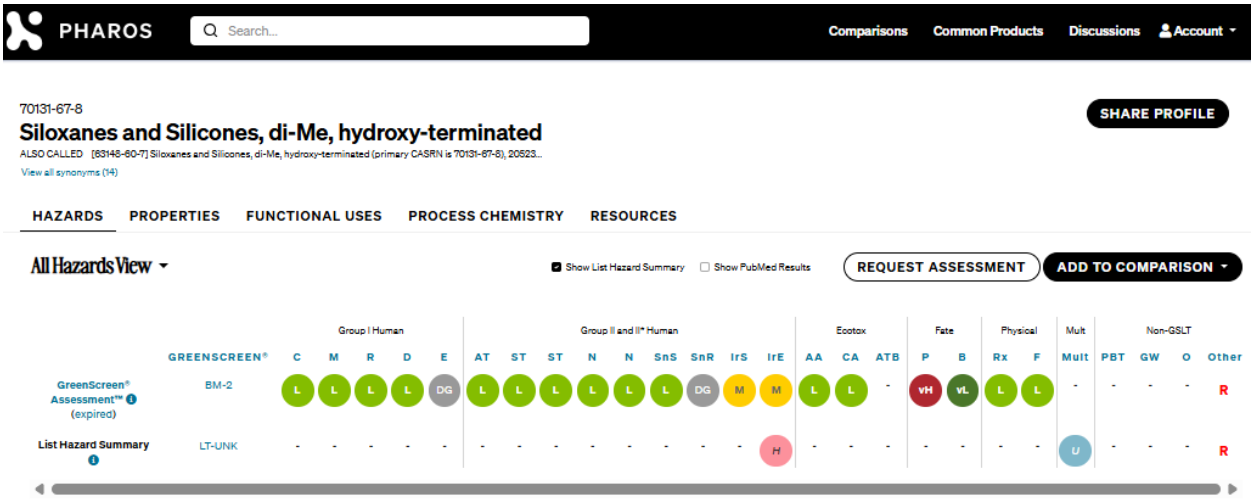
## APPENDIX F: PHAROS OUTPUT FOR SILOXANES AND SILICONES, DI-ME, HYDROXY-TERMINATED (CAS #70131-67-8) (PHAROS 2026)




### Hazard Lists

DOWNLOAD LISTS

| ENDPOINT | HAZARD LEVEL | GREENSCREEN® | LIST NAME | HAZARD DESCRIPTION | OTHER LISTS |
|---|---|---|---|---|---|
| Eye Irritation/Corrosivity | H | LT-UNK | GHS - New Zealand | Eye irritation category 2 | |
| Carcinogenicity,Mutagenicity/Genotoxicity Reproductive Toxicity, Developmental Toxicity, Acute Mammalian Toxicity, or System Toxicity/Organ Effects. | U | LT-UNK | EC - CEPA DSL | Inherently Toxic to Humans (iTH) | |
| Human and/or Aquatic toxicity and/or Persistence and/or Bioaccumulation | U | LT-UNK | German FEA - Substances Hazardous to Waters | Class 1 - Low Hazard to Waters | |

### Restricted Substance Lists (2)

- Living Building Challenge 4.0 - Red List of Materials & Chemicals - Effective July 10, 2026: Watch List Substances Considered for Inclusion in the Living Building Challenge Red List
- TSCA Chemical Substantial Risk Notices: TSCA - Substantial Risk Notices

### Exempt Lists (1)

- GB 9685 National Food Safety Standard (2016): GB 9685 National Food Safety Standard (2016)

### Positive Lists (3)

- Cosmetic Ingredient Review (CIR): Safe as Used
- TCO Certified potential candidate list (tentative - awaiting assessment): TCO Certified potential candidate list (tentative - awaiting assessment)
- US EPA - DfE Safer Chemical Ingredients list (SCIL): Defoamers - Green Half-Circle (Expected Low Concern)

### Known Use Lists (2)

- Australia - National Industrial Chemicals Notification and Assessments (NICNAS): NICNAS
- Food Contact Chemicals Database (FCCdb): Food Contact Chemicals Database Version 5.0

### Country Inventory Lists (7)

- EC - CEPA DSL: DSL-all
- Korea Existing Chemicals List: Existing Chemicals List
- New Zealand Inventory of Chemicals: New Zealand Inventory of Chemicals (NZIoC)
- Philippine Inventory of Chemicals: Philippine Inventory of Chemicals
- The Australian Inventory of Industrial Chemicals: The Australian Inventory of Industrial Chemicals
- The Inventory of Existing Chemical Substance in China - 2013: IECSC-2013
- TSCA Chemical Substance Inventory (Active-Inactive): TSCA Commercially Active

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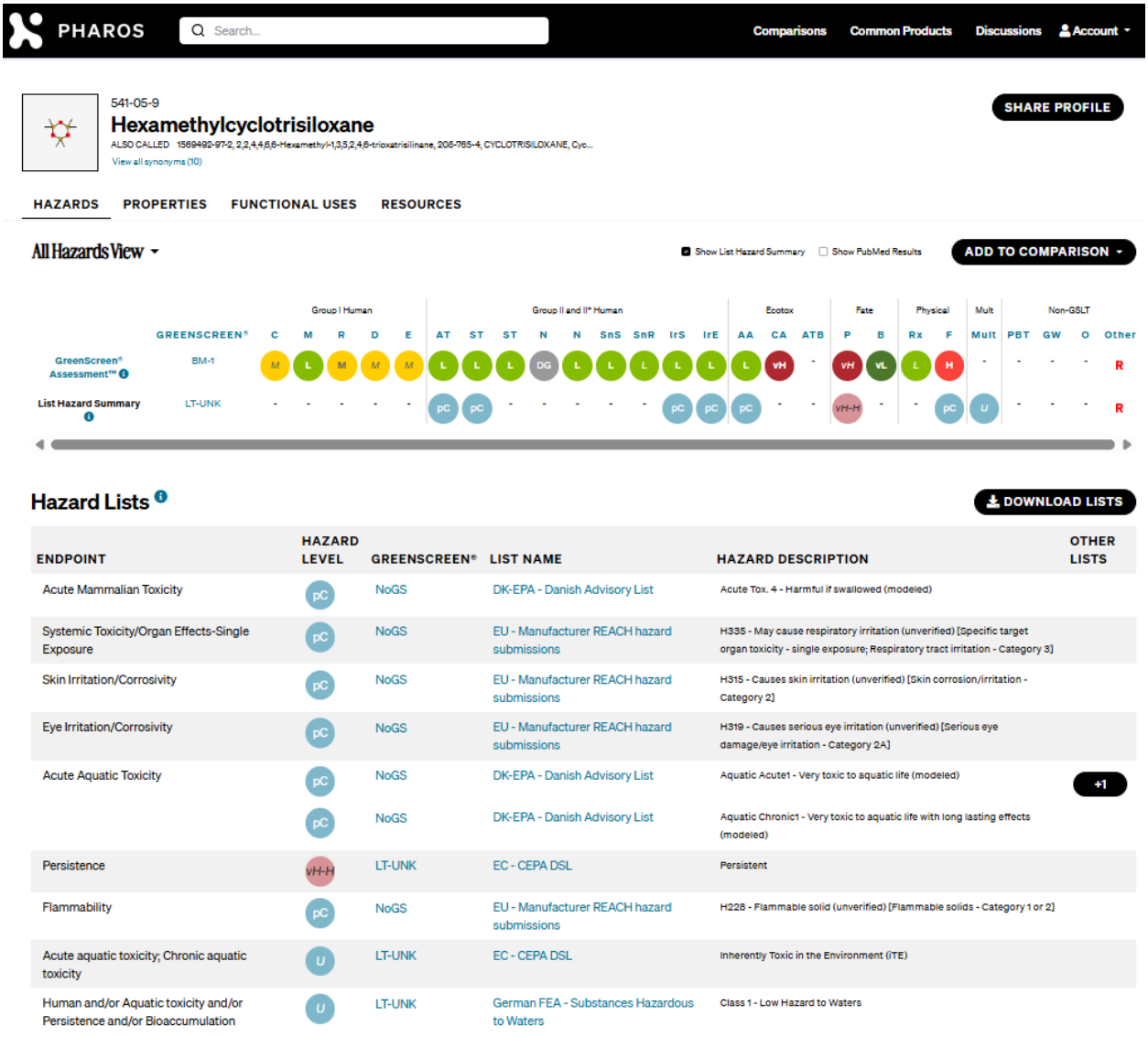
## APPENDIX G: PHAROS OUTPUT FOR D3 (CAS #541-05-9), D4 (CAS #556-67-2), AND D5 (CAS #541-02-6) (PHAROS 2026)



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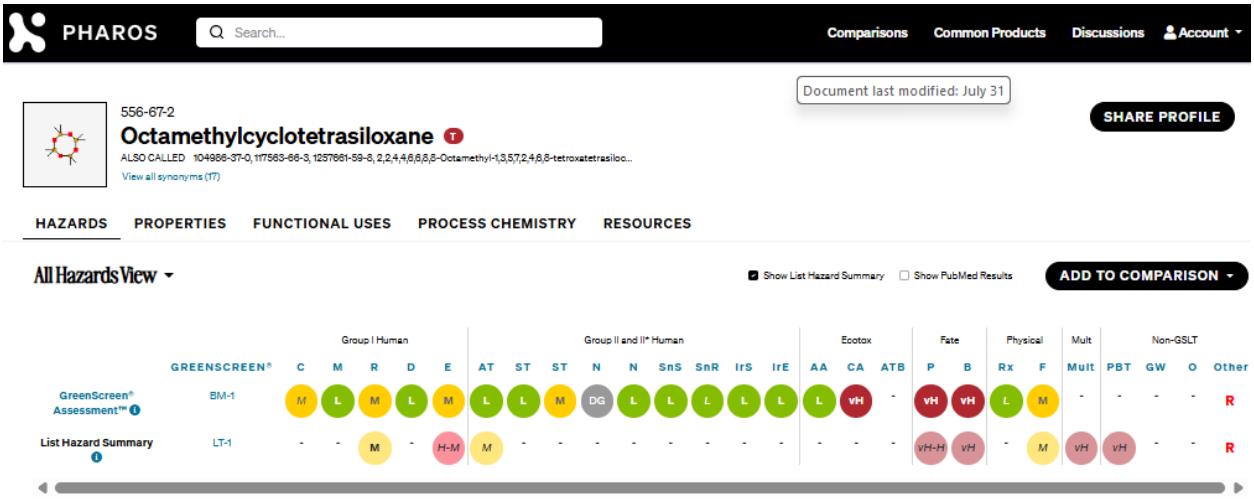


## Hazard Lists

DOWNLOAD LISTS

| ENDPOINT | HAZARD LEVEL | GREENSCREEN® | LIST NAME | HAZARD DESCRIPTION | OTHER LISTS |
|---|---|---|---|---|---|
| Reproductive Toxicity | M | LT-UNK | EU - GHS (H-Statements) Annex 6 Table 3-1 | H361f - Suspected of damaging fertility [Reproductive toxicity - Category 2] | +4 |
| | M | LT-UNK | GHS - Australia | H361f - Suspected of damaging fertility [Reproductive toxicity - Category 2] | |
| | M | LT-UNK | GHS - Japan | H361 - Suspected of damaging fertility or the unborn child [Toxic to reproduction - Category 2] | |
| | M | LT-UNK | GHS - New Zealand | Reproductive toxicity category 2 | |
| | H | NoGS | US EPA - PPT Chemical Action Plans | Reproductive toxicity - TSCA Criteria met | |
| Endocrine Activity | H-M | LT-P1 | ChemSec - SIN List | Endocrine Disruption | +4 |
| | H-M | LT-P1 | EU - Priority Endocrine Disruptors | Category 1 - In vivo evidence of Endocrine Disruption Activity | |
| | H-M | LT-P1 | TEDX - Potential Endocrine Disruptors | Potential Endocrine Disruptor | |
| | pC | NoGS | Endocrine Disruptor Lists (Danish EPA) | ED List II - Substances under evaluation for endocrine disruption under an EU legislation | |
| | pC | NoGS | Endocrine Disruptor Lists (Danish EPA) | ED List III - Substances considered, by the evaluating National Authority, to have endocrine disrupting properties | |
| Acute Mammalian Toxicity | M | LT-UNK | GHS - New Zealand | Acute dermal toxicity category 4 | +1 |
| | M | LT-UNK | GHS - New Zealand | Acute oral toxicity category 4 | |
| Persistence | vH-H | LT-UNK | EC - CEPA DSL | Persistent | +1 |
| | pC | NoGS | US EPA - PPT Chemical Action Plans | Medium environmental persistence - TSCA Criteria met | |
| Bioaccumulation | vH | LT-UNK | EC - CEPA DSL | Bioaccumulative | +2 |
| | pC | NoGS | US EPA - PPT Chemical Action Plans | High bioaccumulation potential - TSCA Criteria met | |
| | pC | NoGS | US EPA - PPT Chemical Action Plans | Moderate bioaccumulation potential - TSCA Criteria met | |
| Flammability | M | LT-UNK | GHS - Japan | H226 - Flammable liquid and vapour [Flammable liquids - Category 3] | +2 |
| | M | LT-UNK | GHS - New Zealand | Flammable liquids category 3 | |
| | pC | NoGS | EU - Manufacturer REACH hazard submissions | H226 - Flammable liquid and vapour (unverified) [Flammable liquids - Category 3] | |

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| | | | | | |
|---|---|---|---|---|---|
| PBT (Persistence, Bioaccumulation & Toxicity) | vH | LT-P1 | ChemSec - SIN List | PBT / vPvB (Persistent, Bioaccumulative, & Toxic / very Persistent & very Bioaccumulative) | +4 |
| | H | LT-P1 | EC - CEPA DSL | Persistent, Bioaccumulative and inherently Toxic (PBiTE) to the Environment (based on aquatic organisms) | |
| | H | LT-P1 | EC - CEPA DSL | Persistent, Bioaccumulative and inherently Toxic (PBiTH) to humans | |
| | U | LT-P1 | OR DEQ - Priority Persistent Pollutants | Priority Persistent Pollutant - Tier 1 | |
| | pC | NoGS | EU - ESIS PBT | Under PBT evaluation | |
| PBT [Persistence, Bioaccumulation, and any of the following: Acute Aquatic Toxicity, Chronic Aquatic Toxicity, Carcinogenicity, Mutagenicity, Reproductive Toxicity, Developmental Toxicity] | U | LT-1 | EU - SVHC List | PBT - Candidate list | +1 |
| | U | LT-1 | EU - SVHC List | PBT - Prioritized for listing | |
| Carcinogenicity, Mutagenicity/Genotoxicity Reproductive Toxicity and/or Developmental Toxicity | U | LT-P1 | ChemSec - SIN List | CMR - Carcinogen, Mutagen &/or Reproductive Toxicant | |
| Reproductive and/or Developmental Toxicity | M | LT-UNK | EU - Annex VI CMRs | Reproductive Toxicity - Category 2 | +2 |
| | pC | NoGS | ChemSec - SIN List | Reproductive and/or developmental | |
| | pC | NoGS | EU - Manufacturer REACH hazard submissions | H361 - Suspected of damaging fertility or the unborn child (unverified) [Reproductive toxicity - Category 2] | |
| Carcinogenicity,Mutagenicity/Genotoxicity Reproductive Toxicity, Developmental Toxicity, Acute Mammalian Toxicity, or System Toxicity/Organ Effects. | U | LT-UNK | EC - CEPA DSL | Inherently Toxic to Humans (iTH) | |
| Acute aquatic toxicity; Chronic aquatic toxicity | U | LT-UNK | EC - CEPA DSL | Inherently Toxic in the Environment (iTE) | |
| vPvB (Persistence, Bioaccumulation) | U | LT-1 | EU - SVHC List | vPvB - Candidate list | +1 |
| | U | LT-1 | EU - SVHC List | vPvB - Prioritized for listing | |
| T & P and/or B [(Chronic Aquatic Toxicity and sometimes Persistence) or (Acute Aquatic Toxicity and Persistence and/or Bioaccumulation)] | U | LT-P1 | GHS - Japan | H410 - Very toxic to aquatic life with long lasting effects [Hazardous to the aquatic environment (chronic) - Category 1] | |
| T & P and/or B [(Chronic Aquatic Toxicity and Persistence) or (Acute Aquatic Toxicity and Persistence and/or Bioaccumulation)] | vH | LT-P1 | GHS - New Zealand | Hazardous to the aquatic environment - chronic category 1 | +5 |
| | U | LT-P1 | EU - GHS (H-Statements) Annex 6 Table 3-1 | H410 - Very toxic to aquatic life with long lasting effects [Hazardous to the aquatic environment (chronic) - Category 1] | |
| | U | LT-P1 | GHS - Australia | H410 - Very toxic to aquatic life with long lasting effects [Hazardous to the aquatic environment (chronic) - Category 1] | |
| | pC | NoGS | EU - Manufacturer REACH hazard submissions | H410 - Very toxic to aquatic life with long lasting effects (unverified) [Hazardous to the aquatic environment (chronic) - Category 1] | |
| | pC | NoGS | EU - Manufacturer REACH hazard submissions | H411 - Toxic to aquatic life with long lasting effects (unverified) [Hazardous to the aquatic environment (chronic) - Category 2] | |
| | pC | NoGS | EU - Manufacturer REACH hazard submissions | H413 - May cause long lasting harmful effects to aquatic life (unverified) [Hazardous to the aquatic environment (chronic) - Category 4] | |
| Human and/or Aquatic toxicity and/or Persistence and/or Bioaccumulation | U | LT-UNK | EC - CEPA Toxic Substances (Sched 1) | CEPA Toxics | +1 |
| | U | LT-P1 | German FEA - Substances Hazardous to Waters | Class 3 - Severe Hazard to Waters | |

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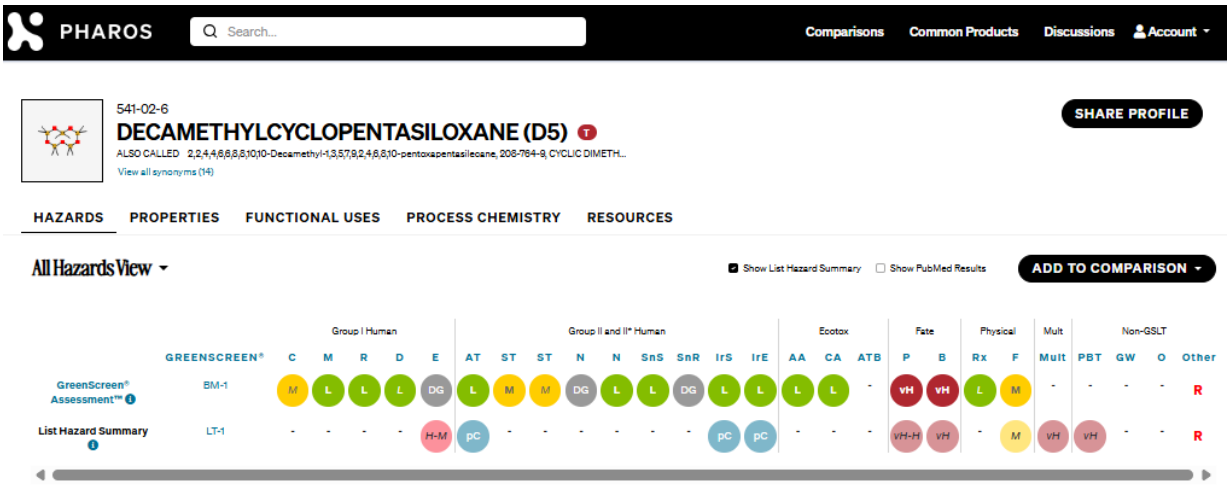


## Hazard Lists

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| ENDPOINT | HAZARD LEVEL | GREENSCREEN® | LIST NAME | HAZARD DESCRIPTION | OTHER LISTS |
|---|---|---|---|---|---|
| Endocrine Activity | H-M | LT-P1 | TEDX - Potential Endocrine Disruptors | Potential Endocrine Disruptor | +1 |
| | pC | NoGS | Endocrine Disruptor Lists (Danish EPA) | ED List II - Substances under evaluation for endocrine disruption under an EU legislation | |
| Acute Mammalian Toxicity | pC | NoGS | EU - Manufacturer REACH hazard submissions | H331 - Toxic if inhaled (unverified) [Acute toxicity (inhalation) - Category 3] | |
| Skin Irritation/Corrosivity | pC | NoGS | EU - Manufacturer REACH hazard submissions | H315 - Causes skin irritation (unverified) [Skin corrosion/irritation - Category 2] | |
| Eye Irritation/Corrosivity | pC | NoGS | EU - Manufacturer REACH hazard submissions | H319 - Causes serious eye irritation (unverified) [Serious eye damage/eye irritation - Category 2A] | |
| Persistence | vH-H | LT-UNK | EC - CEPA DSL | Persistent | |
| Bioaccumulation | vH | LT-UNK | EC - CEPA DSL | Bioaccumulative | |
| Flammability | M | LT-UNK | GHS - Japan | H227 - Combustible liquid [Flammable liquids - Category 4] | +1 |
| | M | LT-UNK | GHS - New Zealand | Flammable liquids category 4 | |
| PBT (Persistence, Bioaccumulation & Toxicity) | vH | LT-P1 | ChemSec - SIN List | PBT / vPvB (Persistent, Bioaccumulative, & Toxic / very Persistent & very Bioaccumulative) | +3 |
| | H | LT-P1 | EC - CEPA DSL | Persistent, Bioaccumulative and inherently Toxic (PBiTE) to the Environment (based on aquatic organisms) | |
| | U | LT-P1 | OR DEQ - Priority Persistent Pollutants | Priority Persistent Pollutant - Tier 1 | |
| | pC | NoGS | EU - ESIS PBT | Under PBT evaluation | |
| PBT [Persistence, Bioaccumulation, and any of the following: Acute Aquatic Toxicity, Chronic Aquatic Toxicity, Carcinogenicity, Mutagenicity, Reproductive Toxicity, Developmental Toxicity] | U | LT-1 | EU - SVHC List | PBT - Candidate list | +1 |
| | U | LT-1 | EU - SVHC List | PBT - Prioritized for listing | |
| Systemic Toxicity/Organ Effects [Repeated Exposure] and/or Neurotoxicity [Repeated Exposure] | M | LT-UNK | GHS - Japan | H373 - May cause damage to organs through prolonged or repeated exposure [Specific target organs/systemic toxicity following repeated exposure - Category 2] | |
| Acute aquatic toxicity; Chronic aquatic toxicity | U | LT-UNK | EC - CEPA DSL | Inherently Toxic in the Environment (iTE) | |
| vPvB (Persistence, Bioaccumulation) | U | LT-1 | EU - SVHC List | vPvB - Candidate list | +1 |
| | U | LT-1 | EU - SVHC List | vPvB - Prioritized for listing | |
| T & P and/or B [(Chronic Aquatic Toxicity and Persistence) or (Acute Aquatic Toxicity and Persistence and/or Bioaccumulation)] | pC | NoGS | EU - Manufacturer REACH hazard submissions | H413 - May cause long lasting harmful effects to aquatic life (unverified) [Hazardous to the aquatic environment (chronic) - Category 4] | |
| Human and/or Aquatic toxicity and/or Persistence and/or Bioaccumulation | U | LT-UNK | German FEA - Substances Hazardous to Waters | Class 1 - Low Hazard to Waters | |

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## APPENDIX H: EPI SUITE™ OUTPUT FOR THE REPRESENTATIVE STRUCTURE OF THE TARGET POLYMER (U.S. EPA 2026)

CAS Number: 70131-67-8
**SMILES : [Si](C)(C)(O)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)(O)**
CHEM : Siloxanes and Silicones, di-Me, hydroxy-terminated
MOL FOR: C8 H26 O5 Si4
MOL WT : 314.64
---------- EPI SUMMARY (v4.11) ----------
Physical Property Inputs:
Log Kow (octanol-water): ------
Boiling Point (deg C) : ------
Melting Point (deg C) : ------
Vapor Pressure (mm Hg) : ------
Water Solubility (mg/L): ------
Henry LC (atm-m3/mole) : ------

Log Octanol-Water Partition Coef (SRC):
Log Kow (KOWWIN v1.69 estimate) = 4.65

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPVP v1.43):
Boiling Pt (deg C): 274.38 (Adapted Stein & Brown method)
Melting Pt (deg C): 39.46 (Mean or Weighted MP)
VP(mm Hg,25 deg C): 0.000296 (Modified Grain method)
VP (Pa, 25 deg C) : 0.0394 (Modified Grain method)
Subcooled liquid VP: 0.0004 mm Hg (25 deg C, Mod-Grain method)
: 0.0533 Pa (25 deg C, Mod-Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.42):
Water Solubility at 25 deg C (mg/L): 3.017
log Kow used: 4.65 (estimated)
no-melting pt equation used

Water Sol Estimate from Fragments:
Wat Sol (v1.01 est) = 301.53 mg/L

ECOSAR Class Program (ECOSAR v1.11):
Class(es) found:
Neutral Organics

Henrys Law Constant (25 deg C) [HENRYWIN v3.20]:
Bond Method : 2.50E-007 atm-m3/mole (2.53E-002 Pa-m3/mole)
Group Method: Incomplete
For Henry LC Comparison Purposes:
User-Entered Henry LC: not entered
Henrys LC [via VP/WSol estimate using User-Entered or Estimated values]:
HLC: 4.062E-005 atm-m3/mole (4.116E+000 Pa-m3/mole)
VP: 0.000296 mm Hg (source: MPBPVP)
WS: 3.02 mg/L (source: WSKOWWIN)

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Log Octanol-Air Partition Coefficient (25 deg C) [KOAWIN v1.10]:
Log Kow used: 4.65 (KowWin est)
Log Kaw used: -4.991 (HenryWin est)
Log Koa (KOAWIN v1.10 estimate): 9.641
Log Koa (experimental database): None

Probability of Rapid Biodegradation (BIOWIN v4.10):
Biowin1 (Linear Model) : 0.5978
Biowin2 (Non-Linear Model) : 0.1886
Expert Survey Biodegradation Results:
Biowin3 (Ultimate Survey Model): 2.5039 (weeks-months)
Biowin4 (Primary Survey Model) : 3.3938 (days-weeks )
MITI Biodegradation Probability:
Biowin5 (MITI Linear Model) : 0.3777
Biowin6 (MITI Non-Linear Model): 0.1301
Anaerobic Biodegradation Probability:
Biowin7 (Anaerobic Linear Model): 0.1995
Ready Biodegradability Prediction: NO

Hydrocarbon Biodegradation (BioHCwin v1.01):
Structure incompatible with current estimation method!

Sorption to aerosols (25 Dec C)[AEROWIN v1.00]:
Vapor pressure (liquid/subcooled): 0.0533 Pa (0.0004 mm Hg)
Log Koa (Koawin est ): 9.641
Kp (particle/gas partition coef. (m3/ug)):
Mackay model : 5.62E-005
Octanol/air (Koa) model: 0.00107
Fraction sorbed to airborne particulates (phi):
Junge-Pankow model : 0.00203
Mackay model : 0.00448
Octanol/air (Koa) model: 0.0791

Atmospheric Oxidation (25 deg C) [AopWin v1.92]:
Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 2.5512 E-12 cm3/molecule-sec
Half-Life = 4.193 Days (12-hr day; 1.5E6 OH/cm3)
Half-Life = 50.310 Hrs
Ozone Reaction:
No Ozone Reaction Estimation
Fraction sorbed to airborne particulates (phi):
0.00325 (Junge-Pankow, Mackay avg)
0.0791 (Koa method)
Note: the sorbed fraction may be resistant to atmospheric oxidation

Soil Adsorption Coefficient (KOCWIN v2.00):
Koc : 1.453E+005 L/kg (MCI method)
Log Koc: 5.162 (MCI method)
Koc : 1575 L/kg (Kow method)

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Log Koc: 3.197 (Kow method)

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v2.00]:
Rate constants can NOT be estimated for this structure!

Bioaccumulation Estimates (BCFBAF v3.01):
Log BCF from regression-based method = 2.737 (BCF = 545.8 L/kg wet-wt)
Log Biotransformation Half-life (HL) = 1.0470 days (HL = 11.14 days)
Log BCF Arnot-Gobas method (upper trophic) = 3.344 (BCF = 2208)
Log BAF Arnot-Gobas method (upper trophic) = 3.425 (BAF = 2661)
log Kow used: 4.65 (estimated)

Volatilization from Water:
Henry LC: 2.5E-007 atm-m3/mole (estimated by Bond SAR Method)
Half-Life from Model River: 4156 hours (173.2 days)
Half-Life from Model Lake : 4.549E+004 hours (1895 days)

Removal In Wastewater Treatment:
Total removal: 63.63 percent
Total biodegradation: 0.58 percent
Total sludge adsorption: 63.04 percent
Total to Air: 0.00 percent
(using 10000 hr Bio P,A,S)

Level III Fugacity Model: (MCI Method)

| | Mass Amount (percent) | Half-Life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Air | 0.518 | 101 | 1000 |
| Water | 6.05 | 900 | 1000 |
| Soil | 50.5 | 1.8e+003 | 1000 |
| Sediment | 43 | 8.1e+003 | 0 |

Persistence Time: 2.3e+003 hr

Level III Fugacity Model: (MCI Method with Water percents)

| | Mass Amount (percent) | Half-Life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Air | 0.518 | 101 | 1000 |
| Water | 6.05 | 900 | 1000 |
| water | (4.96) | | |
| biota | (0.0111) | | |
| suspended sediment | (1.08) | | |
| Soil | 50.5 | 1.8e+003 | 1000 |
| Sediment | 43 | 8.1e+003 | 0 |

Persistence Time: 2.3e+003 hr

Level III Fugacity Model: (EQC Default)

| | Mass Amount (percent) | Half-Life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Air | 0.768 | 101 | 1000 |

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| | | | |
|---|---|---|---|
| Water | 12 | 900 | 1000 |
| water | (11.7) | | |
| biota | (0.026) | | |
| suspended sediment | (0.32) | | |
| Soil | 74.6 | 1.8e+003 | 1000 |
| Sediment | 12.6 | 8.1e+003 | 0 |
| Persistence Time: 1.56e+003 hr | | | |

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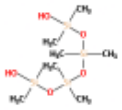
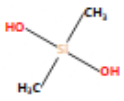
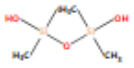
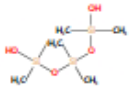
## APPENDIX I: OECD TOOLBOX PROFILE FOR THE REPRESENTATIVE STRUCTURE OF THE TARGET POLYMER (OECD 2026)

| Filter endpoint tree... | 1 [target] |
|---|---|
| Structure |  |
| Comment | |
| **Structure info** | |
| **Additional Ids** | |
| **CAS Number** | 3081-07-0 |
| **CAS-SMILES relation** | High |
| **Chemical name(s)** | 1,7-Tetrasiloxanediol, 1,1,3,3,5,5,7,7-octamethyl- |
| **Identity** | Sources:2 |
| **Molecular formula** | C8H26O5Si4 |
| **Predefined substance type** | Mono constituent |
| **SMILES** | C[Si](C)(O)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O |
| **Profiling** | |
| **Predefined** | |
| **Database Affiliation** | Does not belong to any database |
| **Inventory Affiliation** | DSSTOX |
| **Metabolic Database Affiliation** | Does not belong to any metabolic database |
| **OECD HPV Chemical Categories** | Not categorized |
| **Substance type** | Discrete chemical |
| **US-EPA New Chemical Categories** | Not categorized |
| **Endpoint Specific** | |
| **Carcinogenicity (genotox and nongenotox) alerts by ISS** | No alert found |
| **Respiratory sensitisation** | No alert found |
| **Metabolism/Transformation** | |
| **Hydrolysis simulator (acidic)** | 3 metabolite(s) |
| **Hydrolysis simulator (basic)** | 0 metabolite(s) |
| **Hydrolysis simulator (neutral)** | 0 metabolite(s) |

**Hydrolysis simulator (acidic)**

| metabolite #1 | metabolite #2 | metabolite #3 |
|---|---|---|
| No CAS number | No CAS number | No CAS number |
|  |  |  |

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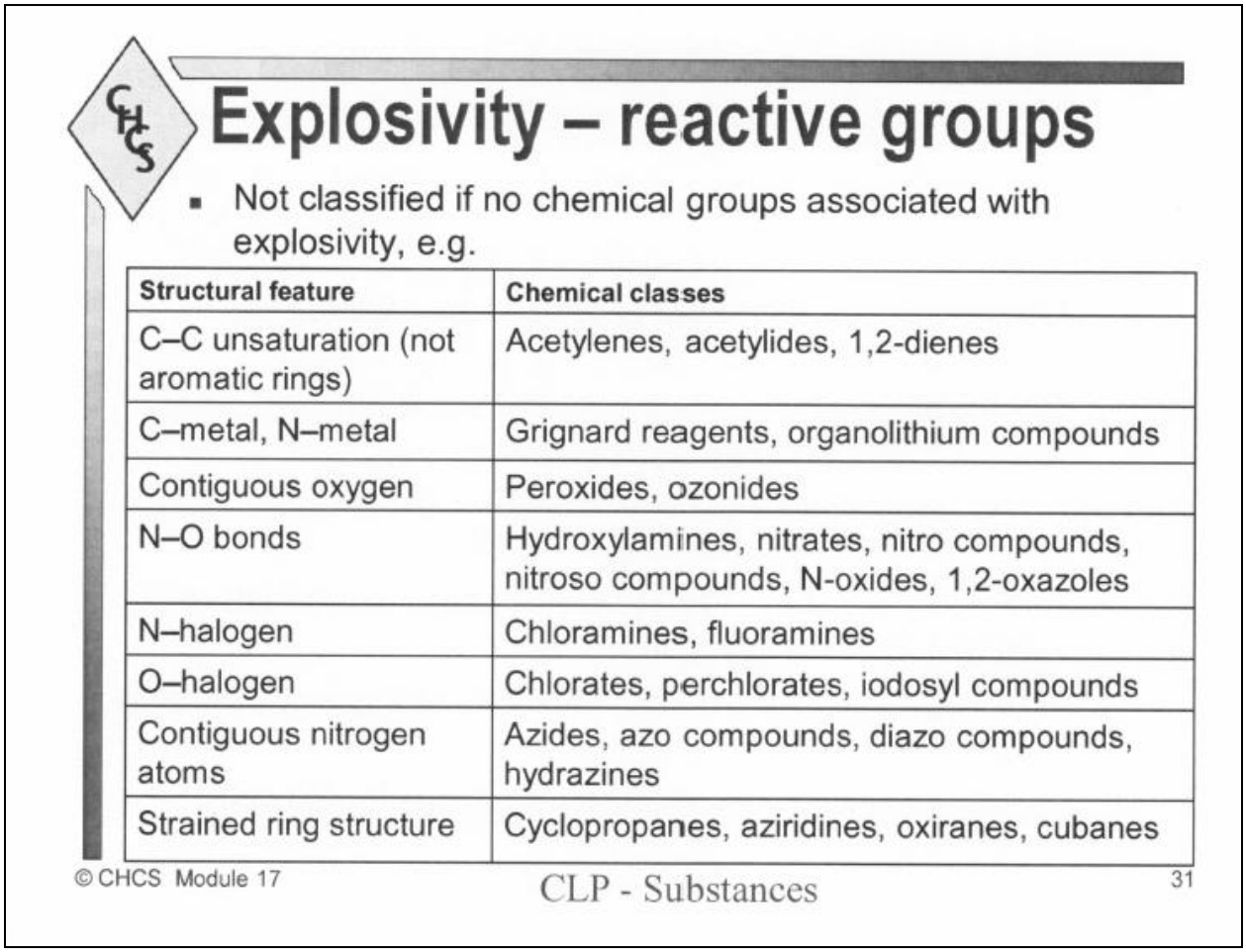
## APPENDIX J: KNOWN STRUCTURAL ALERTS FOR REACTIVITY

### Explosivity – Abbreviated List



# Explosivity – reactive groups

- Not classified if no chemical groups associated with explosivity, e.g.

| Structural feature | Chemical classes |
|---|---|
| C–C unsaturation (not aromatic rings) | Acetylenes, acetylides, 1,2-dienes |
| C–metal, N–metal | Grignard reagents, organolithium compounds |
| Contiguous oxygen | Peroxides, ozonides |
| N–O bonds | Hydroxylamines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles |
| N–halogen | Chloramines, fluoramines |
| O–halogen | Chlorates, perchlorates, iodosyl compounds |
| Contiguous nitrogen atoms | Azides, azo compounds, diazo compounds, hydrazines |
| Strained ring structure | Cyclopropanes, aziridines, oxiranes, cubanes |

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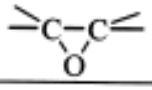
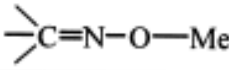
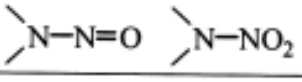
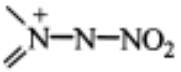
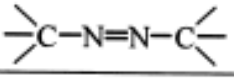
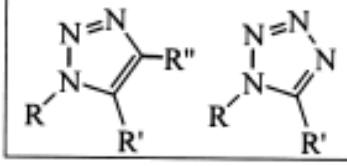
**Table R.7.1-28 Chemical groups associated with explosive properties**

| Chemical group | Chemical Class |
|---|---|
| -C≡C-<br>-C≡C-Metal<br>-C≡C-Halogen | Acetylenic Compounds<br>Metal Acetylides<br>Haloacetylene Derivatives |
|  | Diazo Compounds |
| -N=O -$NO_2$ | Nitroso and Nitro Compounds, |
| R-O-N=O<br>R-O-$NO_2$ | Acyl or Alkyl Nitrites and Nitrates |
|  | 1,2-Epoxides |
|  | Metal Fulminates or *aci*-Nitro Salts |
|  | N-Metal Derivatives (especially heavy metals) |
|  | N-Nitroso and N-Nitro Compounds |
|  | N-Azolium Nitroimidates |
|  | Azo Compounds |
| Ar-N=N-O-Ar | Arene Diazoates |
| $(ArN=N)_2O$, $(ArN=N)_2S$ | Bis-Arenediazo Oxides and Sulfides |
| RN=N-NR'R'' | Triazines |
|  | High-nitrogen Compounds: e.g. Triazoles, Tetrazoles |

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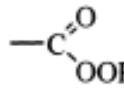
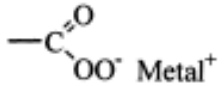
| Chemical group | Chemical Class |
|---|---|
| [1] ROOR',<br>[2]  | Peroxy Compounds:<br>[1] Alkyl hydroperoxides (R'=H), Peroxides (R'=organic);<br>[2] Peroxo acids (R'=H), Peroxyesters (R'=organic) |
| [1] ROOMetal,<br>[2]  | Metal peroxides, Peroxoacids salts |
| $-N_3$ | Azides e.g. $PbN_6$, $CH_3N_3$ |
| $^{-}O-C-N_2^{+}$ | Arenediazonium oxides i.e. inner diazonium salts in which the counter ion is an oxide |
| Ar-N=N-S-<br>Ar-N=N-S-Ar | Diazonium sulfides and derivatives, Arenediazo Aryl Sulfides |
| $XO_n$ | Halogen Oxide: e.g. percholrates, bromates, etc |
| $NX_3$ e.g. $NC1_3$, $RNC1_2$ | N-Halogen Compounds |

Adapted from Bretherick (Bretherick's Handbook of Reactive Chemical Hazards 6th Ed., 1999, Butterworths, London)

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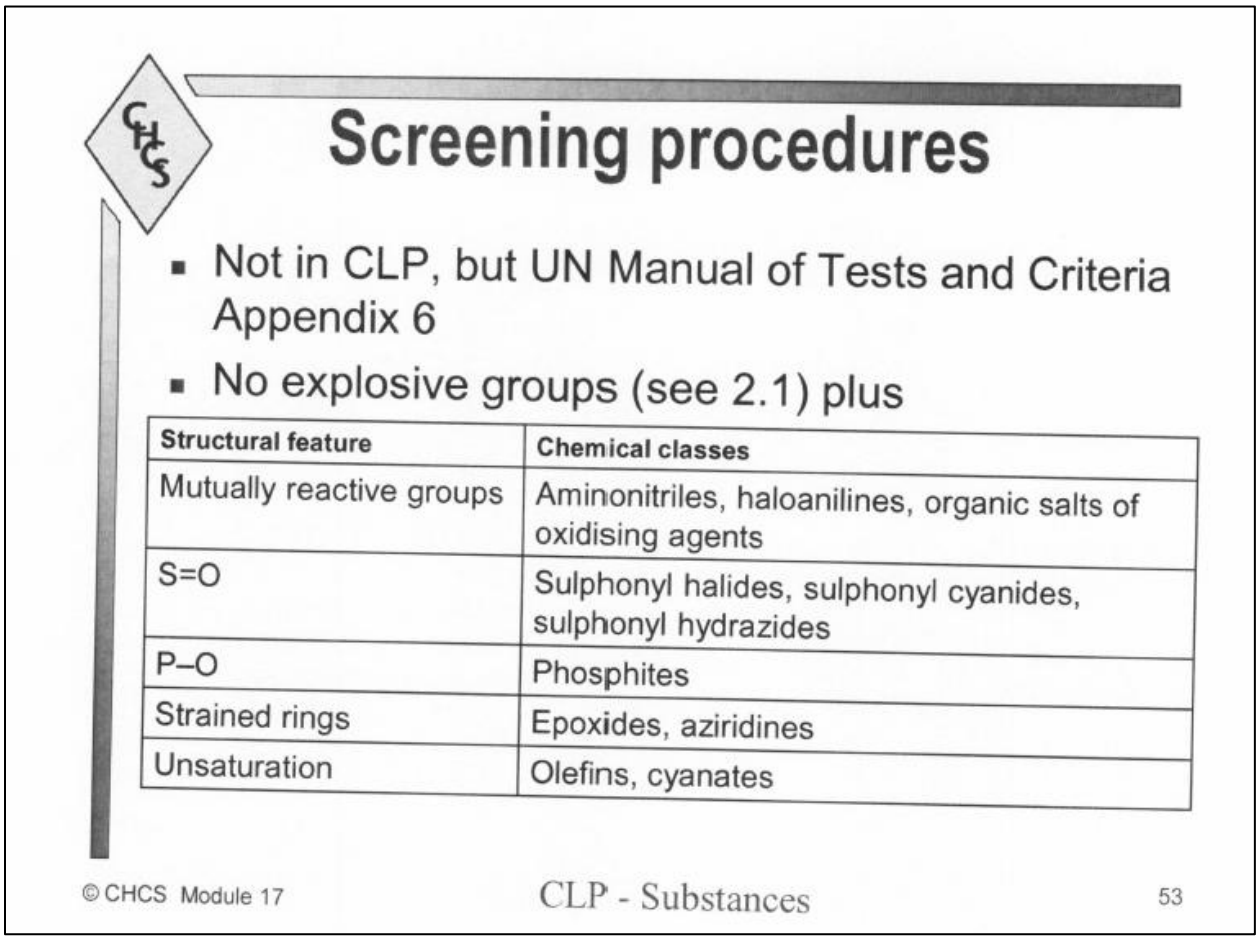
**Self-Reactive Substances**



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**LICENSED GREENSCREEN® PROFILERS**

**Siloxanes and Silicones, di-Me, Hydroxy-Terminated GreenScreen® Evaluation**
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