Vinyl Silicone Polymer (CAS #68083-19-2) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment

Prepared for:

Washington State Department of Ecology

Prepared by:

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October 17, 2014

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GreenScreen® Executive Summary for Vinyl Silicone Polymer (CAS #68083-19-2)

Vinyl silicone polymer is also known as polydimethylsiloxane, vinyl end blocked. Siloxanes are chemical compounds with a backbone of alternating silicon (Si) and oxygen (O) atoms, each silicon atom bearing one or several organic groups. Siloxanes are building blocks for silicone products, such as silicone fluids or silicone elastomers. Vinyl silicone polymers are generally used to make silicone elastomers, sealants, or putty (DEPA 2005).

Vinyl silicone polymer was assigned a GreenScreen® Benchmark Score of 1 ("Avoid—Chemical of High Concern") as it has Very High persistence (P) and bioaccumulation (B). This corresponds to GreenScreen® benchmark classification 1b ("vPvB = very High P + very High B") in CPA 2011. Data gaps (DG) exist for endocrine activity (E) and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Conduct a Data Gap Analysis to assign a final Benchmark score), vinyl silicone polymer meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps. In a worst-case scenario, if vinyl silicone polymer were assigned a High score for the data gaps endocrine activity (E) or respiratory sensitization (SnR*), it would still be categorized as a Benchmark 1 Chemical.

GreenScreen® Benchmark Score for Relevant Route of Exposure:

As a standard approach for GreenScreen® evaluations, all exposure routes (oral, dermal, and inhalation) were evaluated together, so the GreenScreen® Benchmark Score of 1 ("Avoid—Chemical of High Concern") is applicable for all routes of exposure.

GreenScreen® Hazard Ratings for Vinyl Silicone Polymer

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

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 they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Please see Appendix A for a glossary of hazard acronyms.

GreenScreen® Assessment for Vinyl Silicone Polymer (CAS #68083-19-2)

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

Chemical Name: Vinyl Silicone Polymer

CAS Number: 68083-19-2

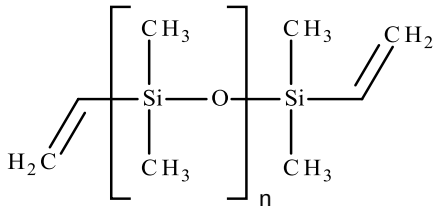
GreenScreen® Assessment Prepared By:
Name: Zach Guerrette, Ph.D.

Title: Toxicologist
Organization: ToxServices LLC
Date: October 2, 2014
Assessor Type: Licensed GreenScreen® Profiler

Quality Control Performed By:
Name: Dr. Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T.
Title: Managing Director and Chief Toxicologist
Organization: ToxServices LLC
Date: October 17, 2014

Confirm application of the *de minimus* rule[3]: N/A

Chemical Structure(s):



(Sigma-Aldrich 2014)

Also called:
Polydimethylsiloxane, vinyl end blocked; Vinyl dimethylsiloxy-terminated polydimethylsiloxane; Siloxanes and Silicones, di-Me, vinyl group-terminated (ChemIDplus 2014)

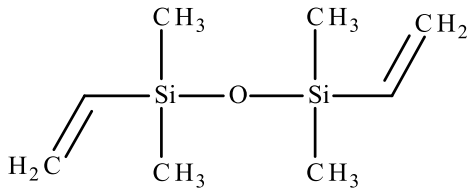
Chemical Structure(s) of Chemical Surrogates Used in the GreenScreen®:
No polymer-specific data were identified for vinyl silicone polymer. Vinyl silicone polymers may vary in molecular weight depending on the size of the polymer chain, where n may vary from 10 to >10,000 (Fedinger et al. 1997). ToxServices used the structural similarity search function of ChemIDplus to identify potential surrogates. Using this approach, ToxServices identified 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4) as a suitable surrogate as 1,1,3,3-tetramethyl-1,3-divinyldisiloxane has the same structure as vinyl silicone polymer with one repeating unit (n=1 in the figure above). 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane represents the most conservative version of vinyl silicone

[1] Use GreenScreen® Assessment Procedure (Guidance) V1.2

[2] GreenScreen® reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen® Practitioner), "CERTIFIED" (by Licensed GreenScreen® Profiler or equivalent) or "CERTIFIED WITH VERIFICATION" (Certified or Authorized assessment that has passed GreenScreen® Verification Program)

[3] Every chemical in a material or formulation should be assessed if it is:
1. intentionally added and/or
2. present at greater than or equal to 100 ppm

polymer as the bioavailability of polymers tends to decrease with increasing size (i.e., more repeating units).



1,1,3,3-Tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4)

Identify Applications/Functional Uses (DEPA 2005)**:**
1.) Elastomers, sealants, and putty.

GreenScreen® Summary Rating for Vinyl Silicone Polymer[4]: Vinyl silicone polymer was assigned a GreenScreen® Benchmark Score of 1 ("Avoid—Chemical of High Concern") as it has Very High persistence (P) and bioaccumulation (B). This corresponds to GreenScreen® benchmark classification 1b ("vPvB = very High P + very High B") in CPA 2011. Data gaps (DG) exist for endocrine activity (E) and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Conduct a Data Gap Analysis to assign a final Benchmark score), vinyl silicone polymer meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps. In a worst-case scenario, if vinyl silicone polymer were assigned a High score for the data gaps endocrine activity (E) or respiratory sensitization (SnR*), it would still be categorized as a Benchmark 1 Chemical.

Figure 1: GreenScreen® Hazard Ratings for Vinyl Silicone Polymer

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

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

Transformation Products and Ratings:
Identify feasible and relevant fate and transformation products (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**[5]

No data were identified for vinyl silicone polymer. A GLP-compliant OECD 111 hydrolysis test identified a hydrolysis half-life of 5.8 days for the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane at

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

pH 7 and 25°C (ECHA 2014). Dimethyl(vinyl) silanol (CAS #5906-75-2) was identified as a hydrolysis product and is not listed in Pharos. Therefore, the Benchmark Score for vinyl silicone polymer is not modified by transformation products.

Functional Use	Life Cycle Stage	Transformation Pathway	Transformation Products	CAS #	Feasible and Relevant?	GreenScreen® List Translator Score or Benchmark Score[6,7]
N/A	End of Life	Hydrolysis	Dimethyl(vinyl) silanol	5906-75-2	Y	Not listed in Pharos

Introduction

Vinyl silicone polymer is also known as polydimethylsiloxane, vinyl end blocked. Siloxanes are chemical compounds with a backbone of alternating silicon (Si) and oxygen (O) atoms, each silicon atom bearing one or several organic groups. Siloxanes are building blocks for silicone products, such as silicone fluids, silicone elastomers, or silicone resins used for paints. Vinyl silicone polymers are generally used to make silicone elastomers, sealants, or putty (DEPA 2005).

ToxServices assessed vinyl silicone polymer against GreenScreen® Version 1.2 (CPA 2013) following procedures outlined in ToxServices' SOP 1.69 (GreenScreen® Hazard Assessment) (ToxServices 2013).

GreenScreen® List Translator Screening Results

The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to identify GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2014) is an online list-searching tool that is used to screen chemicals against the List Translator electronically. It checks all of the lists in the List Translator with the exception of the U.S. Department of Transportation (U.S. DOT) lists (U.S. DOT 2008a,b) and these should be checked separately in conjunction with running the Pharos query. The output indicates benchmark or possible benchmark scores for each human health and environmental endpoint. The output for vinyl silicone polymer can be found in Appendix C and a summary of the results can be found below:

- Vinyl silicone polymer does not have any medium or high hazard results in Pharos.
- Vinyl silicone polymer is not listed on the U.S. DOT (2008a,b) lists.

PhysicoChemical Properties of Vinyl Silicone Polymer

Vinyl silicone polymer is also known as Polydimethylsiloxane, vinyl end blocked. It is a linear polysiloxane. Linear polysiloxanes are characterized by the functional side chains attached to the Si-O backbone and the endgroups terminating the polymer. Endgroups on the polymer determine the use of the polymer, while the side groups together with the end-groups determine the properties of the siloxane. Typical endgroups on a siloxane polymer are methyl, hydroxyl, vinyl or hydrogen. Polydimethylsiloxanes are typically silicone fluids, whereas vinyl- and hydroxyterminated polysiloxanes

[6] The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to screen for GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2014) is an online list-searching tool that is used to screen chemicals against the lists in the List Translator electronically.
[7] The way you conduct assessments for transformation products depends on the Benchmark Score of the parent chemical (See Guidance).

are often used to produce silicone elastomers (DEPA 2005). Siloxanes are highly stable, and physiologically inert, which makes such polymers very persistent in the environment.

Table 1: Physical and Chemical Properties of Vinyl Silicone Polymer (CAS #68083-19-2)

Property	Value	Reference
Molecular formula	Variable - polymer	
SMILES Notation	Variable - polymer	
Molecular weight	Variable – polymer (n ranges from 10 to 10,000)	Fedinger et al. 1997
Physical state	Liquid	Sigma-Aldrich 2014
Appearance	Not identified	
Melting point	Not identified	
Vapor pressure	Not identified	
Water solubility	Not identified	
Dissociation constant	Not identified	
Density/specific gravity	Relative density – 0.965 g/mL at 25°C	Sigma-Aldrich 2014
Partition coefficient	Not identified	

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M, or L): *L*
Vinyl silicone polymer was assigned a score of Low for carcinogenicity based on the lack of structural alerts for carcinogenicity. GreenScreen® criteria classify chemicals as a Low hazard for carcinogenicity when negative data, no structural alerts, and no GHS classification are available (CPA 2012a). The confidence in the score is adjusted as it is based on modeling.

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - No measured data were identified for this endpoint. ToxServices used Toxtree and Oncologic to predict the carcinogenicity of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane.
    - Toxtree 2013 –
      - 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane does not contain structural alerts for genotoxic or non-genotoxic carcinogenicity (see Appendix D).
    - U.S. EPA 2013 –
      - Organosilicon chemicals are generally unreactive and do not have significant carcinogenic potential unless they contain halosilanes or epoxide groups. As 1,1,3,3-tetramethyl-1,3-divinyldisiloxane contains neither of these groups, the carcinogenic potential is low (see Appendix E).

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

Vinyl silicone polymer was assigned a score of Low for mutagenicity/genotoxicity based on negative data for mutagenicity and clastogenicity for the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane. GreenScreen® criteria classify chemicals as a Low hazard for mutagenicity/genotoxicity when negative data for mutagenicity and clastogenicity, no structural alerts, and no GHS classifications are available (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *In vitro*: Negative results for mutagenicity were obtained in a GLP-compliant Ames test conducted according to OECD 471. *Salmonella typhimurium* tester strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and *Escherichia coli* tester strain WP2 uvr A were exposed to 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not identified) at 100-5,000 µg/plate with and without metabolic activation. No increase in the mutation frequency was observed with treatment in the presence or absence of metabolic activation.
    - *In vitro*: Negative results for mutagenicity were obtained in a GLP-compliant mammalian cell gene mutation test conducted according to OECD 476. Mouse lymphoma L5178Y cells were exposed to 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (98.021% purity) at 0.2-10 mM with and without metabolic activation. No increase in the mutation frequency was observed with treatment in the presence or absence of metabolic activation.
    - *In vivo*: Negative results for clastogenicity were obtained in a GLP-compliant mouse micronucleus test conducted according to OECD 474. ICR mice (5/sex/dose group) were administered single oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) in corn oil at 0, 500, 1,00, or 2,000 mg/kg via gavage. Bone marrow samples were isolated for evaluating the frequency of micronuclei. No increase in the frequency of micronuclei was observed in this study.

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

Vinyl silicone polymer was assigned a score of Low for reproductive toxicity based on negative results for reproductive toxicity for the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane. GreenScreen® criteria classify chemicals as a Low hazard for reproductive toxicity when negative data, no structural alerts, and no GHS classification are available (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: A GLP-compliant combined repeated dose toxicity study with reproduction/developmental toxicity screening test conducted according to OECD 422 was performed with Crl:CD(SD) rats (10/sex/dose group, an additional 10 for

control and high dose recovery groups) administered oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (99.1% purity) in corn oil at 0, 50, 150, or 600 mg/kg/day via gavage. Males were dosed for up to 31 days and females were dosed from 14 days prior to mating to lactational day 3 (up to 47 days). The fertility and copulation indices, number of former implantation sites and corpora lutea, number of pups/litter, mean litter size, and postnatal survival were evaluated. No treatment-related effects on reproductive performance, gestation length, or parturition were observed. The study authors identified a reproductive toxicity NOAEL of 600 mg/kg/day based on the lack of effects on reproduction.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): M
Vinyl silicone polymer was assigned a score of Moderate for developmental toxicity based on the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane adversely affecting postnatal survival, pup body weight, and pup clinical conditions in a rat study. GreenScreen® criteria classify chemicals as a Moderate hazard for developmental toxicity when limited or marginal evidence of developmental toxicity is available in animals (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: A GLP-compliant combined repeated dose toxicity study with reproduction/developmental toxicity screening test conducted according to OECD 422 was performed with Crl:CD(SD) rats (10/sex/dose group, an additional 10 for control and high dose recovery groups) administered oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (99.1% purity) in corn oil at 0, 50, 150, or 600 mg/kg/day via gavage. Males were dosed for up to 31 days and females were dosed from 14 days prior to mating to lactational day 3 (up to 47 days). The maternal examinations consisted of clinical signs of toxicity, body weight, food consumption, and ovarian and uterine content (number of corpora lutea and implantations). Offspring evaluations consisted of litter viability, pup body weights, mean litter size, and postnatal survival. A decrease in the number of implantations was observed for high dose females and led to a non-significant decrease in the mean number of pups born and live litter size. Postnatal survival decreased in the high dose group for postnatal days 0 to 1 and 1 to 4 due to two separate total litter losses on postnatal days 1 and 3. The postnatal survival for the high dose group was not significantly different when compared to the controls but was lower than historical control data. Slight decreases in pup birth weights and pup body weight gains on postnatal days 1 to 4 were observed in the high dose group. Increased incidences of pups with cool or pale bodies were noted in the high dose group. The authors identified a developmental toxicity NOAEL and LOAEL of 150 and 600 mg/kg/day, respectively, based on decreased postnatal survival, total litter losses, pup body weight, and adverse clinical findings in the pups.

Endocrine Activity (E) Score (H, M, or L): DG
Vinyl silicone polymer was assigned a score of Data Gap for endocrine disruption based on the lack of data identified for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - No data were identified for this endpoint.

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

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M, or L): L
Vinyl silicone polymer was assigned a score of Low for acute toxicity based on oral LD_{50} values greater than 2,000 mg/kg for the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane. GreenScreen® criteria classify chemicals as a Low hazard for acute toxicity when oral LD_{50} values are greater than 2,000 mg/kg (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - Sigma-Aldrich 2014 –
    - *Oral*: LD_{50} (rat) = greater than 15,440 mg/kg
    - *Dermal*: LD_{50} (rabbit) = greater than 15,440 mg/kg
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: LD_{50} (Sprague-Dawley rat) = greater than 5,000 mg/kg (GLP-compliant)
    - *Oral*: LD_{50} (mouse) = greater than 2,000 mg/kg
    - *Inhalation*: 6-hour whole body vapor LC_{50} (Sprague-Dawley rat) = greater than 1.875 mg/L (GLP-compliant, OECD 412)

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)
***Group II Score (single dose)* (vH, H, M, or L): L**
Vinyl silicone polymer was assigned a score of Low for systemic toxicity (single dose) based on the lack of systemic toxicity observed in acute toxicity tests performed with the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (single dose) when negative data, no structural alerts, and no GHS classification is available (CPA 2012a).

- Authoritative and Screening Lists

  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: In the acute oral toxicity test that identified an oral LD_{50} of greater than 5,000 mg/kg, no treatment-related effects on clinical state, body weight, or gross pathology were observed.
    - *Oral*: No systemic toxicity data were presented for the oral acute toxicity study that identified an oral LD_{50} of greater than 2,000 mg/kg.
    - *Inhalation*: No treatment-related changes to clinical state, body weight, or gross pathology were observed in the acute inhalation study that identified an LC_{50} of greater than 1,875 mg/L.

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

Vinyl silicone polymer was assigned a score of Low for systemic toxicity (repeated dose) based on ToxServices not classifying the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a systemic toxicant following repeat doses under GHS criteria. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (repeated dose) when no GHS classification is available for systemic toxicity following repeat doses (CPA 2012a). The confidence in the classification is reduced due to the lack of data regarding whether adverse effects would occur at oral doses greater than the NOAEL of 150 mg/kg/day and the GHS category 2 guidance value of 300 mg/kg/day.

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: A GLP-compliant combined repeated dose toxicity study with reproduction/developmental toxicity screening test conducted according to OECD 422 was performed with Crl:CD(SD) rats (10/sex/dose group, an additional 10 for control and high dose recovery groups) administered oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (99.1% purity) in corn oil at 0, 50, 150, or 600 mg/kg/day via gavage. Males were dosed for up to 31 days and females were dosed from 14 days prior to mating to lactational day 3 (up to 47 days). Additional control and high dose groups were maintained for an additional 14-day exposure free period following the exposure period. The animals were evaluated for clinical signs of toxicity, body weight, food consumption, hematology, clinical chemistry, gross pathology, and histopathology. At the mid and high dose groups, clear material around the mouth was observed approximately 1 hour after dosing. Red material was also noted around the mouth in the high dose group 1 hour after dosing. Mean body weights decreased for high dose males and females relative to controls during the exposure period. Mean food consumption for high dose males was decreased on study days 0-7 relative to controls. Changes to hematology parameters were observed during the treatment period and during the recovery period, but were considered by the study authors to be non-adverse as they were small in magnitude

and were not associated with gross or histopathological observations. Increased alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma glutamyltransferase activities and increased serum total bilirubin were observed in the high dose group during the treatment period. In the recovery period, small changes were observed in clinical chemistry parameters between the control and high dose groups but were considered by the authors to be within the bounds of the historical control database and were reflective of recovery from treatment. One high dose male exhibited pale kidneys at necropsy. Increased absolute and relative liver weights were observed in all dose groups for males and for females in the mid and high dose groups. Decreased absolute and relative adrenal gland weights were observed in high dose males. Other changes to relative organ weights were considered to be a function of the changes in body weight and not a direct effect of the treatment on those organs. In the recovery groups, increased mean absolute and relative liver weights persisted in the high dose group but the difference was of a lower magnitude than at the end of the treatment period. Minimal to mild hepatocellular hypertrophy was observed in the liver of animals in all dose groups. The distribution of the hypertrophy was diffuse in males while a centrilobular pattern was apparent in females. Bile duct hyperplasia was also observed in high dose males and in mid and high dose females. In the high dose group, the bile ducts were surrounded by few concentric layers of fibrous connective tissue (peribiliary fibrosis) and often contained brown pigmented material which was identified as porphyrin pigment. The hepatocellular hypertrophy was considered to be adaptive and non-adverse, while the changes to the bile duct in combination with the serum chemistry changes were considered to be adverse for the high dose animals. In males of all dose groups, minimal to mild increased concentrations of eosinophilic protenaceous intracytoplasmic and intraluminal droplets (hyaline droplets) were observed in the proximal convoluted tubules of the kidneys. While hyaline droplets are considered to be a normal observation in male rats, the condensation and aggregation pattern of the droplets was more prominent in the treatment male rats, progressing to hyaline droplet nephropathy in 1/4 in the low dose, 4/7 in the mid dose, and 3/7 in the high dose among males with hyaline droplets. The hyaline droplet nephropathy was characterized by dilated tubules having flattened epithelium in the inner stripe of the outer medulla. The tubules contained lightly eosinophilic granular cell debris, also known as granular casts. High dose males produced positive staining results for alpha-2u globulin which, in combination with the other observations in the kidney, was consistent with alpha-2u globulin nephropathy. This type of nephropathy is considered adverse in the rat but is not considered to be relevant for humans. Mild to minimal adrenal cortical atrophy was observed in males of all dose groups. The atrophy was characterized by decreased overall size of the organ and correlated with the decreased adrenal weights. The authors did not consider this observation to be adverse as it was not associated with changes in clinical pathology or gross observations. Minimal to mild vacuolation of the pituitary gland was observed in males of the low, mid, and high dose groups, but it too was considered to be non-adverse by the study authors due to a lack of association with gross observations, changes to clinical pathology, or organ weight changes. In the recovery group, high males exhibited biliary hyperplasia, brown pigment, and peribiliary fibrosis at incidences similar to that observed at the end of the treatment period, indicative of a lack of recovery. Hepatocellular hypertrophy was evident in high dose males and females at an incidence and severity less than at

the end of the treatment period, indicating some degree of recovery. At the end of the recovery period, hyaline droplets and hyaline droplet nephropathy were observed in high dose males at an incidence and severity similar to that observed at the end of the treatment period indicating a lack of recovery. No treatment-related changes were observed in the adrenal glands at the end of the recovery period and the cytoplasmic vacuolation of the pituitary was observed at a decreased incidence and severity than at the end of the treatment period, indicating a trend toward recovery. The study authors identified a NOAEL of 150 mg/kg/day and a LOAEL of 600 mg/kg/day based on the changes to body weight, food consumption, effects to clinical chemistry parameters, and histopathological changes in the liver.

- As the exposure duration was less than 90 days, ToxServices adjusted the GHS guideline values of 10 and 100 mg/kg/day for Category 1 and 2 oral systemic toxicants, respectively, by a factor of 3 (31 days is approximately 1/3 of 90 days) to 30 and 300 mg/kg/day (UN 2013). Since the LOAEL of 600 mg/kg/day for the above study is greater than the adjusted GHS Category 2 guidance value of 300 mg/kg/day, ToxServices did not classify 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a repeat dose toxicant under GHS criteria. The confidence in the classification is reduced due to the lack of data regarding whether adverse effects would occur at doses greater than the NOAEL of 150 mg/kg/day and the GHS category 2 guidance value of 300 mg/kg/day.

- *Oral*: A GLP-compliant repeat dose toxicity study was performed with Sprague-Dawley rats (5/sex/dose group) administered oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (99.1% purity) in corn oil at 0, 100, 500, or 1,000 mg/kg/day for 14 days. The animals were evaluated for clinical signs of toxicity, body weight, food consumption, and organ weights. Animals in the high dose group exhibited red, yellow, and/or clear material on various body surfaces and hunched posture. Body weight decreases were observed in the mid and high dose groups. Food consumption decreased significantly in the high dose group. Increased absolute and relative liver weights were observed in the mid and high dose group males and females. The study authors identified a NOAEL and LOAEL of 100 and 500 mg/kg/day, respectively, based on decreased body weights and increased liver weights observed in the mid and high dose groups.
    - Due to the short exposure period and the lack of histopathological evaluation, ToxServices concluded that this study is not sufficient for use in assigning a score for this endpoint.
- *Inhalation*: A GLP-compliant repeated inhalation exposure study conducted in a manner similar to OECD 412 (only 14 days of exposure, no particle size data) was performed with Sprague-Dawley rats (10/sex/dose group) administered whole body exposures to 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (approximately 99% purity) vapor at 0, 5, 50, or 246 ppm (equivalent to 0, 0.04, 0.38, and 1.88 mg/L, respectively[8]) for 6 hours/day, 5 days/week for 2 weeks. The equivalent concentrations for a 7-day/week exposure frequency were 0, 0.03, 0.27, and 1.34 mg/L, respectively. The animals were evaluated for body weights, organ weights, and histopathology. No mortality or treatment-related effects were observed on

[8] The equivalent concentrations in mg/L were calculated using the following formula: mg/L = (ppm x molecular weight)/24,450. The molecular weight of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane is 186.401 g/mol.

these endpoints. The study authors identified a NOAEC of 1.88 mg/L (equivalent to 1.34 mg/L for a 7-day/week exposure frequency).

- Due to the short exposure period, ToxServices concluded that this study is not sufficient for use in assigning a score for this endpoint.

Neurotoxicity (N)

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

Vinyl silicone polymer was assigned a score of Data Gap for neurotoxicity (single dose) based on the lack of data available for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006, 2014).
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - No data were identified for this endpoint.

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

Vinyl silicone polymer was assigned a score of Low for neurotoxicity (repeated dose) based on ToxServices not classifying the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a neurotoxicant following repeated oral doses. GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (repeated dose) when no GHS classification is available for neurotoxicity following repeated doses (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006, 2014).
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - *Oral*: A GLP-compliant combined repeated dose toxicity study with reproduction/developmental toxicity screening test conducted according to OECD 422 was performed with Crl:CD(SD) rats (10/sex/dose group, an additional 10 for control and high dose recovery groups) administered oral doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) in corn oil at 0, 50, 150, or 600 mg/kg/day via gavage. Males were dosed for up to 31 days and females were dosed for up to 34 days. Additional control and high dose groups were maintained for an additional 14-day exposure free period following the exposure period. The animals were evaluated in a functional battery of tests assessing sensory activity, grip strength, and motor activity during week 4 of the study. Locomotor activity was also assessed during week 4. No treatment-related effects were observed on the open field, home cage, handling, sensory, neuromuscular, or physiological parameters. Treatment-related increases in the mean cumulative total and ambulatory counts were observed for high dose males. Slower habituation over the entire test session was observed for these males. No treatment-related, statistically significant effects were observed for males in the low or mid dose groups or in treated females. ToxServices

identified a neurotoxicity NOAEL and LOAEL of 150 and 600 mg/kg/day, respectively, based on changes to the habituation and activity counts for males in the high dose group

- As the exposure duration was less than 90 days, ToxServices adjusted the GHS guideline values of 10 and 100 mg/kg/day for Category 1 and 2 neurotoxicants, respectively, by a factor of 3 (31 days is approximately 1/3 of 90 days) to 30 and 300 mg/kg/day (UN 2013). Since the LOAEL of 600 mg/kg/day for the above study is greater than the adjusted GHS Category 2 guidance value of 300 mg/kg/day, ToxServices did not classify 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a neurotoxicant following repeat dose under GHS criteria. The confidence in the classification is reduced due to the lack of data regarding whether adverse effects would occur at doses greater than the NOAEL of 150 mg/kg/day and the GHS category 2 guidance value of 300 mg/kg/day.

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

Vinyl silicone polymer was assigned a score of Low for skin sensitization based on negative skin sensitization data for the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane. GreenScreen® criteria classify chemicals as a Low hazard for skin sensitization when negative data, no structural alerts, and no GHS classification are available (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - A GLP-compliant guinea pig maximization test conducted according to OECD 406 was performed with male Hartley guinea pigs (20 in treatment group, 10 in controls) administered dermal doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) as Dow Corning 360 medical fluid (negative control). The induction dose was administered as an undiluted topical application to the shoulder region under semi-occlusive dressing for 48 hours. The challenge dose was applied on day 22 as 0.3 mL undiluted solution to the shaved upper right flank for 24 hours under semi-occlusive dressing. The reactions were scored at 24 and 48 hours after removal of the dressing. The animals were re-challenged on day 29 using the same procedure. No positive reactions were observed in the negative control groups in the initial challenge or in the re-challenge.
    - A second GLP-compliant guinea pig maximization test conducted according to OECD 406 was performed with male Hartley guinea pigs (20 in treatment group, 10 in controls) administered dermal doses of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) as Dow Corning 360 medical fluid (negative control). The induction and challenge doses were applied as intradermal injections with unknown temporal spacing. The reactions were scored at 24 and 48 hours after the challenge dose. The animals were re-challenged on an unspecified day using the same procedure. No positive reactions were observed in the negative control groups in the initial challenge or in the re-challenge.

Respiratory Sensitization (SnR) Group II* Score (H, M, or L): DG
Vinyl silicone polymer was assigned a score of Data Gap for respiratory sensitization based on the lack of data identified for this endpoint.

- Authoritative and Screening Lists
    - *Authoritative:* Not listed on any authoritative lists for this endpoint.
    - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
    - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
    - No data were identified for this endpoint.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M, or L): L
Vinyl silicone polymer was assigned a score of Low for skin irritation/corrosivity based on ToxServices not classifying the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a dermal irritant under GHS criteria. GreenScreen® criteria classify chemicals as a Low hazard for skin irritation/corrosivity when negative data, no structural alerts, and no GHS classification are available (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not listed on any authoritative lists for this endpoint.
    - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
    - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
    - ECHA 2014 –
        - A GLP-compliant skin irritation test conducted according to U.S. FDA regulations (40 CFR part 792) was performed with New Zealand White rabbits (3/sex) administered topical applications of 0.5 mL undiluted 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) to shaved skin under semi-occlusive dressing for 3 minutes, 1 hour, or 4 hours. The reactions were evaluated 48 hours after the removal of the dressing. The mean erythema and edema scores were 0 at every exposure duration tested. The study authors concluded that 1,1,3,3-tetramethyl-1,3-divinyldisiloxane was not irritating to the skin in this study.
            - Based on the results from the above study, ToxServices did not classify 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as a dermal irritant according to GHS Criteria. GHS criteria require that a chemical produce mean erythema or edema scores of ≥ 1.5 and < 2.3 in at least 2 of 3 tested animals from grades at 24, 48, and 72 hours in order to be classified as a dermal irritant (UN 2013).
        - Prolonged, repeated exposure of rabbits to 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) produced moderate redness, very slight, edema, and slight exfoliation or flaking of the skin. No further details were provided.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M, or L): L
Vinyl silicone polymer was assigned a score of Low for eye irritation/corrosivity based on ToxServices not classifying the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as an ocular irritant. GreenScreen® criteria classify chemicals as a Low hazard for eye irritation/corrosivity when negative data, no structural alerts, and no GHS classification are available (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not listed on any authoritative lists for this endpoint.

    - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
    - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
    - ECHA 2014 –
        - An ocular irritation test performed with rabbits (strain, number, and sex not specified) administered ocular instillations of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane (purity not specified) at an unknown concentration and volume produced slight conjunctival redness for the first 24 hours after instillation. No further details were provided.
            - Based on the above results and level of detail, ToxServices did not classify 1,1,3,3-tetramethyl-1,3-divinyldisiloxane as an ocular irritant according to GHS criteria. GHS criteria require that at least 2 of 3 tested animals have corneal opacity scores of at least 1, iritis scores of at least 1, conjunctival redness scores of at least 2, and/or chemosis scores of at least 2 as mean scores following gradings at 24, 48, and 72 hours after instillation for a chemical to be classified as an ocular irritant (UN 2013).

Ecotoxicity (Ecotox)

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

Vinyl silicone polymer was assigned a score of Low for acute aquatic toxicity based on no acute adverse effects expected on aquatic biota exposed to the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane at saturation. GreenScreen® criteria classify chemicals as a Low hazard for acute aquatic toxicity when no adverse acute effects are expected at saturation (CPA 2012a).

- Authoritative and Screening Lists
    - *Authoritative:* Not listed on any authoritative lists for this endpoint.
    - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
    - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
    - ECHA 2014 –
        - 96-hour LC_{50} (*Oncorhynchus mykiss*, rainbow trout) = greater than 0.13 mg/L (GLP-compliant, OECD 203)
        - 48-hour EC_{50} (*Daphnia magna*) = greater than 0.1 mg/L (GLP-compliant, OECD 202)
        - 72-hour growth rate EC_{50} (*Pseudokirchnerella subcapitata*, green algae) = greater than 0.12 mg/L (GLP-compliant, OECD 201)
        - 72-hour yield EC_{50} (*Pseudokirchnerella subcapitata*, green algae) = greater than 0.12 mg/L (GLP-compliant, OECD 201)
        - 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane has a water solubility of 0.207 mg/L in a GLP-compliant OECD 105 test.
    - Based on the absence of adverse acute effects at water concentrations proximal to the water solubility for 1,1,3,3-tetramethyl-1,3-divinyldisiloxane, ToxServices concludes that 1,1,3,3-tetramethyl-1,3-divinyldisiloxane is not likely to cause adverse acute effects on aquatic biota at saturation.

Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L): L
Vinyl silicone polymer was assigned a score of Low for chronic aquatic toxicity based on no chronic adverse effects expected on aquatic biota exposed to the surrogate 1,1,3,3-tetramethyl-1,3-divinyldisiloxane at saturation. GreenScreen® criteria classify chemicals as a Low hazard for chronic aquatic toxicity when no adverse chronic effects are expected at saturation (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - ECHA 2014 –
    - 21-day reproduction, growth, and mobility NOEC (*Daphnia magna*) = 0.12 mg/L (GLP-compliant, OECD 211)
    - 72-hour growth rate NOEC (*Pseudokirchnerella subcapitata*, green algae) = at least 0.12 mg/L (GLP-compliant, OECD 201)
    - 72-hour yield NOEC (*Pseudokirchnerella subcapitata*, green algae) = at least 0.12 mg/L (GLP-compliant, OECD 201)
    - 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane has a water solubility of 0.207 mg/L in a GLP-compliant OECD 105 test.
  - Based on the absence of adverse chronic effects at water concentrations proximal to the water solubility for 1,1,3,3-tetramethyl-1,3-divinyldisiloxane, ToxServices concludes that 1,1,3,3-tetramethyl-1,3-divinyldisiloxane is not likely to cause adverse chronic effects on aquatic biota at saturation.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): vH
Vinyl silicone polymer was assigned a score of Very High for persistence. It is generally accepted that polydimethylsiloxane fluids become permanent residents of sediment, but should not exert adverse environmental effects. As described by Fedinger et al. (1997), PDMS is not expected to biodegrade during wastewater treatment, given its chemical nature and high molecular weight. This conclusion is supported by long-term activated sludge incubation experiments with ^{14}C-labeled PDMS that show no labeled CO_2 generation or volatile organic product formation after 70 days of incubation. Fedenger et al. (1997) report that most PDMS released in the effluent of wastewater treatment plants will be sorbed to suspended solids that eventually deposit into the sediments. Any PDMS not sorbed to suspended solids would be expected to partition to the river water suspended solids and be deposited to bottom sediments.

GreenScreen® criteria classify chemicals as a Very High hazard for persistence when the major environmental compartment is water and the hydrolysis half-life is greater than 180 days or recalcitrant (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.

Bioaccumulation (B) Score (vH, H, M, L, or vL): vH
Vinyl silicone polymer was assigned a score of Very High for bioaccumulation based on a log K_{ow} of 5.40. GreenScreen® criteria classify chemicals as a Very High hazard for bioaccumulation when they have log K_{ow} value greater than 5.0 (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Environment Canada's Domestic Substance List (DSL) - Bioaccumulative
- Vinyl silicone polymer, CAS #68083-19-2 –
  - No data were identified for this endpoint.
- Surrogate: 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane, CAS #2627-95-4 –
  - No data were identified for this endpoint. ToxServices used EPI Suite to model the bioaccumulation of 1,1,3,3-tetramethyl-1,3-divinyldisiloxane.
    - ECHA 2014 –
      - 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane has a log K_{ow} of 5.40 in an OECD 117 test.
    - U.S. EPA 2012 –
      - BCFBAF predicts a BAF of 14,060 for 1,1,3,3-tetramethyl-1,3-divinyldisiloxane based on a measured log K_{ow} of 5.40.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M, or L): *L*
Vinyl silicone polymer was assigned a score of Low for reactivity based on it not being classified as reactive under GHS criteria (2013). GreenScreen® criteria classify chemicals as a Low hazard for reactivity when no GHS classification can be assigned (CPA 2012a). The confidence in the classification is adjusted as it is not based on data or an authoritative list.

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –
  - Sigma-Aldrich 2014 –
    - A material safety data sheet for vinyl silicone polymer states that it has a reactivity rating of 0 from the NFPA ("Normally stable, even under fire exposure conditions, and is not reactive with water") and HMIS ("Materials that are normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosives").
- Based on the MSDS identified above stating that vinyl silicone polymer is nonreactive, ToxServices did not classify vinyl silicone polymer as a reactive chemical based on GHS criteria (UN 2013).

Flammability (F) Score (vH, H, M, or L): L
Vinyl silicone polymer was assigned a score of Low for flammability based on ToxServices not classifying it as flammable under GHS criteria. GreenScreen® criteria classify chemicals as a Low hazard for flammability when no GHS classification can be assigned (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* Not listed on any authoritative lists for this endpoint.
  - *Screening:* Not listed on any screening lists for this endpoint.
- Vinyl silicone polymer, CAS #68083-19-2 –

  - Sigma-Aldrich 2014 –
    - Vinyl silicone polymer has a flash point of greater than 113.00°C in a closed cup test.
    - A material safety data sheet for vinyl silicone polymer presents a flammability rating of 0 from the NFPA ("Materials that will not burn under typical fire conditions (e.g. carbon dioxide), including intrinsically noncombustible materials such as concrete, stone and sand") and HMIS ("Materials that will not burn").
- Based on the MSDS identified above stating that vinyl silicone polymer is nonflammable, ToxServices did not classify vinyl silicone polymer as a flammable chemical based on GHS criteria (UN 2013). GHS flammable liquids have flash points of no greater than 93°C.

References

ChemIDplus. 2014. Entry for Siloxanes and Silicones, di-Me, vinyl group-terminated (CAS #68083-19-2). United States National Library of Medicine. Available at: http://chem.sis.nlm.nih.gov/chemidplus/rn/68083-19-2.

Clean Production Action (CPA). 2011. The GreenScreen® for Safer Chemicals Version 1.2 Benchmarks. Dated October 2011. Available at: http://www.greenscreenchemicals.org/.

Clean Production Action (CPA). 2012a. The GreenScreen® for Safer Chemicals Version 1.2 Criteria. Dated: November 2012. Available at: http://www.greenscreenchemicals.org/.

Clean Production Action (CPA). 2012b. List Translator. Dated February 2012. Available at: http://www.greenscreenchemicals.org/.

Clean Production Action (CPA). 2013. The GreenScreen® for Safer Chemicals Chemical Hazard Assessment Procedure. Version 1.2 Guidance. Dated August 31, 2013. Available at: http://www.greenscreenchemicals.org/.

Danish Environmental Protection Agency (DEPA). 2005. Siloxanes- Consumption, Toxicity and Alternatives. C. Lassen, C. Hansen, S. Mikkelsen, and J. Maag. Environmental Project No 1031. Available at: http://www.miljoestyrelsen.dk/udgiv/publications/2005/87-7614-756-8/pdf/87-7614-757-6.pdf.

European Chemicals Agency (ECHA). 2014. REACH Dossier for 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4). Available at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-dcec8054-dc7b-1bc5-e044-00144f67d031/DISS-dcec8054-dc7b-1bc5-e044-00144f67d031_DISS-dcec8054-dc7b-1bc5-e044-00144f67d031.html.

Fendinger, N.J., R.G. Lehmann & Mihaich. E.M. 1997. Polydimethylsiloxane. In: Chandra, H.G (Ed.). The handbook of environmental chemistry. Vol 3. part: Organosilicon Materials. Springer-Verlag, Berlin.

Grandjean, P., and P.J. Landrigan. 2006. Developmental neurotoxicity of industrial chemicals. Lancet 368: 2167-2178.

Grandjean, P., and P.J. Landrigan. 2014. Neurobehavioral effects of developmental toxicity. The Lancet 13: 330-338.

Pharos. 2014. Pharos Chemical and Material Library Entry for Siloxanes and Silicones, di-Me, vinyl group-terminated (CAS #68083-19-2). Available at: http://www.pharosproject.net/material/.

Sigma-Aldrich. 2014. Safety Data Sheet for Poly(dimethylsiloxane), vinyl terminated (CAS #68083-19-2). Product Number 433012. Version 4.2. Revision date June 25, 2014. Available at: http://www.sigmaaldrich.com/catalog/product/aldrich/433012?lang=en&region=US.

ToxServices. 2013. SOP 1.69: GreenScreen® Hazard Assessments. Dated: August 17, 2013.

Toxtree. 2013. Estimation of Toxic Hazard- A Decision Tree Approach v2.6.0. Available at: http://toxtree.sourceforge.net.

United Nations (UN). 2013. Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Fifth Revised Edition. ST/SG/AC/10/30/Rev.5. Available at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev05/05files_e.html.

United States Department of Transportation (U.S. DOT). 2008a. Chemicals Listed with Classification. 49 CFR § 172.101. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2008-title49-vol2/pdf/CFR-2008-title49-vol2-sec172-101.pdf.

United States Department of Transportation (U.S. DOT). 2008b. Classification Criteria. 49 CFR § 173. Available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title49/49cfr173_main_02.tpl.

United States Environmental Protection Agency (U.S. EPA). 2012. Estimation Programs Interface (EPI) Suite™ Web, v4.11, Washington, DC, USA. Available at: http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm.

United States Environmental Protection Agency (U.S. EPA). 2013. OncoLogic™. Version 8.0. Washington, D.C.

APPENDIX A: Hazard Benchmark Acronyms
(in alphabetical order)

(AA) Acute Aquatic Toxicity

(AT) Acute Mammalian Toxicity

(B) Bioaccumulation

(C) Carcinogenicity

(CA) Chronic Aquatic Toxicity

(D) Developmental Toxicity

(E) Endocrine Activity

(F) Flammability

(IrE) Eye Irritation/Corrosivity

(IrS) Skin Irritation/Corrosivity

(M) Mutagenicity and Genotoxicity

(N) Neurotoxicity

(P) Persistence

(R) Reproductive Toxicity

(Rx) Reactivity

(SnS) Sensitization- Skin

(SnR) Sensitization- Respiratory

(ST) Systemic/Organ Toxicity

APPENDIX B: Results of Automated GreenScreen® Score Calculation for Vinyl Silicone Polymer (CAS #68083-19-2)

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	**Vinyl Silicone Polymer**	**68083-19-2**	*L*	**L**	**L**	**M**	DG	**L**	**L**	*L*	DG	*L*	**L**	DG	**L**	**L**	**L**	**L**	**vH**	**vH**	*L*	**L**

Table 3: Hazard Summary Table

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

Table 4

Chemical Name	Preliminary GreenScreen® Benchmark Score
Vinyl Silicone Polymer	1

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

Table 6

Chemical Name	Final GreenScreen® Benchmark Score
Vinyl Silicone Polymer	1

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												1
2												
3												
4												

APPENDIX C: Pharos Output for Vinyl Silicone Polymer (CAS #68083-19-2)

Siloxanes and Silicones, di-Me, vinyl group-terminated

CAS RN: 68083-19-2

Direct Chemical and Compound Hazard Quickscreen — Detailed Hazard Listings

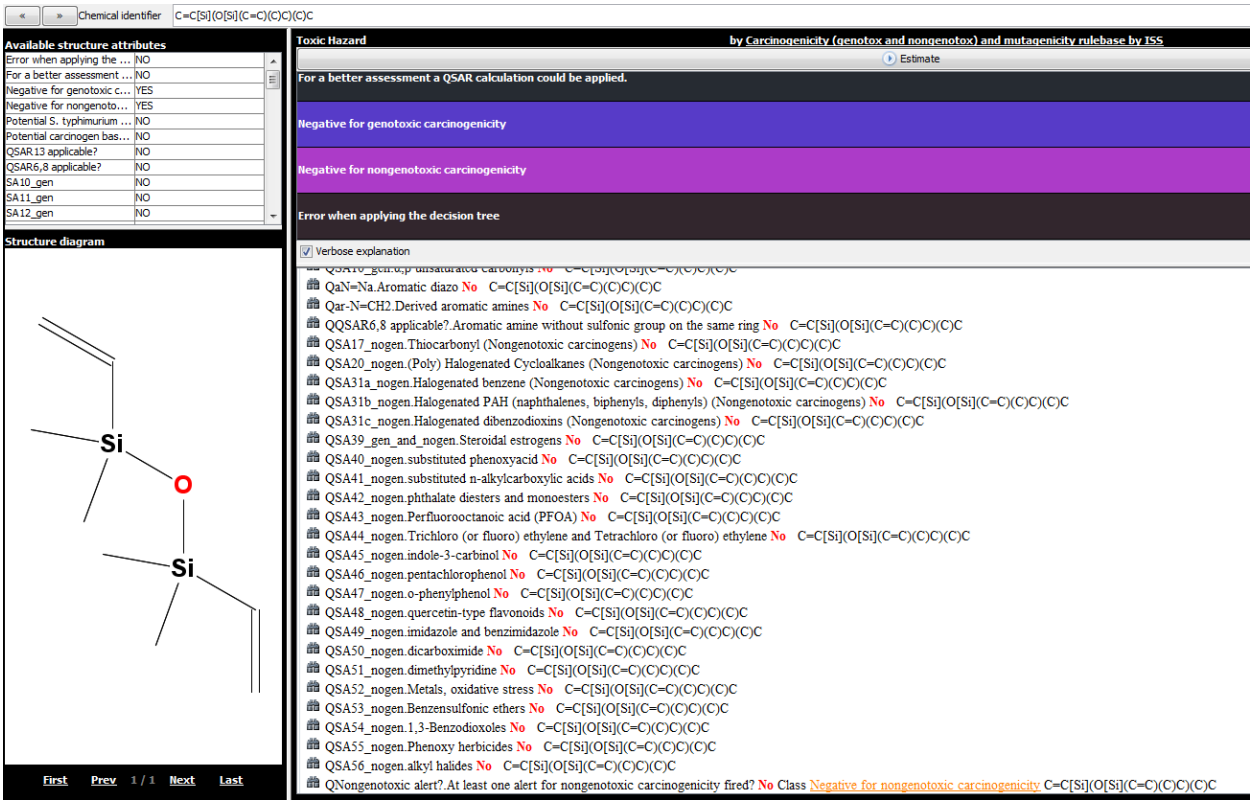
Potential concern...

PBT	Environment Canada - Domestic Substances List (DSL): DSL substances that are Bioaccumulative - GreenScreen Benchmark Unspecified (LT-U)
RESTRICTED LIST	Environment Canada - Domestic Substances List (DSL): Inherently Toxic in the Environment - GreenScreen Benchmark Unspecified (LT-U)

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

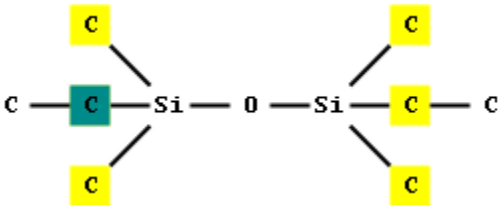
CANCER	DEVELOPMENTAL	REPRODUCTIVE	ENDOCRINE	GENE MUTATION
RESPIRATORY	NEUROTOXICITY	MAMMALIAN	EYE IRRITATION	SKIN IRRITATION
SKIN SENSITIZE	ORGAN TOXICANT	ACUTE AQUATIC	CHRON AQUATIC	TERRESTRIAL
FLAMMABLE	REACTIVE	GLOBAL WARMING	OZONE DEPLETION	

APPENDIX D: Toxtree Carcinogenicity Results for 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4)



APPENDIX E: Oncologic Results for 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4)

OncoLogic Justification Report



SUMMARY :

CODE NUMBER : 2627954

SUBSTANCE ID :

The final level of concern for this disiloxane-type compound is LOW.

JUSTIFICATION:

In general, organosilicon compounds (silanes/siloxanes) are relatively unreactive and are therefore not of significant carcinogenic concern unless they contain reactive or potentially reactive moieties. However, low molecular weight organosilicon compounds which contain small alkoxy group(s) or halogen(s) linked directly to silicon are highly reactive. Although there is a scarcity of data, these alkoxysilanes and halosilanes should be of some uncertain carcinogenic concern if exposure is by inhalation because of silylating activity and irritation. For these alkoxysilanes or halosilanes, their carcinogenic potential is expected to be minimal by other routes due to the instability of the compounds upon contact with aqueous environment. An organosilicon compound which contains epoxide sidechain has been shown to be carcinogenic by the dermal route. Some organosilicon compounds which contain sidechains with terminal double bonds may also be of carcinogenic concern.

This disiloxane-type compound where R1 is ethyl, R2 is methyl, R3 is methyl, R4 is methyl, R5 is methyl and R6 is ethyl, all linked to silicon, is not expected to be reactive. The baseline level of carcinogenicity concern is LOW.

Exposure by any route is not expected to raise the level above LOW.

The final level of concern for this disiloxane-type compound is LOW.

APPENDIX F: EPISuite Modeling Results for 1,1,3,3-Tetramethyl-1,3-divinyldisiloxane (CAS #2627-95-4)

CAS Number: 2627-95-4
SMILES: C=C[Si](O[Si](C=C)(C)C)(C)C
CHEM: Disiloxane, 1,3-diethenyl-1,1,3,3-tetramethyl-
MOL FOR: C8 H18 O1 Si2
MOL WT: 186.40
---------- EPI SUMMARY (v4.11) ----------
Physical Property Inputs:
Log K_{ow} (octanol-water): 5.40
Boiling Point (deg C): ------
Melting Point (deg C): -99.70
Vapor Pressure (mm Hg): 12.75
Water Solubility (mg/L): 0.207
Henry LC (atm-m3/mole): ------

Log Octanol-Water Partition Coef (SRC):
Log K_{ow} (K_{ow}WIN v1.68 estimate) = 5.96

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPVP v1.43):
Boiling Pt (deg C): 131.36 (Adapted Stein & Brown method)
Melting Pt (deg C): -56.85 (Mean or Weighted MP)
VP (mm Hg,25 deg C): 449 (Mean VP of Antoine & Grain methods)
VP (Pa, 25 deg C): 5.98E+004 (Mean VP of Antoine & Grain methods)
MP (exp database): -99.7 deg C
BP (exp database): 39 deg C

Water Solubility Estimate from Log K_{ow} (WSK_{ow} v1.42):
Water Solubility at 25 deg C (mg/L): 0.6518
log K_{ow} used: 5.40 (user entered)
melt pt used: -99.70 deg C

Water Sol Estimate from Fragments:
Wat Sol (v1.01 est) = 0.14048 mg/L

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

Henrys Law Constant (25 deg C) [HENRYWIN v3.20]:
Bond Method: 3.07E-001 atm-m3/mole (3.11E+004 Pa-m^3/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: 1.511E+001 atm-m^3/mole (1.531E+006 Pa-m^3/mole)
VP: 12.8 mm Hg (source: User-Entered)
WS: 0.207 mg/L (source: User-Entered)

Log Octanol-Air Partition Coefficient (25 deg C) [K_{oa}WIN v1.10]:
Log K_{ow} used: 5.40 (user entered)
Log K_{aw} used: 1.099 (HenryWin est)
Log K_{oa} (K_{oa}WIN v1.10 estimate): 4.301
Log K_{oa} (experimental database): None

Probability of Rapid Biodegradation (BIOWIN v4.10):
Biowin1 (Linear Model): 0.6588
Biowin2 (Non-Linear Model): 0.5895
Expert Survey Biodegradation Results:
Biowin3 (Ultimate Survey Model): 2.7872 (weeks)
Biowin4 (Primary Survey Model): 3.5788 (days-weeks)
MITI Biodegradation Probability:
Biowin5 (MITI Linear Model): 0.1964
Biowin6 (MITI Non-Linear Model): 0.0687
Anaerobic Biodegradation Probability:
Biowin7 (Anaerobic Linear Model): 0.0767
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): 1.71E+003 Pa (12.8 mm Hg)
Log K_{oa} (K_{oa}win est): 4.301
Kp (particle/gas partition coef. (m^3/µg)):
Mackay model: 1.76E-009
Octanol/air (K_{oa}) model: 4.91E-009
Fraction sorbed to airborne particulates (phi):
Junge-Pankow model: 6.35E-008
Mackay model: 1.41E-007
Octanol/air (K_{oa}) model: 3.93E-007

Atmospheric Oxidation (25 deg C) [AopWin v1.92]:
Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 53.1984 E-12 cm^3/molecule-sec
Half-Life = 0.201 Days (12-hr day; 1.5E6 OH/cm^3)
Half-Life = 2.413 Hrs.
Ozone Reaction:
OVERALL Ozone Rate Constant = 0.350000 E-17 cm^3/molecule-sec
Half-Life = 3.274 Days (at 7E11 mol/cm^3)
Half-Life = 78.583 Hrs.
Fraction sorbed to airborne particulates (phi):
1.02E-007 (Junge-Pankow, Mackay avg)
3.93E-007 (K_{oa} method)
Note: the sorbed fraction may be resistant to atmospheric oxidation

Soil Adsorption Coefficient (K_{oc}WIN v2.00):
K_{oc}: 1309 L/kg (MCI method)

Log K_{oc}: 3.117 (MCI method)
K_{oc}: 4.856E+004 L/kg (K_{ow} method)
Log K_{oc}: 4.686 (K_{ow} 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 = 3.230 (BCF = 1698 L/kg wet-wt)
Log Biotransformation Half-life (HL) = 1.2181 days (HL = 16.52 days)
Log BCF Arnot-Gobas method (upper trophic) = 3.656 (BCF = 4534)
Log BAF Arnot-Gobas method (upper trophic) = 4.148 (BAF = 1.406e+004)
log Kow used: 5.40 (user entered)

Volatilization from Water:
Henry LC: 15.1 atm-m^3/mole (calculated from VP/WS)
Half-Life from Model River: 1.393 hours
Half-Life from Model Lake: 129.7 hours (5.403 days)

Removal in Wastewater Treatment (recommended maximum 95%):
Total removal: 99.99 percent
Total biodegradation: 0.16 percent
Total sludge adsorption: 54.47 percent
Total to Air: 45.35 percent
(using 10000 hr. Bio P,A,S)

Level III Fugacity Model:

	Mass Amount (percent)	Half-Life (hr.)	Emissions (kg/hr.)
Air	7.16	4.55	1000
Water	87.8	360	1000
Soil	1.19	720	1000
Sediment	3.88	3.24e+003	0

Persistence Time: 70.3 hr.

Sources to Check for GreenScreen® Hazard Assessment

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

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

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

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

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

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

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

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

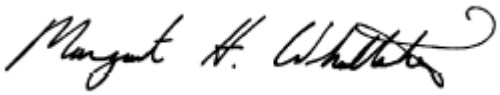
European Chemicals Agency (ECHA) REACH Dossiers: http://echa.europa.eu/

Licensed GreenScreen® Profilers

Vinyl Silicone Polymer GreenScreen® Evaluation Prepared by:

Zach Guerrette, Ph.D.
Toxicologist
ToxServices LLC

Vinyl Silicone Polymer GreenScreen® Evaluation QC'd by:



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